Council Meeting

Thursday, 11 November 2021 at 10:00 am to be held remotely by Zoom

Agenda

	Classification[1]	Rationale[2]
1. **President's introduction**	Oral report Unclassified	n/a
2. **Apologies for absence**	Oral report Unclassified	n/a
3. **Declaration of interests**	Oral report Unclassified	n/a
4. **Minutes**		
i. Meeting held 9 September 2021 - unclassified minutes	Unclassified	n/a
ii. Meeting held 9 September 2021 - classified appendix	**Confidential**	**1, 2, 3, 4**
iii. Remote decision made 20-23 September 2021	Unclassified	n/a
iv. Remote decision made 22 – 25 October 2021	**Confidential**	**1, 3**
5. **Matters arising**		
a. Obituaries	Unclassified	n/a
b. Council correspondence	Oral report Unclassified	n/a
c. CEO update	Oral report Unclassified	n/a
6. **Matters for decision by Council and for report (unclassified items)**		
a. Discretionary Fund	Oral report Unclassified	n/a
b. Legislation Working Party – interim recommendations	Unclassified	n/a

c. New RCVS accreditation standards for veterinary programmes.	Unclassified	n/a
d. Policy for recognising graduates EAEVE-accredited schools for RCVS registration: EAEVE backdating policy	Unclassified	n/a
e. RCVS Investment Policy	Unclassified	n/a
7. **Reports of standing committees – to note**		
a. Advancement of the Professions Committee		
i. Unclassified minutes	Unclassified	n/a
ii. Classified appendix	**Confidential**	**1**
b. Audit and Risk Committee		
i. Unclassified minutes	Unclassified	n/a
ii. Classified appendix	**Confidential**	**1, 2, 3, 4, 5**
c. Education Committee		
i. Unclassified minutes	Unclassified	n/a
ii. Classified appendix	**Confidential**	**1**
d. Finance and Resources Committee		
i. Unclassified minutes	Unclassified	n/a
ii. Classified appendix	**Confidential**	**1, 2, 3, 4**
e. Registration Committee		
i. Meeting held 12 May 2021 - Unclassified minutes	Unclassified	n/a
ii. Meeting held 12 May 2021 - Classified appendix	**Confidential**	**2, 3, 4**
iii. Meeting held 15 September 2021 – Unclassified minutes	Unclassified	n/a
iv. Meeting held 15 September 2021 – Classified appendix	**Confidential**	**1, 2, 3, 4**
f. Standards Committee		
i. Meeting held 16 July 2021 – Unclassified minutes	Unclassified	n/a
ii. Meeting held 16 July 2021 – Classified appendix	**Confidential**	**1, 2, 3**
iii. Meeting held 4 August 2021 – Unclassified minutes	Unclassified	n/a
iv. Meeting held 4 August 2021 – Classified appendix	**Confidential**	**1, 2**
g. Veterinary Nurses Council		
i. Unclassified minutes	Unclassified	n/a
ii. Classified appendix	**Confidential**	**2, 3, 4**

h. PIC/DC Liaison Committee		
i. Unclassified minutes	Unclassified	n/a
ii. Classified appendix	**Confidential**	**1, 3**
8. **Reports of statutory committees – to note**		
a. Preliminary Investigation Committee	Unclassified	n/a
b. RVN Preliminary Investigation Committee	Unclassified	n/a
c. Disciplinary Committee and RVN Disciplinary Committee	Unclassified	n/a
9. **Notices of motion**	Oral report Unclassified	n/a
10. **Questions**	Oral report Unclassified	n/a
11. **Any other College business (unclassified)**	Oral report Unclassified	n/a
12. **Risk Register, equality and diversity (unclassified)**	Oral report Unclassified	n/a
13. **Date of next meeting** Thursday, 20 January 2022 at 10:00 am	Oral report Unclassified	n/a
14. **Matters for decision by Council and for report (confidential items)**		
a. Groupage Export Facilitation Scheme - review	**Confidential**	**1, 2, 4**
b. RCVS accreditation model and the regulation of animal behaviourists	**Confidential**	**2**
c. Estates Strategy – update	Oral report **Confidential**	**1, 3**
d. Budget 2022	**Confidential**	**1, 2, 3**
e. Fellowship by Thesis – ratification	**Private**	**1, 5**
15. **Any other College business (confidential items)**	Oral report **Confidential**	**# TBC**
16. **Risk Register, equality and diversity (confidential items)**	Oral report **Confidential**	**# TBC**

Dawn Wiggins Secretary, RCVS Council 020 7202 0737 / d.wiggins@rcvs.org.uk		

[1]Classifications explained

Unclassified	Papers will be published on the internet and recipients may share them and discuss them freely with anyone. This may include papers marked 'Draft'.
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[2]Classification rationales

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Private	5. To protect information which may contain personal data, special category data, and/or criminal offence data, as listed under the General Data Protection Regulation

Summary

Meeting	Council
Date	11 November 2021
Title	September 2021 Council minutes
Summary	Minutes of the meeting held on Thursday, 9 September 2021.
Decisions required	To approve the unclassified minutes and classified appendix.
Attachments	Classified appendix
Author	Dawn Wiggins Secretary, Council 0207 202 0737 / d.wiggins@rcvs.org.uk

Classifications

Document	**Classification**[1]	**Rationales**[2]
Paper	Unclassified	n/a
Classified appendix	**Confidential**	**1, 2, 3, 4.**

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RCVS Knowledge Annual General Meeting and RCVS Council Meeting

Minutes of the hybrid meeting hosted on Thursday, 9 September 2021 at Belgravia House, 62-64 Horseferry Road, London SW1P 2AF at 10:00 am.

Members:

Dr K A Richards (President in the Chair)
Dr L H Allum
Mrs B S Andrews-Jones
Miss L Belton
Professor D Bray*
Mr J M Castle^
Dr D S Chambers
Dr N T Connell
Dr M A Donald
Dr J M Dyer
Ms L Ford
Dr M M S Gardiner
Dr M O Greene
Professor S A May*
Mrs C-L McLaughlan
Professor T D H Parkin
Dr S Paterson
Professor C J Proudman
Mr M E Rendle
Dr N C Smith
Mr T J Walker^
Dr C M Whiting
Professor J L N Wood
Ms J S M Worthington^

*Denotes absent

^Denotes remote participant

In attendance:

In person:

Mr H Awbery	(Agenda item 15 only)
Ms A K Boag	Chair, RCVS Knowledge Board
Ms E C Ferguson	Registrar
Mr C Gush	Executive Director, RCVS Knowledge
Mr J Loeb	*Veterinary Record*
Ms C L McCann	Director of Operations (DoO)
Mr B Pound	RCVS Knowledge Board/Trustee
Ms J Shardlow	Chair, Audit and Risk Committee
Mr J Simmons	(Agenda item 15 only)
Mr J Trivedy	(Agenda item 15 only)

Remote:

Ms C Ashcroft	*MRCVS online*
Mrs H C Cartlidge	RCVS Knowledge Board/Trustee
Mr I G Dick	RCVS Knowledge Board/Trustee
Dr D Dos Santos	Senior Vice-President, British Veterinary Association (BVA)
Mr P Imrie	*Veterinary Times*
Ms L Lockett	CEO

Dr C H Middlemiss Chief Veterinary Officer (UK), Observer (agenda items 6a-6d only)

RCVS Knowledge

Annual General Meeting

1. RCVS Knowledge Trustees had received their papers in August 2021; the minutes would be recorded separately to the RCVS Council minutes herewith.

Update

2. The Executive Director, RCVS Knowledge, gave an update on the work of the charitable partner to the College. There were three streams to the work:

- Evidence-Based Veterinary Medicine (EBVM)
- Quality Improvement
- Heritage

Evidence-based Veterinary Medicine

3. The main aim was to advance the use of EBVM in veterinary practice and combine it with the clinical expertise of veterinary professionals, and the owner and animal circumstance. Additionally:

- *Veterinary Evidence*: had approximately 15,000 views per month; its readership increasing year on year;
  - 92% of the readership found it useful and beneficial;
  - audio summaries were produced, to date there had been c.70 podcasts downloaded 68,000 times (159 episodes);
- Knowledge Summaries: also known as Critically Appraised Topics (CATs) produced to help veterinary teams solve patient problems efficiently; short critical summaries of the best available information on a defined clinical question;
- Clinical queries: for specific areas of practice, research undertaken within the best available evidence to help reinforce or inform decision-making;
- Library: provides comprehensive access to the various veterinary and in practice journals; *InFOCUS* provides practitioners independent summaries of the latest research that has the potential to impact patient care.

Quality Improvement

4. This stream was focussed on ‘doing the right thing in the right way’. It was discovered that the understanding of the *Code of Professional Conduct* (CoPC) was variable within the profession so this was a way of setting out clinical governance, what needed to be done, how matters could be improved, and how the profession could support itself and implement change:

- supported by leadership within teams;

- Quality Improvement e-learning courses around standards, regulation, benchmarking, toolkits, etc. For example, courses had been developed with the universities regarding understanding EBVM in practice; farm vets with Veterinary Medicines Directorate (VMD) around anti-microbial stewardship in industry and, associations with summaries of how these could help when considering prescribing;

- Benchmarking: Canine Cruciate Registry: this programme offered free, anonymised, data collection and an audit tool to guide decision-making; 150 people had signed up to the Registry to date; bitch spays/castrations post-operative data: out of all of the procedures documented almost 75% were found to have no abnormalities present, whereas 25% required medical intervention;

- provision of support to the profession around Covid regarding control; guidance; research relevant to the veterinary profession; and myth-busting from a professional and public perspective.

Heritage

5. Amongst its historical collection, RCVS Knowledge was proud to have the largest digital collection of veterinary history in the world, including:

   - the oldest book in translation dated 1528;
   - copies of the *Register of Members* back to 1883;
   - details of the Colman Lectures from 1821 – more than 10 years before Charles Darwin set sail on the HMS Beagle;
   - letters from Joseph Lister – surgeon, experimental pathologist, and pioneer of antiseptic surgery – to the founders of the veterinary profession.

6. The team were able to offer support for PhD and Masters students who were studying the historical field of veterinary science.

7. On behalf of Council, the President commended the work of the Knowledge Team.

Council Meeting

President's introduction and welcome to new members

8. The President extended a warm welcome to guests and outlined the order of the meeting. Thereafter the new Council members and Chair, Audit and Risk Committee were welcomed to their first meeting:

   Elected members:
   Dr Louise Allum

Dr Matshidiso (Tshidi) Gardiner
Dr Colin Whiting

Veterinary Schools Council appointed members:
Professor Timothy Parkin – Bristol
Professor Christopher Proudman – Surrey

Chair, RCVS Audit and Risk Committee
Ms Janice Shardlow

Apologies for absence

9. Apologies for absence were received from Professor May.

Declarations of interest

10. There were no declarations of interest.

Minutes

11. Council had had the opportunity to comment electronically on the various sets of unclassified minutes and classified appendices before it. There were no further comments.

12. A vote was taken:

For:	18
Against:	0
Abstain:	5 (new members not on Council on the dates the minutes referred)

13. The unclassified minutes and classified appendices as listed were accepted as a true record by a majority vote.

Matters arising

Obituaries

14. The first notice of obituary was for Professor Roger Short FRCVS, a veterinary surgeon and reproductive biologist who had given the keynote speech at the RCVS Annual General Meeting in 2010. The President noted that the title of his address, *'The way ahead for the veterinary profession in a warming world*' was very prescient for many of the discussions taking place within the profession now around sustainability, the role of vets in the climate emergency and the

upcoming United Nations (UN) Climate Change Conference of the Parties (COP26) in Glasgow in October.

15. The second notice of obituary was for the death of Julia Kneale MBE who, in 1981, was one of the first women to serve as a Veterinary Officer in the Royal Army Veterinary Corps, serving in the UK, Germany and Hong Kong.

Council correspondence

16. The President reported on the following:

RCVS Day 2022

17. This would be held on Friday, 8 July 2022 at One Great George Street, Westminster, subject to any future government restrictions.

RCVS honours and awards

18. College honours and awards usually form part of Royal College Day. Due to the continuing restrictions because of Covid at the time, once more the presentation of these had been postponed. A virtual honours and awards evening would be held on Thursday, 23 September 2021 from 7:00 – 8:15 pm. Council members should contact Deborah Rowlanes in the Events Team on: events@rcvs.org.uk if they were interested in attending.

Tokyo Olympics

19. On behalf of Council, congratulations were offered to Laura Muir and Neah Evans who won silver medals at the recent Olympic Games in 1500m athletics, and cycling – team pursuit, respectively.

CEO update

20. The CEO outlined the paper that detailed the activity and progress against the RCVS Strategic Plan:

- Veterinary Graduate Development Programme (VetGDP): the e-portfolio was soon to be launched; 1,800 graduates had signed up to the programme and would be able to record and monitor their progress, upload documents and submit their reflections;

- sustainability: ongoing work regarding workforce issues and skill shortages was being considered regarding:

    - the impact of Covid;
    - the impact of EU-exit: particularly in relation to certification, the entry of European graduates into the UK;
    - changing demographics/views;
    - new veterinary schools;
    - overseas recruitment;
    - mental health and wellbeing;
    - trying to get the large pool of veterinary surgeons/veterinary nurses that had recently left to consider returning to the profession in the short-term;
    - a Workforce Summit would take place in November under the ViVet banner.

21. The Chair, Standards Committee, added that the Committee had been busy over the summer and thanked members and staff for their hard work and for the extra decisions made around EU-exit, the increased certification needs and the guidance changes required as part of the government decision-making process.

22. Comments and questions included:

- regarding the forthcoming Summit: could it be made clear to the profession the moves to address the staffing problem as there were regular queries as to why we were not undertaking accreditation of other veterinary schools, and whether there was a way to facilitate locum work in the UK;

    - once a date had been set for the Summit it would have a communications plan around it. Some issues were not for the College, and meetings had taken place with stakeholders. A series of Frequently-asked Questions (FAQs) will be loaded to the website, so there would be a lot of information forthcoming;

- Council should specifically congratulate the Fellowship Board on the gender balance that had been achieved in appointing new Fellows this year;

- was it possible to provide more information about the ongoing work around the loss of mutual recognition?

    - consideration was being given to a range of veterinary schools in Europe that were not European Association of Establishments for Veterinary Education (EAEVE) accredited. European matters were complex and not all schools were regulated in the same way as UK schools; a paper would come back to Council in the future. Regarding Australasian schools/graduates and that any subsequent workforce may be part of trade discussions, the College did not wish the profession to be used as a 'bargaining chip';

- was it possible to provide numbers around the options so that Council was able to tell if matters were better/worse in five/10/15 years?

    - data was being gathered that would feed into a workforce model, however, the College was limited as to what it could collect as there were restrictions under the General Data Protection Regulation (GDPR) that prevented it from contacting people once they had left the Register.

23. The report was noted.

Matters for decision by Council and for report (unclassified items)

Discretionary Fund

24. The Director of Operations (DoOps) introduced the paper and explained that the Discretionary Fund was an allocation in the budget for expenditure on items not provided for to allow for new

ideas within a budget year, and to enable strategically important changes to be fast-tracked. There were financial controls in place and the provision in the 2021 budget was £150,000. To date, five applications had been approved that amounted to £115,588, all of which included Value Added Tax (VAT).

25. It was commented that year-on-year there seemed to be an increasing underspend on the fund and it was questioned if the College was making the best use of the money as it was not being invested, and whether the fund should be proactively promoted. It was confirmed that the entire fund would be spent this year including monies carried forward from the previous year. A review of projects had been undertaken to see if it remained necessary to use this fund, if it was not, then that money would be put back into the accounts accordingly.

26. The paper was noted.

RCVS / Veterinary Schools Council Memorandum of Understanding

27. The CEO introduced the paper and reminded Council it had been at the June meeting where clarity had been sought regarding the process of nomination for, and voting on, Veterinary Schools Council (VSC) appointees to RCVS Council, as part of discussions around a proposed MOU with the VSC. This had been confirmed by way of the VSC's byelaws, and the paper was now before Council for approval.

28. There were no questions. A vote was taken to approve the RCVS and VSC Memorandum of Understanding:

For:	23
Against:	0
Abstain	0

29. The Memorandum of Understanding was agreed by a unanimous vote.

Review of RCVS handling of Covid-19 pandemic

30. The CEO introduced the paper and stated that, whilst it was recognised that the pandemic continued, it was an opportunity to consider how the College had coped with the huge volume of work over the last 18 months; what was done well, and what could have been done better. Feedback had been sought from stakeholders and had been generally positive.

31. Furthermore, most decisions had now returned to the various committees, and it was suggested that the Covid-19 Taskforce be stood down, but not disbanded in case there was a need to restart it in the future.

32. Comments and questions included:

- it was emotional to reflect on the Covid response and a tribute to the hard work of everyone, in particular, the veterinary nursing profession;

- was there a Business Continuity Plan going into the pandemic and would it be reviewed?

  - yes, there was a Plan, and there had been a meeting at the end of August to review it. Some changes had been made, in particular, the potential impact of loss of the building was not so great now that it had been proven that work could continue remotely; and it was appreciated communication in a crisis would need to be more layered and nuanced when teams worked in different places;

- a huge debt of gratitude was owed to the Officer Team and everyone in the College for the response to Covid overall – with hindsight it was a very well run operation;

- the CVO said that Defra also wished to officially record its thanks and gratitude to the RCVS and BVA for the responses to the profession; it was appreciated that the government guidance was not specific enough for the huge variety of roles, and feedback would be taken on board. The way the 'machine' worked provided gaps and the RCVS picked up the baton to fill those gaps; the way everyone worked together was very effective;

- re: paragraph 6: misattributing work to other organisations: it was felt that joining webinars and seeing the RCVS and BVA Presidents on screen was like 'mum and dad' were there; it was a strong communication tool but, although if members of the profession were asked to identify the face of the pandemic, then they may possibly say the BVA President. If the pandemic situation was to regress, this tool could provide a calming relief to be able see and hear members of the profession;

- re: flow chart: when that was circulated initially it was fantastic, it was something that could be followed easily. As the pandemic progressed and there were minor iterations, it was harder to see what had changed.

33. The CEO thanked Council for its comments.

34. A vote was taken on whether to stand down the Covid-19 Taskforce (but not disband it):

For:	23
Against:	0
Abstain:	0

35. The standing down of the Covid-19 Taskforce was agreed by a unanimous vote.

Council Culture project – the way forward

36. The CEO outlined the paper and highlighted the importance of committing to a positive change. There was a proposed structure of how work could be taken forward at paragraph 6 of the paper, and comments were invited.

37. Comments and questions included:

- there had been a lot of discussion, it was now time to get on with it;

- how much of this issue and subsequent work was due to the knowledge that it would remain confidential, as it perpetuated the behaviour?

    - Annex B to the paper was confidential as it related to the summary following discussions that had been assured would not be put in the public domain; it was included as background rather than to challenge what members had said. The College endeavoured to have as many papers as possible in the public domain but could not include personal issues under General Data Protection Regulation (GDPR);

    - the working groups proposed in the paper would meet in committee, but it should be possible to publish the minutes of the meetings;

- re: Annex A: Action Plan: the purpose statement was the most important thing, which group would it feed in to?

    - as this was a key item, all groups would be asked to consider a short statement that summarised the purpose of Council (as opposed to the purpose of the College itself); they would also be asked to choose a Group Leader who in turn will report to a Steering Group to discuss progress and work together to produce a set of recommendations that will go to Council for review/decision;

- there was much between the action plan and the slides at Annex B, particularly regarding 360º appraisals that had not been included; it was important that all Council members had an appraisal, not just the lay members on Council when it came to re-appointment;

    - the College was looking at the Charity Governance Code and how it could aid Council to be effective and reflective in the work it did; this was shortly to be considered by Audit and Risk Committee (ARC); 'appraisal' also meant different things to different people nomenclature was less important than effectiveness;

- there was a risk of overlap within the proposed working groups, therefore it was essential to draft specific and clear Terms of Reference (ToR) for each group;

    - noted. ToR should not duplicate but be as inclusive as possible.

38. A vote was taken to approve the proposed steps (mechanism and timetable) as outlined in the paper:

For:	23
Against:	0
Abstain:	0

39. The proposed steps were agreed by a unanimous vote.

Notices of Motion

40. There had been no notices of motion received.

Questions

41. There had been no questions received.

Any other College business (unclassified items)

42. The President welcomed the first all-female Presidential Team:

Dr Kate Richards (herself)	President
Dr Mandisa Greene	Vice-President (Senior)
Dr Melissa Donald	Vice-President (Junior)

Risk Register, Equality and Diversity (unclassified items)

43. No items were identified for inclusion on the Risk Register from the open session of the meeting.

Date of next meeting

44. The date of the next meeting will be Thursday, 11 November 2021, commencing at 10:00 am. The meeting would be held remotely.

Matters for decision by Council and for report (confidential items)

Standards Committee update

45. This had been covered in the open session of the meeting under the CEO report.

Estates Strategy update

46. This information is available in the classified appendix at paragraphs 1 – 5.

Ratification of Vice-Chair, Preliminary Investigation Committee

The President declared an interest that she went to vet school with the candidate, although had not seen him since 1983

47. The Registrar reported that PIC / DC Liaison Committee had agreed the process of selection at its meeting in May. The interviewing panel were unanimous in its decision to select the candidate before Council for ratification.

48. Due diligence around the process was questioned. It was confirmed that the role was to be filled from within the current membership of the Committee; each member of which had been recruited to the Committee via an independent recruitment process, facilitated by an external consultancy agency, who undertook background checks for suitability (Council also ratify those appointments at the end of the recruitment process).

49. A vote was taken to ratify the appointment of Dr David Harding MBE MRCVS as the new Vice-Chair of Preliminary Investigation Committee to 30 June 2023:

For:	23
Against:	0
Abstain:	0

50. The appointment was ratified by a unanimous vote.

Any other College business (confidential items)

Classified appendices from Council meetings/remote decisions

51. There were no comments on the classified appendices of the various minutes.

Boardpacks

52. The CEO raised the matter of how long personal information was stored on the College's meeting paper system, Boardpacks. It was suggested that any papers that contained private data (as specified under GDPR) be removed at the end of each College year. This was agreed by Council. It was also agreed that papers be archived at the end of four years (a Council term), although they would be retrievable on request.

Responses to national media articles

53. This information is available in the classified appendix at paragraphs 6 – 8.

Risk Register, equality and diversity (confidential items)

54. This information is available in the classified appendix at paragraph 9.

Council Workshop: Sustainability

55. This information is available in the classified appendix at paragraphs 10 – 20.

56. The President thanked the facilitators for their help with the workshop and the meeting was brought to a close.

Summary

Meeting	Council
Date	11 November 2021
Title	20 – 23 September 2021 Council minutes
Summary	Minutes of the remote decision held on 20 – 23 September 2021.
Decisions required	To approve the unclassified minutes.
Attachments	None
Author	Dawn Wiggins Secretary, Council 0207 202 0737 / d.wiggins@rcvs.org.uk

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Council

Minutes of the remote decision made between 20 – 23 September 2021 via Boardpacks.

Members:

Dr K A Richards (President in the Chair)
Dr L H Allum
Mrs B S Andrews-Jones
Miss L Belton
Professor D Bray
Mr J M Castle
Dr D S Chambers
Dr N T Connell
Dr M A Donald
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Professor C J Proudman
Mr M E Rendle
Dr N C Smith
Mr T J Walker
Dr C M Whiting
Professor J L N Wood
Ms J S M Worthington

English Language testing

1. In order to sit the Statutory Examination for Membership or to apply for full Registration as a member of the College, the English language test levels had been set at International English Language Testing System (IELTS) Level 7, or Occupational English Test (OET) Level B across all components: reading, writing, speaking.

2. Following requests made to the RCVS to change the levels, Education, and Registration, Committees were asked to consider that instead of IELTS Level 7 / OET Level B across all components that it would be acceptable to have a minimum of IELTS Level 6.5 / OET Level C+ in one component so long as the average score across all components was at least Level 7 / B. Both committees also considered the approach taken by other regulators.

3. The Committees were minded to allow the change, without specifying the component the Level 6.5 / C+ would be permitted, and allow the small degree of flexibility to facilitate access whilst not comprising the overall standard but, in view of previous discussions at Council, sought to obtain Council's approval before implementing the change.

4. A vote was taken:

For:	19
Against:	1
Abstain:	0
Did not vote:	4

5. Dr Whiting experienced technical difficulties and submitted an email vote.

6. The decision to approve a minimum of IELTS Level 6.5 / OET Level C+ in one component so long as the average score across all components was at least IELTS Level 7 / OET Level B was agreed by a majority vote.

7. Council was thanked for its consideration of this matter, and the result would be forwarded to the Education and Registration Teams for immediate action.

Summary

Meeting	Council
Date	11 November 2021
Title	Implementing Legislation Working Party interim recommendations - 'Mini' PICs and the Charter Case Protocol / Committee.
Summary	The paper and annexes set out a number of practical matters for consideration by Council to implement the interim measures as approved by Council – as they relate to the formation of mini – PICs and Charter Case Protocol/ Committee
Decisions required	Council is asked to: a. Approve the establishment of four mini-PICs (Stage 1 PICs) (or such other number as Council deems appropriate); b. Approve the draft amended PIC and DC Protocol; c. Approve the constitution of the Charter Case Committee; d. Approve the draft Charter Case Protocol; e. Approve the draft Charter Case Committee Rules; f. Decide if it wishes the working title 'Charter Case Committee' to be retained or to rename.
Attachments	Annex A: Draft Charter Case Protocol Annex B: Draft Charter Case Committee Rules Annex C: Draft amended PIC / DC Protocol
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Classifications

Document	Classification[1]	Rationales[2]
Paper	Unclassified	n/a
Annex A	Unclassified	n/a
Annex B	Unclassified	n/a
Annex C	Unclassified	n/a

[1]Classifications explained

Unclassified	Papers will be published on the internet and recipients may share them and discuss them freely with anyone. This may include papers marked 'Draft'.
Confidential	Temporarily available only to Council Members, non-Council members of the relevant committee, sub-committee, working party or Board and not for dissemination outside that group unless and until the relevant committee or Council has given approval for public discussion, consultation or publication.
Private	The paper includes personal data which should not be disclosed at any time or for any reason, unless the data subject has agreed otherwise. The Chair may, however, indicate after discussion that there are general issues which can be disclosed, for example in reports to committees and Council.

[2]Classification rationales

Confidential	1. To allow the Committee or Council to come to a view itself, before presenting to and/or consulting with others 2. To maintain the confidence of another organisation 3. To protect commercially sensitive information 4. To maintain public confidence in and/or uphold the reputation of the veterinary professions and/or the RCVS
Private	5. To protect information which may contain personal data, special category data, and/or criminal offence data, as listed under the General Data Protection Regulation

Background

1. Council members will be aware of the changes that were approved by Council back in June 2021 (at the same time as approval of the recommendations of the Legislation Working Party (LWP)).

2. These changes were twofold:

   a. The introduction of a Charter Case Committee (CCC) and Charter Case Protocol (CCP) to allow for a wider range of outcomes by way of written warnings for suitable cases that have crossed the threshold for a disciplinary case. For full details see the **Draft CCP attached at Annex A** for details of the operation of CCCs and **Draft CCC Rules attached at Annex B** (for the constitution of the CCC).

   b. Amending the structure of the concerns process to introduce 'mini' Preliminary Investigation Committees (now referred to as Stage 1 PICs). This involves 'doing away' with the existing Stage 1 process for all concerns currently carried out by the Case Examiner Group (CEG) (which considers whether there is an "arguable case" of serious professional misconduct and if there is then referring on to a full PIC) and replacing with a more streamlined process with only one 'threshold' test – that of realistic prospect of serious professional misconduct carried out by the Stage 1 PIC **(see draft amended PIC / DC Protocol attached at Annex C)**.

   (For full background re: (a), Council is referred back to Section 2 of the paper that was considered by Council in June 2020, paragraphs 44 – 70; for details re: (b) see Section 3 of the same paper, paragraphs 71 – 78).

Bringing the CCCs and mini-PICs into effect

3. Following Council's approval, work has been carried out to start the practical process to bring the changes into effect. This has involved extensive discussions with members of PIC / RVN PIC and staff as well as discussions at PIC / DC liaison Committee in September.

Stage 1 PICs – Constitution

4. Stage 1 PICs require to be made up of three members (one vet (or RVN), one lay, one other) to be quorate.

   - Matters will be considered initially on 'paper', just as is currently the case with a CEG, with all Stage1 PIC members considering and adding their comments to an action plan on the Professional Conduct (Profcon) Case Management System (CMS) as information is provided by the parties.

   - In order to reach a final decision, however, Stage 1 PICs will need to meet (in practice, a virtual meeting). This is consistent with the legislative framework of the College, as the Veterinary Surgeons Act (VSA) 1966, by implication, works on the basis that any PIC will meet to finally decide matters. The RVN rules follow those for veterinary surgeons albeit not covered directly under the VSA.

- Stage 1 PICs will be scheduled to meet once every two weeks to agree / confirm their decisions. Meetings will be scheduled in advance to give members as much notice as possible (and in the event of nothing to consider could of course be cancelled). These meetings will be in addition to the larger (Stage 2) PIC meetings.

- It is anticipated that the main investigation and consideration process, as now, will be undertaken as part of the action plan and that in the overwhelming majority of cases, the meetings of each Stage 1 PIC will simply be a means of confirming or approving the decision worked through in the action plan. This will mean that the meetings are generally short, as the main discussion will already have taken place, and in the majority of cases, the issues are relatively straightforward. The department receives roughly fifty new cases a month, which should translate to around ten to 12 new cases for each month (numbers dependent on the number of Stage 1 PICs formed – see further paragraph 5a-c below). While the speed at which cases progress can vary, on average it is anticipated that around four or five cases will be decided at each meeting.

5. The VSA allows for there to be a maximum of 15 members in the PIC 'pool'; 10 have currently been appointed – including the overall Chair of PIC. It would therefore be possible to recruit up to five additional members from which to create Stage 1 PICs. There has been much discussion around the appropriate number of Stage 1 PICs to be created with various options possible. These included:

   a. Recruit an additional five members and split into five Stage 1 PICs with the overall Chair participating in the Stage1 PICs as well as Chairing all meetings of the larger Stage 2 PIC / carrying out Reviews etc; OR

   b. Recruit an additional five members and split into five Stage 1 PICs but exclude the overall Chair of PIC – thus requiring one member to double up and be part of 2 Stage 1 PICs; OR

   c. Recruit an additional five members and split into four Stage 1 PICs excluding the overall Chair of PIC, but with two 'floating' members available to step in to cover in the event of any absences / illness. Such 'floating' members would therefore have a much-reduced involvement in Stage 1 decisions but could participate in every second meeting of Stage 2 PIC.

6. These options were discussed at length by PIC / DC Liaison Committee. It did not express a definitive preference but was 'leaning' towards Option C, taking the view that it would be preferable that the overall Chair did not participate in Stage 1 PICs not least because to do so would increase the workload and time commitment for the Chair significantly. While the current Chair might be in a position to do this, thinking longer term to Chairs of the future, it would potentially reduce numbers of those able to carry out the role in the future. PIC / DC Liaison Committee also had some concerns about 'floating' members as it was considered that even changing into Stage 2 PICs regularly they might feel less engaged (a concern reiterated by existing PIC members who felt it important that members participate at all levels of decision making).

7. The views of PIC / DC Liaison Committee were taken back to the PIC members for further discussion. At this, there was consensus that it was preferable that the overall Chair of PIC should not participate in Stage 1 PICs. The view that 'floating' members would be less engaged was also strongly re-iterated. It was considered that having one member double up permanently would create workload and timing issues for an individual whereas members expressed a willingness to assist on an ad hoc basis as necessary.

8. While all possibilities remain for Council's consideration, taking all the views expressed to date into account, the following is proposed:

    a. To recruit three further members to the PIC pool taking the total to 13 (including the overall Chair);

    b. For there to be four Stage 1 PICs (excluding the overall Chair of PIC) with members providing cover for absences / illnesses etc as needed;

    c. To ensure consistency and to avoid any group becoming 'set' for the constitution of each of the four Stage 1 PICs to change regularly (every six-12 months);

    d. For members to be allocated to the Stage 1 PICs randomly; cases likewise generally to be allocated randomly. In terms of the VSA, the requirement is for one registrant / one lay / one other, so some groups might have a 'majority' of lay,with some having a 'majority' of registrants (either veterinary surgeons or veterinary nurses). Either would be perfectly acceptable in terms of the legislation. As now individual cases will be allocated to individual Case Managers who will also be allocated to the Stage 1 PICs;

    e. Decisions of the Stage 1 PICs will be by majority decision;

    f. Each Stage 1 PIC meeting to have a 'Lead' (not a formal Chair) but who will be responsible for the conduct of the bi-weekly meetings;

    g. To review operation after 12-months' time.

9. As indicated at paragraph 4 above, while not limited by any of the provisions of the VSA, the process for Stage 1 PICs will be replicated for RVN PIC – in that case it will be necessary to recruit two further members to the RVN pool (one RVN and one lay member) but otherwise the identical process is proposed for the RVN Stage 1 PIC.

Charter Case Committee (CCC) / Protocol (CCP)

10. In some ways the constitution of the CCC is more straight forward as there are no restrictions of the VSA to be considered. The estimated volume of work for this committee is relatively low – we have estimated around 20 cases per annum. The minimum number required would be two: one vet or VN and one lay; but could be any number subject to having enough in the 'pool' to allow for potential conflicts, availability etc., but not so many such that very few cases are undertaken by each individual and members do not build up sufficient experience / expertise.

11. This was discussed by the PIC / DC Liaison Committee who considered that a committee of three would be preferable – one registrant / one lay member / one other. It was of the view that lay members with a broad range of backgrounds, and that someone with legal training would be useful to draft decisions. This could be the lay member or a registrant with additional legal training. As a new committee all members will need to be recruited and it is envisaged that it will be necessary to recruit two veterinary surgeons, two RVNs and two lay members to ensure that there are enough members in the 'pool' to form quorate committees in the event conflicts of interest arise. It is proposed that this will be by independent external recruitment (in the same way as recruitment is carried out for PIC and DC. Council is asked to consider and approve the draft Charter Case Protocol and Rules as set out in Annexes A and B.

Re-naming the Charter Case Committee?

12. The titles 'Charter Case Committee' / 'Charter Case Protocol' were created as working titles pre-Council to express the concept. It was considered by PIC / DC Liaison Committee that Charter Case Protocol / Committee, while understood within the College and accurately reflecting its source, said less about the function of the committee and that it would be preferable if the name could be descriptive of its function, i.e. what it did. Encapsulating this concisely in a short title proved difficult. Numerous suggestions were considered and rejected with one suggestion tentatively put forward – the "Professional Conduct Appraisal Committee". Council is asked if it wishes to adopt this terminology; continue with the existing titles; or consider something else as being more appropriate.

Decisions required

13. Council is asked to:

    a. Approve the establishment of four mini-PICs (Stage 1 PICs) (or such other number as Council deems appropriate);
    b. Approve the draft amended PIC and DC Protocol;
    c. Approve the constitution of the Charter Case Committee;
    d. Approve the draft Charter Case Protocol;
    e. Approve the draft Charter Case Committee Rules;
    f. Decide if it wishes the working title 'Charter Case Committee' to be retained or to rename.

[Charter Case] Protocol

Introduction

1. The Supplementary Royal Charter 2015 (the Charter), requires the RCVS to set, uphold and advance veterinary standards, and to promote, encourage and advance the study and practice of the art and science of veterinary surgery and medicine, in the interests of the health and welfare of animals and in the wider public interest. The Charter also broadens the functions of the RCVS, allowing for a more flexible approach when dealing with some concerns relating to professional conduct.

2. The RCVS recognises that, in some cases, the public interest can be served without the need for a Disciplinary Committee (DC) hearing even where there is a realistic prospect that the DC would find the veterinary surgeon or veterinary nurse guilty of serious professional misconduct (known as 'the realistic prospect test'). This protocol allows for those cases to be dealt with in an alternative and more proportionate way, whilst still protecting the public interest.

3. Using its powers under the Charter, the RCVS has established a committee to deal with such cases. This committee is known as the Charter Case Committee (CCC).

Referral to the CCC

4. The Preliminary Investigation Committee (PIC) or Veterinary Nurses Preliminary Investigation Committee (VN PIC) may refer cases to the CCC where it is satisfied that the realistic prospect test has been met but where the public interest can be served by one of the outcomes set out at paragraph 7 of this protocol and without referral to DC for a hearing. When deciding whether to refer a case to the CCC, the PIC or VN PIC will consider all relevant factors, including the following:

    a. the seriousness of any allegations;

    b. any admissions that have been made;

    c. the level of insight demonstrated;

    d. the complainant's view;

    e. any relevant mitigation;

    f. the previous history of the veterinary surgeon or veterinary nurse;

    g. whether there is any risk to animal welfare or the wider public interest in dealing with the matter in the way proposed;

    h. the risk of repetition and steps taken to address the concerns raised;

i. the time that has elapsed since the alleged incident/s.

5. The PIC or VN PIC may refer suitable cases to the CCC where a veterinary surgeon or Registered Veterinary Nurse (RVN) disputes the allegations made, provided that the matters disputed do not require resolution by DC.

6. Consent from the veterinary surgeon or RVN is not required to refer a case to the CCC, however consent will be sought and obtained where possible.

Powers of the CCC

7. The CCC may:

   a. issue a public warning, to be published on the RCVS website/in the RCVS register for specified period;

   b. issue a confidential warning; or

   c. refer cases back to the PIC or VN PIC.

8. The CCC may only refer cases back to the PIC or VN PIC where:

   a. the CCC does not agree that the case is suitable to be dealt with under this protocol; or

   b. new information is provided that renders the case unsuitable to be dealt with under this protocol.

9. When deciding which of the above outcomes is most suitable in a particular case, the CCC will consider all relevant factors, including those set out at paragraph 4.

CCC process

10. When a case is referred by the PIC or VN PIC, and the CCC agrees that it is suitable to be dealt with under this protocol, the CCC will notify the veterinary surgeon or RVN that the case has been referred and considered. This notification will include:

    a. details of the proposed warning (see paragraph 18);

    b. whether the CCC intends to publish the warning and if so, for how long.

11. The CCC will also invite the veterinary surgeon or RVN to consent to the proposed outcome, or to make representations if they believe a different outcome is more appropriate. If the veterinary surgeon or veterinary nurse agrees to the proposed course of action, they will be invited to confirm this in writing.

12. Once the veterinary surgeon or RVN has responded to the notification and the CCC is satisfied it has sufficient information, a final decision will be issued. If no consent is given, the CCC may still deal with the case in the way proposed and will give reasons for this as part of its final decision.

13. Warnings will be published seven days after the final decision has been issued, i.e. sent to the veterinary surgeon or RVN. The RCVS will not publish:

    a. any confidential information, including that relating to clients or health conditions;

    b. information that may prejudice other legal proceedings or legal, regulatory or disciplinary investigations;

    c. information which directly relates to the private and family life of the veterinary surgeon or RVN concerned;

    d. references to identifiable third parties.

14. If the veterinary surgeon or RVN does not engage with the CCC, the CCC may still proceed as proposed however it must be satisfied that the practitioner is aware of the proposed course of action.

15. The CCC is not bound by its proposal until the final decision has been issued. If the CCC is provided with further information that means the case is no longer suitable to be dealt with under this protocol, it may refer the matter back to the PIC or VN PIC for consideration.

Warnings

16. Warnings state that an aspect of a practitioner's past practice or conduct was unacceptable and that this should not be repeated. Their purpose is to maintain professional standards and help prevent future breaches of the Code of Professional Conduct ('the Code') by the individual concerned, and in the case of public warnings, all professionals regulated by the RCVS.

17. Warnings may be confidential or public, meaning they are published on the RCVS [website/register]. By publishing warnings in suitable cases, the RCVS can restate publicly what the Code requires in particular situations, which helps to promote and maintain professional standards.

18. Warnings issued by the CCC will set out:

    a. the area of concern;

    b. the relevant code provisions and supporting guidance;

    c. the reasons for issuing the warning or advice.

19. A warning will remain on the RCVS [website/register] for a maximum of two years, however the exact length of time in each case will be a matter for the CCC and depend upon the facts of that case.

20. Warnings will remain on an individual's file for a period of five years, after which time they will be removed.

Status of warnings

21. Warnings issued by the CCC will not affect a veterinary surgeon's or RVN's registration status. However, veterinary surgeons and RVNs should bear in mind that they may need to declare such warnings to employers, insurance bodies and other organisations. Details of a warning may also be provided to relevant bodies by the RCVS (e.g. employers or overseas regulatory bodies) where appropriate and in the public interest.

22. If concerns are raised about an individual who has been subject to a warning in the past, the PIC, VN PIC, DC, VN DC or CCC may take that warning into account unless the advice or warning was issued more than five years ago and no longer appears on the file.

Reviews

23. Decisions by the CCC will only be eligible for review where:

    a. the decision may be materially flawed, or

    b. there is new information which may have led to a different decision.

24. In addition, the Registrar must be satisfied that the review is in the public interest or is necessary to prevent injustice to the veterinary surgeon or RVN. Further, cases where the veterinary surgeon or RVN has consented to the warning will not be eligible for review.

25. Where the above criteria are met, reviews will be carried out by a differently constituted CCC and any public record will be amended to show that the decision is under review.

[Charter Case Committee] Rules

Made by the Council of the Royal College of Veterinary Surgeons on XXXX, to come in to force on XXXX

Citation

1. These rules may be cited as the Royal College of Veterinary Surgeons Charter Case Rules 2021.

Interpretation

2. In these rules:-

- “Act” means the Veterinary Surgeons Act 1966;
- “Charter” means the Supplementary Royal Charter 2015;
- “Council” means the Council of the RCVS mentioned in section 1 of the Act;
- "Disciplinary Committee" means the Disciplinary Committee mentioned in section 15 of the Act;
- "Lay person" means a person who is not and never has been a registered veterinary surgeon or a registered or listed veterinary nurse, and is not and never has been entitled to apply to be so registered or listed;
- “Legally qualified” means a solicitor, barrister, Scottish advocate or member of the Northern Irish Bar;
- "Preliminary Investigation Committee" means the Preliminary Investigation Committee set up under section 15 of the Act;
- “Veterinary Nurses’ Council” means the Veterinary Nurses’ Council mentioned in article 13 of the Charter;
- “Veterinary Nurse Disciplinary Committee” means the Veterinary Nurse Disciplinary Committee mentioned in the Royal College of Veterinary Surgeons Veterinary Nurse Conduct and Discipline Rules 2014;
- “Veterinary Nurse Preliminary Investigation Committee” means the Veterinary Nurse Preliminary Investigation Committee mentioned in the Royal College of Veterinary Surgeons Veterinary Nurse Conduct and Discipline Rules 2014 ;

The Charter Case Committee

3. There shall be a Charter Case Committee which shall determine cases referred to it by the Preliminary Investigation Committee or the Veterinary Nurse Preliminary Investigation Committee, or by other means, in line with the Charter Case Protocol.

4. The quorum for decisions of the Charter Case Committee shall be three, to include:

   - a lay member and a veterinary surgeon and one other; or

   - a lay member and a veterinary nurse and one other.

5. One member of the Committee shall be legally qualified, and this member shall have responsibility for drafting the decisions of the Committee.

6. The Committee shall be chaired by a lay person.

Appointment of members

7. The Council will set up a committee (here referred to as "the selection committee") to advise it on the appointment of members of the Charter Case Committee. Before appointing members of the Charter Case Committee, Council will have regard to the advice of the selection committee.

8. The selection committee will not include members of the Council or the Veterinary Nurses Council.

9. The following are ineligible for membership of the Charter Case Committee:

   - members of Council or the Veterinary Nurses' Council;

   - current or previous members of the Preliminary Investigation Committee or Veterinary Nurses Preliminary Investigation Committee (unless three years has lapsed since their membership);

   - current members of the Disciplinary Committee or Veterinary Nurses Disciplinary Committee.

Term of office

10. Appointed members of the Charter Case Committee will hold office for four years or such shorter terms as the Council may determine in a particular case.

Conditions about fitness to be a member of the Charter Case Committee

11. Members of the committees will hold office subject to satisfying the following conditions:

    a. they must at no time have been convicted of an offence involving dishonesty or deception in the United Kingdom, or in relation to the welfare of animals, or where the final outcome of the proceedings was a sentence of imprisonment or detention, the conviction not being a spent conviction;

    b. they must at no time have been removed from the office of charity trustee or trustee for a

charity by reason of any misconduct or mismanagement in the administration of the charity forwhich the person was responsible or to which the person was privy, or which the person contributed to or facilitated by their conduct;

c. they must at no time have been removed from office as the chair, member, convenor or director of any public body on the grounds that it was not in the interests of, or conducive to the good management of, that body that the person should continue to hold that office;

d. they must at no time have been adjudged bankrupt or had sequestration of their estate awarded, the person not having been discharged;

e. they must not be the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order;

f. they must at no time have made a composition or arrangement with, or granted a trustdeed for, their creditors, not having been discharged in respect of it;

g. they must not be disqualified from being a company director;

h. they must not be included in a barred list under statutory provisions for the safeguarding of vulnerable groups;

i. they must at no time have been subject to any investigation or proceedings concerning fitness to practise by any licensing body, if the final outcome of the investigation or proceedings was suspension from a register held by the licensing body (that suspension nothaving been terminated), or erasure from such a register, or a decision that had the effect of preventing practice of the profession licensed or regulated by the licensing body, or only allowing practice subject to conditions which were not lifted;

j. they must at no time have had their name removed from the register of veterinary surgeons under section 16 of the Veterinary Surgeons Act 1966 or the register of veterinary nurses under paragraph 11 of the Royal College of Veterinary Surgeons Veterinary Nurse Conduct and Discipline Rules 2014;

k. they must not have been the subject of a direction under section 16 of the Veterinary Surgeons Act 1966 or the register of veterinary nurses under paragraph 11 of the Royal College of Veterinary Surgeons Veterinary Nurse Conduct and Discipline Rules 2014 for their registration to be suspended, if that suspension remains in operation;

l. they must not have been subject to an adverse finding by any licensing body or regulator as regards their fitness to practise;

m. they must not be, or have been, subject to any investigation or proceedings concerning fitness to practise by any licensing body or by the Council, or at any time convicted of an offence elsewhere than in the United Kingdom, if the Council is satisfied that their membershipof the committee would in view of that investigation or those proceedings or

that conviction be liable to undermine public confidence in the regulation of the veterinary profession;

n. they must undertake any education or training required by the Council and comply withany arrangements as to appraisal of their performance as committee members which the Council may require;

o. they must not be unable to perform their duties as committee members because ofadverse physical or mental health.

12. The Council may remove from office any member of the Charter Case Committee if satisfied that they do not comply with one or more of the conditions mentioned above, or that their membership of the committee would for any other reason be liable to undermine public confidence in the regulation of the veterinary profession.

13. Before removing a member of the Charter Case Committee from office, the Council will set up a panel to advise it on the matter and will have regard to the advice of that panel. The panel will not include members of the Council.

Powers of the Charter Case Committee

14. In line with the Charter Case Protocol, the Charter Case Committee may:

- Issue a warning to a veterinary surgeon or Registered Veterinary Nurse, to be published on the RCVS website for a period of time specified by the Committee, or

- Issue a confidential warning to a veterinary surgeon or Registered Veterinary Nurse, or

- Refer cases back to the Preliminary Investigation Committee or the Veterinary Nurse Preliminary Investigation Committee.

Decisions

15. The CCC may make decisions at a meeting, by reviewing the documents or by other means.

16. Decisions of the CCC shall be by majority.

RCVS SETTING VETERINARY STANDARDS

Preliminary Investigation Committee and Disciplinary Committee protocol

Made by the Council of the Royal College of Veterinary Surgeons on ~~6 November 2014~~XXX, to come into force on ~~the date when the Supplemental Royal Charter of 2014 comes into operation~~XXX

Citation

1. This protocol may be cited as the Royal College of Veterinary Surgeons Preliminary Investigation Committee and Disciplinary Committee Protocol ~~2014~~2021.

Interpretation

2. In this protocol, "the committees" or "the statutory committees" means the Preliminary Investigation Committee and the Disciplinary Committee.

~~3.~~ References to the appointment of members of the committees are to the appointment by the Council of persons other than its own members under paragraph 1 of Schedule 2 to the Veterinary Surgeons Act 1966.

3. "Stage one cases" are those in which the Preliminary Investigation Committee can decide that there is not a realistic prospect of proving serious professional misconduct on the basis of information provided without recourse to further or more extensive investigation.

4. ~~-~~"Stage two cases" are those that may require further investigation (for example, expert evidence or formal statements) in order to determine whether there is a realistic prospect of proving serious professional misconduct.

Appointment of committee members

~~4.~~5. The Council will set up a committee (here referred to as "the selection committee") to advise it on the appointment of members of the statutory committees. Before appointing members of the committees Council will have regard to the advice of the selection committee.

~~5.~~6. The selection committee will not include members of the Council.

~~6.~~7. A person who has served as a member of the Preliminary Investigation Committee will not be appointed to the Disciplinary Committee unless three years have elapsed since the person concerned ceased to be a member of the Preliminary Investigation Committee.

Term of office

8. Appointed members of the committees will hold office for four years or such shorter term as the Council may determine in a particular case.

~~7.~~9. Appointed members may serve for a maximum of two terms.

~~8. Members of the Council elected to serve as members of the committees during the transitional period specified in paragraph 3A of Schedule 2 to the Act will hold office for one year or such shorter term as the Council may determine in a particular case.~~

Conditions about fitness to be a member of a statutory committee

~~9.~~10. Members of the committees will hold office subject to satisfying the following conditions:-

(a) they must at no time have been convicted of an offence involving dishonesty or deception in the United Kingdom, or in relation to the welfare of animals, or where the final outcome of the proceedings was a sentence of imprisonment or detention, the conviction not being a spent conviction;

(b) they must at no time have been removed from the office of charity trustee or trustee for a charity by reason of any misconduct or mismanagement in the administration of the charity for which the person was responsible or to which the person was privy, or which the person contributed to or facilitated by their conduct;

(c) they must at no time have been removed from office as the chair, member, convenor or director of any public body on the grounds that it was not in the interests of, or conducive to the good management of, that body that the person should continue to hold that office;

(d) they must at no time have been adjudged bankrupt or had sequestration of their estate awarded, the person not having been discharged;

(e) they must not be the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order;

(f) they must at no time have made a composition or arrangement with, or granted a trust deed for, their creditors, not having been discharged in respect of it;

(g) they must not be disqualified from being a company director;

(h) they must not be included in a barred list under statutory provisions for the safeguarding of vulnerable groups;

(i) they must at no time have been subject to any investigation or proceedings concerning fitness to practise by any licensing body, if the final outcome of the investigation or proceedings was suspension from a register held by the licensing body (that suspension not having been terminated), or erasure from such a register, or a decision that had the effect of preventing practice of the profession licensed or regulated by the licensing body, or only allowing practice subject to conditions which were not lifted;

(j) they must at no time have had their name removed from the register of veterinary surgeons under section 16 of the Veterinary Surgeons Act 1966;

(k) they must not have been the subject of a direction under section 16 of the Veterinary Surgeons Act 1966 for their registration to be suspended, if that suspension remains in operation;

(l) they must not be, or have been, subject to any investigation or proceedings concerning fitness to practise by any licensing body or by the Council, or at any time convicted of an offence elsewhere than in the United Kingdom, if the Council is satisfied that their membership of the committee would in view of that investigation or those proceedings or that conviction be liable to undermine public confidence in the regulation of the veterinary profession;

(m) their attendance at meetings of the committee must not have fallen below a minimum level of attendance acceptable to the Council;

(n) they must undertake any education or training required by the Council and comply with any arrangements as to appraisal of their performance as committee members which the Council may require;

(o) they must not be unable to perform their duties as committee members because of adverse physical or mental health.

~~10.~~11. The Council may remove from office any member of a statutory committee if satisfied that they do not comply with one or more of the conditions mentioned above, or that their membership of the committee would for any other reason be liable to undermine public confidence in the regulation ofthe veterinary profession.

12. Before removing from office a member of a statutory committee, the Council will set up a panel to advise it on the matter and will have regard to the advice of that panel. The panel will not include members of the Council.

Chair

13. The Council shall designate a member of each statutory committee as chair, as specified in paragraph 1(5) of Schedule 2 of the Act.

Vice-chair~~men~~

~~11.~~14. The Council may from time to time designate one or more members of a statutory committee to bevice-chair~~men~~, and may at any time remove such a designation.

~~**Chairing of meetings of the Preliminary Investigation Committee**~~

~~12. The chairman or a vice-chairman of the Preliminary Investigation Committee shall preside at its meetings. If, during the course of a meeting of the committee, the person presiding ceases to be able to do so by reason of indisposition, conflict of interest or some other cause, the chairman or a vice-chairman or such other member of the committee as the members of the committee present may choose shall preside for the rest of the meeting.~~

Clerk to Preliminary Investigation Committee

~~13.~~15. The registrar shall appoint a clerk to the committee, who may be an employee of the College but not a member of the Council.

Stage one case meetings of the Preliminary Investigation Committee

16. ~~16.~~ Cases at stage one shall be considered at a meeting of the committee (generally consisting of three members), one of whom will lead the meeting. The Clerk shall convene meetings in consultation with the members. Such meetings shall be held fortnightly.

17. Cases can be closed with or without advice at stage one meetings. Matters that cannot be concluded at this point will be referred on to a stage two case meeting.

Stage two case meetings of the Preliminary Investigation Committee

17 Cases at stage two shall be considered at a meeting of the committee. Such meetings are to be held as required.

18 Stage two cases can be closed (with or without advice), referred to the Disciplinary Committee, or referred to the CCC [name tbc].

19 The clerk shall convene stage two case meetings of the committee, having consulted the chair or, in the absence or incapacity of the chair, the vice-chair. At least ten days' notice shall be given of every meeting, unless the chair or vice-chair who is to preside atthe meeting directs that a shorter period is permissible.

18. The agenda for a stage two case meeting of the committee shall state clearly the business to be transacted.

19. The chair or a vice-chair of the Preliminary Investigation Committee shall preside at stage two case meetings. If, during the course of a meeting of the committee, the person presiding ceases to be able to do so by reason of indisposition, conflict of interest or some other cause, the chair or a vice-chair or such other member of the committee as the members of the committee present may choose shall preside for the rest of the meeting.

~~14. The clerk shall convene meetings of the committee, having consulted the chairman or, in the absence or incapacity of the chairman, the vice-chairman or vice-chairmen. At least ten days' notice shall be given of every meeting, unless the chairman or vice-chairman who is to preside at the meeting directs that a shorter period is permissible.~~

~~15. The agenda for a meeting of the committee shall state clearly the business to be transacted.~~

Meetings of the committees

~~16.~~18. The committees may meet and conduct inquiries with less than the full membership of thecommittee being present.

~~17.~~19. Any decision made by one of the committees at such a meeting or inquiry shall be a decision ofthe committee, provided that the quorum for meetings of the committee, as specified in paragraph 3 of Schedule 2 to the Act, is observed.

Reporting to the Council

~~18.~~20. The committees shall report to the Council from time to time on the discharge of their

Commented [GC1]: Not sure we need to specify this, but added for completeness.

functions.

RCVS SETTING VETERINARY STANDARDS

Summary

Meeting	Council
Date	11 November 2021
Title	New RCVS Accreditation Standards and Methodology for Veterinary Degree Programmes
Summary	In 2019, it was agreed that a comprehensive review of the RCVS Accreditation Standards, and the methodology used for the accreditation of veterinary programmes, would be carried out. This was to ensure that RCVS accreditation remained fit for purpose, and in line with international best practice. Following an extensive effort in gathering evidence, including a commissioned review of the published literature, interviews with UK vet schools, interviews with other professional regulators and a mapping exercise of international standards, the Accreditation Review Working Party (ARWP) agreed new Standards and a methodological framework for their implementation. The new accreditation standards and methodology were approved for consultation with the profession by Education Committee in May 2021, and by RCVS Council in June 2021. A consultation subsequently took place which closed in September 2021, which saw strong engagement from a wide range of stakeholders. Proposals for amendments to the standards and methodology arising from the consultation feedback were approved by Education Committee in October 2021. These have now been actioned and the final draft documents are presented to Council for final approval.
Decisions required	Council is asked to approve the new accreditation standards and methodology, for implementation January 2023.
Attachments	Annex 1: New RCVS Accreditation Standards Annex 2: New RCVS Accreditation Methodology Annex 3: Consultation report, with Education Committee minutes
Author	L Prescott-Clements Director of Education L.Prescott-Clements@rcvs.org.uk

Classifications

Document	Classification[1]	Rationales[2]
Paper	Unclassified	n/a
Annex 1	Unclassified	n/a
Annex 2	Unclassified	n/a
Annex 3	Unclassified	n/a

[1]Classifications explained

Unclassified	Papers will be published on the internet and recipients may share them and discuss them freely with anyone. This may include papers marked 'Draft'.
Confidential	Temporarily available only to Council Members, non-Council members of the relevant committee, sub-committee, working party or Board and not for dissemination outside that group unless and until the relevant committee or Council has given approval for public discussion, consultation or publication.
Private	The paper includes personal data which should not be disclosed at any time or for any reason, unless the data subject has agreed otherwise. The Chair may, however, indicate after discussion that there are general issues which can be disclosed, for example in reports to committees and Council.

[2]Classification rationales

Confidential	1. To allow the Committee or Council to come to a view itself, before presenting to and/or consulting with others 2. To maintain the confidence of another organisation 3. To protect commercially sensitive information 4. To maintain public confidence in and/or uphold the reputation of the veterinary professions and/or the RCVS
Private	5. To protect information which may contain personal data, special category data, and/or criminal offence data, as listed under the General Data Protection Regulation

New RCVS Accreditation Standards and Methodology for Veterinary Degree Programmes

1. In 2019, it was agreed that a comprehensive review of the RCVS Accreditation Standards, and the methodology used for the accreditation of veterinary programmes, would be carried out. This was to ensure that RCVS accreditation remained fit for purpose, and in line with international best practice.

2. Following an extensive effort in gathering evidence, including a commissioned review of the published literature, interviews with UK vet schools, interviews with other professional regulators and a mapping exercise of international standards, the Accreditation Review Working Party (ARWP) agreed new Standards and a methodological framework for their implementation.

3. The new Standards are presented in six domains: 1. The Learning Environment, 2. Organisation, Culture and Values, 3. Educational Governance and Quality Improvement, 4. Supporting Students, 5. Supporting Educators, and 6. Curriculum and Assessment. The standards within the domains have been carefully drafted to ensure they are relevant to all programmes regardless of the curriculum or delivery model, and also to avoid duplication across standards which could lead to 'double jeopardy' where a school is penalised across two separate standards for a single issue or deficiency.

4. The new methodology proposed introduces a more meaningful consideration of evidence that standards are being met, avoiding a 'tick-box' exercise and ensuring examples of positive educational outcomes and innovation are recognised. The approach proposed focuses increasingly on outcomes evidence, moving away where appropriate from 'inputs' alone. This is combined with a risk-based approach, which would enable schools with substantial evidence of positive outcomes submitted in advance to have a more 'lighter-touch' visitation which focused solely on any gaps in evidence or the need to triangulate.

5. The new accreditation standards and methodology were approved for consultation with the profession by Education Committee in May 2021, and by RCVS Council in June 2021. A consultation subsequently took place which closed in September 2021, which saw strong engagement from a wide range of stakeholders.

6. Proposals for amendments to the standards and methodology arising from the consultation feedback were approved by Education Committee in October 2021. The full report of the consultation and minutes of the discussions at Education Committee when considering amendments, is included in Annex 3.

7. The amendments approved by Education Committee have now been actioned and the final draft documents are presented to Council for final approval.

SETTING VETERINARY STANDARDS

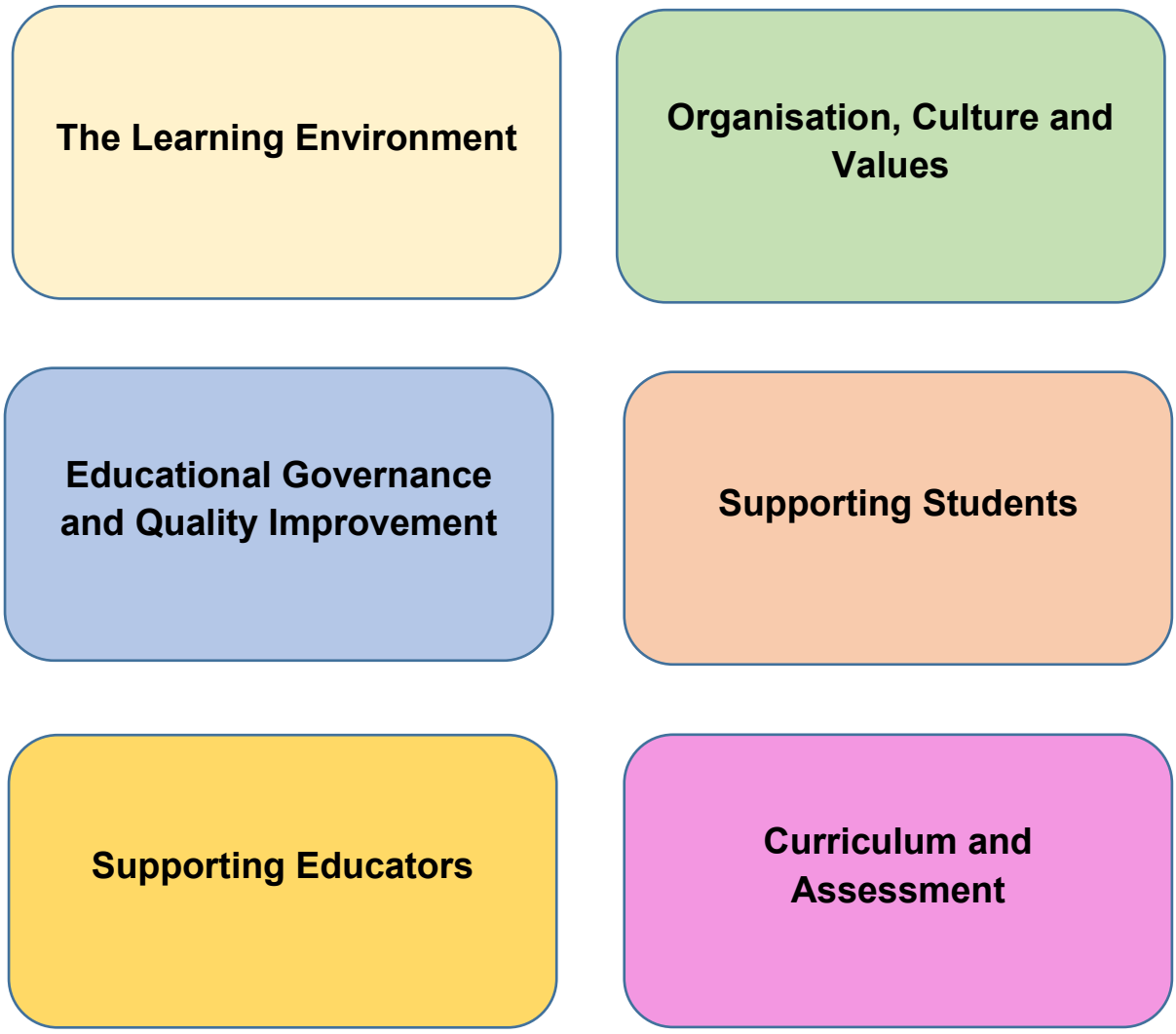
RCVS Standards and Guidance for the Accreditation of Veterinary Degree Programmes

2021

Index

RCVS Accreditation Standards

The RCVS accreditation standards are described within a framework comprising six domains as follows.



Domain 1: The Learning Environment

Standards 1.1 – 1.14

1.1. The spaces, infrastructure, physical and digital resources across the programme must provide an effective and safe learning and teaching environment, support student welfare, and meet the needs of educators and support staff.

Additional guidance:

- *Lecture theatres, teaching laboratories, tutorial rooms, clinical facilities and other teaching spaces must be adequate in number and size, and equipped for the instructional purposes and must be well maintained.*
- *Student welfare needs to be addressed so that there is ready access to adequate study, digital, recreation, locker and food services facilities. The same standards of support and course quality should be delivered regardless of the need for any adjustments for students.*
- *Core teaching sites to have dedicated learning spaces and internet access. Medical records must be comprehensive and maintained in an effective retrieval system.*
- *Schools are encouraged to offer multiple learning modalities across the programme.*

1.2. The learning environments across the programme must ensure the health and safety of students, staff and animals and comply with all relevant jurisdictional legislation including health, safety, biosecurity and UK animal welfare and care standards.

Additional guidance:

- *"Learning environments" encompasses all areas (including off-site) where students are present, including EMS placements. Students should not be attending placements where their health and safety would be compromised, and at a minimum the EMS placement should be reviewed for suitability.*
- *There must be appropriate reporting mechanisms for staff or students to report safety concerns, including when undertaking EMS placements.*
- *Operational policies and procedures should be visible.*
- *The evidence submitted in support of this standard should include details and frequency of audits, and how the school responds to incidents.*
- *For non-UK schools, adherence to local legislation is required, however, students should be taught best practice from a UK context.*

1.3. All learning environments (within the school and off-site) must be quality assured to ensure appropriate standards of teaching, support and learning outcomes are achieved.

Additional guidance:

- *All learning and teaching environments (both on campus and off-site) relate to the infrastructure and the physical resources within it. This includes digital and virtual learning environments.*

1.4. The learning environments across all aspects of the programme must demonstrate good practice standards and promote high standards of animal husbandry and care at all times.

Additional guidance:

- *The school must ensure any hospitals and practices involved with core teaching must meet the relevant RCVS Practice Standards (for UK schools). Practices should be accredited under the RCVS Practice Standards Scheme to Core level as a minimum requirement (although practices should aspire to achieving the higher levels), or to the relevant standard for the teaching undertaken at the establishment (PSS requirement does not extend to EMS placements).*
- *Systems should be in place for students to raise welfare concerns through placement evaluations of other means.*
- *The livestock facilities and animal housing in all learning environments must:*
  - *be sufficient in capacity;*
  - *be of a high standard and well maintained;*
  - *be fit for purpose;*
  - *promote best husbandry, welfare and management practices.*

1.5. Normal and diseased animals of the principal domestic and exotic species must be available for instructional purposes, either as clinical patients or provided by the school. The school must provide access to sufficient numbers and range of animals and animal material to provide the necessary quantity and quality of animal husbandry and clinical instruction to meet the programme learning outcomes and achieve the RCVS Day One Competences.

Additional guidance:

- *"Principal domestic and exotic species" should reflect those commonly encountered in the UK, in both general and specialist practice. Normal and diseased animals, as well as cadavers for post-mortem purposes, must be provided for hands on clinical instruction. Diseases should reflect those regularly encountered in the UK.*
- *"Provided" by the school can relate to live animals presented as patients or 'resident' animals used for teaching, or preserved specimens. However, every attempt should be made for common diseases to be presented in live clinical cases rather than preserved materials.*

- *A judgment will be made against the rationale for how animal numbers are sufficient for students to meet the Day One Competences.*

1.6. There must be sufficient up-to-date and well-maintained learning and teaching equipment to support the programme effectively, readily accessible by students.

Additional guidance:

- *Equipment should be sufficient in number for the student cohorts and a reflection of the equipment used in general practice, including simulations and models.*
- *All students should have adequate opportunity to practice using equipment individually, and not just observing demonstrations in a group or from a distance.*

1.7. The school must ensure students have access to a broad range of diagnostic and therapeutic facilities, of sufficient standard and in number to enable learning outcomes to be met and achievement of the RCVS Day One Competences.

Additional guidance:

- *Facilities available must be sufficient for the number in the student cohort, including but not limited to pharmacy, dentistry, diagnostic imaging, anaesthesia, clinical and anatomical pathology, intensive/critical care, surgeries and treatment facilities, ambulatory services and necropsy facilities.*

1.8. A supervised field service and/or ambulatory programme must be available as part of the programme, in which students are offered multiple opportunities to obtain clinical experience under field conditions.

No further guidance required.

1.9. Appropriate isolation facilities/provision must be available at all sites where clinical instruction is delivered, or be able to be supplied when needed, to meet the need for the isolation and containment of animals with communicable diseases. Students must receive instruction within this environment on how to provide for animal care in accordance with accepted best practice for prevention of spread of infectious agents.

Additional guidance:

- *The size and type of isolation facility/provision will vary in line with relevant industry guidelines and should be appropriate to species being treated. Where permanent isolation facility is not present, the ability to provide such facilities in an emergency must be demonstrated.*

1.10. Clinical education in veterinary public health training must be complemented by direct exposure in commercially run, approved abattoirs.

Additional guidance:

- *Clinical teaching in its entirety can be a combination of virtual teaching and live exposure, but must include direct exposure to a working, commercially approved red or white meat abattoir. Opportunities for further experience must be made available if requested by the student.*
- *Review of facilities during an accreditation visit can either be through video or direct observation.*
- *"Commercially run" refers to commerce or business activity. "Approved" relates to establishments which require veterinary control and are approved by the Food Standards Agency.*

1.11. Patient medical records within all sites used for clinical teaching must be comprehensive and maintained in an effective retrieval system to efficiently support the teaching, research, and service programmes of the school.

Additional guidance:

- *Systems should be fully accessible for all students within the cohort as required for their learning, and a reflection of those used in general practice. Student interaction with patient medical records, at a minimum, would include pricing, client communication logs, patient progress including procedures and client record creation.*
- *Students must receive General Data Protection Regulations (GDPR) training in advance of clinical placements.*

1.12. Students and educators must have timely access to literature and information resources relevant to the programme. An appropriately qualified individual must be available to support students and educators in the effective retrieval of information.

Additional guidance:

- *Learning resources to include scientific and other relevant literature, and internal study resources. Students must be able to access the internet in order to retrieve the information resources at all sites where clinical education takes place.*
- *Students should generally have access to information as they require it in most learning environments. "Timely" refers to a minimum of 'daily', which may be appropriate for teaching taking place on farms or ambulatory settings.*
- *There must be an effective mechanism for students to convey their requests for additional resources relevant to the programme.*
- *Information resources can be provided through print, electronic media or other means.*

1.13. Students and educators must have timely access to non-animal resources relevant to the programme.

Additional guidance:

- *Non-animal resources to support the teaching of procedural and technical skills would include models and simulations such as those found within a typical clinical skills laboratory.*
- *"Timely" in this context would relate to that being sufficient in order for the student to achieve the learning outcomes as required by the programme.*

1.14. The school must establish post-graduate programmes such as internships, residencies, and advanced degrees (e.g., MSc, PhD), that enrich, complement, and strengthen the professional programme.

Additional guidance:

- *Programmes should complement and strengthen areas across the curriculum and schools are required to demonstrate how this is achieved.*
- *If the post-graduate programmes are not currently running, they should be planned to commence within an appropriate timeframe.*

Domain 2: Organisation, Culture and Values

Standards 2.1 - 2.6

2.1. The school demonstrates effective strategic & operational planning, including evidence that goals are being achieved in a timely manner.

Additional guidance:

- *Strategic plans should include short-, mid- and long-term goals.*

2.2. The school must have a system in place to identify, actively monitor and address risks to any aspect of the vet programme.

Additional guidance:

- *Evidence supporting this standard will be dependent on the nature of the risks and/or issues identified.*

2.3. The school can demonstrate a culture which is inclusive, actively seeking and responding to feedback from stakeholders, and involving them in decisions relating to programme development, delivery, and enhancement.

Additional guidance:

- *This standard relates to good practice and organisational culture in the wider context – associated with human welfare, workplace consideration and respect – in addition to the requirement to work within local laws in this area (employment law, human rights etc.)*
- *Stakeholder feedback must include future employers and general practitioners. Schools will be required to demonstrate how they have responded to such feedback.*

2.4. The school must actively promote and maintain a culture that does not discriminate and enhances diversity, consistent with applicable law. Diversity may include, but is not limited to, race, religion, ethnicity, age, gender, gender identity, sexual orientation, cultural and socioeconomic background, national origin, and disability. There must be reporting mechanisms in place for any individual to raise concerns about discrimination and harassment. Universities must be prepared to withdraw from teaching contracts with partner practices / organisations if they fail to respect the guidance for this standard.

Additional guidance:

- *The school and associated sites where learning takes place must demonstrate their commitment to ensuring a culture which is inclusive and diverse. Where active monitoring is not possible, e.g. EMS placements, the minimum requirement would be that there is clear guidance for the provider and an effective reporting mechanism for issues relating to*

diversity, equality, inclusion and harassment. Schools must also have robust protocols for how such reports are acted upon. Demonstration of this commitment would include (but not be limited to) the following areas:

- *Understanding and acting on equality law and their responsibilities*
- *Actively working to increase awareness and understanding of issues affecting anyone they work with that may lead to discrimination or offence*
- *Investment in training, and demonstrating knowledge on equality and diversity matters is implemented*
- *Promoting an open culture of discussing equality and diversity issues in the workplace*

- *Strategies aimed at improving diversity and inclusion should be regularly reviewed and monitored to ensure they are effective and achieving the goals.*
- *Schools should appoint an equality, inclusivity and diversity champion, and recognise that it may be necessary to make reasonable adjustments, for both staff and students, to support inclusivity e.g. to accommodate religious clothing requirements in clinical settings.*
- *A zero-tolerance policy for all forms of discrimination and inappropriate behaviour must be available and clearly communicated to everyone, including staff, members of the public, students and EMS providers. The policy must be acted on consistently by all employers and employees, and managers should know how to handle incidents related to discrimination, and where to seek advice.*
- *Where a distributed teaching site demonstrates that they have not adhered to the guidance in this standard, schools should act/responds appropriately to ensure this standard is met.*
- *"Individual" refers to everyone within the veterinary school community, including staff, and those the school interacts with.*

2.5. The school must demonstrate a no-blame culture that investigates, reflects, and learns from mistakes and adopts effective reporting mechanisms and sharing of best practice. Students and staff should feel safe in raising and reporting concerns, and these must be dealt with effectively.

Additional guidance:

- *A no-blame culture must reach and be the experience of all students and all individuals involved in the delivery of clinical teaching on the veterinary programme (and research within the school).*

2.6. The school must demonstrate a commitment to environmental sustainability, including consideration of the impact of delivering the programme on the environment.

Additional guidance:

- *"Sustainability", could relate to a variety of initiatives. Having an awareness of the importance of sustainability, whilst not necessarily important in terms of clinical skills and knowledge, should still form part of a veterinary surgeon's best practice.*

Domain 3: Educational Governance and Quality Improvement

Standards 3.1 – 3.14

3.1. The school must be part of an accredited institution of Higher Education and be recognised and autonomous within that institution with accountability for the quality of the veterinary programme (including the RCVS standards being met).

Additional guidance:

- *The school must have the autonomy to be able to prioritise the needs of the programme.*

3.2. The school demonstrates a commitment to continuous quality improvement across all accreditation standards and aspects of the programme, informed where possible by measurable outcomes and stakeholder engagement.

Additional guidance:

- *This standard is to demonstrate a commitment to and engagement with effective QI. Quality improvement activity should be robust, systematic, and relevant to veterinary professionals' work.*

3.3. The head of school or dean must be an MRCVS. They must have appropriate knowledge and expertise of the veterinary profession, academic affairs and leadership, and have control over the budget for the veterinary programme.

Additional guidance:

- *For overseas schools, this must be a locally registered veterinary surgeon.*

3.4. Finances must be reviewed regularly in line with strategic plans and be sufficient to sustain and enhance all aspects of the veterinary programme(s) for the duration of all current cohorts, including teaching and learning, infrastructure, teaching resources and students / staff support.

Additional guidance:

- *Finances for other veterinary-related, non-professional programmes must be reported separately.*

3.5. The managerial, academic and support staff must have the necessary skills and experience for their role and be sufficient in number to support the effective design, delivery and quality assurance of all aspects of the programme.

Additional guidance:

- *Evidence should demonstrate all areas are being covered effectively (with rationale).*
- *Where significant changes to the programme are implemented, evidence should include evaluation data demonstrating the impact on programme / students.*
- *Details of staff roles/levels/qualifications, and numbers and roles of staff in each major area of the programme should be provided along with any changes to staffing (with rationale).*

3.6. The school must demonstrate that the recruitment, selection and appointment of students, educators and staff are open, fair, transparent and free from bias.

Additional guidance:

- *A diversity and inclusion strategy and policy needs to be in place and data relating to this should also be reviewed.*

3.7. The school must have effective and transparent educational governance systems, with formal committee structures, which develop and continually monitor, assure, and enhance the quality of veterinary education and the student experience across all aspects of the programme.

Additional guidance:

- *The committee structures need to include staff and student representation (unless a clear rationale can be provided to justify otherwise); the terms of reference and membership for each committee need to be clear and regularly reviewed.*

3.8. The school must have robust mechanisms for quality assurance and improvement, embedded into policy and processes, which routinely gather data to demonstrate that organisational and educational objectives are being met and opportunities for improvement are identified and responded to.

Additional guidance:

- *Quality data should be collected on both educational processes and outcomes.*

3.9. Mechanisms for quality assurance and improvement must encompass both internal and external review and data collection and analysis.

Additional guidance:

- *Quality data should be at module/units of study and assessment and programme/course level.*

3.10. The school must evaluate students' performance, progression and outcomes with respect to information on equality and diversity and provide support for groups where disparities are identified.

Additional guidance:

- *The focus and data should be in line with the school's strategic aims on diversity and inclusion.*
- *Both quantitative and qualitative data may be used to demonstrate that this standard has been met, particularly when low numbers are involved.*

3.11. The school must regularly review curricula, using available quality assurance data and feedback from students, educators and stakeholders, to ensure standards are being met and maintained.

Additional guidance:

- *On-going reviews to curriculum should take place within the cycle of a single cohort. It is anticipated that curriculum review will take place at different levels at different times, and that a large-scale review will not be necessary every year. However, regular and ongoing review is expected in order to keep the programme current.*
- *Curriculum review should include learning outcomes, syllabus, curriculum model, instructional design and assessment frameworks.*
- *The review committee should have a balanced representation from all stakeholders and have a diverse membership, including but not limited to educators, students and employer representation (including general practitioners).*
- *Large-scale reviews should be conducted on a cycle that is at least every 6-8 years in frequency so that all aspects (including employer and outcomes assessment) can be considered in that review.*

3.12. The school must have effective processes in place to monitor attrition and progression rates in relation to admissions and selection criteria and student support if required.

Additional guidance:

- *If data analysis indicates significant changes in attrition and progression rates, these should be acknowledged and actions in place to address these changes.*

3.13. The school must have effective processes in place to ensure that a continual commitment to student learning and teaching is demonstrated within all locations where clinical teaching takes place.

Additional guidance:

- *Contractual arrangements with partner practices must explicitly reference the commitment to student learning and teaching, and data collected to ensure this commitment is met.*
- *Includes all locations where clinical teaching takes place. EMS is not included here as this does not necessarily take place in a location where clinical teaching is delivered.*

3.14. The school must demonstrate that only students who are fully Day One Competent are able to graduate.

Additional guidance:

- *Evidence must be presented that provides RCVS with reasonable assurance that the school's programme outcomes are being achieved. Or, in the case of a school that has yet to produce graduates, how this will be achieved.*
- *Being 'Day One Competent' is more than simply achieving each of the individual Day One Competences in isolation. Being 'Day One Competent' requires the student to be confident and competent in applying knowledge and skills in a holistic sense, across different clinical or professional contexts, at a level ready to start working as a veterinary practitioner.*

Domain 4: Supporting Students

Standards 4.1 – 4.15

4.1. Effective processes must be in place to support the physical, emotional and welfare needs of students.

Additional guidance:

- *This includes, but is not limited to, learning support and counselling services, careers advice, fair and transparent mechanisms for dealing with student illness, impairment and disability, provision of reasonable accommodations/adjustments for disabled students, consistent with all relevant equality and/or human rights legislation.*

4.2. The school must have a strategy for widening participation which considers all aspects of diversity and engages students from different ethnic and social backgrounds. The school must be proactive in their marketing to attract a diverse cohort of applicants and regularly review, and provide evidence of, their progress towards targets.

Additional guidance:

- *Admissions data should include initial applications, screened applications and successful applications data.*
- *Marketing activities should be wide ranging and regularly reviewed for impact.*
- *Where widening participation targets can be set, these should be sufficiently ambitious to address any national challenges around diversity within the profession.*

4.3. The school must provide accurate and current information regarding the educational programme easily available for prospective students. The information must include the accreditation status of the degree course (whether by RCVS or other relevant accrediting bodies), selection and progression criteria, the demands of the course and the requirements for eventual registration/licence, including fitness to practise.

Additional guidance:

- *In this context, "fitness to practise", relates to meeting the physical, mental and legal demands of the role.*

(Supporting guidance in this area is also being updated by RCVS.)

4.4. Selection and progression criteria must be clearly defined, defensible, consistent and free from discrimination or bias. The criteria must also include relevant factors other than academic performance. The academic requirements for entering the programme must be sufficient for the student to cope with the demands of the programme upon entry.

Additional guidance:

- *There must be a clear rationale in place for the criteria set, to demonstrate how they ensure students are sufficiently prepared for the demands of the programme. Criteria for progression must reliably identify students with the capability to continue through the course.*
- *If there are any exceptional admissions, there must be clear justifications documented.*

(Supporting guidance in this area is also being updated by RCVS.)

4.5. The school must demonstrate their selection and progression criteria and processes are effective in identifying students with the potential to achieve the RCVS Day One Competences. This must be achieved through regular and effective training for staff involved and the routine collection and analysis of selection and progression data, to enable them to evaluate, reflect and adjust the selection and progression criteria where necessary.

Additional guidance:

- *There must be a clear commitment to continual evaluation and review to achieve the best possible outcomes.*

4.6. There must be clear policies and procedures as to how applicants with disabilities or illness will be considered and, if appropriate, accommodated on the programme, taking into account the requirement that all students must be capable of meeting the RCVS Day One Competences by the time they graduate.

Additional guidance:

- *Details should also cover those students who may become disabled during the course.*

(Supporting guidance in this area is also being updated by RCVS.)

4.7. Students must be actively supported to develop resilience, self-reflection and professional values in line with the RCVS Code of Professional Conduct and must not be subject to behaviour which undermines their professional confidence, performance or self-esteem at any sites where teaching and / or learning takes place.

Additional guidance:

- *The 2020 Day One Competences now have increased focus on resilience and professional skills.*
- *This standard includes EMS placements.*
- *Evidence should include data on how this area is being monitored, and the processes in place and actions / follow-up taken if an incident occurs*

4.8. Students must receive continuous and effective educational support to enable them to achieve the learning outcomes of the programme and the RCVS Day One Competences, including the provision of regular, constructive and meaningful feedback on their performance and progress in a timely manner.

Additional guidance:

- *Whilst there may not be a specific feedback policy, we would expect there to be some level of guidance to ensure consistency of approach throughout the programme.*
- *Evidence demonstrating how feedback is meaningful to students may recognise how different approaches to feedback are appropriate in different areas of the programme.*

4.9. Effective processes must be in place by which students can convey their needs and wants to the school. The school must demonstrate how student feedback is considered and acted upon.

Additional guidance:

- *There should be a variety of methods which are inclusive by design, available to the students to effectively convey their needs and wants in terms of support.*

4.10. The school must provide students with a mechanism, anonymously if they wish, to offer suggestions, comments, and complaints regarding the compliance of the school with the RCVS standards for accreditation and that Day One Competences are being met. All such feedback from students must be reported to the RCVS as part of the annual report.

Additional guidance:

- *The methods available to students to provide feedback need to be accessible to all.*
- *Students must have mechanisms to raise concerns about any aspect of the programme, anonymously if they wish.*

4.11. The basis for decisions on progression (including academic progression and professional fitness to practise) must be explicit and readily available to the students. The school must provide evidence that it has effective processes in place to identify and provide remediation and appropriate support (including termination) for students who are not performing adequately in any area of the programme.

Additional guidance:

- *Decisions on progression must remain fair and consistent and any temporary amendments made to accommodate changes in local or global conditions must be clearly communicated to the student body.*

4.12. The school must ensure that students are competent and sufficiently experienced in animal handling before they begin clinical placements and / or workplace learning, and that they are fully briefed regarding all relevant Health and Safety matters.

Additional guidance:

- *There should be a mechanism in place to assess whether students can demonstrate they have the relevant skills necessary to progress to a clinical placement.*
- *A Health and Safety briefing to be included before any animal handling and before student attendance at a work-based environment.*
- *Animal handling experience to include the majority of common UK species across the domains of companion animal, production animal and equine.*

4.13. Mechanisms for dealing with student misconduct and/or the exclusion of students from the programme, either for academic reasons, misconduct or under fitness to practise procedures, must be explicit.

Additional guidance:

- *Policies and procedures must be clearly communicated to the student body.*

4.14. The school must have in place effective processes for the resolution of student grievances.

Additional guidance:

- *Student grievances may include interpersonal conflict or harassment.*

4.15. School policies for managing appeals against decisions, including admissions, academic and progression decisions, must be transparent and publicly available.

Additional guidance:

- *Types of data may include successful/ unsuccessful reviews, how many made it through to panel review, and outcomes.*

Domain 5: Supporting Educators

Standards 5.1 – 5.6

5.1. The school must ensure that all educators who are involved with student teaching have successfully completed, or are working towards, a quality assured programme of teacher training, which effectively prepares educators for their roles.

Additional guidance:

- *Academic staff must have protected time for completion of teacher training studies and be provided with feedback.*
- *The programme should include learning and teaching theory/ practice and pedagogy at an appropriate level.*
- *This applies to permanent members of university staff who were regularly involved with student teaching (rather than "one-off" lectures and / or guest speakers etc.) in addition to all educators outside of the university staff, such as practitioners in partner practices involved in teaching students. Graduate students, interns, residents and Masters students undertaking less formal, but no less regular, teaching of undergraduate students are also included.*
- *Where staff are working towards this requirement, an appropriate timeframe for completion must be agreed.*

5.2. All educators involved in teaching and / or supporting students' learning within the programme must demonstrate their continued competence and effectiveness.

Additional guidance:

- *To include, but not be restricted to, full and part time staff, residents, interns or postgraduate students, adjuncts or off-campus contracted educators.*
- *To include regular evaluation and feedback on performance from students and peers.*
- *This Standard applies to all educators delivering clinical teaching to students (on campus or in partner practices off-site), but not EMS.*
- *There must be the opportunity provided for educators to engage with CPD within their workload. The school must ensure that all educators who are involved with student teaching are supported in their role as educators through regular training and CPD relevant to their role.*

5.3. An appraisal system for all staff must be in place. The school must provide evidence that it has a comprehensive, effective and publicised programme for the professional development of staff. Promotion criteria must be appropriate, clear and explicit.

Additional guidance:

- *School staff at all levels will be expected to engage with an appraisal process.*

5.4. The school must support educators by dealing effectively with concerns of difficulties they face as part of their educational responsibilities. Effective processes must be in place to support the physical, emotional and welfare needs of staff.

Additional guidance:

- *Guidance for staff on how to report concerns about the behaviours of other staff / whistleblowing must be accessible to all staff. A transparent and independent analysis of such data must be in place.*
- *The support of non-academic staff who are involved in teaching should also be considered (for example, technicians, veterinary nurses, etc.).*

5.5. Academic positions must offer the security and benefits necessary to maintain stability, morale, continuity, and competence of the educators. Educators and staff must have a balanced workload of teaching research and service depending on their role; and must have reasonable opportunity and resources for participation in scholarly activities.

Additional guidance:

- *In the event of significant changes in staff stability then evidence would be required to demonstrate that actions are in place to address the issues.*

5.6. The school must provide staff with a mechanism, anonymously if they wish, to offer suggestions, comments, and complaints regarding compliance of the school with the RCVS standards for accreditation and that Day One Competences are being met. All such feedback from staff must be reported to the RCVS as part of the annual report.

Additional guidance:

- *The methodologies available to staff to communicate feedback needs to be able to meet their individual needs to ensure the mechanism is available to all.*
- *Staff must have mechanisms to raise concerns about any aspect of the programme, anonymously if they wish.*

Domain 6: Curriculum and Assessment

Standards 6.1 – 6.22

6.1. Veterinary programmes must be designed and delivered to ensure that students, upon graduation, have achieved the programme learning outcomes (targeted at FHEQ level 7 or equivalent) and the RCVS Day One Competences.

No further guidance required.

6.2. The curriculum shall extend over a period equivalent to a minimum of five academic years and must include a sufficient quantity and quality of hands-on clinical education to ensure students are prepared to meet the requirements of the veterinary role upon graduation.

Additional guidance:

- *4-year graduate entry programmes are also applicable. Entry to a 4-year course (Accelerated Graduate Entry) must include a Bachelors Level degree in a relevant science subject.*
- *A "sufficient quantity" would normally equate to a minimum of the equivalent to one year of workplace-based hands-on clinical education (not including EMS) across the programme, but will depend on the type, duration and intensity of training, and any shorter duration must be rigorously evidenced as being able to achieve the desired outcomes.*

6.3. Veterinary programmes must be underpinned by pedagogical theory or based on best educational practice, involving input from educators, students, employers and other relevant stakeholders, and subject to regular evaluation and review.

Additional guidance:

- *It would be good practice for schools to engage with their own pedagogy research as well as drawing upon evidence based upon theory and practice during the design and delivery of their programme.*
- *'Relevant stakeholders' would include future employers and general practitioners.*
- *'Best educational practice' refers to best practice according to current evidence.*

6.4. The majority of clinical education delivered by the School must focus upon casework in the 'general practice' context, reflecting the reality of veterinary practice in society.

Additional guidance:

- *Anything more than 70% constitutes a 'majority'. (See separate definitions of 'Clinical Education', 'general practice' and 'casework'.)*

- *Clinical Education delivered by the University includes all clinical teaching and training within the programme delivered by academic staff (and not EMS).*
- *It is recognised that some general practice teaching can be delivered within a specialist environment, however schools must demonstrate how students within these environments are taught reflecting a general practice context.*
- *The proportions of clinical education in different contexts (general practice, referral / specialist casework) must also be provided in Annual Monitoring data.*

6.5. The curriculum must describe appropriate learning outcomes which represent and effectively align the required knowledge, skills, and behaviours of a veterinary surgeon with teaching, learning and assessment activities within a cohesive framework.

Additional guidance:

- *The syllabus should encompass all of the knowledge, skills and behaviours to enable a graduate to meet the Day One Competences. (See Appendix 1 to this document for an appropriate list of core subjects.)*

6.6. Under all teaching situations students must be actively engaged in the case. In the majority of cases, students must be actively involved in the investigation and management of the patient (including practical aspects of diagnosis and treatment, as well as clinical reasoning and decision-making).

Additional guidance:

- *Students must also be involved in all aspects of the case including financial and economic factors, which are of high significance in the majority of first opinion cases, and client communication.*

6.7. The programme must give students the opportunity to learn and practice alongside other members of the veterinary team in an holistic manner that reflects the reality of veterinary practice in society.

Additional guidance:

- *To include provision of nursing care and instruction in nursing procedures.*
- *The allied professional team may include, but is not restricted to, Registered Veterinary Nurses (RVNs), practice managers, embryo transfer technicians, AI technicians, equine dental technicians, farriers, nutritionists, behaviourists, physiotherapists, veterinary specialists, Official Auxiliaries/meat hygiene inspectors, blood samplers, animal care assistants/handlers, groomers, hydro-therapists, and others.*

6.8. Students must be supported to gain experience which consolidates their learning throughout the programme through the completion of Extra Mural Studies (EMS). This must be delivered in line with RCVS EMS Policy.

Additional guidance:

- *Students must complete 38 weeks of EMS spread across all years prior to graduation, made up of 12 weeks pre-clinical EMS, and 26 weeks of clinical EMS. Please see the RCVS EMS Policy for the full policy and related guidance.*

6.9. There must be an appropriate structure and resources in place to ensure the oversight, coordination and quality assurance of EMS. There must also be sufficient administrative support in place to assist the students.

Additional guidance:

- *There should be at least one member of academic staff that holds overall responsibility for EMS. This does not necessarily need to a be veterinary surgeon, however a level of understanding of how veterinary practices and other veterinary fields within and related to the profession operate, would be recommended.*
- *Students that are struggling to access placements or meet EMS requirements must be actively supported in achieving these outcomes by the EMS coordinator.*
- *Quality assurance should include a check that insurances are in place and that the placement has been assessed regarding student health and safety. Placements should be considered on their suitability for meeting learning objectives, and placement providers should be aware of what stage the student is up to in their learning. Schools must communicate with providers so that everyone is clear on their roles and responsibilities during EMS. Student feedback should also be considered in determining the suitability of a placement for future EMS.*

6.10. The school must have processes in place to ensure that students are supported in the identification of relevant learning outcomes for their EMS placements, and record and reflect on their achievement.

Additional guidance:

- *Students should be supported and given flexibility to tailor EMS to their own specific educational needs. This must include but not be limited to; students setting their own learning objectives (to include both clinical, non-clinical and professional skills), either in consultation with tutors or independently; and maintaining a reflective record of their EMS placements.*

6.11. The EMS experience must be individual to the student, and they must be able to tailor their experience based on their own learning needs.

Additional guidance:

- *Students should be provided with guidance from their tutors, both before and after placements to plan and review their learning needs before planning future placements.*

Students should also be able to frame their clinical EMS based on their own career aspirations.

6.12. There must be a system in place which allows for feedback from EMS providers of students' performance during EMS placements to be communicated with relevant academic staff.

Additional guidance:

- *Feedback should be on technique and clinical skills, as well as attitude and professional skills.*

6.13. The school must demonstrate that EMS placements consolidate skills which have previously been taught during the programme.

Additional guidance:

- *EMS must compliment IMR and not as an extension of it. Personal learning objectives should be agreed based on prior learning, rather than any teaching requirements.*

6.14. The school must develop and implement a comprehensive and robust assessment strategy, at the programme and modular/unit level, which provides evidence that students meet the requirements for progression across the programme and the Day One Competences upon completion.

Additional guidance:

- *Assessment needs to be built into key points within the curriculum, and upon completion of the programme.*
- *Assessment methods should reflect the holistic nature of practice within the workplace, and provide assurance that graduates can translate and assimilate individual competences into holistic working practices.*
- *Schools should ensure that the summative end-of-course assessment ensures that students demonstrate competence in each discipline and/or construct within the assessment (i.e. no compensation across these elements).*

6.15. The validity, reliability and educational impact of assessments must be appropriate to their purpose (high/low stakes) and evidenced through relevant evaluation data.

Additional guidance:

- *Validity data should include both construct and content validity as a minimum.*
- *Levels of reliability should be in line with accepted benchmarks for the nature and purpose of the assessment (e.g. High stakes assessments would normally be expected to have*

reliability with a coefficient of 0.7 or more). Composite reliability across programmatic assessments is also appropriate.

- *The assessment content, timings and outcomes should be reviewed regularly to ensure they remain fit for purpose.*
- *Direct assessment of clinical, non-clinical and professional skills and holistic clinical practice must form a significant component of the overall process of assessment in the clinical disciplines. 'Holistic clinical practice' refers to students being able to apply knowledge, skills and competences across a spectrum of clinical cases and contexts as would be seen in veterinary practice.*
- *"High stakes assessments", refer to those which lead to progression or completion of any component of the programme, or the programme as a whole.*

6.16. The assessment tasks and grading criteria for each unit of study in the programme must be clearly identified, and available to students in a timely manner well in advance of their assessment. Requirements to pass including the effect of barrier assessments must be explicit.

Additional guidance:

- *Any changes to assessment strategy or grading criteria must be communicated effectively in a timely manner.*

6.17. Assessments must be designed and carried out by individuals with appropriate expertise in the area being assessed, who have been trained in their role as an assessor and understand what is required to make the process robust, including honesty, fairness, consistency, and judgements free from bias.

Additional guidance:

- *In all areas where assessment (either formative or summative) takes place, the assessor should have appropriate training, which can take place within and/or external to the vet school.*

6.18. Assessment load must be sufficient to provide both formative and summative feedback to support students' progress, and to evidence achievement, remaining cognisant of workloads for staff and students.

No further guidance required.

6.19. The school must have appropriate moderation processes in place to ensure parity within and between individual units of study, across the programme, with other institutions; and to ensure that each student is treated without bias.

Additional guidance:

- *Moderation processes should include both internal and external verification.*

6.20. There must be a system for students to keep a record of the quality and quantity of their clinical experience and reflect on their development of clinical and non-clinical skills over the duration of the programme. These records must be regularly reviewed by an educator to inform an individualised development plan. Consolidated data must contribute to the quality improvement of the programme.

Additional guidance:

- *Reflective records can be in any relevant format, but would assist the students if they mirrored the systems currently used for CPD and VetGDP.*

6.21. The school must demonstrate a commitment to research lead teaching throughout the veterinary programme.

Additional guidance:

- *Curriculum content must be evidence-based and informed by research, although not every member of staff needs to be actively involved in research projects.*

6.22. All students must be trained in scientific method and research techniques. All students must have opportunities to participate in research programmes.

Additional guidance:

- *Students must have the opportunity to participate in research, but not every student needs to be actively engaged in research.*
- *All students must be trained in the principles and practice of evidence-based veterinary medicine, including being able to acquire, appraise and apply appropriate evidence from a range of sources in their professional practise.*
- *Students must be given the opportunity to apply research to practice.*

Appendix 1: Core subjects to be included in the syllabus *Core subjects to be formally reviewed by PQSC in January 2022, and agreed prior to implementation of the new Standards*

The curriculum should include the following:

- understanding of biological principles and processes of veterinary significance
- expertise in recognising and advising on normal animal structure and function, husbandry, behaviour, nutrition and feeding, reproduction and breeding, homeostasis, pathophysiology, agents of disease and the natural history and clinical manifestations of important animal diseases
- expertise in medicine, surgery, and anaesthesia applicable to a broad range of common species. Students must develop entry-level skills in physical examination and laboratory diagnostic techniques and interpretation (including clinical pathology, diagnostic imaging and necropsy), disease prevention, biosecurity, therapy (including surgery and pharmacotherapeutics), patient management and care (including primary care, intensive care, emergency medicine, surveillance and isolation procedures) for individual animals, herds, flocks and other populations
- knowledge, skills, values, attitudes and behaviours necessary to contribute, as a veterinarian, to promoting animal health and well being, within changing societal expectations
- clinical, epidemiological, pathophysiological and regulatory skills in management of animal diseases which are:
    - endemic to the UK and the EU
    - endemic to and of special consideration in the country in which the school is located;
    - exotic to the UK and the EU and which are currently regarded as being of concern as potential emergency animal diseases or diseases of global veterinary significance
    - significant emerging diseases
- entry level capability (to OIE standards) in preventive medicine/epidemiology, zoonoses, food safety and hygiene, regulation of animals and animal products, and management of the interrelationship of animals and the environment. This training must include experience in abattoirs.
- professional level problem solving skills in evidence-based diagnosis and clinical management, and data and information management skills
- capacity for professional communication; the ability to acquire information from the owners of animals by direct interaction as well as retrieval of archival data from medical records, communication with colleagues, regulatory bodies and clients
- skills in application of professional ethics, delivery of professional services to the public, personal and business finances and management. An appreciation of the breadth of veterinary science, career opportunities and relevant information about the veterinary profession
- self-management skills in identifying and meeting personal learning needs, maintaining well being and professional relationships.

Appendix 2: Extra-Mural Studies Policy

Extra Mural Studies Policy

Extra Mural Studies (EMS) is a part of students' overall clinical education, and placements are a vital component of the veterinary degree as they provide a unique opportunity for students to gain valuable hands-on experience and practice skills acquired during the veterinary programme, in a further range of 'real workplace learning' contexts. Students are encouraged to identify their own intended learning outcomes for EMS, and undertake EMS placements in areas which complement and enhance their learning and which they feel will benefit them most.

Unlike Intra Mural Rotations (IMR), during which the core teaching of the veterinary programme is delivered formally, the learning which takes place on EMS placements is experiential, focused on the students understanding and applying knowledge and skills from core teaching into a range of workplace contexts. This experiential learning is highly valuable for students as they are able to augment the training they have already received with real-life, hands-on experience that cannot necessarily be captured as part of the curriculum, to help them develop into capable and confident veterinary surgeons. It is also an opportunity to give students further experience in decision making, team working and communication, as well as offer an insight into how finances work in practices away from an academic setting.

EMS placements offer an important insight and introduction into the professional career of a veterinary surgeon, and give vital experience to students before they graduate. EMS also represents the beginning of a life-long cycle of continuing their own professional development outside of a traditional teaching context, which continues after graduation and throughout their career.

Students will, of course, acquire further knowledge and skills whilst on EMS placements. However, all Day One Competences must be covered by the Clinical Education delivered by the University, and EMS placements should not be used to address gaps within core Clinical Education.

Policy

1. A total of **38 weeks** of EMS must be completed over the course of the veterinary degree programme before students are able to graduate.

2. Of these, **12 weeks** must be devoted to **pre-clinical/animal husbandry EMS** (AHEMS), to be completed throughout the pre-clinical years of the programme (usually 1st and 2nd years, however this could be up to the 3rd year in extended or intercalated programmes). Where appropriate for the curriculum model, some clinical EMS may be completed before the third year. However, in these cases, all pre-clinical/AHEMS for the species relevant to the placement being undertaken must have been completed to ensure the safety of the student.

3. The remaining **26 weeks** must be undertaken as **clinical EMS**, to be completed regularly over the final 3 years of the course (or clinical years) before graduation, with normally a recommended minimum of 6 weeks to be completed per year.

Pre-clinical/Animal handling (AH) EMS – 12 weeks

Pre-clinical, or animal husbandry EMS takes place during the earlier years of the veterinary degree course to allow students to gain further experience in animal husbandry and handling of animals in all common domestic species, in authentic, working environments where animals may be less used to being handled than in academic settings. Students can also begin to develop their professional skills with clients and animal owners.

4. 12 weeks is the minimum amount of pre-clinical/AHEMS required, and students are permitted to carry out further weeks should they wish and be able to, separate to the 26 weeks of clinical EMS.

5. Of the 12 weeks required, RCVS stipulates that **at least 1 week** of pre-clinical/AHEMS must take place in each of the main three disciplines: equine, production animal, and small animal. The students intended learning outcomes should be agreed between tutor, student and placement provider before the placement commences, and reflected upon afterwards.

6. It is important for students to be thoroughly briefed on the health and safety aspects of handling animals; therefore students must only undertake pre-clinical/AHEMS in areas where they have already received sufficient teaching and training.

7. The placements can take place in any order, and more than 1 week can take place in a certain area or species domain.

8. Universities are able to consider granting exemptions on a very exceptional basis (for example for students on an accelerated 4-year programme, who have considerable animal handling experience gained on a previous course at tertiary level, or through extensive and relevant work experience). However, any time saved by allowing exemption in one particular area should be spent on developing skills in other areas, or with other species.

9. The remaining weeks of pre-clinical/AHEMS placements can be undertaken in any areas where a student has a particular interest, or where they feel it would be of benefit to them.

10. All pre-clinical/AHEMS placements must take place in person with the student attending on-site. This is to ensure that the student will be directly involved with handling animals and observing animal behaviours during the placement.

11. All pre-clinical/AHEMS placements must directly involve the student in a way that helps to broaden their experience based on the knowledge and skills they have already acquired during core teaching.

12. It is suggested that placements should usually take place within an environment that is outside of the usual teaching environment of the veterinary school.

13. Any placements where a student is not directly involved in handling animals and / or observing animal behaviours for a significant majority of the time spent there, would not be considered appropriate pre-clinical EMS/AHEMS.

Clinical EMS – 26 weeks

Clinical EMS placements are where students are able to further develop their clinical, technical and professional skills that they have been taught in IMR, through experiential learning in real workplace contexts. Clinical EMS placements will take place regularly during the clinical years of the veterinary programme, prior to graduation, with a minimum of six weeks completed per year.

14. Unlike pre-clinical/AHEMS, there is no stipulation as to how many weeks are required for each species or placement type, and students are encouraged to undertake clinical EMS in the areas they feel would interest them and benefit them most. The students intended learning aims and objectives should be agreed with their tutor and placement provider prior to the placement taking place.

15. 26 weeks is the minimum amount of clinical EMS required, and students are free to carry out further weeks should they wish and be able to.

16. Students should only be gaining further experience on clinical EMS placements in clinical skills that they have already been taught through IMR. It is acknowledged that students may learn new techniques and acquire further knowledge whilst on clinical EMS placements, however the responsibility of formally teaching students must still remain with the veterinary school. Clinical EMS must complement what students have learned on IMR, and not act as an extension of it.

17. Clinical EMS must take place in person, with the student attending on-site getting “hands-on”, direct clinical experience with animals. This is to ensure that the student will have the opportunity to further develop the skills they have learned through core teaching, during the EMS placement.

18. Normally clinical EMS placements would be expected to last at least two weeks, however it is recognised that some placements of a certain nature may not require more than one week.

19. Long term research placements can count towards the clinical EMS requirement at the discretion of the school, if a student has an interest in entering the research field, for example.

20. It is suggested that clinical EMS placements should usually take place within an environment that is outside of the usual teaching environment of the veterinary school and its partners.

21. All clinical EMS placements must directly involve the student in a way that helps to broaden their experience based on the knowledge and skills they have already acquired during core teaching.

Professional EMS

22. As part of clinical EMS, up to 2 weeks of “professional EMS” can be allowed for, which could be work placements that may not necessarily be clinically based or be directly involving animals. For example, the following types of placement can be permitted for “professional EMS”:

- Administrative placements with veterinary bodies and/or government;
- Veterinary business placements;
- Veterinary diagnostic laboratory placements;
- Veterinary Public Health placements;
- Named Veterinary Surgeon placements.

(This list is not exhaustive)

23. More than 2 weeks of professional EMS is encouraged at the school’s discretion if a student has a specific and genuine interest in gaining further experience in a non-clinical setting.

24. Professional EMS is not a mandatory requirement as part of clinical EMS.

Guidance on RCVS EMS Policy

Sign-off

1. The RCVS EMS Policy must be implemented by the veterinary school, and the school will have the final sign off on all EMS placements. Where flexibility is allowed for within the policy, it is up to the veterinary school to make the final decision on what is and is not accepted for EMS placements.

Number of weeks

2. As stated in the policy, the requirement for completion of EMS is 38 weeks: 12 weeks pre-clinical, or animal handling (AHEMS), EMS; and 26 weeks clinical EMS. This is the minimum requirement – students can obtain further weeks if they are able to.

3. The length of a week should primarily be based on the providers' working week. For example, if a placement provider has asked the student to be present from Monday to Saturday, then that would constitute one week. The vet school will always have the final sign off on what constitutes a "week" of EMS, and it is advised that common sense and discretion is applied.

4. It is accepted that some weeks' placements may be longer than others. The minimum amount of time for a working week would be expected to be 5 days. Exceptions can be made for bank holidays.

5. Placements may not necessarily have to take place over consecutive days. For example, a student could attend a placement over consecutive weekends which could count towards the requirement. Again, in this instance the school would need to make the final judgement over how many "weeks" the placement would count for based on the amount of days attended.

6. Schools are encouraged to make allowances for students' absence if a placement may fall outside the time of a usual university week. For example, if a placement finishes on a Sunday night and a student may be unable to travel back in time for a Monday lecture, they should be excused.

International EMS placements

7. The RCVS does not have any stipulations about international EMS. Both pre-clinical/AHEMS and clinical EMS placements can take place overseas at the discretion of the individual schools. Schools should ensure that the correct insurance arrangements are in place before any international placements take place.

Pre-Clinical/AHEMS

Species requirement

8. The RCVS EMS Policy states that at least 1 week of pre-clinical/AHEMS must take place in each of the three main disciplines: equine; production animal; and small animal. This is to ensure that students gain some further exposure to animals across each of the main areas.

9. Within each species area, there is no specific stipulation as to which species the placement should be centred around centred around.

10. Students can spend more than 1 week in any of the stipulated disciplines if they wish.

11. Schools may implement their own species requirements in addition or further to the RCVS Policy to make up for any of the remaining 9 weeks, but in doing so it should be made clear to the students that this is a specific requirement of the school itself.

12. RCVS does not stipulate any specific order of discipline or species that placements need to be completed in. However, schools may implement their own timetables based on the curriculum.

Types of pre-clinical/AHEMS placement

13. RCVS does not stipulate which placements would be “accepted” for pre-clinical/AHEMS. As stated above, it is up to the individual veterinary school to give the final sign-off on which placements will be accepted for pre-clinical/AHEMS.

14. RCVS would not expect schools to be allowing any e-learning type placement for pre-clinical/AHEMS.

15. RCVS would not expect schools to be allowing any type of placement where the student is not directly involved in animal handling.

16. RCVS would encourage the majority of pre-clinical/AHEMS placements to take place off-campus and away from university farms or hospitals, or any locations were IMR is delivered, to allow students to gain further experience outside of the veterinary school environment. However, on-campus placements are allowed for within the policy.

Clinical EMS

Species requirement

17. There is no stipulation on species requirement from RCVS for clinical EMS. This is to encourage more freedom for the individual student and tutor to be able to identify both areas in which further development may be needed, but also to give individual students the ability to hone down a particular area of interest themselves.

18. Vet schools are free to interpret the policy by implementing their own species requirements, however in doing so, it should be made clear to the students that this is a specific requirement of the school itself.

Length of placement

19. The policy states that clinical placements would be expected to last at least 2 weeks. This is to allow time for students to get a better feel of the environment and cases seen whilst on placement, as well as being able to give the provider more time to be able to offer more effective mentorship and guidance. However, this is not a strict requirement, and placements of 1 week can be allowed for, and this should be down to the school's discretion.

20. There is no maximum limit to a placement length. However, it is recognised that the length of any particular placement would likely be influenced by a combination of any, or all, of the schools' timetables and curricula; availability of the provider; and the student's own time and availability.

Types of placement

21. Similarly to pre-clinical/AHEMS, RCVS does not stipulate which placements would be "accepted" for clinical EMS. This again is down to the individual school to sign-off.

22. RCVS would not expect schools to be allowing any e-learning type placements for clinical EMS.

23. RCVS would encourage the majority of clinical EMS placements to take place off-campus and away from university farms or hospitals, or any locations were IMR is delivered, to allow students to gain further experience outside of the veterinary school environment. However, on-campus placements are allowed for within the policy.

24. RCVS would not usually expect schools to be allowing any type of placement where the student is not gaining direct clinical experience with animals. However, as laid out in the policy, longer term research placements can be allowed as part of the clinical EMS requirement. This is not a standard requirement, and allowing such a placement would be at the discretion of the school.

Professional EMS

25. The basis for the 2 weeks allowance of "professional EMS", i.e. non clinical placements, or those placements that do not directly involve animals, is that the majority of graduates will end up in clinical practice, and therefore RCVS would expect students to gain as much experience in clinical areas as possible before graduation. However, it is recognised that not all graduates will move into clinical practice, or may still be unsure whilst studying. Therefore, more than 2 weeks of professional EMS can be allowed for at the school's discretion if a student has a genuine interest in a particular area of non-clinical work. Multiple professional EMS placements can also be allowed for in this instance.

26. Professional EMS placements that are not necessarily clinically based, but are clinically related can also be allowed for above the standard 2 week allowance. For example leadership, management or veterinary business focussed placements.

27. Professional EMS is not mandatory, however schools are free to implement their own policies which may include it. In doing so, it must be a standardised maximum of 2 weeks (with more to be allowed for in genuine cases of student interest as detailed in point 25) and it should be made clear to the students that this is a specific requirement of the school itself.

Annex 2

RCVS Accreditation Methodology for Veterinary Programmes

November 2021

1. Introduction

The Royal College of Veterinary Surgeons (RCVS) has a statutory responsibility under the Veterinary Surgeons Act 1966, for regulating the professional education of veterinary surgeons and veterinary practitioners (to include vet nurses). In order to safeguard the interests of the public and animals, the RCVS sets the standards for veterinary education, and ensures only those who have completed a recognised qualification are eligible to practice in the UK.

RCVS accreditation of veterinary degree programmes provides assurance that standards are being met and drives the quality improvement of veterinary education. The accreditation of qualifications is an evidence-based, peer reviewed process that ensures that not only are the published standards being met and maintained by each educational establishment, but also that educational innovation and good practice is recognised and shared with stakeholders. RCVS accreditation activities have been developed to be consistent, transparent, valid, and reliable and the qualifications are subject to a rigorous quality assurance cycle that is flexible enough to respond to the changing demands made of the profession as well as to allow for a variety of programme delivery models.

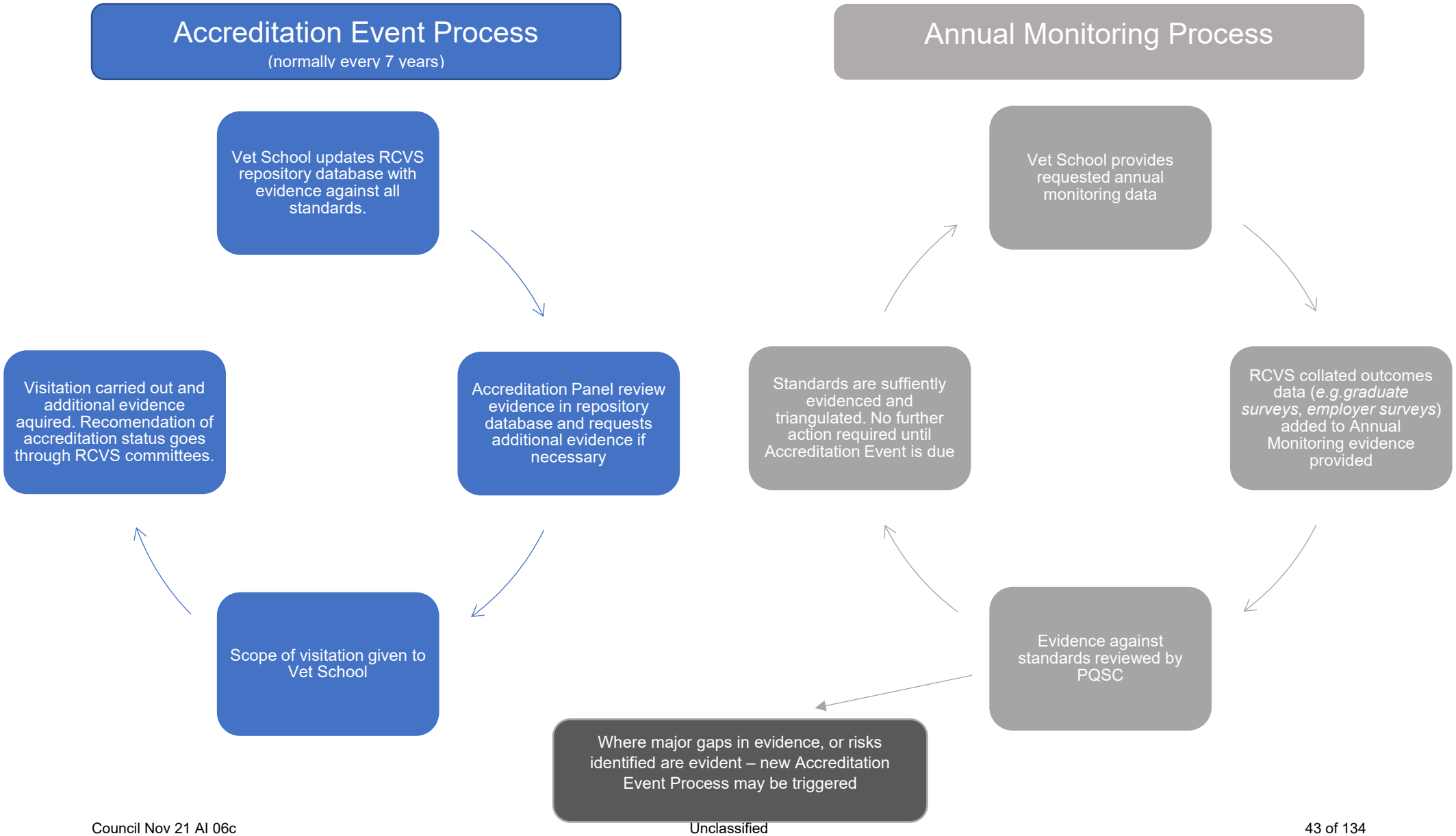
The accreditation process recognises the ways in which veterinary care and professional education have evolved over recent years and continues to develop, and draws upon advances in quality assurance methodology. To provide the best possible assurance on quality, RCVS accreditation of veterinary degrees is moving from a process previously based primarily on the consideration of ‘inputs’ (e.g. policies and procedures) to a hybrid approach which also considers outcome-focused evidence on how standards are being met. This approach provides the flexibility to assure educational standards are achieved across different models of programme delivery, including ‘traditional’, community-based, local partnerships and work-based approaches.

Furthermore, the increased assurance provided through evidence demonstrating positive or effective outcomes, enables a more risk-based approach to accreditation to be adopted. Through a combination of annual data monitoring and risk-based accreditation events including bespoke visitations, the accreditation cycle enhances the opportunity to recognise emerging issues early so that attention can be focused on potentially higher risk areas of the education programme and the appropriate support can be delivered in a timely fashion.

1.1 Glossary of Terms

Accreditation Cycle	This is the whole cycle including the Accreditation Event every 7 years and the annual monitoring process.
Annual Monitoring Process	The annual process of data collection from the Vet School.
Accreditation Event	This encompasses everything outside of the annual monitoring process – the school updating the repository for the accreditation review, the consideration of evidence and the bespoke visitation.
Accreditation Review	This is the initial review of the school's evidence against the accreditation standards which will ultimately shape the scope of the visitation.
Accreditation Panel	The panel that reviews the school's evidence against each standard during the accreditation event; membership is agreed by Education Committee in advance of the school being due to begin the Accreditation Event after 7 years.
Accreditation Visit	The visitation that is carried out; this will be bespoke and the scope decided on by the Accreditation Panel following the initial review of evidence in the repository (i.e. focusing upon standards where more evidence or triangulation of evidence is required).

2. The Accreditation Cycle



3. Accreditation Event

The Accreditation Event encompasses a review of evidence submitted by the vet school against all the accreditation standards (the accreditation review) and, using a risk-based approach, a bespoke visitation to focus on the standards where further evidence is required to demonstrate they have been met (or to triangulate existing evidence).

An Accreditation Event will take place for each veterinary programme every 7 years as standard to fit in with the approved period of accreditation, unless triggered earlier as a result of the annual monitoring process or notification of substantial changes to the programme, or as recommended by RCVS education committee following the last accreditation event.

Schools will have been notified when receiving their accreditation status following an Accreditation Event of the planned timeframe for the next event (subject to Annual Monitoring). However, approximately six months before the accreditation of an established veterinary programme is due to lapse, the RCVS will contact the veterinary school to begin the next Accreditation Event.

3.1: Accreditation Panel

The appointment of members of each Accreditation Panel is ratified by RCVS Education Committee, following recommendation from its Primary Qualifications Sub-Committee (PQSC). This will be done in advance of the Accreditation Event.

The members of any Accreditation Panel will be chosen from a list of people that are on the RCVS list of accreditation experts, and who have successfully completed the required training. All panel members will be asked to confirm that they have no conflicts of interest with the school.

The Accreditation Panel will comprise up to six members, plus a student representative, with the necessary combination of educational and subject expertise, clinical and academic experience. Between them, panel members will have a mix of expertise to cover the basic sciences, paraclinical, and clinical sciences in order to be able to consider all aspects of the curriculum. At least one panel member must a practitioner with a background in clinical practice outside of academia (with up-to-date knowledge of current general practice), and at least one panel member must be an educationalist (either from a veterinary or healthcare-related profession, i.e. someone with further expertise on higher education curricula, assessment standards and educational delivery models).

The panel must include someone who holds, or who has recently held, a senior academic position and who understands the organisation and funding of universities and the complex requirements for veterinary education.

The Chair of the panel must have already had experience of being an Accreditation Panel member and have recent experience as a committee Chair in addition to having completed the RCVS training for Accreditation Panel Chairs.

The Accreditation Panel may also include multiple observers in either a quality assurance role, or in a training role attending with a view to participating as a panel member at a future date.

3.2. Stage 1: School is invited to prepare evidence in support of accreditation standards

Evidence against the accreditation standards should be submitted into the secure online repository database, where all accumulated data and evidence against each of the accreditation standards will be stored (including any annual monitoring data) for each programme. This will be hosted on RCVS servers and access will be restricted to those involved in the review of evidence as part of accreditation.

Schools will be able to upload documents and evidence to their secure online repository database at any time, to prevent peaks in administrative burden. However, when Schools are formally notified of their upcoming Accreditation Event six months in advance, they will be invited to prepare and upload evidence in support of the accreditation standards.

Guidance around potential evidence for each standard is provided in the separate document ***"Examples of Evidence in support of RCVS Accreditation Standards"***. This guidance is intended to provide a useful resource to Schools when considering the different sources of evidence they may wish to submit. However, it is important to note that the list is not intended to be exhaustive or prescriptive, and the school should submit any data or documentation which it feels demonstrates compliance. Whilst RCVS can provide guidance on suggested types of evidence which may meet a standard, this will be high-level and not prescriptive, as what is appropriate for one programme or delivery model may not be relevant for another. The RCVS is committed to providing an open dialogue with schools, prior to and during an accreditation event regarding the suitability of evidence.

All evidence should be entered directly into the repository and any additional information forwarded through an alternative medium will not be accepted, unless through prior and exceptional arrangement.

All documentary evidence must be itemised by accreditation standard and indexed carefully to ensure ease of retrieval by those carrying out the review during the accreditation event. Each item provided in the repository should also include a short, concise description, to capture what is contained within.

The RCVS will support and supplement the data submitted by schools, with outcomes data gathered through independent surveys of graduates, students, and employers.

Once the school has been through the initial process of supplying evidence, at the point of the next Accreditation Event they will only need to supply further evidence if any significant changes in relation to any standards has taken place, i.e. facilities upgrades, curricula updates etc.

3.3. Stage 2: Review of evidence in the repository

The RCVS Education Department will begin the initial review of the evidence submitted to the repository (stage 1), in addition to the consideration of relevant annual monitoring data and any outcomes data collected by RCVS e.g. graduate or employer surveys. A summary of this evidence review will be given to the Accreditation Panel, noting any standards which appear to have strong evidence supporting them, as well as standards lacking evidence or where additional triangulation is required. All Accreditation Panel members will have access to the full evidence within the repository.

Once the school confirms that all documentary evidence has been uploaded to the repository, by the published date, the Accreditation Panel will begin their consideration of the data against each of the

accreditation standards. This will be done using an Accreditation Standards Rubric, using the summary of evidence as a template to check against the information in the repository. Each member will be asked to consider evidence submitted for all the standards, in order to provide a reliable assessment and a balanced approach.

Each panel member will carry out their initial review independently, adding to the rubric showing where evidence to support compliance is present, or where gaps in evidence are apparent and further evidence needs to be obtained during the visitation. Each rubric entry will be linked to specific sources of evidence considered to support each standard, and the evidence that triangulated this to ensure that the rationale and transparency of the panel's decisions can be demonstrated. In the majority of cases, for already established programmes, the panel will be looking for triangulation of any input data with evidence on processes and / or outcomes. Against each standard there will be the option to mark as compliant, exemplary, minor concern, or major concern (at this stage).

Any additional evidence may be requested in documentary format, or it may be more relevant to gather this through the visit to the Vet School.

On completion of the independent reviews, RCVS Education Department will summarise the findings of the panel in a report. The panel will then agree on which standards have already been met and triangulated, and begin to consider the priorities for the accreditation visit.

3.4. Stage 3: The Accreditation Visit

A bespoke accreditation visit follows the initial accreditation review. The accreditation review will determine the scope, focus and duration of the visit.

The Accreditation Panel will have considered the summarised findings and the evidence within the repository and have completed the rubric independently. The panel Chair will then notify the Education Department on the standards to be prioritised during the accreditation visit. All members of the Accreditation Panel will attend the accreditation visit.

Once the scope and focus of the visit has been identified, a date for the accreditation visit (and estimated duration) will be agreed by RCVS in consultation with the veterinary school. This will normally be agreed at least three months prior to the visit.

For established veterinary programmes, it may not be necessary to revisit areas where they have been able to submit sufficient and relevant evidence to demonstrate continual compliance, resulting in a shorter visitation which focusses on areas needing further triangulation of evidence, or where there have been recent changes or new risks. For newer programmes, where outcomes data may be limited and facilities will not be so familiar to the RCVS, a longer and more in-depth accreditation visit would be necessary.

The length and focus of an accreditation visit will be risk-based, depending on the outcome of the Accreditation Review.

Wherever possible, to ensure reliability and coherence, the accreditation panel will work as a group for the visit, to enable each member to see the relationship between the various parts of the curriculum and the degree. Circumstances may arise, however, which justify the Chair delegating specific tasks to a subgroup of the panel.

A visitation will always include meetings with students from each cohort year, meetings with managerial, academic and support staff, tours of facilities as required, plus a representative sample of any off-campus sites responsible for the delivery of core teaching (determined by RCVS). Video evidence of the facilities in off-campus partner practices may also be invited so that in person visits are not necessary. Locations to be visited or that require video evidence will be selected by the RCVS.

The accreditation panel expects to meet groups of staff who represent a broad range of disciplines and levels of experience, extra-mural and any adjunct staff, students, and external stakeholders. Wherever possible, to promote an open and honest dialogue between staff members and the accreditation panel, senior staff members of the school should not be present at meetings on each standard, unless directly involved in that area. Accreditation panel members may wish to speak to as wide a range of individuals as possible, so repetition of staff members across multiple meetings should be discouraged.

Prior to an accreditation event, RCVS will invite a sample of recent graduates to provide feedback on the programme, focused on the student experience and outcomes, which will be added to the evidence gathered through graduate/employer surveys in the repository.

Opportunities will be offered for all students, educators (including any educators within contracted partner practices) and support staff, to meet with the accreditation panel confidentially to discuss any aspect of the programme's achievement of the accreditation standards. These confidential sessions must be advertised by the school to all staff, students and educators within partner practices at least 1 month in advance of the visitation, and the RCVS staff member's contact details provided so that individuals can communicate privately with the visiting panel if they wish. These meetings will be arranged to take place virtually over a two-week window prior to the visit if needed. There will also be the opportunity for all students, managerial, academic and support staff and educators within partner practices to provide feedback on the standards anonymously through an online tool.

Visitation schedules will be structured so that the visit can be an iterative process, allowing for on-site changes if required, and including additional time to allow further consultation with key individuals and groups if necessary.

3.5. Accreditation Standards Rubric

The Accreditation Standards Rubric completed during the Accreditation Review, will be used by the accreditation panel as a starting point for the further evaluation of evidence on the visit.

During the visitation, the rubric will be considered by the whole panel at the end of each day, so that areas which need further exploration with the school can be identified, as well as agreeing on areas of compliance.

Any area of deficiency must be supported by commentary. 'Recommendations' are actions which the school *must* address in order to retain accreditation, whereas 'Suggestions' are provided to support programme improvement and not mandatory for accreditation purposes. Any suggestion or recommendation must be linked to a specific deficiency, and cross referenced with specific evidence (or lack of).

Areas of excellence or innovation with the programme will also be highlighted, and also cross referenced to supporting evidence. Each standard has been developed to be as independent as possible, to avoid a situation whereby a deficiency and / or recommendation would be applicable across multiple standards. Therefore, a deficiency or recommendation made against one standard would not also need to be repeated against another standard.

At the end of the visitation, the accreditation panel will then agree their decision on areas of compliance and recommendation.

The completed Accreditation Standards Rubric will be published on the RCVS website once finalised and agreed by RCVS Committees.

3.6. Verbal feedback to school

After the visitation has concluded, the accreditation panel will meet the Vice Chancellor of the university (or equivalent), and the head and senior staff of the school, to provide a factual summary of the strengths and opportunities for improvement of the programme in relation to the RCVS standards.

Any areas of excellence, innovation, suggestions, and recommendations from the panel will be communicated, and the next steps of the process outlined. The Chair will confirm that the panel are not the decision makers, and that the completed rubric showing their findings will be considered by RCVS committees, before the decision on accreditation is taken and the Accreditation Event formally ends.

3.7. RCVS committee process

Following the visitation, a report comprising the completed rubric highlighting the triangulated evidence supporting each accreditation standard and panel commentary will be returned to the school for a check of factual accuracy, usually within one month. Once the school has confirmed factual accuracy, the rubric will be considered by the RCVS's PQSC, which will review the evidence and confirm or amend any recommendations.

The report is then sent to the Vice Chancellor of the university for a formal response. The Veterinary Surgeons Act 1966 specifies that, for UK schools, the university may, within the period of two months from the receipt of the report, "make observations on or objections to the report" to RCVS. The university is invited to comment to RCVS on its responses to any recommendations in the report.

On receipt of a formal response from the university, this is considered again by RCVS's PQSC, which will then make a recommendation on accreditation status to RCVS's Education Committee, having taken the university's response into account. The RCVS will endeavour to make this process as efficient as possible.

Following a decision by the RCVS Education Committee, the school will be notified of the result and both the outcome and report / rubric will be published on the RCVS website, including all recommendations, suggestions, and commendations. Areas of excellence and innovation will be recognised and highlighted on these website pages, as well as at quality improvement events hosted by the RCVS, where vet schools will be invited to present their innovative practices to a wider audience.

3.8: Dashboard

Hosted on the RCVS website will be a dashboard of accreditation reports. Alongside reports from veterinary school accreditation events, detailing the programmes achievement of the RCVS accreditation standards, there will be the results of thematic analysis reviews.

4. Annual monitoring

The RCVS requires annual reports for accredited veterinary programmes from each school as standard. For UK Schools this is done in accordance with Section 5(5) of the Veterinary Surgeons Act 1966.

Within the online repository database hosted by RCVS for each school, there will be a section for annual monitoring data to be submitted.

4.1. Annual monitoring process within the accreditation cycle

Annual monitoring data will be required for each accredited programme, to be submitted annually in the same month as the most recent accreditation decision was agreed by Education Committee. For example, a programme awarded full accreditation for 7 years in November 2021, will be required to submit annual monitoring data annually each November until their next accreditation event takes place.

The annual monitoring data will be initially reviewed by personnel within the RCVS Education Team and then reported to the Primary Qualifications Sub-Committee (PQSC) for consideration, following which a recommendation of further action could be made to Education Committee (see section 4.2 below). Data is considered by RCVS's PQSC on a school-by-school basis, in order to monitor trends and changes at each school.

The data required of each school for annual monitoring purposes will comprise the following:

- Standard data sets (see Appendix 2)
- Details of any significant changes to the programme (itemised by Domain / Standard), and evidence relating to these changes and how standards continue to be maintained
- Data required to demonstrate progress towards addressing any recommendations or suggestions made at the most recent accreditation event (until PQSC consider these to have been achieved).

Annual monitoring data will be reviewed, alongside any RCVS collated outcomes data (e.g. employer surveys, graduate surveys), or any new risks identified during the normal cycle, and then considered by PQSC. If PQSC considers that further action is required as a result, this will be recommended to RCVS Education Committee, which will decide whether further evidence needs to be requested or an Accreditation Event needs to take place earlier in the cycle for an accredited programme.

Feedback on the review of Annual Monitoring data will be provided to the school within 1 month of the review date by PQSC, or in the event that a recommendation for further action is made to Education Committee, within 1 month of the decision by Education Committee.

Data collected through the annual monitoring will not be published, other than limited data around student numbers, which forms part of the annual RCVS report, "RCVS Facts". The full dataset will however be available internally to other RCVS committees for consideration if required.

4.2. Accreditation Event triggered by Annual Monitoring data

In the result of further action being required as a result of the review of annual monitoring data, an Accreditation Event will commence, regardless of when the next event would have been scheduled to take place. The process would follow that as laid out in section 3. If an accreditation visit is required, schools will receive at least three months' notice following the review of evidence.

5: Classification of accreditation – *Classification titles and descriptions to be formally reviewed by PQSC in January 2022, and agreed prior to implementation of the new Standards*

Options for decisions on accreditation of veterinary degrees are as follows:

a) **Accreditation for seven years** subject to the annual monitoring of evidence/data. If annual monitoring remains satisfactory, re-accreditation will be subject to a full Accreditation Event in the seventh year.

b) **Accreditation for a shorter period** if significant deficiencies are identified: accreditation will be subject to the deficiencies being addressed within a specified time period and subject to satisfactory annual monitoring evidence/data. The RCVS will normally undertake a reconsideration of evidence against the accreditation standards where deficiency has been highlighted before the accreditation period expires to monitor progress in addressing any identified concerns. Following review, RCVS may elect to hold a further Accreditation Event for the programme. The Accreditation Event may cover all the standards or a more focussed event that concentrates on progress with addressing specific deficiencies. Consideration of a shorter period of accreditation subject to conditions will apply where there are either a) one or more major deficiencies, or b) a series of lesser deficiencies which, taken together, could have a significant impact on students' education, but which are deemed to be rectifiable within a given period of time.

c) **Accreditation may be denied.** This category applies where the RCVS considers that the deficiencies are so serious that they are unlikely to be rectifiable within a reasonable period of time. It is, in effect, a final warning to a school that if urgent action is not taken RCVS will move to terminal accreditation.

d) **Terminal accreditation** may apply if the school is unable to meet RCVS's standards, and/or if a school voluntarily closes. The procedures for terminal accreditation must be followed by the veterinary school (see below). For previously accredited UK veterinary schools where accreditation is denied by RCVS, the final decision to revoke or suspend their Recognition Order would be made by the Privy Council (see below). For non-UK schools, if accreditation is denied for a programme that was previously accredited, the school may be placed on "terminal accreditation" and it will be the responsibility of the school to present an immediate plan to RCVS for approval showing how the deficiencies will be addressed to allow adequate progress of the existing students to meet RCVS Day One Competences.

e) **Accreditation is denied.** This option would be relevant where neither 'Accreditation may be denied' nor 'Terminal accreditation' would be applicable. It applies when RCVS considers that the deficiencies are sufficiently serious that the school should not receive accreditation. The RCVS will inform the veterinary school of its concerns and the grounds on which they are based. The veterinary school would be able to request a re-Accreditation Event once it had addressed the deficiencies identified.

5.1: Procedures for schools with the classification of Terminal Accreditation

The classification of terminal accreditation is intended to protect the interests of students who enrolled before accreditation was withdrawn. Terminal accreditation may continue no longer than necessary to protect the educational interests of such students. Provided the school complies with the conditions

for terminal accreditation, students enrolled on the programme before terminal accreditation was assigned will be able to graduate with an accredited degree that will entitle them to register as Members of RCVS. If the school recruits students after terminal accreditation is assigned, those students will graduate with a non-recognised degree and may not be able to practise in the UK unless they sit the RCVS examination.

The head of the school and the Vice-Chancellor of the university are notified in writing of the classification of terminal status and the reasons for this.

During the first six months after the assignment of terminal accreditation, the school must submit a detailed plan describing how it will ensure that the educational interests of currently enrolled students will be met.

Each year that the school holds terminal accreditation status, the school will provide a detailed report to the RCVS describing how the plan is being followed and how it has been altered with respect to students who entered before terminal accreditation was assigned.

To maintain terminal accreditation status, the school must:

a) immediately cease enrolment of additional students;

b) commit resources adequate to complete the education of currently enrolled students;

c) ensure that deficiencies cited do not worsen.

During a period of terminal accreditation, representatives from RCVS may visit the school and report on whether the school is meeting the conditions for terminal accreditation. The reported information and that furnished in writing by the school will be considered by RCVS to determine if terminal accreditation should continue.

If a veterinary school on terminal accreditation fails to abide by this procedure, RCVS may terminate its accreditation immediately, such that no further graduates will be eligible to register with RCVS.

6: Consultative Accreditation Event

The purpose of a Consultative Accreditation Event is to assess the overall compliance of a veterinary school based outside of the UK with RCVS standards and to provide feedback to the school. A school may request a Consultative Accreditation Event in preparation for applying for accreditation from RCVS.

Consultative events are advisory and the results are not published or made public. The Consultative Accreditation Event and processes are linked and consultative events follow a similar process to that in place for accreditation events.

6.1: Requesting a Consultative Accreditation event

The Head of the Veterinary School must write to the RCVS with a formal request for a Consultative accreditation event. RCVS will discuss the request for the consultative event through its Primary Qualifications Sub-Committee (PQSC) and will provide a formal response to the request, together with suggested dates.

6.2 The Consultative Accreditation Event Panel

PQSC will recommend the appointment of an Accreditation Panel, to include a Chair and two additional members. PQSC's recommendations will be ratified by Education Committee. Names of panel members will be shared with the Head of the Veterinary School, who may ask for reconsideration of an appointment where a nominated panel member has a conflict of interest that cannot be managed during the event process. Education Committee has the final authority on the appointment of panel members.

6.3: Consultative Accreditation Event Timetable

The duration and scope of a consultative event will be agreed between RCVS and the school in advance.

6.4: Consultative Visit Report

The report of the consultative visit will include comments against the RCVS standards and highlight any areas which are considered exemplary. It will also be explained that any outcome of the consultative visit may not reflect the outcome of a full formal accreditation event. The report is not published.

The report is signed off by the Chair of the accreditation panel and passed back to the veterinary school for a factual accuracy check. The report is then considered by PQSC, which provides feedback to the school and to Education Committee.

6.5: Fees for Consultative Events

RCVS may charge a fee for a consultative accreditation event. The fee is reviewed annually. This covers the full event (review of evidence and any visitation to the school), together with up to 5 days for visit preparation. In addition, the RCVS will charge Loss of Earnings plus travel, subsistence and accommodation costs for the accreditation panel. This fee must be paid prior to the event.

7: Mock Accreditation Event

A Mock Accreditation Event can be requested by existing RCVS accredited UK schools. A Mock Accreditation Event would follow a similar process to that in place for actual accreditation events. A school may request a Mock Accreditation Event in preparation for an upcoming accreditation event. There would be no formal findings from a mock event and for that reason there would be no formal report or recommendations made, although feedback would be provided.

Mock events can only take place once a school has been through the full cycle at least once.

7.1: Requesting a Mock Accreditation Event

The Head of the Veterinary School must write to the RCVS with a formal request for a Mock Accreditation Event. RCVS will discuss the request for the mock event through its Primary Qualifications Sub-Committee (PQSC) where the reasons for the request will be considered. A formal response to the request would then be provided to the school by PQSC, together with suggested dates if the mock event is agreed to.

7.2 The Mock Accreditation Event Panel

PQSC will recommend the appointment of an Accreditation Panel, to include a Chair and two additional members. PQSC's recommendations will be ratified by Education Committee. Names of panel members will be shared with the Head of the Veterinary School, who may ask for reconsideration of an appointment where a nominated panel member has a conflict of interest that cannot be managed during the event process. Education Committee has the final authority on the appointment of panel members.

7.3: Mock Accreditation Event Timetable

The duration and scope of a mock event will be agreed between RCVS and the school in advance.

7.4: Fees for Mock Events

RCVS will charge a fee for a mock accreditation event. The fee is reviewed annually. This covers the full event (review of evidence and any visitation to the school), together with up to 5 days for visit preparation. In addition, the RCVS will charge Loss of Earnings plus travel, subsistence and accommodation costs for the visiting team. This fee must be paid prior to the event.

8: Accreditation of overseas veterinary programmes

To be considered for accreditation by RCVS, an overseas veterinary degree must satisfy the following:

- The level of clinical instruction must be comparable to that required of veterinary schools in the United Kingdom. Overseas veterinary degrees must meet the same accreditation criteria as UK schools; including the requirement for students to meet the RCVS Day One Competences by the time they graduate.

- The degree of the overseas veterinary school must be recognised as a professional veterinary qualification by the relevant authorities (government and/or veterinary licensing body) in its own region/country.

- The overseas veterinary school must normally have been producing graduates for at least five years or a sufficient number of its graduates must have submitted themselves for the RCVS statutory membership examination to allow a judgement of the standard of the overseas school to be reached.

- RCVS will appoint an Accreditation Panel to undertake a formal Accreditation Event for the overseas veterinary school. As part of the accreditation event, the visitation will be at the expense of the overseas school. Before the visitation, the university must pay the RCVS accreditation fee applicable at the time of the application, as well as paying for full travel, accommodation and loss of earnings allowance for all the RCVS visitors, including business class air fares for flights of seven hours or more. Accreditation cannot be granted until RCVS's fees and costs have been reimbursed in full.

- The first Accreditation Event of an overseas veterinary school not previously recognised by RCVS should normally be undertaken wholly by RCVS, although some joint working with another accrediting body may be considered, depending on the circumstances, at the discretion of RCVS's Education Committee.

- An overseas university whose veterinary degree is accredited by RCVS will be required to submit annual monitoring reports to RCVS. RCVS reserves the right to undertake further accreditation events during the period of accreditation to ensure that any recommendations made are being implemented, and also to exchange quality assurance and monitoring information about the degree programme with the university's national accrediting body where applicable. Costs for any such events will be charged to the university.

9: Accreditation for new veterinary programmes

The Veterinary Surgeons Act 1966, Section 4, includes provision for veterinary graduates of UK universities that do not have a Privy Council Recognition Order (i.e., new veterinary degrees or existing veterinary degrees that have lost their recognised status). The Privy Council may:

a) *After consultation with the Council of the College; and*
b) *If it is of the opinion that the training provided to students of veterinary surgery attending at that university satisfies the requirements of Article 38 of the directive… direct the College to hold examinations in veterinary surgery for the students… attending at that university; and any such student passing any such examination shall be entitled to be registered in the register and shall on being so registered become a member of the College.*

Any UK university that is considering offering a professional veterinary degree and applying to the Privy Council for a Recognition Order must liaise with RCVS concerning its plans for the programme at an early stage. Draft curriculum and assessment plans must be submitted together with a timeline for implementation, plans for facilities, staffing and an indication of the intended student numbers. Once the formal decision has been made by the university to offer a veterinary programme, a series of six-monthly meetings will be arranged with the RCVS to consider the development of the degree, leading up to the initial interim visitation in year three of the first cohort of students. The process will follow similarly to an Accreditation Event for an existing school as detailed in section 3.4, with an Accreditation Panel formed to review the initial evidence described above has been submitted, before the Accreditation Visitation Team being formed for the interim visit.

Following the initial interim visit, RCVS will provide feedback to the university on the draft programme, in terms of whether it appears to meet the current RCVS standards and policies. Any obvious gaps will be identified, but it will be for the university to determine how such gaps might be rectified. RCVS can provide advice on its standards and accreditation methodology but does not offer any form of provisional approval as this stage, as it is not within its power to do so. Recognition, if granted, comes from the UK's Privy Council, on advice from the RCVS.

RCVS will make arrangements for one or more accreditation events encompassing full or short interim visitations to evaluate the programme and will discuss options for examinations with the university. Depending on its evaluation of the curriculum and assessment arrangements, RCVS may decide to either set a separate qualifying examination for final year students or, alternatively, may make arrangements for the joint examination of students with the university through the appointment of RCVS External Examiners.

If it is agreed to appoint RCVS External Examiners and run a joint qualifying examination, the university will need to agree that the RCVS appointed External Examiners will have the final decision-making power over the eventual pass list, so that the examination may count as the RCVS qualifying examination for registration purposes.

Having consulted on the draft curriculum and delivery plans before the first student intake has started the programme, RCVS will aim to undertake its first Accreditation Event and full site visit when the programme has reached its third year in order to make an assessment of how the plans are working, and to evaluate the progress of the new school towards achieving the RCVS standards. A further Accreditation Event and full site visitation will be undertaken during the programme's fifth year of operation, in order to make a recommendation to the Privy Council on recognition. Additional

accreditation reviews and visitations may be undertaken in the meantime by one or more RCVS visitors to observe examinations and other assessments. As part of each accreditation event, before each site visit, the school will need to provide RCVS with documentation relating to each standard, recognising that some of this evidence will allude to future plans rather than outcomes assessments.

Graduates of UK veterinary schools are not automatically entitled to RCVS membership until the degree has received the Recognition Order from the Privy Council, and this may take a number of months even after a positive recommendation from RCVS. In the absence of a Recognition Order, graduates will be able to register and practise in the UK only if they pass the RCVS qualifying examination (or joint examination overseen by RCVS External Examiners as described above). The university must ensure that students applying to join the programme understand the status of the degree and that, whilst there is a route to registration for them, there is no automatic entitlement.

10. RCVS accreditation appeal procedure

Scope of Appeals

1. This appeals procedure applies where an institution questions the formal outcomes of the accreditation process, where it can:
    - demonstrate that the outcome is not based on sound evidence, **and/or**
    - that published standards have not been correctly applied **and/or**
    - that published processes have not been consistently implemented.
2. No appeal will be entertained in respect of the individual comment(s) made by the visiting team and contained within the accreditation report.

Definition of terms

3. In these rules:
    - "appeals panel" means a panel of the Committee constituted to hear an appeal;
    - "College" means the Royal College of Veterinary Surgeons;
    - "Committee" means the Examination Appeals Committee;
    - "lay person" means a person who is not a veterinary surgeon or a registered veterinary nurse and has never been entitled to be registered as such;
    - "registrar" means the registrar of the College;
    - "the Council" means the Council of the College;
    - “formal outcome of the accreditation process” means the category of accreditation into which the institution has been placed **and/or** the period of accreditation that has been granted
    - “published standards” means the standards contained within the version of the “RCVS standards and procedures for the accreditation of veterinary degrees” that applies to the visit in question
    - “published processes” means the processes contained within the version of the “RCVS standards and procedures for the accreditation of veterinary degrees” that applies to the visit in question

Lodging of an appeal

4. An institution must inform the registrar of its intention to appeal not later than two weeks from receipt of the letter confirming the formal outcome of the accreditation event. The appeal must then be made in writing by the Dean or Head of School no later than six weeks from receipt of the letter confirming the formal outcome of the accreditation event.

Initial consideration of appeals

5. The first stage of the appeal process will involve a review of the process that had been followed by RCVS in reaching its accreditation decision, together with the argued basis for the appeal, by both PQSC and Education Committee at their next scheduled meetings. The Chair of the relevant Accreditation Panel may be asked to participate in the review process. The outcome of this review will be to either accept or dismiss the appeal. If accepted, Education Committee will review its original decision and may decide to amend it. It should be noted that acceptance of the appeal may not necessarily result in a change to the original decision.

6. An appeal will only be dismissed on one or more of the following grounds:

    - It relates to the individual comments made by the Accreditation Panel
    - It gives insufficient information to enable any judgement to be made
    - It is frivolous, vexatious or relates to a minor irregularity in the conduct of the accreditation process
    - It is unnecessary because deficiencies in the accreditation process have already been acknowledged and appropriate action taken

7. If the appeal is dismissed on any of the grounds mentioned, the institution may nevertheless elect to have the appeal considered by the Accreditation Appeals Panel. The institution must pay a fee of £5000, but this will be refunded if the appeal is upheld.

Composition of the Committee

8. The Committee will be appointed by or on behalf of the Council. It will include veterinary surgeons, registered veterinary nurses and lay persons. Two members of the Committee will be designated by or on behalf of the Council as its Chairman and Vice-Chairman.

Accreditation Appeals Panel

9. The Committee will act through panels when dealing with appeals. An appeals panel will consist of between three and five members of the Examination Appeals Committee chosen by the Chairman of the Committee and will include one person who is not a member of Council.

10. The panel will select its own Chair. All members must sign a declaration confirming that they have no conflict of interest with the appellant institution and a statement to indicate that they will strictly adhere to the "*RCVS standards and procedures for the accreditation of veterinary*

degrees" as well as the "*Policy on managing potential conflicts of interest for visitation team members"*.

11. The appellant institution will be provided with copies of any information, apart from legal advice, which is made available to the appeals panel and will be given a reasonable opportunity to comment and make any further representations before the panel considers the appeal.

12. The appellant institution has the right to nominate an observer to attend the meeting of the panel. An observer may respond to questions from the panel; however they will not have voting rights when it comes to decision making. The Chair of the Accreditation Panel may also be requested to attend the meeting as an observer to assist with any points of clarification.

13. An appeals panel will not include a person who has been involved in the initial assessment of the appeal, had any involvement in the visitation to the appellant institution or has any personal connection with the appellant institution which might bring that person's independence or impartiality into question.

14. The proceedings of an appeals panel will take place in camera and will remain confidential after the conclusion of the appeal.

15. The appeals panel may:

    a. uphold the appeal and direct Education Committee to reconsider its decision

    b. uphold the appeal, but confirm that the decision should remain unchanged

    c. dismiss the appeal

16. Once the panel has reached a decision, by majority vote, its Chair will inform the registrar of its decision by submitting an adjudicating statement, including its reasoning. The registrar will arrange for the outcomes of the appeal to be communicated to the appellant institution, PQSC and Education Committee.

17. The decision of the panel shall be conclusive for all purposes.

18. Until the end of the appeal process, the visitation report will not be published, and the appellant institution holds its current accreditation status.

11. Training for Accreditation Panel Members

To be drafted

12. Quality Assurance of the Accreditation Process

Feedback

RCVS seeks feedback from the veterinary school staff, students and stakeholders involved in the visitation, as well as the Accreditation Panel members, immediately after the visit. Feedback surveys are sent to the Vet School by the Education Quality Improvement Manager for distribution to all staff, students, alumni and stakeholders who took part in the accreditation visit, and to the Accreditation Panel members. These are followed up with a selection of verbal feedback opportunities. All feedback (verbal and written) will be collected up to a month after the end of the accreditation visit.

Thematic Report

Feedback is collated by the RCVS Education Quality Improvement Manager and summarised in a thematic report which is presented to the Audit and Risk Committee (ARC) and noted by PQSC. The findings are considered, and any appropriate recommendations are made to Education Committee, should any changes in the RCVS accreditation methodology be necessary. The ARC monitors the quality assurance of RCVS' accreditation activities and a further review of quality assurance is carried out by the European Association for Quality Assurance in Higher Education (ENQA) every 5 years.

All feedback remains confidential and will not be shared with vet school staff or students but is used to develop the RCVS accreditation procedures.

Appendix 1: Accreditation rubric example

Standard		Repository Evidence Type = Input, Process or Outcomes						Cross reference with another standard ?	Further evidence needed on visitation?	Visitation Evidence Type - Input, Process or Outcomes						Recommended Outcome		
		Supporting evidence # 1	Type	Supporting evidence # 2	Type	Supporting evidence # 3	Type			Supporting evidence # 1	Type	Supporting evidence # 2	Type	Supporting evidence # 3	Type	Standard Met	Partially Met	Not Met
1.1	The spaces, infrastructure, physical and digital resources across the programme must provide an effective learning and teaching environment, support student welfare, and meet the needs of educators and support staff.	*Student numbers broken down against lecture and seminar room capacity*	*Input*	*strategy for development / maintenance of digital and physical infrastructure*	*input*				*Yes*	*Tour of new facilities*	*outcome*	*discussion with staff and students to establish how the space is used and if it is fit for purpose*	*outcome*			X		
1.2	The learning environments across the programme must ensure the health and safety of students, staff and animals and comply with all relevant jurisdictional legislation including health, safety, biosecurity and UK animal welfare and care standards.	*Health and Safety Policy Biosecurity Policy Procedure for staff and student inductions to include health and safety and animal welfare*	*Input*	*Incident logs for on-site farm*	*Outcome*	*Detailed audit reports of health and safety committee meetings with actions and responses (with photo / video of new safety measures implemented)*	*process*		*No*							*X*		
1.3	All learning environments (within the School and off-site) should be quality assured to ensure they are conducive to learning and teaching, and support the achievement of learning objectives.	*Details of student facilities available at off-campus locations including mitigation of barriers to learning*	*Input*						*Yes (need process / outcomes evidence for triangulation)*	*Verbal feedback from students confirmed dissatisfaction of outside learning environments - poor internet connection, lack of quiet study area, dangerous practice standards*	*Process and outcome*	*Practice QA checklist not sufficient*	*Process*	Student feedback and evaluations not yet acted upon	Outcome			X
1.4	The learning environments across all aspects of the programme must demonstrate good practice standards and promote high standards of animal husbandry and care at all times.	*PSS Certification of all IMR practices (in-date)*	*Input*	*Results of School internal QA Audits*	*Process*				*No*							X		
4.1	The school must have a strategy for widening participation which considers all aspects of diversity, and engages students from different ethnic and social backgrounds. The school must be proactive in their marketing to attract a diverse cohort of applicants and regularly review, and provide evidence of, their progress towards targets.	*Detailed admissions policy and strategy documents, the contents of which detail appropriate and ambitious targets for widening participation across relevant groups*	*Input*	*Demographic data across recent years on admissions, progression and graduation demonstrates targets on increasing diversity are being met*	*Outcome*	*Committee minutes record consistent reviews whether targets being met, and identifies action plans to improve outcomes where progress is limited*	*Process*		*No*							X		
4.2	The school must provide accurate and current information regarding the educational programme easily available for prospective students. The information must include the accreditation status of the degree course (whether by RCVS or other relevant accrediting bodies), selection and progression criteria, the demands of the course and the requirements for eventual registration/licence, including fitness to practise	*Marketing and other information available and readily accessible, with all the necessary information included. All information is current and reviewed regularly (updated versions evident in repository)*	*Input*						*Yes (need process / outcomes evidence for triangulation)*	*Review of attrition data (inc. associated reasons for leaving the programme)*	*Outcome*					X		
4.3	Selection and progression criteria must be clearly defined, fair, defensible, consistent and free from discrimination or bias. The criteria should also include relevant factors other than academic performance. The academic requirements for entering the programme should be sufficient for the student to cope with the demands of the programme upon entry	*Selection and progression policy and strategy documents, including rationale*	*Input*	*Data analysis on admissions, progression and attrition rates, with a focus on any trends associated with different grades / criteria at the point of selection*	*Outcome*				*No*							X		

4.4	The school must demonstrate their selection and progression criteria and processes are effective in identifying students with the potential to achieve the RCVS Day One Competences. This must be achieved through regular and effective training for staff involved and the routine collection and analysis of selection and progression data, to enable them to evaluate, reflect and adjust the selection and prog	*Training programme content for staff, including selection data analysis, selection methods (if appropriate) and standardisation*	*Input*						*Yes (need process / outcomes evidence for triangulation)*	*Longitudinal data on trends / correlations between selection criteria and progression rates*	*Outcome*	*Verbal accounts / answers from relevant staff describing process for (and example of) when criteria have been adjusted as a result of data analysis / reflection*	*Process & outcome*			X		
4.5	There must be clear policies and procedures as to how applicants with disabilities or illness will be considered and if appropriate, accommodated on the programme, taking into account the requirement that all students must be capable of meeting the RCVS Day One Competences by the time they graduate.	*Policy for admitting and supporting students with disabilities or illness*	*Input*	*Details of those students with a disability and how they are accommodated on the programme in order to meet Day One Competences.*	*Process*	*Achievement rates of students with disabilities*	*Outcome*		*No*							X		

Guidance on the accreditation rubric

- The template will be a living document, populated at each stage of the accreditation event by RCVS staff and visitors to demonstrate compliance with each standard.
- Additional boxes can be added if required at each stage, where multiple forms of evidence are submitted and considered.
- Generally, there would need to be multiple sources of evidence including process / outcomes evidence as appropriate in order for a standard to not be explored further in the visitation (risk-based approach).
- The repository will be indexed against each standard, and schools will be able to upload new evidence each year (e.g. annual reports) in order to build a comprehensive longitudinal picture. This would add strength to the evidence which would be a factor in the risk-analysis.
- RCVS collected data such as graduate / employer surveys will also be shared with schools, to add to their own repository.
- The rubric will be considered by RCVS committees when reaching an accreditation decision.

Appendix 2 Standard data required for Annual Monitoring purposes

The following datasets will be required as standard for annual monitoring purposes. Detailed tables will be provided to schools for this purpose.

- Student numbers for each cohort within the programme, including:
    - UK, EU and overseas student numbers
    - Admissions and progression data
    - Diversity data

- Staff numbers, including FTE, roles (including educators within partner practices)

- Student achievement data for each cohort, including diversity data, progression, final outcome, attrition and exclusion data.

- Clinical caseload per student (by species, with % cases where students directly involved in the work up of the case, and % in a first opinion, general practice context identified).

- EMS weeks completed per cohort.

- Student appeals data – total numbers, unsuccessful / upheld, basis for appeal.

Summary

Meeting	Education Committee
Date	14 October 2021
Title	New RCVS accreditation standards and methodology.
Summary	Following the agreed consultation exercise on the new accreditation standards and methodology, the results report is attached for review. RCVS Education Committee is invited to consider the proposed actions within the report and agree on any amendments. The agreed actions will then be taken forward to produce a final version for consideration and sign-off by RCVS Council.
Decisions required	To agree on the new accreditation standards and accreditation methodology for veterinary programmes, and recommend to RCVS Council as final.
Attachments	Results Report.
Author	Linda Prescott-Clements Director of Education L.Prescott-Clements@rcvs.org.uk 020 7202 0732

Classifications

Document	Classification[1]	Rationales[2]
Paper	Confidential	1

[1]Classifications explained	
Confidential	Temporarily available only to Council Members, non-Council members of the relevant committee, sub-committee, working party or Board and not for dissemination outside that group unless and until the relevant committee or Council has given approval for public discussion, consultation or publication.
[2]Classification rationales	
Confidential	1. To allow the Committee or Council to come to a view itself, before presenting to and/or consulting with others 2. To maintain the confidence of another organisation 3. To protect commercially sensitive information 4. To maintain public confidence in and/or uphold the reputation of the veterinary professions and/or the RCVS
Private	5. To protect information which may contain personal data, special category data, and/or criminal offence data, as listed under the General Data Protection Regulation

RCVS consultation on proposals for new accreditation standards and accreditation methodology for veterinary programmes

Results Report

2021

RCVS Education Department

Education@rcvs.org.uk

Index

1. Executive summary

This report presents the findings from the consultation on the draft RCVS Accreditation Standards and Accreditation Methodology for veterinary degree programmes, conducted between 19 July and 3 September 2021.

The consultation was open to all members of the profession and key stakeholders, and 107 responses were received. Within these responses, feedback from 25 veterinary organisations was provided, including the Association of Veterinary Students (AVS), the British Veterinary Association (BVA), the Veterinary Schools Council (VSC) and a number of employer representatives.

The consultation asked for feedback regarding the relevance of the six domains of standards proposed, the individual standards within each domain and the new methodology.

Respondents supported the six domains proposed, considering these to be relevant and appropriate. Although a degree of concern was noted that these changes move away from the current format of standards of other international accreditors and the potential impact on joint accreditations, RCVS is already working with the International Accreditors Working Group (IAWG) to address this and ensure joint working can continue.

Feedback on the **Standards within Domain 1: Learning Environment** were mostly supportive, with the majority of suggestions being to add further clarification in the guidance. However, there were mixed views on the standard relating to the need for abattoir experience. A number of respondents indicated that the knowledge and learning outcomes associated with this area could be taught using virtual resources, and there were concerns about the availability of abattoirs willing to give access to students. However, many stakeholders felt that students experiencing this environment was vitally important. As a result, it has been proposed that this standard is amended to indicate that student attendance at a red *or* white meat abattoir is required (which would provide the student with the experience of the environment) rather than attendance at both red *and* white meat abattoirs. Other suggestions relating to this domain focused on the need for further clarification or detail in the guidance.

There was strong support from respondents with regard to the **Standards within Domain 2: Organisation, Culture and Values** aiming to strengthen the diversity of the profession, through the consideration of outcomes evidence. There was also support for the need for schools to demonstrate a no-blame culture within learning environments. A number of respondents wanted the need for requirements around stakeholder engagement to go further, suggesting employer and general practitioner input should be specified and also the need for schools to demonstrate how they have responded to stakeholder feedback.

Feedback on the **Standards within Domain 3: Educational Governance and Quality Improvement** were also supportive, with few suggestions other than those for additional clarification in the guidance. A number of respondents felt the standard specifying the Head of School's qualification should stipulate that they should be MRCVS / FRCVS.

There was a high level of agreement with the proposed **Standards within Domain 4: Supporting Students**. Feedback indicated that the commitment to widening participation and increasing diversity within the profession was particularly welcomed. Some respondents also noted the need for non-academic qualities to be part of the admissions requirements.

The **Standards within Domain 5: Supporting Educators** were widely welcomed by respondents. Suggestions for amendments were mostly associated with the need for additional clarity in the guidance, particularly around the requirements and scope of teaching qualifications for educators.

Perhaps not surprisingly, a high number of comments were made in response to the **Standards within Domain 6: Curriculum and Assessment**. Most comments were supportive of the new standards in this domain, however two key themes emerged within the feedback relating to the amount of clinical education which takes place in the general practice context, and the proposals for Extra-Mural Studies (EMS).

The need for clinical education to be set in the general practice context was also considered in the Graduate Outcomes consultation which reported in 2019. The profession indicated that the majority of clinical education should be in a general practice context, which led to this standard being added to the domain. However, the definition of 'majority' was questioned, and different stakeholders disagreed on what would be appropriate. Many vet schools felt anything over 50% was a majority and therefore sufficient, whereas employers mostly indicated a higher proportion of teaching should be in this context. This differing standpoint was also evident in the responses to this consultation, and there was strong support from a number of stakeholders and veterinary organisations for an increased proportion of clinical education to be in general practice.

The standards associated with Extra Mural Studies (EMS), and the EMS policy, was also commented upon by many. Many of these comments referenced the challenges experienced around the implementation of EMS, as well as the importance of EMS. RCVS is taking forward a number of initiatives to look at EMS policy separately to this, which will feed into future iterations of accreditation standards.

There was strong support for the new **accreditation methodology**, particularly the move to consider more evidence on the outcomes of programmes, rather than primarily focusing on 'inputs'. The move to a risk-based approach was also supported. Suggestions made to this aspect of the consultation were mostly around the need for underpinning detail of processes to be included.

The themes emerging from the feedback to the consultation are reported in detail for each section, alongside proposed actions and rationale for the suggestions made for changes or improvements. These will be considered by RCVS Education Committee and actioned where appropriate prior to the final documents being considered by RCVS Council.

2. Background

The RCVS Standards for Accreditation set out the requirements of university veterinary schools and veterinary degree programmes for them to be recognised by the RCVS, and consequently their graduates becoming MsRCVS. The current Standards (https://www.rcvs.org.uk/setting-standards/accrediting-primary-qualifications/accrediting-veterinary-degrees/accreditation-standards/) were developed in 2014 (implemented in 2015), and it is was agreed in September 2019 that a further comprehensive review should be carried out.

The aim of the review was to ensure that the RCVS' approach to accreditation was fit for purpose, robust across different models of veterinary curricula and programme delivery, and in line with international best practice in both the veterinary and other healthcare related fields.

The review of (i) accreditation standards and (ii) accreditation process (methods) was taken forward in parallel, as follows:

(i) Accreditation Standards

a. A comprehensive mapping exercise of current RCVS Accreditation Standards against those of other international accreditors of veterinary degree programmes
b. A review of the accreditation standards of other UK professional regulators, including those in medicine, dentistry, nursing and pharmacy
c. Comprehensive feedback from stakeholders

(ii) Accreditation Processes / Methodology

a. A literature review of the published evidence on different accreditation processes (methods) and their impact in terms of quality assurance and quality improvement
b. Semi-structured interviews with other UK accreditors of professional degree programmes, to understand the processes they use, what works well and any challenges encountered
c. Semi-structured interviews with a selection of vet schools, including representation of different models of curricula and programme delivery ('traditional', community-based and fully distributed), to gather feedback on current RCVS processes, and what works well / the challenges
d. Observations of accreditation visits hosted by other international accreditors of veterinary degree programmes

All information was primarily considered by the Accreditation Review Working Party (ARWP), chaired by Professor Nigel Gibbens, which comprised representation from the Veterinary Schools Council (VSC), representatives from veterinary schools covering a range of different curricula models, practitioners, student and new graduate representation, as well as independent involvement from the Quality Assurance Agency (QAA) and the General Medical Council (GMC). The proposals for new standards and methodology were also considered by both the Primary Qualifications Sub-Committee (PQSC) and Education Committee. Standards relating to clinical education and extra-mural studies (EMS) were also considered by the Graduate Outcomes EMS and Clinical Education working group (GO EMS CE), which had been tasked with taking forward suggestions from these areas of the Graduate Outcomes consultation which reported in 2019.

Accreditation Standards

The current RCVS standards for accreditation of veterinary degrees requires schools to meet 111 individual standards covering 12 subject areas. Following an exercise of comparing these against both other international veterinary accreditors and other professions, the ARWP agreed on a list of further standards, which were felt would add value to the RCVS' current set of requirements.

However, these additions would have resulted in there being over 180 standards, even after taking into account duplication of themes. The reason for this was, in part, that individual standards had become highly specific, with multiple standards contributing to a single quality indicator. It was decided that a new approach was needed and following review against international best practice in other healthcare related sectors, a new set of standards comprising 75 individual standards across 6 subject domains was established.

Mapping against the 2015 standards was completed, and it was confirmed that all areas within the previous standards were covered within the new standards and that there were no 'gaps'. In many cases, some of the 2015 standards were felt to be better placed within the wording for the guidance for the standard rather than detailed as part of the standard itself. The language was also adapted to reflect the need for demonstrable evidence for each standard. A further exercise was carried out to demonstrate how each standard relates to the quality of a programme to ensure that each standard was meaningful and not a 'tick-box exercise', and potential sources of evidence (inputs, processes and outputs) which an institution could provide to demonstrate compliance have also been identified.

Accreditation Methodology

A systematic review of the professional accreditation literature, completed by the Australian Council for Educational Research (ACER) on behalf of the RCVS, provided the evidence-base for the decision to move towards a more outcomes-focused and risk-based approach to accreditation (available upon request).

Following consideration of this evidence, a number of principles for a future RCVS accreditation process were agreed by RCVS committees.

Principles

- RCVS should take a 'hybrid' approach to the accreditation of veterinary programmes, which ensures the evidence base upon which decisions are made, against each of the standards, is clear and transparent.

- The 'hybrid' approach should consider 'inputs' (design / implementation features of the veterinary programme) and 'outcomes' data (impact of the programme on students and the profession), and take a risk-based view to ensure school visitations remain proportionate.

- Effective measures of programme outcomes will be identified and developed if necessary, to provide the evidence required to support the hybrid approach.

- A visitation will always take place, but the focus and duration of the visit will be determined through consideration of the evidence provided by the school in advance and through annual monitoring.

- Quality improvement (QI) will become an explicit component of the accreditation process.

- Expertise within the RCVS Education Department should be used to support the accreditation review panel, through an initial review of submitted evidence and reporting to the chair of the panel.

- Evidence considered in support of accreditation standards should be direct, from multiple sources and triangulated where possible.

These principals were used by the ARWP in drafting a new methodology for RCVS accreditation of veterinary programmes. The new approach to accreditation focuses less on 'inputs', which do not always necessarily provide strong assurance of quality, to focus increasingly on 'outcomes' or 'process' evidence, which more clearly demonstrate a positive impact or outcome. Our new approach is also risk-based, meaning that where an established school collates strong outcomes evidence on a longitudinal basis, this can be considered in advance and result in a 'lighter touch' visitation by the accreditation panel, which focuses only on the areas where there are gaps in evidence, or triangulation is needed, or physical resources need to be seen.

Accreditation panels typically work with a 'rubric' which lists the standards and evidence gathered to support each of them, and this translates into the recommendations in the report. In efforts to maintain objectivity, this rubric has become increasingly prescriptive, detailing the exact evidence which is needed to meet the standard. However, this often leads to problems when trying to apply it across increasingly varied models of curriculum and programme delivery – evidence suitable from a traditional programme model may be different to that from a distributed model, but both appropriate to demonstrate quality in a specific area. It can also lead to 'double jeopardy' where a lack of evidence can result in deficiencies being reported across more than one standard, which may give an unnecessarily negative impression.

The new approach also includes an accreditation rubric, which will be a 'living document' used by the accreditation panel to monitor evidence gathered (both in advance in a repository and subsequently at the visitation). This will also support the 'risk-based' dynamic of the process – where substantial outcomes-based and triangulated evidence is available to the accreditation panel in the repository at the start of an accreditation event, the panel may consider this to be sufficient to have met the standard without the need to gather further information in this area at the visitation. The new rubric will also help ensure the transparency of the decision-making process, as the evidence used by the accreditation panel will be clear to the committees making the decisions on accreditation outcomes.

EMS Policy and Guidance

In parallel to the work undertaken on revising the accreditation standards relating to EMS, the GO EMS CE working group also created an updated EMS Policy and supporting guidance to complement the individual standards and provide more clarification for schools when interpreting the requirements. This document was approved through the ARWP, PQSC and Education Committee (where it was finalised with a majority vote).

Concerns have been expressed by vet school stakeholders that the number of weeks of EMS has not been reduced. The rationale for this is that there is a significant risk that, without additional measures in place to improve the consistent quality across EMS placements, there could be unintended consequences and a negative impact on students many of which report a lack of confidence following graduation. This could further impact the already high attrition rates within the profession. However, to establish whether a reduced number of weeks EMS could provide similar levels of experience if an outcomes-based approach with increased quality assurance was adopted, it is intended to pilot this approach in future. Furthermore, RCVS Education Committee is taking forward a number of other workstreams to support the implementation of EMS, including the development of a national database for accessing and booking placements and facilitating dialogue between students and providers, and more detailed guidance on good practice.

3. Consultation process

The consultation was initially open for 6 weeks, however, RCVS extended this to allow an extra week for people to respond as the consultation period fell during school holidays.

Consultation survey responses were completed online via SurveyMonkey and were also accepted by email. This consultation was available for anyone to complete, and members of the following groups particularly encouraged to respond - veterinary surgeons and veterinary nurses, vet & VN students, members of the wider practice team, and representatives of veterinary and wider industry organisations.

The consultation was widely publicised in order to reach out to veterinary audiences. Methods of communications included emails to all registered veterinary surgeons and nurses, articles in RCVS News and on RCVS social media platforms. The consultation was also shared directly with key educational stakeholders and veterinary organisations.

Qualitative analysis was conducted on all responses to the consultation. Each response was carefully assessed, and the key themes have been identified and summarised in the following sections of this report. Responses were reviewed in relation to arguments supporting or opposing the proposals, and suggestions for how the draft standards and methodology could be improved. Comments included in this report are used to succinctly illustrate common themes. Where these are taken from submissions from individuals, they remain anonymous, whereas organisations are named.

4. Results

4.1. Demographic data

The consultation received a total of 107 valid responses. A response was considered to be 'valid' if it contained any feedback to any of the consultation questions. Although 534 individuals engaged with the consultation, the majority of these provided no information beyond the demographic questions. Throughout this report, the term "responses" only refers to those valid responses, as detailed above.

The number of responses to each of the questions within the consultation are highlighted in Table 4.1a below. At least half of the respondents provided feedback in each of the areas of the consultation, with most responses being submitted in response to the Standards within Domain 6: Curriculum and assessment with 71% of respondents providing feedback in this area.

Table 4.1a

Number of responses to each section of the consultation (submitted to SurveyMonkey)

Consultation Question	Consultation section	No. of responses	% total responses
1	The classification of standards into 6 domains	68	62%
2	Standard 1: Learning environment	69	63%
3	Standard 2: Organisation, culture and values	62	57%
4	Standard 3: Educational governance and quality improvement	64	59%
5	Standard 4 Supporting students	64	59%
6	Standard 5: Supporting educators	64	59%
7	Standard 6: Curriculum and assessment	77	71%
8	Feedback on the proposed new methodology for carrying out RCVS accreditation events for veterinary degrees	63	58%
9	Any further feedback	54	50%

Of the 107 responses, 19 stated they were providing feedback on behalf of an organisation, and 88 were responding as an individual. Of those responding as an individual, 80 were veterinary surgeons, 6 were Registered Veterinary Nurses (RVN), one was a veterinary student and one was a retired teacher.

Although 19 responses from organisations were received, several of these represented more than one organisation.

The following organisations provided feedback to the consultation:

1. Association of Veterinary Students (AVS)
2. Australasian Veterinary Boards Council (AVBC)
3. British Association of Equine Dental Technicians (BAEDT)
4. British Veterinary Association (BVA), Association of Government Veterinarians (AGV), Associations of Vets in Industry (AVI), British Equine Veterinary Association (BEVA), British Small Animal Veterinary Association (BSAVA), British Veterinary Poultry Association (BVPA), British Veterinary Zoological Society (BVZS), Veterinary Management Group (VMG),

Association for Veterinary Teaching and Research Work (AVTRW) (AVS and SPVS were also listed in this response *as well as providing their own individual response*)

5. British Veterinary Chronic Illness Support (BVCIS)
6. Consortium on Workplace Based Education & Learning (COWBEL)
7. Linneaus Veterinary Limited
8. Pets at Home Vet Group (Vets4Pets)
9. Pig Veterinary Society (PVS)
10. Royal Veterinary College (RVC)
11. Scotland's Rural College (SRUC)
12. Society of Practising Veterinary Surgeons (SPVS)
13. St. George's University (SGU)
14. University of Edinburgh (UoE)
15. University of Glasgow (UoG)
16. University of Liverpool (UoL)
17. University of Surrey (UoS)
18. Veterinary Schools Council (VSC)
19. VetPartners

4.2. Consultation Question 1: Classification of Standards into 6 Domains

In general, the overwhelming majority of respondents were supportive of the classification of the new accreditation standards into the 6 domains described, with feedback indicating that respondents felt these categories were suitable for maintaining standards in all appropriate areas of the veterinary programme. Feedback also indicated that the division of the new accreditation standards into broader domains provide greater clarity, less ambiguity and helped to reduce any overlap or duplication of standards (which was highlighted as an issue with the current accreditation standards).

> *"I think the six domains are a useful framework covering the significant aspects of the educational environment that an accrediting authority should rightly be concerned with."*
>
> Respondent from private clinical practice

A number of respondents suggested that an additional domain should be added specifically around student selection and admissions. However, standards relating to admissions are already part of Domain 4 (a subsequent section of the survey) and therefore feedback on this area was considered in response to that domain.

Some respondents from vet schools, in addition to the response from the VSC, noted with a degree of concern that the new standards would take RCVS out of alignment with international accreditation agencies' standards, which could impact the feasibility of joint visitations.

A summary of the suggestions in response to this question within the consultation and the proposed actions (with rationale) are shown in Table 4.2.

Table 4.2 Suggestions regarding the 6 domains of standards, and proposed actions / rationale

Suggestion	Action? Yes / No	Rationale
Add a separate domain specifically on student selection and admissions.	No	Specific standards around selection and admissions already included in Domain 4.
Concerns on the impact on future joint international visitations.	Yes	Workstream already planned with IAWG to explore future way forward.

4.3. Consultation Question 2: Standards within Domain 1 – *The Learning Environment*

Respondents were generally supportive of the standards within this domain, recognising that a robust framework relating to the learning environment would lead to ensuring a high-quality educational experience.

Some concerns were expressed relating to the standard referencing abattoir experience. Whilst there was some support for retaining a physical abattoir visit during the programme to provide the students with this unique experience, other respondents questioned the need for both red and white meat abattoir experiences, arguing that most of the teaching of knowledge in this area can be achieved outside of the abattoir. Those working in veterinary schools cited the lack of control over the availability of these placements as being the greatest challenge, and respondents working in government highlighted the successful use of virtual abattoir experiences during the pandemic. It was argued by practising members and stakeholder organisations, however, that the use of virtual materials should only be used to complement learning, and that students needed to have hands-on experience in this important area of the sector.

> *"The requirement for direct exposure to a working, commercially approved red and white meat abattoir in the guidance is focused on how the teaching is delivered and not the outcomes of what students will achieve."*
>
> Respondent from a vet school

> *"The visits to abattoirs must be compulsory, together with cutting plants and down the line in the meat processing industry. Virtual and videos can be a good complement, but students should be exposed hands on to this very important part of the degree."*
>
> Respondent from the Government Sector

A number of respondents suggested the need for specific targets to be prescribed where standards referred to "*sufficient standard*" or "*sufficient number*" (e.g. numbers / amount of resources per student, lists of core species, or other inputs). These suggestions came through particularly strongly from those working within veterinary schools, but also some individuals in practice who felt that the lack of defined minimums could lead to variable standards across schools. However, specific inputs would be in conflict with the move to a more outcomes-focussed approach to accreditation, and in specifying minimum thresholds there is the risk of creating a tick-box exercise that doesn't raise standards. A degree of flexibility is required to allow Schools to be able to demonstrate how their specific curriculum / delivery model and resources are adequate to achieve the required outcomes in terms of successful training of veterinary students. Furthermore, different curriculum and delivery models will have different requirements when it comes to resources. However, it is recognised that schools will need support in the interpretation of specific standards and understanding in appropriate types of evidence, and therefore RCVS is committed to an ongoing dialogue with individual schools on types of evidence to support each standard, in addition to the written guidance provided.

Another theme emerging from the feedback related to the need for the language in the accreditation standards and guidance to relate to both physical and digital learning resources, reflecting the increasing amount of course material being delivered electronically.

Table 4.3 Suggestions regarding the Standards within Domain 1 – The Learning Environment and proposed actions / rationale

Standard	Suggestion / Feedback	Action? Yes / No	Actions / Rationale
1.1 The spaces, infrastructure, physical and digital resources across the programme must provide an effective and safe learning and teaching environment, support student welfare, and meet the needs of educators and support staff.	Allow scope for adjustments to be made to the learning environment, especially accessibility. The same standards of support and course quality should be delivered regardless of the need for any adjustments.	Yes	Add reference for the need to deliver the same standards of support and course quality regardless of the need for any adjustments to the guidance.
	Guidance to include a requirement for staff training and IT support.	No	Staff training already addressed in Domain 5.
	Add guidance on what constitutes 'acceptable facilities'.	No	Need to avoid prescribed lists, so support will be given to individual schools via ongoing dialogue relating to their specific delivery / curriculum model.
	Confirmation that the provisions listed must be provided on site at the vet school, as schools could rely on main university services which are often on different campuses.	No	Centralised services are often more affordable for a university. Local is desirable, not essential.
	Need to reference the need for equity in student access to digital resources.	Yes	Add to the guidance.
1.2 The learning environments across the programme must ensure the health and safety of students, staff and animals and comply with all relevant jurisdictional legislation including health, safety, biosecurity and UK animal welfare and care standards.	Clarify areas where a non-UK accredited school would or would not need to comply with UK legislation / local legislation.	Yes	Add to guidance, adherence to local laws, but students should be taught best practice in terms of a UK context.
	Add guidance relating to support available from EMS placement providers.	No	Addressed in Domain 6.
	Learning environments are defined as those which "encompass all areas (inc. off-site) where students are present". Needs to be made explicit if this relates to EMS placements/sites so that the responsibilities of HEPs, placement providers and students are clear to all.	Yes	Students should not be attending placements where their health and safety would be compromised. This includes EMS and will be made explicit in the guidance. EMS

			coordinators should review suitability of placements.
1.3 All learning environments (within the school and off-site) should be quality assured to ensure appropriate standards of teaching, support and learning outcomes are achieved.	Clarification required as to whether the standard relates to all sites where training takes place, particularly, for distributive clinical training. The type of sites (e.g. core sites versus elective sites) that require quality assurance assessment should be clarified to allow for those programs to fully comply with these standards. Additionally, does this standard apply to educators and credentials for educators?	Yes	Guidance says ALL sites but could clarify that it relates to physical facilities (not educators).
	Given the shift to hybrid models of education, consider how this standard would apply to virtual learning environments. Digital resources and teaching should also be incorporated into elements of quality assurance.	Yes	Add reference digital/virtual to guidance.
	Consider how EMS placements will be quality assured, and how this can be achieved without placing extra bureaucratic burdens on EMS.	No	Clarify doesn't include EMS, as EMS quality assurance addressed in Standard 6.9.
	Clarify the meaning of quality assurance of learning environment. Further guidance on the expectations of schools would be helpful.	No	It is not the aim of the standards to be prescriptive.
1.4 The learning environments across all aspects of the programme must demonstrate good practice standards and promote high standards of animal husbandry and care at all times.	In regions where smaller, less lucrative practices abound, not all will have attained RCVS Accreditation which may in turn, limit student exposure. Suggest include 'working towards' practices where evidence can be presented with clear timelines that would precede student exposure?	No	If a school wishes to use a practice for its teaching, it should support the practice in reaching a standard before placing students there.
	How will this be implemented for EMS? Will it only be participants in PSS that can take students?	Yes	Add clarification to guidance that this does not extend to EMS placements.

1.5 Normal and diseased animals of the principal domestic and exotic species must be available for instructional purposes, either as clinical patients or provided by the school. The school must provide access to sufficient numbers and range of animals and animal material to provide the necessary quantity and quality of animal husbandry and clinical instruction to meet the programme learning outcomes and achieve the RCVS Day One Competences.	Define which species should be included and provide baseline animal numbers required.	No	Committees have agreed that prescribed species lists should be avoided. Prescribing ratios also too prescriptive within this model. However, support will be provided to schools through ongoing open dialogue around evidence to meet these standards.
	The practical aspects of general practice should be catered for, inc. clinical management and handling of cases and an understanding of animal behaviour.	No	Addressed within standard 6, and Day One Competences (D1C).
	No mention to laboratory animals. Many veterinary colleagues and paraprofessionals work in government or industry labs. We need to encourage exposure to these as well.	No	This level of detail is not appropriate for this standard.
1.6 There must be sufficient up-to-date and well-maintained learning and teaching equipment to support the programme effectively, readily accessible by students.	Clarify if / how this standard will apply to distributed models of education.	No	All standards apply to all programmes, regardless of the curriculum / delivery model. Distributed practices should be evaluated by the school and evidence provided that their equipment is well maintained and up to date.
	Add to guidance that students should all have the opportunity to practice using equipment individually, and not just ‘seeing’ how equipment is used in a group or from a distance.	Yes	Add to guidance.
1.7 The school must ensure students have access to a broad range of diagnostic and	Add Dentistry to this as it is a vital area of general practice in which undergraduates come to general practice with insufficient knowledge and understanding.	Yes	Add dentistry to the list in the guidance.

therapeutic facilities, of sufficient standard and in number to enable learning outcomes to be met and achievement of the RCVS Day One Competences.	There should be a day 1 competency for ultrasound.	No	Ultrasound is already part of D1Cs.
	Add reference to the need for business focus?	No	Business focus not relevant to diagnostic and therapeutic facilities. Also included in D1C.
	State the number of students per facility/resource appropriate to enable students to get sufficient 'hands on' training.	No	Prescribed ratios/numbers not appropriate. Numbers would depend on the facility / available resources within.
	Reference clinical pathology and anatomic pathology (the mention of necropsy facilities is not enough).	Yes	Change to Clinical/anatomic pathology in the guidance.
1.8 A supervised field service and/or ambulatory programme must be available as part of the programme, in which students are offered multiple opportunities to obtain clinical experience under field conditions.	No relevant comments or suggestions.		

1.9 Appropriate isolation facilities must be available at the sites where clinical instruction is delivered, or be able to be supplied when needed, to meet the need for the isolation and containment of animals with communicable diseases. Students must receive instruction within this environment on how to provide for animal care in accordance with accepted best practice for prevention of spread of infectious agents.	Clarify if the requirement for isolation facilities extends to non-clinical facilities such as farms.	Yes	Reword the standard and guidance to indicate that it relates to all sites, however the type of isolation facilities / provision and policy will vary in line with relevant industry guidelines. i.e. ‘Appropriate isolation facilities / provision’.
1.10 Clinical education in veterinary public health training must be complemented by direct exposure in commercially run, approved abattoirs.	There should be recognition of the challenges faced in securing access to both red and white meat abattoirs, both in the UK and overseas.	Yes	Adjust guidance to read that there must be direct exposure to a working, commercially approved red OR white meat abattoir, with opportunities to be made available for further experience if requested by the student. Clarify that overseas programmes must also meet this standard (noting change above).
	Students need the opportunity to experience the role of vets in abattoirs and direct exposure is key to this. This can be complemented by virtual materials, but not replaced entirely (many practitioners responded to this effect).		
	Define both 'commercially run' and ‘approved’ as it relates to abattoirs.	Yes	Clarify in guidance. ‘Approved’ is government terminology.

1.11 Medical records within all sites used for clinical teaching must be comprehensive and maintained in an effective retrieval system to efficiently support the teaching, research, and service programmes of the school.	Clarify if the medical records refer to patients, staff or students.	Yes	Specify “patient medical records” in the guidance.
	Access to medical records is important but more clarity is required about the level of student interaction with the records and the GDPR training that students will receive.	Yes	Guidance states that systems should be fully accessible to students, however, further detail needs to be added around the level of student interaction with records and the requirement for students to receive GDPR training in advance.
1.12 Students and educators must have timely access to literature and information resources relevant to the programme. An appropriately qualified individual should be available to support students and educators in the effective retrieval of information.	The guidance currently stipulates that students require internet access at all sites where clinical education takes place. This is not practical on many farms or more remote sites.	Yes	Clarify the guidance to ensure this standard relates to all locations where teaching takes place, and that ‘timely’ refers to a minimum of ‘daily’. (for information resources, not models – see below).
	There is currently no mention of non-animal methods of teaching procedural and technical skills.	Yes	Split this standard into two parts – one for information resources and one for non-animal resources. Define timely for non-animal resources separately .
1.13 The school must establish post-graduate programmes such as internships, residencies, and advanced degrees (e.g., MSc, PhD), that enrich, complement, and strengthen the professional programme.	Why is there no accreditation of post graduate studies within the standards?	No	The remit of the accreditation is to review undergraduate programmes only.
	Could the standard stipulate the type of research to be undertaken, such as limiting research to veterinary science related subjects only?	No	Universities have the right to pursue research in any areas of interest that it feels complements and strengthens the professional programme.

General comments about Domain 1.	Add more specific guidelines around accessibility for both staff and students experiencing short but chronic periods of health conditions which may temporarily prevent them from accessing the curriculum. Also for those who may experience short periods of external situations which may prevent traditional access to the curriculum.	Yes	Add to guidance – schools are encouraged to offer multiple learning modalities across the programme – Standard 1.1
	Should it be mandatory for all vet schools to host their own veterinary clinic or hospital?	No	RCVS does not specify curriculum / delivery models. There are many ways of achieving the outcomes of the veterinary programme.
	Should the accreditation cover recreational facilities and items such as lockers? Is this part of the veterinary degree?	No	Student welfare and work life balance is to be encouraged. Lockers are already specified in the guidance for 1.1.

4.4. Consultation Question 3: Standards within Domain 2 – *Organisation, Culture and Values*

An overwhelming majority of the respondents to the consultation supported efforts to strengthen the diversity of the profession through the standards in this domain and welcomed the move to consider outcomes evidence in this respect rather than policy (an 'input') alone without any need to demonstrate if and how targets are being achieved.

> *"It is well recognised that minority groups are poorly represented in veterinary science degrees. Much more needs to be done in supporting these groups into vet schools and vet schools should have to demonstrate how they are actively supporting this."*
>
> Respondent from private clinical practice

> *"It is essential that the whole veterinary profession encourages greater diversity and works to make the profession more accessible for minority and under-represented groups."*
>
> Response representing veterinary associations

There was also substantial support for ensuring that all environments associated with learning demonstrate a no-blame culture with effecting mechanisms in place for reporting and responding to reports of discrimination. The need to obtain outcomes evidence in this respect was emphasised.

Another recurring theme emerging from the consultation responses was the desire for stakeholder input to include feedback/involvement from future employers and general practitioners, and for there to be a requirement for schools to demonstrate how they have responded to any stakeholder feedback. This came through clearly from not only from the responses from veterinary organisations (BVA etc), but also from individuals in clinical practice who, as future employers of graduates, felt strongly that they should have a mechanism to feedback on the areas of a programme which would benefit from further development or enhancement.

> *"The term 'stakeholders' should be better defined in this standard, specifically to make clear whether this includes future employers."*
>
> Response representing veterinary associations

> *"General practice is an important 'stakeholder' (over 80% of the profession are general practitioners), but the views of general practitioners are often ignored."*
>
> Response representing veterinary associations

In general, there was support for the need for schools to demonstrate a commitment to sustainability to feature within the accreditation standards, although a small number of respondents argued that this is not relevant since it does not relate specifically to educational outcomes. There were also questions

from both organisational and individual respondents as to how sustainability could be evaluated and a request for guidance on what to aim for.

Additional suggestions relating to the standards within this domain focused on providing further guidance and examples of good practice, which have been added to the action list in Table 4.4.

Table 4.4 Suggestions regarding the Standards within Domain 2 – Culture, Organisation and Values - and proposed actions / rationale

Standard	Suggestion / Feedback	Action? Yes / No	Actions / Rationale
2.1 The school demonstrates effective strategic & operational planning, including evidence that goals are being achieved in a timely manner.	Add more detail – goals should need to align with RCVS goals and be coordinated between schools.	No	Schools develop their own strategic plan.
2.2 The school must have a system in place to identify, actively monitor and address risks to any aspect of the vet programme.	No suggestions received.		
2.3 The school can demonstrate a culture which is inclusive, actively seeking and responding to feedback from stakeholders, and involving them in decisions relating to programme development, delivery, and enhancement.	Add clarification whether this standard is seeking to recognise the importance of human welfare and workplace consideration, or a requirement to work within the various laws (e.g. employment, human rights etc.). Presumably, as with animal welfare laws, compliance with local laws would be required (rather than UK laws, for a non-UK school) – this requires clarification.	Yes	Add clarification to the guidance.
	It is unclear how 'culture' can be assessed, other than through discussions with staff / students to ensure this is happening in practice. Provide guidance on how outcomes will be considered in this area, and the criteria used.	Yes	Examples of evidence will be provided in the guidance.
	Need stakeholder feedback to include that from future employers and general practitioners, and the school required to demonstrate how they've responded.	Yes	Add to guidance for this standard.

2.4 The school must actively promote and maintain a culture that does not discriminate and enhances diversity, consistent with applicable law. Diversity may include, but is not limited to, race, religion, ethnicity, age, gender, gender identity, sexual orientation, cultural and socioeconomic background, national origin, and disability. There must be reporting mechanisms in place for any individual to raise concerns about discrimination and harassment.	Include guidance on good practice in this respect. i.e. employers and employees (including EMS providers) must understand and act on equality law and their responsibilities, and everyone should work to increase their awareness and understanding of issues affecting anyone they work with that may lead to discrimination or offence. To support this, employers should invest in training and be able to signpost to resources on diversity matters, ensure that any knowledge gained is implemented, and develop an open culture of discussing equality issues in the workplace. Employers should regularly review any strategies aimed at improving diversity and inclusion and should appoint or nominate an equality, inclusivity and diversity champion, recognise it may be necessary to make reasonable adjustments, for both staff and students, to support inclusivity e.g. to accommodate religious clothing requirements in clinical settings. Veterinary workplaces should be inclusive. A zero-tolerance policy for all forms of discrimination and inappropriate behaviour must be available and clearly communicated to everyone, including staff, members of the public, students and EMS providers. The policy must be acted on consistently by all employers and employees, and managers should know how to handle incidents related to discrimination, and where to seek advice.	Yes	Suggestions to be included in the guidance.
	Stipulate that Universities should withdraw from distributed teaching contracts if providers fail to respect the guidance for this standard.	Yes	Add to standard wording and guidance that schools should act / respond appropriately to ensure this standard is met.

	Alongside the mechanisms for reporting, AVS feel there must be specific, robust protocols for handling of any reports. Any reporting mechanisms must also be accessible, while still protecting the individual from further discrimination or harassment.	Yes	It is already the intention that outcomes evidence will be required in addition to the process / mechanism for reporting – this will be clarified further in the guidance.
	AVS are glad that this point regards 'any individual' but would like confirmation that it includes everyone within the vet school community, including staff, and those the school interacts with.	Yes	Clarification and suggested range of staff to be included in the guidance.
2.5 The school must demonstrate a no-blame culture that investigates, reflects, and learns from mistakes and adopts effective reporting mechanisms and sharing of best practice. Students and staff should feel safe in raising and reporting concerns, and these should be dealt with effectively.	Suggest there needs to be an independent means by which to report failures in upholding culture and values so victims feel safe to speak up and report problems.	No	Already covered within Domains 4 and 5.
2.6 The school must demonstrate a commitment to sustainability, including consideration of the impact of delivering the programme on the environment.	Strengthen guidance to promote examples of sustainability initiatives e.g. promote BVA, Vet Sustain, BVNA and SPVS greener practice checklist.	No	Whilst good examples, RCVS cannot promote specific initiatives within the accreditation standards.
	Does this standard refer to other types of sustainability e.g. financial sustainability?	Yes	Reword standard to avoid any ambiguity.

4.5. Consultation Question 4: Standards within Domain 3 – *Educational Governance and Quality Improvement*

Overall, the responses to the consultation demonstrated support for the new accreditation standards around educational governance and quality improvement, with few disagreeing with any specific areas or individual standards, and many comments or questions simply requesting either further additional guidance or stipulation of examples.

> *"The re-working of these standards is greatly appreciated and sensible. Thank you. Clarity! I think this is helpful and can only impact positively on diversity and excellence."*
>
> Respondent from private clinical practice

The proposed standard that does not stipulate that the Head of School must be a veterinary surgeon provoked a number of responses, with the overwhelming majority against this suggestion.

> *"As it stands, the guidance is unclear as to whether a 'head of school' must be a veterinary surgeon (and MRCVS/FRCVS); this should be clarified as it is an important distinction, and we believe that vet schools should be led by those with veterinary degrees."*
>
> Respondent from a veterinary employer

Other minor trends in the specific comments to the remaining standards in this domain showed that there was some concern relating to schools' admissions requirements, with a number of respondents commenting that they seemed to be overly based on academic performance, so the insistence on further criteria being applied was welcomed.

There were a few comments around the need for general practitioners to be more involved as stakeholders in the construction of curricula and clinical teaching. However, these issues would be considered more within Standard 6.3.

The proposed actions following suggestions to the standards in this domain are included in Table 4.5.

Table 4.5 Suggestions regarding the Standards within Domain 3 – Educational Governance and Quality Improvement - and proposed actions / rationale

Standard	Suggestion / Feedback	Action? Yes / No	Actions / Rationale
3.1 The school must be part of an accredited institution of Higher Education and be recognised and autonomous within that institution with accountability for the quality of the veterinary programme (including the RCVS standards being met).	No suggestions made.	No	
3.2 The school demonstrates a commitment to continuous quality improvement across all accreditation standards and aspects of the programme, informed where possible by measurable outcomes and stakeholder engagement.	Specify students as part of the stakeholder engagement process.	No	Students are defined as stakeholders in the guidance for standards in Domain 2.
3.3 The head of school must have appropriate knowledge and expertise of the veterinary profession, academic affairs and leadership, and have control over the budget for the veterinary programme.	RCVS should stipulate that the Head of School needs to be MRCVS/FRCVS. Respondents stated that they believed it was important for the vet school to be led by a vet, and to not do so would also conflict with other accrediting bodies' own requirements.	Yes	Change wording to "The head of school or dean should be MRCVS/FRCVS (or, for overseas schools, a locally registered veterinary surgeon) and must have appropriate knowledge and expertise of the veterinary profession, academic affairs and leadership, and have control over the budget for the veterinary programme.
3.4	No suggestions made.	No	

Finances must be reviewed regularly in line with strategic plans, and be sufficient to sustain and enhance all aspects of the veterinary programme(s) for the duration of all current cohorts, including teaching and learning, infrastructure, teaching resources and students / staff support.			
3.5 The managerial, academic and support staff should have the necessary skills and experience for their role, and be sufficient in number to support the effective design, delivery and quality assurance of all aspects of the programme.	The skills and expertise for each staff role should be defined, i.e. levels and qualifications required.	No	Prescription not appropriate as roles vary. Schools should demonstrate staff have the necessary skills for their role.
	Issues such as Brexit would be likely to impact the recruitment of EBVS Residents, and post graduate students, who are often highly involved in delivery of teaching, particularly in clinical rotations.	No	Noted, but not relevant to standard itself.
3.6 The school must demonstrate that the recruitment, selection and appointment of students, educators and staff are open, fair, transparent and free from bias.	No suggestions made.	No	
3.7 The school must have effective and transparent educational governance systems, with formal committee structures, which develop and continually monitor, assure, and enhance the quality of veterinary education and the student experience across all aspects of the programme.	The guidance indicates that student representation on committees is specified as a requirement. Should the standard also specify staff (or possibly outside representation) if appropriate.	Yes	It could be taken as read that school committees would be made up of staff, however could clarify in guidance that students would be expected on committees *as well as* staff.
	The membership of some committees is specified by other external bodies in certain countries: e.g. the USDE stipulates the composition of some core committees of the vet school. Therefore, it was	Yes	Update guidance to clarify that veterinary school committees should have student representation, unless a

	argued that the vet school should be able to provide justification if it considers that there are committees on which student representation is not appropriate.		clear rationale can be provided to justify otherwise.
3.8 The school must have robust mechanisms for quality assurance and improvement, embedded into policy and processes, which routinely gather data to demonstrate that organisational and educational objectives are being met and opportunities for improvement are identified and responded to.	No suggestions made.	No	
3.9 Mechanisms for quality assurance and improvement must encompass both internal and external review and data collection and analysis	No suggestions made.	No	
3.10 The school must evaluate students' performance, progression and outcomes with respect to information on equality and diversity, and provide support for groups where disparities are identified.	This could give the impression of positive discrimination and / or bias. Stating that evaluating students' performance with regard to protected characteristics is right and proper. However, the solution to "provide support for groups where disparities are identified", was a deficit approach to difference (i.e., the students are the problem, and we need to fix them). Instead if there are disparities, schools should be looking inwards: what are they teaching, how are they teaching, why are they doing it this way – i.e., the curriculum is the problem, rather than the student/s.	No	Possible misunderstanding of standard – it is not saying that diverse groups should be given preferential treatment, but schools should be identifying if and where support may need to be given if specific groups are struggling.

3.11 The school must regularly review curricula, using available quality assurance data and feedback from students, educators and stakeholders, to ensure standards are being met and maintained.	This standard clarifies the role of the Curriculum Committee, however question the inclusion of "regularly review curricula", and how often "regular" should be and what exactly a "review" was. Proposed standards indicate that curriculum review should occur within the cycle of a cohort. AVBC had concerns regarding this time interval for whole-of-program review, although they agreed it is entirely appropriate to have more frequent partial reviews in response to QA activities.	No	Existing guidance is clear enough on regularity of review and what it constitutes, however RCVS will continue open dialogue with schools as necessary.
3.12 The school must have effective processes in place to monitor attrition and progression rates in relation to admissions and selection criteria and student support if required.	Attrition rates post qualification should also be mentioned in the standard.	No	Noted, however post qualification attrition can be based on a number of factors and RCVS collects data from the profession separately to the accreditation process.
3.13 The school must have effective processes in place to ensure that all locations where clinical teaching takes place, must demonstrate a continual commitment to student learning and teaching.	Need for further clarity in the additional guidance for this standard to specify whether or not this standard also includes IMR, and EMS placements.	Yes	Updated guidance to clarify it includes IMR. EMS not included here as it does not necessarily take place in a location where clinical teaching is delivered.
3.14 The school must demonstrate that only students who are fully Day One Competent are able to graduate.	Day One Competences were not sufficient and / or the standards could not truly ensure that graduates were truly Day One Competent.	Yes	Add clarity on the difference between achieving individual D1C and being confident and competent in applying these in a holistic sense at a level ready to start working as a veterinary practitioner.

4.6. Consultation Question 5: Standards within Domain 4 – *Supporting Students*

There was overall agreement to the standards within this domain, with relatively few suggestions for amendments or additions put forward by respondents. Respondents to the consultation particularly welcomed the commitment to widening participation and increasing diversity within the standards, and also the focus on students' wellbeing.

> *"In 4.1. a good emphasis on social backgrounds. I think we are failing in attracting students from state schools."*
>
> Respondent from private clinical practice

> *"Delighted to see the commitment to widening participation. These standards seem fair."*
>
> Response from a vet school

A number of respondents expressed concerns around student selection in line with those to domain 3. The feedback indicated that individuals are concerned about the resilience of students prior to and upon graduation, and that more should be done in the admissions process to be able to identify which prospective students would be better prepared to cope with the demands of the veterinary degree and a career in the veterinary profession. However, it was acknowledged that this would be difficult to fully identify, which was mirrored in some comments which questioned how schools could effectively test or assess resilience in students. Despite this however, there was general agreement that this should be included within the standards.

> *"We feel that certain things are essential to understanding and maintaining a veterinary career specifically with respect to applicant personality, mindset, aptitude for customer service, empathy, resilience, personal leadership, analysis of risk & risk-benefit and decision-making. We feel these should be valued as highly if not more so than academic abilities."*
>
> Respondent from a veterinary employer

The suggestions and proposed actions / rationale for standards within Domain 4 are shown in Table 4.6.

Table 4.6 Suggestions regarding the Standards within Domain 4 – Supporting Students - and proposed actions / rationale

Standard	Suggestion / Feedback	Action? Yes/No	Actions / Rationale
4.1 The school must have a strategy for widening participation which considers all aspects of diversity, and engages students from different ethnic and social backgrounds. The school must be proactive in their marketing to attract a diverse cohort of applicants and regularly review, and provide evidence of, their progress towards targets.	No suggestions made.	No	
4.2 The school must provide accurate and current information regarding the educational programme easily available for prospective students. The information must include the accreditation status of the degree course (whether by RCVS or other relevant accrediting bodies), selection and progression criteria, the demands of the course and the requirements for eventual registration/licence, including fitness to practise.	This standard may be difficult to interpret as it referred to RCVS guidance that was 'currently being updated'".	No	Noted – guidance will be available when completed.
4.3 Selection and progression criteria must be clearly defined, defensible, consistent and free from discrimination or bias. The criteria should also include relevant factors other than academic performance. The academic requirements for entering the programme should be sufficient for the student to cope with the demands of the programme upon entry.	Admissions criteria should include further factors rather than just academic performance.	No	Already included in the standard.

4.4 The school must demonstrate their selection and progression criteria and processes are effective in identifying students with the potential to achieve the RCVS Day One Competences. This must be achieved through regular and effective training for staff involved and the routine collection and analysis of selection and progression data, to enable them to evaluate, reflect and adjust the selection and progression criteria where necessary.	Vet schools should be admitting students based on other reasons that just academic performance.	No	Already included in standard 4.3.
4.5 There must be clear policies and procedures as to how applicants with disabilities or illness will be considered and, if appropriate, accommodated on the programme, taking into account the requirement that all students must be capable of meeting the RCVS Day One Competences by the time they graduate.	No suggestions made.	No	
4.6 Students must be actively supported to develop resilience, self-reflection and professional values in line with the RCVS Code of Professional Conduct, and should not be subject to behaviour which undermines their professional confidence, performance or self-esteem at any sites where teaching and / or learning takes place.	As the standard was currently worded, a school could demonstrate it had met the standard by an 'absence of complaint'. Suggest it is re-written in a positive way such that schools would be required to show evidence of positive activities they were taking even in lieu of any complaints.	Yes	Reword standard with more positive language, i.e. "should" rather than "should not".
4.7 Students must receive continuous and effective educational support to enable them to achieve the learning outcomes of the programme and the RCVS Day	No suggestions made.	No	

One Competences, including the provision of regular, constructive and meaningful feedback on their performance and progress in a timely manner.			
4.8 Effective processes must be in place to support the physical, emotional and welfare needs of students.	Reorder this standard to be the first standard in this domain, for better alignment with subsequent standards.	Yes	Make this standard the new 4.1.
4.9 Effective processes must be in place by which students can convey their needs and wants to the school. The school should demonstrate how student feedback is considered and acted upon.	No suggestions made.	No	
4.10 The school must provide students with a mechanism, anonymously if they wish, to offer suggestions, comments, and complaints regarding compliance of the school with the RCVS standards for accreditation and that Day One Competences are being met. All such feedback from students must be reported to the RCVS as part of the annual report.	This mechanism should also be available for educators and support staff and incorporated into Domain 5: Supporting educators.	Yes	Add as new standard in Domain 5.
4.11 The basis for decisions on progression (including academic progression and professional fitness to practise) must be explicit and readily available to the students. The school must provide evidence that it has effective processes in place to identify and provide remediation and appropriate support (including termination) for students who are not performing adequately in any area of the programme.	No suggestions made.	No	

4.12 The school must ensure that students are competent and sufficiently experienced in animal handling before they begin clinical placements and / or workplace learning, and that they are fully briefed regarding all relevant Health and Safety matters.	No suggestions made.	No	
4.13 Mechanisms for dealing with student misconduct and/or the exclusion of students from the programme, either for academic reasons, misconduct or under fitness to practise procedures, must be explicit.	No suggestions made.	No	
4.14 The school must have in place effective processes for the resolution of student grievances.	No suggestions made.	No	
4.15 School policies for managing appeals against decisions, including admissions, academic and progression decisions, must be transparent and publicly available.	No suggestions made.	No	
General comment relevant to this domain.	Pre-requisite work experience requirements could put off potential “good” vets who aren’t able to obtain this prior to going to university. RCVS should indicate exactly what conditions might make a student unfit to enter a veterinary programme and also any that might require either suspension from study or removal from the programme. Particularly around severe mental ill health.	No	RCVS cannot set admissions requirements.

General comment relevant to this domain.	The need to develop students' resilience more to counter attrition rates, whilst others questioned whether this could truly be assessed.	No	Noted wider issue, addressed in Domain 3.
General comment relevant to this domain.	Increased provision of mentorship and education-based training of staff in workplaces providing EMS placements would help staff to be able to confidently support and mentor students to develop both clinical and non-clinical skills, as well as supporting insights into opportunities for different career paths. This could be achieved through a future VetGDP module that highlights the ways in which mentoring skills can be applied to EMS students, giving those who undertake the VetGDP a common framework and shared language associated with mentorship.	Yes	No action relating to these accreditation standards – however this is being actioned as part of wider RCVS policy, not in relation to accreditation standards for veterinary programmes as not implemented by schools.

4.7. Consultation Question 6: Standards within Domain 5 – *Supporting Educators*

The standards within this domain were widely welcomed by respondents.

> *"This is excellent! Really pleased to see such a clear focus on what has been a perturbing area for many of us. Excellent people deserve recognition and support."*
>
> Response from an individual working within a vet school

> *"These proposals are robust and in the interests of the profession and it's future"*
>
> Response from a vet school

A key theme emerging from the feedback on the standards within this domain related to the teaching qualifications of educators involved in the delivery of the curriculum. There appeared to be some misunderstanding of the guidance whereby it is not necessary for an educator to have completed a teacher training qualification **before** commencing their teaching role, requiring the guidance for this to be clarified (see Table 4.7 below). There were also a number of comments which questioned the scope of this standard, and which staff are required to have a teaching qualification (i.e. whether this includes interns, residents, PhD students, IMR practitioners and temporary staff).

A number of respondents highlighted the need to define the scope of 'continued competence' in terms of whether it should include educational and / or veterinary competence, as well as the inclusion of online literacy. Respondents welcomed the support of educators in terms of their emotional and welfare needs as well as a balanced workload and it was suggested that an additional standard could be added to provide a mechanism for feedback from staff.

Additional suggestions made included references to the need for clarification within the guidance on the scope of some standards within this domain.

The proposed actions and rationale for suggestions made regarding standards within this domain are shown in Table 4.7.

Table 4.7 Suggestions regarding the Standards within Domain 5 – Supporting Educators - and proposed actions / rationale

Standard	Suggestion / Feedback	Action? Yes/No	Actions / Rationale
5.1 The school must ensure that all educators who are involved with student teaching have successfully completed a quality assured programme of teacher training, which effectively prepares educators for their roles.	To have all staff completed training before commencing teaching may be unrealistic. This requirement could be amended to note “studying towards” rather than “completed”.	Yes	Amend wording to include “working towards”. Add in the guidance that there should be an appropriate timeframe for completion to prevent educators being signed up to teacher training but never finishing it.
	How might this affect senior educators who do not have a formal teaching qualification?	No	All educators, even if they have been in post for several years without a relevant teaching qualification, will need to gain such a qualification.
	No mention of educators on off-site locations, eg nursing staff in the clinical environment. A full CertHE may not be attractive or suitable for all nursing staff to undertake and a shorter/lighter-touch programme that is quality assured will be an additional resource to secure.	No	Standard already refers to all involved with student teaching (i.e. includes off-site locations), and specific programmes are not prescribed.
	Does the teacher training apply to those educators who are outside of the university staff, such as practitioners in partner practices of distributed and community models, who deliver clinical training.	Yes	Add wording to guidance to further clarify that all these educators are included.
	How does this relate to graduate students, interns, residents and Masters students doing less formal but no less regular teaching of undergrads?	Yes	Adjust wording in guidance to include these educators
	The definition of non-permanent staff seems to be limited to guest speakers; consideration should also be given to exemption for those on fixed-term contracts, for	No	Short term and non-permanent staff can be “working towards” a qualification, or complete a low level qualification.

	example to cover periods of m/paternity leave of permanent faculty.		
5.2 All educators involved in teaching and / or supporting students' learning within the programme must demonstrate their continued competence and effectiveness.	Not clear how an intern could demonstrate their continued competence as a teacher when they are in the early stages of learning themselves.	No	Already addressed in the guidance (regular evaluation and feedback on performance).
	It is not clear whether this would apply to EMS providers and those providing IMR placements.	Yes	Add that it applies to IMR educators in guidance, and not EMS.
	Reference to private practice CPD, employee rights to 5 days paid CPD, and to re-accreditation/requirement for CPD.	Yes	Add to guidance that there must be the opportunity for educators to engage with CPD within their workload.
	Should be stipulated that all MRCVS educators are required to spend a percentage of their time either in first opinion clinical practice or observing first opinion clinical practice so that they can ensure that the education they are providing is directly relevant to a prospective MRCVS.	No	This type of practice is stipulated in standard 6.4 and therefore it is up to the Vet School to recruit and train accordingly.
	How do educators demonstrate continued competence? Suggested wording – "The school must ensure that all educators who are involved with student teaching are supported in their role as educators through regular training and CPD relevant to their role".	Yes	Add suggested wording to the guidance.
5.3 An appraisal system for all staff must be in place. The school must provide evidence that it has a comprehensive, effective and publicised programme for the professional development of staff. Promotion criteria must be appropriate, clear and explicit.	It is important to recognise that many of the activities undertaken by staff may not fit neatly into the career progression guidelines of the university. For example, many educators spend large proportions of their time engaged in clinical activity. There should be further clarity as to how vet schools should measure and value this activity in relation to career progression.	No	The activity of staff should relate to their effectiveness as educators.

	A specific requirement to involve working vets in the education process, and to support them to deliver teaching of a high standard, should be included, to ensure curricula remain relevant to actual, current veterinary practice.	No	Already referenced in standards 2.3, 3.11, 6.3.
	"Promotion criteria must be appropriate, clear and explicit" - and should focus on teaching. Current promotion criteria in certain universities still give too much weight to research output rather than the skills and experience required to help undergraduates become successful vets.	No	This is a comment on Vet School practice and not relevant to the standard.
5.4 The school must support educators by dealing effectively with concerns of difficulties they face as part of their educational responsibilities. Effective processes must be in place to support the physical, emotional and welfare needs of staff	Further guidance is required for this standard to illustrate how educators can be supported in dealing with the difficulties they face as part of the educational responsibilities.	No	The specifics of how a university supports educators is their policy.
	Schools should also offer educators a mechanism, anonymously if they wish, to offer suggestions, comments, and complaints regarding compliance of the school with the RCVS standards for accreditation and that Day One Competences are being met. All such feedback from educators must be reported to the RCVS as part of the annual report.	Yes	Add to Domain as Standard 5.6.
	Whistle-blowing or reporting concerns, especially about the behaviour of other staff needs to be taken more seriously and examined in a more independent way.	Yes	Add whistleblowing to guidance.
	The support of non-academic staff who are involved in teaching (most commonly in a practical rather than formal lecture setting) should be considered (e.g. technicians, veterinary nurses etc.).	Yes	Add these roles to the guidance.

5.5 Academic positions must offer the security and benefits necessary to maintain stability, morale, continuity, and competence of the educators. Educators and staff should have a balanced workload of teaching, research and service depending on their role; and should have reasonable opportunity and resources for participation in scholarly activities.	The stipulation of types of contracts for staff is prescriptive and it should be the institution that determine the types of contracts and leaders who work out the balance of workload amongst their staff. This might include fixed term contracts, flexible working and working in an entirely unbalanced way e.g. entirely teaching or entirely research.	No	Standard is not stipulating contract types
	Research should include across departments, and universities. Relieve educators of the obligation to seek research funding and publish over and above their obligation to develop improvements to their own teaching.	No	This is the rationale of the university contracts.
General suggestions relating to this Domain.	To increase the supply of vets to these positions, greater emphasis should be placed on academia as a career route for vets as part of the undergraduate veterinary degree programme.	No	Update EMS guidance examples which references different types of workplaces (professional EMS).

4.8. Consultation Question 7: Standards within Domain 6 – *Curriculum and Assessment*

The responses to this section of the consultation focused strongly on the need for the design of the curriculum to focus on clinical education set within the general practice context and the delivery of EMS. There were some comments about research and its focus, and some suggestions regarding the content of the curriculum, although the list of core subjects has not yet been published[1].

There was a range of comments relating to the length / duration of the curriculum programme and the

> *"Strongly support the idea that the majority of training should be for General Practice and not specialisation…… students should be given the confidence to build on their general knowledge of surgery to attempt procedures they have not done before."*
>
> Respondent from private clinical practice

> *"Elements here are revolutionary and largely most welcome! The focus on 'generalism' and exposure to first opinion caseloads is greatly appreciated and comprises a major shift towards smoothing the transition of our graduates into general practice. A major step forward which will hopefully be rapidly registered in decreasing stressors and increasing resilience in practice."*
>
> Respondent working in a vet school

quantity of hands-on clinical experience. Several respondents from vet schools expressed a desire for further clarity on the definition of a "sufficient amount" equating to the equivalent of one year of work-based learning. However, there were no responses about this time period from practicing vets, or those outside education.

A key feature of the feedback, with many respondents making comments, related to the standard which now states the proportion of clinical education that needs to focus on casework in the 'general practice' context. This standard was implemented following the Graduate Outcomes consultation with the profession, which reported the need for the 'majority' of clinical education to be in a general practice context. However, the precise wording of this standard has been subject to significant debate during RCVS committee meetings, in terms of the definition of 'majority'. It had been agreed that the guidance for this standard should recommend that anything more that 50% represents a 'majority'. In this consultation, there was strongly divided opinion on this matter, with many responses expressing concern that limiting the casework in a 'general practice' context to anything over 50% didn't go far enough and most respondents wanted an increase to this figure. This opinion was shared by some respondents who are working within an educational setting and those from other sectors within the veterinary profession. One respondent went as far as suggesting a figure of 75% in order to more accurately reflect the proportion of vets in general practice.

[1] Currently being drafted.

> *“The majority of clinical education delivered by the university should focus upon casework in the ‘general practice’ context" is undermined by the clarifier "Anything more than 50% constitutes a ‘majority’." This is likely to perpetuate the unfortunate fact that much of clinical teaching is in a referral setting and taught by specialists with a limited knowledge of current general practice. The standard should stipulate "a significant majority " and the clarifier removed or changed to "at least 75%.”*
>
> Respondent working in clinical practice

> *“Veterinary Programmes should reflect the needs of the eventual employers (80% in General Practice) See above 6.4 The majority of clinical education (and training) should take place in practice.”*
>
> Respondent working in clinical practice

Similarly, the response submitted jointly from several key veterinary organisations called for a greater emphasis on clinical education in the general practice context, whilst recognising a degree of balance with teaching around referral cases was essential.

> *“With the majority of new graduates entering general practice and this forming the basis of their future professional development, we consider that a focus on general practitioner/ primary care roles would be of benefit to students. We are also aware that concerns have been raised that university and referral practice teaching is not always preparing students for the cases and decision making that they will encounter in first opinion practice”*
>
> *“Therefore, there is a balance to be struck between providing clinical education from both generalists and specialists for undergraduates, such that students have a suitably rounded foundation both in terms of skill set and expectations”*
>
> Response from BVA, AGV, AVI, AVS, AVTRW, BEVA, BSAVA, BVPA, BVZS, SPVS and VMG

Most respondents submitting feedback on behalf of vet schools were not in favour of increasing the definition of ‘majority’ and felt that the ‘general practice’ experience could be gained within a referral/specialist setting.

> *“Whilst the principle that the teaching should be focused on skills relevant to general practice is not disputed, it should be recognised that this could still be achieved in a specialised environment – and some general practice skills such as anaesthesia, diagnostic imaging, and emergency care can be better taught in a more specialised environment.”*
>
> Response from a UK vet school

Another key theme within the consultation feedback for this domain was about the completion of Extra Mural Studies (EMS) and the EMS Policy. The comments received relate to a number of standards within this domain; not only to the completion of EMS by students but also the coordination of EMS by the vet school, selection of EMS placements by students, recording and reflecting of EMS by students, and feedback from providers.

Some respondents expressed concern about the availability of placements, in light of increasing Intra Mural Rotations (IMR) and distributed models and the impact of Covid-19 on practices. Although the period of 38 weeks was questioned, there were no suggestions for an alternative period through which students would gain similar experience. It was suggested that the outcomes of the individual placements is of greatest significance, in order to reflect the different experiences that students will have on a placement and the experiences that they require in order to consolidate their studies.

There was support for the provision of an administrative structure to coordinate and quality assure EMS placements within schools, although concern that there shouldn't be an additional burden on the placement providers.

The majority of respondents felt that increased communication from schools would help the EMS provider to understand what is required of the students on placement, as well as the students expressing their learning needs whilst on a placement.

A minority of respondents felt that the RCVS should limit research in vet schools to subjects related to veterinary science.

The actions and rationale proposed, as a result of the suggestions made to standards in this domain, are include in Table 4.8.

Table 4.8 Suggestions regarding the Standards within Domain 6 – Curriculum and Assessment - and proposed actions / rationale

Standard	Suggestion / Feedback	Action? Yes / No	Actions / Rationale
6.1 Veterinary programmes must be designed and delivered to ensure that students, upon graduation, have achieved the programme learning outcomes (targeted at FHEQ level 7 or equivalent) and the RCVS Day One Competences.	Allow scope for adjustments to be made to the requirement for Day One Competence to be demonstrated through the use of simulation or direction. This is to allow for widening participation.	No	Evidence that a graduate is Day One Competent needs to be performed on live individuals whilst being mindful of animal welfare, as on graduation, a vet needs to be able to work with live patients.
6.2 The curriculum shall extend over a period equivalent to a minimum of five academic years and must include a sufficient quantity and quality of hands-on clinical education to ensure students are prepared to meet the requirements of the veterinary role upon graduation.	Suggest that the 4 year study programme is not sufficient length to encompass all the requirements of the veterinary programme, and should the RCVS specify entry requirements for a veterinary programme as stated in the guidance?	No	The 4 year accelerated programme is specifically designed for entrants who already have a relevant educational experience, such as a science degree. Therefore, this must be a pre-requisite for entry to this specific programme.
	Include a definition for “sufficient amount” of hands-on clinical education in order to define the length of time to which this equates, as well as considering the wording to include “other experiential training” as well as hands-on clinical.	No	The length of time is to reflect the differing term and year lengths of each vet school. New methodology intends to avoid prescribing as outcomes based. The wording to just include “hands-on clinical education” reflects the nature of the profession. This does not include EMS which could be considered as ‘experiential training’.

6.3 Veterinary programmes should be underpinned by pedagogical theory or based on best educational practice, involving input from educators, students, employers and other relevant stakeholders, and subject to regular evaluation and review.	A number of respondents indicated stakeholders should include future employers and general practitioners.	Yes	Add these stakeholders specifically within the guidance.
6.4 The majority of clinical education delivered by the university should focus upon casework in the 'general practice' context, reflecting the reality of veterinary practice in society.	Many arguments put forward around the definition of 'majority' (see summary above).		
	Respondents from most schools argue that teaching in the referral/specialist setting enables the student to explore future career aspirations, as well as being able to learn first opinion skills within a specialist environment. The specialist/referral setting in the vet school encourages research opportunities and post graduate programmes, which may disappear if the emphasis becomes teaching first opinion practice. Therefore, is it necessary to specify that the majority of casework should focus on the "general practice" context.	Yes	Standard already refers to a general practice 'context' rather than setting, for this reason. Ensure this is reflected throughout the guidance.
	A wide range of respondents and stakeholder organisations thought 50% was not sufficient, and suggestions of 70 or 80% were more in line with their expectations, in order to adequately prepare graduates for a realistic caseload, including discussion of	Yes	Increase the definition to 70%.

	economic factors, and to reflect the fact that high numbers of graduates move into first opinion practices.		
6.5. The curriculum must describe appropriate learning outcomes which represent and effectively align the required knowledge, skills, and behaviours of a veterinary surgeon with teaching, learning assessment activities within a cohesive framework.	Veterinary surgeons may require a wide range of skills depending on their role and the sector in which they operate. This can include project management skills, people management skills, and an ability to analyse evidence to provide advice and leadership on national or international situations which may affect animal and human populations and large commercial businesses. Should these skills be added to the curriculum map?	No	Already covered in the standard wording as just states appropriate learning outcomes. Professional skills are covered in D1C. Guidelines for appropriate list of core subjects is being drafted.
6.6. Under all teaching situations students must be actively engaged in the case. In the majority of cases, students must be actively involved in the investigation and management of the patient (including practical aspects of diagnosis and treatment, as well as clinical reasoning and decision-making).	Can the additional guidance for this standard also recommend that students should be actively engaged with the financial aspects of the case and be actively involved in discussing the financial factors influencing decision-making.	Yes	Add financial aspects of the case to the guidance. Financial and economic factors are of high significance in the majority of first opinion cases. Add 'all aspects of the case including…'
	As client interaction forms an essential part of every case can it be added to the guidance. Decision-making may be influenced by client input as well as the diagnostic and treatment options. This may also include the ability of the client to administer treatment or give care.	Yes	Add client communication to the guidance and include consideration of client ability to provide care or administer treatment. Add 'all aspects of the case including…'
	Concerns that this is not happening consistently in referral hospitals – RCVS should collate evidence to support this either in referral settings or IMR.	No	Already part of the proposals to gather outcomes evidence.
6.7. The programme must give students the opportunity to learn	The allied professionals team could also include Registered Veterinary Nurses (RVNs), Official Auxiliaries/ Meat hygiene inspectors, Embryo transfer	Yes	Add list to guidance and include an encompassing comment "this may include but is not restricted to..."

and practice alongside other members of the veterinary team in an holistic manner that reflects the reality of veterinary practice in society.	technicians, Equine dental technicians, Foot trimmers, AI technicians, Farriers, Blood samplers, Groomers, Hydro-therapists, Behaviourists, Physiotherapists, and Animal care assistants.		
	With the advancement of technology, new ways of working that are likely to become more prevalent in practice, for example, remote consultations - should these be included in the curriculum?	No	It is intended that the lists and guidance are not overly specific in order to future proof the standards. Amendments can be made in future if this becomes the norm.
6.8. Students must be supported to gain experience which consolidates their learning throughout the programme through the completion of Extra Mural Studies (EMS). This must be delivered in line with RCVS EMS Policy.	Do all EMS placements have to take place outside the usual teaching environment?	No	The wording in the EMS policy is *"It is suggested that placements should usually take place within an environment that is outside of the usual teaching environment of the veterinary school."* Which indicates that although preferable, it is not mandatory.
	Must an EMS placement come AFTER the IMR for a particular skill? This may not be practical due to the range of skills and procedures students will come across in practice.	No	The EMS policy states *"16. Students should only be gaining further experience on clinical EMS placements in clinical skills that they have already been taught through IMR. It is acknowledged that students may learn new techniques and acquire further knowledge whilst on clinical EMS placements, however the responsibility of formally teaching students must still remain with the veterinary school. Clinical EMS must complement what students have learned on IMR, and not act as an extension of it."* This acknowledges the range of skills and techniques students may encounter during an EMS placement, but that

			an EMS placement is not the medium though which these skills should be taught.
	In order to meet the demand for vets within VPH and food inspection, it is suggested that there should be a mandatory placement within the VPH context stipulated within the EMS policy, as there is currently no stated requirement.	No	VPH and other areas of professional practice are optional but not mandatory. The EMS policy states *"there is no stipulation as to how many weeks are required for each species or placement type, and students are encouraged to undertake clinical EMS in the areas they feel would interest them and benefit them most."* This is to allow students to select the placements that best support their learning and interests. However, there is no reason why an individual vet school may not chose to make a VPH placement mandatory for their students.
	There should be a clause within the PSS scheme to make taking EMS students a mandatory element to accreditation	No	The PSS has recently undergone an update and this was not part of that. It may not be appropriate for all EMS placements to be PSS accredited, in particular, non-clinical placements, so inclusion of EMS within the PSS is unlikely to impact on student placements. RCVS is initiating a separate piece of work looking at the long-term future of EMS and this can be reconsidered as part of that if appropriate.

	There are increasing issues with finding EMS placements for students due to increased demand for IMR placements; decreasing the opportunity for students to find paid work during vacation time in order to support themselves, thus reducing widening participation; increasing the number of vet schools impacting available placements.	Not for accreditation standards	RCVS recognises the issues surrounding EMS and is exploring alternatives and other initiatives as a result of previous feedback.
	Why is 38 weeks specified – what is the reason? EMS is not quality assured so may have dubious educational value. EMS delivery should be measured by the students outcomes and not by the number of weeks.	No	Currently there is no evidence to increase or decrease this amount –an outcomes-based approach is being piloted with schools in the future to explore options regarding the optimal amount if quality assured.
	There is a lack of consistency of requirement across schools causing anxiety for students It should enable exposure to a range of different veterinary environments (clinical and non-clinical) to increase awareness of the variety of placements available.	No	The new EMS policy aims to make implementation requirements more consistent across schools, whilst enabling flexibility for individual students. It also refers to a range of environments.
	Provision for AHEMS and clinical EMS to be accessible to all students, including those with health conditions or disabilities.	No	Addressed within other standards relating to accessibility.
	It is considered that many students no longer have core skills taught at Vet School with increasing dependence on the goodwill of EMS providers to train/teach core skills. There is a need for much greater clarity of the role of EMS in the provision of experience/teaching core skills.	No	Already stated in the EMS policy, that EMS is not to teach skills for the first time, but to consolidate and practice skills that have already taught.

6.9. There must be an appropriate structure and resources in place to ensure the oversight, coordination and quality assurance of EMS. There must also be sufficient administrative support in place to assist the students.	The additional guidance should specify that students should be supported where they are struggling to find placements or meet EMS requirements due to issues with accessing placements.	Yes	Add this to the guidance as the role of EMS co-ordinator.
	The guidance should specify that there should be mechanisms in place for students to report concerns about an EMS placement should they feel unsafe or experience discrimination and inappropriate behaviour.	No	Already part of Standard 2.4.
	What is the level of QA that is required and how can this be demonstrated? Will QA have an impact on the relationship between VS and provider?	Yes	Add clarity to guidance and examples of potential evidence.
	Increased communication between schools and providers is needed, including the aims of EMS, expectations of students and the school.	No	This is already being addressed through RCVS initiatives to develop a national database to facilitate communication between student and provider, and additional guidance on 'what good EMS looks like'.
6.10. The school must have processes in place to ensure students identify relevant learning outcomes on EMS, and record and reflect on their achievement.	There should be a formal structure in place whereby students can communicate their individual learning objectives to the provider, as well as details of the course structure and the school expectations	No	This is to be actioned by the Vet School, and will also be addressed by the initiatives in development at RCVS as indicated above.
	Clinical and non-clinical/professional skills should be included.	Yes	Guidance to include clinical, non-clinical and professional skills – *This must include but not be limited to; students setting their own learning objectives (to include both clinical, non-clinical and professional skills), either in consultation*
6.11. The EMS experience should be individual to the student, and	EMS providers should have a clear idea of the objectives that the student has for their placement, as well as their current level of knowledge and skills.	No	To be provided by the Vet School to the provider

they should be able to tailor their experience based on their own learning needs.			
	EMS co-ordinators should be aware of the breadth and variety of placements available and advise accordingly.	No	Agreed, but types of placement are already included in EMS policy and guidance.
6.12. There must be a system in place which allows for feedback from EMS providers of students' performance during EMS placements to be communicated with relevant academic staff.	No suggestions made	No	
6.13. The school must demonstrate that EMS placements consolidate skills which have previously been taught during the programme.	EMS is a vital part of student learning. It cannot be limited to 'consolidating skills' that they have been taught 'during the programme' EMS providers must also be able to teach those skills that are missed or lacking within the programme.	No	See EMS policy – EMS is not a teaching tool, but is to practice and consolidate skills within a variety of workplace environments. The new policy recognises that valuable learning takes place on EMS, but skills should not be taught for the first time on EMS.
	Effective implementation of this standard would also require increased communication between vet schools and EMS providers so that they know which skills have been taught at each stage.	Yes	Covered in guidance for Standard 6.11 above, and supported by RCVS initiatives including national EMS database.
6.14. The school must develop and implement a comprehensive and robust assessment strategy, at the programme and modular level, which provides evidence that students meet the requirements for progression	No suggestions made	No	

across the programme and the Day One Competences upon completion.			
6.15. The validity, reliability and educational impact of assessments should be appropriate to their purpose (high/low stakes) and evidenced through relevant evaluation data.	A reliability coefficient of 0.7 or more for high-stakes assessment is highly proscriptive.	Yes	There is strong evidence within health professions education literature to support this – many suggest a coefficient of 0.8 for high stakes assessments. Guidance to include clarification that composite reliability across programmatic assessments is also appropriate.
	Clarity of wording to include direct assessment of professional skills, ref holistic clinical practice.	Yes	Adjust the wording in the guidance to add professional skills – "*direct assessment of clinical, non-clinical and professional skills...*" and clarify what is meant by holistic practice assessment.
6.16. The assessment tasks and grading criteria for each unit of study in the programme must be clearly identified, and available to students in a timely manner well in advance of their assessment. Requirements to pass including the effect of barrier assessments must be explicit.	No suggestions made.	No	
6.17. Assessments must be designed and carried out by individuals	Does this also apply to the pre-clinical course, and for assessments carried out for those units/modules that	No	Assessment covers all aspects of the course – clinical and pre-clinical and is to fit the nature of the delivery.

with appropriate expertise in the area being assessed, who have been trained in their role as an assessor and understand what is required to make the process robust, including honesty, fairness, consistency, and judgements free from bias.	are taught in combined classes (for example, combining veterinary and medical students for common aspects)?		
6.18. Assessment load should be sufficient to provide feedback to support students' progress, and to evidence achievement, remaining cognisant of workloads for staff and students.	Can there be a clearer definition of "reasonable" levels of expectations for student workload through the course, as well as for staff.	No	The levels may vary depending on the number of staff and students as well as the nature of the programme delivery. Therefore, no set requirements should be prescribed.
	The feedback needs to be stated to be both formative and summative, as all of one type would not fulfil the intention of this standard.	Yes	Adjust the wording of the standard to state both formative and summative feedback be provided.
6.19. The school must have appropriate moderation processes in place to ensure parity within and between individual units of study, across the programme, with other institutions; and to ensure that each student is treated without bias.	Could the parity between units of study also cover assessments to ensure that assessments across the programme and other institutions are equal.	No	It is not practicable for all institutions to have the same assessments.
6.20. There must be a system for students to keep a record of the	This should also include relevant non-clinical experiences e.g. communication skills.	Yes	Adjust wording in standard to "reflect on their development of clinical and non-clinical skills over the duration of …"

quality and quantity of their clinical experience, and reflect on their development over the duration of the programme. These records must be regularly reviewed by an educator to inform an individualised development plan. Consolidated data should contribute to the quality improvement of the programme.	Recording alone is not enough.	No	Standard states that there is more than recording to be expected (i.e. reflection), but also regular review to feed into individualised development plans.
6.21. The school must demonstrate a commitment to research lead teaching throughout the veterinary programme.	To prescribe that the research to be carried out by vet schools should only relate directly to veterinary science or to the profession.	No	Comments about the type of research have already been addressed in Standard 1.13.
6.22. All students must be trained in scientific method and research techniques. All students must have opportunities to participate in research programmes.	Could there be additional guidance to suggest that students must have the opportunity to participate in research programmes and apply the research to practice (not just clinical practice).	Yes	Add wording to guidance - “the opportunity to apply research to practice”.

4.9. Consultation Question 8: New accreditation methodology

The consultation requested feedback on the n4ew accreditation methodology proposals, in addition to the new standards themselves. Respondents were asked to ***"please provide feedback on the proposed new methodology for carrying out RCVS accreditation events for veterinary degrees".***

A total of 55 valid responses to this question were received: 50 via the online survey and a further five responses sent separately by email.

Of the 55 responses providing feedback on the proposed new accreditation methodology, 11 were submitted on behalf of the following organisations:

- University of Liverpool
- University of Surrey
- Royal Veterinary College
- Scottish Rural University College (SRUC)
- Society for Practicing Veterinary Surgeons (SPVS)
- Consortium on Workplace-Based Education & Learning (COWBEL)
- Vets4Pets / Pets at Home Group
- Vet Partners
- Veterinary Schools Council (VSC)
- St. George's University (SGU)
- Australasian Veterinary Boards Council (AVBC)

The remaining 44 responses were submitted by individual members of the profession, of which

- Private clinical practice – 23
- Charities – 3
- Vet schools, universities and colleges – 11
- Government service – 1
- Industry and commerce – 1
- Other – 5

The responses were overwhelmingly positive, with the vast majority in support of the new methodology proposals in principle. This was the case from respondents working in either clinical practice or within vet schools or universities.

> *"I welcome the proposals, in particular the focus on outcomes as being as improvement on the current accreditation guidelines and methodology and the accumulation of evidence on a rolling basis."*
>
> Respondent working in a vet school

> *"I like an outcomes-based approach. Many items required can be determined by reporting. Some items need visits (in person and/or electronic)."*
>
> Respondent working in private clinical practice

Respondents particularly welcomed the move to a more risk-based approach, as well as the increased focus on outcomes to evidence that accreditation standards are being met. Support for these aspects of the methodology was also evident in the feedback from some of the stakeholder organisations responses, including AVBC, VSC and some individual vet schools. Feedback from a large corporate employer group also reported satisfaction with the approach.

Very few respondents reported concerns with the overarching methodology proposed, and these appeared to misunderstand certain aspects, highlighting where we need to be clearer perhaps in the documentation. For example, one respondent expressed concern regarding the transparency of the process and would like outcomes to be published and available to the public. The proposals do indicate that details of the evidence provided which demonstrates each standard has been met will be published on the RCVS website (instead of the accreditation reports which are all currently published on the website). However, further clarity will be added that this publication will include any recommendations, suggestions, commendations and innovations / good practice.

In addition to the support for the methodology, feedback was received with helpful suggestions for points of further clarification and implementation. The themes emerging from these suggestions are highlighted in Table 4.9 below, along with proposed actions and rational for consideration by Education Committee.

Table 4.9 Suggestions regarding the new accreditation methodology and proposed actions / rationale

Area	Suggestion / Feedback	Action? Yes / No	Actions / Rationale
Timescales for notice of accreditation event	Need for clarity on notice period prior to visitation – 3 months suggested.	Yes	Enhance clarity in guidance on timescales for notification of accreditation event, the visitation and an 'out-of-cycle' event following review of annual monitoring.
Annual Monitoring (AM) reporting details	More detail & clarity re processes required, including review dates & process, synchronised cycle for all schools or staggered, timeline for feedback / reporting outcomes, training for AM data reviewers.	Yes	Add further details to guidance documents.
Process for new schools	Clarify the process and data required for accreditation events for new schools.	Yes	Add / revise section in guidance.
	Provide guidance for 'interim' visits.	Yes	Add / revise section in guidance.
Evidence must include feedback from recent graduates and graduate employers	Should include general feedback not only focus on D1C.	Yes	RCVS to invite sample of recent graduates to provide feedback (via Teams / zoom) prior to event, to add to evidence from graduate / employer surveys in repository, to be focused on student experience (not duplicating D1C info).
Panel member composition	At least one panel member (practitioner or other) should have up-to-date knowledge of current general practice.	Yes	Methodology to be updated to reflect this suggestion.
	Panel should include a recent graduate and more practitioners in addition to a student.	No	These stakeholders are important but covered in the action above. Amend criteria to state 'a minimum' of one practitioner and use more if possible.

	Preference for the full panel to be present at the visitation component.	Yes	Methodology to be updated to reflect this suggestion.
	Clarify that no panel members will have conflict of interest i.e. have studied / worked at that school.		Methodology to be updated to reflect this suggestion.
Event implementation	Hold accreditation event in public to increase transparency.	No	Panels already have a range of experts, student rep, QA observers. Proposed new rubric will add transparency to both the decision-makers in committees and the public when published.
Repository details	Will the logging of docs to the repository be in a continuous improvement cycle i.e. schools log outcomes as they appear.	Yes	Clarify in documents that schools will have the flexibility to upload documents and evidence at any time, to prevent peaks of admin burden.
Changes to Rubric	Add column to show where potential overlap / links across standards.	Yes	Add column as suggested.
	Requests for specific details of what evidence would be appropriate in meeting standards.	Yes	Add additional clarification as to why guidance can incorporate examples of evidence, but should not prescribe (flexible across delivery models), and reference that schools can check with RCVS through open dialogue on appropriate evidence.
Clarification of process links to partner practices	Evidence gathering / assessment of partner practices involved in rotations should be more robust.	Yes	Clarify in guidance that process and outcomes data for IMR practices needs to be complete across all practices and detailed, i.e. QA / training records for all, student feedback etc. Add contacts from partner practices to list of those invite to confidential sessions (held remotely in advance of visit).
Panel training	Further details needed.	Yes	Under development and will be added prior to implementation.
Publication of data	Details of recommendations, suggestions and commendations should be published in addition to the completed rubric.	Yes	Add clarification to methodology documents.

Administration	VSC concerns increased admin for schools.	No	Accept there may be increased admin at the start but this should be easier for schools in the longer term, particularly if they take the opportunity to upload evidence to the repository as it is gathered. Many examples of outcomes evidence will already be collected by schools for other purposes, such as student surveys, internal QA reviews etc.
Data collection	VSC concerns that new schools will find outcomes data difficult.	Yes	See above actions. Process to be clarified in guidance, and open dialogue invited with schools prior to and during accreditation event regarding suitable evidence.
Join visitation with IAWG members	Concerns these will be compromised due to changes.	Yes	IAWG met Sept 8th & 9th 2021 and agreed an action to progress work to consider future approaches to joint visitations.
Accreditation cycle	Move from maximum 7 year cycle to 5 year to ensure every student cohort can feedback.	No	Student feedback from every cohort will still be considered via data within the repository. Move to a ‘standard’ 5 year cycle would increase regulatory burden. Risk-based approach and annual monitoring mitigates risk of longer period.

4.10. Consultation Question 9: Any additional feedback

The feedback submitted to this final question within the consultation was initially analysed by theme, and where the content related to previous sections (for example EMS, a particular standard / domain or the methodology), these are referenced.

The additional feedback not relevant elsewhere is highlighted below in Table 4.10 with proposed actions and rationale.

Some respondents used this section to summarise their feelings on the new proposals:

> *"Truly grateful to see many these changes moving us away from stereotype's and towards embracing diversity and innovation. Especially cheered by the recognition of vet school culture and our need to preserve staff as well as student needs."*
>
> Organisational response from an educational establishment

> *"Thank you for the opportunity to comment on the Draft RCVS Standards document. The RCVS is applauded in its approach to update and improve the Standards of Accreditation."*
>
> Response from COWBEL

> *"I think this has been well thought through and is long overdue. The proposals will enhance both the students, the staff and the quality of graduates."*
>
> Response from a retired vet

> *"Overall it looks like a good format to me and is an improvement over the existing standards."*
>
> Response from a vet in private clinical practice

Table 4.10 Further suggestions from respondents with proposed actions and rationale

Suggestion / Feedback	Action? Yes / No	Actions / Rationale
Clarify the PreClin/AHEMS exceptional exemptions, and how this reduces the number of weeks AHEMS. This is particularly relevant for 4-year programmes where the first year is necessarily highly intensive due to its "conversion" nature.	Yes	Clarify in guidance (both exemptions, and policy for 4 year programme) around impact of exemption on number of weeks (Standard 6.8).
The document refers to modules and programmes but not all curricula use this terminology. To ensure parity across programmes, could reference instead be made to "units of study and assessment" and "programme/course"?	Yes	Amend wording.
Clarify further the definitions in the glossary, including 'specialism', 'referral / advanced care', 'general practice', 'generalism' and 'primary care'.	Yes	Committees have considered these extensively, however these definitions will be revisited to see if further clarity can be provided.

5. Next Steps

RCVS Education Committee is invited to consider the proposed actions within this report, and agree the amendments to the draft Accreditation Standards and Methodology documents.

The agreed actions will then be taken forward to produce a final version for consideration and sign-off by RCVS Council.

Education Committee – Extraordinary Meeting

Meeting held on 14 October 2021

Present:

Dr Sue Paterson	Chair
Mr Danny Chambers	
Ms Kate Dakin	Student Representative
Dr Jo Dyer	
Ms Linda Ford	
Dr Niall Connell	
Prof. Nigel Gibbens	
Prof. Chris Proudman	
Prof. Stuart Reid	
Prof. Tim Parkin	
Prof. Susan Rhind	
Ms Susan Howarth	
Ms Anna Bradbury	Student Representative

In attendance:

Ms Lizzie Lockett	CEO, RCVS
Dr Linda Prescott-Clements	Director of Education, RCVS
Mr Jordan Nicholls	
Ms Jenny Soreskog-Turp	
Mr Duncan Ash	
Ms Laura Hogg	
Ms Britta Crawford	
Ms Jude Bradbury	
Ms Kirsty Williams	
Ms Rebecca Smith	
Mr Kieran Thakrar	

Apologies

1. Apologies were given by Kate Richards.

Matters Arising

2. The meeting discussed the consultation report which presented the feedback from the profession on the draft RCVS Accreditation Standards and Accreditation Methodology for veterinary degree programmes, conducted between 19 July and 3 September 2021.

3. The consultation was open to all members of the profession and key stakeholders, and 107 responses were received. Within these responses, feedback from 25 veterinary organisations was provided, including the Association of Veterinary Students (AVS), the British Veterinary Association (BVA), the Veterinary Schools Council (VSC) and a number of employer representatives.

4. The consultation asked for feedback regarding the relevance of the six domains of Standards proposed, the individual Standards within each domain and the new methodology. The report presented the analysis of feedback received according to each Standard, and proposed actions with rationale. All Standards were discussed in turn and actions agreed or alternative suggestions put forward.

5. Standard 1.2 - it was raised that Schools cannot quality assure the environment of EMS, so it was suggested that further clarification be provided in the guidance on expectations.

6. It was suggested that Standard 1.4 was focused on good practice which does not mean a practice was required to be involved in the practice standards scheme for EMS. It was suggested that this was further clarified.

7. It was suggested that on page 18, the term necropsy should be replaced as the term is commonly used for humans rather than animals.

   (Secretary's note: Traditionally the term "necropsy" has been used to refer to a post-mortem examination on an animal species, while "autopsy" has been reserved exclusively for human patients, therefore no change was made.)

8. It was debated as to whether abattoir experience should be within red *and* white meat abattoirs, or red *or* white meat. It was decided that the standard should state red *or* white meat for in-person experience, as virtual resources had been developed to support student teaching across all related learning outcomes and the in-person experience was associated with understanding the real environment. The schools were concerned that this standard was reliant on 3rd party organisations, therefore, the term 'must' was difficult to ensure. It was proposed that the term 'must' should be replaced to 'should'. It was also commented that the term 'commercially approved' abattoir needed to be defined.

9. It was agreed that the challenge of changing 'must' to 'should' would result in making this an optional standard which was not the intention of the accreditation standards. After debate, it was decided that the integrity of the standards was important, therefore, and the term 'must' was kept.

10. On page 20, it was noted that 'timely internet access' did not mean at the exact time of the placement, but within a reasonable time period. Further clarification was to be developed.

11. It was noted that a Head of School or Dean 'must' be an MRCVS (not 'should').

12. Regarding standard 3.12 - attrition rates were debated, and it was noted that the RCVS created the VetGDP to lower attrition rates post-graduation. It was decided to not include post-graduation attrition rates in the standards, as it could not be attributed to be a particular school. Other life factors could cause post graduate attrition rates. The data of post-graduate attrition could still be gathered, but this was not in relation to the accreditation standards.

13. It was noted that it was the University who needed a process for any whistleblowing.

14. For Standard 6.3, the term ‘should’ would be changed to ‘must’ and that the term ‘general practitioners’ should be extended to ‘general practitioners/veterinary surgeons in general practice’.

15. For Standard 6.4, it was suggested to define ‘general practice’. The increase to 70% was accepted.

16. For Standard 6.8, it was debated that PSS accreditation should include the requirement for practices to host EMS placements. It was agreed to hold off on EMS discussions until after the EMS stakeholder event which was to occur in November.

Next Actions

17. The changes that were discussed in this meeting and highlighted in the original paper were agreed. All amendments are to be made and then the final documents are to be presented to Council.

Date of Next Meeting

18. This was an extraordinary meeting; therefore, the next meeting will follow the normal Education Committee schedule which is 16 November 2022.

Summary

Meeting	Council
Date	Thursday, 11 November 2021
Title	Policy for recognising graduates from EAEVE-accredited schools for RCVS registration: EAEVE backdating policy.
Summary	In preparation for the UK leaving the EU and the Mutual Recognition of Professional Qualifications (MRPQ) Directive no longer being in place, RCVS Council agreed a temporary decision to continue to accept graduates from European Association of Establishments for Veterinary Education (EAEVE) accredited schools for registration purposes. It has recently come to light that EAEVE currently has a policy of 'backdating' reaccreditation following a successful revisit, after an establishment's accreditation status had been lost two years prior. This means that the status of the school at a previous point in time can change, making it difficult to apply the criteria when deciding whether to accept a graduate for registration.
Decisions required	Council is asked to decide whether RCVS should use the accreditation status of the school at the point at which the graduate completed their programme, or from the most current list of accredited schools supplied by EAEVE.
Attachments	
Author	L Prescott-Clements Director of Education L.Prescott-Clements@rcvs.org.uk

Classifications

Document	**Classification[1]**	**Rationales[2]**
Paper	Unclassified	n/a

[1]Classifications explained	
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[2]Classification rationales	
Confidential	1. To allow the Committee or Council to come to a view itself, before presenting to and/or consulting with others 2. To maintain the confidence of another organisation 3. To protect commercially sensitive information 4. To maintain public confidence in and/or uphold the reputation of the veterinary professions and/or the RCVS
Private	5. To protect information which may contain personal data, special category data, and/or criminal offence data, as listed under the General Data Protection Regulation

Policy for recognising graduates from EAEVE-accredited schools for RCVS registration

Background

1. Upon departure from the EU, the Mutual Recognition of Professional Qualifications (MRPQ) legislation no longer applied to the UK. In June 2018, RCVS Council approved plans and contingencies recommended by the Brexit Taskforce, in the event of a no-deal Brexit. This included that graduates from veterinary schools approved or accredited by the European Association of Establishments for Veterinary Education (EAEVE) are recognised for a transitional period.

2. In March 2019, RCVS Council was asked to consider the operationalisation of this temporary decision, in particular whether *all* graduates from EAEVE-accredited schools should be recognised regardless of when the school received EAEVE status, or whether RCVS should recognise only those who graduated after the school had received its EAEVE status.

3. Council agreed that individuals who had graduated from a veterinary course before it received EAEVE approval / accreditation would not be eligible and would need to take the Statutory Examination for Membership. The rationale for this was primarily that there was no assurance in the educational standards of a veterinary programme prior to it receiving EAEVE accreditation.

Policy application

4. In order to establish whether an individual is eligible to register, the RCVS has been using a combination of the latest EAEVE published list of accredited schools[1] and an RCVS list of historical inspection data. Where 'anomalies' have been identified, i.e. where the graduate stated their school was EAEVE-accredited but it was not present on the EAEVE list, RCVS contacted EAEVE directly to ascertain whether the applicant graduated from an EAEVE accredited school.

5. Recently, when investigating some cases where the EAEVE accreditation status appeared to change on the list, it came to light that EAEVE has a policy of backdating an accreditation status where there had been a successful revisit to a school following the award of 'no accreditation' two years earlier. It is not currently known how many applicants this has affected, however data will be collected going forward.

6. The EAEVE policy (Standard Operating Procedures 2019) states that, where a school has several major deficiencies evident it is awarded 'Non-Accreditation' status. The school may then request a 're-visit' two years later. Where the re-visit is successful, and the school is re-awarded 'accreditation', the status on the EAEVE list is 'backdated' two years to the time of the unsuccessful visit.

   For example:

[1] EAEVE updates their current list only, it does not publish historical data.

A school visited by EAEVE in March 2019 receives several major deficiencies relating to the standards and is awarded 'Non-Accreditation'. Graduates from summer 2019 and 2020 enquiring with RCVS at that time if they are eligible to register are told they are not eligible, as their school is not accredited by EAEVE (confirmed on the EAEVE list). The 're-visit' to the School in March 2021 is successful, and they receive Accreditation status. EAEVE updates their list backdating the accreditation status to 'Accredited' to the unsuccessful visit in 2019. This means that the same graduates would now be eligible to register with RCVS according to the EAEVE list.

7. As the award of 'Non-Accreditation' status is only given when there are several major deficiencies in standards, there is little assurance that those graduating during this period would have received the required standard of education in order to be able to practise in the UK. Also, where a school with non-accreditation status is successful at their two-year re-visit, although this demonstrates the major deficiencies have been addressed, there is no way of understanding when this was achieved within that period.

8. A decision is required on the interpretation of such cases in terms of being eligible to register with RCVS. Two options are presented below.

	Application of Policy	Assurance / Risks
Option 1	RCVS collects longitudinal data on EAEVE accreditation status every six months, to establish a clear timeline of when accreditation status is in place (or absent). Graduates are only eligible to register with the RCVS if their school was 'accredited' at the point of their graduation.	Provides assurance that the educational standards were in place when that graduate was completing their programme.
Option 2	RCVS considers the most recent EAEVE list of accredited schools.	Graduates from schools which have had their accreditation status suspended then reinstated and backdated, would be eligible to register despite graduating from a school for which there had been several major deficiencies in standards, and which was not accredited at the time of their graduation.

Decision required

9. Council is asked to choose either option 1 or option 2 above, or suggest another option that may be preferable.

Summary	
Meeting	RCVS Council
Date	11 November 2021
Title	Investment Policy
Summary	A draft investment policy for the RCVS, including ethical / responsible investments, was considered at the September meeting of the Finance and Resources Committee. Following, a recommendation from the Environment and Sustainability Working Party, it was agreed that RCVS should divest from fossil fuels. The policy is now presented for discussion and approval.
Decisions required	RCVS Council is asked to consider and approve the investment policy and agree to divest form fossil fuels.
Attachments	None
Author	Corrie L McCann Operations Director 0207 202 0724 /c.mccann@rcvs.org.uk

Classifications

Document	Classification[1]	Rationales[2]
Paper	Unclassified	n/a

[1]Classifications explained

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[2]Classification rationales

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Private	5. To protect information which may contain personal data, special category data, and/or criminal offence data, as listed under the General Data Protection Regulation

Background

1. The RCVS has powers to invest monies in investments, securities or property. Limited powers of investment management have been given to the College's stockbroker Investec Wealth & Investment Management Ltd. The Finance and Resources Committee (FRC) receives reports from them at each meeting, they also attend FRC once a year and also meet with the Treasurer.

2. The investment objective is to achieve a balance between capital and income growth in a diversified portfolio of equities, bonds, cash and commercial property. UK equity exposure is mainly through direct companies, but trusts are also used for exposure to smaller UK companies, overseas equities and property. Performance is measured against an agreed customised benchmark of holdings of 23% fixed interest, 40% UK equities, 25% overseas equities, 5% property, 5% infrastructure and 2% cash.

3. The RCVS currently has no formal investment policy, and so is also missing a formalised approach to ethical/responsible investment.

4. RCVS is not a charity but the annual accounts are prepared in accordance with the Charities Statement of Recommended Practice (SORP), which enables comparisons with similar bodies and a consistent reporting standard. The Charity Commission (CC) provides guidance on what should be in an investment policy and on ethical investments. The current CC guidance is being reviewed and a recent consultation closed in May.

Charity Commission guidance when preparing investment and ethical investment policies

5. The current Charity Commission guidance states trustees have the option to make financial investments in ways that align with their charity's purpose and values. Previously labelled 'ethical investment' it is now referred to as 'responsible investment':
Charities and investment matters: a guide for trustees - GOV.UK (www.gov.uk)

6. The guidance states the reason for charities investing is so that they can further their charitable aims. If trustees have considered the relevant issues, taken advice where appropriate and reached a reasonable decision, they are unlikely to be criticised for their decisions for adopting a particular investment policy.

7. Trustees can decide to invest ethically, even if the investment provides a lower rate of return than an alternative investment. Ethical investment means investing in a way that reflects a charity's values and ethos and does not run counter to its aims.

8. FRC considered the current guidance and confirmed that the RCVS should follow the Charity Commission recommendations on ethical investing and the wider work from the E&SWP should be considered.

What should be included in an investment policy?

9. An investment policy should include:

a) scope of investment powers
b) investment objectives
c) attitude to risk
d) how much is available for investing, liquidity needs and timing of returns
e) who can make investment decisions
f) how investment will be managed, benchmarks and targets against which performance will be measured, and reporting requirements.

10. In the case of RCVS, investment managers have been appointed to manage the portfolio and the policy should include the responsibility and remit of the investment managers, together with the principles the investment manager must apply when making investment decisions on behalf of the organisation reporting requirements.

Ethical/responsible investment

11. If the RCVS follow the CC guidance any ethical investment policy should be aligned to our purpose and values, which are:

Our Mission

- As a regulator is to set, uphold and advance veterinary standards.
- As a Royal College we promote, encourage and advance the study and practice of the art and science of veterinary surgery and medicine. We do all these things in the interest of animal health and welfare and in the wider public interest.

Our values

12. We underpin all our work with our core values:
    - Diverse and inclusive
    - Compassionate
    - Forward-looking,
    - Straight-talking.

13. Areas often considered when looking at ethical investments include armaments, tobacco, fossil fuels and animal testing. RCVS does not invest in tobacco, pornography, gambling, high interest rate lending and armaments.

14. RCVS has 1% of the portfolio directly invested in fossil fuels and 0.3% via funds, a total of 1.3%. FRC agreed that RCVS should divest from fossil fuels.

15. In relation to animal testing, it was felt this was not as clear cut as it may seem, and that some animal testing was undertaken in compliance with the Animals (Scientific Procedures) Act (A(SP)A) and supported by veterinary surgeons to ensure animal health and welfare, but it may be considered unethical in terms of some definitions. It was agreed that investments relating to animal testing with rigorous controls under A(SP)A should be viewed on a case-by-case basis.

16. Investec can scan individual companies held in the portfolio for any of these issues.

17. It is proposed that RCVS only invests in companies that align with our mission and values. This currently means we do not invest in armaments and tobacco, and this is expanded to cover other areas. RCVS should review each category of investment and see which could have a negative impact on the College.

RCVS Investment policy

18. The following wording is proposed for the investment policy:

    1. Scope of investment powers
       The investment powers and purpose are laid down in the supplemental Royal Charter 2015:

       The College shall have full power by and in its name to receive, lend, borrow and invest money; to take by gift or otherwise and hold, grant, demise or otherwise dispose of real or personal property; enter into contractual relations; and generally to do such lawful acts and things in any part of the world as in the Council's opinion may be calculated to facilitate, or may be conducive or incidental to, the achievement of the objects of the College.

    2. Investment objective
       The current investment objective is to:
       achieve a balance between capital and income growth in a diversified portfolio of equities, bonds, cash and commercial property. UK equity exposure is mainly through direct companies, but trusts are also used for exposure to smaller UK companies, overseas equities and property.

    3. Attitude to risk
       The current attitude to risk has been identified by Investec as medium risk.

    4. How much is available for investing, liquidity needs and timing of returns?
       The RCVS has a reserves policy and a policy for how much is kept as cash and how it is held. Cash levels above the policy are available for investing on other assets.

    5. Who can make investment decisions?
       Investment decisions are made by the Finance and Resources Committee (FRC) whose terms of reference include managing the assets and investments of the RCVS. All decisions made by FRC are reported to RCVS Council.

       Discretionary management of the investment portfolio is delegated to an investment manager whose appointment is overseen by FRC. The current managers are Investec who manage the portfolio in line with the remit given and performance measured against a bespoke benchmark.

    6. Reporting requirements

Investec report to each FRC meeting. Investec also attend meetings as requested and meet with the Treasurer. They report regularly to the Finance Team and RCVS has access to an online portal and can view portfolio details at any time.

Summary

19. RCVS Council is asked to consider and approve:

a) the investment policy, and,
b) The decision to divest from fossil fuels.

Summary

Meeting	Council
Date	11 November 2021
Title	Advancement of the Professions Committee Report 14 Sept 2021
Summary	To note the attached minutes of the meeting held on 14 Sept 2021. In particular, to note the following: • The Committee agreed to fund a sixth and final meeting of the Environment and Sustainability Working Party to finish any outstanding work. • The Committee approved proposed updates and changes to the Fellowship application process.
Decisions required	None
Attachments	Classified Appendix
Author	Ceri Chick Secretary APC c.chick@rcvs.org.uk / 0207 856 1034

Classifications

Document	**Classification[1]**	**Rationales[2]**
Paper	Unclassified	n/a
Classified Appendix	**Confidential**	**1**

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Minutes of the Advancement of the Professions Committee meeting held on Tuesday, 14 September 2021 at 2pm via Microsoft Teams.

Members:

Ms A Boag	Chair, Board of Trustees for RCVS Knowledge
Dr N Connell	Chair, Diversity and Inclusion Group
Prof S Dawson	Chair, Mind Matters Initiative
Dr J Dyer	Council member
Dr M Gardiner	Council member, Deputy Lead for Global Development
Dr M Greene (Chair)	Senior Vice-President, Council member
Professor J Innes*	Chair, RCVS Fellowship Board
Ms L Lockett	Chief Executive Officer
Dr S Paterson	Chair, Environment and Sustainability Working Group
Mr M Rendle	Vet Nurse Futures Project Board liaison point
Dr C Tufnell	Innovation and Global lead
Mr T Walker	Lay Council Member
Dr C Whiting	Council Member, Deputy lead for Innovation

In attendance:	Ms C Chick	Senior Leadership Officer
	Miss G Gill	Leadership and Inclusion Manager
	Mrs A Belcher	Director for Advancement of the Professions
	Miss S Rogers	ViVet Manager
	Miss A Hanson	Mind Matters Initiative Officer
	Mr I Holloway	Director of Communications
	Ms L Quigley	Mind Matters Initiative Manager
	Miss J Macdonald	Vet Nurse Futures Project Manager
	Mr B Myring	Policy and Public Affairs Manager
	Miss R Greaves	Policy and Public Affairs Officer

Dr M Fraser	Chair, Fellowship Science Advisory Panel (for agenda item 6 only)
Dr C Scudamore	Vice-Chair, RCVS Fellowship Board (acting in absence of Prof. J Innes)

Welcome and apologies for absence

1. The Chair welcomed all present to the meeting of the APC and noted that the meeting would be recorded for minuting purposes.

2. It was noted that the Committee welcomed a new Chair, Dr Greene, and three new members; Dr Dyer, Dr Gardiner and Dr Whiting.

3. No apologies were received from the Committee.

Declarations of Interest

4. There were no new declarations of interest from the Committee.

Minutes of the last meeting, held on 11 May 2021

5. The minutes were approved as an accurate record of the meeting.

Matters Arising

6. No new matters were arising.

Updates from APC workstreams

7. The responsible Committee members or the relevant staff lead provided an update on each of the eight workstreams within the scope of the APC; this reflected the contents of the paper (APC September 21 AI01).

8. The Committee considered these updates, as well as other specific matters raised that were brought to it for discussion and, in some cases, decision. These are highlighted below, in addition to the main questions and comments prompted by each update.

Diversity and Inclusion Working Group

9. British Veterinary Chronic Illness Support (BVCIS) had been invited to join the Diversity and Inclusion Group (DIG), with Claire Hodgeson as its representative.

10. The RCVS/Veterinary Schools Council's joint report on Black, Asian and Ethnic Minority student support, which included guidance on the wearing of religious clothing, was in its final stages and set to be presented to the Committee at its meeting in November 2021.

11. A chronic illness survey was to be discussed and progressed at the next DIG meeting, which would seek to gain valuable insight into student and practising professionals' experiences of chronic illness within the professions in order to catalyse positive change.

Environment and Sustainability

12. The Environment and Sustainability Working Group's activities were discussed at Agenda Item 4 (APC Sept21 AI04).

Fellowship

13. It was reported that a total of 38 new Fellows had been welcomed into the Fellowship in 2021. This was particularly significant as over half of all successful candidates were women for the first time in the Fellowship's history. It was noted that one of the Fellowship's main aims was to increase diversity within the professions, and the high number of female applicants was therefore encouraging to see.

14. The Fellowship Board had reviewed and agreed to changes to the Fellowship application process. These would be reviewed by the Committee at Agenda Item 5 (APC Sept21 AI05).

15. It was noted that a recruitment campaign for Credentials Panellists had been successful, with 17 new members being appointed, the majority being women. It was also noted that the Fellowship was aiming to take a mentorship approach to encourage and assist professionals to apply for Fellowship. Feedback was also offered to unsuccessful applicants.

16. The Fellowship Science Advisory Panel (FSAP) had met in July and was becoming more active. It was noted to be reviewing a number of topics to invigorate discussion. This would be further discussed in Agenda Item 6 (APC Sept21 AI06).

17. It was noted that there was an aim to increase discussion between Fellows, and options were being considered to facilitate this.

18. The annual Fellowship event had been organised and would take place online for a week spanning from 30 September to 7 October, with the content being released throughout the week. Among other activities, the event would include the student research competition, Fellows of the Future, which had received a large number of applications from veterinary students across the country. The Committee was encouraged to attend the event to support the Fellowship and to encourage attendance from the professions.

19. The Chair commented that the Fellowship seemed to be becoming a much more active society and thanked the Fellowship Board for its efforts.

Global Strategy

20. It was noted that efforts were being made to market the Practice Standards Scheme globally, with a formal proposal due to be taken to the next Committee meeting for this to be taken forward by the appropriate parties.

21. The Committee was reminded of research that had been carried out some time ago amongst overseas members to gain insight into how they engaged with the College. This would be analysed again to see if any fresh activities could be developed.

22. The CEO noted that she had attended a meeting of the International Veterinary Regulators Network over summer. Valuable discussion had taken place around the reaction to and support given to members during Covid, with ideas being shared on how the organisations could help each other.

Innovation

23. It was noted that the professions had adapted to novel ways of working during the pandemic. To support this, ViVet had organised a number of Innovation Reflection Sessions to assist professionals to identify what innovation had been developed, and how it could be used effectively again in the future.

24. ViVet's next key activity would be the Workforce Summit, exploring what a more sustainable future for the professions could look like. The Summit would explore the current challenges facing the professions in terms of recruitment, retention and return, and aim to develop solutions, utlising some of ViVet's innovation-led techniques. This event would likely take place in late autumn 2021.

25. The Innovation Workshop Series continued to support the ViVet project aim to ensure that veterinary professionals were equipped with innovation capabilities.

Leadership

26. It was noted that the Leadership team was still awaiting confirmed costs and contract from the NHS Leadership Academy. Those wishing to take the course were encouraged to sign up to a waiting list on the RCVS website.

27. As an added and interim provision, work was underway to create a Leadership knowledge bank on the RCVS website, named the RCVS Leadership Library. The resource would aim to provide useful resources for those looking to develop their leadership knowledge and skills before embarking on a formal training programme.

28. It was noted that a new Leadership and Inclusivity Manager had been employed within the Advancement of the Professions team who would be overseeing the Leadership initiative. The Committee welcomed Miss Gill to the College.

29. The Leadership section of the RCVS website would shortly be updated and existing material reviewed to ensure that it was up-to-date and accessible, and reflected a diverse veterinary community. Members of the Diversity and Inclusion Group would be consulted on this.

Mind Matters Initiative

30. The Mind Matters Initiative had launched a new app named MMI Kite, that encouraged wellbeing through microlearning. At the time of the meeting, around 300 people had registered to download and use the app in the first week. It was noted that some veterinary practitioners struggled with the microlearning aspect, however, the purpose of the app was to be able to learn wellbeing techniques in easy, quick sections so as not to add to a busy day.

31. It was reported that the Initiative had released a Wellbeing Survey for student veterinary nurses, newly-qualified nurses and Clinical Coaches, which had received around 670 responses, to help inform future work within the veterinary nursing profession. It was noted that the respondents had been very generous with their time, and were thanked for this.

32. It was noted that the Wellbeing Survey had shown a disappointing amount of bullying and discrimination amongst those surveyed, with 96% of respondents either agreeing or strongly agreeing that bullying was an issue. However, it was positive to note that there had been a large number of respondents noting that they had chosen the right job and had access to good support through Clinical Coaches and other means. It was noted that this survey would work to inform an MMI event for student veterinary nurses and Clinical Coaches in November. It was noted that this information could also feed into the Leadership initiative to form a synergy between MMI and Leadership, with managing anxiety as one focus of activity.

33. MMI was also working towards developing its strategic plan for the next five years, alongside an evaluation of the activities so far.

34. It was noted that a new MMI Officer had been employed to support the initiative under the supervision of the MMI Manager. The Committee welcomed Miss A Hanson to the College.

RCVS Knowledge

35. The Committee congratulated Amanda Boag, the Chair of the RCVS Knowledge Board of Trustees, on receiving Fellowship of the RCVS in 2021.

36. It was noted that RCVS Knowledge would be reviewing its online content and resources to determine how these would fit into the new RCVS Academy.

37. The Canine Cruciate Registry Launch had taken place in July 2021, and had been well attended.

38. The RCVS Knowledge Awards were open to nominations with the deadline being in December 2021. It was noted that there was the potential for a large number of nominations in this round,

as challenges faced through the pandemic had brought forth previously unforeseen opportunities for work and research.

VN Futures

39. It was noted that activities had been planned for the upcoming British Veterinary Nursing Association (BVNA) Congress.

40. The VNF Interim report had been drafted and was planned for publication at the end of September 2021.

41. Animations were being developed for the promotion of the veterinary nursing profession to school children and were being adapted to be suitable for various age groups.

42. It was noted that the synergy with the Mind Matters Initiative had been hugely successful with the development and release of the Wellbeing Survey.

Environment and Sustainability Working Group progress report

43. The Committee was presented with an update on the progress of the Environment and Sustainability Working Group.

44. The Committee was reminded of the Working Group's terms of reference, which included both internal and external (profession-facing) policy.

45. It was noted that for internal purposes, the College had enrolled on the Investors in the Environment (IiE) scheme. The Chair of the Working Group thanked the College's Green Team. which was hugely active in engaging with this initiative and progressing rapidly towards the Bronze Award.

46. A recommendation from the Working Group would be presented to the RCVS Finance and Resources Committee around divestment in fossil fuels, which had been presented to and agreed upon by the Committee at the previous meeting.

47. It was noted that the majority of the profession-facing initiatives were being channelled through the Practice Standards Scheme (PSS), which was believed to be the most effective way of showing leadership in this sector. Research had been undertaken to find a consultant to devise the most efficient way of incorporating these initiatives into PSS and possibly creating a Sustainability Award. A consultant had been selected out of a shortlist by representatives from PSS.

48. The Working Group continued to work with the UK Health Alliance on Climate Change (UKHACC) and had pledged to work together on a number of initiatives, namely their Net-Zero Surgery Group, which may include collaboration with the RCVS Fellowship. It was noted that veterinary-specific sustainability groups would also be included in conversations in the future.

49. The Working Group had submitted a proposal for funding for a final meeting, to complete any outstanding activities. It was clarified that the Group was a task and finish group and would end after the final proposed sixth meeting, however, there would still be a role for the Environment and Sustainability Council lead on the Committee. The Committee agreed to fund a final, sixth meeting of the Environment and Sustainability Working Group.

Fellowship Application process review

50. The Committee was presented with a paper that outlined proposed updates and changes to the RCVS Fellowship's application process. The Fellowship Board had reviewed and accepted these changes at its most recent meeting.

51. It was noted that, as the Fellowship's current main aim was to increase diversity and inclusion within the Fellowship, a review of the current materials, resources and requirements for the application process had been carried out.

52. It was proposed that the Fellowship make the following changes to the application process, to take effect from the 2021-2022 round of Fellowship applications and going forward;

    a) Application bundle requirements
        i. Fellowship applicants should only require two signed referee forms, rather than a formal reference.
        ii. To agree a new form template presented.

    b) Application allocation
        i. Fellowship applications should be initially assessed by five Credentials Panellists instead of three.

    c) To suggest and agree to any changes to the application forms for each Fellowship route.

53. It was noted that the question on the Fellowship application form of "How long have you been a member of the RCVS" should be removed from the updated form to ensure that there is no unconscious bias around age or length of serivce.

54. The Committee approved the proposed changes to the Fellowship application process.

Fellows Science Advisory Panel Update

55. This information is available in the classified appendix in paragraphs 1-5.

Any other business

56. The Chair thanked the Committee for its continued efforts.

57. It was noted that there should be continued efforts to advance the Primary Care project, and the Committee would see to this going forward.

Date of next meeting

58. The Chair closed the meeting noting the next meeting would be in the afternoon of 16 November 2021, online.

Summary	
Meeting	Council
Date	11 November 2021
Title	Audit and Risk Committee (ARC) Minutes 16 Sept 2021
Summary	Minutes of the ARC in September 2021
Decisions required	n/a
Attachments	Confidential Appendix
Author	Alan Quinn-Byrne Governance Officer/Secretary a.quinn-byrne@rcvs.org.uk / T 020 7227 3505

Classifications

Document	Classification[1]	Rationales[2]
Paper	Unclassified	n/a
Classified appendix	**Confidential**	**1, 2, 3, 4, 5**

[1]Classifications explained	
Unclassified	Papers will be published on the internet and recipients may share them and discuss them freely with anyone. This may include papers marked 'Draft'.
Confidential	Temporarily available only to Council Members, non-Council members of the relevant committee, sub-committee, working party or Board and not for dissemination outside that group unless and until the relevant committee or Council has given approval for public discussion, consultation or publication.
Private	The paper includes personal data which should not be disclosed at any time or for any reason, unless the data subject has agreed otherwise. The Chair may, however, indicate after discussion that there are general issues which can be disclosed, for example in reports to committees and Council.

[2]Classification rationales	
Confidential	1. To allow the Committee or Council to come to a view itself, before presenting to and/or consulting with others 2. To maintain the confidence of another organisation 3. To protect commercially sensitive information 4. To maintain public confidence in and/or uphold the reputation of the veterinary professions and/or the RCVS
Private	5. To protect information which may contain personal data, special category data, and/or criminal offence data, as listed under the General Data Protection Regulation

Minutes of a hybrid meeting of the Audit and Risk Committee (ARC) held at Belgravia House and via Microsoft Teams on 16 September 2021

Members:

Ms J Shardlow	Lay member, Chair
Prof D Bray	Lay member of RCVS Council
Mr V Olowe	Lay member
Mr K Gill	Lay member
Dr M M S Gardiner	Council Member

In attendance:

Dr N T Connell	Treasurer
Ms L Lockett	CEO
Ms C McCann	Director of Operations (DoOps)
Ms K Williams	Education Quality Improvement Manager
Mr R Burley	Chief Technology Officer (CTO)
Mr I A Holloway	Director of Communications (Docomo)
Mr A Quinn-Byrne	Secretary to ARC / Governance Officer

Apologies for absence and Welcome

1. There were no apologies for absence.

2. This meeting was Ms Shardlow's first meeting as Chair of Audit and Risk Committee.

3. The Chair welcomed Mr Ken Gill and Dr Matshidiso Gardiner as new members of the Committee.

Declarations of interest

4. Mr Gill declared the following:

    - Independent Audit Committee Member of the General Medical Council (GMC)
    - Chair of Council of Inns of Court
    - Chair and Non-Executive Director of Countess of Chester NHS Foundation Trust
    - Board Member of Policy Connect

Minutes of the Audit and Risk Committee meeting held on 13 May 2021

5. The minutes of the last meeting were accepted as a true record.

CEO Update

6. The CEO provided an oral update to the Committee, the following points were noted:

- Belgravia House had returned to full office opening hours five days a week, a new "Where We Work" Policy had been implemented and the requirement to attend the office would depend very much on people's circumstances, discussions with their Line Manager, and business needs.

- Veterinary Graduate Development Programme (VetGDP): the e-portfolio was to be launched imminently; 1,800 graduates had signed up to the programme and would be able to record and monitor their progress, upload documents and submit their reflections;

- There was ongoing work regarding workforce issues and skill shortages, focusing on 'recruit, retain, return', including:

    - the impact of Covid;
    - the impact of EU-Exit: particularly in relation to certification, the entry of European graduates into the UK;
    - changing demographics/views;
    - new veterinary schools;
    - overseas recruitment from non-EU countries;
    - mental health and wellbeing; and other factors affecting retention
    - trying to get the large pool of veterinary surgeons/veterinary nurses that had recently left to consider returning to the profession in the short-term; it was noted that the College could do more in terms of analysing the reasons why people left the profession or went on to the non-practising category of the Register and research was underway.
    - Confidential information is available in the classified appendix at paragraph 1.

- A Workforce Summit would take place in November under the ViVet banner.

- Legislation Working Party (LWP) work regarding reforms would come to the Committee for information, in due course. The work focussed on reform to the legislation that governed the RCVS; The Veterinary Surgeons Act (VSA) 1966, which had proven to be outdated for 2021.

- Confidential information is available in the classified appendix at paragraphs 2-5.

- The consultation on veterinary undergraduate standards was ongoing.

Assurance Map and Corporate Risk Register

7. The Assurance Map and RCVS Corporate Risk Register were taken as one item on the agenda. The Committee praised the work that had been undertaken on the Map over the last year.

8. The Committee was updated on changes to the Risk Register since its last meeting in May 2021. The following were highlighted:

9. Confidential information is available in the classified appendix at paragraphs 6-11.

Charity Governance Code

10. The Charity Governance Code was presented to the Committee.

11. The Committee was satisfied with the comprehensiveness of the document, noting that it was a key document in terms of mapping governance throughout the organisation and was a very worthwhile piece of work that had been undertaken by staff.

12. Confidential information is available in the classified appendix at paragraph 12.

13. The Committee requested that this be removed as a reoccurring agenda item and requested that it come before the Committee in May 2022 as a full update prior to the financial statements being approved.

Action: Charity Governance Code full update from Governance Officer May 2022.

Communications Department Risk Register

14. The Director of Communications presented the Communications Department Risk Register to the Committee.

15. The following points were noted:

16. Confidential information is available in the classified appendix at paragraphs 13-20.

17. The Committee praised the work that had taken place on the Communications Risk Register and noted it was a comprehensive document.

Data Sharing Paper

18. Following the request by the Finance and Resources Committee (FRC) in May 2021, the RCVS Chief Technology Officer (CTO) presented a paper to the Committee to ascertain its views from a risk perspective on data sharing by the RCVS.

19. Confidential information is available in the classified appendix at paragraphs 21-29.

The European Association for Quality Assurance in Higher Education (ENQA) update

20. The Education Quality Improvement Manager report was shared with the Committee containing the details of ENQA activity that had taken place both related to the accreditation recommendations and suggestions, and in the wider context of membership, since the review in September 2020.

21. Confidential information is available in the classified appendix at paragraphs 30-31.

Any other business (AOB)

22. There was no other business to raise.

Date of next meeting

23. The next meeting would be Thursday, 18 November 2021.

Summary	
Meeting	Council
Date	11 November 2021
Title	Education Committee Minutes of the meeting held on 14 September 2021
Summary	Council to note Education Committee Minutes of the meeting held on 14 September 2021
Decisions required	To note
Attachments	Classified Appendix
Author	Britta Crawford Education Manager b.crawford@rcvs.org.uk/ 020 7202 0777

Classifications		
Document	**Classification[1]**	**Rationales[2]**
Paper	Unclassified	n/a
Classified appendix	**Confidential**	**1**

Education Committee

Minutes of the meeting held on 14 September 2021

Members:	Dr Niall Connell		
	Ms Linda Ford	-	Lay member
	Professor Tim Parkin		
	Mrs Susan Howarth		
	Dr Susan (Sue) Paterson	-	Chair
	Professor Chris Proudman		
	Professor Stuart Reid		
	Professor Susan Rhind		
	Dr Colin Whiting		
	Ms Anna Bradbury	-	Student representative
	Ms Kate Dakin	-	Student representative
By invitation:	Dr Melissa Donald	-	CertAVP Sub-Committee Chair
	Mr Danny Chambers	-	Adv Practitioner Panel Chair
	Dr Joanne Dyer	-	EMS Co-ordinators Liaison Group and PQSC Chair
	*Professor Nigel Gibbens	-	Chair of Accreditation Review Group
In attendance:	Mr Duncan Ash	-	Senior Education Officer
	Dr Jude Bradbury	-	Examinations Manager
	Dr Linda Prescott-Clements	-	Director of Education
	Mrs Britta Crawford		Committee Secretary
	Ms Laura Hogg		Senior Education Officer
	Mr Jordan Nicholls		Lead for Undergraduate Education
	Ms Beckie Smith	-	Education Assistant
	Ms Jenny Soreskog-Turp		Lead for Postgraduate Education
	Mr Kieran Thakrar		Education Assistant
	Mrs Kirsty Williams		Quality Assurance Manager
		-	
	Ms Lizzie Lockett		CEO
	Dr Kate Richards	-	Officer Team Observer

*attended for AI9

Apologies for absence and welcome

1. There were no apologies.

2. The meeting was held in a hybrid fashion at Belgravia House and via “Teams” due to the ongoing Covid-19 pandemic.

3. The Chair thanked the Education Department for their hard work, and for maintaining all the work streams on top of all the extra work created by Covid-19, which was reflected in the volume and depth of papers prepared for the meeting. Her thanks were appreciated.

4. The chair welcomed the new members of the Committee and Jude Bradbury as the new Examinations Manager in the Education Department.

Declarations of interest

5. Niall Connell declared his association with Glasgow and that he has a role in providing students with feedback. Sue Paterson declared that she was now president of the World Association for Veterinary Dermatologists. Chris Proudman declared that he was Head of Surrey veterinary School and also co-investigator for the Fellowship ratification mentioned later in the papers. Kate Richards declared that she was part of the consultant steering group for SRUC and Stuart Reid declared that he is Chair of Vet Schools Council (VSC)

Minutes

6. The minutes of the meeting held on 11 May 2021 were agreed as an accurate record.

Matters arising

7. The Committee heard that the actions from the minutes had been completed or were included in the agenda.

Education Department update

8. The Director of Education, Dr Linda Prescott-Clements, gave an oral update on the work of the Education Department. The Committee heard that the department had made presentations at the pre-conference workshop at the Veterinary Education (VetED) conference; LPC had presented to a VSC stakeholder meeting on EMS and the department had hosted an EMS student which had been proved useful to both parties. The IAWG had met virtually, and full minutes will come to this Committee in November. RCVS shared their new accreditation standards and IAWG members provided feedback and it was agreed that there will be a working group set up at to look at joint visitations. The VetGDP has drawn interest from the College of Family Physicians in Canada who are keen to develop a similar programme.

Primary Qualifications Sub-Committee (PQSC)

Report of the sub-committee held on 16 August 2021

9. The report of the PQSC meeting held on the 16 August 2021 was received and noted by Education Committee. Some items that were noted, which did not form part of the Education Committee agenda, were that the year-3 visitation to CityU in Hong Kong had taken place, and feedback agreed upon to give back to the school ahead of their final visitation in 2023, and that

PQSC had agreed to not include a detailed species list in the requirements for the new accreditation standards. It had been agreed that instead of a prescriptive list, a general statement would be drafted to demonstrate that students would need to be aware of what species were common to the UK, and that visitors would need to be pragmatic about what was covered within a schools' curriculum

Surrey Visitation

10. Chris Proudman left the room for the discussion. The report of the visitation to the University of Surrey, School of Veterinary Medicine in March 2021 and the University response to the visitors' recommendations and suggestions were presented to Education Committee for review, along with a recommendation on accreditation status from PQSC. PQSC had reported that there were concerns relating to the sustainability of the programme with increased student numbers (which had been a concern from the 2019 visitation), as well as staff workload and assessment validity.

11. PQSC agreed to recommend to Education Committee that the BVMSci (Hons) programme at the University of Surrey be granted '*Accreditation for a shorter period*', with a focussed revisit to be undertaken within two years to look at the issues of staffing, resource, and capacity, as well as progress with addressing the suggestions and recommendations from the visitation report.
It had also been recommended that the Covid-related 12-18 month follow-up 'in-person' visitation (a requirement from the virtual visitation guidelines) be postponed and combined with this two year focused revisit.

12. Education Committee agreed to the recommendation from PQSC without further comment.

Action: RCVS to write to Surrey with the accreditation status.

Glasgow Visitation

13. The report of the visitation to the University of Glasgow, School of Veterinary Medicine in March 2021 and the University response to the visitors' recommendations and suggestions were presented to Education Committee for review.

14. It was reported that PQSC had noted the commendations and relatively few suggestions/ recommendations within the visitation report, and also that where recommendations had been made, the University response had indicated sensible plans in place to address issues, with specific timeframes/targets identified.

15. Overall, PQSC reported no major concerns about the veterinary programme at Glasgow and agreed to recommend to Education Committee that the BVMS programme at the University of Glasgow be granted "*Accreditation for seven years"* subject to satisfactory annual monitoring reports.

16. This recommendation was agreed to by Education Committee without further comment.

Action: RCVS to write to Glasgow with the accreditation status.

Melbourne Visitation

17. The report of the joint AVBC/RCVS/AVMA/SAVC visitation to the University of Melbourne Veterinary School in May 2021 was presented to Education Committee for review. The Self-Evaluation Report (SER) was also presented for background information.

18. In considering the report, it was reported that PQSC had noted several concerns which did not appear to have been sufficiently addressed by the Dean's comments. Members had felt that the issues relating to the school's governance, the curriculum, communication problems between the senior team and faculty, and financial issues all cast doubts over the sustainability of the programme.

19. It was on this basis that PQSC recommended to Education Committee that the DVM programme at Melbourne University be granted "*Accreditation for a shorter period"* with a full revisit across all standards to occur in 2023. Education Committee agreed to this recommendation without further comment.

Action: RCVS to write to Melbourne with the accreditation status.

EMS

EMS Database

20. A draft specification of the planned EMS database was received. It was noted that this was an initial draft which had taken into account earlier discussions with EMS co-ordinators and other stakeholders (SPVS, BVA, AVS), and the specification set out the desired functions of the database. Education Committee were asked if they had any comments on the draft, and also to approve the next stage of the process which would be to proceed to further stakeholder consultation and further development with the RCVS IT department.

21. It was noted that some vet schools already had their own internal EMS booking databases, and there were slight concerns that for the database to be completely successful, it would need buy in from all vet schools. However, it was reported that throughout the earlier discussions, whilst no official confirmation had been given, there had been indications that all schools would welcome a centralised database.

22. There were also a few concerns around duplications of processes around any internal booking and feedback processes that the schools may have in place with providers separately, but it was hoped that the new database would be able to cater for all schools so this would be avoided. It was also noted that as well as all universities using the database, it would also heavily rely on providers using and trusting the database which was acknowledged, and a lot would need to be done in terms of communications with providers in order to get them on board, taking into account what their motivations would be for signing up to be listed on the database.

23. It was also agreed that RCVS would need to make it clear that any providers listed on the database were not approved or accredited in any way, and that the listings were purely voluntary.

24. It was acknowledged that it would be less straight forward to be able to list some pre-clinical or professional EMS placements, such as farms and non-clinical placement opportunities, and also overseas placements. It was a suggested that the database could be initially introduced to the clinical EMS cohort years where the overwhelming majority of placements would be UK practices before rolling out the database to the pre-clinical years, using the momentum of a growing database to attract non-veterinary placement providers to sign up.

25. There was a question around whether it was intended to work in a similar way to "Trip Adviser" with a reviewing or rating system built into the database so that students and providers would be able to leave public feedback following placements, however it was clarified that this had never been the intention. It was noted that some schools do keep feedback about placements and RCVS was happy for schools to keep this being an internal arrangement.

26. It was noted that as part of the specification RCVS could remove providers where problems had been encountered, so there would be a mechanism to address any concerns with placements that were listed, and it was agreed that this would need to follow a robust formal process.

27. With some schools using the Student Experience Log (SEL), it was asked whether or not there were any plans to integrate the new database into this. It was clarified that the new database formed part of a wider IT project which included a revamp of the old SEL and create a new system for students to record their learning and experience, and there would be plans for these two systems to eventually become integrated.

28. Schools would always require there to be some sign off around health and safety and insurance before placements could go ahead, and it was also noted that RCVS intends to include a process around this within the booking system.

29. It was noted that the current timeline for the project was to implement the database in Autumn 2022, however this was dependent on other projects. There was a question around the resources for the project, however it was clarified that as plans were still at a very early stage, further details on this would follow at a later date once more concrete plans could be put into place.

30. A number of suggestions to add to the functionality were noted, and members were thanked for their input.

31. Education Committee approved the proposal to proceed to stakeholder consultation and encouraged involvement with as many employer and practitioner groups as possible, as well as representation from the students and vet schools.

Action: Specification to be updated and shared with stakeholders

EMS Pilot

32. A number of challenges are faced around the implementation of EMS as identified in Graduate Outcomes Consultation and subsequently as result of the pandemic. Ultimately, the vet schools would favour a reduction in the weeks requirement, however the profession still has concerns about the confidence and preparedness of recent graduates when they start work. It is difficult for RCVS to agree to any immediate reductions, as graduates themselves also agreed that EMS offers vital experience, and they feel that the number of weeks are about right. To explore whether a higher quality EMS experience could achieve a similar outcome with fewer weeks of EMS. RCVS had agreed to consider running an outcomes-based EMS pilot, which could reduce the prescribed number of weeks which would lessen the administrative burden for schools, but also focus on getting sufficient and effective experience for students.

33. It was reported that initial ideas had been discussed in the Education Department, with the intention to bring full plan to Education Committee at its next meeting. Members were invited to submit any ideas or suggestions by email.

34. Noting the recent consultation on the new accreditation standards (which once approved would need to be implemented by the vet schools), it was asked whether this would be the right time to also launch a pilot for EMS, given that it could come at a time of large change within the vet schools. This was acknowledged; however, it was clarified that the standards would be implementing more changes to the way that evidence was gathered and considered rather than how the vet schools delivered their programmes, and also EMS was becoming too much of a big issue to keep side-lined.

Statutory Membership Exam

Outcomes from the 2021 diet

35. The outcome from the 2021 diet was discussed and the committee was advised that three refugees had sat the exam this year but unfortunately none passed the written component. The committee recognised that there may be more refugee applications for the 2022 exam. These numbers will be reported to finance when there is more information on the amount of aid required.

Consideration for scores for English Language Test Components

36. The committee were asked to consider the current requirements for English language tests to allow applicants to register with the RCVS as some candidates may have an average score of 7 (for IELTS) but are below 7 in one component. The committee discussed the requirements from other UK regulatory bodies which have different allowances to the RCVS. It was discussed that the RCVS requirements should link to the requirements of the UK vet schools.

37. Education committee members were supportive of allowing one component of the test to have a slightly lower score (IELTS 6.5) as long the overall average was above 7.

ACTION: The committee decided that this should go to Council for further discussion.

Accreditation Standards Consultation

38. The accreditation standards consultation was noted by Education Committee. The consultation deadline was extended, therefore, it closed on Friday 10 September 2021. The statistics showed that there were 107 valid responses, 25 of these were from organisations.

39. Overall, it was noted that the responses had been positive, and analysis is on-going. In terms of feedback on the methodology section it was stated that the RCVS education team were to focus on the development of the following areas:
    - Clarification of annual monitoring reports
    - Clarification of timeframes and the process of a new vet school
    - Further details to be provided about the repository
    - Considerations for joint international visitations.

40. Education Committee agreed to an extraordinary meeting during October to discuss the results of the consultation once the full report is available.

Veterinary Graduate Development Programme (VetGDP)

41. The committee heard that the VetGDP was launched at the end of July, enabling graduates, VetGDP Advisers and Practices to sign up and complete their VetGDP declarations. Graduates then discuss and choose the EPAs most relevant to their roles with their VetGDP Adviser and could then begin manually recording activities. The committee was provided with statistic for the number of stakeholders signed up to the programme.

42. The e-portfolio had been launched on the morning of the meeting together with a suite of communications across medias to encourage and explain engagement with the programme. A full report will be brought to the Committee in November.

RCVS Covid-19 Taskforce Update

43. A paper outlining the recent review of the RCVS temporary EMS policy was received, and members noted that the clinical EMS requirement for the cohort year class of 2023 had been reduced to 13 weeks, with the next review to take place in November.

44. It was also confirmed that the new 1st year students (class of 2026) would be expected to complete the normal pre-clinical EMS requirement of 12 weeks, but that this would be kept under consideration as part of the on-going reviews to the temporary requirements.

45. It was noted that the RCVS Covid-19 Taskforce would no longer meet unless in the event of another large-scale national lockdown. Therefore, going forward Education Committee would instead consider any issues relating to temporary policy that were still being affected due to the pandemic, such as the reviews to temporary EMS policy, and requirements around abattoir teaching.

Certificate in Advanced Veterinary Practice (CertAVP)

46. The minutes from the subcommittee meeting were noted.

Remote synoptic Exams

47. The Committee discussed continuing the use of remote synoptic exams and the advantages and disadvantages of using this method. The Committee agreed that the option to take the synoptic examination remotely should remain.

CPD

Update from Compliance Panel

48. Education Committee received and noted the minutes from the meetings on the 26 May and 2 September 2021. Ms Ford briefed the committee about the discussions and recommendations from the Panel.

49. The CPD audits will go ahead this year after being paused in 2020, the plan was to do a targeted sample group to focus on users that are not using 1CPD or not updated their 1CPD record but due to resource issues within the IT team, the audit will be conducted in the same way as previous years with a random sample group of 10%.

50. It was noted that overseas members are less likely to use 1CPD and the Panel discussed the risks and benefits of enforcing the requirement to use 1CPD. The Panel felt that a wider discussion about overseas vets will be useful and will bring back a report to Education Committee for further discussion.

Action: CPD Report regarding overseas vets will be presented to EC in February.

Update from CPD Policy Working Party

51. Education Committee noted the terms of reference for the new CPD Policy and Compliance Sub-committee which will replace the CPD Policy Working Party. It was felt that the membership should be expended to include external stakeholders, especially in relations to policy discussions. Education Committee had previously discussed the benefits of having external stakeholders as part of the CPD Policy WP and had suggested to explore options for setting up external CPD group to discuss policy and wider CPD issues. The Panel felt that would be useful to have some external stakeholders as co-opted members of the Panel rather than having an additional group/committee. Education Committee agreed that it would be useful to add two educationalists to the group.

Action: Education department to update membership of the committee

RCVS Review of Vet School Covid-19 plans

52. The Committee noted a summary of the review of vet schools Covid-19 plans for the latest quarter and understood that the full plans had been reviewed by PQSC.

Advanced Practitioner Status

List of approved Advanced Practitioners

53. The list of approved Advanced Practitioners was noted.

Advanced Practitioner Review

54. There was some discussion around the key findings from the focus groups and how they re-iterated the comments that arose from the evaluation survey which had been previously discussed by Education Committee. It was highlighted that the Veterinary Nursing team were looking to create a similar status for nurses and were following progress with the AP evaluation to avoid having any similar issues i.e. confusion of the name. It was suggested to research how other medical professions address their career pathways and the title names for these. There was some discussion around whether it was beneficial to keep trying to promote the status if employers and AP's themselves see no benefits of the status, however as it does provide large personal benefits, more clarification and promotion of the status itself should help in the status being seen and used more widely and positively.

55. The committee agreed to the next steps around clarifying what it means to be an Advanced Practitioner and the benefits, and also identifying a pathway for those that have been awarded the status. The committee suggested that there should be two task and finish groups created to address these points and a plan would be brought to the next meeting.

Action: Plans for the AP Task and Finish groups to be presented at the meeting in November

Advanced Practitioner Statistics

56. The Committee noted the statistics and were pleased to see that a majority of APs had re-accredited.

Risk Register

57. The committee reviewed the reports and based on the discussions at the meeting thought it would be useful to add a risk around future implications for EMS and to update the controls around VetGDP.

Action: Education Department to update Risk register

Fellowship Subcommittee

58. The Fellowship Sub-Committee had put forward a recommendation to award the Diploma of Fellowship by Thesis to candidate T/771, following the examiners' initial recommendation. Education Committee agreed to recommend the award to Council for final ratification.

Any other business

59. Liverpool requested that their RCVS visitation be brought forward a year to be in line with the EAEVE visitation. The Committee learned that this would create a very large visitation group of

perhaps 21 people as EAEVE had a stipulation that no visitors could come from the country in which the University was being assessed. This would mean that the RCVS would be the party forced to compromise and left in a minority. Committee members agreed from past experiences that a large group was difficult to keep cohesive and didn't make sense from a Quality Assurance perspective.

60. The Committee agreed that it would be possible to offer Liverpool a visitation close in date to the EAEVE visit, so that they could utilise the same resources but that a joint visitation would be too problematic.

Date of Next Meeting

16 November 2021

Britta Crawford
September 2021
b.crawford@rcvs.org.uk

Summary

Meeting	Council
Date	11 November 2021
Title	Finance and Resources Committee (FRC) Minutes dated 16 September 2021
Summary	Minutes of the FRC in September 2021
Decisions required	None
Attachments	Confidential Appendix
Author	Alan Quinn-Byrne Governance Officer/Secretary a.quinn-byrne@rcvs.org.uk / T 020 7227 3505

Classifications

Document	Classification[1]	Rationales[2]
Paper	Unclassified	n/a
Classified appendix	**Confidential**	**1, 2, 3, 4**

[1]Classifications explained	
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[2]Classification rationales	
Confidential	1. To allow the Committee or Council to come to a view itself, before presenting to and/or consulting with others 2. To maintain the confidence of another organisation 3. To protect commercially sensitive information 4. To maintain public confidence in and/or uphold the reputation of the veterinary professions and/or the RCVS
Private	5. To protect information which may contain personal data, special category data, and/or criminal offence data, as listed under the General Data Protection Regulation

Minutes of the Finance and Resources Committee (FRC) hybrid meeting held at Belgravia House, London and remotely via Microsoft Teams on Thursday, 16 September 2021.

Members:

Dr N T Connell	Chair / RCVS Treasurer
Dr S Paterson	Representative from Education Committee
Dr M O Greene	Representative from Advancement of Professions Committee
Ms J S M Worthington	Lay Member RCVS Council
*Ms C-L McLaughlan	Representative from Standards Committee
*Mr M E Rendle	RCVS Council / Veterinary Nurse Chair
Dr M A Donald	Representative from PIC/DC Liaison Committee
Mr T J Walker	Lay Member RCVS Council
Ms J Davidson	Representative from Veterinary Nurses' Council
*Professor S A May	Elected member RCVS Council

*Denotes absent.

In attendance:

Ms L Lockett	CEO
Ms E Ferguson	Registrar / Director of Legal Services
Ms C McCann	Director of Operations (DoO)
Mr A Quinn-Byrne	Secretary / Governance Officer
Mr C Turner	Head of Finance

Apologies for absence

1. Apologies were received from Professor May, Ms McLaughlan and Mr Rendle.

Declarations of interest

2. There were no new declarations of interest.

Minutes of the meeting held on 13 May 2021

3. The minutes were agreed to be a true reflection of the meeting.

4. It was noted that the Secretary would look through the action list for FRC and remove items that had already been discussed.

Action: Sec to update Action List for FRC

Update from the Director of Operations (DoO)

5. There were no fraud items to report to the Committee.

6. The HR Team provided an update for FRC; there had been sixteen new starters and twelve leavers since the last FRC meeting.

7. Confidential information is available in the classified appendix at paragraphs 1-3.

Items to note

Appeals Committee

8. There were no new appeals to report.

Reports of Committees

9. Preliminary Investigation Committee / Displinary Committee Liaison Committee -– there were no new updates to report.

10. Standards Committee – there were no new updates to report.

11. Registration Committee – it was confirmed that Ms Linda Ford would be the Registration Committee representative at Finance and Resources Committee from November 2021.

12. Education Committee – it was confirmed that previous statutory examinations for membership had to be held face to face. Education Committee had made a change to this, to allow exams to be made available online.

13. Advancement of the Professions Committee (APC) –a paper requesting a further meeting of the Environmental and Sustainability Working Party (E&SWP) is detailed later in these minutes.

Corporate Risk Register

14. The Corporate Risk Register had been circulated to the Committee and included an update from the Governance Officer.

15. Confidential information is available in the classified appendix at paragraph 4.

16. It was noted that the report circulated on updates to the risks was excellent in keeping the Committee updated on risk movement.

17. Confidential information is available in the classified appendix at paragraphs 5-8

Management Accounts

18. The Management Accounts were presented to the Committee for the seven months to 31 July 2021.

19. Confidential information is available in the classified appendix at paragraph 9.

Investment update

20. An update on the RCVS Investment Portfolio by Investec was circulated to the Committee prior to the meeting. There was praise for the work of Investec from the Committee

21. It was noted that the Treasurer, Director of Operations, and Governance Officer would meet with Investec to receive an update on investments and discuss ethical investing. A full update on investments would be presented by Investec at the FRC meeting in November 2021.

Action: Chair (Treasurer), Dir of Operations and Governance Officer to arrange meeting with Portfolio manager at Investec

Budget 2022

22. A draft budget was circulated to the Committee.

23. Confidential information is available in the classified appendix at paragraphs 10-19.

Investment Policy

24. An RCVS Investment policy was discussed it was agreed that the investment policy will go to RCVS Council for discussion and approval.

25. Confidential information is available in the classified appendix at paragraphs 20-27.

Update on Environmental and Sustainability Working Party

26. The Environmental and Sustainability Working Party (E&SWP) outlined a proposal for the approval of one extra meeting for the E&SWP.

27. In the original Terms of Reference for the group, it was agreed that E&SWP would meet five times in 2021, however, to ensure the work of the group could be fully realised it was recommended that one more meeting would be required before its dissolution. It was confirmed that one extra meeting would ensure a smooth transition of policies and work streams to the College committees and teams in order for work to progress. The meeting would also look at how E&SWP work could

be embedded into a long-term strategy for the RCVS and would be an opportunity to finalise the draft report made by the Working Party to go forward to APC for approval.

28. Confidential information is available in the classified appendix at paragraph 28.

29. The Committee approved the extra meeting and its associated costs.

Council Election Paper

30. Confidential information is available in the classified appendix at paragraph 29-30.

Any Other Business

31. There was no other business to discuss.

Date of next meeting

32. The next meeting would be held remotely on Thursday, 18 November 2021 at 2:00 pm.

Summary

Meeting	RCVS Council
Date	11 November 2021
Title	Registration Committee Minutes 12 May 2021
Summary	A meeting of the RCVS Registration Committee Agenda Item, Temp Registration of Official Veterinarians Decision: The Committee recommend to RCVS Council that registration decisions for entry on the RCVS Temporary Register for specific functions as Official Veterinarians (OVs) are delegated to the Registrar. Agenda Item, E-Certificate Approval Decision: Committee approves issuing of e-certificates for all UK graduates as standard practice Agenda Item, Language Testing Requirements Decision: The Committee have agreed that the OET test at band C is a reasonable alternative and this will be proposed to Council by email.
Decisions required	To note the minutes
Attachments	Classified appendix
Author	Alan Quinn-Byrne Governance Officer/Secretary a.quinn-byrne@rcvs.org.uk / T 020 7227 3505

Classifications

Document	Classification[1]	Rationales[2]
Paper	Unclassified	n/a
Classified appendix	**Confidential**	**2, 3, 4**

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Private	5. To protect information which may contain personal data, special category data, and/or criminal offence data, as listed under the General Data Protection Regulation

Minutes of the Registration Committee held on 12 May 2021 online via Microsoft Teams.

Members:

Mrs Belinda Andrews-Jones	
Dr Niall Connell	Senior Vice-President - Chair
Prof Susan Dawson	Treasurer
Ms Eleanor Ferguson	Registrar
Ms Linda Ford	
Dr Mandisa Green	President
Ms Lizzie Lockett	CEO
Ms Corrie McCann	Director of Operations
Mr Martin Peaty	
Dr Kate Richards	
Dr Chris Tufnell	
Mr A Quinn-Byrne	Secretary to ARC / Governance Officer

*Not in attendance – apologies received

Apologies for absence

1. There were no apologies for absence.

Declarations of interest

2. There were no new declarations of interest

Minutes of Meeting held on 1 October 2020

3. The minutes of the meeting held on 1 October 2020 were accepted as a true record.

Temporary registration of Official Veterinarians

4. The registrar presented a paper to the Registration Committee This paper proposed the delegation of registration decisions to the Registrar for the temporary registration of Official Veterinarians.

5. The committee was asked to recommend to RCVS Council that registration decisions for entry on the RCVS Temporary Register for specific functions as Official Veterinarians (OVs) are delegated to the Registrar.

6. The Committee requested that they receive updates from the Registration team on data as to the number of applications approved. It was confirmed that if this decision is agreed by RCVS Council, the Registration Department will provide regular data on approved applications to the Registration Committee.

7. It was confirmed that no applications have come in yet but it is expected to see an increase in these within the coming weeks.

8. The Committee were happy with the proposal.

Decision: The Committee recommend to RCVS Council that registration decisions for entry on the RCVS Temporary Register for specific functions as Official Veterinarians (OVs) are delegated to the Registrar.

E- Certificates for UK Graduates

9. The Head of Insight and Engagement presented a paper to the Committee to consider a plan to issue e-certificates for all UK graduates as standard practice. The Committee is invited to discuss and approve the proposal.

10. The paper provided to the Committee provided some background it was noted that during the pandemic, overseas registrations were carried out online, and the UK graduation ceremonies did not take place. The e-certificate was discussed, adapted, agreed and designed towards the end of 2020 to replace the physical registration certificate during this time and decisions around its use for overseas members and the 2020 UK graduate cohort were made by the Covid Taskforce following a trial. The issue is now brought to the Registration Committee so that the longer-term use of the e-certificate for all registrants can be considered.

11. A concern around fraud was raised and the question of whether the e-certificates could be duplicated. It was noted that fraud is always a risk, however there is also several mitigations in place to prevent or spot fraud on an organisational level. The positive environmental impact was also noted on using e-certificates.

12. It was noted in order to avoid large number of requests coming from Vet Schools make it clear to Vet schools to request e-certificates only when students request one.

13. A discussion took place regarding the charging of a fee for administration of e-certificates, it was decided that it would be launched without a fee and then further discussions around introducing a fee could be discussed in the future.

14. The Committee were content with approval of the proposal.

Decision: Committee approves issuing of e-certificates for all UK graduates as standard practice

IELTS – Language Testing

15. Due to the difficulties in sorting a language test with IELTS or OET, RCVS gave Eville & Jones (E&J) the opportunity to seek a review of alternative language test provider for some of their applicants. The one proviso is the provider must be on par with IELTS. In order to be eligible their vets must meet IELTS level 5.

16. E&J completed a review of language test suppliers and has requested to use Pearson's PTE Academic. Registration committee were informed of the standard of the Pearson language test and whether it might be considered as an alternative to IELTS level 5. This was raised due to ongoing difficulties in Europe in accessing IELTS language testing sites. The Committee were not sufficiently assured of the levels presented to them.

17. Post meeting Note: The Committee were informed by the Registrar via email that an alternative language test may be an option after it was confirmed the OET language test (which is approved by the RCVS for the stat exam in addition to IELTS) has now become available online for candidates. The Committee were asked to vote via email on whether this can be considered as an alternative to IELTS for those seeking temporary registration as OVS. The Committee have agreed that the OET test at band C is a reasonable alternative and this will be proposed to Council by email.

Decision: The Committee have agreed that the OET test at band C is a reasonable alternative and this will be proposed to Council by email.

Letter from Practice Group

18. Confidential information is available in the classified appendix at paragraph 1.

AOB

19. Confidential information is available in the classified appendix at paragraphs 2-3.

Date of next meeting

15 September 2021

Summary	
Meeting	RCVS Council
Date	11 November 2021
Title	Minutes of Registration Committee held 15 September 2021.
Summary	Minutes of the Registration Committee
Decisions required	To note the minutes
Attachments	Classified Appendix
Author	Alan Quinn-Byrne Governance Officer/Secretary a.quinn-byrne@rcvs.org.uk / T 020 7227 3505

Classifications

Document	Classification[1]	Rationales[2]
Paper	Unclassified	n/a
Classified appendix	**Confidential**	**1, 2, 3, 4**

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Private	5. To protect information which may contain personal data, special category data, and/or criminal offence data, as listed under the General Data Protection Regulation

Minutes of the Registration Committee meeting held on 15 September 2021 at Belgravia House, 62-62 Horseferry Road, London SW1P 2AF.

Members:

Dr Melissa Donald	Chair
Mrs Belinda Andrews-Jones	
Dr Niall Connell	Treasurer
Prof Christopher Proudman	
Ms Eleanor Ferguson	Registrar
Ms Linda Ford	
Dr Mandisa Green	
Ms Lizzie Lockett	CEO
Ms Corrie McCann	Director of Operations
Mr Neil Smith	
Dr Kate Richards	President
Mr A Quinn-Byrne	Secretary to ARC / Governance Officer

*Not in attendance – apologies received

Apologies for absence

1. There were no apologies for absence.

Declarations of interest

2. There were no new declarations of interest

Minutes of Meeting held on 12 May 2021

3. The minutes of the meeting held on 12 May 2021 were accepted as a true record.

Regulation of Behaviourists

4. Confidential information is available in the classified appendix at paragraphs 1-7.

Update on Temporary Registration of Official Veterinarians

5. The Committee were provided with an update on figures (in the form of a table) on the temporary Registration of Official Veterinarians to date.

6. It was highlighted to the Committee temporary Registration of Official Veterinarians were approved at the Council meeting in March 2021, to overcome long-standing concerns about the recruitment and retention of OVs providing meat hygiene official controls.

7. All applications for Temporary Registration of Official Veterinarians are processed and approved by the College's Registration Department. Since the new Temporary Registration of Official Veterinarians Policy was triggered by DEFRA on 1 June 2021 seventeen new applications have been approved, no applications have been rejected. Four applications are currently being processed, of this one applicant is being employed.

8. It was noted to the Committee the average time between a new application being submitted to the RCVS and receiving all the necessary documents and payment is 26 calendar days. Reasons for the delays in receiving all the required documents (in order of the most common issues): -

- Availability of language test sites
- Waiting for payment
- Waiting for documents from the school
- Incomplete application form (this is now less of an issue)

Temporary Registration of Official Veterinarians (OVS) language requirements

9. The Registrar outlined the paper regarding language requirements for the Temporary Registration of Official Veterinarians (OVS), in particular, the timeline of events and the various language tests available and currently accepted to date.

10. The merits and accessibility of the Pearson Test of English (PTE) was discussed. . It was noted that some UK universities accepted the PTE and a lot of work had already been done around quality assurance and international student business models

11. The Committee also considered the International English Language Testing System (IELTS) Indicator Test. It was noted that the Indicator Test might help with accessibility but that it was only an 'indication' of English skills – it was not monitored in the same way as the actual IELTS test at a physical centre; nor was it widely accepted by regulators, e.g. the General Medical Council (GMC).

12. It was further noted that if the Committee accepted the IELTS Indicator Test, it would only be in relation to Temporary Registration of OVs (i.e. a pass at the higher Level 7 in a centre-based test would still be required before entry onto the full RCVS Register). Furthermore, applicants were required to take a separate language test recognised by the Home Office for visa requirements, therefore it would not provide a 'one exam' only solution but might offer an alternative in availability.

13. The Committee did not approve the use of the IELTS indicator Test for Temporary Registration of OV applications (in addition to IELTS centre-based tests and Occupational English Tests (OET)) because of the potential of associated risks.

14. The Committee agreed that further research should be commissioned regarding the equivalence of the PTE and should include information about examination integrity.

Temporary Registration Postgraduate study

15. The Committee considered the paper and noted the emphasis that it would be for people coming to study, subject to meeting the English requirements set by the school they would attend, be time-limited, and would not apply to any other 'sphere' of temporary registration.

16. It was noted that internships had been included as post-graduate study. Internship was in fact a commercial environment as well as a form of self-development and the levels of supervision in place was questioned. It was felt this area needed further consideration.

17. It was suggested that courses of study / internship should be categorised as they may differ across veterinary schools and could create a potential conflict to the specifications under this route to Temporary Registration. The Committee agreed that more work should be undertaken before it could make a decision on this matter.

Language Testing

18. In order to sit the Statutory Examination for Membership (SEM), or apply for full Registration, it was necessary that any applicant would have attainted IELTS Level 7 (or B in OET) across all components – reading, writing, speaking, listening. In considering the request made to RCVS that instead of IELTS Level 7 (or B in OET) across all components as per the current arrangements, that it would be acceptable to have a minimum of IELTS Level 6.5 (C+ in OET) in one component so long as the average score across all components was at least Level 7, the Committee looked at the approach taken by other regulators.

19. It was noted that Education Committee had also considered the same request the previous day.

20. The view was expressed that the level should not go lower than Level 6.5 in any component; that it was a reasonable adjustment; and would apply across the board for SEM and full Registration.

21. The Committee agreed this change (without specifying the component in which the Level 6.5 would be permitted) to allow the small degree of flexibility to facilitate access whilst not compromising overall standards, but that it should go up to Council for approval before implementing.

    Afternote: As both Education, and Registration, Committees were minded to allow this change, in view of previous discussions in this topic at Council they sought to obtain Council's approval before implementing. A (remote) vote was taken and the decision was agreed by a majority vote. Thereafter, the result was forwarded to the Education and Registration Teams for immediate action.

Application for Temporary Registration

22. An application for Temporary Registration was heard by the Committee, the application was for Postgraduate Study.

23. The Committee accepted the application but requested that they are given more time to review the documentation for these applications.

Any other Business

24. The Committee agreed to appoint Ms Linda Ford as Registration Committees representative at Finance and Resources Committee.

Date of Next meeting

3pm on 17 November 2021

Summary

Meeting	Council
Date	11 November 2021
Title	Standards Committee Minutes
Summary	Minutes of Standards Committee held remotely on Friday, 16 July 2021, at 10am. The Committee's attention is drawn to the classified appendix.
Decisions required	None
Attachments	Classified appendix
Author	Beth Jinks Standards and Advisory Lead b.jinks@rcvs.org.uk

Classifications

Document	**Classification[1]**	**Rationales[2]**
Paper	Unclassified	n/a
Classified appendix	**Confidential**	**1, 2, 3**

1 Classifications explained

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Minutes of the Standards Committee held remotely on Friday, 16 July 2021, at 10 am

Members:	Dr L Allum	
	Ms B Andrews-Jones	
	Miss L Belton	
	Mr M Castle	
	Dr D Chambers	
	Dr M A Donald	Chair
	Dr M Gardiner	
	Ms C-L McLaughlan	
	Prof T Parkin	
	Mrs C Roberts	

In attendance:	Ms E C Ferguson	Registrar
	Ms G Kingswell	Head of Legal Services (Standards)
	Ms B Jinks	Standards and Advisory Lead
	Ms S Bruce-Smith	Senior Standards and Advice Officer
	Dr M Greene	Senior Vice President/Council observer

AI 1 Apologies for absence and declarations of interest

1. The Chair welcomed the Senior Vice President to the meeting as an observer.

2. Apologies were received from Claire Roberts.

3. There were no new conflicts of interests declared, however Danny Chambers reminded the Committee that he provides consultancy work to online veterinary wellness platform ‘MyDogDoc’.

AI 2 Covid-19 temporary guidance on remote prescribing – Confidential

4. Confidential minutes relating to this agenda item can be found in paragraphs 1-5 of the confidential appendix.

AI 3 Any other business

5. The Chair requested that those who are interested in becoming Vice-Chair of this Committee or the Standards Committee’s Finance Resource Committee representative volunteer via email to the Chair. The positions will then be agreed at or before this Committee’s September meeting.

Date of next meeting

6. It was explained that there will be two extra meetings before the next scheduled meeting of this Committee: 1) to discuss 'under care' survey results, 2) to discuss issue relating to the certification of fish exports. Dates for these meetings will be established shortly.

Action: Standards and Advice Lead

Table of actions

Paragraph(s)	Action	Assigned to
6	Plan two additional Standards Committee meetings	**Standards and Advice Lead**

Summary

Meeting	Council
Date	11 November 2021
Title	Standards Committee Minutes
Summary	Minutes of Standards Committee held remotely on Wednesday, 4 August 2021, at 2pm. The Committee's attention is drawn to the classified appendix.
Decisions required	None
Attachments	Defra proposal (**Annex A**) (**Confidential**) Regulations containing the definition of 'aquatic animals' (**Annex B**)
Author	Kimberley Richardson Senior Standards and Advice Officer/Solicitor Secretary to the Certification Sub-Committee k.richardson@rcvs.org.uk / 0207 202 0757

Classifications

Document	Classification[1]	Rationales[2]
Minutes	Unclassified	N/A
Classified appendix	**Confidential**	**1, 2**
Annex A	**Confidential**	**1, 2**
Annex B	Unclassified	N/A

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Minutes of the Standards Committee held remotely on Wednesday, 4 August 2021, at 2pm

Members:

Dr L Allum	
Ms B Andrews-Jones	
Miss L Belton	
Mr M Castle	
Dr D Chambers	
Dr M A Donald	Chair
Dr M Gardiner	
Ms C-L McLaughlan	
Prof T Parkin	
Mrs C Roberts	

In attendance:

RCVS

Ms E C Ferguson	Solicitor/Registrar/Director of Legal Services
Ms B Jinks	Standards and Advisory Lead
Ms S Bruce-Smith	Senior Standards and Advice Officer
Mx K Richardson	Senior Standards and Advice Officer/Solicitor

DEFRA

Dr E Robertson	
Dr B Oidtmann	Head of Aquatic Animal Health Policy
C Harrold	
Mr D Lee	Joint Head of Aquatic Animal Health and Zoonoses and Endemic Diseases Policy
Dr M Lopez	Head of Veterinary Trade Facilitation
J De Vere	
A Gadsby	

Other

D Smith	CEFAS
Dr S Voas	Chief Veterinary Officer (Scotland) (CVO Scotland)
Mr R Soutar	Head of Veterinary Services, Scottish Sea Farms

AI 1 Apologies for absence and declarations of interest

1. Apologies were given for Mandisa Greene, Tim Parkin, Belinda Andrews-Jones, and Claire Roberts.

2. There were no new declarations of interest.

AI 2 Certification of Fish – Confidential

3. Confidential minutes relating to this agenda item can be found in the confidential appendix.

AI 3 Any other business

4. It was noted that there were two volunteers for the new vice chair, and one volunteer for the position of Finance Resource Committee representative, and a decision would be made at the next meeting in relation to the Under Care Review.

Date of next meeting

5. The date of the next Committee meeting is 21 August 2021.

Table of actions

6. Please see confidential appendix.

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2016/429 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 March 2016

on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2), Article 114 and Article 168(4)(b) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) The impact of transmissible animal diseases and the measures necessary to control those diseases can be devastating for individual animals, animal populations, animal keepers and the economy.

(2) As recent experiences have demonstrated, transmissible animal diseases may also have a significant impact on public health and food safety.

(3) In addition, adverse interactive effects can be observed with regard to biodiversity, climate change and other environmental aspects. Climate change may influence the emergence of new diseases, the prevalence of existing diseases and the geographic distribution of disease agents and vectors, including those affecting wildlife.

(4) In order to ensure high standards of animal and public health in the Union and the rational development of the agriculture and aquaculture sectors, and to increase productivity, animal health rules should be laid down at Union level. Those rules are necessary in order, inter alia, to contribute to the completion of the internal market and to avoid the spread of infectious diseases. Those rules should also ensure, as far as possible, that the existing animal health status in the Union is maintained and that consequent improvement of that status is supported.

([1]) OJ C 170, 5.6.2014, p. 104.
([2]) Position of the European Parliament of 15 April 2014 (not yet published in the Official Journal) and position of the Council at first reading of 14 December 2015.

(5) The current Union legislation on animal health consists of a series of linked and interrelated basic acts that lay down rules on animal health applying to intra–Union trade, entry into the Union of animals and products, disease eradication, veterinary controls, notification of diseases and financial support in relation to different animal species, but an overarching legal framework, laying down harmonised principles across the sector, is missing.

(6) Financial rules relating to the support of animal health objectives are provided for in Regulation (EU) No 652/2014 of the European Parliament and of the Council ([1]) and do not form part of this Regulation. In addition, the rules covering the official controls of animal health measures provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council ([2]) and in Council Directives 89/662/EEC ([3]), 90/425/EEC ([4]), 91/496/EEC ([5]) and 97/78/EC ([6]) should be used to regulate official controls in the area of animal health.

(7) This Regulation does not contain provisions which regulate animal welfare. However, animal health and welfare are linked: better animal health promotes better animal welfare, and vice versa. When disease prevention and control measures are carried out in accordance with this Regulation, their effect on animal welfare, understood in the light of Article 13 of the Treaty on the Functioning of the European Union (TFEU), should be considered in order to spare the animals concerned any avoidable pain, distress or suffering. Animal welfare legislation, such as Council Regulations (EC) No 1/2005 ([7]) and (EC) No 1099/2009 ([8]), should necessarily continue to apply and should be properly implemented. The rules laid down in this Regulation should not duplicate, or overlap with, the rules laid down in that legislation.

(8) The Commission's communication of 19 September 2007 on a new Animal Health Strategy for the European Union (2007-2013) where 'Prevention is better than cure' aims to promote animal health by placing greater emphasis on preventive measures, disease surveillance, disease control and research, in order to reduce the incidence of animal diseases and minimise the impact of outbreaks when they do occur. It proposes the adoption of a single and simplified regulatory framework for animal health seeking convergence with international standards while ensuring a firm commitment to high standards of animal health.

(9) The aim of this Regulation is to implement the commitments and visions provided for in that Animal Health Strategy, including the 'One health' principle, and to consolidate the legal framework for a common Union animal health policy through a single, simplified and flexible regulatory framework for animal health.

(10) Animals may suffer from a broad range of infectious or non–infectious diseases. Many diseases can be treated, or have an impact only on the individual animal concerned, or do not spread to other animals or to humans. On the other hand, transmissible diseases may have a broader impact on animal or public health, with effects felt at population level. The animal health rules laid down in this Regulation should be limited to those latter diseases alone.

([1]) Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (OJ L 189, 27.6.2014, p. 1).

([2]) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

([3]) Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (OJ L 395, 30.12.1989, p. 13).

([4]) Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (OJ L 224, 18.8.1990, p. 29).

([5]) Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC (OJ L 268, 24.9.1991, p. 56).

([6]) Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

([7]) Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p. 1).

([8]) Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, p. 1).

(11) In laying down those animal health rules, it is essential that consideration be given to the links between animal health and public health, the environment, food and feed safety, animal welfare, food security, economic, social and cultural aspects.

(12) The Sanitary and Phytosanitary Measures (SPS) Agreement, to which the Union is a party, regulates the use of measures necessary to protect human, animal or plant life or health so that they do not arbitrarily or unjustifiably discriminate between World Trade Organisation (WTO) members. If international standards exist, they are required to be used as a basis for Union measures. However, the parties to the SPS Agreement have the right to set their own relevant standards, provided that such standards are based on scientific evidence.

(13) As regards animal health, the SPS Agreement refers to the standards of the World Organisation for Animal Health (OIE) relating to animal health conditions for international trade. In order to reduce the risk of trade disruption, Union animal health measures should aim at an appropriate level of convergence with OIE standards.

(14) In specific circumstances where a significant animal or public health risk exists but scientific uncertainty persists, Article 5(7) of the SPS Agreement, which has been interpreted for the Union in the Commission communication of 2 February 2000 on the precautionary principle, allows members of that Agreement to adopt provisional measures on the basis of available pertinent information. In such circumstances, the member concerned is required to obtain the additional information necessary for a more objective assessment of risk and to review the measure accordingly within a reasonable period of time.

(15) The risk assessment on the basis of which the measures under this Regulation are taken should be based on the available scientific evidence and undertaken in an independent, objective and transparent manner. Due account should also be taken of the opinions of the European Food Safety Authority (EFSA) established by Article 22(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([1]).

(16) Regulation (EC) No 1069/2009 of the European Parliament and the Council ([2]) lays down both public and animal health rules for certain animal by–products and derived products in order to prevent and minimise risks to public and animal health arising from those products, and in particular to protect the safety of the food and feed chain. In order to avoid any overlap of Union legislation, this Regulation should therefore only apply to animal by-products and derived products where specific rules are not laid down in Regulation (EC) No 1069/2009, and where an animal health risk is involved. For instance, Regulation (EC) No 1069/2009 does not regulate how to handle animal by–products and derived products in the context of disease control measures, and so those issues are duly covered by this Regulation.

(17) In addition, specific rules on transmissible animal diseases, including those transmissible to humans ('zoonoses'), are already laid down in Regulation (EC) No 999/2001 of the European Parliament and of the Council ([3]), Directive 2003/99/EC of the European Parliament and of the Council ([4]) and Regulation (EC) No 2160/2003 of the European Parliament and of the Council ([5]), and specific rules on communicable diseases in humans are laid down in Decision No 1082/2013/EU of the European Parliament and of the Council ([6]). Those acts should remain in force following the adoption of this Regulation. Accordingly, in order to avoid any overlap of Union legislation, this Regulation should only apply to zoonoses to the extent that specific rules are not already laid

([1]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

([2]) Regulation (EC) No 1069/2009 of the European Parliament and the Council of 21 October 2009 laying down health rules as regards animal by–products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

([3]) Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

([4]) Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31).

([5]) Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food–borne zoonotic agents (OJ L 325, 12.12.2003, p. 1).

([6]) Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

down in those other Union acts. In addition, this Regulation applies without prejudice to the rules provided for in other Union legislative acts, such as in the fields of veterinary medicine and animal welfare.

(18) Diseases occurring in animals which are kept by humans can have severe impacts on the agriculture and aquaculture sectors, on public health, on the environment and on biodiversity. However, as such animals are kept by humans, disease prevention and control measures are often easier to apply to them than to wild animals.

(19) Nevertheless, diseases occurring in wild animal populations may have a detrimental effect on the agriculture and aquaculture sectors, on public health, on the environment and on biodiversity. It is therefore appropriate that the scope of this Regulation should, in such cases, cover wild animals, both as potential victims of those diseases and as their vectors. For the purposes of this Regulation, the term 'wild animals' covers all animals that are not kept by humans, including stray and feral animals, even if they are of species that are normally domesticated.

(20) Animal diseases are not only transmitted through direct contact between animals or between animals and humans. They are also carried further afield through water and air systems, vectors such as insects, or the semen, oocytes and embryos used in artificial insemination, oocyte donation or embryo transfer. Disease agents may also be contained in food and other products of animal origin such as leather, fur, feathers, horn and any other material derived from the body of an animal. Moreover, various other objects such as transport vehicles, equipment, fodder and hay and straw may diffuse disease agents. Therefore, effective animal health rules need to cover all paths of infection and material involved therein.

(21) Animal diseases may have detrimental effects on the distribution of animal species in the wild, and thus affect biodiversity. Microorganisms causing such animal diseases can therefore be considered as invasive alien species within the framework of the United Nations Convention on Biological Diversity. The measures provided for in this Regulation also take account of biodiversity and thus this Regulation should cover animal species and disease agents, including those defined as invasive animal species, which play a role in the transmission of, or are affected by, diseases covered by this Regulation.

(22) Union legislation adopted prior to this Regulation lays down separate animal health rules for terrestrial and aquatic animals. Council Directive 2006/88/EC [1] lays down specific rules for aquatic animals. Yet in most cases, the main principles for good animal health governance and good animal husbandry are applicable to both groups of animal species. Accordingly, this Regulation should cover both terrestrial and aquatic animals and should align those animal health rules where applicable. However, for certain aspects, in particular the registration and approval of establishments and the traceability and movements of animals within the Union, this Regulation adheres to the approach adopted in the past, which was to lay down different sets of animal health rules for terrestrial and aquatic animals due to their different environments and accordingly different requirements to safeguard health.

(23) Union legislation adopted prior to this Regulation, and in particular Council Directive 92/65/EEC [2], also lays down basic animal health rules for other animal species not regulated in other Union acts, such as reptiles, amphibians, marine mammals, and others which are not aquatic or terrestrial animals as defined in this Regulation. Usually, such species do not present a significant health risk for humans or other animals and therefore only a few animal health rules, if any, apply. In order to avoid unnecessary administrative burdens and costs, this Regulation should adhere to the approach adopted in the past, namely to provide the legal framework enabling detailed animal health rules to be laid down for movements of such animals and their products if the risks involved so require.

(24) Humans often keep certain animals as pets in their households to keep them company. The keeping of such pet animals for purely private purposes, including ornamental aquatic animals in households, both indoors and outdoors, generally poses a lower health risk compared to other ways of keeping or moving animals on a

[1] Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14).

[2] Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).

broader scale, such as those common in agriculture, aquaculture, animal shelters and the transport of animals more generally. Therefore, it is not appropriate that the general requirements concerning registration, record keeping and movements within the Union should apply to such pet animals, as this would represent an unjustified administrative burden and cost. Registration and record keeping requirements should therefore not apply to pet keepers. In addition, specific rules should apply to non–commercial movements of pet animals within the Union.

(25) Some defined groups of animals, for which special animal health rules exist in this Regulation, need to be listed as species in an annex, due to the varied nature of the group concerned. This is the case for the group of hoofed mammals classified as ungulates. The list of such animals may need to be changed in the future due to reasons of changed taxonomy. Therefore, in order to take account of such changes, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the list of ungulates set out in Annex III to this Regulation.

(26) Not all transmissible animal diseases can or should be prevented and controlled through regulatory measures, for example if the disease is too widespread, if diagnostic tools are not available, or if the private sector can take measures to control the disease by itself. Regulatory measures to prevent and control transmissible animal diseases may have important economic consequences for the relevant sectors and may disrupt trade. It is therefore essential that such measures are applied only when they are proportionate and necessary, such as when a disease presents, or is suspected to present, a significant risk to animal or public health.

(27) Furthermore, the preventive and control measures for each transmissible animal disease should be 'tailor–made' in order to address its unique epidemiological profile, its consequences and its distribution within the Union. The preventive and control rules applying to each of them should therefore be disease-specific.

(28) For transmissible animal diseases, a disease condition is usually associated with clinical or pathological manifestation of the infection. However, for the purpose of this Regulation, which aims to control the spread of, and eradicate, certain transmissible animal diseases, the disease definition should be wider in order to include other carriers of the disease agent.

(29) Some transmissible animal diseases do not easily spread to other animals or to humans and thus do not cause economic or biodiversity damage on a wide scale. Therefore, they do not represent a serious threat to animal or public health in the Union and can thus, if desired, be addressed by means of national rules.

(30) For transmissible animal diseases that are not subject to measures laid down at Union level, but which are of some economic importance for the private sector at a local level, the latter should, with the assistance of the competent authorities of the Member States, take action to prevent or control such diseases, for instance through self–regulatory measures or the development of codes of practice.

(31) In contrast to the transmissible animal diseases described in recitals 29 and 30, highly transmissible animal diseases may easily spread across borders and, if they are also zoonoses, they may also have an impact on public health and food safety. Hence highly transmissible animal diseases and zoonoses should be covered by this Regulation.

(32) Antimicrobial resistance, understood as the ability of microorganisms to survive or to grow in the presence of a concentration of an antimicrobial agent which is usually sufficient to inhibit or kill microorganisms of the same species, is increasing. Action No 5 advocated in the Communication from the Commission to the European Parliament and the Council entitled 'Action plan against the rising threats from antimicrobial resistance' emphasises the preventive role to be played by this Regulation and the consequent expected reduction of the use of antibiotics in animals. This resistance of microorganisms to antimicrobials to which they were previously responsive complicates the treatment of infectious diseases in humans and animals and may thus pose a threat to human or animal health. As a result, microorganisms that have developed resistance to antimicrobials should be treated as if they were transmissible diseases, and thus covered by the scope of this Regulation. This will enable action to be taken against antimicrobial-resistant organisms where appropriate and necessary.

(33) New hazards associated with certain diseases or species may develop in particular due to changes in trade patterns, the environment, the climate, animal husbandry and farming traditions, but also as a result of social changes. Scientific progress may also lead to new knowledge concerning, and increased awareness of, existing diseases. Furthermore, diseases and species that are important today may be marginalised in the future. Therefore the scope of this Regulation should be broad and the rules laid down should be focused on diseases with high public relevance. The OIE has, with the support of the European Commission, produced a study on the 'Listing and categorisation of priority animal diseases, including those transmissible to humans' and a tool for such an exercise, which aims to develop a system of disease prioritisation and categorisation. That tool is an example of a systematic approach to the collection and assessment of information about animal diseases.

(34) It is necessary to establish a harmonised list of transmissible animal diseases ('listed diseases') which pose a risk to animal or public health in the Union, whether across the whole Union or only in parts. The five diseases already identified in this Regulation should be supplemented by a list of diseases set out in an annex. The Commission should review and amend that annex in accordance with a set of criteria. The power to adopt acts amending the annex should therefore be delegated to the Commission in accordance with Article 290 TFEU.

(35) Diseases with the potential to pose serious risks to public or animal health and to result in impacts on health, the economy or the environment may emerge in the future. Implementing powers to lay down disease prevention and control measures for such emerging diseases should be conferred on the Commission to adopt adequate measures to address potential negative consequences of those diseases even if they have not been fully assessed in view of their potential listing. Such measures are without prejudice to emergency measures and could continue to apply to emerging diseases pending a decision on their listing.

(36) Listed diseases will require different management approaches. Some highly contagious diseases which are currently not present in the Union require stringent measures to immediately eradicate them as soon as they occur. In cases where such diseases are not promptly eradicated and become endemic, a long-term compulsory eradication programme will be required. For other diseases that may already be present in parts of the Union, compulsory or optional eradication is required. In these cases, it is appropriate to put in place restrictions on movements of animals and products, such as a prohibition of movements to and from affected areas, or simply to test the animals or products concerned prior to dispatch. In other instances it might be appropriate merely to implement a programme of surveillance of the distribution of the disease in question, without taking further measures.

(37) Criteria should be laid down to ensure that all relevant aspects are considered when determining which transmissible animal diseases should be listed for the purposes of this Regulation.

(38) The rules laid down by this Regulation for the prevention and control of a specific transmissible animal disease should apply to species of animals which can transmit the disease in question, by virtue of being susceptible to it or by acting as its vector. In order to ensure uniform conditions for the implementation of this Regulation, it is necessary to establish a harmonised list of species to which the measures for specific listed diseases are to apply at Union level ('listed species') and implementing powers to lay down such a list should thus be conferred on the Commission.

(39) The categorisation process should be based on predefined criteria such as the profile of the listed disease in question, the level of its impact on animal and public health, animal welfare and the economy of the Union, the risk of its spreading and the availability of disease prevention and control measures in respect of that listed disease. Implementing powers should be conferred on the Commission to lay down which listed diseases are to be subject to which rules.

(40) Such rules should apply as regards listed diseases that do normally not occur in the Union and for which immediate eradication measures need imperatively to be taken as soon as they are detected, such as classical swine fever, as regards listed diseases that need to be controlled in all Member States with the goal of eradicating them throughout the Union, which could include diseases such as brucellosis, as regards listed diseases which are of relevance to some Member States and for which measures are needed to prevent them from spreading to parts of the Union that are officially free of, or that have eradication programmes for that, listed disease, which could

include diseases such as infectious bovine rhinotracheitis, as regards listed diseases for which measures are needed to prevent them from spreading on account of their entry into the Union or movements between Member States, which could include diseases such as equine infectious anaemia, and as regards listed diseases for which there is a need for surveillance within the Union, which could include diseases such as anthrax.

(41) The disease profile of a given disease may change, as well as the risks associated with the disease and other circumstances. For such cases, the implementing powers conferred on the Commission should also include the power to modify the category into which a particular listed disease falls, and therefore the measures to which it is subject.

(42) Operators working with animals are in the best position to observe and ensure the health of the animals and to monitor products under their responsibility. They should therefore bear primary responsibility for carrying out measures for the prevention and control of the spread of diseases among animals and the monitoring of products under their responsibility.

(43) Biosecurity is one of the key prevention tools at the disposal of operators and others working with animals to prevent the introduction, development and spread of transmissible animal diseases to, from and within an animal population. The role of biosecurity is also recognised in the impact assessment for the adoption of this Regulation, in which possible impacts are specifically assessed. The biosecurity measures adopted should be sufficiently flexible, suit the type of production and the species or categories of animals involved and take account of the local circumstances and technical developments. Implementing powers should be conferred on the Commission to lay down minimum requirements necessary for the uniform application of biosecurity measures in the Member States. Nevertheless, it should always remain within the power of operators, Member States or the Commission to promote prevention of transmissible diseases through higher biosecurity standards by developing their own guides to good practice. While biosecurity may require some upfront investment, the resulting reduction in animal disease should be a positive incentive for operators.

(44) Biocidal products, such as disinfectants for veterinary hygiene or food and feed areas, insecticides, repellents or rodenticides, play an important role in biosecurity strategies, both at farm level and during animal transport. They should therefore be considered part of biosecurity.

(45) Knowledge of animal health, including of disease symptoms, consequences of diseases and possible means of prevention including biosecurity, treatment and control, is a prerequisite for efficient animal health management and essential in ensuring the early detection of animal diseases. Operators and animal professionals should therefore acquire such knowledge as appropriate. That knowledge may be acquired by different means, for example formal education, but also through the Farm Advisory System existing in the agricultural sector or by informal training to which national and Union farmer organisations and other organisations may be valuable contributors.

(46) Veterinarians and aquatic animal health professionals play a crucial role in all aspects of animal health management, and general rules concerning their roles and responsibilities should be laid down in this Regulation.

(47) Veterinarians have the education and the professional qualifications attesting to their having acquired the knowledge, skills and competencies necessary, inter alia, to diagnose diseases and treat animals. In addition, in some Member States for historical reasons, or due to the lack of veterinarians dealing with aquatic diseases, there exists a specialised profession called 'aquatic animal health professionals'. These professionals are traditionally not veterinarians but they practice aquatic animal medicine. This Regulation should therefore respect the decision of those Member States which recognise that profession. In those cases, aquatic animal health professionals should have the same responsibilities and obligations as veterinarians concerning their specific area of work. This approach is in line with the OIE Aquatic Animal Health Code.

(48) Member States, and in particular their competent authorities responsible for animal health, are amongst the key actors in the prevention and control of transmissible animal diseases. The competent authority for animal health

plays an important role in relation to surveillance, eradication, disease control measures, contingency planning and raising disease awareness, in the facilitation of animal movements, and in international trade by the issuing of animal health certificates. In order to be able to perform their duties under this Regulation, Member States depend on having access to adequate financial, infrastructural and personnel resources throughout their territories, including laboratory capacity and scientific and other relevant know–how.

(49) The competent authority cannot always perform all the activities required to be carried out by them under this Regulation due to limited resources. For that reason, it is necessary to provide a legal basis for the delegation of the performance of certain activities to veterinarians who are not official veterinarians. For the same reason, Member States should also be allowed to authorise natural or legal persons to perform certain activities under certain conditions.

(50) In order to ensure that the necessary conditions are laid down for the general application of disease prevention and control measures across the Union, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the delegation of the performance of other activities which the competent authority may delegate to veterinarians other than official veterinarians.

(51) Optimal animal health management can only be achieved in cooperation with animal keepers, operators, veterinarians, animal health professionals, other stakeholders and trading partners. In order to secure their support, it is necessary to organise decision-making procedures and the application of the measures provided for in this Regulation in a clear, transparent and inclusive manner.

(52) The competent authority should also take appropriate steps to keep the public informed, especially when there are reasonable grounds to suspect that animals or products may present a risk for animal or public health or when a case is of public interest. In those cases, the animals or products concerned may originate from within the Union or enter the Union from outside. The latter may also be brought into the Union by persons travelling from outside the Union with their personal luggage. Thus, the information provided to citizens should also cover the risks involved with such situations.

(53) In order to avoid the release of disease agents from laboratories, institutes and other facilities handling disease agents, it is vital that they take appropriate biosecurity, biosafety and bio–containment measures. This Regulation should therefore provide for safety measures to be observed during the handling or transportation of such disease agents, vaccines and other biological products. The obligation imposed in that regard should also apply to any legal or natural person who is involved in such an activity. In order to ensure that safety standards are respected in the handling of highly contagious biological agents, vaccines and other biological products, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the safety measures in those laboratories, institutes and facilities and for movements of disease agents.

(54) Early detection and a clear chain of disease notification and reporting are crucial for effective disease control. In order to achieve an efficient and quick response, Member States should ensure that any suspicion or confirmation of an outbreak of certain listed diseases should be immediately notified to the competent authority.

(55) Veterinarians are key actors in the investigation of diseases and a key link between operators and the competent authority. They should therefore be notified by the operator concerned in cases of abnormal mortalities, other serious disease problems, or significantly decreased production rates with an undetermined cause.

(56) In order to ensure the effective and efficient notification of, and to clarify different circumstances related to, abnormal mortalities and other signs of serious diseases, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of criteria to determine when relevant circumstances for notification occur and to lay down the rules for further investigation, where this is relevant.

(57) For certain listed diseases, it is vital that a Member State should immediately notify the Commission and the other Member States about an outbreak in its territory. Such notification will enable neighbouring or other affected Member States to take precautionary measures when appropriate.

(58) On the other hand, for some diseases immediate notification and action are not necessary. In those cases, the gathering of information and reporting in relation to the occurrence of those diseases is essential in order to control the disease situation and where necessary to take disease prevention and control measures. This reporting requirement may also apply to diseases which are subject to Union-wide notification but where additional information is needed for the implementation of effective disease prevention and control measures. In order to ensure that the correct information and data needed to prevent the spread or to control each particular disease are collected in the right timeframe, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the matters to be reported.

(59) A key purpose of disease notification and reporting is to generate reliable, transparent and accessible epidemiological data. A computerised interactive information system for the effective collection and management of surveillance data should be established at Union level for listed diseases and, when relevant, for emerging diseases or antimicrobial-resistant pathogens. That system should promote optimal data availability, facilitation of data exchange, and reduction of administrative burdens for the competent authorities of the Member States by merging disease notification and reporting within the Union and at international level into a single process operated through the database of the OIE. Steps should also be taken to ensure consistency in exchanges of information in accordance with Directive 2003/99/EC.

(60) In order to ensure uniform conditions for the implementation of the Union disease notification and reporting rules, implementing powers should be conferred on the Commission to establish a list of diseases which are subject to Union notification and Union reporting rules as provided for in this Regulation and to establish the necessary procedures, formats, data and information exchanges regarding disease notification and reporting.

(61) Surveillance is a key element of disease control policy. It should provide for the early detection of transmissible animal diseases and efficient notification thereof, thereby enabling the sector concerned and the competent authority to implement, where feasible, timely disease prevention and control measures, and allowing the disease in question to be eradicated. Furthermore, it should supply information on the animal health status of each Member State and of the Union, thereby substantiating certification of freedom from disease and facilitating trade with third countries.

(62) Operators observe their animals on a regular basis and are best positioned to detect abnormal mortalities or other serious disease symptoms. Operators are therefore the cornerstone of any surveillance and essential for the surveillance undertaken by the competent authority.

(63) To ensure close collaboration and exchange of information between operators and veterinarians or aquatic animal health professionals, and to supplement the surveillance undertaken by operators, establishments should, as appropriate for the type of production concerned and other relevant factors, be subject to animal health visits. In order to ensure uniform conditions for the carrying-out of animal health visits, implementing powers should be conferred on the Commission to lay down minimum requirements.

(64) It is essential that the competent authority have in place a system of surveillance for the listed diseases which are subject to surveillance. This should also apply to emerging diseases, where the potential health risks of the disease concerned should be assessed and epidemiological data collected for that assessment. In order to ensure the best use of resources, information should be collected, shared and used in the most effective and efficient manner possible.

(65) The surveillance methodology, frequency and intensity should be adapted to each specific disease and should take into account the specific purpose of the surveillance, the animal health status in the zone concerned and any additional surveillance conducted by operators. The appropriate epidemiological surveillance actions could range from a simple notification and reporting of the occurrence or suspicion of a listed or an emerging disease, or other anomalies, such as abnormal mortalities and other signs of disease, to a specific and comprehensive surveillance programme, which would normally include additional sampling and testing regimes.

(66) Depending on the epidemiological profile of a disease and the relevant risk factors, a specific surveillance programme comprising defined and structured activities may need to be put in place. In such cases, it is appropriate that Member States develop targeted surveillance programmes. Where such programmes are relevant for the Union as a whole, rules should be laid down providing for harmonised application of such programmes.

(67) Such programmes should be consistent with Union objectives and therefore coordinated at Union level. To that end, they should be submitted to the Commission. Furthermore, Member States implementing such specific surveillance programmes should also submit regular reports on the results of those programmes to the Commission. In order to ensure uniform conditions for the implementation of surveillance programmes, implementing powers should be conferred on the Commission to establish a list of diseases subject to surveillance programmes and to set up harmonised procedures, formats, data, information exchange and criteria to be used for the evaluation of the surveillance programmes.

(68) It will often be necessary to provide details about the appropriate format of surveillance for different diseases, ranging from those diseases where surveillance can be limited to activities such as reporting and notification to diseases where an in–depth Union–wide specific surveillance programme needs to be established. Therefore, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the surveillance design, the criteria to establish the relevance of a disease to be subject to a surveillance programme relevant for the Union and for official confirmation of outbreaks, the case definitions of the diseases concerned and requirements for surveillance programmes in relation to their content, the information to be included in such programmes and their period of application.

(69) Member States that are not free or are not known to be free from listed diseases which are subject to eradication measures as provided for in this Regulation should be required to establish compulsory eradication programmes to eradicate those diseases where eradication is compulsory in the Union.

(70) On the other hand, there are some diseases which are of Union concern but for which it is not necessary to require Member States to eradicate the disease in question. It should be open to Member States to establish optional eradication programmes for such diseases if they decide that eradication is important for them. Such optional eradication programmes would be recognised at Union level and would entail the implementation of certain relevant disease control measures. They may also enable the Member State concerned, subject to approval by the Commission, to require certain guarantees when receiving animals from other Member States or from third countries.

(71) In order to ensure uniform conditions for the implementation of disease eradication programmes, implementing powers should be conferred on the Commission to lay down the procedures for the submission of such programmes, performance indicators, and reporting.

(72) Furthermore, a Member State should have the possibility of declaring the whole of its territories, zones or compartments thereof free of one or more of listed diseases which are subject to rules on compulsory or optional eradication programmes, in order to be protected against the introduction of such listed diseases from other parts of the Union or from third countries or territories. A clear harmonised procedure, including the necessary criteria for disease–free status, should be established for that purpose. In order to ensure uniform conditions for the implementation of the recognition of disease–free status within the Union, it is necessary that such a disease–free status be officially approved, and implementing powers to approve such status should therefore be conferred on the Commission.

(73) The OIE has introduced the concept of compartmentalisation in the framework of the Terrestrial and Aquatic Animal Health Codes ('the OIE Codes'). In Union legislation adopted prior to this Regulation, that concept is recognised only for particular animal species and diseases specified in specific Union legislation, namely for avian influenza and aquatic animal diseases. This Regulation should establish the possibility of using the compartment system for other animal species and diseases. In order to lay down the detailed conditions and rules for the recognition and approval of compartments and the requirements relating to them, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission.

(74) Member States should make their disease–free territories, zones and compartments thereof publicly known for the purpose of informing trading partners and facilitating trade.

(75) In order to lay down the detailed conditions for the recognition of disease–free status, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the criteria and

conditions for obtaining such status, the evidence needed to substantiate certification of freedom from disease, special disease prevention and control measures, including non–vaccination status, where relevant, restrictions, information to be provided, derogations, and conditions for the maintenance, suspension, withdrawal or restoration of disease–free status.

(76) In order to ensure uniform conditions for the implementation of procedures to obtain disease-free status, implementing powers should be conferred on the Commission to establish the listed diseases which may be subject to compartmentalisation and to lay down detailed rules on formats for the submission of applications and exchanges of information.

(77) The presence of an entirely non–immune population of animals, susceptible to certain listed diseases, requires permanent disease awareness and preparedness. Contingency plans have proved to be a crucial tool for the successful control of disease emergencies in the past. In order to ensure the availability of this effective and efficient tool for the control of disease emergencies, and that it is sufficiently flexible to adjust to emergency situations, implementing powers should be conferred on the Commission to lay down necessary rules for the implementation of contingency plans.

(78) Past animal health crises have shown the benefits of having specific, detailed and rapid procedures for the management of disease emergencies. Those organisational procedures should ensure a rapid and effective response and should improve coordination of efforts on the part of all parties involved, including in particular the competent authorities and the stakeholders. They should also include cooperation with the competent authorities of neighbouring Member States and third countries and territories, where feasible and relevant.

(79) To ensure the applicability of contingency plans in real emergency situations, it is essential to practise the systems concerned and to test that they are working. To that end, the competent authorities of the Member States should carry out simulation exercises, in cooperation with the competent authorities of the neighbouring Member States and third countries and territories, where feasible and relevant.

(80) In order to ensure uniform conditions for the implementation of contingency plans and simulation exercises, implementing powers should be conferred on the Commission to lay down rules for the practical implementation of those plans and exercises.

(81) Veterinary medicinal products such as vaccines, hyper-immune sera and antimicrobials play an important role in the prevention and control of transmissible animal diseases. The Impact Assessment for the adoption of this Regulation highlights in particular the importance of vaccines as a tool in the prevention, control and eradication of animal diseases.

(82) However, control strategies for some transmissible animal diseases require prohibition or restriction of the use of certain veterinary medicinal products, as their use would hamper the effectiveness of those strategies. For example, certain veterinary medicinal products may mask the manifestation of a disease, make the detection of a disease agent impossible or render a swift and differential diagnosis difficult and thus endanger the correct detection of disease.

(83) However, those control strategies may vary substantially between different listed diseases. This Regulation should therefore provide for rules on the use of veterinary medicinal products for the prevention and control of certain listed diseases and for harmonised criteria to be taken into consideration when determining whether or not to use, and how to use, vaccines, hyper–immune sera and antimicrobials. In order to ensure a flexible approach and to address the specificities of different listed diseases and the availability of effective treatments, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the restrictions on, prohibitions of or obligations to use certain veterinary medicinal products within the framework of the control of certain listed diseases. In urgent cases and in order to address emerging risks with possibly devastating implications for animal or public health, the economy, society or the environment, it should be possible for the measures in this regard to be adopted by means of the urgency procedure.

(84) Following the conclusions of the expert opinion on vaccine and/or diagnostic banks for major animal diseases, steps should also be taken to make it possible for the Union and the Member States to establish reserves of antigens, vaccines and diagnostic reagents for listed diseases that represent a serious threat to animal or public

health. The establishment of a Union antigen, vaccine and diagnostic reagent bank would promote attainment of the Union's animal health objectives by permitting a quick and effective response when the resources of the bank are required, and would represent an efficient use of limited resources.

(85) In order to ensure such a quick and effective response, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the establishment and management of such banks, and safety standards and requirements for their operation. However, this Regulation should not provide for the adoption of rules on the financing of the disease prevention and control measures, including vaccination.

(86) Criteria for priority access to the Union antigen, vaccine and diagnostic reagent banks' resources should be established in order to ensure their effective distribution in emergencies.

(87) For reasons of security in relation to bio–terrorism and agro–terrorism, certain detailed information concerning the Union antigen, vaccine and diagnostic reagent banks should be treated as classified information and its publication should be prohibited. As regards the same type of information in relation to national vaccine banks, the constitutional requirements of different Member States as regards freedom of information should be respected while ensuring that the information in question is treated as classified information.

(88) In order to ensure uniform conditions for the management of the Union antigen, vaccine and diagnostic reagent banks, implementing powers should be conferred on the Commission to lay down detailed rules concerning which biological products are to be included in those banks and for which diseases, and detailed rules on the supply, quantities, storage, delivery, procedural and technical requirements for antigens, vaccines and diagnostic reagents and the frequency and content of submissions of information to the Commission.

(89) In the event of an outbreak of a listed disease considered to represent a high risk to animal or public health in the Union, Member States should ensure that immediate disease control measures to eradicate the disease in question are taken in order to protect animal and public health.

(90) The competent authority should be responsible for initiating the first investigations to confirm or rule out an outbreak of a highly contagious listed disease which is considered to represent a high risk to animal or public health in the Union.

(91) The competent authority should put in place preliminary disease control measures to prevent the possible spread of the listed disease, and should undertake an epidemiological enquiry.

(92) As soon as a listed disease is confirmed, the competent authority should take the necessary disease control measures, if necessary including the establishment of restricted zones, to eradicate and prevent the further spread of that disease.

(93) The occurrence of a listed disease in wild animals may pose a risk to public health and the health of kept animals. Special rules should therefore be laid down, where necessary, for measures to control and eradicate diseases in wild animals.

(94) There may be cases where small populations of certain animals, such as rare breeds and species, may be endangered by standard disease control measures in the event of an occurrence of a listed disease. The protection of such breeds and species may require modified measures to be taken by the competent authority. However, such modification should not hamper the overall control of that disease.

(95) For listed diseases which are not highly contagious and which are subject to compulsory rules requiring their eradication, the disease control measures should be implemented in such a way as to prevent the spread of the disease in question, in particular to non–infected areas. However, those measures may possibly be more limited than, or may be different from, those applicable in relation to the most dangerous listed diseases. This Regulation

should therefore provide for special rules for those less dangerous diseases. Member States that have an optional eradication programme in place should also implement such disease control measures. In some cases, depending on the disease profile and the epidemiological situation, eradication may be a long-term objective, while the short-term aim may be to control the disease. However, the level and intensity of disease control measures should be proportionate and should take into account the characteristics of the listed disease in question, its distribution and its significance for the Member State concerned by it and for the Union as a whole.

(96) In order to ensure the effective application of the disease control measures provided for in this Regulation by operators, pet keepers and competent authorities, and taking into account the specificities of the disease-control measures for particular listed diseases and the risk factors involved, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the detailed disease-control measures to be implemented in the event of suspicion or confirmation of a listed disease in establishments, other locations and restricted zones.

(97) In order to provide for the possibility for the Commission to adopt special disease control measures on a temporary basis in the event that the disease control measures laid down in this Regulation are not sufficient or appropriate to address the risk involved, implementing powers should be conferred on the Commission concerning the laying down of special disease control measures for a limited period of time.

(98) The registration of certain transporters and establishments keeping terrestrial animals or handling germinal products or transporting them is necessary in order to allow the competent authority to perform adequate surveillance and to prevent, control and eradicate transmissible animal diseases.

(99) To avoid unjustified administrative burdens and costs, Member States should be able, on a limited basis, to exempt from the registration obligation certain types of establishments posing a low risk. Implementing powers should be conferred on the Commission in order to achieve a harmonised approach to the granting of such exemptions. Such a harmonised approach is particularly necessary in order to prevent certain types of establishments from being excluded from the registration obligation. This is particularly relevant not only as regards those establishments which pose a more than insignificant risk to animal health but also as regards establishments which pose a more than insignificant risk to public health. An example of such risk is the keeping of animals that live in close contact with, or proximity to, humans, such as the breeding of dogs at a level involving a certain continuity of activities and a certain degree of organisation with the primary aim of their being sold for the purpose of becoming pet animals in households.

(100) Where a certain type of establishment keeping terrestrial animals or handling or storing germinal products poses a particular animal health risk, it should be subject to approval by the competent authority.

(101) To avoid unjustified administrative burdens and costs, particularly to enterprises posing a low risk, flexibility should where possible be built into the relevant measures, making it possible to adapt the system of registration and approval to local and regional conditions and production patterns.

(102) In some cases, harmonisation of certain conditions for registration or approval across the Union is desirable or necessary. For example, germinal products establishments and assembly operations should meet certain conditions and should be approved in order to comply with international standards, thereby enabling the Union to provide animal health guarantees to third countries when trading. Such conditions should also involve requirements for specific training or professional qualifications for certain very specific establishments or operations (e.g. for embryo collection teams), or even the obligation for specific supervision by the competent authority. The Commission should therefore be empowered to adopt delegated acts in accordance with Article 290 TFEU concerning those detailed requirements, in order to provide for such specific conditions.

(103) In the interest of reducing administrative burdens, registrations and approvals should, where possible, be integrated into a registration or approval system which the Member State concerned may already have established for other purposes.

(104) Operators have first–hand knowledge of the animals under their care. They should therefore maintain up–to–date records of information which is relevant for assessing the animal health status, for traceability and for an epidemiological enquiry in the event of the occurrence of a listed disease. Those records should be easily accessible to the competent authority.

(105) In order to ensure the availability of up–to–date information concerning registered establishments and operators and approved establishments, competent authorities should establish and keep a register of such establishments and operators. The power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the detailed information to be included in the register of establishments and operators.

(106) In order to be approved by the competent authority, an establishment should have to fulfil certain requirements. Before granting the approval, the competent authority should have to verify by means of an on–site visit whether all requirements have been met. In some cases, not all conditions can be met immediately, but the remaining deficiencies do not present a significant risk to animal or public health. In such cases, it should be possible for the competent authority to grant a conditional approval, followed by another on–site visit to verify that progress has been made. In those cases, the competent authority should provide the necessary effective guidance to the operators of the establishments concerned, in order that the operator in question understands the deficiency and can plan for its successful resolution.

(107) Efficient traceability is a key element of disease control policy. Identification and registration requirements specific to the different species of kept terrestrial animals and germinal products should be in place in order to facilitate the effective application of the disease prevention and control rules provided for in this Regulation. In addition, it is important to provide for the possibility of establishing an identification and registration system for species for which such arrangements do not exist at present, or when changing circumstances and risks so warrant.

(108) For certain animal species for which it is important to be able to trace individual animals or groups, a physical means of identification should be required. This entails the animal in question being physically marked, tagged, microchipped or otherwise identified by means of a method which can be seen or detected on or in its body and which cannot easily be removed.

(109) In order to ensure the smooth operation of the identification and registration system and to ensure traceability, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of obligations concerning databases, detailed identification and registration requirements concerning different animal species, including exemptions and conditions for such exemptions, and documents.

(110) It is appropriate to reduce administrative burdens and costs and to provide for flexibility of the system in circumstances where the traceability requirements can be achieved by means other than those set out in this Regulation. The Commission should therefore be empowered to adopt delegated acts in accordance with Article 290 TFEU concerning derogations from the identification and registration requirements.

(111) In order to ensure uniform conditions for the implementation of the identification and registration system and traceability, implementing powers should be conferred on the Commission to lay down rules concerning the technical specifications for databases, means of identification, documents and formats, and deadlines.

(112) An important tool for preventing the introduction and spread of a transmissible animal disease is the use of restrictions on movements of animals and products that may transmit that disease. However, restricting the movement of animals and products may have a severe economic impact and may interfere with the operation of the internal market. Such restrictions should therefore be applied only where necessary and proportionate to the risks involved. This approach is in line with the principles laid down in the SPS Agreement and the OIE international standards.

(113) The general requirements laid down in this Regulation should apply to all animal movements, such as the prohibition of the movement of animals from an establishment where there are abnormal mortalities or other disease symptoms with an undetermined cause or disease prevention requirements during transport.

(114) The legal framework currently laid down in Union animal health legislation, for the movement of terrestrial animals and products lays down harmonised rules primarily for such movements between Member States, while leaving it up to the Member States to determine the necessary movement requirements within their territory. A comparison between the current situation and an option whereby rules for movements within Member States would also be harmonised at Union level was set out at length in the impact assessment for the adoption of this

Regulation. It has been concluded that the current approach should be maintained, as complete harmonisation of all movements would be very complex and the benefits in terms of the facilitation of movements between Member States do not outweigh the negative impact this could have on the ability to control diseases.

(115) For animals that are moved between Member States, a set of basic animal health requirements should apply. In particular, animals should not be moved from establishments with abnormal mortalities or signs of disease of unknown cause. However, mortalities, even if abnormal, which are linked to scientific procedures authorised under Directive 2010/63/EU of the European Parliament and of the Council ([1]) and which are not of infectious origin related to listed diseases, should not be a reason to prevent movements of animals intended for scientific purposes.

(116) However, this Regulation should provide for flexibility in order to facilitate the movement of species and categories of terrestrial animals that pose a low risk in terms of spreading listed diseases between Member States. In addition, further possibilities for derogations should be provided for in cases where Member States or operators successfully put in place alternative risk-mitigating measures such as high levels of biosecurity and effective surveillance systems.

(117) Ungulates and poultry are groups of animal species of high economic significance and are subject to specific movement requirements under Union legislation adopted prior to this Regulation, namely Council Directives 64/432/EEC ([2]), 91/68/EEC ([3]), 2009/156/EC ([4]), 2009/158/EC ([5]) and, in part, Directive 92/65/EEC. The main rules governing the movement of animals of those species should be laid down in this Regulation. The detailed requirements which largely depend on the diseases that may be transmitted by different species or categories of animals should be regulated in subsequent Commission acts, taking into account the specificities of the diseases, species and categories of animals in question.

(118) As assembly operations for ungulates and poultry pose a particularly high risk of disease, it is appropriate to limit the number that can be carried out in one movement between Member States, and to lay down specific rules in this Regulation to protect the health of the animals involved and prevent the spread of transmissible animal diseases. Those assembly operations would normally take place in an establishment approved for that purpose, or, when permitted by a Member State of origin, the first assembly operation, on one means of transport such as a lorry, through the collection of animals from different locations in that Member State.

(119) Depending on the listed diseases and listed species concerned, it is necessary to lay down specific animal health requirements for certain animal species other than kept ungulates and poultry. Rules for these species were also laid down in the legal framework applicable prior to this Regulation and in particular in Directive 92/65/EEC. That Directive lays down specific rules for the movement of animal species including bees, bumble bees, apes, dogs and cats and this Regulation should therefore provide a legal basis for the adoption of delegated and implementing acts laying down specific movement rules for those animal species.

(120) Confined establishments, usually used for the keeping of laboratory animals or zoo animals, normally involve a high level of biosecurity and a favourable and well-controlled health status, and are subject to fewer movements or to movements solely within the closed circuits of those establishments. The status of confined establishments, for which operators may apply on a voluntary basis, was first introduced in Directive 92/65/EEC, which lays down rules and requirements for approval and movement requirements for approved bodies, institutes and centres. The system thereby established enables those establishments to exchange animals amongst themselves with fewer movement requirements, at the same time providing health guarantees within the circuit of confined establishments. Consequently, it has been broadly accepted by the operators and used as a voluntary option. It is therefore appropriate in this Regulation to preserve the concept of confined establishments and also to lay down rules for movement between those establishments.

([1]) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).
([2]) Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ 121, 29.7.1964, p. 1977/64).
([3]) Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra–Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19).
([4]) Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae (OJ L 192, 23.7.2010, p. 1).
([5]) Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs (OJ L 343, 22.12.2009, p. 74).

(121) For scientific purposes, such as research or diagnostic purposes, and in particular for those authorised in accordance with Directive 2010/63/EU, it may be necessary to move animals which do not fulfil the general animal health requirements laid down in this Regulation and which represent a higher animal health risk. Those kinds of movements should not be prohibited or unduly restricted by this Regulation, as this could impede otherwise authorised research activities and delay scientific progress. None the less, it is essential that rules be laid down in this Regulation to ensure that movements of those animals take place in a safe manner.

(122) Movement patterns of circus animals, animals kept in zoos, animals intended for exhibition and certain other animals often deviate from the movement patterns of other kept species. In adapting Union rules on animal movements specific consideration should be given to such animals, taking into account specific risks and alternative risk-mitigation measures.

(123) In order to ensure that the objectives referred to in recitals 112 to 122 of this Regulation are achieved, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning disease prevention measures in transport operations, specific rules for the movement of certain animal species and special circumstances, such as assembly operations or rejected consignments, and special requirements or derogations for other types of movements, such as movement for scientific purposes.

(124) In order to ensure the possibility of applying special rules for movements where the usual movement rules are not sufficient or appropriate to limit the spread of a certain disease, implementing powers should be conferred on the Commission to lay down special movement rules for a limited period of time.

(125) Movements of kept terrestrial animals between Member States should comply with the requirements applicable to such movements. In the case of animals of species which present a health risk or which are of greater economic importance, they should be accompanied by an animal health certificate issued by the competent authority.

(126) To the extent technically, practically and financially feasible, there should be recourse to technological developments in order to reduce the administrative burdens on operators and competent authorities in relation to certification and notification by using information technology to replace paper documentation and to facilitate notification procedures, and by using such technology as far as possible for multiple purposes.

(127) In cases where there is no requirement for an animal health certificate to be issued by a competent authority, an operator who moves animals to another Member State should issue a self–declaration document which confirms that the animals meet the movement requirements laid down in this Regulation.

(128) In order to ensure that the objectives referred to in recitals 125, 126 and 127 of this Regulation are achieved, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning rules on the content of animal health certificates, information obligations, derogations from the animal health certification requirements, specific certification rules, and the obligations of official veterinarians to conduct appropriate checks before the signing an animal health certificate.

(129) Notification of movements of animals and germinal products between Member States, and in some cases within the national territories of Member States, is essential in order to ensure the traceability of the animals and germinal products concerned, where these movements may be linked to a risk of spreading transmissible animal diseases. Such movements should therefore be notified and registered by means of an integrated computerised veterinary system ('Traces'). The Traces system integrates into a single architecture the computerised systems provided for in Article 20 of Directive 90/425/EEC and in Council Decision 92/438/EEC ([1]) respectively, based on Commission Decisions 2003/24/EC ([2]) and 2004/292/EC ([3]).

([1]) Council Decision 92/438/EEC of 13 July 1992 on computerization of veterinary import procedures (Shift project), amending Directives 90/675/EEC, 91/496/EEC, 91/628/EEC and Decision 90/424/EEC, and repealing Decision 88/192/EEC (OJ L 243, 25.8.1992, p. 27).
([2]) Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerised veterinary system (OJ L 8, 14.1.2003, p. 44).
([3]) Commission Decision 2004/292/EC of 30 March 2004 on the introduction of the Traces system and amending Decision 92/486/EEC (OJ L 94, 31.3.2004, p. 63).

(130) In order to ensure uniform conditions for the implementation of the rules laid down in this Regulation on animal health certification and movement notification, implementing powers should be conferred on the Commission to lay down rules concerning the model animal health certificates, self–declaration documents, formats and deadlines for movement notification for both terrestrial and aquatic animals, germinal products and, where also relevant, products of animal origin.

(131) The specific nature of movements of pet animals represents an animal health risk which deviates significantly from that of other kept animals. Specific, less stringent rules for such movements should therefore be laid down in this Regulation. Such less stringent rules are only justified, however, if the pet animal genuinely accompanies its owner during the owner's movement, or within a limited period thereafter, and if no more than five pet animals as referred to in Part A of Annex I are moved together with their owner at one time. In order to ensure that pet animals do not pose a significant risk for the spread of transmissible animal diseases, and in order to clarify the exceptional situations in which more than five pet animals may accompany the owner, or when the pet animal is to be moved within a longer time-frame before or after the owner moves, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the detailed rules for movements of those animals. In order to ensure uniform conditions for the implementation of the animal health requirements laid down in this Regulation concerning the movements of pet animals, implementing powers should be conferred on the Commission to lay down rules concerning the disease prevention and control measures to be taken for such movements.

(132) Wild animals may for various reasons represent an animal and public health risk, for example if they are moved into an establishment or from one environment to another environment. Appropriate preventive measures for movement of those animals may need to be taken to avoid the spread of transmissible animal diseases. In order to ensure that wild animals do not pose a significant risk for the spread of transmissible animal diseases, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the additional requirements for movements of wild terrestrial animals.

(133) Germinal products can represent a similar risk of spreading transmissible animal diseases to live animals. In addition, there are specificities in their production which are related to high health demands for breeding animals and which call for stricter or particular animal health requirements concerning the donor animals. In order to ensure safe movements of germinal products, to maintain their expected high health standard and to take into account certain specific uses of such products, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the detailed requirements for movement of germinal products of certain animal species, special requirements applicable to, for example, their movement for scientific purposes, and derogations from the animal health certification obligation.

(134) Products of animal origin can represent a risk for the spreading of transmissible animal diseases. Food safety requirements for products of animal origin laid down in Union legislation ensure good hygiene practices and reduce the animal health risks of such products. However, for certain types of products, specific animal health measures, such as disease control and emergency measures, should be laid down in this Regulation in order to ensure that products of animal origin do not spread animal diseases. In order to ensure safe movements of products of animal origin in these particular cases, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the establishment of detailed rules for movements of products of animal origin in relation to disease control measures taken, the obligations in respect of animal health certification and derogations from those rules where the risk involved with such movements and the risk-mitigation measures in place so permit.

(135) When Member States take national measures concerning movements of animals and germinal products, or decide to take national measures to limit the impact of transmissible animal diseases other than listed diseases within their territory, those national measures should not interfere with the rules on the internal market laid down in Union legislation. It is therefore appropriate to set the framework for such national measures and to ensure that they remain within the limits permitted under Union law.

(136) The registration and approval of aquaculture establishments is necessary in order to allow the competent authority to perform adequate surveillance and to prevent, control and eradicate transmissible animal diseases. Directive 2006/88/EC requires all establishments which move aquatic animals to be authorised. That system of

authorisation should be maintained under this Regulation, notwithstanding the fact that, in some official languages of the Union, this Regulation uses different terms to refer to the authorisation system from those used in Directive 2006/88/EC.

(137) The slaughter and processing of aquaculture animals which are subject to disease control measures may spread transmissible animal diseases, for example as a result of the discharge from processing establishments of effluents containing pathogens. It is therefore necessary to approve processing establishments which fulfil the risk-mitigation measures for such slaughter and processing operations. This Regulation should therefore provide for the approval of disease control aquatic food establishments.

(138) In order to ensure the availability to the public of up–to–date information concerning registered and approved establishments, the competent authority should establish and keep a register of such establishments. The power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the information to be included in registers of aquaculture establishments and the record-keeping requirements for aquaculture establishments and transporters.

(139) In order to ensure uniform conditions for the implementation of the rules laid down in this Regulation concerning the registration and approval of aquaculture establishments and disease control aquatic food establishments, record-keeping and registers of establishments, implementing powers should be conferred on the Commission to lay down rules concerning the information obligations, derogations and other implementing rules in that regard.

(140) As it is not feasible in most cases to individually identify aquatic animals, the keeping of records by aquaculture establishments, disease control aquatic food establishments and transporters is an essential tool in ensuring the traceability of aquatic animals. Records also serve as a valuable tool for the surveillance of the health situation of establishments.

(141) As in the case of terrestrial animals, it is necessary to lay down harmonised rules on the movement of aquatic animals, including rules on animal health certification and movement notification.

(142) Directive 2006/88/EC lays down rules for movements of aquatic animals which apply equally to movements within and between Member States. The key determining factor in relation to rules on the movement of aquatic animals is the health status, as regards listed diseases, of the Member State, zones and compartments of destination.

(143) However, Directive 2006/88/EC excludes from its scope wild aquatic animals caught or harvested for direct entry into the food chain. By contrast, this Regulation retains them within its scope, but excludes them from the definition of aquaculture animals. It should therefore provide for possible measures in relation to such aquatic animals where, taking into account their proportionality, such measures are justified by the risks involved.

(144) Consequently, the principle explained in recital 142 should also apply to movements of aquatic animals that are not defined as aquaculture animals but are covered by the scope of this Regulation. This applies, in particular, to aquatic animals with an unknown or confirmed disease positive health status, regardless of their final use. As movements of live wild aquatic animals with an unknown or confirmed disease positive health status and intended for human consumption may also pose a risk of spreading listed or emerging diseases, the same system of rules should also apply to them. This includes those wild aquatic animals, harvested or caught for human consumption, which are moved and temporarily kept while awaiting slaughter.

(145) However, disproportionate movement restrictions and unnecessary administrative burdens for establishments and operators within the commercial fisheries sector should be avoided. Consequently, in cases where such live wild aquatic animals are intended for human consumption, the rules in question should in principle apply only to movements of live wild aquatic animals which pose a significant risk of spreading listed or emerging diseases into

Member States, zones or compartments which have been declared free of certain listed diseases or which are subject to eradication programmes with regard to those diseases.

(146) To encourage Member States to enhance the health status of their aquatic populations, certain adjustments and added flexibility should be introduced in this Regulation.

(147) In order to ensure control of the movement of aquatic animals, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the disease prevention measures applicable to transport, specific rules applicable to movements of certain categories of aquatic animals for different purposes, specific requirements or derogations in respect of certain types of movements, such as movements for scientific purposes, and additional requirements for movements of wild aquatic animals.

(148) In order to ensure the possibility of temporary derogations and specific requirements for movements of aquatic animals, where the movement rules laid down in this Regulation are not sufficient or appropriate to limit the spread of a particular listed disease, implementing powers should be conferred on the Commission to lay down special movement rules or derogations for a limited period of time.

(149) Union aquaculture production is extremely diverse as regards species and production systems, and this diversification is rapidly increasing. This may require the adoption at Member State level of national measures concerning diseases other than those regarded as listed diseases in accordance with this Regulation. However, such national measures should be justified, necessary and proportionate to the goals to be achieved. Furthermore, they should not affect movements between Member States unless they are necessary in order to prevent the introduction, or to control the spread, of disease. National measures affecting trade between Member States should be approved and regularly reviewed at Union level.

(150) Currently, listed diseases concern animal species other than those defined by this Regulation as terrestrial and aquatic species, such as reptiles, amphibians, insects and others, only to a very limited extent. It is therefore not appropriate to require that all the provisions of this Regulation should apply to those animal species. However, if a disease which concerns species other than terrestrial and aquatic species should become listed, the relevant animal health requirements of this Regulation should apply to those species, in order to ensure that adequate and proportionate disease prevention and control measures may be taken.

(151) In order to ensure the possibility of laying down movement rules for animals that are not defined as terrestrial or aquatic animals by this Regulation, and germinal products and products of animal origin deriving from such animals, when a risk so warrants, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the registration and approval of establishments, record-keeping and registers, identification and registration and traceability movement requirements, animal health certification and self–declaration and movement notification obligations in respect of animals, germinal products and products of animal origin deriving from those species.

(152) Whenever necessary in order to ensure uniform conditions for the implementation of the animal health requirements for those other animal species and germinal products and products of animal origin deriving from them, implementing powers should be conferred on the Commission to lay down detailed rules concerning those requirements.

(153) In order to prevent the introduction of listed diseases and emerging diseases into the Union, it is necessary to have in place efficient rules on the entry into the Union of animals, germinal products and products of animal origin that may transmit such diseases.

(154) In order to guarantee the health status of the Union, this Regulation lays down provisions concerning movements of animals and products within the Union. It is therefore appropriate, so as not to jeopardise that status, to impose conditions for the entry of animals and products into the Union that are no less strict than those applicable to movements within the Union.

(155) In order to ensure that animals, germinal products and products of animal origin from third countries or territories fulfil animal health requirements that provide guarantees equivalent to those provided for in Union legislation, it is essential that they be subject to appropriate controls by the competent authority of the third country or territory from which they are exported to the Union. Where relevant, the health status of a third country or territory of origin should be verified prior to accepting entry into the Union of such animals, germinal products and products of animal origin. Consequently, only third countries and territories which can demonstrate that they meet the animal health standards for entry of the animals and products into the Union should be eligible to export them to the Union and be listed for that purpose.

(156) For some species and categories of animals, germinal products and products of animal origin, the Union lists of third countries and territories from which entry into the Union is permitted have not been established in Union acts adopted prior to the date of adoption of this Regulation. In those cases, pending the adoption of rules pursuant to this Regulation, Member States should be permitted to determine from which countries and territories those animals, germinal products and products of animal origin may be permitted to enter their territory. In so determining, Member States should take into account the criteria laid down in this Regulation for the Union lists of third countries and territories.

(157) In order to ensure that the animal health requirements for entry into the Union provided for in this Regulation are complied with, and that they are in line with the principles of the OIE Codes, all animals, germinal products and products of animal origin entering the Union should be accompanied by an animal health certificate issued by the competent authority of the third country or territory of origin confirming that all the animal health requirements for entry into the Union are complied with. However, deviation from this rule should be permitted in respect of commodities which pose a low animal health risk.

(158) Animal health certificates may stand on their own, but certification is often required in Union legislation for other purposes, for example in order to certify that public health or animal welfare requirements of animals or products have been complied with. This has to be taken into account. In order to minimise administrative burdens and costs, those animal health certificates should also be permitted to include information required under other Union legislation concerning food and feed safety and animal welfare.

(159) Diseases may be spread by means other than animals, germinal products, products of animal origin and animal by–products and derived products. For instance, vehicles, transport containers, hay, straw, plant products, materials that may have been in contact with infected animals and equipment may also spread disease. Where necessary, measures should be taken to prevent disease transmission by those means.

(160) In order to ensure the appropriate level of detail for the requirements for entry into the Union, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the adoption of supplementary rules for the approval of establishments in third countries and territories and derogations, animal health requirements for the entry into the Union of consignments from third countries and territories and animal health requirements for disease agents, other materials, means of transport and equipment which may transmit animal diseases.

(161) In order to ensure uniform conditions for the implementation of animal health requirements for the entry into the Union of consignments of animals, germinal products and products of animal origin, implementing powers should be conferred on the Commission to lay down rules on, inter alia, the list of third countries and territories from which the entry into the Union of animals, germinal products and products of animal origin is allowed and on the contents and format of model animal health certificates.

(162) Past experience has shown that when an outbreak of a serious disease occurs in Member States or in third countries or territories from which animals or products enter the Union, disease prevention and control measures have to be taken immediately to prevent its introduction and limit its spread. Such an emergency may

involve listed diseases, emerging diseases or other animal health hazards. In that context, it should be made clear which disease prevention and control measures provided for by this Regulation may be used in the event of the occurrence of a listed or emerging disease or hazard. In all such cases, it is essential that measures can be taken at very short notice and without any delay. As such measures would restrict movement within or into the Union, they should be implemented at Union level whenever possible.

(163) In order to ensure an effective and quick reaction to emerging risks, implementing powers should be conferred on the Commission to lay down emergency measures.

(164) The Commission should adopt immediately applicable implementing acts in duly justified cases relating to, inter alia, measures regarding emerging diseases, the stocking, supply, storage, delivery and other procedures of Union antigen, vaccine and diagnostic reagent banks, the laying down of special disease control measures and derogations for a limited period of time, special rules on movements for terrestrial and aquatic animals applying for a limited period of time, emergency measures, and the listing of third countries and territories for the purposes of entry into the Union.

(165) This Regulation lays down general and specific rules for the prevention and control of transmissible animal diseases and ensures a harmonised approach to animal health across the Union. In some areas, such as general responsibilities for animal health, notification, surveillance, registration and approval or traceability, the Member States should be allowed or encouraged to apply additional or more stringent national measures. However, such national measures should be permitted only if they do not compromise the animal health objectives set out in this Regulation and are not inconsistent with the rules laid down herein, and provided that they do not hinder movements of animals and products between Member States, unless this is necessary in order to prevent the introduction, or to control the spread, of disease.

(166) The national measures referred to in recital 165 should be subject to a simplified notification procedure in order to reduce the administrative burden. Experience has shown that the general notification procedure laid down in Directive 98/34/EC of the European Parliament and of the Council ([1]) has been an important tool for guiding and improving the quality of national technical regulations — in terms of increased transparency, readability and effectiveness — in non–harmonised or partly harmonised areas. It is therefore appropriate that this general notification procedure applies.

(167) Currently, Union rules on animal health are laid down in the following acts of the European Parliament and of the Council and in subsequent Commission acts adopted pursuant to them:

Directive 64/432/EEC, Council Directive 77/391/EEC ([2]), Council Directive 78/52/EEC ([3]), Council Directive 80/1095/EEC ([4]), Council Directive 82/894/EEC ([5]), Council Directive 88/407/EEC ([6]), Council Directive 89/556/EEC ([7]), Council Directive 90/429/EEC ([8]),

([1]) Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37).
([2]) Council Directive 77/391/EEC of 17 May 1977 introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle (OJ L 145, 13.6.1977, p. 44).
([3]) Council Directive 78/52/EEC of 13 December 1977 establishing the Community criteria for national plans for the accelerated eradication of brucellosis, tuberculosis and enzootic leukosis in cattle (OJ L 15, 19.1.1978, p. 34).
([4]) Council Directive 80/1095/EEC of 11 November 1980 laying down conditions designed to render and keep the territory of the Community free from classical swine fever (OJ L 325, 1.12.1980, p. 1).
([5]) Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community (OJ L 378, 31.12.1982, p. 58).
([6]) Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra–Community trade in and imports of semen of domestic animals of the bovine species (OJ L 194, 22.7.1988, p. 10).
([7]) Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra–Community trade in and importation from third countries of embryos of domestic animals of the bovine species (OJ L 302, 19.10.1989, p. 1).
([8]) Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra–Community trade in and imports of semen of domestic animals of the porcine species (OJ L 224, 18.8.1990, p. 62).

Directive 91/68/EEC, Council Decision 91/666/EEC ([1]), Council Directive 92/35/EEC ([2]), Directive 92/65/EEC, Council Directive 92/66/EEC ([3]), Council Directive 92/118/EEC ([4]), Council Directive 92/119/EEC ([5]), Council Decision 95/410/EC ([6]), Council Directive 2000/75/EC ([7]), Council Decision 2000/258/EC ([8]), Council Directive 2001/89/EC ([9]),

Council Directive 2002/60/EC ([10]), Council Directive 2002/99/EC ([11]), Council Directive 2003/85/EC ([12]), Council Regulation (EC) No 21/2004 ([13]), Council Directive 2004/68/EC ([14]), Council Directive 2005/94/EC ([15]), Directive 2006/88/EC, Council Directive 2008/71/EC ([16]), Directive 2009/156/EC, Directive 2009/158/EC, Regulation (EU) No 576/2013 of the European Parliament and of the Council ([17]).

(168) This Regulation provides for the rules on the identification and registration of bovine animals while rules for beef labelling remain outside of its scope. Regulation (EC) No 1760/2000 of the European Parliament and of the Council ([18]) provides for the rules on the identification and registration of bovine animals and for the rules on beef labelling. It should thus be amended to repeal its provisions on the identification and registration of bovine animals while those concerning beef labelling would have to remain in force.

(169) With a view to guaranteeing the reliability of the arrangements provided for in existing Regulations establishing systems for the identification and registration of bovine, ovine and caprine animals, that legislation requires the Member States to carry out adequate and efficient control measures. Such adequate and efficient official control measures should also be preserved in the future. As part of the 'Smarter rules for safer food' package of proposals, this Regulation does not envisage provisions on official controls since those rules should be provided for in the framework of the proposed horizontal legislation on official controls. However, even if the proposed new horizontal rules on official controls were not to enter into force at the same time as this Regulation, the

([1]) Council Decision 91/666/ EEC of 11 December 1991 establishing Community reserves of foot–and–mouth disease vaccines (OJ L 368, 31.12.1991, p. 21).
([2]) Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness (OJ L 157, 10.6.1992, p. 19).
([3]) Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease (OJ L 260, 5.9.1992, p. 1).
([4]) Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC (OJ L 62, 15.3.1993, p. 49).
([5]) Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease (OJ L 62, 15.3.1993, p. 69).
([6]) Council Decision 95/410/EC of 22 June 1995 laying down the rules for the microbiological testing by sampling in the establishment of origin of poultry for slaughter intended for Finland and Sweden (OJ L 243, 11.10.1995, p. 25).
([7]) Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue (OJ L 327, 22.12.2000, p. 74).
([8]) Council Decision 2000/258/EC of 20 March 2000 designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines (OJ L 79, 30.3.2000, p. 40).
([9]) Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever (OJ L 316, 1.12.2001, p. 5).
([10]) Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever (OJ L 192, 20.7.2002, p. 27).
([11]) Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (OJ L 18, 23.1.2003, p. 11).
([12]) Council Directive 2003/85/EC of 29 of September 2003 on Community measures for the control of foot–and–mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (OJ L 306, 22.11.2003, p. 1).
([13]) Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC (OJ L 5, 9.1.2004, p. 8).
([14]) Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC (OJ L 139, 30.4.2004, p. 321).
([15]) Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC (OJ L 10, 14.1.2006, p. 16).
([16]) Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (OJ L 213, 8.8.2008, p. 31).
([17]) Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non–commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1).
([18]) Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 (OJ L 204, 11.8.2000, p. 1).

existing horizontal rules on official controls would allow the Commission to ensure an equivalent level of control.

(170) The rules laid down in the legislative acts referred to in recital 167 are to be replaced by this Regulation and by subsequent Commission acts to be adopted pursuant to this Regulation. Accordingly, those legislative acts should be repealed. However, to ensure legal clarity and avoid a legal vacuum, the repeal should in the first place take effect only when the relevant delegated and implementing acts are adopted pursuant to this Regulation. It is therefore necessary to empower the Commission to determine the dates when the repeal of those legislative acts is to take effect, while the legislator should set a deadline.

(171) The following Council acts in the area of animal health are obsolete and should be expressly repealed in the interests of clarity of Union legislation: Council Decision 78/642/EEC ([1]), Council Directive 79/110/EEC ([2]), Council Directive 81/6/EEC ([3]), Council Decision 89/455/EEC ([4]), Council Directive 90/423/EEC ([5]), Council Decision 90/678/EEC ([6]), Council Directive 92/36/EEC ([7]), Council Directive 98/99/EC ([8]).

(172) The requirements set out in this Regulation should not apply until the key delegated and implementing acts have been adopted by the Commission pursuant to this Regulation, allowing a period of 24 months from the adoption of the key acts until the date when they start to apply, thus permitting Member States and operators to duly adapt to the new rules. In addition, it is appropriate to provide for a period of at least 36 months for the Commission to elaborate the new rules.

(173) In order to ensure legal certainty as regards the application of rules for the identification and registration of animals and disease control measures for certain animal diseases and zoonoses, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the date on which Regulation (EC) No 21/2004 and Directives 92/66/EEC, 2000/75/EC, 2001/89/EC, 2002/60/EC, 2003/85/EC, 2005/94/EC and 2008/71/EC are to cease to apply, whilst a deadline in that regard should be set in this Regulation.

(174) In line with the preventive approach to animal health that is promoted by this Regulation, the special measures concerning salmonella that applied to live animals dispatched to Finland and Sweden prior to 20 April 2016 should continue to apply and Regulation (EC) No 2160/2003 should be amended accordingly.

(175) Considering the recent adoption of Regulation (EU) No 576/2013, it is desirable to allow for a long transitional period before the corresponding rules set out in this Regulation start to apply.

(176) The implementing powers provided for in this Regulation should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ([9]).

([1]) Council Decision 78/642/EEC of 25 July 1978 on health protection measures in respect of the Republic of Botswana (OJ L 213, 3.8.1978, p. 15).

([2]) Council Directive 79/110/EEC of 24 January 1979 authorizing the Italian Republic to postpone the notification and implementation of its national plans for the accelerated eradication of brucellosis and tuberculosis in cattle (OJ L 29, 3.2.1979, p. 24).

([3]) Council Directive 81/6/EEC of 1 January 1981 authorizing the Hellenic Republic to communicate and to implement its national plans for the accelerated eradication of brucellosis and tuberculosis in cattle (OJ L 14, 16.1.1981, p. 22).

([4]) Council Decision 89/455/EEC of 24 July 1989 introducing Community measures to set up pilot projects for the control of rabies with a view to its eradication or prevention (OJ L 223, 2.8.1989, p. 19).

([5]) Council Directive 90/423/EEC of 26 June 1990 amending Directive 85/511/EEC introducing Community measures for the control of foot–and–mouth disease, Directive 64/432/EEC on animal health problems affecting intra- Community trade in bovine animals and swine and Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat or meat products from third countries (OJ L 224, 18.8.1990, p. 13).

([6]) Council Decision 90/678/EEC of 13 December 1990 recognizing certain parts of the territory of the Community as being either officially swine fever free or swine fever free (OJ L 373, 31.12.1990, p. 29).

([7]) Council Directive 92/36/EEC of 29 April 1992 amending, with regard to African horse sickness, Directive 90/426/EEC on animal health conditions governing the movement and import from third countries of equidae (OJ L 157, 10.6.1992, p. 28).

([8]) Council Directive 98/99/EC of 14 December 1998 amending Directive 97/12/EC amending and updating Directive 64/432/EEC on health problems affecting intra–Community trade in bovine animals and swine (OJ L 358, 31.12.1998, p. 107).

([9]) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(177) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(178) This Regulation should not create a disproportionate administrative burden or economic impact for small and medium-sized enterprises. Under this Regulation, based on consultation with stakeholders, the special situation of small and medium-sized enterprises has been taken into account. A potential universal derogation from the requirements of this Regulation for such enterprises has not been considered, in view of the public policy objectives of protecting animal health and public health. However, a number of derogations for such enterprises should be provided for in relation to the different requirements of this Regulation, taking into account the risks involved.

(179) Since the objectives of this Regulation, namely to lay down animal health rules for animals, germinal products, products of animal origin, animal by–products and derived products to the extent that they are not covered by specific rules in other Union legislation, and other material that may be involved in the spread of transmissible animal diseases, cannot be sufficiently achieved by the Member States but can rather be better achieved at Union level through a common and coordinated legal framework for animal health, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

PART I

GENERAL RULES

CHAPTER 1

Subject matter, aim, scope and definitions

Article 1

Subject matter and aim

1. This Regulation lays down rules for the prevention and control of animal diseases which are transmissible to animals or to humans.

Those rules provide for:

(a) the prioritisation and categorisation of diseases of Union concern and for the establishment of responsibilities for animal health (Part I: Articles 1 to 17);

(b) the early detection, notification and reporting of diseases, surveillance, eradication programmes and disease–free status (Part II: Articles 18 to 42);

(c) disease awareness, preparedness and control (Part III: Articles 43 to 83);

(d) the registration and approval of establishments and transporters, movements and traceability of animals, germinal products and products of animal origin within the Union (Part IV: Articles 84 to 228; and Part VI: Articles 244 to 248 and 252 to 256);

(e) the entry of animals, germinal products, and products of animal origin into the Union and the export of such consignments from the Union (Part V: Articles 229 to 243; and Part VI: Articles 244 to 246 and 252 to 256);

(f) non–commercial movements of pet animals into a Member State from another Member State or from a third country or territory, (Part VI: Articles 244 to 256);

(g) the emergency measures to be taken in the event of a disease emergency situation (Part VII: Articles 257 to 262).

2. The rules referred to in paragraph 1:

(a) aim to ensure:

(i) improved animal health to support sustainable agricultural and aquaculture production in the Union;

(ii) the effective functioning of the internal market;

(iii) a reduction in the adverse effects on animal health, public health and the environment of:

— certain diseases;

— the measures taken to prevent and control diseases;

(b) take into account:

(i) the relationship between animal health and:

— public health;

— the environment, including biodiversity and valuable genetic resources, as well as the impact of climate change;

— food and feed safety;

— animal welfare, including the sparing of any avoidable pain, distress or suffering;

— antimicrobial resistance;

— food security;

(ii) the economic, social, cultural and environmental consequences arising from the application of disease control and prevention measures;

(iii) relevant international standards.

Article 2

Scope

1. This Regulation shall apply to:

(a) kept and wild animals;

(b) germinal products;

(c) products of animal origin;

(d) animal by–products and derived products, without prejudice to the rules laid down in Regulation (EC) No 1069/2009;

(e) facilities, means of transport, equipment and all other paths of infection and material involved or potentially involved in the spread of transmissible animal diseases.

2. This Regulation shall apply to transmissible diseases, including zoonoses, without prejudice to the rules laid down in:

(a) Decision No 1082/2013/EU;

(b) Regulation (EC) No 999/2001;

(c) Directive 2003/99/EC;

(d) Regulation (EC) No 2160/2003.

Article 3

Scope of Parts IV, V and VI

1. Title I of Part IV (Articles 84 to 171) shall apply to:

(a) terrestrial animals, and animals which are not terrestrial animals but which may transmit diseases affecting terrestrial animals;

(b) germinal products from terrestrial animals;

(c) products of animal origin from terrestrial animals.

2. Title II of Part IV (Articles 172 to 226) shall apply to:

(a) aquatic animals, and animals which are not aquatic animals but which may transmit diseases affecting aquatic animals;

(b) products of animal origin from aquatic animals.

3. Title III of Part IV (Articles 227 and 228) shall apply to:

(a) other animals;

(b) germinal products and products of animal origin from the other animals referred to in point (a).

4. Parts IV and V shall not apply to non–commercial movements of pet animals as referred to in paragraph 6 of this Article or to non–commercial movements of pet animals within a Member State.

5. Movements of pet animals, other than non–commercial movements, shall comply with the animal health requirements laid down in Parts IV and V.

The Commission shall adopt delegated acts in accordance with Article 264 concerning the adaptations which are necessary in order to ensure that Parts IV and V are correctly applied to pet animals, in particular to take account of the fact that pet animals are kept in households by pet keepers.

6. Part VI shall only apply to non–commercial movements of pet animals that comply with the requirements laid down in Articles 245 and 246 as regards the maximum number of animals that may accompany their owner and the maximum number of days elapsing between the movement of the owner and the movement of the animal.

Article 4

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) 'animals' means vertebrate and invertebrate animals;

(2) 'terrestrial animals' means birds, terrestrial mammals, bees and bumble bees;

(3) 'aquatic animals' means animals of the following species, at all life stages, including eggs, sperm and gametes:

  (a) fish belonging to the superclass *Agnatha* and to the classes *Chondrichthyes*, *Sarcopterygii* and *Actinopterygii*;

  (b) aquatic molluscs belonging to the phylum *Mollusca*;

  (c) aquatic crustaceans belonging to the subphylum *Crustacea*;

(4) 'other animals' means animals of species other than those falling within the definition of terrestrial or aquatic animals;

(5) 'kept animals' means animals which are kept by humans, including, in the case of aquatic animals, aquaculture animals;

(6) 'aquaculture' means the keeping of aquatic animals where the animals remain the property of one or more natural or legal persons throughout the rearing or culture stages, up to and including harvesting, excluding the harvesting or catching for the purposes of human consumption of wild aquatic animals which are subsequently temporarily kept while awaiting slaughter without being fed;

(7) 'aquaculture animals' means any aquatic animals subject to aquaculture,

(8) 'wild animals' means animals which are not kept animals;

(9) 'poultry' means birds that are reared or kept in captivity for:

(a) the production of:

(i) meat;

(ii) eggs for consumption;

(iii) other products;

(b) restocking supplies of game birds;

(c) the purpose of breeding of birds used for the types of production referred to in points (a) and (b);

(10) 'captive birds' means any birds other than poultry that are kept in captivity for any reason other than those referred to in point (9), including those that are kept for shows, races, exhibitions, competitions, breeding or selling;

(11) 'pet animal' means a kept animal of the species listed in Annex I which is kept for private non–commercial purposes;

(12) 'pet keeper' means a natural person, and may include a pet owner, keeping a pet animal;

(13) 'pet owner' means a natural person indicated as the owner in the identification document referred to in point (c) of Article 247, point (c) of Article 248(2), point (c) of Article 249(1) and point (c) of Article 250(2);

(14) 'non–commercial movement' means any movement of a pet animal accompanying its owner and which

(a) does not have as its aim either the sale of or another form of transfer of ownership of the pet animal concerned; and

(b) is part of the movement of the pet owner:

(i) either under his direct responsibility; or

(ii) under the responsibility of an authorised person, in cases where the pet animal is physically separated from the pet owner;

(15) 'authorised person' means any natural person who has authorisation in writing from the pet owner to carry out the non–commercial movement of the pet animal on behalf of the pet owner;

(16) 'disease' means the occurrence of infections and infestations in animals, with or without clinical or pathological manifestations, caused by one or more disease agents;

(17) 'disease agent' means a pathogen transmissible to animals or to humans which is capable of causing a disease in animals;

(18) 'listed diseases' means diseases listed in accordance with Article 5(1);

(19) 'disease profile' means the criteria of a disease referred to in point (a) of Article 7;

(20) 'listed species' means an animal species or group of animal species listed in accordance with Article 8(2), or, in the case of emerging diseases, an animal species or group of animal species which meets the criteria for listed species laid down in Article 8(2);

(21) 'hazard' means a disease agent in, or a condition of, an animal or product with the potential to have an adverse effect on the health of humans or animals;

(22) 'risk' means the likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse effect on animal or public health;

(23) 'biosecurity' means the sum of management and physical measures designed to reduce the risk of the introduction, development and spread of diseases to, from and within:

(a) an animal population, or

(b) an establishment, zone, compartment, means of transport or any other facilities, premises or location;

(24) 'operator' means any natural or legal person having animals or products under his responsibility, including for a limited duration of time, but excluding pet keepers and veterinarians;

(25) 'transporter' means an operator transporting animals on his own account or on account of a third party;

(26) 'animal professional' means a natural or legal person having an occupational relationship with animals or products, other than operators or veterinarians;

(27) 'establishment' means any premises, structure, or, in the case of open-air farming, any environment or place, where animals or germinal products are kept, on a temporary or permanent basis, except for:

(a) households where pet animals are kept;

(b) veterinary practices or clinics;

(28) 'germinal products' means:

(a) semen, oocytes and embryos intended for artificial reproduction;

(b) hatching eggs;

(29) 'products of animal origin' means:

(a) food of animal origin, including honey and blood;

(b) live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, intended for human consumption; and

(c) animals other than those referred to in point (b) intended to be prepared with a view to being supplied live to the final consumer;

(30) 'animal by–products' means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, excluding germinal products;

(31) 'derived products' means products obtained from one or more treatments, transformations or steps in the processing of animal by–products;

(32) 'products' means:

(a) germinal products;

(b) products of animal origin;

(c) animal by–products and derived products;

(33) 'official control' means any form of control carried out by a competent authority for the purpose of verifying compliance with this Regulation;

(34) 'health status' means the disease status as regards the listed diseases relevant for a particular listed species with respect to:

(a) an animal;

(b) animals within:

(i) an epidemiological unit;

(ii) an establishment;

(iii) a zone;

(iv) a compartment;

(v) a Member State;

(vi) a third country or territory;

(35) 'zone' means:

(a) for terrestrial animals, an area of a Member State, third country or territory with a precise geographical delimitation, containing an animal subpopulation with a distinct health status with respect to a specific disease or specific diseases subject to appropriate surveillance, disease control and biosecurity measures;

(b) for aquatic animals, a contiguous hydrological system with a distinct health status with respect to a specific disease or specific diseases that forms an area that is referred to in one of the following:

(i) an entire water catchment from the source of a waterway to the estuary or lake;

(ii) more than one water catchment;

(iii) part of a water catchment from the source of a waterway to a barrier that prevents the introduction of a specific disease or diseases;

(iv) part of a coastal area with a precise geographical delimitation;

(v) an estuary with a precise geographical delimitation;

(36) 'water catchment' means an area or basin of land bounded by natural features such as hills or mountains, into which all run–off water flows;

(37) 'compartment' means an animal subpopulation contained in one or more establishments and, in the case of aquatic animals, in one or more aquaculture establishments, under a common biosecurity management system with a distinct health status with respect to a specific disease or specific diseases subject to appropriate surveillance, disease control and biosecurity measures;

(38) 'quarantine' means the keeping of animals in isolation with no direct or indirect contact with animals outside the epidemiological unit, for the purpose of ensuring that there is no spread of one or more specified diseases while the animals in isolation are undergoing observation for a specified length of time and, if appropriate, testing and treatment;

(39) 'epidemiological unit' means a group of animals with the same likelihood of exposure to a disease agent;

(40) 'outbreak' means the officially confirmed occurrence of a listed disease or an emerging disease in one or more animals in an establishment or other place where animals are kept or located;

(41) 'restricted zone' means a zone in which restrictions on the movements of certain animals or products and other disease control measures are applied, with a view to preventing the spread of a particular disease into areas where no restrictions are applied; a restricted zone may, when relevant, include protection and surveillance zones;

(42) 'protection zone' means a zone around and including the location of an outbreak, where disease control measures are applied in order to prevent the spread of the disease from that zone;

(43) 'surveillance zone' means a zone which is established around the protection zone, and where disease control measures are applied in order to prevent the spread of the disease from the protection zone;

(44) 'hatching eggs' means eggs, laid by poultry or captive birds, intended for incubation;

(45) 'ungulates' means the animals listed in Annex III;

(46) 'germinal product establishment' means:

(a) in relation to semen, an establishment where semen is collected, produced, processed or stored;

(b) in relation to oocytes and embryos, a group of professionals or structure supervised by a team veterinarian competent to perform the collection, production, processing and storage of oocytes and embryos;

(c) in relation to hatching eggs, a hatchery;

(47) 'hatchery' means an establishment which collects, stores, incubates and hatches eggs for the supply of:

(a) hatching eggs;

(b) day–old chicks or hatchlings of other species;

(48) 'confined establishment' means any permanent, geographically limited establishment, created on a voluntary basis and approved for the purpose of movements, where the animals are:

(a) kept or bred for the purposes of exhibitions, education, the conservation of species or research;

(b) confined and separated from the surrounding environment; and

(c) subject to animal health surveillance and biosecurity measures;

(49) 'assembly operation' means the assembling of kept terrestrial animals from more than one establishment for a period shorter than the required residency period for the species of animals concerned;

(50) 'residency period' means the minimum period necessary in order to ensure that an animal which has been introduced into an establishment is not of a lower health status than that of the animals in that establishment;

(51) 'Traces' means the integrated computerised veterinary system with a single architecture provided for in Decisions 2003/24/EC and 2004/292/EC;

(52) 'disease control aquatic food establishment' means a food business approved in accordance with Article 179;

(53) 'official veterinarian' means a veterinarian authorised by the competent authority and appropriately qualified to perform official activities in accordance with this Regulation;

(54) 'official veterinarian in a third country or territory' means a veterinarian in a third country or territory corresponding to an official veterinarian as referred to in point (53);

(55) 'competent authority' means the central veterinary authority of a Member State responsible for the organisation of official controls and any other official activities in accordance with this Regulation or any other authority to which that responsibility has been delegated;

(56) 'competent authority of a third country or territory' means the authority in a third country or territory corresponding to the competent authorities referred to in point (55).

CHAPTER 2

Listed diseases and emerging diseases and listed species

Article 5

Listing of diseases

1. The disease-specific rules for the prevention and control of diseases provided for in this Regulation shall apply to:

(a) the following listed diseases:

(i) foot and mouth disease;

(ii) classical swine fever;

(iii) African swine fever;

(iv) highly pathogenic avian influenza;

(v) African horse sickness; and

(b) the listed diseases set out in the list in Annex II.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning amendments to the list referred to in point (b) of paragraph 1 of this Article.

3. A disease shall be included on the list referred to in point (b) of paragraph 1 of this Article if it has been assessed in accordance with Article 7 and it meets:

(a) all of the following criteria:

(i) scientific evidence indicates that the disease is transmissible;

(ii) animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union;

(iii) the disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character;

(iv) diagnostic tools are available for the disease; and

(v) risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union; and

(b) at least one of the following criteria:

(i) the disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character;

(ii) the disease agent has developed resistance to treatments which poses a significant danger to public and/or animal health in the Union;

(iii) the disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union;

(iv) the disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism; or

(v) the disease has or could have a significant negative impact on the environment, including biodiversity, of the Union.

4. The Commission shall adopt delegated acts in accordance with Article 264 concerning the removal of a disease from the list referred to in point (b) of paragraph 1 of this Article when that disease no longer fulfils the criteria provided for in paragraph 3 of this Article.

5. The Commission shall review the listing of each disease in the light of newly available significant scientific data.

Article 6

Emerging diseases

1. The rules for the prevention and control of diseases shall apply to emerging diseases as provided for in this Regulation.

2. A disease other than a listed disease shall be considered to be an emerging disease ('emerging disease') provided it has the potential to meet the criteria for listing diseases provided for in Article 5(3) and:

(a) results from the evolution or change of an existing disease agent;

(b) is a known disease spreading to a new geographic area, species or population;

(c) is diagnosed for the first time in the Union; or

(d) is caused by an unrecognised or a previously unrecognised disease agent.

3. The Commission shall, by means of implementing acts, take the necessary measures regarding an emerging disease which fulfils the criteria set out in paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4. On duly justified imperative grounds of urgency relating to a disease representing an emerging risk having a highly significant impact, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

5. Any obligation on operators in respect of an emerging disease, as set out in this Regulation, shall only apply if the Commission has adopted an implementing act for that disease in accordance with paragraph 3 of this Article or if the disease is covered by a contingency plan in accordance with Article 43.

Article 7

Assessment parameters for the listing of diseases

The Commission shall use the following assessment parameters in order to determine whether a disease meets the conditions requiring it to be listed in accordance with Article 5(2):

(a) the disease profile, which shall comprise the following:

  (i) the animal species concerned by the disease;

  (ii) the morbidity and mortality rates of the disease in animal populations;

  (iii) the zoonotic character of the disease;

  (iv) the resistance to treatments, including antimicrobial resistance;

  (v) the persistence of the disease in an animal population or in the environment;

  (vi) the routes and speed of transmission of the disease between animals and, when relevant, between animals and humans;

  (vii) the absence or presence and distribution of the disease in the Union, and, where the disease is not present in the Union, the risk of its introduction into the Union;

  (viii) the existence of diagnostic and disease control tools;

(b) the impact of the disease on:

(i) agricultural and aquaculture production and other parts of the economy, as regards:

— the level of presence of the disease in the Union;

— the loss of production due to the disease;

— other losses;

(ii) human health, as regards:

— transmissibility between animals and humans;

— transmissibility between humans;

— the severity of human forms of the disease;

— the availability of effective prevention or medical treatment in humans;

(iii) animal welfare;

(iv) biodiversity and the environment;

(c) its potential to generate a crisis situation and its potential use in bioterrorism;

(d) the feasibility, availability and effectiveness of the following disease prevention and control measures:

(i) diagnostic tools and capacities;

(ii) vaccination;

(iii) medical treatments;

(iv) biosecurity measures;

(v) restrictions on the movement of animals and products;

(vi) killing of animals;

(vii) disposal of carcasses and other relevant animal by–products;

(e) the impact of disease prevention and control measures, as regards:

(i) the direct and indirect costs for the affected sectors and the economy as a whole;

(ii) their societal acceptance;

(iii) the welfare of affected subpopulations of kept and wild animals;

(iv) the environment and biodiversity.

Article 8

Listing of species

1. The disease-specific rules for listed diseases provided for in this Regulation and the rules adopted pursuant to this Regulation shall apply to listed species.

2. The Commission shall, by means of implementing acts, establish a list of species as referred to in paragraph 1 of this Article that fulfil the criteria set out in paragraph 3 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

That list shall comprise those animal species, or groups of animal species which pose a considerable risk for the spread of specific listed diseases, based on the following criteria:

(a) the susceptibility of the animal population at risk;

(b) the duration of the incubation period and infective period for the animals concerned;

(c) the capability of those animals to carry those specific diseases.

3. Animal species or groups of animal species shall be added to the list if they are affected or if they pose a risk for the spread of a specific listed disease because:

(a) they are susceptible to a specific listed disease or scientific evidence indicates that such susceptibility is likely; or

(b) they are vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely.

4. The Commission shall, by means of implementing acts, remove animal species or groups of animal species from the list when:

(a) the relevant listed disease in relation to which the animal species or group of animal species concerned has been listed has been removed from the list of diseases; or

(b) scientific evidence indicates that the species or group of species concerned no longer fulfils the criteria set out in paragraph 3.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 9

Disease prevention and control rules to be applied to different categories of listed diseases

1. Disease prevention and control rules shall apply to listed diseases as follows:

(a) As regards listed diseases that do not normally occur in the Union and for which immediate eradication measures must be taken as soon as they are detected, the following rules shall apply, as relevant:

(i) the rules for disease awareness and preparedness provided for in Title I of Part III (Articles 43 to 52);

(ii) the disease control measures provided for in Chapter 1 of Title II of Part III (Articles 53 to 71); and

(iii) the rules for compartmentalisation provided for in Article 37(1).

For those listed diseases, the measures referred to in point (b), as appropriate, as well as points (d) and (e), shall also apply, as relevant.

(b) As regards listed diseases which must be controlled in all Member States with the goal of eradicating them throughout the Union, the following rules shall apply, as relevant:

(i) the rules for compulsory eradication programmes provided for in Article 31(1);

(ii) the rules for disease–free Member States and zones provided for in Article 36;

(iii) the rules for compartmentalisation provided for in Article 37(2); and

(iv) the disease control measures provided for in Articles 72 to 75, Articles 77 to 79 and Articles 81 and 83.

For those listed diseases, the measures referred to in points (d) and (e) shall also apply, as relevant.

(c) As regards listed diseases which are of relevance to some Member States and for which measures are needed to prevent them from spreading to parts of the Union that are officially disease-free or that have eradication programmes for the listed disease concerned, the following rules shall apply, as relevant:

(i) the rules for optional eradication provided for in Article 31(2);

(ii) the rules for disease–free Member States and zones provided for in Article 36;

(iii) the rules for compartmentalisation provided for in Article 37(2); and

(iv) the rules for disease control measures provided for in Articles 76, 77, 78, 80, 82 and 83.

For those listed diseases, the measures referred to in points (d) and (e) shall also apply, as relevant.

(d) As regards listed diseases for which measures are needed to prevent them from spreading on account of their entry into the Union or movements between Member States, the following rules shall apply, as relevant:

(i) the rules for movement within the Union provided for in Chapters 3 to 6 of Title I (Articles 124 to 169), Chapters 2 and 3 of Title II of Part IV (Articles 191 to 225) and Chapters 2 and 3 of Part VI (Articles 247 to 251); and

(ii) the rules for entry into the Union and export from the Union provided for in Part V (Articles 229 to 243).

The listed diseases referred to in points (a), (b) and (c) shall also be considered as listed diseases under this point, as well as those referred to in point (e), where the risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products.

(e) As regards listed diseases for which there is a need for surveillance within the Union, the following rules shall apply, as relevant:

(i) the rules for notification and reporting provided for in Chapter 1 of Part II (Articles 18 to 23); and

(ii) the rules for surveillance provided for in Chapter 2 of Part II (Articles 24 to 30).

The listed diseases referred to in points (a), (b) and (c) shall also be considered as listed diseases under this point.

2. The Commission shall, by means of implementing acts, determine the application of the disease prevention and control rules referred to in paragraph 1 to the respective listed diseases on the basis of the criteria set out in Annex IV, also in the light of newly available significant scientific data.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

3. The Commission shall, by means of implementing acts, modify the application of the disease prevention and control rules referred to in paragraph 2 to the respective listed diseases when the disease in question no longer fulfils the criteria laid down in the relevant Section of Annex IV, also in the light of newly available significant scientific data.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4. On duly justified imperative grounds of urgency relating to a listed disease representing an emerging risk having a highly significant impact, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

CHAPTER 3

Responsibilities for animal health

Section 1

Operators, animal professionals and pet keepers

Article 10

Responsibilities for animal health and biosecurity measures

1. Operators shall:

(a) as regards kept animals and products under their responsibility, be responsible for:

(i) the health of kept animals;

(ii) prudent and responsible use of veterinary medicines, without prejudice to the role and responsibility of veterinarians,

(iii) minimising the risk of the spread of diseases;

(iv) good animal husbandry;

(b) where appropriate, take such biosecurity measures regarding kept animals, and products under their responsibility, as are appropriate for:

(i) the species and categories of kept animals and products;

(ii) the type of production; and

(iii) the risks involved, taking into account:

— geographical location and climatic conditions; and

— local circumstances and practices;

(c) where appropriate, take biosecurity measures regarding wild animals.

2. Animal professionals shall take action to minimise the risk of the spread of diseases in the context of their occupational relationship with animals and products.

3. Point (a) of paragraph 1 shall also apply to pet keepers.

4. The biosecurity measures referred to in point (b) of paragraph 1 shall be implemented, as appropriate, through:

(a) physical protection measures, which may include:

(i) enclosing, fencing, roofing, netting, as appropriate;

(ii) cleaning, disinfection and control of insects and rodents;

(iii) in the case of aquatic animals, where appropriate:

— measures concerning the water supply and discharge;

— natural or artificial barriers to surrounding water courses that prevent aquatic animals from entering or leaving the establishment concerned, including measures against flooding or infiltration of water from surrounding water courses;

(b) management measures, which may include:

(i) procedures for entering and exiting the establishment for animals, products, vehicles and persons;

(ii) procedures for using equipment;

(iii) conditions for movement based on the risks involved;

(iv) conditions for introducing animals or products into the establishment;

(v) quarantine, isolation or separation of newly introduced or sick animals;

(vi) a system for safe disposal of dead animals and other animal by–products.

5. Operators, animal professionals and pet keepers shall cooperate with the competent authority and veterinarians in the application of the disease prevention and control measures provided for in this Regulation.

6. The Commission may, by means of implementing acts, lay down minimum requirements necessary for the uniform application of this Article.

Such implementing acts shall reflect the matters referred to in point (b) of paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 11

Knowledge of animal health

1. Operators and animal professionals shall have adequate knowledge of:

(a) animal diseases, including those that are transmissible to humans;

(b) biosecurity principles;

(c) the interaction between animal health, animal welfare and human health;

(d) good practice of animal husbandry for the animal species under their care;

(e) resistance to treatments, including antimicrobial resistance, and its implications.

2. The content and the level of knowledge required in accordance with paragraph 1 shall depend on:

(a) the species and categories of kept animals or products under the responsibility of the operators and animal professionals concerned and the nature of their occupational relationship with those animals or products;

(b) the type of production;

(c) the tasks performed.

3. The knowledge provided for in paragraph 1 shall be acquired in one of the following ways:

(a) professional experience or training;

(b) existing programmes in agricultural or aquaculture sectors that are relevant for animal health;

(c) formal education;

(d) other experience or other training which results in the same level of knowledge as that covered by points (a), (b) or (c).

4. Operators selling or otherwise transferring the ownership of future pet animals shall provide basic information to the future pet keeper, regarding the matters referred to in paragraph 1, as relevant for the pet animal in question.

Section 2

Veterinarians and aquatic animal health professionals

Article 12

Responsibilities of veterinarians and aquatic animal health professionals

1. Veterinarians shall in the course of their activities which fall within the scope of this Regulation:

(a) take all appropriate measures to prevent the introduction, development and spread of diseases;

(b) take action to ensure the early detection of diseases by carrying out proper diagnosis and differential diagnosis to rule out or confirm a disease;

(c) play an active role in:

(i) raising animal health awareness, and awareness of the interaction between animal health, animal welfare and human health;

(ii) disease prevention;

(iii) the early detection of, and rapid response to, diseases.

(iv) raising awareness of resistance to treatments, including antimicrobial resistance, and its implications;

(d) cooperate with the competent authority, operators, animal professionals and pet keepers in the application of the disease prevention and control measures provided for in this Regulation.

2. Aquatic animal health professionals may undertake activities assigned to veterinarians under this Regulation in relation to aquatic animals provided that they are authorised to do so by the Member State concerned under national law. In that event, paragraph 1 shall apply to those aquatic animal health professionals.

3. Veterinarians and aquatic animal health professionals shall maintain and develop their professional capacities related to their areas of activities which fall within the scope of this Regulation.

Section 3

Member States

Article 13

Member States' responsibilities

1. In order to ensure that the competent authority for animal health has the capability to take the necessary and appropriate measures, and to carry out the activities, required by this Regulation, each Member State shall, at the appropriate administrative level, ensure that competent authority has:

(a) qualified personnel, facilities, equipment, financial resources and an effective organisation covering the whole territory of the Member State;

(b) access to laboratories with the qualified personnel, facilities, equipment and financial resources needed to ensure the rapid and accurate diagnosis and differential diagnosis of listed diseases and emerging diseases;

(c) sufficiently trained veterinarians involved in performing the activities referred to in Article 12.

2. Member States shall encourage operators and animal professionals to acquire, maintain and develop the adequate knowledge of animal health provided for in Article 11 through relevant programmes in agricultural or aquaculture sectors or formal education.

Article 14

Delegation by a competent authority of official activities

1. The competent authority may delegate one or more of the following activities to veterinarians other than official veterinarians:

(a) practical application of measures under the eradication programmes provided for in Article 32;

(b) supporting the competent authority in carrying out surveillance as provided for in Article 26 or in relation to surveillance programmes as provided for in Article 28;

(c) activities related to:

(i) disease awareness, preparedness and control as provided for in Part III, concerning:

— sampling activities and implementation of investigations and epidemiological enquiries within the framework of Article 54, points (b) to (g) of Article 55(1), and Articles 57, 73, 74, 79 and 80 in the event of the suspected presence of a disease, and any implementing and delegated acts adopted pursuant to those Articles;

— carrying out activities relating to disease control measures in the event of an outbreak of disease, as regards activities listed in Article 61, points (a), (b), (e), (f) and (i) of Article 65(1), Article 70(1), Articles 79 and 80, and Article 81(1) and (2), and any implementing and delegated acts adopted pursuant to those Articles;

— carrying out emergency vaccination in accordance with Article 69;

(ii) registration, approval, traceability and movements as provided for in Part IV;

(iii) issuing and completing the identification documents for pet animals as provided for in point (c) of Article 247, point (c) of Article 248(2), point (c) of Article 249(1) and point (c) of Article 250(2);

(iv) the application and use of means of identification as referred to in point (a)(ii) of Article 252(1).

2. Member States may provide for natural or legal persons to be authorised to perform activities referred to in points (a), (b) and (c)(i), (ii) and (iv) of paragraph 1 for specifically identified tasks for which those persons have sufficient specific knowledge. In that event, paragraph 1 of this Article and the responsibilities laid down in Article 12 shall apply to those persons.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning other activities which may be delegated to veterinarians in addition to those provided for in paragraph 1, and, as appropriate, to prescribe the necessary circumstances and conditions for such delegation.

The Commission shall take account of the nature of those activities and of relevant international standards when adopting those delegated acts.

Article 15

Public information

Where there are reasonable grounds to suspect that animals or products originating from within the Union or entering from outside the Union may present a risk, the competent authority shall take appropriate steps to inform the public of the nature of the risk and the measures which are taken or about to be taken to prevent or control that risk, taking into account the nature, seriousness and extent of that risk and the public interest in being informed.

Section 4

Laboratories, facilities and other natural and legal persons handling disease agents, vaccines and other biological products

Article 16

Obligations of laboratories, facilities and others handling disease agents, vaccines and other biological products

1. Laboratories, facilities and other natural or legal persons handling disease agents for the purpose of research, education, diagnosis or the production of vaccines and other biological products shall, whilst taking into account any relevant international standards:

(a) take appropriate biosecurity, biosafety and bio–containment measures to prevent the escape of the disease agents and their subsequent contact with animals outside the laboratory or other facility handling disease agents for those purposes;

(b) ensure that the movement of disease agents, vaccines and other biological products between laboratories or other facilities does not give rise to a risk of the spread of listed and emerging diseases.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the safety measures for the prevention and control of listed and emerging diseases as regards laboratories, facilities and other natural or legal persons handling the disease agents, vaccines and other biological products in relation to:

(a) biosecurity, biosafety and bio–containment measures;

(b) movement requirements for disease agents, vaccines and other biological products.

Article 17

Animal health laboratories

1. Official laboratories for animal health, consisting of Union reference laboratories, national reference laboratories and official animal health laboratories, shall, in fulfilling their tasks and responsibilities, cooperate within a network of Union animal health laboratories.

2. The laboratories referred to in paragraph 1 shall cooperate under the coordination of the Union reference laboratories, to ensure that the surveillance, notification and reporting of diseases, eradication programmes, the definition of disease–free status, and the movements of animals and products within the Union, their entry into the Union and exports to third countries or territories provided for in this Regulation, are based on state–of–the–art, solid and reliable laboratory analyses, tests and diagnoses.

3. The results and reports provided by the official laboratories shall be subject to the principles of professional secrecy and confidentiality and the duty of notification to the competent authority which designated them, irrespective of the natural or legal person who requested the laboratory analyses, tests or diagnoses.

4. In the event that an official laboratory in one Member State conducts diagnostic analyses on samples from animals originating in another Member State, that official laboratory shall notify the competent authority of the Member State from which the samples originated:

(a) immediately of any results indicating the suspicion or detection of a listed disease as referred to in point (a) of Article 9(1);

(b) without undue delay of any results indicating the suspicion or detection of a listed disease as referred to in point (e) of Article 9(1) other than those referred to in point (a) of Article 9(1).

PART II

DISEASE NOTIFICATION AND REPORTING, SURVEILLANCE, ERADICATION PROGRAMMES, DISEASE–FREE STATUS

CHAPTER 1

Disease notification and reporting

Article 18

Notification within Member States

1. Member States shall ensure that operators and other relevant natural or legal persons:

(a) immediately notify the competent authority where there are any reasons to suspect the presence in animals of a listed disease as referred to in point (a) of Article 9(1), or where the presence of such a disease is detected in animals;

(b) as soon as practicable notify the competent authority where there are any reasons to suspect the presence in animals of a listed disease as referred to in point (e) of Article 9(1) other than those referred to in point (a) of Article 9(1), or where the presence of such a disease is detected in animals;

(c) notify a veterinarian of abnormal mortalities and other signs of serious disease or significant decreased production rates with an undetermined cause, for further investigation, including sampling for laboratory examination when the situation so requires.

2. Member States may decide that the notifications provided for in point (c) of paragraph 1 may be directed to the competent authority.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) criteria to determine whether the circumstances requiring notification described in point (c) of paragraph 1 occur;

(b) detailed rules for the further investigation provided for in point (c) of paragraph 1.

Article 19

Union notification

1. Member States shall immediately notify the Commission and the other Member States of any outbreaks of listed diseases as referred to in point (e) of Article 9(1) for which an immediate notification is required in order to ensure the timely implementation of necessary risk management measures, taking into account the disease profile.

2. The notification provided for in paragraph 1 shall contain the following information on the outbreak:

(a) the disease agent and, where relevant, the subtype;

(b) the relevant dates, in particular those of the suspicion and the confirmation of the outbreak;

(c) the type and location of the outbreak;

(d) any related outbreaks;

(e) the animals involved in the outbreak;

(f) any disease control measures taken in relation to the outbreak;

(g) the possible or known origin of the listed disease;

(h) the diagnostic methods used.

Article 20

Union reporting

1. Member States shall report to the Commission and to the other Member States the information on listed diseases referred to in in point (e) of Article 9(1) for which:

(a) immediate notification of an outbreak is not required under Article 19(1);

(b) immediate notification of an outbreak is required under Article 19(1), but additional information is required to be reported to the Commission and the other Member States on:

(i) surveillance in accordance with the rules laid down in an implementing act adopted in accordance with Article 30;

(ii) an eradication programme in accordance with the rules laid down in an implementing act adopted in accordance with Article 35.

2. The reports provided for in paragraph 1 shall include information on:

(a) the detection of the listed diseases referred to in paragraph 1;

(b) the results of surveillance when required in accordance with rules adopted in accordance with point (d)(ii) of Article 29 or point (b)(ii) of Article 30(1);

(c) the results of surveillance programmes when required in accordance with Article 28(3) and rules adopted in accordance with point (d)(ii) of Article 29 or point (b)(ii) of Article 30(1);

(d) eradication programmes when required in accordance with Article 34 and rules laid down in an implementing act adopted in accordance with Article 35.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning provisions supplementing the requirements of paragraph 2 and reporting on other matters concerning surveillance and eradication programmes where necessary in order to ensure an efficient application of the disease prevention rules and control rules laid down in this Regulation.

Article 21

Notification and reporting regions

The Member States shall establish notification and reporting regions for the purpose of the notification and reporting provided for in Articles 19 and 20.

Article 22

Computerised information system for Union notification and Union reporting of diseases

The Commission shall set up and manage a computerised information system for the operation of the mechanisms and tools for the notification and reporting requirements provided for in Articles 19, 20 and 21.

Article 23

Implementing powers concerning Union notification and Union reporting and the computerised information system

The Commission shall, by means of implementing acts, lay down rules for the notification and reporting requirements and the computerised information system provided for in Articles 19 to 22 with respect to:

(a) those listed diseases referred to in point (e) of Article 9(1) which are to be subject to immediate notification by the Member States as well as the necessary measures relating to the notification, in accordance with Article 19;

(b) the information to be provided by the Member States in the reporting provided for in Article 20;

(c) procedures for the establishment and use of the computerised information system provided for in Article 22 and transitional measures for the migration of the data and the information from existing systems into the new system and its full operability;

(d) the format and structure of the data to be entered into the computerised information system provided for in Article 22;

(e) the deadlines and frequencies of the notification and reporting provided for in Articles 19 and 20, which shall be done at times and frequencies which ensure transparency and the timely application of the necessary risk management measures, based on the disease profile and the type of outbreak.

(f) the listing of notification and reporting regions provided for in Article 21.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 2

Surveillance

Article 24

Operators' surveillance obligation

For the purpose of detecting the presence of listed diseases and emerging diseases, operators shall:

(a) observe the health and behaviour of animals under their responsibility;

(b) observe any changes in the normal production parameters in the establishments, animals or germinal products under their responsibility that may give rise to a suspicion of being caused by a listed disease or emerging disease;

(c) look for abnormal mortalities and other signs of serious disease in animals under their responsibility.

Article 25

Animal health visits

1. Operators shall ensure that establishments under their responsibility receive animal health visits from a veterinarian when appropriate due to the risks posed by the establishment in question, taking into account:

(a) the type of establishment;

(b) the species and categories of kept animals on the establishment;

(c) the epidemiological situation in the zone or region as regards listed and emerging diseases to which the animals in the establishment are susceptible;

(d) any other relevant surveillance, or official controls to which the kept animals and type of establishment are subject.

Such animal health visits shall take place at frequencies that are proportionate to the risks posed by the establishment concerned.

They may be combined with visits for other purposes.

2. The animal health visits provided for in paragraph 1 shall be made for the purpose of disease prevention, in particular through:

(a) the provision of advice to the operator concerned on biosecurity and other animal health matters, as relevant for the type of establishment and the species and categories of kept animals on the establishment.

(b) the detection of, and information on, signs indicative of the occurrence of listed diseases or emerging diseases;

3. The Commission may, by means of implementing acts, lay down minimum requirements necessary for the uniform application of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 26

The competent authority's surveillance obligation

1. The competent authority shall conduct surveillance to detect the presence of listed diseases as referred to in point (e) of Article 9(1) and relevant emerging diseases.

2. The surveillance shall be designed in such a way as to ensure the timely detection of the presence of the listed diseases referred to in point (e) of Article 9(1) and emerging diseases by means of the collection, collation and analysis of relevant information relating to the disease situation.

3. The competent authority shall, whenever possible and appropriate, make use of the results of the surveillance conducted by operators and the information obtained through animal health visits in accordance with Articles 24 and 25, respectively.

4. The competent authority shall ensure that surveillance meets the requirements provided for in Article 27 and in any rules adopted pursuant to point (a) of Article 29.

5. The competent authority shall ensure that the information obtained through the surveillance provided for in paragraph 1 is collected and used in an effective and efficient manner.

Article 27

Methodology, frequency and intensity of surveillance

The design, means, diagnostic methods, frequency, intensity, targeted animal population, and sampling patterns of the surveillance provided for in Article 26 shall be appropriate and proportionate to the objectives of the surveillance, taking into account:

(a) the disease profile;

(b) the risk factors involved;

(c) the health status in:

  (i) the Member State, zone or compartment thereof subject to the surveillance;

  (ii) the Member States and third countries or territories which either border on, or from which animals and products enter into, that Member State, zone or compartment thereof;

(d) surveillance conducted by operators in accordance with Article 24, including animal health visits as referred to in Article 25, or by other public authorities.

Article 28

Union surveillance programmes

1. The competent authority shall undertake surveillance as provided for in Article 26(1) within the framework of a surveillance programme when a disease is relevant for the Union in accordance with point (c) of Article 29.

2. Member States establishing a surveillance programme in accordance with paragraph 1 shall submit it to the Commission.

3. Member States implementing a surveillance programme in accordance with paragraph 1 shall submit regular reports on the results of the implementation of that programme to the Commission.

Article 29

Delegation of powers

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) the design, means, diagnostic methods, frequency, intensity, targeted animal population, and sampling patterns of the surveillance provided for in Article 27;

(b) the criteria for the official confirmation and case definitions of listed diseases as referred to in point (e) of Article 9(1), and, where relevant, of emerging diseases;

(c) the criteria used to establish the relevance of a disease which is to be subject to a surveillance programme relevant for the Union for the purposes of point (a) of Article 30(1), taking into account the disease profile and the risk factors involved;

(d) requirements for surveillance programmes as provided for in Article 28(1) regarding:

(i) the contents of surveillance programmes;

(ii) the information to be included in the submission of surveillance programmes in accordance with Article 28(2) and regular reports in accordance with Article 28(3);

(iii) the period of application of surveillance programmes.

Article 30

Implementing powers

1. The Commission shall, by means of implementing acts, lay down requirements concerning surveillance and surveillance programmes as provided for in Articles 26 and 28 and in the rules adopted pursuant to Article 29, as regards:

(a) establishing which of the listed diseases referred to in point (e) of Article 9(1) are to be subject to surveillance programmes in accordance with Article 28, including the geographical scope of such programmes;

(b) the format and procedure for:

(i) the submission of those surveillance programmes for information to the Commission and other Member States;

(ii) the reporting to the Commission on the results of the surveillance.

2. The Commission may, by means of implementing acts, lay down the criteria to be used for evaluating the surveillance programmes referred to in Article 28.

3. The implementing acts referred to in paragraphs 1 and 2 of this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 3

Eradication programmes

Article 31

Compulsory and optional eradication programmes

1. Member States which are not free, or not known to be free, from one or more of the listed diseases referred to in point (b) of Article 9(1) throughout their territory, or in zones or compartments thereof, shall:

(a) establish a programme for the eradication of, or demonstration of freedom from, that listed disease, to be carried out in the animal populations concerned by that disease and covering the relevant parts of their territory or the relevant zones or compartments thereof ('compulsory eradication programme'), to apply until the conditions for the grant of disease–free status in the territory of the Member State or zone concerned, as provided for in Article 36(1), or compartment, as provided for in Article 37(2), are fulfilled;

(b) submit the draft compulsory eradication programme to the Commission for approval.

2. Member States which are not free, or not known to be free, from one or more of the listed diseases referred to in point (c) of Article 9(1) and which decide to establish a programme for the eradication of that listed disease, to be carried out in the animal populations concerned by the disease in question and covering the relevant parts of their territory or zones or compartments thereof ('optional eradication programme'), shall submit a draft of that programme to the Commission for approval, where the Member State concerned asks for the recognition, within the Union, of animal health guarantees as regards the disease in question for movements of animals or products.

Such an optional eradication programme shall apply until:

(a) the conditions for the grant of disease–free status in the territory of the Member State or zone concerned, as provided for in Article 36(1), or compartment, as provided for in Article 37(2), are fulfilled; or

(b) it is established that the conditions for the grant of disease–free status cannot be achieved and that the programme no longer fulfils its purpose; or

(c) the Member State concerned withdraws the programme.

3. The Commission shall, by means of implementing acts, approve:

(a) draft compulsory eradication programmes submitted to it for approval in accordance with paragraph 1;

(b) draft optional eradication programmes submitted to it for approval in accordance with paragraph 2,

if the conditions set out in this Chapter are met.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4. On duly justified imperative grounds of urgency relating to a listed disease representing a risk having a highly significant impact, the Commission shall adopt immediately applicable implementing acts provided for in point (a) of paragraph 3 of this Article in accordance with the procedure referred to in Article 266(3).

The Commission may, for duly justified reasons, by means of implementing acts, approve an amendment proposed by the Member State concerned or withdraw the approval of eradication programmes approved in accordance with points (a) and (b) of paragraph 3 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

5. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) the disease control strategies, intermediate and final targets for specific diseases, and period of application of eradication programmes;

(b) derogations from the requirement for the submission of eradication programmes for approval, as provided for in point (b) of paragraph 1 of this Article and in paragraph 2 thereof, where such approval is not necessary due to the adoption of rules regarding those programmes in accordance with Articles 32(2) and 35;

(c) the information to be provided by Member States to the Commission and to the other Member States concerning derogations from the requirement for approval of eradication programmes as provided for in point (b) of this paragraph.

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 amending or discontinuing rules adopted pursuant to point (b) of this paragraph.

Article 32

Measures under compulsory and optional eradication programmes

1. Eradication programmes shall consist of at least the following measures:

(a) disease control measures for the eradication of the disease agent from establishments, compartments and zones in which a disease occurs and to prevent re–infection;

(b) surveillance to be carried out in accordance with the rules laid down in Articles 26 to 30 to demonstrate:

(i) the effectiveness of the disease control measures provided for in point (a);

(ii) freedom from the listed disease;

(c) disease control measures to be taken in the event of positive surveillance results.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning the following elements to ensure the effectiveness of eradication programmes:

(a) disease control measures as provided for in point (a) of paragraph 1;

(b) disease control measures to be taken to avoid re–infection of the targeted animal population with the disease in question in establishments, zones and compartments;

(c) surveillance design, means, diagnostic methods, frequency, intensity, targeted animal population and sampling patterns;

(d) disease control measures to be taken in the event of positive surveillance results for the listed disease as provided for in point (c) of paragraph 1;

(e) criteria for vaccination, where relevant and appropriate for the disease or species in question.

Article 33

Content of compulsory and optional eradication programmes submitted for approval to the Commission

Member States shall include the following information in applications for approval of compulsory and optional eradication programmes submitted to the Commission in accordance with Article 31(1) and (2):

(a) a description of the epidemiological situation of the listed disease covered by the compulsory or optional eradication programme in question;

(b) a description and demarcation of the geographical and administrative area or the compartment covered by the eradication programme;

(c) a description of the disease control measures of the eradication programme as provided for in Article 32(1) and in the rules adopted pursuant to Article 32(2);

(d) a description of the organisation, supervision and roles of the parties involved in the eradication programme;

(e) the estimated duration of the eradication programme;

(f) the intermediate targets of, and the disease control strategies for implementing, the eradication programme.

Article 34

Reporting

Member States implementing eradication programmes shall submit to the Commission:

(a) reports enabling the Commission to monitor achievement of the intermediate targets of the on-going eradication programmes as referred to in point (f) of Article 33;

(b) a final report after completion of the eradication programme in question.

Article 35

Implementing powers

The Commission shall, by means of implementing acts, lay down rules concerning the information, format and procedural requirements provided for in Articles 31 to 34 as regards:

(a) the submission of draft compulsory and draft optional eradication programmes for approval;

(b) performance indicators;

(c) reporting to the Commission and other Member States on the results of the implementation of compulsory or optional eradication programmes.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 4

Disease–free status

Article 36

Disease–free Member States and zones

1. A Member State may apply to the Commission for approval of disease–free status for one or more of the listed diseases referred to in points (b) and (c) of Article 9(1), for one or more of the relevant animal species, for its entire territory or for one or more zones thereof, provided that one or more of the following conditions are fulfilled:

(a) none of the listed species for the disease covered by the application for disease–free status is present anywhere in the territory of the Member State concerned or in the relevant zone or zones covered by the application;

(b) the disease agent is known not to be able to survive in the entire territory of the Member State, or in the relevant zone or zones covered by the application, according to the criteria referred to in point (a)(ii) of Article 39;

(c) in the case of listed diseases only transmitted by vectors, none of the vectors are present, or they are known not to be able to survive in the entire territory of the Member State, or in the relevant zone or zones covered by the application, according to the criteria referred to in point (a)(ii) of Article 39;

(d) freedom from the listed disease has been demonstrated by:

  (i) an eradication programme complying with the rules laid down in Article 32(1) and rules adopted pursuant to paragraph 2 of that Article; or

  (ii) historical and surveillance data.

2. Applications by Member States for disease–free status shall include evidence demonstrating that the conditions for disease–free status laid down in paragraph 1 are fulfilled.

3. A Member State may in certain specific cases apply to the Commission for approval of disease–free status for one or more of the listed diseases referred to in point (a) of Article 9(1), and in particular for approval of non–vaccination status for the entire territory, or for one or more zones thereof, provided that the following conditions are fulfilled:

(a) freedom from the listed disease has been demonstrated by:

  (i) an eradication programme complying with the rules laid down in Article 32(1) and rules adopted pursuant to paragraph 2 of that Article; or

  (ii) historical and surveillance data;

(b) it has been demonstrated that vaccination against the disease would lead to costs which would exceed those resulting from maintaining freedom from disease without vaccination.

4. The Commission shall, by means of implementing acts, approve, subject to amendments where necessary, applications by Member States for disease–free status or non-vaccination status when the conditions referred to in paragraphs 1 and 2 and, as relevant, paragraph 3 are fulfilled.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 37

Compartments

1. A Member State may apply to the Commission for recognition of the disease–free status of compartments for listed diseases referred to in point (a) of Article 9(1), and for the protection of the disease–free status of such a compartment in the event of an outbreak of one or more of those listed diseases in its territory, provided that:

(a) the introduction of the listed disease or listed diseases covered by the application can be effectively prevented at compartment level, taking into account the disease profile;

(b) the compartment covered by the application is subject to a single common biosecurity management system designed to ensure the disease–free status of all establishments forming part of it; and

(c) the compartment covered by the application has been approved by the competent authority for the purposes of movements of animals and products thereof in accordance with:

(i) Articles 99 and 100 for compartments keeping terrestrial animals and products thereof;

(ii) Articles 183 and 184 for compartments keeping aquaculture animals and products thereof.

2. A Member State may apply to the Commission for recognition of the disease–free status of compartments for one or more of the listed diseases referred to in points (b) and (c) of Article 9(1), provided that:

(a) the introduction of the listed disease or listed diseases covered by the application can be effectively prevented at compartment level, taking into account the disease profile;

(b) one or more of the following conditions are complied with:

(i) the conditions laid down in Article 36(1) are fulfilled;

(ii) the establishments of the compartment covered by the application have started or resumed their activities and have established a common biosecurity management system designed to ensure the freedom from disease of that compartment;

(c) the compartment covered by the application is subject to a single common biosecurity management system designed to ensure the disease–free status of all establishments forming part of it; and

(d) the compartment covered by the application has been approved by the competent authority for the purposes of movements of animals and products thereof in accordance with:

(i) Articles 99 and 100 for compartments keeping terrestrial animals and products thereof;

(ii) Articles 183 and 184 for compartments keeping aquaculture animals and products thereof.

3. Applications by Member States for recognition of the disease–free status of compartments in accordance with paragraphs 1 and 2 shall include evidence demonstrating that the conditions laid down in those paragraphs are fulfilled.

4. The Commission shall, by means of implementing acts:

(a) recognise, subject to amendments where necessary, the disease–free status of compartments, when the conditions laid down in paragraph 1 or paragraph 2 and in paragraph 3 are fulfilled;

(b) determine for which of the listed diseases referred to in points (a), (b) and (c) of Article 9(1) the disease–free compartments may be established.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning provisions supplementing those contained in this Article, on:

(a) the requirements for recognition of the disease-free status of compartments as provided for in paragraphs 1 and 2 of this Article, based on the profile of the listed diseases referred to in points (a), (b) and (c) of Article 9(1), concerning at least:

(i) surveillance results and other evidence needed to substantiate freedom from disease;

(ii) biosecurity measures;

(b) the detailed rules for the approval by the competent authority of the disease–free status of compartments as provided for in paragraphs 1 and 2; and

(c) rules concerning compartments which are located in the territory of more than one Member State.

Article 38

Lists of disease–free Member States, zones or compartments

Each Member State shall establish and maintain an up-to-date list of its territory or zones with disease–free status as provided for in Article 36(1) and (3), and of its compartments with disease-free status, as provided for in Article 37(1) and (2), when applicable.

Member States shall make those lists publicly available. The Commission shall assist the Member States in making the information contained in those lists available to the public by providing on its internet page the links to the internet–based information pages of the Member States.

Article 39

Delegation of powers concerning the disease–free status of Member States and zones

The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) detailed rules for the disease–free status of Member States and zones thereof, based on the different disease profiles, concerning:

(i) the criteria to be used to substantiate claims by Member States that no listed species are present or able to survive in their territory and the evidence required to substantiate such claims, as provided for in point (a) of Article 36(1);

(ii) the criteria to be used, and the evidence required, to substantiate claims that a disease agent or vector is not able to survive, as provided for in points (b) and (c) of Article 36(1);

(iii) the criteria to be used, and the conditions to be applied, to determine freedom from the disease in question, as referred to in point (d) of Article 36(1);

(iv) surveillance results and other evidence needed to substantiate freedom from disease;

(v) biosecurity measures;

(vi) restrictions and conditions for vaccination in disease-free Member States and zones thereof;

(vii) the establishment of zones separating disease–free zones or zones under the eradication programme from restricted zones ('buffer zones');

(viii) zones which are located in the territory of more than one Member State;

(b) derogations from the requirement for approval by the Commission of disease–free status for one or more listed diseases referred to in points (b) and (c) of Article 9(1), as laid down in Article 36(1), where such approval is not necessary on account of detailed rules for freedom from disease having been laid down in rules adopted pursuant to point (a) of this Article;

(c) the information to be provided by Member States to the Commission and the other Member States to substantiate declarations of disease–free status, without the adoption of an implementing act in accordance with Article 36(4), as provided for in point (b) of this Article.

Article 40

Implementing powers

The Commission shall, by means of implementing acts, lay down detailed requirements concerning the information to be provided by Member States to the Commission and the other Member States to substantiate declarations of disease–free status of territories, zones and compartments in accordance with Articles 36 to 39, and the format and procedures for:

(a) applications for recognition of disease–free status of the entire territory of the Member State concerned, or zones and compartments thereof;

(b) exchanges of information between the Member States and the Commission on disease-free Member States, or zones and compartments thereof.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 41

Maintenance of disease–free status

1. Member States shall only maintain disease–free status for their territories, or zones or compartments thereof, as long as:

(a) the conditions for disease–free status laid down in Article 36(1) and Article 37(1) and (2), and rules laid down pursuant to paragraph 3 of this Article and Article 39, continue to be fulfilled;

(b) surveillance, taking into account the requirements provided for in Article 27, is undertaken to verify that the territory, zone or compartment concerned continues to be free of the listed disease for which it was approved or recognised as having disease–free status;

(c) restrictions are applied on movements of animals, and where relevant products derived therefrom, of listed species for the listed disease for which the disease–free status was approved or recognised, into the territory, zone or compartment concerned, in accordance with the rules laid down in Parts IV and V;

(d) other biosecurity measures are applied to prevent the introduction of the listed disease for which it was approved or recognised as having disease–free status.

2. A Member State shall immediately inform the Commission if the conditions referred to in paragraph 1 for maintaining disease–free status are no longer met.

3. The Commission shall adopt delegated acts in accordance with Article 264 concerning the following conditions for maintaining disease–free status:

(a) surveillance as provided for in point (b) of paragraph 1;

(b) biosecurity measures as provided for in point (d) of paragraph 1.

Article 42

Suspension, withdrawal and restoration of disease–free status

1. Where a Member State becomes aware, or has reason to suspect, that any of the conditions for maintaining its status as a disease–free Member State or zone or compartment thereof, have been breached, it shall immediately:

(a) where relevant, depending on the risk, suspend or restrict movements of the listed species, for the listed disease for which it was approved or recognised as having disease-free status, to other Member States, zones or compartments with a higher health status for that listed disease;

(b) where relevant for the prevention of the spread of a listed disease for which disease–free status has been approved or recognised, apply the disease control measures provided for in Title II of Part III.

2. The measures provided for in paragraph 1 shall be lifted where further investigation confirms that:

(a) the suspected breach has not taken place; or

(b) the suspected breach has not had a significant impact and the Member State concerned can provide assurances that the conditions for maintaining its disease–free status are again fulfilled.

3. Where further investigation by the Member State concerned confirms that there has been an outbreak of the listed disease for which it obtained disease–free status, or that other significant breaches of the conditions for maintaining disease–free status as referred to in Article 41(1) have occurred, or where there is a significant likelihood of this having occurred, the Member State shall immediately inform the Commission thereof.

4. The Commission shall, by means of implementing acts, withdraw without undue delay the approval of the disease–free status of a Member State or zone granted in accordance with Article 36(4) or the recognition of the disease–free status of a compartment granted in accordance with Article 37(4) after obtaining the information from the Member State concerned that the conditions for maintaining the disease–free status are no longer met.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

5. On duly justified imperative grounds of extreme urgency, where the listed disease referred to in paragraph 3 of this Article spreads in a rapid manner, carrying with it the risk of a highly significant impact on animal or public health, the economy or society, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 266(3).

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning provisions supplementing the rules for the suspension, withdrawal and restoration of disease–free status set out in paragraphs 1 and 2 of this Article.

PART III

DISEASE AWARENESS, PREPAREDNESS AND CONTROL

TITLE I

DISEASE AWARENESS AND PREPAREDNESS

CHAPTER 1

Contingency plans and simulation exercises

Article 43

Contingency plans

1. The Member States shall, after appropriate consultation of experts and relevant stakeholders, draw up, and keep up to date, contingency plans and, where necessary, detailed instruction manuals laying down the measures to be taken in the Member State concerned in the event of the occurrence of a listed disease referred to in point (a) of Article 9(1) or, as the case may be, of an emerging disease, in order to ensure a high level of disease awareness and preparedness and the ability to launch a rapid response.

2. Those contingency plans and, where applicable, detailed instruction manuals shall cover at least the following matters:

(a) the establishment of a chain of command within the competent authority and with other public authorities, to ensure a rapid and effective decision–making process at Member State, regional and local level;

(b) the framework for cooperation between the competent authority and the other public authorities and relevant stakeholders involved, to ensure that actions are taken in a coherent and coordinated manner;

(c) access to:

  (i) facilities;

  (ii) laboratories;

  (iii) equipment;

  (iv) personnel;

  (v) emergency funds;

  (vi) all other appropriate materials and resources necessary for the rapid and efficient eradication of the listed diseases referred to in point (a) of Article 9(1) or of emerging diseases;

(d) the availability of the following centres and groups with the necessary expertise to assist the competent authority:

  (i) a functional central disease control centre;

  (ii) regional and local disease control centres, as appropriate for the administrative and geographical situation of the Member State concerned;

  (iii) operational expert groups;

(e) implementation of the disease control measures provided for in Chapter 1 of Title II for the listed diseases referred to in point (a) of Article 9(1) and for emerging diseases;

(f) provisions on emergency vaccination, where appropriate;

(g) principles for the geographical demarcation of the restricted zones established by the competent authority in accordance with Article 64(1);

(h) coordination with neighbouring Member States and neighbouring third countries and territories, where appropriate.

Article 44

Implementing powers for contingency plans

The Commission shall, by means of implementing acts, lay down necessary measures concerning the implementation in the Member States of the contingency plans provided for in Article 43(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 45

Simulation exercises

1. The competent authority shall ensure that simulation exercises concerning the contingency plans provided for in Article 43(1) are carried out regularly or at appropriate intervals:

(a) to ensure a high level of disease awareness and preparedness and the ability to launch a rapid response in the Member State concerned;

(b) to verify the functionality of those contingency plans.

2. Where feasible and appropriate, simulation exercises shall be carried out in close collaboration with the competent authorities of neighbouring Member States and neighbouring third countries and territories.

3. Member States shall make available to the Commission and to the other Member States, on request, a report on the main results of the simulation exercises carried out.

4. When appropriate and necessary, the Commission shall, by means of implementing acts, lay down rules concerning the practical implementation of simulation exercises in the Member States, relating to:

(a) the frequencies of simulation exercises;

(b) simulation exercises covering more than one listed disease referred to in point (a) of Article 9(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 2

The use of veterinary medicinal products for disease prevention and control

Article 46

The use of veterinary medicinal products for disease prevention and control

1. The Member States may take measures concerning the use of veterinary medicinal products for listed diseases, to ensure the most efficient prevention or control of those diseases, provided that such measures are appropriate or necessary.

Those measures may cover the following:

(a) prohibitions and restrictions on the use of veterinary medicinal products;

(b) the compulsory use of veterinary medicinal products.

2. Member States shall take the following criteria into consideration when determining whether or not to use, and how to use, veterinary medicinal products as prevention and control measures for a specific listed disease:

(a) the disease profile;

(b) the distribution of the listed disease in:

(i) the Member State concerned;

(ii) the Union;

(iii) where relevant, neighbouring third countries and territories;

(iv) third countries and territories from which animals and products are brought into the Union;

(c) the availability and effectiveness of the veterinary medicinal products in question, and the risks attaching to them;

(d) the availability of diagnostic tests for detecting infections in animals treated with the veterinary medicinal products concerned;

(e) the economic, social, animal welfare and environmental impact of the use of the veterinary medicinal products concerned compared to other available disease prevention and control strategies.

3. Member States shall take appropriate preventive measures concerning the use of veterinary medicinal products for scientific studies or for the purposes of developing and testing them under controlled conditions to protect animal and public health.

Article 47

Delegation of powers for the use of veterinary medicinal products

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning what might constitute appropriate and necessary measures as set out in Article 46, in relation to:

(a) prohibitions and restrictions on the use of veterinary medicinal products;

(b) specific conditions for the use of veterinary medicinal products for a specific listed disease;

(c) risk-mitigation measures to prevent the spread of listed diseases through animals treated with the veterinary medicinal products or products from such animals;

(d) surveillance for specific listed diseases following the use of vaccines and other veterinary medicinal products.

2. The Commission shall take into account the criteria set out in Article 46(2) when laying down the rules provided for in paragraph 1 of this Article.

3. Where, in the case of emerging risks, imperative grounds of urgency so require, the procedure provided for in Article 265 shall apply to rules adopted pursuant to paragraph 1 of this Article.

CHAPTER 3

Antigen, vaccine and diagnostic reagent banks

Article 48

The establishment of Union antigen, vaccine and diagnostic reagent banks

1. For listed diseases referred to in point (a) of Article 9(1) in respect of which vaccination is not prohibited by a delegated act adopted pursuant to Article 47, the Commission may establish and be responsible for managing Union antigen, vaccine and diagnostic reagent banks for the storage and replacement of stocks of one or more of the following biological products:

(a) antigens;

(b) vaccines;

(c) vaccine master seed–stocks;

(d) diagnostic reagents.

2. The Commission shall ensure that the Union antigen, vaccine and diagnostic reagent banks provided for in paragraph 1:

(a) store sufficient stocks of the appropriate type of antigens, vaccines, vaccine master seed–stocks and diagnostic reagents for the specific listed disease in question, taking into account the needs of Member States estimated in the context of the contingency plans provided for in Article 43(1);

(b) receive regular supplies and timely replacements of antigens, vaccines, vaccine master seed–stocks and diagnostic reagents;

(c) are maintained and moved in conformity with the appropriate biosecurity, biosafety and bio–containment requirements laid down in Article 16(1) and in accordance with delegated acts adopted pursuant to Article 16(2);

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) the management, storage and replacement of stocks of the Union antigen, vaccine and diagnostic reagent banks as provided for in paragraphs 1 and 2 of this Article;

(b) the biosecurity, biosafety and bio–containment requirements for the operation of those banks, respecting the requirements provided for in Article 16(1) and taking into account the delegated acts adopted pursuant to Article 16(2).

Article 49

Access to the Union antigen, vaccine and diagnostic reagent banks

1. The Commission shall, upon request, provide for the delivery of the biological products referred to in Article 48(1) from the Union antigen, vaccine and diagnostic reagent banks, provided that stocks are available, to:

(a) in the first place, Member States; and

(b) third countries or territories, provided that such delivery is primarily intended to prevent the spread of a disease into the Union.

2. The Commission shall, in the event of the limited availability of stocks, prioritise access to the stocks to be delivered pursuant to paragraph 1 based on:

(a) the disease circumstances under which the request is made;

(b) the existence of a national antigen, vaccine and diagnostic reagent bank in the requesting Member State or third country or territory;

(c) the existence of Union measures for compulsory vaccination laid down in delegated acts adopted pursuant to Article 47.

Article 50

Implementing powers concerning the Union antigen, vaccine and diagnostic reagent banks

1. The Commission shall, by means of implementing acts, lay down rules for Union antigen, vaccine and diagnostic reagent banks, specifying for the biological products referred to in Article 48(1):

(a) which of those biological products are to be included in the Union antigen, vaccine and diagnostic reagent banks and for which of the listed diseases referred to in point (a) of Article 9(1);

(b) the types of those biological products that are to be included in the Union antigen, vaccine and diagnostic reagent banks and in what quantities for each specific listed disease referred to in point (a) of Article 9(1) for which the bank in question exists;

(c) the requirements concerning the supply, storage and replacement of those biological products;

(d) the delivery of those biological products from the Union antigen, vaccine and diagnostic reagent banks to the Member States and to third countries and territories;

(e) procedural and technical requirements for the inclusion of those biological products in the Union antigen, vaccine and diagnostic reagent banks and for requesting access to them.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

2. On duly justified imperative grounds of urgency relating to a listed disease referred to in point (a) of Article 9(1) representing a risk of a highly significant impact, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 266(3).

Article 51

Confidentiality of information concerning the Union antigen, vaccine and diagnostic reagent banks

Information on the quantities and subtypes of the biological products referred to in Article 48(1) stored in the Union antigen, vaccine and diagnostic reagent banks shall be treated by the Commission as classified information and shall not be published.

Article 52

National antigen, vaccine and diagnostic reagent banks

1. Member States that have established national antigen, vaccine and diagnostic reagent banks for listed diseases referred to in point (a) of Article 9(1) for which Union antigen, vaccine and diagnostic reagent banks exist, shall ensure that their national antigen, vaccine and diagnostic reagent banks comply with the biosecurity, biosafety and bio–containment requirements laid down in point (a) of Article 16(1) and in delegated acts adopted in accordance with Article 16(2) and point (b) of Article 48(3).

2. Member States shall provide the Commission with up–to–date information on:

(a) the existence or the establishment of the national antigen, vaccine and diagnostic reagent banks referred to paragraph 1;

(b) the types of antigens, vaccines, vaccine master-seed stocks and diagnostic reagents and the quantities thereof held in such banks;

(c) any changes in the operation of such banks.

That information shall be treated as classified information by the Commission and shall not be published.

3. The Commission may, by means of implementing acts, lay down rules specifying the content, frequency and format of the submission of the information provided for in paragraph 2.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

TITLE II

DISEASE CONTROL MEASURES

CHAPTER 1

Disease control measures for listed diseases as referred to in point (a) of Article 9(1)

Section 1

Disease control measures in the event of suspicion of a listed disease in kept animals

Article 53

Obligations on operators and other relevant natural and legal persons concerned

1. In the event of suspicion of a listed disease as referred to in point (a) of Article 9(1) in kept animals, in addition to complying with the notification obligation laid down in Article 18(1) and pending any disease control measures being taken by the competent authority in accordance with Articles 54(1) and 55(1), Member States shall take measures to ensure that operators and other relevant natural and legal persons concerned take the appropriate disease control measures provided for in points (c), (d) and (e) of Article 55(1), to prevent the spread of that listed disease from the affected animals, establishments and locations under their responsibility to other unaffected animals or to humans.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules for supplementing the disease control measures provided for in paragraph 1 of this Article.

Article 54

Investigation by the competent authority in the event of suspicion of a listed disease

1. In the event of suspicion of a listed disease as referred to in point (a) of Article 9(1) in kept animals, the competent authority shall conduct without delay an investigation to confirm or rule out the presence of that listed disease.

2. For the purpose of the investigation provided for in paragraph 1, the competent authority shall, when appropriate, ensure that:

(a) official veterinarians carry out a clinical examination of a representative sample of the kept animals of listed species for the listed disease in question;

(b) official veterinarians take appropriate samples from those kept animals of listed species and other samples for examination in laboratories designated for that purpose by the competent authority;

(c) such designated laboratories carry out examinations to confirm or rule out the presence of the listed disease in question.

3. The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules supplementing the rules for investigations by competent authorities as provided for in paragraph 1 of this Article.

Article 55

Preliminary disease control measures by competent authorities

1. The competent authority shall, in the event that it suspects the presence of a listed disease as referred to in point (a) of Article 9(1) in kept animals, carry out the following preliminary disease control measures, subject to national requirements for gaining access to private residences, pending the results of the investigation provided for in Article 54(1) and the carrying-out of the disease control measures provided for in Article 61(1):

(a) place the establishment, food and feed business or animal by–products establishment concerned, or any other location where the disease is suspected of having occurred, including locations where the suspected disease may have originated, under official surveillance;

(b) compile an inventory of:

(i) the kept animals in the establishment, food and feed business, or animal by–products establishment concerned, or in any other location;

(ii) the products in that establishment, food and feed business, or animal by–products establishment, or in any other location, where relevant for the spread of that listed disease;

(c) ensure that appropriate biosecurity measures are applied to prevent the spreading of that listed disease agent to other animals or to humans;

(d) when appropriate to prevent the further spread of the disease agent, ensure that the kept animals of listed species for that listed disease are isolated, and that they are prevented from coming into contact with wildlife;

(e) restrict the movements of kept animals, products and, if appropriate, people, vehicles and any material or other means by which the disease agent could have spread to or from the establishment, food and feed business or animal by–products establishment, or from any other location where that listed disease is suspected, as far as necessary to prevent its spread;

(f) take any other necessary disease control measures, taking into account the disease control measures provided for in Section 4 of this Chapter, concerning:

(i) the application of the investigation by the competent authority provided for in Article 54(1) and disease control measures provided for in points (a) to (d) of this paragraph to other establishments, food and feed businesses, or animal by–products establishments, or to any other location;

(ii) the establishment of any temporary restricted zones which are appropriate, taking into account the disease profile;

(g) initiate the epidemiological enquiry provided for in Article 57(1).

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules supplementing those laid down in paragraph 1 of this Article as regards the specific and detailed disease control measures to be taken depending on the listed disease referred to in point (a) of Article 9(1), based on the risks involved for:

(a) the species or category of animals concerned;

(b) the type of production concerned.

Article 56

Review and extension of the preliminary disease control measures

The disease control measures provided for in Article 55(1) shall be:

(a) reviewed by the competent authority, as appropriate, following the findings of:

(i) the investigation provided for in Article 54(1);

(ii) the epidemiological enquiry provided for in Article 57(1);

(b) further extended to other locations as referred to in point (a) of Article 55(1), where necessary.

Section 2

Epidemiological enquiry

Article 57

Epidemiological enquiry

1. The competent authority shall carry out an epidemiological enquiry in the event of the confirmation of a listed disease as referred to in point (a) of Article 9(1) in animals.

2. The epidemiological enquiry provided for in paragraph 1 shall aim to:

(a) identify the likely origin of the listed disease in question and the means of its spread;

(b) calculate the likely length of time that the listed disease has been present;

(c) identify establishments and epidemiological units therein, food and feed businesses or animal by–products establishments, or other locations, where animals of listed species for the suspected listed disease may have become infected, infested or contaminated;

(d) obtain information on the movements of kept animals, persons, products, vehicles, any material or other means by which the disease agent could have been spread during the relevant period preceding the notification of the suspicion or confirmation of the listed disease;

(e) obtain information on the likely spread of the listed disease in the surrounding environment, including the presence and distribution of disease vectors.

Section 3

Disease confirmation in kept animals

Article 58

Official confirmation by the competent authority of a listed disease as referred to in point (a) of Article 9(1)

1. The competent authority shall base an official confirmation of a listed disease as referred to in point (a) of Article 9(1) on the following information:

(a) the results of the clinical and laboratory examinations provided for in Article 54(2);

(b) the preliminary or final results of the epidemiological enquiry provided for in Article 57(1);

(c) other available epidemiological data.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning the requirements to be fulfilled for the official confirmation referred to in paragraph 1 of this Article.

Article 59

Lifting of preliminary disease control measures where the presence of the listed disease has been ruled out

The competent authority shall continue to apply the preliminary disease control measures provided for in Article 55(1) and Article 56 until the presence of the listed disease in question, as referred to in point (a) of Article 9(1), has been ruled out on the basis of the information referred to in Article 58(1) or rules adopted pursuant to Article 58(2).

Section 4

Disease control measures in the event of confirmation of disease in kept animals

Article 60

Immediate disease control measures to be taken by the competent authority

In the event of an official confirmation in accordance with Article 58(1) of an outbreak of a listed disease as referred to in point (a) of Article 9(1) in kept animals, the competent authority shall immediately:

(a) declare the affected establishment, food or feed business, animal by–products establishment or other location as officially infected with that listed disease;

(b) establish a restricted zone appropriate for that listed disease;

(c) implement the contingency plan provided for in Article 43(1) to ensure full coordination of the disease control measures.

Article 61

Affected establishments and other locations

1. In the event of an outbreak of a listed disease as referred to in point (a) of Article 9(1) in kept animals, the competent authority shall immediately take one or more of the following disease control measures, subject to national requirements for gaining access to private residences, in an establishment, food or feed business, animal by–products establishment, or any other location referred to in point (a) of Article 60, in order to prevent the further spread of that listed disease:

(a) the imposition of restrictions on movements of persons, animals, products, vehicles or any other material or substance that may be contaminated and contribute to the spread of the listed disease;

(b) the killing and disposal or slaughtering of animals that may be contaminated or contribute to the spread of the listed disease;

(c) the destruction, processing, transformation or treatment of products, feed, or any other substances, or the treatment of equipment, means of transport, plants or plant products, or water which may be contaminated, as appropriate to ensure that any disease agent or vector of the disease agent is destroyed;

(d) the vaccination or treatment with other veterinary medicinal products of kept animals in accordance with Article 46(1) and Article 69 and any delegated acts adopted pursuant to Article 47;

(e) the isolation, quarantine or treatment of animals and products that are likely to be contaminated and contribute to the spread of the listed disease;

(f) the cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures to be applied to the affected establishment, food or feed business, animal by–products establishment or other locations to minimise the risk of spread of the listed disease;

(g) the taking of a sufficient number of appropriate samples needed to complete the epidemiological enquiry provided for in Article 57(1);

(h) the laboratory examination of samples;

(i) any other appropriate measures.

2. When determining which of the disease control measures provided for in paragraph 1 are appropriate to take, the competent authority shall take the following into account:

(a) the disease profile;

(b) the type of production, and epidemiological units within the affected establishment, food or feed business, animal by–products establishment or other location;

3. The competent authority shall only authorise the repopulation of the establishment concerned, or of any other location, when:

(a) all appropriate disease control measures and laboratory examinations provided for in paragraph 1 have been successfully completed;

(b) a sufficient period of time has elapsed to prevent re–contamination of the affected establishment, food or feed business, animal by–products establishment or other location with the listed disease that caused the outbreak referred to in paragraph 1.

Article 62

Epidemiologically linked establishments and locations

1. The competent authority shall extend the disease control measures provided for in Article 61(1) to other establishments, epidemiological units therein, food or feed businesses, or animal by–products establishments, or any other location, or means of transport where the epidemiological enquiry provided for in Article 57(1) or the results of clinical or laboratory investigations or other epidemiological data, give reason to suspect the spread to, from or through them of the listed disease referred to in point (a) of Article 9(1) in respect of which such measures were taken.

2. If the epidemiological enquiry provided for in Article 57(1) shows that the likely origin of the listed disease referred to in point (a) of Article 9(1) is another Member State, or if it is likely that that listed disease has spread to another Member State, the competent authority shall inform that Member State and the Commission without delay.

3. Should any of the events referred to in paragraph 2 occur, the competent authorities of the different Member States shall cooperate in a further epidemiological enquiry and in the application of disease control measures.

Article 63

Delegation of powers in respect of disease control measures in affected and epidemiologically linked establishments and other locations

The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules on the disease control measures to be taken by the competent authority in accordance with Articles 61 and 62 in affected and epidemiologically linked establishments, food or feed businesses, or animal by–products establishments, and other locations in respect of any listed disease referred to in point (a) of Article 9(1), including rules on which disease control measures referred to in Article 61(1) are to be applied in relation to each listed disease.

Those detailed rules shall cover the following matters:

(a) the conditions and requirements for the disease control measures provided for in points (a) to (e) of Article 61(1);

(b) the procedures for cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures as provided for in point (f) of Article 61(1), specifying, where appropriate, the use of biocidal products for those purposes;

(c) the conditions and requirements for sampling and laboratory examination as provided for in points (g) and (h) of Article 61(1);

(d) the detailed conditions and requirements in respect of repopulation as provided for in Article 61(3);

(e) the carrying-out of the necessary disease control measures provided for in Article 62 in epidemiologically linked establishments, other locations and means of transport.

Article 64

Establishment of restricted zones by the competent authority

1. The competent authority shall establish a restricted zone as referred to in point (b) of Article 60 around the affected establishment, food or feed business, animal by–products establishment or other location where the outbreak of a listed disease as referred to in point (a) of Article 9(1) in kept animals has occurred, where appropriate taking into account:

(a) the disease profile;

(b) the geographical situation of the restricted zone;

(c) the ecological and hydrological factors of the restricted zone;

(d) the meteorological conditions;

(e) the presence, distribution and type of vectors in the restricted zone;

(f) the results of the epidemiological enquiry provided for in Article 57(1) and other studies carried out and epidemiological data;

(g) the results of laboratory tests;

(h) the disease control measures applied;

(i) other relevant epidemiological factors.

The restricted zone shall include, when appropriate, a protection and surveillance zone of a defined size and configuration.

2. The competent authority shall continuously assess and review the situation and, when appropriate in order to prevent the spread of the listed disease referred to in point (a) of Article 9(1), shall:

(a) adapt the boundaries of the restricted zone;

(b) establish additional restricted zones.

3. Where restricted zones as provided for in paragraph 1 are situated in the territory of more than one Member State, the competent authorities of those Member States shall cooperate in establishing them.

4. The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules for the establishment and modification of restricted zones, including protection or surveillance zones.

Article 65

Disease control measures in restricted zones

1. The competent authority shall ensure that, subject to national requirements for gaining access to private residences, one or more of the following disease control measures are taken in the restricted zone concerned, in order to prevent the further spread of a listed disease as referred to in point (a) of Article 9(1):

(a) the identification of establishments, food or feed businesses, animal by–products establishments or other locations with kept animals of listed species for that listed disease;

(b) visits to establishments, food or feed businesses, animal by–products establishments or other locations with kept animals of listed species for that listed disease, and, where necessary, examinations, sampling and laboratory examination of the samples taken;

(c) the imposition of conditions for the movement of persons, animals, products, feed, vehicles and any other material or substance that may be contaminated or contribute to the spread of that listed disease within and from the restricted zone and transport through the restricted zone;

(d) biosecurity requirements for:

  (i) the production, processing and distribution of products of animal origin;

  (ii) the collection and disposal of animal by–products;

  (iii) the collection, storage and handling of germinal products;

(e) the vaccination and treatment with other veterinary medicinal products of kept animals in accordance with Article 46(1) and any delegated acts adopted pursuant to Article 47;

(f) cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures;

(g) the designation or where relevant, approval of a food business establishment for the purposes of the slaughtering of animals or the treatment of products of animal origin originating from the restricted zone;

(h) the identification and traceability requirements for the movement of animals, germinal products or products of animal origin;

(i) other necessary biosecurity and risk-mitigating measures to minimise the risk of the spread of that listed disease.

2. The competent authority shall:

(a) take all necessary measures to fully inform persons in the restricted zone of the restrictions in force and the nature of the disease control measures;

(b) impose the necessary obligations on operators in order to prevent the further spread of the listed disease in question.

3. When determining which of the disease control measures provided for in paragraph 1 are to be taken, the competent authority shall take the following into account:

(a) the disease profile;

(b) the types of production;

(c) the feasibility, availability and effectiveness of those disease control measures.

Article 66

Operators' obligations regarding movements in restricted zones

1. In restricted zones as provided for in Article 64(1), operators shall only move the kept animals and products with the permission of the competent authority and in accordance with any instructions given by that authority.

2. Operators keeping animals and products in a restricted zone as provided for in Article 64(1) shall notify to the competent authority intended movements of kept animals and products within or out of the restricted zone in question. In so far as the competent authority has imposed notification obligations in accordance with point (b) of Article 65(2), the operators concerned shall notify in accordance with those obligations.

Article 67

Delegation of powers concerning disease control measures in restricted zones

The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules on the disease control measures to be taken in restricted zones as provided for in Article 65(1) for each listed disease referred to in point (a) of Article 9(1), including rules on which disease control measures referred to in Article 65(1) are to be applied in the case of each listed disease.

Those detailed rules shall cover the following matters:

(a) the conditions and requirements for the disease control measures provided for in points (a), (c), (d), (e), (g), (h) and (i) of Article 65(1);

(b) the procedures for cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures as provided for in point (f) of Article 65(1), specifying, where appropriate, the use of biocidal products for those purposes;

(c) the necessary surveillance which is to be conducted following the application of the disease control measures and laboratory examinations provided for in point (b) of Article 65(1);

(d) other specific disease control measures to limit the spread of specific listed diseases as referred to in point (a) of Article 9(1).

Article 68

Maintaining disease control measures in restricted zones and delegated acts

1. The competent authority shall continue to apply the disease control measures provided for in this Section until the following conditions are met:

(a) the disease control measures appropriate to the listed disease referred to in point (a) of Article 9(1) for which they were applied have been carried out;

(b) the final cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures has been carried out as appropriate for:

   (i) the listed disease referred to in point (a) of Article 9(1) for which the disease control measures have been applied;

(ii) the affected species of kept animals;

(iii) the type of production;

(c) adequate surveillance, as appropriate for the listed disease referred to in point (a) of Article 9(1) for which the disease control measures have been applied, and for the type of establishment or location concerned, has been carried out in the restricted zone substantiating the eradication of that listed disease.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules for the disease control measures to be taken by the competent authority, as provided for in paragraph 1, in relation to:

(a) the final procedures for cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures and, where appropriate, the use of biocidal products for those purposes;

(b) the design, means, methods, frequency, intensity, targeted animal population and sampling patterns of surveillance aimed at the restoration of disease–free status after the outbreak;

(c) repopulation of the restricted zone concerned after the completion of the disease control measures provided for in paragraph 1 of this Article, taking into account the conditions for repopulation provided for in Article 61(3).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules for the disease control measures to be taken by the competent authority, as provided for in paragraph 1, in relation to other disease control measures necessary for the restoration of disease–free status.

Article 69

Emergency vaccination

1. Where relevant for the effective control of a listed disease as referred to in point (a) of Article 9(1) for which disease control measures apply, the competent authority may:

(a) develop a vaccination plan;

(b) establish vaccination zones.

2. When deciding on the vaccination plan and the establishment of vaccination zones as provided for in paragraph 1, the competent authority shall take the following into account:

(a) the requirements for emergency vaccination set out in the contingency plans provided for in Article 43;

(b) the requirements for the use of vaccines as provided for in Article 46(1) and any delegated acts adopted pursuant to Article 47.

3. Vaccination zones as provided for in point (b) of paragraph 1 of this Article shall meet the requirements in respect of risk-mitigating measures to prevent the spread of listed diseases and surveillance as laid down in any delegated acts adopted in accordance with points (c) and (d) of Article 47(1).

Section 5

Wild animals

Article 70

Wild animals

1. Where the competent authority of an affected Member State suspects or officially confirms the presence of a listed disease as referred to in point (a) of Article 9(1) in wild animals, it shall:

(a) conduct, where relevant for that particular listed disease, surveillance in the wild animal population;

(b) take the necessary disease prevention and control measures.

2. The disease prevention and control measures provided for in point (b) of paragraph 1 of this Article may include one or more of the measures laid down in Article 53 to 69 and shall take into account the disease profile and the affected wild animals and the risk of transmission of diseases to animals and humans.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) criteria and procedures for surveillance pursuant to point (a) of paragraph 1 of this Article in the case of official confirmation of a listed disease as referred to in point (a) of Article 9(1), in accordance with Article 27;

(b) detailed rules supplementing the disease prevention and control measures to be taken pursuant to point (b) of paragraph 1 of this Article in the case of official confirmation of a listed disease as referred to in point (a) of Article 9(1).

When adopting those delegated acts, the Commission shall take into account the disease profile and the listed species for the listed disease referred to paragraph 1 of this Article.

Section 6

Additional disease control measures by the Member States, coordination by the Commission and temporary special disease control rules

Article 71

Additional disease control measures, coordination of measures and temporary special disease control rules concerning Sections 1 to 5 (Articles 53 to 70)

1. Member States may take disease control measures additional to those provided for in Article 55, Article 61(1), Article 62, Article 65(1) and (2) and Article 68(1) and in any delegated acts adopted pursuant to Article 63, Article 67 and Article 68(2), provided that such measures respect the rules laid down in this Regulation and are necessary and proportionate to control the spread of a listed disease as referred to in point (a) of Article 9(1), taking into account:

(a) the particular epidemiological circumstances;

(b) the type of establishments, other locations and production concerned;

(c) the species and categories of animals involved;

(d) economic or social conditions.

2. Member States shall inform the Commission without delay of:

(a) the disease control measures taken by their competent authority as provided for in Articles 58, 59, 61, 62, 64 and 65, Article 68(1), Article 69 and Article 70(1) and (2) and in any delegated acts adopted pursuant to Articles 63 and 67 and Articles 68(2) and 70(3);

(b) any additional disease control measures taken by them as provided for in paragraph 1.

3. The Commission shall review the disease situation and the disease control measures taken by the competent authority and any additional disease control measures taken by the Member State concerned, in accordance with this Chapter, and may, by means of implementing acts, lay down special disease control measures for a limited period of time, under conditions appropriate to the epidemiological situation, where:

(a) those disease control measures are found not to be suited to the epidemiological situation;

(b) the listed disease referred to in point (a) of Article 9(1) appears to be spreading despite the disease control measures taken in accordance with this Chapter.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4. On duly justified imperative grounds of urgency relating to a disease representing an emerging risk of a highly significant impact, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

CHAPTER 2

Disease control measures for listed diseases as referred to in points (b) and (c) of Article 9(1)

Section 1

Disease control measures in the event of suspicion of disease in kept animals

Article 72

Obligations on operators and other relevant natural and legal persons concerned in relation to listed diseases as referred to in point (b) of Article 9(1)

1. In the event of suspicion of a listed disease as referred to in point (b) of Article 9(1) in kept animals, in addition to complying with the notification obligation laid down in Article 18(1) and pending any disease control measures being taken by the competent authority in accordance with Article 74(1), Member States shall take measures to ensure that operators and other relevant natural and legal persons concerned take disease control measures as referred to in point (a) of Article 74(1) and in any delegated acts adopted pursuant to Article 74(4), to prevent the spread of that listed disease from the affected animals, establishments and other locations under their responsibility to other unaffected animals or to humans.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules for supplementing the disease control measures as provided for in paragraph 1 of this Article.

Article 73

Investigation by the competent authority in the event of suspicion of a listed disease as referred to in point (b) of Article 9(1)

1. In the event of suspicion of a listed disease as referred to in point (b) of Article 9(1) in kept animals, the competent authority shall conduct without delay an investigation to confirm or rule out the presence of that listed disease.

2. For the purpose of the investigation provided for in paragraph 1, the competent authority shall ensure that:

(a) official veterinarians carry out a clinical examination of a representative sample of the kept animals of listed species for the listed disease in question;

(b) official veterinarians take appropriate samples from those kept animals of listed species and other samples for examination in laboratories designated for that purpose by the competent authority;

(c) such designated laboratories carry out examinations to confirm or rule out the presence of the listed disease in question.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules supplementing the rules for investigations as provided for in paragraph 1 of this Article.

Article 74

Preliminary disease control measures by the competent authority for listed diseases as referred to in point (b) of Article 9(1)

1. The competent authority shall, in the event that it suspects a listed disease as referred to in point (b) of Article 9(1) in kept animals, carry out the following preliminary disease control measures, subject to national requirements for gaining access to private residences, pending the results of the investigation provided for in Article 73(1) and the carrying-out of the disease control measures provided for in Article 79:

(a) apply disease control measures to limit the spread of that listed disease from the affected territory, establishment, food or feed business, animal by–products establishment or other location;

(b) initiate, where necessary, an epidemiological enquiry, taking into account the rules for such enquiry laid down in Article 57(1).

2. In addition to the measures referred to in paragraph 1, the competent authority may, in the cases referred to in that paragraph, take additional preliminary disease control measures, provided that those measures respect the provisions of this Regulation and are in accordance with Union law.

3. The preliminary disease control measures provided for in paragraphs 1 and 2 shall be appropriate and proportionate to the risk posed by the listed disease in question, taking into account the following:

(a) the disease profile;

(b) the kept animals affected;

(c) the health status of the Member State, zone, compartment or establishment in which the listed disease is suspected;

(d) the preliminary disease control measures provided for in Article 55(1) and Article 56 and in any delegated act adopted pursuant to Article 55(2).

4. The Commission shall adopt delegated acts in accordance with Article 264 concerning rules for listed diseases as referred to in point (b) of Article 9(1) supplementing those laid down in paragraph 1 of this Article, while taking into account the matters referred to in paragraph 3, as regards:

(a) the preliminary disease control measures to be taken to prevent the spread of the listed disease, as provided for in point (a) of paragraph 1;

(b) the application of the preliminary disease control measures provided for in point (a) of paragraph 1 to other establishments, epidemiological units therein, food or feed businesses and animal by–products establishments or other locations;

(c) the establishment of temporary restricted zones which are appropriate in light of the disease profile.

Article 75

Review and extension of the preliminary disease control measures for listed diseases as referred to in point (b) of Article 9(1)

The disease control measures provided for in Article 74(1) shall be:

(a) reviewed by the competent authority, as appropriate, following the findings of the investigation provided for in Article 73(1) and, where relevant, the epidemiological enquiry provided for in point (b) of Article 74(1);

(b) further extended to other locations, as referred to in point (b) of Article 74(4), where necessary.

Article 76

Obligations of operators and other relevant natural and legal persons and measures to be taken by the competent authority in the event of suspicion of listed diseases as referred to in point (c) of Article 9(1)

1. In the event of suspicion of a listed disease as referred to in point (c) of Article 9(1) in a Member State that has opted for the eradication programme covering the relevant parts of its territory or zones or compartments thereof, as provided for in Article 31(2), that Member State shall take measures to ensure that operators and other relevant natural and legal persons concerned take appropriate measures as provided for in Article 72(1), pending any disease control measures being taken by the competent authority in accordance with paragraph 2 of this Article.

2. The competent authority of a Member State that has opted for the eradication of a listed disease as referred to in paragraph 1 shall, in the event that it suspects the disease in question in kept animals:

(a) conduct without delay an investigation to confirm or rule out the presence of that listed disease in accordance with Article 73(1) and (2);

(b) pending the results of the investigation provided for in point (a) and the carrying-out of disease control measures in accordance with Article 80(1), carry out the preliminary disease control measures provided for in Article 74(1) and (2).

3. The competent authority shall review and extend the preliminary disease control measures referred to in point (b) of paragraph 2, in accordance with Article 75.

4. Paragraphs 1, 2 and 3 of this Article shall also apply to Member States or zones which have obtained disease–free status, in order to maintain that status, in accordance with Article 36, or to compartments in accordance with Article 37(2).

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules supplementing rules in respect of:

(a) the disease control measures provided for in paragraph 1;

(b) the investigation provided for in point (a) of paragraph 2;

(c) the preliminary disease control measures to be taken to prevent the spread of the listed disease, as provided for in point (b) of paragraph 2.

Section 2

Disease confirmation in kept animals

Article 77

Official confirmation of disease by the competent authority

1. The competent authority shall base an official confirmation of a listed disease as referred to in point (b) or (c) of Article 9(1) on the following information:

(a) the results of the clinical and laboratory examinations provided for in Article 73(2);

(b) the epidemiological enquiry provided for in point (b) of Article 74(1), where relevant;

(c) other available epidemiological data.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning the requirements to be fulfilled for the official confirmation referred to in paragraph 1.

Article 78

Lifting preliminary disease control measures when the occurrence of a disease is ruled out

The competent authority shall continue to apply the preliminary disease control measures provided for in Article 74(1), Article 75 and point (b) of Article 76(2) until the presence of the listed disease in question has been ruled out in accordance with Article 77(1) and any rules adopted pursuant to Article 77(2).

Section 3

Disease control measures in the event of confirmation of disease in kept animals

Article 79

Disease control measures by the competent authority for listed diseases as referred to in point (b) of Article 9(1)

In the event of an official confirmation in accordance with Article 77(1) of an outbreak of a listed disease as referred to in point (b) of Article 9(1) in kept animals, the competent authority shall, in a Member State, zone or compartment, as relevant for that outbreak:

(a) apply the disease control measures laid down in the compulsory eradication programme provided for in Article 31(1) for that listed disease; or

(b) where the Member State or zone, or compartment, has obtained disease–free status in accordance with Article 36 or Article 37 respectively:

(i) take one or more of the measures laid down in Articles 53 to 69 proportionate to the risk posed by the listed disease in question, and

(ii) where necessary, initiate the compulsory eradication programme for that listed disease.

Article 80

Disease control measures to be taken by the competent authority for listed diseases referred to in Article 9(1)(c)

1. In the event of an official confirmation in accordance with Article 77(1) of an outbreak of a listed disease as referred to in point (c) of Article 9(1) in kept animals in a Member State that has opted for an eradication programme covering the relevant parts of its territory or zones or compartments thereof, as provided for in Article 31(2), as relevant for that listed disease and that outbreak, the competent authority shall apply the disease control measures laid down in the optional eradication programme.

2. The competent authority may take disease control measures additional to those provided for in paragraph 1 which may include one or more of the measures laid down in Articles 53 to 69 and shall be proportionate to the risk posed by the listed disease in question and shall take into account:

(a) the disease profile;

(b) the kept animals affected;

(c) economic and social impacts.

3. In the event of an official confirmation in accordance with Article 77(1) of an outbreak of a listed disease as referred to in point (c) of Article 9(1) in kept animals in a Member State, zone or compartment that has obtained disease–free status in accordance with Article 36 or Article 37, and in order to maintain that status, the competent authority shall take one or more of the measures laid down in Articles 53 to 69. Those measures shall be proportionate to the risk posed by the listed disease in question and shall take into account:

(a) the disease profile;

(b) the kept animals affected;

(c) economic and social impacts.

Section 4

Wild animals

Article 81

Disease control measures for listed diseases as referred to in point (b) of Article 9(1) in wild animals

In the event that the competent authority of an affected Member State suspects or officially confirms the outbreak of a listed disease as referred to in point (b) of Article 9(1) in wild animals, it shall throughout its territory, or in the area or zone concerned, as relevant for that outbreak:

(a) apply the disease control measures laid down in the compulsory eradication programme provided for in Article 30(1) for that listed disease; or

(b) initiate a compulsory eradication programme, where the eradication programme provided for in Article 31(1) for that listed disease has not yet been applied due to the previous absence of that disease or freedom from it, and if measures for wild animals are necessary in order to control and prevent the spread of that disease.

Article 82

Disease control measures for listed diseases as referred to in point (c) of Article 9(1) in wild animals

1. In the event that a competent authority suspects or officially confirms a listed disease as referred to in point (c) of Article 9(1) in wild animals and the affected Member State has opted for the eradication of the disease in question, and provided that measures for wild animals are envisaged in the optional eradication programme provided for in Article 31(2) for that listed disease, the competent authority shall apply the disease control measures laid down in that optional eradication programme throughout the territory of the Member State, area or zone concerned, as relevant for that suspicion or official confirmation.

2. The competent authority may take disease control measures additional to those provided for in paragraph 1, which may include one or more of the measures laid down in Articles 53 to 69 and shall be proportionate to the risk posed by the listed disease in question and shall take into account:

(a) the disease profile;

(b) the affected wild animals and the risk of transmission of diseases to animals and humans; and

(c) economic, social and environmental impacts.

3. In the event of an official confirmation of an outbreak of a listed disease as referred to in point (c) of Article 9(1) in wild animals in a Member State, zone or compartment that has obtained disease–free status in accordance with Article 36 or Article 37, and in order to maintain that status, the competent authority shall take one or more of the measures laid down in Articles 53 to 69. Those measures shall be proportionate to the risk posed by the listed disease in question and shall take into account:

(a) the disease profile;

(b) the affected wild animals and the risk of transmission of diseases to animals and humans;

(c) the relevance of the presence of the disease in wild animals in relation to the health status of kept animals; and

(d) economic, social and environmental impacts.

Section 5

Coordination by the Commission and temporary special disease control rules

Article 83

Coordination of measures by the Commission and temporary special rules concerning Sections 1 to 4

1. Member States shall inform the Commission of:

(a) disease control measures taken by their competent authorities in accordance with Articles 77(1), 78, 79 and 81 and with any delegated acts adopted pursuant to Article 77(2) in respect of a listed disease as referred to in point (b) of Article 9(1);

(b) disease control measures taken by their competent authorities in accordance with Articles 77(1), 78, 80(1) and 82 and with any delegated acts adopted pursuant to Article 77(2) in respect of a listed disease as referred to in point (c) of Article 9(1).

2. The Commission shall review the disease situation and the disease control measures taken by the competent authority in accordance with this Chapter and may, by means of implementing acts, lay down special rules for disease control measures for a limited period of time in respect of a listed disease as referred to in point (b) or point (c) of Article 9(1), under conditions appropriate to the epidemiological situation, where:

(a) those disease control measures taken by the competent authority in question are found not to be suited to the epidemiological situation;

(b) that listed disease appears to be spreading despite the disease control measures taken in accordance with this Chapter, where relevant.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

3. On duly justified imperative grounds of urgency relating to a listed disease as referred to in point (b) or point (c) of Article 9(1) representing an emerging risk of a highly significant impact, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

PART IV

REGISTRATION, APPROVAL, TRACEABILITY AND MOVEMENTS

TITLE I

TERRESTRIAL ANIMALS, GERMINAL PRODUCTS AND PRODUCTS OF ANIMAL ORIGIN FROM TERRESTRIAL ANIMALS

CHAPTER 1

Registration, approval, record-keeping and registers

Section 1

Registration of establishments and certain types of operators

Article 84

Obligation of operators to register establishments

1. Operators of establishments keeping terrestrial animals or collecting, producing, processing or storing germinal products shall, in order for their establishments to be registered in accordance with Article 93, before they commence such activities:

(a) inform the competent authority of any such establishment under their responsibility;

(b) provide the competent authority with the following information:

(i) the name and address of the operator concerned;

(ii) the location of the establishment and a description of its facilities;

(iii) the categories, species and numbers or quantities of kept terrestrial animals or germinal products which they intend to keep on the establishment, and the capacity of the establishment;

(iv) the type of establishment; and

(v) any other aspects of the establishment which are relevant for the purpose of determining the risk posed by it.

2. Operators of establishments referred to in paragraph 1 shall inform the competent authority of:

(a) any changes in the establishment in question concerning the matters referred to in point (b) of paragraph 1;

(b) any cessation of activity by the operator or establishment concerned.

3. Establishments which are subject to approval in accordance with Article 94(1) shall not be required to provide the information referred to in paragraph 1 of this Article.

Article 85

Derogations from the obligation of operators to register establishments

By way of derogation from Article 84(1), Member States may exempt from the registration requirement certain categories of establishments posing an insignificant risk, as provided for in an implementing act adopted in accordance with Article 86(2). Member States shall inform the Commission of such exemptions.

Article 86

Implementing powers concerning the obligation of operators to register establishments

1. The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators for the purpose of the registration of establishments as provided for in Article 84(1), including the time-limits by which such information is to be provided.

2. The Commission shall, by means of implementing acts, lay down rules concerning the types of establishments that may be exempted by the Member States from the registration requirement in accordance with Article 85, on the basis of:

(a) the species, categories and numbers of kept terrestrial animals and germinal products on the establishment in question and the capacity of that establishment;

(b) the type of establishment; and

(c) the movements of kept terrestrial animals or germinal products into and out of the establishment.

3. The implementing acts referred to in this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 87

Registration obligations of transporters of kept ungulates and delegated acts

1. Transporters of kept ungulates engaged in the transportation of those animals between Member States or between a Member State and a third country shall, in order to be registered in accordance with Article 93, before they commence such activities:

(a) inform the competent authority of their activity;

(b) provide that competent authority with information on:

  (i) the name and address of the transporter concerned;

  (ii) the categories, species and numbers of kept ungulates for which transportation is planned;

  (iii) the type of transport;

  (iv) the means of transport.

2. Transporters as referred to in paragraph 1 shall inform the competent authority of:

(a) any changes concerning the matters referred to in point (b) of paragraph 1;

(b) any cessation of the transport activity.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 supplementing the rules provided for in paragraph 1 of this Article, requiring other types of transporters whose transport activity poses specific and significant risks for certain species or categories of animals to provide adequate information for the purposes of registration of their activity.

Article 88

Derogations from the registration obligation of transporters of kept ungulates

By way of derogation from Article 87(1), Member States may exempt from the registration requirement certain categories of transporters whose transport activity poses an insignificant risk, as provided for in an implementing act adopted in accordance with Article 89(2). Member States shall inform the Commission of such exemptions.

Article 89

Implementing powers concerning the registration obligation of transporters

1. The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by transporters for the purposes of registration of their activity, as provided for in Article 87(1) and (3), including the time-limits by which such information is to be provided.

2. The Commission shall, by means of implementing acts, lay down rules concerning the types of transporters that may be exempted by Member States from the registration requirement in accordance with Article 86, on the basis of:

(a) the distances over which they transport the ungulates in question; and

(b) the categories, species and number of ungulates which they transport.

3. The implementing acts referred to in this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 90

Registration obligation of operators conducting assembly operations independently of an establishment

1. Operators conducting assembly operations for kept ungulates and poultry, independently of an establishment, including those who buy and sell animals, shall, in order to be registered in accordance with Article 93, before they commence their activities, provide the competent authority with information on:

(a) the name and address of the operator concerned;

(b) the species and categories of kept ungulates and poultry covered by their activity.

2. Operators as referred to in paragraph 1 shall inform the competent authority of:

(a) any changes concerning the matters referred to in paragraph 1;

(b) any cessation of activity by the operator concerned.

Article 91

Derogations from the registration obligation of operators conducting assembly operations

By way of derogation from Article 90(1), Member States may exempt from the registration requirement certain categories of operators conducting assembly operations posing an insignificant risk, as provided for in an implementing act adopted in accordance with Article 92(2). Member States shall inform the Commission of such exemptions.

Article 92

Implementing powers concerning the registration obligation of operators conducting assembly operations

1. The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators for the purpose of registration as provided for in Article 90(1), including the time-limits by which such information is to be provided.

2. The Commission shall, by means of implementing acts, lay down rules concerning the types of operators that may be exempted by Member States from the registration requirement in accordance with Article 91, provided that the activity of such operators poses an insignificant risk and on the basis of species, the categories and numbers of kept terrestrial animals covered by their activity.

3. The implementing acts referred to in this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 93

Obligation of the competent authority concerning registration

A competent authority shall register:

(a) establishments in the register provided for in Article 101(1), where the operator concerned has provided the information required in accordance with Article 84(1);

(b) transporters in the register provided for in Article 101(1), where the transporter concerned has provided the information required in accordance with Article 87(1) and (3);

(c) operators conducting assembly operations independently of an establishment, in the register provided for in Article 101(1), where the operator concerned has provided the information required in accordance with Article 90(1).

The competent authority shall assign each establishment, transporter and operator as referred to in points (a) to (c) of the first paragraph with a unique registration number.

Section 2

Approval of certain types of establishments

Article 94

Approval of certain establishments and delegated acts

1. Operators of the following types of establishments shall apply to the competent authority for approval in accordance with Article 96(1) and shall not commence their activities until their establishment has been approved in accordance with Article 97(1):

(a) establishments for assembly operations of ungulates and poultry from which those animals are moved to another Member State or which receive animals from another Member State;

(b) germinal product establishments for bovine, porcine, ovine, caprine and equine animals from which germinal products of those animals are moved to another Member State;

(c) hatcheries from which hatching eggs or poultry are moved to another Member State;

(d) establishments keeping poultry from which poultry intended for purposes other than slaughter or hatching eggs are moved to another Member State;

(e) any other type of establishment for kept terrestrial animals which poses a significant risk and is required to be approved in accordance with rules laid down in a delegated act adopted in accordance with point (b) of paragraph 3.

2. Operators shall cease activity at an establishment as referred to in paragraph 1 where:

(a) the competent authority withdraws or suspends its approval in accordance with Article 100(2); or

(b) in the event of conditional approval, granted in accordance with Article 99(3), the establishment in question fails to comply with the outstanding requirements referred to in Article 99(3) and does not obtain a final approval in accordance with Article 97(1).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) derogations from the requirement for operators of the types of establishments referred to in points (a) to (d) of paragraph 1 to apply to the competent authority for approval, where those establishments pose an insignificant risk;

(b) the types of establishments which must be approved in accordance with point (e) of paragraph 1;

(c) special rules for the cessation of activities for germinal product establishments as referred to in point (b) of paragraph 1.

4. When adopting delegated acts as provided for in paragraph 3, the Commission shall base those acts on the following criteria:

(a) the species and categories of kept terrestrial animals or germinal products in an establishment;

(b) the number of species and number of kept terrestrial animals or germinal products kept in an establishment;

(c) the type of establishment and type of production; and

(d) the movements of kept terrestrial animals or germinal products into and out of those types of establishments.

Article 95

Approval of status of confined establishments

Operators of establishments wishing to obtain the status of a confined establishment shall:

(a) apply to the competent authority for approval in accordance with Article 96(1);

(b) move kept animals to or from their establishment in accordance with the requirements provided for in Article 137(1) and any delegated acts adopted in accordance with Article 137(2) only after their establishment has obtained an approval of that status from the competent authority in accordance with Articles 97 and 99.

Article 96

Obligation of operators to provide information with a view to obtaining approval and implementing acts

1. Operators shall, for the purposes of their application for approval of their establishment as provided for in Article 94(1) and point (a) of Article 95, provide the competent authority with the following information:

(a) the name and address of the operator concerned;

(b) the location of the establishment concerned and a description of its facilities;

(c) the categories, species and number of kept terrestrial animals or germinal products relevant for the approval which are kept on the establishment;

(d) the type of establishment;

(e) other aspects of the establishment, related to its specificity, which are relevant in determining the risk, if any, posed by it.

2. Operators of establishments as referred to in paragraph 1 shall inform the competent authority of:

(a) any changes in the establishments concerning the matters referred to in points (a), (b) or (c) of paragraph 1;

(b) any cessation of activity by the operator or establishment concerned.

3. The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators in their application for approval of their establishment in accordance with paragraph 1, and the time-limits by which the information referred to in paragraph 1 and in point (b) of paragraph 2 is to be provided.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 97

Granting of, and conditions for, approval of establishments and delegated acts

1. Competent authorities shall only grant approval of establishments as provided for in Article 94(1) and point (a) of Article 95 where such establishments:

(a) comply with the following requirements, where appropriate, in relation to:

(i) quarantine, isolation and other biosecurity measures taking into account the requirements provided for in point (b) of Article 10(1) and any rules adopted pursuant to Article 10(2);

(ii) surveillance requirements as provided for in Article 24 and, where relevant for the type of establishment concerned and the risk involved, in Article 25;

(iii) record-keeping as provided for in Articles 102 and 103 and any rules adopted pursuant to Articles 106 and 107;

(b) have facilities and equipment that are:

(i) adequate to reduce the risk of the introduction and spread of diseases to an acceptable level, taking into account the type of establishment concerned;

(ii) of a capacity adequate for the number of kept terrestrial animals or the volume of germinal products concerned;

(c) do not pose an unacceptable risk as regards the spread of diseases, taking into account the risk-mitigation measures in place;

(d) have adequately trained personnel for the activity of the establishment concerned;

(e) have in place a system which enables the operator concerned to demonstrate to the competent authority compliance with points (a) to (d).

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) quarantine, isolation and other biosecurity measures as referred to in point (a)(i) of paragraph 1;

(b) surveillance as referred to in point (a)(ii) of paragraph 1;

(c) facilities and equipment as referred to in point (b) of paragraph 1;

(d) responsibilities, competence and specialised training of personnel and veterinarians as provided for in point (d) of paragraph 1 for the activity of germinal products establishments and establishments for assembly operations of ungulates and poultry;

(e) the necessary supervision by the competent authority of germinal products establishments and establishments for assembly operations of ungulates and poultry.

3. When establishing the rules to be laid down in the delegated acts to be adopted pursuant to paragraph 2, the Commission shall base those rules on the following matters:

(a) the risks posed by each type of establishment;

(b) the species and categories of kept terrestrial animals relevant for the approval;

(c) the type of production concerned;

(d) typical movement patterns of the type of establishment and species and categories of animals kept in those establishments.

Article 98

Scope of the approval of establishments

The competent authority shall expressly specify in the approval of an establishment granted pursuant to Article 97(1), following an application made in accordance with Article 94(1) or point (a) of Article 95:

(a) for which of the types of establishments referred to in Article 94(1) and Article 95, and in the rules adopted pursuant to point (b) of Article 94(3), the approval applies;

(b) for which species and categories of kept terrestrial animals or germinal products of those species the approval applies.

Article 99

Procedures for the granting of approval by the competent authority

1. The competent authority shall establish procedures for operators to follow when applying for approval of their establishments in accordance with Article 94(1), Article 95 or Article 96(1).

2. Upon receipt of an application for approval from an operator, the competent authority shall, in accordance with Article 94(1) or point (a) of Article 95, make an on–site visit.

3. Provided that the requirements referred to in Article 97 and paragraphs (1) and (2) of this Article are fulfilled, the competent authority shall grant the approval.

4. Where an establishment does not fulfil all requirements for approval as referred to in Article 97, the competent authority may grant conditional approval of an establishment if it appears, on the basis of the application by the operator concerned and the subsequent on–site visit as provided for in paragraph 2 of this Article, that the establishment meets all the main requirements that provide sufficient guarantees that the establishment does not pose a significant risk.

5. Where conditional approval has been granted by the competent authority in accordance with paragraph 4 of this Article, it shall grant full approval only where it appears from another on–site visit to the establishment, carried out within three months of the date of the grant of conditional approval, or from documentation provided by the operator within three months from that date, that the establishment meets all the requirements for approval provided for in Article 97(1) and the rules adopted pursuant to Article 97(2).

Where the on–site visit or the documentation referred to in the first subparagraph shows that clear progress has been made but that the establishment still does not meet all of those requirements, the competent authority may prolong the conditional approval. However, conditional approval shall not be granted for a period exceeding, in total, six months.

Article 100

Review, suspension and withdrawal of approvals by the competent authority

1. The competent authority shall keep approvals of establishments granted in accordance with Articles 97 and 99 under review, at appropriate intervals based on the risk involved.

2. Where a competent authority identifies serious deficiencies in an establishment as regards compliance with the requirements laid down in Article 97(1) and the rules adopted pursuant to Article 97(2), and the operator of that establishment is not able to provide adequate guarantees that those deficiencies will be eliminated, the competent authority shall initiate procedures to withdraw the approval of the establishment.

However, the competent authority may merely suspend, rather than withdraw, approval of an establishment where the operator can guarantee that it will eliminate those deficiencies within a reasonable period of time.

3. Approval shall only be granted after withdrawal or restored after suspension in accordance with paragraph 2 when the competent authority is satisfied that the establishment fully complies with all the requirements of this Regulation appropriate for that type of establishment.

Section 3

Registers of the competent authority

Article 101

Registers to be kept by the competent authority

1. Each competent authority shall establish and keep up to date registers of:

(a) all establishments and operators registered with it pursuant to Article 93;

(b) all establishments approved by it in accordance with Articles 97 and 99.

It shall make the registers referred to in points (a) and (b) of the first subparagraph available to the Commission and to the competent authorities of other Member States in so far as the information contained therein is relevant for movements of kept terrestrial animals and germinal products thereof between Member States.

It shall make the register of approved establishments as referred to in point (b) of the first subparagraph available to the public in so far as the information contained therein is relevant for movements of kept terrestrial animals and germinal products thereof between Member States.

2. Where appropriate and relevant, a competent authority may combine the registration referred to in point (a) of the first subparagraph of paragraph 1 and the approvals referred to in point (b) of the first subparagraph of paragraph 1 with registration for other purposes.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the detailed information to be included in the registers provided for in points (a) and (b) of the first subparagraph of paragraph 1, and the availability to the public of the register provided for in point (b) of the first subparagraph of paragraph 1.

Section 4

Record-keeping

Article 102

Record-keeping obligations of operators of establishments other than germinal products establishments

1. Operators of establishments subject to the requirement of registration in accordance with Article 93, or approval in accordance with Article 97(1), shall keep and maintain records containing at least the following information:

(a) the species, categories, number and, where applicable, identification of kept terrestrial animals on their establishment;

(b) movements of kept terrestrial animals into and out of their establishment, stating as appropriate:

  (i) their place of origin or destination;

  (ii) the date of such movements;

(c) the documents required to accompany kept terrestrial animals arriving at or leaving their establishment in accordance with point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), point (b) of Article 115, point (b) of Article 117, Article 143(1) and (2), Article 164(2) and any rules adopted pursuant to Articles 118 and 120 and points (b) and (c) of Article 144(1);

(d) mortality of kept terrestrial animals on their establishment;

(e) biosecurity measures, surveillance, treatments, test results and other relevant information as appropriate for:

(i) the species and categories of kept terrestrial animals in the establishment;

(ii) the type of production;

(iii) the type and size of the establishment;

(f) the results of any animal health visits required in accordance with Article 25(1).

The records shall be kept and maintained in paper or electronic form.

2. Establishments presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in paragraph 1.

3. Operators of establishments shall keep the records provided for in paragraphs 1 and 2 on their establishment concerned and shall:

(a) make them immediately available to the competent authority on request;

(b) retain them for a minimum period to be prescribed by the competent authority, which may not be less than three years.

4. By way of derogation from paragraph 3, operators may be exempted from the obligation to keep records of some or all of the matters provided for in paragraph 1 when the operator concerned:

(a) has access to the computerised database referred to in Article 109 for the relevant species and the database already contains the information to be included in the records; and

(b) has the up–to–date information entered directly into the computerised database.

Article 103

Record-keeping obligations of germinal product establishments

1. Operators of germinal product establishments shall keep and maintain records containing at least the following information:

(a) the breed, age, identification and health status of donor animals used for the production of germinal products;

(b) the time and place of collection, and the processing and storage, of germinal products collected, produced or processed;

(c) the identification of the germinal products together with details of their place of destination, if known;

(d) the documents required to accompany germinal products arriving at or leaving the establishment in question in accordance with Article 162 and Article 164(2) and any rules adopted pursuant to Article 162(3) and (4);

(e) where relevant, the results of clinical and laboratory tests;

(f) laboratory techniques used.

2. Establishments presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in paragraph 1.

3. Operators of germinal product establishments shall keep the records provided for in paragraphs 1 and 2 on their establishment and:

(a) make them immediately available to the competent authority on request;

(b) retain them for a minimum period to be prescribed by the competent authority, which may not be less than three years.

Article 104

Record-keeping obligations of transporters

1. Transporters shall keep and maintain records containing at least the following information:

(a) the establishments visited by them;

(b) the categories, species and number of kept terrestrial animals transported by them;

(c) the cleaning, disinfection and disinfestation of the means of transport used;

(d) details of the documents accompanying the animals in question, including their document numbers.

The records shall be kept and maintained in paper or electronic form.

2. Transporters presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in paragraph 1.

3. Transporters shall keep the records provided for in paragraphs 1 and 2:

(a) in such a manner that they can be made immediately available to the competent authority on request;

(b) for a minimum period to be prescribed by the competent authority, which may not be less than three years.

Article 105

Record-keeping obligations of operators conducting assembly operations

1. Operators conducting assembly operations subject to the registration requirement laid down in Article 93 shall keep and maintain records containing at least the following information:

(a) the species, categories, numbers and identification of kept terrestrial animals under their responsibility;

(b) movements of kept terrestrial animals under their responsibility, stating as appropriate:

  (i) their place of origin and destination;

  (ii) the date of such movements;

(c) the documents required to accompany kept terrestrial animals moved under their responsibility in accordance with point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), point (b) of Article 115, point (b) of Article 117, Article 143(1) and (2), Article 164(2) and any rules adopted pursuant to Articles 118 and 120 and points (b) and (c) of Article 144(1);

(d) mortality of kept terrestrial animals under their responsibility; and

(e) biosecurity measures, surveillance, treatments, test results and other relevant information as appropriate for the species and categories of kept terrestrial animals under their responsibility.

The records shall be kept and maintained in paper or electronic form.

2. Operators whose activities present a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in paragraph 1.

3. Operators shall:

(a) make the records referred to in paragraph 1 available to the competent authority on request;

(b) retain those records for a minimum period to be prescribed by the competent authority, which may not be less than three years.

Article 106

Delegation of powers concerning record-keeping

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules supplementing the record-keeping requirements provided for in Articles 102, 103, 104 and 105, as regards:

(a) information to be recorded in addition to that provided for in Articles 102(1), 103(1), 104(1) and 105(1);

(b) additional requirements for record-keeping in respect of germinal products collected, produced or processed in a germinal products establishment after that establishment ceased its activities.

2. When establishing the rules to be laid down in delegated acts as provided for in paragraph 1, the Commission shall base those rules on the following matters:

(a) the risks posed by each type of establishment or activity;

(b) the species and categories of kept terrestrial animals or germinal products in the establishment concerned, or transported to or from that establishment;

(c) the type of production on the establishment or the type of activity;

(d) the typical movement patterns and categories of the animals concerned;

(e) the number of kept terrestrial animals or volume of germinal products under the responsibility of the operator concerned.

Article 107

Implementing powers concerning exemptions from the record-keeping requirements

The Commission may, by means of implementing acts, lay down rules concerning the types of establishments and operators that may be exempted by Member States from the record-keeping requirements provided for in Articles 102, 103, 104 and 105, as regards:

(a) establishments keeping, or operators handling or transporting, a small number of kept terrestrial animals or a small volume or number of germinal products;

(b) species or categories of kept terrestrial animals or germinal products.

When adopting those implementing acts, the Commission shall base those acts on the criteria laid down in Article 106(2).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 2

Traceability requirements for kept terrestrial animals and germinal products

Section 1

Kept terrestrial animals

Article 108

Member States' responsibility for establishing a system for the identification and registration of kept terrestrial animals

1. Member States shall have in place a system for the identification and registration of those species of kept terrestrial animals for which such a system is required by this Regulation and by any rules adopted pursuant to it. Such a system shall, when appropriate, provide for the recording of the movements of such animals.

2. When establishing the system referred to in paragraph 1, Member States shall take into account:

(a) the species or categories of kept terrestrial animals concerned;

(b) the risk posed by that species or category.

3. The system provided for in paragraph 1 shall include the following elements:

(a) the means to identify kept terrestrial animals individually or in groups;

(b) identification documents, movement documents and other documents for identifying and tracing kept terrestrial animals as referred to in Article 110;

(c) up–to–date records in establishments as provided for in points (a) and (b) of Article 102(1);

(d) a computer database of kept terrestrial animals as provided for in Article 109(1).

4. The system provided for in paragraph 1 shall be designed in such a manner that it:

(a) ensures the efficient application of the disease prevention and control measures provided for in this Regulation;

(b) facilitates the traceability of kept terrestrial animals and their movements within and between Member States and their entry into the Union;

(c) ensures the efficient interoperability, integration and compatibility of the elements of that system;

(d) ensures that the system, to the extent appropriate, is adapted to:

(i) the computerised information system for Union notification and reporting provided for in Article 22;

(ii) TRACES;

(e) ensures a coherent approach in respect of the different animal species covered by the system.

5. Member States may when appropriate:

(a) use the whole or part of the system provided for in paragraph 1 for purposes other than those referred to in points (a) and (b) of paragraph 4;

(b) integrate the identification documents, movement documents and other documents referred to in Article 110 with the animal health certificates or self–declaration document provided for in Article 143(1) and (2) and Article 151(1) and in any rules adopted pursuant to points (b) and (c) of Article 144(1) and Article 151(3) and (4);

(c) designate another authority or authorise another body or a natural person to ensure the practical application of the identification and registration system provided for in paragraph 1 of this Article, including the issuing of identification documents and the drawing-up of models as provided for in points (a), (b) and (c) of Article 110(1).

Article 109

Member States' obligation to establish and maintain a computer database of kept terrestrial animals

1. The Member States shall establish and maintain a computer database for the recording of at least:

(a) the following information related to kept animals of the bovine species:

(i) their individual identification as provided for in point (a) of Article 112;

(ii) the establishments keeping them;

(iii) their movements into and from those establishments;

(b) the following information related to kept animals of the ovine and caprine species:

(i) information on their identification as provided for in point (a) of Article 113(1) and the number of animals at the establishments keeping them;

(ii) the establishments keeping them;

(iii) their movements into and from those establishments;

(c) the following information related to kept animals of the porcine species:

(i) information on their identification as provided for in Article 115 and the number of animals at the establishments keeping them;

(ii) the establishments keeping them;

(iii) their movements into and from those establishments;

(d) the following information related to kept animals of the equine species:

(i) their unique code as provided for in Article 114;

(ii) the method of identification provided for in point (b) of Article 114(1) linking the animal concerned with the identification document referred to in point (iii) where relevant;

(iii) the relevant identification details from the identification document provided for in point (c) of Article 114(1), as determined in the rules adopted pursuant to Articles 118 and 120;

(iv) the establishments where those animals are habitually kept;

(e) information related to kept terrestrial animals of species other than those referred to in points (a), (b), (c) and (d) of this paragraph, when this is provided for in the rules adopted pursuant to paragraph 2.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the recording of information related to animal species other than those referred to in points (a), (b), (c) and (d) of paragraph 1 of this Article in the computer database provided for in that paragraph where necessary, due to the specific and significant risks posed by those species, in order to:

(a) ensure the efficient application of the disease prevention measures and control measures provided for in this Regulation;

(b) facilitate the traceability of kept terrestrial animals, their movements between Member States and their entry into the Union.

Article 110

Obligation of the competent authority in respect of identification documents, movement documents and other documents for the identification and tracing of kept terrestrial animals

1. Each competent authority shall:

(a) issue identification documents in respect of kept terrestrial animals where those documents are required by point (c) of Article 114(1) and point (b) of Article 117 and by rules adopted pursuant to Articles 118 and 120;

(b) issue identification documents in respect of bovine animals as required by point (b) of Article 112, unless Member States exchange electronic data with other Member States within the framework of an electronic exchange system from the date when the Commission recognises the full operability of that system;

(c) draw up models of movement documents and other documents for the identification and tracing of kept terrestrial animals, when required by point (b) of Article 113(1), point (b) of Article 115, point (b) of Article 117 and any rules adopted pursuant to Articles 118 and 120.

2. Point (b) of paragraph (1) is without prejudice to the right of Member States to adopt national rules on the issuing of passports for animals not intended for movement between Member States.

Article 111

Public availability of information on means of identification

Each competent authority shall inform the Commission of, and make publicly available, information on:

(a) contact points for the computer databases established by the Member States in accordance with Article 109(1);

(b) the authorities or bodies responsible for issuing identification documents, movement documents and other documents in accordance with Article 110, taking into account point (c) of Article 108(5);

(c) the means of identification that are to be used for each species and category of kept terrestrial animals in accordance with point (a) of Article 112, point (a) of Article 113(1), Article 114(1), point (a) of Article 115, point (a) of Article 117 and any rules adopted pursuant to Articles 118 and 120;

(d) the prescribed format for the issuing of the identification documents and other documents referred to in Article 110.

Article 112

Operators' obligations in respect of the identification of kept animals of the bovine species

Operators keeping animals of the bovine species shall:

(a) ensure that those kept animals are identified individually by a physical means of identification;

(b) ensure that those kept animals, when they are moved between Member States, are issued with an identification document from the competent authority or designated authority or authorised body of origin, unless the conditions laid down in point (b) of Article 110(1) are met;

(c) ensure that that identification document:

(i) is kept, correctly completed and updated by the operator concerned; and

(ii) accompanies those kept terrestrial animals at the time of movement, when such document is required by point (b);

(d) transmit the information on movements of those kept animals from and to the establishment concerned, and all births and deaths in that establishment, to the computer database provided for in Article 109(1).

Article 113

Operators' obligations in respect of the identification of kept animals of the ovine and caprine species

1. Operators keeping kept animals of the ovine and caprine species shall:

(a) ensure that those kept animals are each identified by a physical means of identification;

(b) ensure that those kept animals are accompanied by a correctly completed movement document based on the model drawn up by the competent authority in accordance with Article 110 when they are moved from the establishment keeping those animals within the Member State concerned;

(c) transmit the information on movements of those kept animals from and to the establishment to the computer database provided for in Article 109(1).

2. Member States may exempt operators from the requirement to ensure that kept animals of the ovine and caprine species are accompanied by movement documents during movements within their territory, provided that:

(a) the information contained in the relevant movement document is included in the computer database provided for in Article 109(1);

(b) the system for the identification and registration of kept animals of the ovine and caprine species provides level of traceability equivalent to that provided by movement documents.

Article 114

Operators' obligations in respect of the identification and registration of kept animals of the equine species

1. Operators keeping kept animals of the equine species shall ensure that those animals are individually identified by:

(a) a unique code which is recorded in the computer database provided for in Article 109(1);

(b) a physical means of identification or other method which unequivocally links the kept animal with the identification document provided for in point (c) of this paragraph and issued by the competent authority in accordance with Article 110;

(c) a correctly completed single lifetime identification document.

2. Operators of kept animals of the equine species shall ensure that the information on those animals is transmitted to the computer database provided for in Article 109(1).

Article 115

Operators' obligations in respect of the identification and registration of kept animals of the porcine species

Operators keeping kept animals of the porcine species shall:

(a) ensure that those kept animals are each identified by a physical means of identification;

(b) ensure that those kept animals are accompanied by a correctly completed movement document based on the model drawn up by the competent authority in accordance with point (b) of Article 110(1) when they are moved from the establishment keeping those animals within the Member State concerned;

(c) transmit the information relating to the establishment keeping those animals to the computer database provided for in Article 109(1).

Article 116

Derogations concerning movements of kept animals of the porcine species

By way of derogation from point (b) of Article 115, Member States may exempt operators from the requirement to ensure that kept animals of the porcine species are accompanied by correctly completed movement documents based on the model drawn up by the competent authority for movements within the Member State concerned, provided that:

(a) the information contained in such movement documents is included in the computer database established by that Member State in accordance with Article 109(1);

(b) the system for the identification and registration of kept terrestrial animals of the porcine species provides a level of traceability equivalent to that provided by such movement documents.

Article 117

Operators' obligation in respect of the identification of kept terrestrial animals other than animals of the bovine, ovine, caprine, porcine and equine species

Operators shall ensure that kept terrestrial animals of species other than those of the bovine, ovine, caprine, porcine and equine species fulfil the following requirements, when required by the rules adopted pursuant to Articles 118 and 120:

(a) they are identified, either individually or in groups;

(b) they are accompanied by correctly completed and updated identification documents, movement documents or other documents for the identification and tracing of animals, as appropriate for the animal species concerned.

Article 118

Delegation of powers concerning identification and registration

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) detailed requirements for the means and methods of identification of kept terrestrial animals provided for in point (a) of Article 112, point (a) of Article 113(1), Article 114(1), point (a) of Article 115 and point (a) of Article 117, including their application and use;

(b) rules on the information to be included in:

(i) the computer databases provided for in points (a) to (d) of Article 109(1);

(ii) the identification and movement documents provided for in point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), and point (b) of Article 115;

(c) rules on the exchange of electronic data between computer databases of Member States as referred to in point (b) of Article 110(1).

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) detailed requirements for alternative means and methods of identification to those referred to in point (a) of paragraph 1 of this Article, as well as exemptions and special provisions for certain categories of animals or circumstances and conditions for such exemptions;

(b) specific provisions for the identification or movement documents provided for in point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), point (b) of Article 115 and point (b) of Article 117 that have to accompany animals when they are moved;

(c) detailed requirements for the identification and registration of kept terrestrial animals of species other than the bovine, ovine, caprine, porcine and equine species where necessary, taking into account the risks posed by the species concerned, in order to:

(i) ensure the efficient application of the disease prevention and control measures provided for in this Regulation;

(ii) facilitate the traceability of kept terrestrial animals, and their movements within and between Member States and their entry into the Union;

(d) rules on the information to be included in:

(i) the computer databases provided for in point (e) of Article 109(1);

(ii) the identification and movement documents provided for in point (b) of Article 117;

(e) rules on the identification and registration of kept terrestrial animals as referred to in Articles 112 to 117 after their entry into the Union.

3. When establishing the rules to be laid down in the delegated acts provided for in this Article, the Commission shall base those rules on the considerations provided for in Article 119(2).

Article 119

Delegation of powers concerning derogations from the traceability requirements

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning derogations for operators from the identification and registration requirements provided for in Articles 112, 113, 114 and 115:

(a) in cases where one or more of the elements listed in Article 108(3) are not necessary in order to meet the requirements provided for in points (a) and (b) of Article 108(4); and

(b) when other traceability measures in place in the Member States guarantee that the level of traceability of the animals in question is not compromised,

as well as transitional measures required for the practical application of such derogations.

2. When establishing the rules to be laid down in the delegated acts provided for in paragraph 1, the Commission shall base those rules on the following considerations:

(a) the species and categories of kept terrestrial animals concerned;

(b) the risks involved for those kept terrestrial animals;

(c) the number of animals in the establishments concerned;

(d) the type of production in the establishments where those terrestrial animals are kept;

(e) movement patterns for the species and categories of kept terrestrial animals concerned;

(f) considerations concerning the protection and conservation of the species of kept terrestrial animals concerned;

(g) the performance of the other traceability elements of the system for the identification and registration of kept terrestrial animals referred to in Article 108(3).

Article 120

Implementing powers concerning the traceability of kept terrestrial animals

1. The Commission shall, by means of implementing acts, adopt rules:

(a) for uniform access to data contained in, and the technical specifications and operational rules of, the computer databases referred to in points (a) to (d) of Article 109(1);

(b) on the technical conditions and modalities for the exchange of electronic data between computer databases of Member States and the recognition of full operability of the data exchange systems referred to in point (b) of Article 110(1).

2. The Commission may, by means of implementing acts, adopt rules:

(a) for the uniform application of the identification and registration system provided for in Article 108(1) for different species or categories of kept terrestrial animals, in order to ensure its efficient operation;

(b) for the uniform application of point (c) of Article 108(5) concerning the authorised bodies or natural persons referred to in Article 108(5) and the conditions for their designation;

(c) on the technical specifications and procedures, formats, design and operational rules for the means and methods of identification, including:

(i) the time periods for the application of the means and methods of identification;

(ii) the removal, modification or replacement of the means and methods of identification and the deadlines for such operations; and

(iii) the configuration of the identification code;

(d) on the technical specifications, formats and operational rules for the identification and movement documents provided for in point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), point (b) of Article 115 and point (b) of Article 117;

(e) for uniform access to data contained in, and the technical specifications and operational rules of, the computer databases referred to in point (e) of Article 109(1);

(f) on the deadlines, obligations and procedures for the transmission of information by operators or other natural or legal persons and for the registration of kept terrestrial animals in the computer databases;

(g) on guidelines and procedures for electronic identification of animals, where relevant;

(h) on the practical application of exemptions from the identification and registration requirements provided for in the rules adopted pursuant to Article 119(1).

3. The implementing acts referred to in this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Section 2

Germinal products

Article 121

Traceability requirements for germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species

1. Operators producing, processing or storing germinal products shall mark germinal products of kept animals of the bovine, caprine, ovine, porcine and equine species in such a way that they can be clearly traced to:

(a) the donor animals;

(b) the date of collection; and

(c) the germinal product establishments where they were collected, produced, processed and stored.

2. The marking provided for in paragraph 1 shall be designed in such a way as to ensure:

(a) the efficient application of the disease prevention and control measures provided for in this Regulation;

(b) the traceability of the germinal products, their movements within and between Member States and their entry into the Union.

Article 122

Delegation of powers concerning traceability requirements for germinal products

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning traceability requirements for germinal products of kept terrestrial animals of the bovine, caprine, ovine, porcine and equine species supplementing the rules laid down in Article 121;

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning traceability requirements for germinal products of kept terrestrial animals of species other than of the bovine, caprine, ovine, porcine and equine species, where necessary for:

(a) the efficient application of the disease prevention and control measures provided for in this Regulation;

(b) the traceability of those germinal products, their movements within and between Member States and their entry into the Union.

3. When adopting the delegated acts provided for in paragraph 1, the Commission shall base those acts on the following matters:

(a) the species of kept terrestrial animals from which the germinal products originate;

(b) the health status of donor animals;

(c) the risk involved with such germinal products;

(d) the type of germinal products;

(e) the type of collection, production, processing or storage of germinal products;

(f) the movement patterns for the relevant species and categories of kept terrestrial animals and their germinal products;

(g) considerations concerning the protection and conservation of species of kept terrestrial animals;

(h) other elements that may contribute to the traceability of germinal products.

Article 123

Implementing powers concerning traceability requirements for germinal products

The Commission shall, by means of implementing acts, lay down rules concerning:

(a) technical requirements and specifications for marking as provided for in Article 121(1);

(b) operational requirements for the traceability provided for in delegated acts adopted pursuant to Article 122(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 3

Movements within the Union of kept terrestrial animals

Section 1

General requirements for movements

Article 124

General requirements for movements of kept terrestrial animals

1. Operators shall take appropriate preventive measures to ensure that the movement of kept terrestrial animals does not jeopardise the health status at the place of destination with regard to:

(a) the listed diseases referred to in point (d) of Article 9(1);

(b) emerging diseases.

2. Operators shall only move kept terrestrial animals from their establishments and receive such animals if the animals in question fulfil the following conditions:

(a) they come from establishments that have been:

(i) registered by the competent authority in accordance with Article 93; or

(ii) approved by the competent authority in accordance with Articles 97(1) and 98, when required by Article 94(1) or Article 95; or

(iii) granted a derogation from the registration requirement laid down in Article 84;

(b) they fulfil the identification and registration requirements laid down in Articles 112, 113, 114, 115 and 117 and the rules adopted pursuant to Articles 118 and 120.

Article 125

Disease prevention measures in relation to transport

1. Operators shall take the appropriate and necessary preventive measures to ensure that:

(a) the health status of kept terrestrial animals is not jeopardised during transport;

(b) transport operations of kept terrestrial animals do not cause the potential spread of listed diseases as referred to in point (d) of Article 9(1) to humans and animals;

(c) cleaning and disinfection of, and control of insects and rodents with respect to, equipment and means of transport and other adequate biosecurity measures are taken, as appropriate to the risks involved with the transport operations concerned.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) the conditions and requirements for cleaning and disinfection of, and control of insects and rodents with respect to, equipment and means of transport and the use of biocidal products for those purposes;

(b) other appropriate biosecurity measures as provided for in point (c) of paragraph 1 of this Article.

Section 2

Movements between Member States

Article 126

General requirements for movements of kept terrestrial animals between Member States

1. Operators shall only move kept terrestrial animals to another Member State if the animals in question fulfil the following conditions:

(a) they show no disease symptoms;

(b) they come from a registered or approved establishment:

(i) where there are no abnormal mortalities with an undetermined cause;

(ii) which is not subject to movement restrictions affecting the species to be moved in accordance with the rules laid down in Article 55(1), point (a) of Article 61(1), Article 62, point (c) of Article 65(1), Article 74(1) and Article 79 and the rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 71(3), 74(4), and 83(2) or the emergency measures provided for in Articles 257 and 258 and any rules adopted pursuant to Article 259, unless derogations from movement restrictions have been granted in accordance with those rules;

(iii) which is not situated in a restricted zone in accordance with rules laid down in point (f)(ii) of Article 55(1), Articles 64 and 65, Article 74(1), Article 79 and any rules adopted pursuant to Article 67, Article 71(3), Article 74(4) and Article 83(2) or the emergency measures provided for in Articles 257 and 258 and any rules adopted pursuant to Article 259, unless derogations have been granted in accordance with those rules;

(c) they have not been in contact with kept terrestrial animals which are subject to movement restrictions as referred to in point (b)(ii) and (iii) or kept terrestrial animals of a listed species of a lower health status, for an adequate period of time prior to the date of the intended movement to another Member State, thereby minimising the possibility of spreading disease, taking into account the following matters:

(i) the incubation period and routes of transmission of the listed diseases and emerging diseases in question;

(ii) the type of establishment concerned;

(iii) the species and category of kept terrestrial animals moved;

(iv) other epidemiological factors;

(d) they fulfil the relevant requirements provided for in Sections 3 to 8 (Articles 130 to 154).

2. Operators shall take all necessary measures to ensure that kept terrestrial animals moved to another Member State are consigned directly to their place of destination in that other Member State unless they need to stop at a place of resting for animal welfare reasons.

Article 127

Obligations of operators at the place of destination

1. Operators of establishments and slaughterhouses receiving kept terrestrial animals from another Member State shall:

(a) check that:

(i) the means or methods of identification provided for in point (a) of Article 112, point (a) of Article 113(1), points (a) and (b) Article 114(1), point (a) of Article 115 and point (a) of Article 117 and the rules adopted pursuant to Articles 118 and 120 are in place;

(ii) the identification documents provided for in point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), point (b) of Article 117 and the rules adopted pursuant to Articles 118 and 120 are in place and are correctly completed;

(b) check that the animal health certificates provided for in Article 143 and in any rules adopted pursuant to points (b) and (c) of Article 144(1) or the self–declaration documents provided for in Article 151 and the rules adopted pursuant to Article 151(3) and (4) are in place;

(c) inform the competent authority of the place of destination, after checking the kept terrestrial animals received, of any irregularity with regard to:

(i) the kept terrestrial animals received;

(ii) the means or methods of identification referred to in point (a)(i);

(iii) the documents referred to in points (a)(ii) and (b).

2. In the event of any irregularity as referred to in point (c) of paragraph 1, the operator shall isolate the animals concerned by that irregularity until the competent authority of the place of destination has taken a decision regarding them.

Article 128

Prohibition on movements of kept terrestrial animals for disease eradication purposes outside the territory of a Member State

Operators shall not move kept terrestrial animals intended to be slaughtered for disease eradication purposes as part of an eradication programme, as provided for in Article 31(1) or (2), to another Member State unless the Member State of destination and, where relevant, the Member State of passage authorise the movement in advance.

Article 129

General requirement applicable to operators in respect of movements of kept terrestrial animals passing through Member States but intended for export from the Union to third countries or territories

Operators shall ensure that kept terrestrial animals intended for export to a third country or territory and passing through the territory of another Member State fulfil the requirements laid down in Articles 124, 125, 126 and 128.

Section 3

Specific requirements in respect of movements to other Member States of ungulates and poultry

Article 130

Movements of kept ungulates and poultry to other Member States

Operators shall only move kept ungulates and poultry from an establishment in one Member State to another Member State if the animals in question fulfil the following conditions as regards the listed diseases referred to in point (d) of Article 9(1):

(a) they show no clinical symptoms or signs of listed diseases as referred to in point (d) of Article 9(1) at the time of movement;

(b) they have been subject to a residency period appropriate to those listed diseases, taking into account the species and category of kept ungulates and poultry to be moved;

(c) for a period of time appropriate for those listed diseases and the species and category of ungulates or poultry to be moved, no kept ungulates or poultry have been introduced into the establishment of origin when a requirement to that effect is laid down in the rules adopted in accordance with Article 131 or Article 135;

(d) they are presumed not to pose a significant risk of spreading of those listed diseases at the place of destination, based on:

  (i) the health status concerning relevant diseases for species or categories of kept ungulates and poultry moved, taking into account the health status at the place of destination;

  (ii) the results of laboratory or other examinations necessary in order to provide guarantees regarding the health status required for the movement in question;

  (iii) the application of vaccination or other disease prevention or risk-mitigation measures aimed at limiting the spread of the relevant disease to the places of destination or passage.

Article 131

Delegation of powers in respect of movements of kept ungulates and poultry to other Member States

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) residency periods as referred to in point (b) of Article 130;

(b) the period of time necessary in order to limit the introduction of kept ungulates or poultry into establishments prior to movement as provided for in point (c) of Article 130;

(c) supplementary requirements to ensure that kept ungulates and poultry do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1), as provided for in point (d) of Article 130);

(d) other necessary risk-mitigation measures supplementing the requirements laid down in Article 130.

2. When establishing the rules to be laid down in the delegated acts provided for in paragraph 1, the Commission shall base those rules on the following considerations:

(a) the listed diseases referred to in point (d) of Article 9(1) relevant for the listed species or the category of kept ungulates or poultry to be moved;

(b) the health status as regards listed diseases referred to in point (d) of Article 9(1) in the establishments, compartments, zones and Member States of origin and destination;

(c) the type of establishment concerned and the type of production at the places of origin and destination;

(d) the type of movement concerned;

(e) the species and categories of kept ungulates or poultry to be moved;

(f) the age of the kept ungulates or poultry to be moved;

(g) other epidemiological factors.

Article 132

Kept ungulates and poultry moved to another Member State and intended for slaughter

1. Operators of slaughterhouses receiving kept ungulates and poultry from another Member State shall slaughter those animals as soon as possible following their arrival and at the latest within a timeframe to be laid down in delegated acts adopted pursuant to paragraph 2.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning the time of slaughter provided for in paragraph 1 of this Article.

Section 4

Assembly operations in respect of kept ungulates and poultry

Article 133

Derogation in respect of assembly operations

1. By way of derogation from Article 126(2), operators may subject kept ungulates and poultry to a maximum of three assembly operations during a movement from a Member State of origin to another Member State.

2. The assembly operations provided for in paragraph 1 of this Article shall only take place in an establishment approved for that purpose in accordance with Article 97(1) and Article 99(3) and (4).

However, the Member State of origin may allow an assembly operation on its territory to take place on a means of transport, collecting kept ungulates or poultry directly from their establishments of origin, provided that those animals are not unloaded again during that operation and before arriving:

(a) at the establishment or final place of destination; or

(b) for the subsequent assembly operation in an establishment approved for that purpose in accordance with Article 97(1) and Article 99(4) and (5).

Article 134

Disease prevention requirements in respect of assembly operations

Operators conducting assembly operations shall ensure that:

(a) the kept ungulates and poultry assembled have the same health status; where they do not, the lower health status applies to all such animals assembled;

(b) the kept ungulates and poultry are assembled and moved to their final place of destination in another Member State as soon as possible after leaving their establishment of origin, and at the latest within a timeframe to be laid down in delegated acts adopted pursuant to point (c) of Article 135;

(c) the necessary biosecurity measures are taken to ensure that the kept ungulates and poultry assembled:

(i) do not come into contact with kept ungulates or poultry having a lower health status;

(ii) do not pose a significant risk for the spread of the listed diseases referred to in point (d) of Article 9(1) to the kept ungulates or poultry at the place where the assembly operation takes place;

(d) the kept ungulates and poultry are identified where so required by this Regulation and are accompanied by the following documents:

(i) the identification and movement documents as provided for in point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), point (b) of Article 115 and point (b) of Article 117 and any rules adopted pursuant to Articles 118 and 120, unless derogations are provided for in accordance with Articles 113(2) and 119;

(ii) the animal health certificates as provided for in Article 143 and point (c) of Article 144(1), unless derogations are provided for in the rules adopted pursuant to point (a) of Article 144(1);

(iii) the self–declaration document as provided for in Article 151.

Article 135

Delegation of powers concerning assembly operations

The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) specific rules for assembly operations, where other risk-mitigation measures, in addition to those provided for in points (b) and (c) of Article 134, are in place;

(b) criteria under which Member States of origin may allow assembly operations to take place on means of transport, as provided for in the second subparagraph of Article 133(2);

(c) the timeframe between the time of departure of the kept ungulates or poultry from their establishment of origin and their departure from the assembly operation to their final destination in another Member State, as referred to in point (b) of Article 134;

(d) detailed rules as regards the biosecurity measures provided for in point (c) of Article 134.

Section 5

Movements to other Member States of kept terrestrial animals other than kept ungulates and poultry

Article 136

Movements of kept terrestrial animals other than kept ungulates and poultry to other Member States and delegated acts

1. Operators shall only move kept terrestrial animals other than kept ungulates or poultry from an establishment in one Member State to another Member State if the animals in question do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) at the place of destination.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules to ensure that kept terrestrial animals other than kept ungulates or poultry do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1), as provided for in paragraph 1 of this Article.

3. When establishing the detailed rules to be laid down in the delegated acts provided for in paragraph 2, the Commission shall base those rules on the following considerations:

(a) the listed diseases referred to in point (d) of Article 9(1) relevant for the listed species or the category of kept terrestrial animals to be moved;

(b) the health status as regards the listed diseases referred to in point (d) of Article 9(1) in the establishments, compartments, zones and Member States of origin and the place of destination;

(c) the types of establishment and the types of production at the place of origin and the place of destination;

(d) the types of movement in respect of the final use of animals at the place of destination;

(e) the species and categories of kept terrestrial animals to be moved;

(f) the age of the kept terrestrial animals to be moved;

(g) other epidemiological factors.

Section 6

DErogating from, and supplementing, risk-mitigation measures for movements of kept terrestrial animals

Article 137

Kept terrestrial animals intended for confined establishments and delegated acts

1. Operators shall only move kept terrestrial animals to a confined establishment if the animals in question fulfil the following conditions:

(a) they originate from another confined establishment;

(b) they do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to listed species or to categories of animals at the confined establishment of destination, except where the movement in question is authorised for scientific purposes.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) detailed rules for movements of kept terrestrial animals into confined establishments in addition to those provided for in paragraph 1 of this Article;

(b) specific rules for movements of kept terrestrial animals into confined establishments where the risk-mitigation measures in place guarantee that such movements do not pose a significant risk for the health of kept terrestrial animals within that confined establishment and the surrounding establishments.

Article 138

Movements of kept terrestrial animals for scientific purposes and delegated acts

1. The competent authority of the place of destination may, subject to the agreement of the competent authority of the place of origin, authorise movements of kept terrestrial animals into the territory of the Member State of destination, for scientific purposes, where those movements do not comply with the requirements of Sections 1 to 5 (Articles 124 to 136), with the exception of Articles 124 and 125, point (b)(ii) of Article 126(1) and Article 127.

2. The competent authority of the place of destination shall only grant derogations as provided for in paragraph 1 under the following conditions:

(a) the competent authorities of the places of destination and origin:

(i) have agreed on the conditions for such movements;

(ii) ensure that the necessary risk-mitigation measures are in place so that those movements do not jeopardise the health status in places en route and in the place of destination with regard to the listed diseases referred to in point (d) of Article 9(1); and

(iii) have notified, where relevant, the competent authorities of the Member States of passage of the derogation granted and of the conditions under which it is granted; and

(b) those movements of those animals take place under the supervision of the competent authorities of the places of origin and destination, and where relevant, the competent authorities of the Member States of passage.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules for the granting of derogations by competent authorities, supplementing those provided for in paragraphs 1 and 2 of this Article.

Article 139

Derogations concerning recreational use, sporting and cultural events, work near borders and grazing

1. The competent authority of the place of destination may grant derogations from the requirements of Sections 2 to 5 (Articles 126 to 136), with the exception of points (a),(b) and (c) of Article 126(1) and Articles 127 and 128, for intra–Union movements of kept terrestrial animals between Member States where such movements are for:

(a) recreational use near borders;

(b) exhibitions, and sporting, cultural and similar events, organised near borders;

(c) grazing of kept terrestrial animals in grazing areas shared between Member States; or

(d) work done by kept terrestrial animals near borders of Member States.

2. Derogations by the competent authority of the place of destination for movements of kept terrestrial animals for the purposes provided for in paragraph 1 shall be agreed on between the Member States of origin and destination and appropriate risk-mitigation measures shall be taken to ensure that such movements do not pose a significant risk.

3. The Member States referred to in paragraph 2 shall inform the Commission of the granting of derogations as provided for in paragraph 1.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules for the granting of derogations by the competent authority of the place of destination, supplementing those provided for in paragraph 1 of this Article.

Article 140

Delegation of power concerning circuses, exhibitions, sporting events and recreational use, zoos, pet shops, animal shelters and wholesalers

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) specific requirements supplementing the rules laid down in Sections 2 to 5 (Articles 126 to 136) for movements of kept terrestrial animals for the following purposes:

(i) circuses, zoos, pet shops, animal shelters and wholesalers;

(ii) exhibitions and sporting, cultural and similar events;

(b) derogations from Sections 2 to 5 (Articles 126 to 136), with the exception of points (a), (b) and (c) of Article 126(1) and Articles 127 and 128, for movements of kept terrestrial animals as referred to in point (a) of this Article.

Article 141

Implementing power to adopt temporary rules for movements of specific species or categories of kept terrestrial animals

1. The Commission may, by means of implementing acts, lay down temporary rules, by way of addition or alternative to those laid down in this Chapter, for movements of specific species or categories of kept terrestrial animals where:

(a) the movement requirements provided for in Article 130, Article 132(1), Articles 133 and 134, Articles 136(1), 137(1) and 138(1) and (2) and Article 139 and the rules adopted pursuant to Articles 131(1) and 132(2), Article 135, Articles 136(2), 137(2), 138(3) and 139(4) and Article 140 are not effectively mitigating the risks posed by the movement of such animals; or

(b) a listed disease as referred to in point (d) of Article 9(1) appears to be spreading despite the movement requirements laid down in accordance with Sections 1 to 6 (Articles 124 to 142).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

2. On duly justified imperative grounds of urgency relating to diseases representing a risk of a highly significant impact and taking into account the matters referred to in Article 142, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 266(3).

Article 142

Matters to be taken into account in the adoption of delegated and implementing acts as provided for in this Section

When establishing the rules to be laid down in the delegated and implementing acts provided for in Articles 137(2), 138(3) and 139(4) and Articles 140 and 141, the Commission shall base those rules on the following matters:

(a) the risks involved with the movements referred to in those provisions;

(b) the health status as regards the listed diseases referred to in point (d) of Article 9(1) at the places of origin, passage and destination;

(c) listed animal species for the listed diseases referred to in point (d) of Article 9(1);

(d) biosecurity measures in place at the places of origin, passage and destination

(e) any specific conditions in establishments under which the kept terrestrial animals are kept;

(f) specific movement patterns of the type of establishment and the species and category of kept terrestrial animals concerned;

(g) other epidemiological factors.

Section 7

Animal health certification

Article 143

Obligation of operators to ensure that animals are accompanied by an animal health certificate

1. Operators shall only move the following species and categories of kept terrestrial animals to another Member State if the animals in question are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 149(1):

(a) ungulates;

(b) poultry;

(c) kept terrestrial animals other than ungulates and poultry, intended for a confined establishment;

(d) kept terrestrial animals other than those referred to in points (a), (b) and (c) of this paragraph, when required in accordance with delegated acts adopted pursuant to point (c) of Article 144(1).

2. In cases where kept terrestrial animals are allowed to leave a restricted zone as provided for in point (f)(ii) of Article 55(1), Article 56 and Article 64(1) and are subject to disease control measures as provided for in Articles 55(1), 65(1), 74(1), Article 79 or Article 80 or rules adopted pursuant to Article 55(2), Article 67, Articles 71(3) and 74(4), Article 83(3) or Article 259, and the animals in question are of species subject to those disease control measures, operators shall only move such kept terrestrial animals within a Member State or from one Member State to another Member State when the animals to be moved are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 149(1).

The competent authority may decide that such a certificate does not have to be issued for movements of kept terrestrial animals within the Member State in question when that authority considers that an alternative system is in place ensuring that the consignment of such animals is traceable and that those animals fulfil the animal health requirements for such movement.

3. Operators shall take all necessary measures to ensure that the animal health certificate referred to in paragraph 1 of this Article accompanies the kept terrestrial animals from their place of origin to their final place of destination, unless specific measures are provided for in rules adopted pursuant to Article 147.

Article 144

Delegation of powers concerning the obligation of operators to ensure that animals are accompanied by an animal health certificate

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) derogations from the animal health certification requirements provided for in Article 143(1), for movements of kept terrestrial animals which do not pose a significant risk for the spread of a disease on account of:

  (i) the species or categories of the kept terrestrial animals that are being moved and the listed diseases referred to in point (d) of Article 9(1) for which they are listed species;

  (ii) the methods of keeping and the type of production of those species and categories of kept terrestrial animals;

  (iii) the intended use of the kept terrestrial animals; or

  (iv) the place of destination of the kept terrestrial animals; including those cases where their place of destination is in the same Member State as their place of origin but they pass through another Member State in order to reach their place of destination;

(b) special rules for animal health certification as provided for in Article 143(1) where specific risk-mitigation measures concerning surveillance or biosecurity are taken, taking into account the matters provided for in paragraph 2 of this Article, which ensure:

  (i) the traceability of the kept terrestrial animals being moved;

  (ii) that the kept terrestrial animals being moved fulfil the animal health requirements for movements provided for in Sections 1 to 6 (Articles 124 to 142);

(c) the requirement for animal health certification for movements of species and categories of kept terrestrial animals other than those referred to in points (a), (b) and (c) of Article 143(1) in cases where animal health certification is imperative in order to ensure that the movement in question complies with the animal health requirements for movements provided for in Sections 1 to 6 (Articles 124 to 142).

2. When establishing the special rules provided for in point (b) of paragraph 1, the Commission shall take the following matters into account:

(a) the assessment by the competent authority of the biosecurity put in place by operators as provided for in point (b) of Article 10(1) and any rules adopted pursuant Article 10(6);

(b) the ability of the competent authority, in so far as may be necessary and appropriate, to take measures and to engage in activities required by this Regulation as provided for in Article 13(1);

(c) the level of knowledge of animal health as provided for in Article 11 and the encouragement thereof provided for in Article 13(2);

(d) the carrying-out of the animal health visits provided for in Article 25 or other relevant surveillance or official controls in place;

(e) the performance by the competent authority of its obligations under the Union notification and reporting system provided for in Articles 19 to 22 and in the rules adopted pursuant to Article 20(3) and Article 23;

(f) the application of surveillance as provided for in Article 26 and surveillance programmes as provided for in Article 28 and in any rules adopted pursuant to Articles 29 and 30.

3. The Commission shall take the matters referred to in point (a)(i) to (iv) of paragraph 1 into account when establishing the requirements for animal health certification provided for in point (c) of paragraph (1).

Article 145

Contents of animal health certificates

1. The animal health certificate referred to in Article 143 shall contain the following information:

(a) the establishment or place of origin, the establishment or place of destination and, where relevant, establishments for assembly operations or for rests, of the kept terrestrial animals concerned;

(b) the means of transport and the transporter;

(c) a description of the kept terrestrial animals;

(d) the number of kept terrestrial animals;

(e) the identification and registration of kept terrestrial animals, where required by Articles 112, 113, 114, 115 and 117 and by any rules adopted pursuant to Articles 118 and 120, unless derogations are provided for in accordance with Article 119; and

(f) the information needed to demonstrate that the kept terrestrial animals fulfil the relevant animal health requirements in respect of movements provided for in Sections 1 to 6 (Articles 124 to 142).

2. The animal health certificate may include other information required under other Union legislation.

Article 146

Delegation of powers and implementing acts concerning the content of animal health certificates

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) detailed rules on the content of animal health certificates as provided for in Article 145(1) for different species and categories of kept terrestrial animals and for specific types of movements as provided for in the rules adopted pursuant to Article 147;

(b) additional information to be contained in the animal health certificate provided for in Article 145(1).

2. The Commission may, by means of implementing acts, lay down rules for model forms of animal health certificates. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 147

Delegation of powers concerning specific types of movements of kept terrestrial animals

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning specific measures derogating from, or supplementing, the obligation of operators to ensure that animals are accompanied by an animal health certificate as provided for in Article 143 and in the rules adopted pursuant to Article 144, for the following types of movements of kept terrestrial animals:

(a) movements of kept ungulates and poultry passing through the assembly operations provided for in Article 133 prior to reaching their final place of destination;

(b) movements of kept terrestrial animals which are required to return to their place of origin or to be moved to a different destination, for one or more of the following reasons:

  (i) their intended journey was unexpectedly interrupted for animal welfare reasons;

  (ii) unforeseen accidents or events during the journey;

  (iii) they were rejected at the place of destination in a Member State or at the external border of the Union;

  (iv) they were rejected at a place of assembly or resting;

  (v) they were rejected in a third country or territory;

(c) movements of kept terrestrial animals intended for exhibitions, and sporting, cultural and similar events, and their subsequent return to their place of origin.

Article 148

Operators' obligations to cooperate with the competent authority for the purposes of animal health certification

Operators shall:

(a) provide the competent authority with all the information necessary to complete the animal health certificate provided for in Article 143(1) and (2) and in any rules adopted pursuant to Article 146(1) or Article 147, in advance of the intended movement;

(b) where necessary, ensure that the kept terrestrial animals in question are subjected to documentary, identity and physical checks as provided for in Article 149(3).

Article 149

Responsibility of the competent authority for animal health certification

1. The competent authority shall, upon request by an operator, issue an animal health certificate for the movement of kept terrestrial animals, where required by Article 143 or by delegated acts adopted pursuant to Article 144(1), provided that the following movement requirements have been complied with:

(a) those provided for in Article 124, Article 125(1), Articles 126, 128, 129, 130, 133 and 134, Articles 136(1) and 137(1), Article 138 and Article 139;

(b) those provided for in delegated acts adopted pursuant to Articles 125(2) and 131(1), Article 135, Articles 136(2), 137(2), 138(4) and 139(4) and Article 140;

(c) those provided for in implementing acts adopted pursuant to Article 141.

2. Animal health certificates shall:

(a) be verified, stamped and signed by an official veterinarian;

(b) remain valid for the period of time provided for in the rules adopted pursuant to point (c) of paragraph 4, during which the kept terrestrial animals covered by it continue to fulfil the animal health guarantees contained in it.

3. Before signing an animal health certificate, the official veterinarian concerned shall verify, by means of documentary, identity and physical checks as provided for by delegated acts adopted pursuant to paragraph 4, that the kept terrestrial animals covered by it fulfil the requirements of this Chapter.

4. The Commission shall adopt delegated acts in accordance with Article 264 laying down rules concerning:

(a) the types of documentary, identity and physical checks and examinations in relation to different species and categories of kept terrestrial animals that must be carried out by the official veterinarian in accordance with paragraph 3 in order to verify compliance with the requirements of this Chapter;

(b) the timeframes for the carrying-out of such documentary, identity and physical checks and examinations and the issuing of animal health certificates by the official veterinarian prior to the movement of consignments of kept terrestrial animals;

(c) the duration of the validity of animal health certificates.

Article 150

Electronic animal health certificates

Electronic animal health certificates, produced, handled and transmitted by means of Traces, may replace accompanying animal health certificates as provided for in Article 149(1) where:

(a) such electronic animal health certificates contain all the information that the model form of animal health certificate is required to contain in accordance with Article 145 and any rules adopted pursuant to Article 146;

(b) the traceability of the kept terrestrial animals in question and the link between those animals and the electronic animal health certificate is ensured;

(c) the competent authorities of the Member States of origin, passage and destination are able to have access to the electronic documents at all times during the transport.

Article 151

Self–declaration by operators for movements to other Member States

1. Operators at the place of origin shall issue a self–declaration document for movements of kept terrestrial animals from their place of origin in one Member State to their place of destination in another Member State, and shall ensure that it accompanies such animals, where they are not required to be accompanied by an animal health certificate as provided for in Article 143(1) and (2).

2. The self–declaration document provided for in paragraph 1 shall contain the following information concerning the kept terrestrial animals in question:

(a) their place of origin, their place of destination and, when relevant, any places of assembly or rest;

(b) the means of transport and the transporter;

(c) a description of the kept terrestrial animals, their species, category and quantity;

(d) identification and registration where required in accordance with Articles 112, 113, 114 and 115, point (a) of Article 117 and any rules adopted pursuant to Articles 118 and 120;

(e) the information needed to demonstrate that the kept terrestrial animals fulfil the animal health requirements for movements provided for in Sections 1 to 6 (Articles 124 to 142).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) detailed rules on the content of the self–declaration document provided for in paragraph 2 of this Article for different species and categories of animals;

(b) information to be contained in the self–declaration document in addition to that provided for in paragraph 2 of this Article.

4. The Commission may, by means of implementing acts, lay down rules for the model forms of the self–declaration document provided for in paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Section 8

Notification of movements of kept terrestrial animals to other Member States

Article 152

Obligation of operators concerning the notification of movements of kept terrestrial animals to other Member States

Operators other than transporters shall notify the competent authority in their Member State of origin in advance of intended movements of kept terrestrial animals from that Member State to another Member State where:

(a) the animals must be accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Articles 149 and 150 and any rules adopted pursuant to Article 149(4);

(b) the animals must be accompanied by an animal health certificate for kept terrestrial animals where they are being moved from a restricted zone and are subject to disease control measures as referred to in Article 143(2);

(c) the animals are granted a derogation from the animal health certification requirement provided for in point (a) of Article 144(1) or are subject to special rules as provided for in point (b) of Article 144(1);

(d) notification is required in accordance with delegated acts adopted pursuant to Article 154(1).

For the purposes of the first paragraph of this Article, operators shall provide the competent authority of their Member State of origin with all the necessary information to enable it to notify the movements of the kept terrestrial animals to the competent authority of the Member State of destination in accordance with Article 153(1).

Article 153

Responsibility of the competent authority to notify movements to other Member States

1. The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of kept terrestrial animals as referred to in Article 152.

2. The notification referred to in paragraph 1 shall be carried out prior to the movement in question and, whenever possible, through Traces.

3. Member States shall designate regions for the management of notifications of movements as provided for in paragraph 1.

4. By way of derogation from paragraph 1, the competent authority of the Member State of origin may authorise the operator concerned to notify, partially or completely, movements of kept terrestrial animals through Traces to the competent authority of the Member State of destination.

Article 154

Delegation of power and implementing acts for the notification of movements by operators and by the competent authority

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) the requirement for advance notification by operators, in accordance with Article 152, of movements between Member States of kept terrestrial animals of species or categories other than those referred to in points (a) and (b) of that Article, where traceability of such movements of those species or categories is necessary in order to ensure compliance with the animal health requirements for movements laid down in Sections 1 to 6 (Articles 124 to 142);

(b) the information needed in order to notify movements of kept terrestrial animals as provided for in Articles 152 and 153;

(c) the emergency procedures for the notification of movements of kept terrestrial animals in the event of power cuts and other disturbances of Traces;

(d) the requirements for the designation of regions by Member States for the management of notifications of movements, as provided for in Article 153(3).

2. The Commission may, by means of implementing acts, lay down rules concerning:

(a) the details concerning notifications of movements of kept terrestrial animals by:

(i) operators to the competent authority of their Member State of origin in accordance with Article 152;

(ii) the competent authority of the Member State of origin to the Member State of destination in accordance with Article 153;

(b) the deadlines for:

(i) the provision by the operator of the necessary information referred to in Article 152 to the competent authority of the Member State of origin;

(ii) the notification of movements of kept terrestrial animals by the competent authority of the Member State of origin as referred to in Article 153(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 4

Movements of wild terrestrial animals

Article 155

Wild terrestrial animals

1. Operators shall only move wild animals from a habitat in one Member State to a habitat or an establishment in another Member State where:

(a) the movements of the wild animals in question from their habitat are carried out in such a way that they do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) or emerging diseases en route or at the place of destination;

(b) the wild animals do not come from a habitat in a restricted zone which is subject to movement restrictions concerning the animal species to which they belong due to the occurrence of a listed disease as referred to in point (d) of Article 9(1) or of an emerging disease, as provided for in Article 70(2) and in any rules adopted pursuant to point (b) of Article 70(3), Article 71(3) and Article 83(3) or the emergency measures provided for in Articles 257 and 258 and any rules adopted pursuant to Article 259, unless derogations have been granted in accordance with those rules;

(c) the wild animals are accompanied by an animal health certificate or other documents where animal health certification is necessary in order to ensure compliance with the animal health requirements for movements provided for in points (a) and (b) of this paragraph and the rules adopted pursuant to points (c) and (d) of Article 156(1);

(d) the movements are notified by the competent authority of the Member State of origin to the competent authority of the Member State of destination, where animal health certification is required by the rules adopted pursuant to point (c) of Article 156(1); and

(e) the competent authority of the Member State of origin and the competent authority of the Member State of destination have agreed to such movement.

2. When animal health certification is required by the rules adopted pursuant to point (c) of Article 156(1), the requirements provided for in Articles 145 and 148, Article 149(1), (2) and (3) and Article 150, and in the rules adopted pursuant to Articles 146 and 147 and Article 149(4) shall apply to movements of wild terrestrial animals.

3. When notification of movements is required in accordance with point (d) of paragraph 1 of this Article, the requirements provided for in Articles 152 and 153 and in the delegated acts adopted pursuant to Article 154(1) shall apply to movements of wild terrestrial animals.

Article 156

Empowerments concerning the movement of wild terrestrial animals

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) the animal health requirements for movements of wild terrestrial animals provided for in points (a) and (b) of Article 155(1);

(b) the animal health requirements for the introduction of wild terrestrial animals when they are moved from the wild into establishments;

(c) the types of movements of wild terrestrial animals for which, or the situations in which, an animal health certificate or other document is required to accompany such movements, and the requirements concerning the contents of such certificates or other documents;

(d) the notification by the competent authority of the Member State of origin to the competent authority of the Member State of destination in the case of movements of wild terrestrial animals between Member States, and the information to be included in such notification.

2. The Commission may, by means of implementing acts, lay down rules specifying the requirements provided for in Article 155 and in the delegated acts adopted pursuant to paragraph 1 of this Article, concerning:

(a) model forms of animal health certificates and other documents which are required to accompany movements of wild terrestrial animals, when provided for in delegated acts adopted pursuant to point (c) of paragraph 1 of this Article;

(b) the details of the notification to be given by the competent authority of the Member State of origin and the deadlines for such notifications, when provided for in rules adopted pursuant to point (d) of paragraph 1 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 5

Movements within the Union of germinal products

Section 1

General requirements

Article 157

General requirements for movements of germinal products

1. Operators shall take appropriate preventive measures to ensure that movements of germinal products do not jeopardise the health status of kept terrestrial animals at the place of destination with regard to:

(a) the listed diseases referred to in point (d) of Article 9(1);

(b) emerging diseases.

2. Operators shall only move germinal products from their establishments, and receive such germinal products, if the products in question fulfil the following conditions:

(a) they come from establishments that have been:

(i) entered in the register of establishments by the competent authority in accordance with point (a) of the first paragraph of Article 93 and no derogation has been granted by the Member State of origin in accordance with Article 85;

(ii) approved by the competent authority in accordance with Article 97(1), when such approval is required by Article 94(1) or Article 95;

(b) they fulfil the traceability requirements of Article 121(1) and any rules adopted pursuant to Article 122(1).

3. Operators shall comply with the requirements of Article 125 for the transport of germinal products of kept terrestrial animals.

4. Operators shall not move germinal products from an establishment in one Member State to an establishment in another Member State unless the competent authority of the Member State of destination gives its express authorisation for such movement, where those germinal products are required to be destroyed for disease eradication purposes as part of an eradication programme as provided for in Article 31(1) or (2).

Article 158

Obligations for operators at the place of destination

1. Operators of establishments at the place of destination receiving germinal products from an establishment in another Member State shall:

(a) check for the presence of:

(i) marks in accordance with Article 121 and with rules adopted pursuant to Article 122;

(ii) animal health certificates as provided for in Article 161;

(b) after checking the germinal products received, inform the competent authority of the place of destination of any irregularity with regard to;

(i) the germinal products received;

(ii) the marks referred to in point (a)(i);

(iii) the animal health certificates referred to in point (a)(ii).

2. In the event of an irregularity as referred to in point (b) of paragraph 1, the operator concerned shall keep the germinal products stored separately until the competent authority has taken a decision regarding them.

Section 2

Movements to other Member States of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry

Article 159

Operators' obligations in respect of movements to other Member States of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry

1. Operators shall only move germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to another Member State if those germinal products fulfil the following conditions:

(a) they are collected, produced, processed and stored in germinal product establishments approved for that purpose in accordance with Article 97(1) and Article 99;

(b) they have been collected from donor animals which fulfil the necessary animal health requirements, in order to ensure that the germinal products do not spread listed diseases;

(c) they have been collected, produced, processed, stored and transported in such a way as to ensure that they do not spread listed diseases as referred to in point (d) of Article 9(1).

2. Operators shall not move germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry from a germinal product establishment which is subject to movement restrictions affecting the listed species in question in accordance with:

(a) points (a), (c) and (e) of Article 55(1), point (f)(ii) of Article 55(1), Article 56, point (a) of Article 61(1), Article 62(1), point (c) of Article 65(1), Article 74(1), and Articles 79 and 80;

(b) rules adopted pursuant to Article 55(2), Articles 63 and 67, and Articles 71(3), 74(4) and 83(2); and

(c) emergency measures as provided for in Articles 257 and 258 and rules adopted pursuant to Article 259, unless derogations have been provided for in rules adopted pursuant to Article 258.

The restrictions provided for in this paragraph shall not apply to cases where the germinal products were collected before the outbreak in question occurred and those products have been stored separately from other germinal products.

Article 160

Delegation of power in respect of movements to other Member States of germinal products of kept animals of the bovine, porcine, ovine, caprine and equine species and germinal products of poultry

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning the animal health requirements for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to other Member States as provided for in Article 159, specifying:

(a) rules for the collection, production, processing and storage of germinal products of those kept animals in approved establishments as referred to in point (a) of Article 159(1);

(b) animal health requirements as provided for in point (b) of Article 159(1) for kept donor animals from which germinal products were collected, and concerning isolation or quarantine for those animals;

(c) laboratory and other tests to be carried out on kept donor animals and germinal products;

(d) animal health requirements for the collection, production, processing, storage or other procedures and transport provided for in point (c) of Article 159(1).

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the animal health requirements for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to other Member States as provided for in Article 159, specifying derogations for operators from the rules provided for in Article 159, taking into account the risks attached to such germinal products and any risk-mitigation measures in place.

Section 3

Animal health certification and notification of movements

Article 161

Operators' obligations concerning animal health certification for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry and delegated acts

1. Operators shall only move germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to another Member State where such products are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with paragraph 3;

2. In cases where germinal products of kept animals are allowed to leave a restricted zone subject to:

(a) disease control measures as provided for in point (f)(ii) of Article 55(1), Articles 56, 64 and 65, Article 74(1) and Article 79, and the rules adopted pursuant to Article 55(2), Article 67, Articles 71(3) and 74(4), Article 83(2), or

(b) emergency measures as provided for in Articles 257 and 258 and the rules adopted pursuant to Article 259,

and those germinal products are of species subject to those disease control or emergency measures, operators shall only move such germinal products within a Member State or from one Member State to another Member State when they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 149(1), unless derogations have been granted from the animal health certification requirement in accordance with the rules referred in this subparagraph.

The competent authority may decide that such a certificate does not have to be issued for movements of germinal products within the Member State concerned when that authority considers that an alternative system is in place ensuring that the consignment of such germinal products is traceable and that those germinal products comply with the animal health requirements for such movement.

3. Operators shall take all necessary measures to ensure that the animal health certificate referred to in paragraph 1 accompanies the germinal products from their place of origin to their place of destination.

4. The competent authority shall, upon request by an operator, issue an animal health certificate for the movements of germinal products referred to in paragraph 1, provided that the relevant requirements referred to in Chapter 5 of Title I of Part IV have been complied with.

5. Articles 148, 149 and 150, and the rules adopted pursuant to Articles 146 and 147 and Article 149(4), shall apply to the animal health certification of the germinal products referred to in paragraph 1 of this Article. Article 151(1) and the rules adopted pursuant to Article 151(3) shall apply to the self–declaration of movements of germinal products.

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning derogations from the animal health certificate requirements provided for in paragraph 1 of this Article as regards movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry which do not pose a significant risk for the spread of listed diseases due to:

(a) the nature of the germinal products concerned or the species of animal that those products come from;

(b) the methods of production and processing at the germinal product establishment;

(c) the intended use of the germinal products;

(d) alternative risk-mitigation measures in place for the type and category of germinal products and the germinal product establishment;

(e) the place of destination of the germinal products, when the place of destination is in the same Member State as the place of origin but the germinal products pass through another Member State in order to reach the place of destination.

Article 162

Content of animal health certificates

1. The animal health certificate for the germinal products provided for in Article 161 shall contain at least the following information:

(a) the germinal product establishment of origin and the establishment or place of destination;

(b) the type of the germinal products and the species of kept donor animals;

(c) the volume or number of the germinal products;

(d) the marking of the germinal products, when required by Articles 121(1) and by any rules adopted pursuant to Article 122(1);

(e) the information needed to demonstrate that the germinal products of the consignment fulfil the movement requirements for the relevant species as provided for in Articles 157 and 159 and in any rules adopted pursuant to Article 160.

2. The animal health certificate for germinal products as provided for in Article 161 may include other information required under other Union legislation.

3. The Commission shall adopt delegated acts in accordance with Article 264 concerning the information to be contained in the animal health certificate pursuant to paragraph 1 of this Article;

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning animal health certification for different types of germinal products and of different animal species.

5. The Commission may, by means of implementing acts, lay down rules concerning model forms of animal health certificates for germinal products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 163

Notification of movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to other Member States

1. Operators shall:

(a) inform the competent authority in their Member State of origin in advance of the intended movement of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to another Member State when:

  (i) the germinal products in question are required to be accompanied by an animal health certificate in accordance with Article 161(1) or (2);

  (ii) notification of movement is required in accordance with delegated acts adopted pursuant to point (a) of paragraph 5 of this Article for germinal products, taking into account paragraph 3 of this Article;

(b) provide all the necessary information to enable the competent authority of the Member State of origin to notify the movement of the germinal products to the competent authority of the Member State of destination in accordance with paragraph 2.

2. The competent authority of the Member State of origin shall notify, prior to the movement in question and whenever possible through Traces, the competent authority of the Member State of destination of any movement of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry in accordance with the rules adopted pursuant to paragraphs 5 and 6.

3. Member States shall use, for the management of notifications, regions designated in accordance with Article 153(3).

4. Article 153(4) shall apply to the notification of germinal products by operators.

5. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) the requirement for advance notification by operators of movements of germinal products between Member States in accordance with point (a)(ii) of paragraph 1 of this Article, where traceability of such movements is necessary in order to ensure compliance with the animal health requirements for movements laid down in Sections 1 and 2 (Articles 157 to 160);

(b) information necessary to notify movements of germinal products as provided for in paragraph 1 of this Article;

(c) the emergency procedures for the notification of movements of germinal products in the event of power cuts and other disturbances of Traces.

6. The Commission may, by means of implementing acts, lay down rules concerning:

(a) the provision of information on movements of germinal products by operators to the competent authority of their Member State of origin in accordance with paragraph 1;

(b) notification by the competent authority of the Member State of origin to the Member State of destination of movements of germinal products in accordance with paragraph 2;

(c) the deadlines for:

(i) the provision of the information referred to in paragraph 1 by the operator to the competent authority of the Member State of origin;

(ii) notification by the competent authority of the Member State of origin of movements of germinal products as referred to in paragraph 2.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Section 4

Movements to other Member States of germinal products of kept terrestrial animals of species other than bovine, ovine, caprine, porcine and equine species and germinal products of poultry

Article 164

Germinal products of kept terrestrial animals other than those of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry

1. Operators shall only move germinal products of kept terrestrial animals of species other than those of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to another Member State if those products do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to listed species at the place of destination, taking into account the health status at the place of destination.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning animal health requirements, animal health certification and notification requirements for movements of germinal products of kept terrestrial animals of species other than those of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry, taking into account the following matters:

(a) listed diseases as referred to in point (d) of Article 9(1) for the listed species concerned;

(b) the species of animals from which the germinal products have been collected and the type of germinal product;

(c) the health status at the places of origin and of destination;

(d) the type of collection, production, processing and storage;

(e) other epidemiological factors.

3. Where animal health certification and notification of movements of germinal products are required in accordance with paragraph 2:

(a) the rules provided for in Articles 161(1) to (5), 162 (1) and (2) and the rules adopted pursuant to Articles 161(6) and 162(3) to (5) shall apply for such certification;

(b) the rules provided for in Article 163(1), (2) and (4) and the rules adopted pursuant to Article 163(5) shall apply for notification of movements.

Section 5

Derogations

Article 165

Germinal products intended for scientific purposes and delegated acts

1. The competent authority of the place of destination may, subject to the agreement of the competent authority of the place of origin, authorise movements of germinal products into the territory of the Member State of destination, for scientific purposes, where those movements do not fulfil the requirements of Articles 159 to 164.

2. The competent authority shall only grant derogations provided for in paragraph 1 under the following conditions:

(a) the competent authorities of the places of destination and origin:

  (i) have agreed on the conditions for the movements proposed;

  (ii) ensure that necessary risk-mitigation measures are in place so that those movements do not jeopardise the health status en route and in the place of destination with regard to the listed diseases referred to in point (d) of Article 9(1);

  (iii) have notified, where relevant, the competent authorities of Member States of passage of the derogation granted and of the conditions under which it is granted;

(b) those movements take place under the supervision of the competent authorities of the places of origin and destination, and where relevant, of the competent authorities of any Member States of passage.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the rules for the granting of derogations by competent authorities, supplementing those provided for in paragraphs 1 and 2 of this Article.

CHAPTER 6

Production, processing and distribution within the Union of products of animal origin

Article 166

General animal health obligations for operators and delegated acts

1. Operators shall take appropriate preventive measures to ensure that, during all stages of the production, processing and distribution of products of animal origin in the Union, such products do not cause the spread of:

(a) listed diseases as referred to in point (d) of Article 9(1), taking into account the health status of the place of production, processing or destination;

(b) emerging diseases.

2. Operators shall ensure that products of animal origin do not come from establishments or food businesses, or are not obtained from animals which come from establishments, that are subject to:

(a) emergency measures as provided for in Articles 257 and 258 or any rules adopted pursuant to Article 259, unless derogations from the requirement provided for in paragraph 1 of this Article are provided for in rules adopted pursuant to Article 259;

(b) movement restrictions applicable to kept terrestrial animals and products of animal origin, as provided for in point (c) of Article 32(1), point (e) of Article 55(1), Article 56, point (a) of Article 61(1), Article 62(1), point (c) of Article 65(1), point (b) of Article 70(1), point (a) of Article 74(1), point (b) of Article 76(2), Article 76(3), Article 79, Article 81 and Article 82(2) and (3) and in the rules adopted pursuant to Article 55(2), Articles 63 and 67, Article 70(3), Article 71(3), Article 74(4), Article 76(5) and Article 83(2), unless derogations from those movement restrictions have been provided for in those rules.

3. The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed requirements supplementing those referred to:

(a) in paragraph 1 of this Article on preventive measures, including risk-mitigation measures, and

(b) in paragraph 2 of this Article in relation to restrictions on movements of products of animal origin.

4. When adopting the delegated acts referred to in paragraph 3, the Commission shall base those acts on:

(a) the listed disease in question, as referred to in point (d) of Article 9(1), and species concerned by it and

(b) the risks involved.

Article 167

Operators' obligations with regard to animal health certificates and delegated acts

1. Operators shall only move the following products of animal origin within a Member State or to another Member State where the products in question are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with paragraph 3:

(a) products of animal origin that:

  (i) are allowed to be moved from a restricted zone subject to emergency measures as provided for in rules adopted pursuant to Article 259;

  (ii) originate from animals of species subject to those emergency measures;

(b) products of animal origin that:

(i) are allowed to be moved from a restricted zone subject to disease control measures in accordance with Article 32(1), point (f)(ii) of Article 55(1), Article 56, point (a) of Article 61(1), Article 62(1), Article 64, point (c) of Article 65(1), point (b) of Article 70(1), point (a) of Article 74(1) and Articles 79 and 80 and any rules adopted pursuant to Article 55(2), Articles 63 and 67 and Articles 71(3), 74(4) and 83(2),

(ii) originate from animals of species subject to those disease control measures.

The competent authority may decide that such a certificate does not have to be issued for movements of products of animal origin within the Member State concerned when that authority considers that an alternative system is in place ensuring that consignments of such products are traceable and that those products fulfil the animal health requirements for such movements.

2. Operators shall take all necessary measures to ensure that the animal health certificate referred to in paragraph 1 accompanies the products of animal origin from their place of origin to their place of destination.

3. The competent authority shall, upon request by the operator concerned, issue an animal health certificate for movements of products of animal origin as referred to in paragraph 1, provided that the relevant requirements referred to in this Article have been complied with.

4. Articles 148, 149 and 150 and the rules adopted pursuant to Articles 146 and 147 and Article 149(4) shall apply to the animal health certification of movements of products of animal origin as referred to in paragraph 1 of this Article.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning derogations from the animal health certificate requirements provided for in paragraph 1 of this Article and the conditions for such derogations, in respect of movements of products of animal origin which do not pose a significant risk for the spread of diseases due to:

(a) the types of products of animal origin concerned;

(b) the risk-mitigation measures applied to the products of animal origin, thereby reducing the risks of the spread of diseases;

(c) the intended use of the products of animal origin;

(d) the place of destination of the products of animal origin.

Article 168

Content of animal health certificates and delegated and implementing acts

1. The animal health certificate for products of animal origin provided for in Article 167(1) shall contain at least the following information:

(a) the establishment or place of origin and the establishment or place of destination;

(b) a description of the products of animal origin concerned;

(c) the quantity of the products of animal origin;

(d) the identification of the products of animal origin, when required by point (h) of Article 65(1) or by any rules adopted pursuant to point (a) of the second paragraph of Article 67;

(e) the information needed to demonstrate that the products of animal origin fulfil the movement restriction requirements provided for in Article 166(2) and in any rules adopted pursuant to Article 166(3).

2. The animal health certificate referred to in paragraph 1 may include other information required under other Union legislation.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the information to be contained in the animal health certificate provided for in paragraph 1 of this Article.

4. The Commission may, by means of implementing acts, lay down rules concerning model forms of animal health certificates for products of animal origin referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 169

Notification of movements of products of animal origin to other Member States

1. Operators shall:

(a) inform the competent authority in their Member State of origin in advance of intended movements of products of animal origin when the consignments in question are required to be accompanied by an animal health certificate in accordance with Article 167(1);

(b) provide all necessary information to enable the competent authority of the Member State of origin to notify the movement in question to the competent authority of the Member State of destination in accordance with paragraph 2.

2. The competent authority of the Member State of origin shall, prior to the movement and whenever possible through Traces, notify the competent authority of the Member State of destination of movements of products of animal origin in accordance with the rules adopted pursuant to paragraphs 5 and 6.

3. Member States shall use, for the management of notifications, regions designated in accordance with Article 153(3).

4. Article 153(4) shall apply to the notification of movements of products of animal origin by operators.

5. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) the information needed for the notification of movements of products of animal origin as provided for in paragraph 1 of this Article;

(b) the emergency procedures for the notification of movements of products of animal origin in the event of power cuts and other disturbances of Traces.

6. The Commission may, by means of implementing acts, lay down rules concerning:

(a) the information to be provided by operators to the competent authority of their Member State of origin concerning movements of products of animal origin in accordance with paragraph 1;

(b) notification of movements of products of animal origin to be given by the competent authority of the Member State of origin to the Member State of destination in accordance with paragraph 2;

(c) the deadlines for:

  (i) provision of the information referred to in paragraph 1 by the operator concerned to the competent authority of the Member State of origin;

  (ii) notification of movements of products of animal origin to be given by the competent authority of the Member State of origin as referred to in paragraph 2.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 7

Scope of national measures

Article 170

National measures concerning disease control and movements of animals and germinal products

1. Member States shall remain free to take national measures to control listed diseases as referred to in points (d) and (e) of Article 9(1) with regard to movements of terrestrial animals and germinal products thereof within their own territories.

2. Those national measures shall:

(a) take account of the rules on movements of animals and germinal products laid down in Chapters 3 (Articles 124 to 154), 4 (Articles 155 and 156) and 5 (Articles 157 to 165), and shall not be inconsistent with those rules;

(b) not hinder the movement of animals and products between Member States;

(c) not exceed the limits of what is appropriate and necessary in order to prevent the introduction and spread of the listed diseases referred to in points (d) and (e) of Article 9(1).

Article 171

National measures designed to limit the impact of diseases other than listed diseases

Where a disease other than a listed disease constitutes a significant risk for the health of kept terrestrial animals in a Member State, the Member State concerned may take national measures to control that disease and may restrict movements of kept terrestrial animals and germinal products, provided those measures do not:

(a) hinder the movement of animals and products between Member States;

(b) exceed the limits of what is appropriate and necessary in order to control that disease.

TITLE II

AQUATIC ANIMALS AND PRODUCTS OF ANIMAL ORIGIN FROM AQUATIC ANIMALS

CHAPTER 1

Registration, approval, record-keeping and registers

Section 1

Registration of aquaculture establishments

Article 172

Obligation of operators to register aquaculture establishments

1. Operators of aquaculture establishments shall, in order for their establishments to be registered in accordance with Article 173, before they commence such activities:

(a) inform the competent authority of any aquaculture establishment under their responsibility;

(b) provide the competent authority with the following information:

(i) the name and address of the operator concerned;

(ii) the location of the establishment and a description of its facilities;

(iii) the species, categories and quantities (numbers, volume or weight) of aquaculture animals which they intend to keep on the aquaculture establishment and the capacity of the aquaculture establishment;

(iv) the type of aquaculture establishment; and

(v) any other aspects of the establishment which are relevant for the purpose of determining the risk posed by it.

2. Operators of aquaculture establishments referred to in paragraph 1 shall inform the competent authority in advance of:

(a) any significant changes in the aquaculture establishment in question concerning the matters referred to in point (b) of paragraph 1;

(b) any cessation of activity by the operator or aquaculture establishment concerned.

3. Aquaculture establishments which are subject to approval in accordance with Article 176(1) and Article 177 shall not be required to provide the information referred to in paragraph 1 of this Article.

4. An operator may apply for registration as provided for in paragraph 1 to cover a group of aquaculture establishments, provided that they fulfil either of the following conditions:

(a) they are located in an epidemiologically linked area and all operators in that area operate under a common biosecurity system;

(b) they are under the responsibility of the same operator and operate under a common biosecurity system, and the aquaculture animals of the establishments concerned form part of a single epidemiological unit.

Where an application for registration covers a group of establishments, the rules laid down in paragraphs 1 to 3 of this Article and in point (b) of the first paragraph of Article 173, and the rules adopted pursuant to Article 175 which are applicable to a single aquaculture establishment, shall be applicable to the group of aquaculture establishments as a whole.

Article 173

Obligations of the competent authority concerning the registration of aquaculture establishments

A competent authority shall register:

(a) aquaculture establishments in the register of aquaculture establishments provided for in Article 185(1), where the operator concerned has provided the information required in accordance with Article 172(1);

(b) groups of aquaculture establishment in that register, provided that the criteria laid down in Article 172(4) are complied with.

The competent authority shall assign each establishment or group of establishments as referred to in this Article with a unique registration number.

Article 174

Derogations from the obligation of operators to register aquaculture establishments

By way of derogation from Article 172(1), Member States may exempt from the registration requirement certain aquaculture establishments posing an insignificant risk, as provided for in an implementing act adopted in accordance with Article 175.

Article 175

Implementing powers concerning derogations from the obligation to register aquaculture establishments

1. The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators for the purpose of the registration of aquaculture establishments as provided for in Article 172(1), including the time-limits by which such information is to be provided.

2. The Commission shall, by means of implementing acts, lay down rules concerning the types of aquaculture establishments that may be exempted by Member States from the registration requirement in accordance with Article 174, based on:

(a) the species, categories and quantity (number, volume or weight) of aquaculture animals on the aquaculture establishment in question and the capacity of that establishment;

(b) the movements of aquaculture animals into and out of the aquaculture establishment.

3. The implementing acts referred to in this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Section 2

Approval of certain types of aquaculture establishments

Article 176

Approval of certain aquaculture establishments and delegated acts

1. Operators of the following types of aquaculture establishments shall apply to the competent authority for approval in accordance with Article 180(1):

(a) aquaculture establishments where aquaculture animals are kept with a view to their being moved therefrom, either alive or as products of aquaculture animal origin;

(b) other aquaculture establishments which pose a significant risk due to:

  (i) the species, categories and number of aquaculture animals kept there;

  (ii) the type of aquaculture establishment concerned;

  (iii) movements of aquaculture animals into and out of the aquaculture establishment concerned.

2. By way of derogation from paragraph 1, Member States may exempt from the obligation to apply for approval operators of the following types of establishment:

(a) aquaculture establishments producing a small quantity of aquaculture animals for supply for human consumption either:

  (i) to the final consumer directly; or

  (ii) to local retail establishments directly supplying the final consumer;

(b) ponds and other installations where the population of aquatic animals is maintained only for recreational fishing purposes, by restocking with aquaculture animals which are confined and unable to escape;

(c) aquaculture establishments keeping aquaculture animals for ornamental purposes in closed facilities,

provided that the establishment in question does not pose a significant risk.

3. Unless a derogation has been granted under paragraph 4 of this Article, operators shall not commence activity at an aquaculture establishment as referred to in paragraph 1 of this Article until that establishment has been approved in accordance with Article 181(1), and shall cease such activity at an aquaculture establishment referred to in paragraph 1 of this Article where:

(a) the competent authority withdraws or suspends its approval in accordance with Article 184(2); or

(b) in the event of conditional approval, granted in accordance with Article 183(3), the aquaculture establishment concerned fails to comply with the outstanding requirements referred to in Article 183(4) and does not obtain a final approval in accordance with Article 183(3).

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) derogations from the requirement for operators to apply to the competent authority for approval of the types of aquaculture establishments referred to in point (a) of paragraph 1, concerning types of establishments other than those specified in points (a)(i) and (ii) of paragraph 2, where those establishments do not pose a significant risk;

(b) the types of aquaculture establishments which must be approved in accordance with point (b) of paragraph 1.

5. When adopting delegated acts as provided for in paragraph 4, the Commission shall base those acts on the following criteria:

(a) the species and categories of aquaculture animals kept in an aquaculture establishment;

(b) the type of aquaculture establishment and the type of production; and

(c) typical movement patterns of the type of aquaculture establishment concerned and of the species or category of aquaculture animals concerned.

6. An operator may apply for approval of a group of aquaculture establishments, provided that the requirements provided for in points (a) and (b) of the first paragraph of Article 177 are complied with.

Article 177

Approval by the competent authority of groups of aquaculture establishments

The competent authority may grant approval as provided for in Article 181(1) covering a group of aquaculture establishments, provided that the aquaculture establishments in question comply with either of the following conditions:

(a) they are located in an epidemiologically linked area and all operators in that area operate under a common biosecurity system; however, any on–shore or off–shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs intended for human consumption (so-called 'dispatch centres'), establishment with tanks fed by clean seawater in which live bivalve molluscs are placed for the time necessary to reduce contamination to make them fit for human consumption (so-called 'purification centres') and similar establishments located inside such an epidemiologically linked area must be approved individually;

(b) they are under the responsibility of the same operator; and

  (i) operate under a common biosecurity system; and

  (ii) the aquaculture animals of the establishments concerned form part of the same epidemiological unit.

When a single approval is granted for a group of aquaculture establishments, the rules laid down in Article 178 and Articles 180 to 184 and the rules adopted pursuant to Articles 180(2) and 181(2), which are applicable to a single aquaculture establishment, shall be applicable to the whole group of aquaculture establishments.

Article 178

Approval of status of confined aquaculture establishments

Operators of aquaculture establishments wishing to obtain the status of a confined establishment shall:

(a) apply to the competent authority for approval in accordance with Article 180(1);

(b) move aquaculture animals to or from their establishment in accordance with the requirements provided for in Article 203(1) and any delegated acts adopted in accordance with Article 203(2) only after their establishment has obtained an approval of that status from the competent authority in accordance with Article 181 or 183.

Article 179

Approval of disease control aquatic food establishments

Operators of disease control aquatic food establishments shall:

(a) ensure that the necessary approval in accordance with Article 4 of Regulation (EC) No 853/2004 of the European Parliament and of the Council [1] has been obtained; and

(b) apply to the competent authority, in accordance with Article 180(1), for approval to slaughter or process aquatic animals for disease control purposes in accordance with point (b) of Article 61(1), Article 62 and Articles 68(1), 79 and 80 and the rules adopted pursuant to Article 63 and Articles 70(3) and 71(3).

Article 180

Obligation of operators to provide information with a view to obtaining approval

1. Operators shall, for the purposes of their application for approval of their establishment as provided for in Article 176(1), Article 177, point (a) of Article 178 and Article 179, provide the competent authority with the following information:

(a) the name and address of the operator concerned;

(b) the location of the establishment concerned and a description of its facilities;

(c) the species, categories and quantities (numbers, volume or weight) of aquaculture animals relevant for the approval which are kept on the establishment;

(d) the type of aquaculture establishment;

(e) in cases of approval of a group of aquaculture establishments, details showing that the group in question complies with the conditions laid down in Article 177;

(f) other aspects of the mode of operation of the aquaculture establishment in question which are relevant for determining the risk, posed by it;

(g) the water supply to, and discharge of water from, the establishment;

(h) the establishment's biosecurity measures.

2. Operators of establishments as referred to in paragraph 1 shall inform the competent authority in advance of:

(a) any changes in the establishments concerning the matters referred to in paragraph 1;

(b) any cessation of activity by the operator or establishment concerned.

[1] Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

3. The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators in their application for approval of their establishment, in accordance with paragraph 1, including the time-limits by which such information is to be provided.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 181

Granting of, and conditions for, approval and delegated acts

1. The competent authority shall only grant approvals of aquaculture establishments as referred to in Article 176(1) and point (a) of Article 178, groups of aquaculture establishments as referred to in Article 177 and disease control aquatic food establishments as referred to in Article 179, where such establishments:

(a) comply with the following requirements, where appropriate, in relation to:

(i) quarantine, isolation and other biosecurity measures taking into account the requirements provided for in point (b) of Article 10(1)) and any rules adopted pursuant to Article 10(6);

(ii) surveillance requirements as provided for in Article 24, where relevant for the type of establishment concerned and the risk involved, in Article 25;

(iii) record-keeping as provided for in Articles 186 to 188 and any rules adopted pursuant to Articles 189 and 190;

(b) have facilities and equipment that are:

(i) adequate to reduce the risk of the introduction and spread of diseases to an acceptable level, taking into account the type of establishment concerned;

(ii) of a capacity adequate for the species, categories and quantity (numbers, volume or weight) of aquatic animals concerned;

(c) do not pose an unacceptable risk as regards the spread of diseases, taking into account the risk-mitigation measures in place;

(d) have in place a system which enables the operator concerned to demonstrate to the competent authority that the requirements laid down in points (a), (b) and (c) are fulfilled.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) quarantine, isolation and other biosecurity measures as referred to in point (a)(i) of paragraph 1;

(b) surveillance as referred to in point (a)(ii) of paragraph 1;

(c) facilities and equipment as referred to in point (b) of paragraph 1.

3. When establishing the rules to be laid down in the delegated acts to be adopted pursuant to paragraph 2, the Commission shall base those rules on the following matters:

(a) the risks posed by each type of establishment;

(b) the species and categories of aquaculture or aquatic animals relevant for the approval;

(c) the type of production concerned;

(d) typical movement patterns of the type of aquaculture establishment and species and categories of animals kept in those establishments.

Article 182

Scope of the approval of establishments

The competent authority shall expressly specify in the approval of an aquaculture establishment or a disease control aquatic food establishment granted pursuant to Article 181(1) following an application made in accordance with Article 176, Article 177, point (a) of Article 178 or Article 179:

(a) for which of the types of aquaculture establishments referred to in Article 176(1) and point (a) of Article 178, groups of aquaculture establishments referred to in Article 177 and disease control aquatic food establishments referred to in Article 179, and in any rules adopted pursuant to point (b) of Article 176(4), the approval applies;

(b) for which species and categories of aquaculture animals the approval applies.

Article 183

Procedures for the granting of approval by the competent authority

1. The competent authority shall establish procedures for operators to follow when applying for approval of their establishments in accordance with Article 176(1) and Articles 178 and 179.

2. Upon receipt of an application for approval from an operator in accordance with Article 176(1), Article 178 or Article 179, the competent authority shall make an on–site visit.

3. Provided that the requirements referred to in Article 181 are fulfilled, the competent authority shall grant the approval.

4. Where an establishment does not fulfil all requirements for approval as referred to in Article 181, the competent authority may grant conditional approval of an establishment if it appears, on the basis of the application by the operator concerned and the subsequent on-site visit provided for in paragraph 2 of this Article, that the establishment meets all the main requirements that provide sufficient guarantees that the establishment does not pose a significant risk.

5. Where conditional approval has been granted by the competent authority in accordance with paragraph 4 of this Article, it shall grant full approval only where it appears from another on–site visit to the establishment, carried out within three months from the date of the grant of conditional approval, or from documentation provided by the operator within three months from that date, that the establishment meets all the requirements for approval provided for in Article 181(1) and the rules adopted pursuant to Article 181(2).

Where the on–site visit or the documentation referred to in the first subparagraph shows that clear progress has been made but that the establishment still does not meet all of those requirements, the competent authority may prolong the conditional approval. However, conditional approval shall not be granted for a period exceeding, in total, six months.

Article 184

Review, suspension and withdrawal of approvals by the competent authority

1. The competent authority shall keep approvals of establishments granted in accordance with Article 181(1) under review, at appropriate intervals based on the risk involved.

2. Where a competent authority identifies serious deficiencies in an establishment as regards compliance with the requirements laid down in Article 181(1) and the rules adopted pursuant to Article 181(2), and the operator of that establishment is not able to provide adequate guarantees that those deficiencies will be eliminated, the competent authority shall initiate procedures to withdraw the approval of the establishment.

However, the competent authority may merely suspend, rather than withdraw, approval of an establishment where the operator can guarantee that it will eliminate those deficiencies within a reasonable period of time.

3. Approval shall only be granted after withdrawal or restored after suspension in accordance with paragraph 2 when the competent authority is satisfied that the establishment fully complies with all the requirements of this Regulation appropriate for that type of establishment.

Section 3

Register of aquaculture establishments and disease control aquatic food establishments

Article 185

Register of aquaculture establishments and disease control aquatic food establishments

1. Each competent authority shall establish and keep up to date a register of:

(a) all aquaculture establishments registered in accordance with Article 173;

(b) all aquaculture establishments approved in accordance with Article 181(1);

(c) all disease control aquatic food establishments approved in accordance with Article 181(1).

2. The register of aquaculture establishments provided for in paragraph 1 shall contain the following information:

(a) the name and address of the operator and the registration number of the establishment in question;

(b) the location of the aquaculture establishment or, as the case may be, of the group of aquaculture establishments concerned;

(c) the type of production at the establishment;

(d) the water supply to, and discharge from, the establishment, when relevant;

(e) the species of aquaculture animals kept at the establishment;

(f) up–to–date information on the health status of the registered aquaculture establishment, or, as the case may be, of the group of establishments, as regards the listed diseases referred to in point (d) of Article 9(1).

3. For establishments approved in accordance with Article 181(1), the competent authority shall make publicly available by electronic means at least the information referred to in points (a), (c), (e) and (f) of paragraph 2 of this Article, subject to data protection requirements.

4. Where appropriate and relevant, a competent authority may combine the registration provided for in paragraph 1 with registration for other purposes.

5. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) the relevant detailed information to be included in the register of aquaculture establishments provided for in paragraph 1 of this Article;

(b) the public availability of that register.

Section 4

Record-keeping and traceability

Article 186

Record-keeping obligations of operators of aquaculture establishments

1. Operators of aquaculture establishments subject to the requirement of registration in accordance with Article 173, or approval in accordance with Article 181(1), shall keep and maintain records containing at least the following information:

(a) the species, categories and quantities (numbers, volume or weight) of aquaculture animals on their establishment;

(b) movements of aquaculture animals and products of animal origin obtained from those animals into and out of their establishment, stating as appropriate:

(i) their place of origin or destination;

(ii) the date of such movements;

(c) the animal health certificates, in paper or electronic form, required to accompany movements of aquaculture animals arriving at the aquaculture establishment in accordance with Article 208 and the rules adopted pursuant to points (a) and (c) of Article 211(1) and Article 213(2);

(d) mortality in each epidemiological unit and other disease problems at the aquaculture establishment as relevant for the type of production;

(e) biosecurity measures, surveillance, treatments, test results and other relevant information as appropriate for:

(i) the species and categories of the aquaculture animals on the establishment;

(ii) the type of production at the aquaculture establishment;

(iii) the type and size of the aquaculture establishment;

(f) the results of any animal health visits required in accordance with Article 25(1).

The records shall be kept and maintained in paper or electronic form.

2. Aquaculture establishments presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in points (c), (d) and (e) of paragraph 1, provided that traceability is ensured.

3. Operators of aquaculture establishments shall keep the records provided for in paragraph 1 on their aquaculture establishment concerned and shall:

(a) keep them in such a way that the tracing of the place of origin and destination of aquatic animals can be guaranteed;

(b) make them available to the competent authority on request;

(c) retain them for a minimum period to be prescribed by the competent authority, which may not be less than three years.

By way of derogation from the requirement that the records are to be kept on their establishment concerned, as set out in the first subparagraph, when it is physically not possible to keep the records on that establishment, they shall be kept in the office from which the business is administered.

Article 187

Record-keeping obligations of disease control aquatic food establishments

1. Operators of disease control aquatic food establishments subject to approval in accordance with Article 179 shall keep and maintain records of:

(a) all movements into and from their establishment of aquaculture animals and products of animal origin obtained from such animals;

(b) discharge of water and relevant biosecurity measures.

2. Operators of disease control aquatic food establishments shall:

(a) keep the records provided for in paragraph 1 on their establishment and shall make them available to the competent authority on request;

(b) retain those records for a minimum period to be prescribed by the competent authority, which may not be less than three years.

The records shall be kept and maintained in paper or electronic form.

Article 188

Record-keeping obligations of transporters

1. Transporters of aquatic animals intended for aquaculture establishments or to be released into the wild shall keep and maintain records in relation to:

(a) the species, categories and quantities (numbers, volume or weight) of aquatic animals transported by them;

(b) mortality rates of the aquaculture animals and wild aquatic animals in question during transport, in so far as is practicable for the type of transport and the species of aquaculture animals and wild aquatic animals transported;

(c) aquaculture establishments and disease control aquatic food establishments visited by the means of transport;

(d) any exchange of water that took place during transport, specifying the sources of new water and sites of release of water;

(e) the cleaning and disinfection of the means of transport.

The records shall be kept and maintained in paper or electronic form.

2. Transporters presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in paragraph 1, provided that traceability is ensured.

3. Transporters shall keep the records provided for in paragraph 1:

(a) in such a manner that they can be made immediately available to the competent authority on request;

(b) for a minimum period to be prescribed by the competent authority, which may not be less than three years.

Article 189

Delegation of powers concerning record-keeping

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules supplementing the record-keeping requirements provided for in Articles 186, 187 and 188, as regards information to be recorded by operators in addition to that provided for in Articles 186(1), 187(1) and 188(1).

2. The Commission shall take the following matters into account when adopting the delegated acts provided for in paragraph 1:

(a) the risks posed by each type of aquaculture establishment or transport;

(b) the species and categories of aquatic animals kept on the aquaculture establishment concerned, or transported to or from that establishment;

(c) the type of production of the establishment;

(d) typical movement patterns for the type of aquaculture establishment or disease control aquatic food establishment;

(e) the numbers, volume or weight of aquatic animals kept on the establishment or transported to or from it.

Article 190

Implementing powers concerning exemptions from the record-keeping requirements

The Commission may, by means of implementing acts, lay down rules concerning the types of aquaculture establishments and operators that may be exempted by Member States from the record-keeping requirements provided for in Articles 186 and 188, as regards:

(a) operators of certain categories of aquaculture establishments and transporters;

(b) aquaculture establishments keeping, or transporters transporting, respectively, a small number of aquaculture animals or a small number of aquatic animals;

(c) certain species and categories of aquatic animals.

When adopting those implementing acts, the Commission shall base those acts on the criteria provided for in Article 189(2).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 2

Movements within the Union of aquatic animals

Section 1

General requirements for movements

Article 191

General requirements for movements of aquatic animals

1. Operators shall take appropriate measures to ensure that the movement of aquatic animals does not jeopardise the health status at the place of destination with regard to:

(a) the listed diseases referred to in point (d) of Article 9(1);

(b) emerging diseases.

2. Operators shall only move aquatic animals into an aquaculture establishment or for human consumption purposes, or release them into the wild, if the animals in question fulfil the following conditions:

(a) they come, except in the case of wild aquatic animals, from establishments that have been:

  (i) registered by the competent authority in accordance with Article 173,

  (ii) approved by that competent authority in accordance with Articles 181 and 182, when required by Article 176(1), Article 177 or Article 178, or

  (iii) granted a derogation from the registration requirement laid down in Article 173.

(b) they are not subject to:

  (i) movement restrictions affecting the species and categories concerned in accordance with the rules laid down in Article 55(1), Article 56, Article 61(1), Articles 62, 64 and 65, point (b) of Article 70(1), Article 74(1), Article 79 and Article 81 and the rules adopted pursuant to Article 55(2), Articles 63 and 67 and Articles 70(3), 71(3), 74(4) and 83(2); or

  (ii) the emergency measures laid down in Articles 257 and 258 and the rules adopted pursuant to Article 259.

However, operators may move those aquatic animals where derogations from the movement restrictions for such movements or release are provided for in Title II of Part III (Articles 53–83) or derogations from emergency measures are provided for in rules adopted pursuant to Article 259.

3. Operators shall take all necessary measures to ensure that aquatic animals, after leaving their place of origin, are consigned directly to the final place of destination.

Article 192

Disease prevention measures in relation to transport

1. Operators shall take the appropriate and necessary disease prevention measures to ensure that:

(a) the health status of aquatic animals is not jeopardised during transport;

(b) transport operations of aquatic animals do not cause the potential spread of listed diseases as referred to in point (d) of Article 9(1) to humans or animals en route, and at places of destination;

(c) cleaning and disinfection of equipment and means of transport and other adequate biosecurity measures are taken, as appropriate to the risks involved with the transport operations concerned;

(d) any exchanges of water and discharges of water during the transport of aquatic animals intended for aquaculture or release into the wild are carried out at places and under conditions which do not jeopardise the health status with regard to the listed diseases referred to in point (d) of Article 9(1) of:

(i) the aquatic animals being transported;

(ii) any aquatic animals en route to the place of destination;

(iii) aquatic animals at the place of destination.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) the conditions and requirements for cleaning and disinfection of equipment and means of transport in accordance with point (c) of paragraph 1 of this Article and the use of biocidal products for such purposes;

(b) other appropriate biosecurity measures during transport as provided for in point (c) of paragraph 1 of this Article;

(c) water exchanges and discharges of water during transport as provided for in point (d) of paragraph 1 of this Article.

Article 193

Change of intended use

1. Aquatic animals which are moved for destruction or slaughter in accordance with the following measures shall not be used for any other purpose:

(a) any of the disease control measures provided for in point (c) of Article 32(1) and Article 55(1), Articles 56, 61, 62, 64, 65 and 70, Articles 74(1) and (2) and Articles 79, 80, 81 and 82 and in the rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 70(3), 71(3) and 74(4), and Article 83(2);

(b) emergency measures as provided for in Articles 257 and 258 and in rules adopted pursuant to Article 259.

2. Aquatic animals moved for human consumption, aquaculture, release into the wild or any other purpose, shall not be used for any purpose other than the intended one.

3. By way of derogation from paragraph 2, the competent authority of the place of destination may authorise a change of use of aquatic animals for a purpose other than that originally intended, provided that the new use does not pose a higher risk to the health status of the aquatic animals at the place of destination than the originally intended use.

Article 194

Obligations of operators at the place of destination

1. Operators of aquaculture establishments and disease control aquatic food establishments receiving aquatic animals and operators receiving aquatic animals for release into the wild shall, before the aquatic animals are unloaded:

(a) check that, where required, one of the following documents is present:

(i) the animal health certificates provided for in Article 208(1), Article 209 and Article 223(1) and in the rules adopted pursuant to Articles 189, 211 and 213;

(ii) the self–declaration documents provided for in Article 218(1) and in the rules adopted pursuant to Article 218(3) and (4);

(b) inform the competent authority of the place of destination, after checking the aquatic animals received, of any irregularity with regard to:

(i) the aquatic animals received;

(ii) the documents referred to in point (a)(i) and (ii).

2. In the event of any irregularity as referred to in point (b) of paragraph 1, the operator shall isolate the aquatic animals concerned by that irregularity until the competent authority of the place of destination has taken a decision regarding them.

Article 195

General requirements in respect of movements of aquaculture animals passing through Member States but intended for export from the Union to third countries or territories

Operators shall ensure that aquaculture animals intended for export to a third country or territory and passing through the territory of another Member State fulfil the requirements laid down in Articles 191, 192 and 193.

Section 2

Aquatic animals intended for aquaculture establishments or release into the wild

Article 196

Abnormal mortalities or other serious disease symptoms

1. Operators shall only move aquatic animals from an aquaculture establishment or from the wild to another aquaculture establishment, or release them into the wild, if the animals in question:

(a) show no disease symptoms; and

(b) originate from an aquaculture establishment or environment where there are no abnormal mortalities with an undetermined cause.

2. By way of derogation from paragraph 1, the competent authority may, on the basis of an evaluation of the risks involved, authorise the movement or release of aquatic animals as referred to in that paragraph, provided that the animals in question originate from a part of the aquaculture establishment or from the wild that is independent of the epidemiological unit where the abnormal mortalities or other disease symptoms have occurred.

If the movement or release referred to in this paragraph is to be made to another Member State, it shall only be authorised by the competent authority if the competent authorities of the Member State of destination and, where relevant, of the Member States of passage have given their consent to such movement or release.

Article 197

Movements of aquaculture animals intended for Member States, zones or compartments which have been declared disease-free or which are subject to an eradication programme, and delegated acts

1. Operators shall only move aquaculture animals of listed species relevant for one or more of the listed diseases referred to in points (b) or (c) of Article 9(1) to an aquaculture establishment, or for release into the wild, in a Member State, zone or compartment which has been declared free of those listed diseases in accordance with Article 36(4) or 37(4), if the animals in question originate from a Member State, or a zone or compartment thereof, which has been declared free of those diseases.

2. Operators shall only move aquaculture animals of listed species relevant for one or more of the listed diseases referred to in points (b) or (c) of Article 9(1) to an aquaculture establishment, or for release into the wild, in a Member State, zone or compartment subject to an eradication programme for one or more of those listed diseases as provided for in Article 31(1) or (2), if the animals in question originate from a Member State, or a zone or compartment thereof, which has been declared free of those listed diseases.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning derogations from the movement or release requirements laid down in paragraphs 1 and 2 of this Article which do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) on account of:

(a) the species, categories, and life stage of the aquaculture animals concerned;

(b) the type of establishment of origin and of destination;

(c) the intended use of the aquaculture animals;

(d) the place of destination of the aquaculture animals;

(e) treatments, processing methods and other special risk-mitigation measures applied at the place of origin or destination.

Article 198

Derogations by Member States concerning the obligation of operators for movement of aquaculture animals between Member States, zones or compartments which are subject to an eradication programme

By way of derogation from Article 197(1) and (2), Member States may authorise operators to move aquaculture animals into a zone or compartment for which an eradication programme has been established in accordance with Article 31(1) and (2) as regards the listed diseases referred to in points (b) and (c) of Article 9(1), from another zone or compartment for which such a programme has also been established for the same listed diseases, provided that such movement will not jeopardise the health status of the Member State, zone or compartment of destination.

If such movements are to be made to another Member State, the competent authority shall only authorise them if the competent authorities of the Member State of destination and, where relevant, of the Member States of passage, have given their consent to them.

Article 199

Member States' measures concerning the release of aquatic animals into the wild

Member States may require that aquatic animals may be released into the wild only if they originate from a Member State, or a zone or compartment thereof, which has been declared disease–free in accordance with Article 36(1) or Article 37(1) as regards one or more of the listed diseases referred to in points (b) and (c) of Article 9(1) for which the species of aquatic animals to be moved is a listed species, regardless of the health status of the area where those aquatic animals are to be released.

Article 200

Movements of wild aquatic animals intended for Member States, or zones or compartments thereof, which have been declared disease–free or which are subject to an eradication programme, and delegated acts

1. Articles 196, 197 and 198 shall apply to movements of wild aquatic animals intended for an aquaculture establishment or for release into the wild.

2. Operators shall take the appropriate and necessary disease prevention measures when moving wild aquatic animals between habitats to ensure that:

(a) such movements do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to aquatic animals at the place of destination; and

(b) risk-mitigation or other adequate biosecurity measures are in place where necessary to ensure compliance with point (a).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the disease prevention and risk-mitigation measures to be taken by operators as provided for in paragraph 2 of this Article. Pending the adoption of such delegated acts, the competent authority of the place of destination may decide on such measures.

Section 3

Aquatic animals intended for human consumption

Article 201

Movements of live aquaculture animals intended for human consumption in Member States, or in zones or compartments thereof, which have been declared disease–free or which are subject to an eradication programme, and delegated acts

1. Operators shall only move live aquaculture animals of listed species relevant for listed diseases as referred to in points (b) or (c) of Article 9(1) intended for human consumption to a Member State, or to a zone or compartment thereof, which has been declared disease-free in accordance with Article 36(4) or Article 37(4) or for which a eradication programme has been established in accordance with Article 31(1) or (2), as regards one or more of the listed diseases referred to in points (b) and (c) of Article 9(1), if the animals in question originate from a Member State, or a zone or compartment thereof, which has been declared disease–free in accordance with Article 36(4) or Article 37(4).

2. By way of derogation from paragraph 1 of this Article, Member States may authorise operators to introduce live aquaculture animals into a zone or compartment for which an eradication programme has been established in accordance with Article 31(1) or (2) as regards the listed diseases referred to in points (b) and (c) of Article 9(1), from another zone or compartment for which such a programme has also been established as regards the same diseases within that Member State, provided that such movement will not jeopardise the health status of the Member State or of the zone or compartment thereof.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the derogations provided for in paragraph 2 of this Article in respect of movements of live aquaculture animals which do not pose a significant risk of spreading of diseases on account of:

(a) the species, categories, and live stage of the aquaculture animals concerned;

(b) the methods of keeping the aquaculture animals and the type of production in the aquaculture establishments of origin and of destination;

(c) the intended use of the aquaculture animals;

(d) the place of destination of the aquaculture animals;

(e) treatments, processing methods and other special risk-mitigation measures applied at the place of origin or the place of destination.

Article 202

Movements of live wild aquatic animals intended for Member States, or zones or compartments thereof, which have been declared disease–free or which are subject to an eradication programme, and delegated acts

1. Article 201(1) and (2) and the rules adopted pursuant to Article 201(3) shall apply to movements of live wild aquatic animals intended for human consumption and which are intended for Member States, or zones or compartments thereof, which have been declared disease–free in accordance with Articles 36(4) or 37(4) or which are subject to an eradication programme in accordance with Article 31(1) or (2), where the measures adopted pursuant thereto are necessary in order to ensure that the animals in question do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to aquatic animals at the place of destination.

2. Paragraph 1 of this Article shall also apply to live aquatic animals not covered by the definition of aquaculture animals contained in Article 4(7).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning movement requirements for wild aquatic animals intended for human consumption, supplementing paragraphs 1 and 2 of this Article.

Section 4

Derogations from Sections 1 to 3 (Articles 191 to 202) and additional risk-mitigation measures

Article 203

Aquatic animals intended for confined establishments for aquaculture and delegated acts

1. Operators shall only move aquatic animals to a confined establishment for aquaculture if the animals in question fulfil the following conditions:

(a) they originate from another confined establishment for aquaculture;

(b) they do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to listed species of animals at the confined establishment for aquaculture of destination, except where the movement in question is authorised for scientific purposes.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) detailed rules for movements of aquaculture animals to confined establishments for aquaculture in addition to those provided for in paragraph 1 of this Article;

(b) specific rules for movements of aquaculture animals to confined establishments for aquaculture where the risk-mitigation measures in place guarantee that such movements do not pose a significant risk for the health of aquaculture animals within that confined establishment for aquaculture and the surrounding establishments.

Article 204

Movements of aquatic animals for scientific purposes and delegated acts

1. The competent authority of the place of destination may, subject to the agreement of the competent authority of the place of origin, authorise movements of aquatic animals into the territory of the Member State of destination, for scientific purposes, where those movements do not fulfil the requirements of Sections 1 to 3 (Articles 191 to 202), with the exception of Article 191(1) and (3) and Articles 192, 193 and 194.

2. The competent authority referred to in paragraph 1 shall only grant derogations as provided for in that paragraph under the following conditions:

(a) the competent authorities of the places of destination and origin:

(i) have agreed on the conditions for such movements;

(ii) ensure that the necessary risk-mitigation measures are in place so that movements of the aquatic animals in question do not jeopardise the health status in places en route and in the places of destination with regard to the listed diseases referred to in point (d) of Article 9(1);

(iii) have notified, where relevant, the competent authorities of the Member States of passage of the derogation granted and of the conditions under which it is granted;

(b) those movements take place under the supervision of the competent authorities of the places of origin and destination, and where relevant, the competent authorities of the Member States of passage.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules for the granting of derogations by competent authorities, supplementing those provided for in paragraphs 1 and 2 of this Article.

Article 205

Other specific uses of aquatic animals, specific requirements and derogations and delegation of powers

1. Operators shall take the necessary preventive measures to ensure that movements of aquatic animals intended for the specific purposes or uses listed in point (a)(i) to (vi) of paragraph 2 of this Article do not pose a risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to aquatic animals at the place of destination.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) specific requirement supplementing the rules laid down in Sections 1 to 3 (Articles 191 to 202) and for movements of aquatic animals for the following purposes:

(i) zoos, pet shops, wholesalers and garden ponds;

(ii) exhibitions;

(iii) sports fishing, including fishing baits;

(iv) cultural and similar events;

(v) commercial aquaria; or

(vi) health care and other similar uses.

(b) derogations from Sections 1 to 3 (Articles 191 to 202) with the exception of Article 191(1) and (3) and Articles 192, 193 and 194 for the movements of aquatic animals referred to in point (a) of this paragraph, provided that adequate biosecurity provisions are in place to ensure that those movements do not pose a significant risk to the health status of the place of destination.

Article 206

Implementing power to adopt temporary rules for movements of specific species or categories of aquatic animals

1. The Commission may, by means of implementing acts, lay down temporary rules, by way of addition or alternative to those laid down in this Chapter, for movements of specific species or categories of aquatic animals where:

(a) the movement requirements provided for in Article 196, Article 197(1), Articles 198 and 199, Article 200(1) and (2), Article 201 and Articles 202(1), 203(1), 204(1) and (2) and the rules adopted pursuant to Articles 197(3), 200(3), 202(3), 203(2) and 204(3) and Article 205 do not efficiently mitigate the risks posed by the movement of those aquatic animals; or

(b) a listed disease as referred to in point (d) of Article 9(1) appears to be spreading despite the movement requirements laid down in accordance with Sections 1 to 4 (Articles 191 to 207).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

2. On duly justified imperative grounds of urgency relating to a listed disease representing a risk of a highly significant impact and taking into account the matters referred to in Article 205, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 266(3).

Article 207

Matters to be taken into account in the adoption of delegated and implementing acts as provided for in this Section

When establishing the rules to be laid down in the delegated and implementing acts provided for in Article 203(2), Article 204(3) and Articles 205 and 206, the Commission shall base those rules on:

(a) the risks involved with the movements referred to in those provisions;

(b) the health status as regards the listed diseases referred to in point (d) of Article 9(1) at the places of origin, passage and destination;

(c) listed aquatic animal species for the listed diseases referred to in point (d) of Article 9(1);

(d) biosecurity measures in place at the places of origin, passage and destination;

(e) any specific conditions under which the aquaculture animals are kept;

(f) specific movement patterns of the type of aquaculture establishment and the species or category of aquatic animals concerned;

(g) other epidemiological factors.

Section 5

Animal health certification

Article 208

Obligation of operators to ensure that aquaculture animals are accompanied by an animal health certificate

1. Operators shall only move aquaculture animals if they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 216(1), where the animals in question are of listed species for the listed diseases referred to in points (b) and (c) of Article 9(1) and are intended for introduction into a Member State, or a zone or compartment thereof, which has been declared disease–free in accordance with Articles 36(4) and 37(4) or for which an eradication programme has been established as provided for in Article 31(1) or (2) as regards one or more of the listed diseases referred to in points (b) and (c) of Article 9(1).

2. Operators shall only move aquaculture animals if they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 216(1), where the animals in question are of listed species for the relevant disease(s) referred to in points (a) and (b) of Article 9(1) and are allowed to leave a restricted zone subject to disease control measures as provided for in point (f)(ii) of Article 55(1), Articles 56 and 64 or Articles 65(1), 74(1), 79 and rules adopted pursuant to Article 55(2), Articles 67 and 68, Articles 71(3), 74(4) and 83(2) and Article 259 for one or more of the listed diseases referred to in points (a) and (b) of Article 9(1).

3. Operators shall take all necessary measures to ensure that the animal health certificate accompanies the aquaculture animals from their place of origin to their final place of destination, unless specific measures are provided for in rules adopted pursuant to Article 214.

Article 209

Obligation of operators to ensure that other aquatic animals are accompanied by an animal health certificate and implementing power

1. In cases where, due to the risk involved with the movement of aquatic animals other than aquaculture animals, animal health certification is required in accordance with the rules provided for in point (a) of Article 211(1), operators shall only move those aquatic animals if the animals in question are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 216(1).

2. Article 208 shall also apply to aquatic animals other than aquaculture animals intended for an aquaculture establishment or release into the wild. Where the competent authority of the Member State of origin concludes that certification is not feasible due to the nature of the place of origin of the aquatic animals in question, it may authorise their movement without an animal health certificate subject to the consent of the competent authority of the place of destination.

3. This Article shall not apply to wild aquatic animals harvested or caught for direct human consumption.

Article 210

Grant of derogations by Member States in respect of national animal health certification

By way of derogation from the animal health certification requirements laid down in Articles 208 and 209, Member States may grant derogations for movements of certain consignments of aquatic animals without an animal health certificate within their territories provided that they have in place an alternative system to ensure that consignments of such animals are traceable and those consignments comply with the animal health requirements for such movements provided for in Sections 1 to 4 (Articles 191 to 207).

Article 211

Delegation of powers and implementing acts concerning animal health certification in respect of aquatic animals

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) the requirement for animal heath certification for movements of aquatic animals other than aquaculture animals as referred to in Article 209(1), in cases where animal health certification is imperative in order to ensure that the movement in question complies with the following animal health requirements for the listed species of animals concerned:

   (i) the requirements provided for in Sections 1 to 4 (Articles 191 to 207) and the rules adopted pursuant to those Sections;

   (ii) disease control measures as provided for in Article 55(1), Article 56, Article 61(1), Articles 62 and 64, and Article 65(1), Article 74(1), and Articles 79 and 80 or the rules adopted pursuant to Article 55(2), Articles 63, 67 and 68, and Articles 71(3), 74(4) and 83(2);

   (iii) emergency measures as provided for in the rules adopted pursuant to Article 259;

(b) special rules for animal health certification as provided for in Articles 208 and 209 where specific risk-mitigation measures are taken by the competent authority to ensure:

   (i) the traceability of the aquatic animals being moved;

(ii) that the aquatic animals being moved fulfil the animal health requirements for movements provided for in Sections 1 to 4 (Articles 191 to 207);

(c) derogations from the animal health certificate requirements provided for in Articles 208 and 209 and the conditions for such derogations for movements of aquatic animals which do not pose a significant risk of the spread of diseases, on account of:

(i) species, the categories or live stage of the aquatic animals concerned;

(ii) the methods of keeping and the type of production of those species and categories of aquaculture animals;

(iii) the intended use of the aquatic animals; or

(iv) the place of destination of the aquatic animals.

2. The Commission shall, by means of implementing acts, lay down rules concerning the obligation of operators, as provided for in Article 209(2), to ensure that wild aquatic animals intended for an aquaculture establishment are accompanied by an animal health certificate.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 212

Contents of animal health certificates

1. The animal health certificate referred to in Articles 208, 209 and 210 shall contain at least the following information:

(a) the establishment or place of origin, the establishment or place of destination and, where relevant for the spread of diseases, any establishment or place visited en route;

(b) a description, including the species and category, of the aquatic animals concerned;

(c) the quantity (number, volume or weight) of aquatic animals;

(d) the information needed to demonstrate that the aquatic animals fulfil the relevant animal health requirements in respect of movements provided for in Sections 1 to 4 (Articles 191 to 207).

2. The animal health certificate may include other information required under other Union legislation.

Article 213

Delegation of powers and implementing acts concerning the content of animal health certificates

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning the content of animal health certificates as provided for in Article 212(1):

(a) detailed rules on the content of those animal health certificates provided for in Article 212(1) for different species and categories of aquatic animals;

(b) additional information to be contained in the animal health certificate provided for in Article 212(1).

2. The Commission may, by means of implementing acts, lay down rules concerning the model forms for the animal health certificates.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 214

Delegation of powers concerning specific types of movements of aquatic animals to the place of destination

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning specific measures supplementing the requirements for animal health certification provided for in Article 208 and 209 for the following types of movements of aquatic animals:

(a) movements of aquatic animals which are required to return to their place of origin or to be moved to a different destination, for one or more of the following reasons:

(i) their intended journey was unexpectedly interrupted for animal welfare reasons;

(ii) unforeseen accidents or events during the journey;

(iii) they were rejected at the place of the destination in another Member State or at the external border of the Union;

(iv) they were rejected in a third country or territory;

(b) movements of aquaculture animals intended for exhibitions and for sporting, cultural and similar events, and their subsequent return to their place of origin.

Article 215

Operators' obligations to cooperate with the competent authorities for the purposes of animal health certification

Operators shall:

(a) provide the competent authority with all the information necessary to complete the animal health certificate provided for in Articles 208 and 209 and in the rules adopted pursuant to Articles 211, 213 and 214, in advance of the intended movement;

(b) where necessary, ensure that the aquatic animals in question are subjected to documentary, identity and physical checks as provided for in Article 216(3) and in the rules adopted pursuant to Article 216(4).

Article 216

Responsibility of the competent authority for animal health certification and delegated acts

1. The competent authority shall, upon request by an operator, issue an animal health certificate for the movement of aquatic animals, where required by Articles 208 and 209, or by rules adopted pursuant to Articles 211 and Article 214, provided that the following animal health requirements have been complied with, as relevant:

(a) those provided for in Article 191, Article 192(1), Articles 193, 195 and 196, Article 197(1), Articles 198 and 199, Article 200(1) and (2), Article 201, Article 203(1) and Article 204(1) and (2);

(b) those provided for in delegated acts adopted pursuant to Articles 192(2), 197(3), 200(3), 201(3), 202(3), 203(2) and 204(3) and Article 205;

(c) those provided for in implementing acts adopted pursuant to Article 206.

2. Animal health certificates shall:

(a) be verified, stamped and signed by an official veterinarian;

(b) remain valid for the period of time, provided for in the rules adopted pursuant to point (c) of paragraph 4, during which the aquatic animals covered by it must continue to fulfil the animal health guarantees contained in it.

3. Before signing an animal health certificate, the official veterinarian concerned shall verify, by means of documentary, identity and physical checks as provided for by delegated acts adopted pursuant to paragraph 4 where appropriate, that the aquatic animals covered by it fulfil the requirements of this Chapter, taking into account the species and categories of aquatic animals concerned and the animal health requirements.

4. The Commission shall adopt delegated acts in accordance with Article 264 laying down rules concerning:

(a) the types of documentary, identity and physical checks and examinations in relation to different species and categories of aquatic animals that must be carried out by the official veterinarian in accordance with paragraph 3 in order to verify compliance with the requirements of this Chapter;

(b) the timeframes for the carrying-out of such documentary, identity and physical checks and examinations, and the issuing of animal health certificates by the official veterinarian prior to the movement of consignments of aquatic animals;

(c) the duration of the validity of animal health certificates.

Article 217

Electronic animal health certificates

Electronic animal health certificates, produced, handled and transmitted by means of Traces, may replace accompanying animal health certificates as provided for in Article 216(1) where such electronic animal health certificates:

(a) contain all the information that the model form of animal health certificate is required to contain in accordance with Article 212(1) and the rules adopted pursuant to Article 213;

(b) ensure the traceability of the aquatic animals in question and the link between those animals and the electronic animal health certificate;

(c) ensure that the competent authorities of the Member States of origin, passage and destination are able to have access to the electronic documents at all times during the transport.

Article 218

Self–declaration by operators for movements of aquaculture animals to other Member States and delegated acts

1. Operators at the place of origin shall issue a self–declaration document for movements of aquaculture animals from their place of origin in one Member State to their place of destination in another Member State, and shall ensure that it accompanies such aquaculture animals, where they are not required to be accompanied by an animal health certificate as provided for in Articles 208 and 209 or in any rules adopted pursuant to Articles 211 and Article 214.

2. The self–declaration document provided for in paragraph 1 shall contain at least the following information concerning the aquaculture animals in question:

(a) their places of origin and destination, and, when relevant, any places en route;

(b) the means of transport

(c) a description of the aquaculture animals, and their categories, species and quantity (numbers, volume or weight), as relevant for the animals concerned;

(d) the information needed to demonstrate that the aquaculture animals fulfil the movement requirements provided for in Sections 1 to 4 (Articles 191 to 207).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) detailed rules on the content of the self–declaration document provided for in paragraph 2 of this Article for different species and categories of aquaculture animals;

(b) additional information to be contained in the self–declaration document to the one provided for in paragraph 2 of this Article.

4. The Commission may, by means of implementing acts, lay down rules for a model form of the self–declaration document provided for in paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Section 6

Notification of movements of aquatic animals to other Member States

Article 219

Obligation of operators concerning the notification of movements of aquatic animals to other Member States

1. Operators other than transporters shall notify the competent authority in their Member State of origin in advance of intended movements of aquatic animals from one Member State to another Member State where:

(a) the aquatic animals are required to be accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Articles 208 and 209 and any rules adopted pursuant to Article 211 and Article 214(2);

(b) the aquatic animals are required to be accompanied by an animal health certificate for aquatic animals when they are being moved from a restricted zone as referred to in Article point (a) of 208(2);

(c) the aquaculture animals and wild aquatic animals being moved are intended for:

(i) an establishment subject to registration in accordance with Article 173 or approval in accordance with Articles 176 to 179;

(ii) release into the wild;

(d) notification is required in accordance with delegated acts adopted pursuant to Article 221.

2. For the purposes of the notification provided for in paragraph 1 of this Article, operators shall provide the competent authority of their Member State of origin with all the necessary information to enable it to notify the movement to the competent authority of the Member State of destination in accordance with Article 220(1).

Article 220

Responsibility of the competent authority to notify movements of aquatic animals to other Member States

1. The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of aquatic animals as referred to in Article 219, unless a derogation has been granted in accordance with point (c) of Article 221(1) as regards such notification.

2. The notification referred to in paragraph 1 shall be carried out prior to the movement in question and, whenever possible, through Traces.

3. Member States shall designate regions for the management of notifications of movements as provided for in paragraph 1.

4. By way of derogation from paragraph 1, the competent authority of Member State of origin may authorise the operator concerned to notify, partially or completely, movements of aquatic animals through Traces to the competent authority of the Member State of destination.

Article 221

Delegation of powers and implementing acts for the notification of movements of aquatic animals by operators and by the competent authority

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning:

(a) the requirement for advance notification by operators, in accordance with Article 219, of movements between Member States of aquatic animals of species or categories other than those referred to in points (a), (b) and (c) of Article 219(1), where traceability of such movements is necessary in order to ensure compliance with the animal health requirements laid down in this Chapter;

(b) the information needed in order to notify movements of aquatic animals as provided for in Articles 219 and 220(1);

(c) derogations from the notification requirements provided for in point (c) of Article 219(1) for species and categories of aquatic animals or types of movements which pose an insignificant risk;

(d) the emergency procedures for notification of movements of aquatic animals in the event of power cuts or other disturbances of Traces;

(e) the requirements for the designation of regions by Member States as provided for in Article 220(3).

2. The Commission may, by means of implementing acts, lay down rules concerning:

(a) the details of notifications by:

(i) operators to the competent authority of the Member State of origin of movements of aquatic animals in accordance with Article 219;

(ii) the competent authority of the Member State of origin to the Member State of destination of movements of aquatic animals in accordance with Article 220(1);

(b) the deadlines for:

(i) the provision by operators of the necessary information referred to in Article 219(2) to the competent authority of the Member State of origin;

(ii) the notification of movements by the competent authority of the Member State of origin as referred to in Article 220(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 3

Production, processing and distribution within the Union of products of animal origin from aquatic animals, other than live aquatic animals

Article 222

General animal health obligations for operators and delegated acts

1. Operators shall take appropriate preventive measures to ensure that, during all stages of the production, processing and distribution of products of animal origin from aquatic animals, other than live aquatic animals, those products do not cause the spread of:

(a) listed diseases as referred to in point (d) of Article 9(1), taking into account the health status of the place of production, processing and destination;

(b) emerging diseases.

2. Operators shall ensure that products of animal origin from aquatic animals, other than live aquatic animals, do not come from establishments or food businesses, or are not obtained from animals which come from such establishments or food businesses, that are subject to:

(a) emergency measures as provided for in Articles 257 and 258 and any rules adopted pursuant to Article 259, unless derogations have been provided for in respect of those rules in Part VII (Articles 257 to 262);

(b) movement restrictions applicable to aquatic animals and products of animal origin from aquatic animals, as provided for in point (c) of Article 32(1), point (e) of Article 55(1), Article 56, point (a) of Article 61(1), Article 62(1), point (c) of Article 65(1), point (b) of Article 70(1), point (a) of Article 74(1), point (b) of Article 76(2), Article 76(3), Article 79, Article 81 and Article 82(2) and (3) and the rules adopted pursuant to Article 55(2), Articles 63 and 67, and Articles 70(3), 71(3), 74(4), 76(5) and 83(2), unless derogation from those movement restrictions have been provided for in those rules.

3. The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed requirements supplementing those referred to in paragraph 2 of this Article in relation to movements of products of animal origin from aquatic animals other than live aquatic animals, as regards:

(a) the diseases, and species of aquatic animals concerned by the diseases, for which emergency measures or movement restrictions as referred to in paragraph 2 of this Article apply;

(b) the types of products of animal origin from aquatic animals;

(c) the risk-mitigation measures applied to the products of animal origin from aquatic animals at the places of origin and destination;

(d) the intended use of the products of animal origin from aquatic animals;

(e) the place of destination of the products of animal origin from aquatic animals.

4. This Article shall not apply to products of animal origin from wild aquatic animals harvested or caught for direct human consumption.

Article 223

Animal health certificates and delegated acts

1. Operators shall only move the following products of animal origin from aquatic animals other than live aquatic animals where those products are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with paragraph 3:

(a) products of animal origin from aquatic animals that:

(i) are allowed to leave a restricted zone subject to emergency measures as provided for in rules adopted pursuant to Article 259; and

(ii) originate from aquatic animals of species subject to those emergency measures;

(b) products of animal origin from aquatic animals that:

(i) are allowed to leave a restricted zone subject to disease control measures in accordance with point (c) of Article 32(1), point (c) of Article 55(1), Article 56, point (a) of Article 61(1), Articles 62(1) and 63(1), point (c) of Article 65(1), point (b) of Article 70(1), point (a) of Article 74(1) and Article 79 and the rules adopted pursuant to Article 55(2), Articles 63 and 67 and Articles 71(3), 74(4) and 83(2); and

(ii) originate from aquatic animals of species subject to those disease control measures.

2. By way of derogation from paragraph 1, such a certificate shall not be required for movements of products of animal origin from wild aquatic animals, provided that:

(a) alternative risk-mitigation measures authorised by the competent authority are in place to ensure that those movements do not pose a risk of the spread of listed diseases;

(b) consignments of such products are traceable.

3. Operators shall take all necessary measures to ensure that the animal health certificate referred to in paragraph 1 accompanies the products of animal origin from their place of origin to their place of destination.

4. The competent authority shall, upon request by the operator concerned, issue an animal health certificate for movements of products of animal origin other than live aquatic animals as referred to in paragraph 1, provided that the relevant requirements referred to in this Article have been complied with.

5. Article 212 and Articles 214 to 217 and the rules adopted pursuant to Article 213 and Article 216(4) shall apply to the animal health certification of movements of products of animal origin other than live aquatic animals as referred to in paragraph 1 of this Article.

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning requirements and detailed rules on the animal health certificate to accompany products of animal origin other than live aquatic animals, as referred to in paragraph 1 of this Article, taking into account:

(a) the types of products of animal origin concerned;

(b) the risk-mitigation measures applied to the products concerned which reduce the risks of the spread of diseases;

(c) the intended use of those products;

(d) the place of destination of those products.

Article 224

Content of animal health certificates and delegated and implementing acts

1. The animal health certificate for products of animal origin from aquatic animals, other than live aquatic animals, shall contain at least the following information:

(a) the establishment or place of origin and the establishment or place of destination;

(b) a description of the products of animal origin concerned;

(c) the quantity (numbers, volume or weight) of the products of animal origin;

(d) the identification of the products of animal origin, when required by point (h) of Article 65(1) or by any rules adopted pursuant to Article 67;

(e) the information needed to demonstrate that the products concerned fulfil the movement restriction requirements provided for in Article 222(2) and in any rules adopted pursuant to Article 222(3).

2. The animal health certificate referred to in paragraph 1 may include other information required under other Union legislation.

3. The Commission shall adopt delegated acts in accordance with Article 264 concerning amending and supplementing the information to be contained in the animal health certificate as provided for in paragraph 1 of this Article.

4. The Commission may, by means of implementing acts, lay down rules concerning model forms of animal health certificates as provided for in paragraph 1 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 225

Notification of movements of products of animal origin to other Member States

1. Operators shall:

(a) inform the competent authority in the Member State of origin in advance of intended movements of products of animal origin from aquatic animals, other than live aquatic animals, when the consignments in question are required to be accompanied by an animal health certificate in accordance with Article 223(1);

(b) provide all necessary information to enable the competent authority of the Member State of origin to notify the movement in question to the Member State of destination in accordance with paragraph 2 of this Article.

2. The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of products of animal origin from aquatic animals, other than live aquatic animals, in accordance with Article 220(1).

3. Articles 219 and 220 and any rules adopted pursuant to Article 221 shall be applicable to the notification of products of animal origin from aquatic animals, other than live aquatic animals.

CHAPTER 4

National measures

Article 226

National measures designed to limit the impact of diseases other than listed disease

1. Where a disease other than a listed disease as referred to in point (d) of Article 9(1) constitutes a significant risk for the health of aquatic animals in a Member State, the Member State concerned may take national measures to prevent the introduction, or to control the spread, of that disease.

Member States shall ensure that those national measures do not exceed the limits of what is appropriate and necessary in order to prevent the introduction, or to control the spread, of the disease in question within the Member State concerned.

2. Member States shall notify the Commission in advance of any proposed national measures as referred to in paragraph 1 that may affect movements of aquatic animals and products of animal origin from aquatic animals between Member States.

3. The Commission shall approve and, if necessary, amend the national measures referred to in paragraph 2 of this Article by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4. The approval referred to in paragraph 3 shall only be granted where the establishment of movement restrictions between Member States is necessary in order to prevent the introduction, or to control the spread, of the disease referred to in paragraph 1, taking into account the overall impact on the Union of the disease in question and of the measures taken.

TITLE III

ANIMALS OF SPECIES OTHER THAN THOSE DEFINED AS TERRESTRIAL AND AQUATIC ANIMALS, AND GERMINAL PRODUCTS AND PRODUCTS OF ANIMAL ORIGIN FROM SUCH OTHER ANIMALS

Article 227

Animal health requirements concerning other animals, and germinal products and products of animal origin of such other animals

Where other animals are of a listed species for a listed disease as referred to in point (d) of Article 9(1), and those other animals or their germinal products or products of animal origin represent a risk to public or animal health in the Union, one or more of the following requirements shall apply:

(a) the requirements concerning registration, approval, record-keeping and registers for establishments and transporters provided for in Chapter 1 of Title I and Chapter 1 of Title II (Articles 84 to 101 and Articles 172 to 175);

(b) the requirements concerning traceability provided for in Articles 108 to 111 and Article 117 for other animals and Article 122 for germinal products;

(c) movement requirements:

  (i) as regards other animals mainly living in a terrestrial environment or that are normally affected by diseases of terrestrial animals, taking into account the criteria provided for in points (d) and (e) of Article 228(3), the requirements provided for in Section 1 (Articles 124 and 125) and Section 6 of Chapter 3 of Title I of Part IV (Articles 137 to 142) and Chapter 4 of Title I of Part IV (Articles 155 and 156);

  (ii) as regards other animals mainly living in aquatic environment or that are normally affected by diseases of aquatic animals, taking into account the criteria provided for in points (d) and (e) of Article 228(3), the requirements provided for in Sections 1 to 4 of Chapter 2 of Title II of Part IV (Articles 191 to 207);

  (iii) as regards germinal products, the general requirements for movements provided for in Articles 157 and 158 and the special requirements for movements to other Member States provided for in Articles 164 and 165;

  (iv) as regards products of animal origin, the general animal health obligations incumbent on operators in respect of the production, processing and distribution within the Union of products of animal origin provided for in Articles 166 and 222;

(d) the animal health certification obligation incumbent on operators and competent authorities and the self–declaration incumbent on operators:

  (i) as regards other animals, pursuant to the rules provided for in Articles 143 to 151 or Articles 208 to 218;

  (ii) as regards germinal products, pursuant to the rules provided for in Articles 161 and 162;

  (iii) as regards products of animal origin, pursuant to the rules provided for in Articles 165 and 168 or Articles 223 and 224;

(e) the obligation to notify movements incumbent on operators and competent authorities, taking into account the requirements provided for in Articles 152, 153, 154, 163 and 169 and in Articles 219 to 221 and 225.

Article 228

Delegation of powers and implementing acts concerning animal health requirements for other animals, and germinal products and products of animal origin of other animals

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning any specific requirements for other animals, and their germinal products or products of animal origin, which are necessary in order to mitigate the risk of the listed diseases referred to in point (d) of Article 9(1), as provided for in Article 227.

2. The Commission may adopt implementing acts concerning detailed rules for the implementation of the disease control and prevention measures provided for in paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

3. When adopting the delegated acts and implementing acts provided for in paragraphs 1 and 2, the Commission shall base those acts on the following criteria:

(a) the species or categories of other animals listed in accordance with Article 8(2) as listed species for one or more listed diseases, for which certain disease prevention and control measures provided for in this Regulation apply;

(b) the profile of the listed disease in question, which concerns species and categories of other animals referred to in point (a);

(c) the feasibility, availability and effectiveness of disease prevention and control measures for the listed species concerned by those measures;

(d) the prevailing terrestrial or aquatic living environment of those other animals;

(e) the types of diseases that are affecting such other animals, which can be either diseases normally affecting terrestrial or aquatic animals, regardless of the prevailing living environment referred to in point (d).

PART V

ENTRY INTO THE UNION AND EXPORT

CHAPTER 1

Entry into the Union of animals, germinal products and products of animal origin from third countries and territories

Section 1

Requirements for the entry into the Union

Article 229

Requirements for entry into the Union of animals, germinal products and products of animal origin

1. Member States shall permit the entry into the Union of consignments of animals, germinal products and products of animal origin from third countries or territories only if those consignments fulfil the following requirements, unless such animals, germinal products or products of animal origin are covered by a derogation granted pursuant to Article 239(2):

(a) without prejudice to Article 230(2), they come from a third country or territory listed in accordance with Article 230(1) for the particular species and category of animals, or germinal products or products of animal origin concerned, or from a zone or compartment thereof;

(b) they come from establishments which are approved and listed, where such approval and listing is required by Article 233;

(c) they fulfil the animal health requirements for entry into the Union laid down in Article 234(1) and in any delegated acts adopted pursuant to Article 234(2), where such requirements are laid down for the animal, germinal product or product of animal origin concerned;

(d) they are accompanied by an animal health certificate and by declarations and other documents where required by Article 237(1) or by rules adopted pursuant to Article 237(4);

2. The operators responsible for the consignment in question shall present consignments of animals, germinal products and products of animal origin from third countries or territories for the purposes of official control as provided for in Article 3 of Directive 91/496/EEC and Article 3 of Directive 97/78/EC.

Section 2

Listing of third countries and territories

Article 230

Lists of third countries and territories from which the entry into the Union of animals, germinal products and products of animal origin is permitted, and implementing and delegated acts

1. The Commission may, by means of implementing acts, draw up lists of third countries and territories from which the entry into the Union of specific species and categories of animals, germinal products and products of animal origin is to be permitted, based on the following criteria:

(a) the animal health legislation of the third country or territory concerned and the rules on the entry into that third country or territory of animals, germinal products and products of animal origin from other third countries and territories;

(b) the assurances provided by the competent authority of the third country or territory concerned as regards the efficient implementation and control of the animal health legislation referred to in point (a);

(c) the organisation, structure, resources and legal powers of the competent authority in the third country or territory concerned;

(d) the animal health certification procedures in the third country or territory concerned;

(e) the animal health status of the third country or territory concerned, or of zones and compartments thereof, with regard to:

(i) listed diseases and emerging diseases;

(ii) any aspects of animal and public health or the environmental situation in the third country or territory concerned, or in a zone or compartment thereof, which may pose a risk to animal or public health or the environmental status of the Union;

(f) the guarantees which the competent authority of the third country or territory concerned can provide regarding compliance or equivalence with the relevant animal health requirements applicable in the Union;

(g) the regularity and speed with which the third country or territory concerned supplies information concerning infectious or contagious animal diseases in its territory to the World Organisation for Animal Health (OIE), in particular information concerning the diseases listed in the OIE Codes;

(h) the results of controls carried out by the Commission in the third country or territory concerned;

(i) any experience gathered from previous entries of animals, germinal products and products of animal origin from the third country or territory concerned and the results of official controls carried out at the point of entry into the Union on such animals, germinal products and products of animal origin.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

2. Pending the adoption of the lists provided for in paragraph 1, and provided that such lists have not been drawn up pursuant to the Union legislation referred to in Article 270(2), Member States shall determine from which third countries and territories specific species and categories of animals, germinal products or products of animal origin may enter the Union.

For the purposes of the first subparagraph of this paragraph, Member States shall take into account the criteria for inclusion in the lists of third countries and territories provided for in points (a) to (i) of paragraph 1 of this Article.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning derogations from paragraph 2 of this Article, limiting the possibility for Member States to decide from which third countries and territories a specific species and category of animal, germinal product or product of animal origin may enter the Union, where necessary due to the risk posed by that specific species and category of animal, germinal product or product of animal origin.

Article 231

Information to be included in the lists of third countries and territories

The Commission shall specify the following information for each third country or territory in the lists provided for in Article 230(1):

(a) the species and categories of animals, germinal products or products of animal origin that may enter the Union from that third country or territory;

(b) whether the animals, germinal products or products of animal origin specified in accordance with point (a) may enter the Union from the whole territory of that third country or territory or only from one or more zones or compartments thereof;

(c) specific conditions and animal health guarantees concerning listed diseases.

Article 232

Suspension and withdrawal from the lists of third countries and territories and implementing acts

1. The Commission shall, by means of implementing acts, withdraw a country or territory from the lists provided for in Article 230(1), or suspend the entry into the Union of animals, germinal products or products of animal origin from a third country or territory, or from a zone or compartment thereof, for any of the following reasons:

(a) the third country or territory concerned, or one or more zones or compartments thereof, no longer complies with the criteria laid down in Article 230(1), where relevant for the entry into the Union of a particular species and category of animal, germinal product or product of animal origin;

(b) the animal health situation in the third country or territory concerned, or in a zone or compartment thereof, is such that a suspension or withdrawal from the lists is necessary in order to protect the animal health status of the Union;

(c) the Commission has requested the third country or territory concerned to supply up-to–date information on the animal health situation and other matters referred to in Article 230(1), and that third country or territory has not provided such information;

(d) the third country or territory concerned has refused to agree to controls being carried out by the Commission on behalf of the Union in its territory.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

2. On duly justified imperative grounds of urgency relating to a serious risk of the introduction into the Union of a listed disease as referred to in point (d) of Article 9(1), the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

3. The Commission may, by means of implementing acts, reinstate in the lists provided for in Article 230(1) a third country or territory, or a zone or compartment thereof, that has been withdrawn from those lists, or may re–authorise the entry into the Union of animals, germinal products or products of animal origin from a third country or territory, or from a zone or compartment thereof, from which entry into the Union has been suspended, for one of the following reasons:

(a) for the reasons referred to in point (a) or (c) of paragraph 1 of this Article, provided that the third country or territory concerned demonstrates that it complies with the listing criteria provided for in Article 230(1);

(b) for the reason referred to in point (b) of paragraph 1 of this Article, provided that the third country or territory concerned provides appropriate guarantees that the animal health situation that gave rise to the suspension or withdrawal has been resolved or no longer represents a threat to animal or public health within the Union;

(c) for the reason referred to in point (d) of paragraph 1 of this Article, provided that:

(i) the third country or territory concerned has agreed to controls being carried out by the Commission on behalf of the Union in its territory; and

(ii) the results of those controls by the Commission show that the third country or territory concerned, and the zones or compartments thereof, comply with the listing criteria provided for in Article 230(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Section 3

Approval and listing of establishments in third countries and territories

Article 233

Approval and listing of establishments

1. Member States shall only permit the entry into the Union of terrestrial animals and germinal products thereof originating from an establishment of a type for which approval is required in the Union in accordance with Article 94(2) and the rules adopted pursuant to Article 94(3) and Article 95, if the establishment in question in the third country or territory concerned:

(a) complies with animal health requirements in that third country or territory which are equivalent to the rules for establishments of that type applicable in the Union;

(b) is approved and listed by the competent authority of the third country or territory of dispatch, unless alternative risk-mitigation measures in place in that third country or territory provide equivalent guarantees for animal health within the Union.

2. The Commission shall collect the lists of approved establishments referred to in point (b) of paragraph 1 received from the competent authorities of the third countries or territories concerned.

3. The Commission shall provide to the Member States any new or updated lists of approved establishments received from the third countries or territories concerned, and shall make them publicly available.

4. The Commission shall, by means of implementing acts, adopt any rules necessary in order to ensure uniform application of point (b) of paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Section 4

Entry into the Union of species and categories of animals, germinal products and products of animal origin

Article 234

Animal health requirements for the entry into the Union of species and categories of animals, germinal products and products of animal origin

1. The animal health requirements for the entry into the Union of species and categories of animals, germinal products and products of animal origin from third countries or territories shall:

(a) be as stringent as the animal health requirements laid down in this Regulation and in the rules adopted pursuant thereto applicable to movements of the species and categories of animals, germinal products or products of animal origin in question within the Union; or

(b) offer equivalent guarantees to the animal health requirements applicable to the species and categories of animals, germinal products or products of animal origin provided for in Part IV (Articles 84 to 228) of this Regulation.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning the animal health requirements for:

(a) the entry into the Union of species and categories of animals, germinal products and products of animal origin from third countries or territories;

(b) the movement within the Union and handling of those animals, germinal products and products of animal origin after their entry into the Union, where this is necessary in order to mitigate the risk involved.

3. Pending the adoption of delegated acts laying down animal health requirements as regards a particular species and category of animal, germinal product or product of animal origin provided for in paragraph 1 of this Article, Members State may, following an evaluation of the risks involved, apply national rules, provided that those rules comply with the requirements laid down in that paragraph and provided that they take into account the matters referred to in Articles 235 and 236.

Article 235

Matters to be taken into account in delegated acts provided for in Article 234 with regard to the entry into the Union of animals

The Commission shall take the following matters into account when laying down, in delegated acts as provided for in Article 234(2), animal health requirements for the entry into the Union of particular species and categories of animals:

(a) the listed diseases referred to in point (d) of Article 9(1) and emerging diseases;

(b) the health status of the Union concerning the listed diseases referred to in point (d) of Article 9(1) and emerging diseases;

(c) the listed species with regard to those listed diseases referred to in point (d) of Article 9(1) and emerging diseases;

(d) the age and sex of the animals concerned;

(e) the origin of the animals concerned;

(f) the type of establishment concerned and the type of production at the places of origin and of destination;

(g) the intended place of destination;

(h) the intended use of the animals concerned;

(i) any risk-mitigation measures in place in the third countries or territories of origin or transit, or after the arrival of the animals concerned into the territory of the Union;

(j) animal health requirements applicable to movements of those animals within the Union;

(k) other epidemiological factors;

(l) international animal health trade standards, relevant to the species and categories of those animals.

Article 236

Matters to be taken into account in delegated acts as provided for in Article 234 with regard to the entry into the Union of germinal products and products of animal origin

The Commission shall take the following matters into account when laying down, in delegated acts as provided for in Article 234(2), the animal health requirements for the entry into the Union of germinal products and products of animal origin:

(a) the listed diseases referred to in point (d) of Article 9(1) and emerging diseases;

(b) the health status of the animals from which the germinal products or products of animal origin originate and of the Union concerning the listed diseases referred to in point (d) of Article 9(1) and emerging diseases;

(c) the type and nature of particular germinal products or products of animal origin, treatments, processing methods and other risk-mitigation measures that have been applied at the places of origin, dispatch of consignment or destination;

(d) the type of establishment and the type of production at the places of origin and of destination;

(e) the intended place of destination;

(f) the intended use of the germinal products or products of animal origin concerned;

(g) animal health requirements applicable to movements of the germinal products and products of animal origin concerned within the Union;

(h) other epidemiological factors;

(i) international animal health trade standards, relevant for the germinal products and products of animal origin in question.

Section 5

Animal health certificates, declarations and other documents

Article 237

Animal health certificates, declarations and other documents for entry into the Union

1. Member States shall only permit the entry into the Union of consignments of animals, germinal products and products of animal origin if such consignments are accompanied by one or both of the following:

(a) an animal health certificate issued by the competent authority of the third country or territory of origin, unless a derogation is provided for in point (a) of paragraph 4;

(b) declarations or other documents, where required by the rules adopted pursuant to point (b) of paragraph 4.

2. Member States shall not permit the entry into the Union of consignments of animals, germinal products and products of animal origin unless the animal health certificate referred to in point (a) of paragraph 1 has been verified and signed by an official veterinarian in a third country or territory in compliance with certification requirements equivalent to those laid down in Article 149(3) or 216(3) and any rules adopted pursuant to Article 149(4) or 216(4).

3. Member States shall permit electronic animal health certificates that are produced, handled and transmitted by means of Traces to replace the accompanying animal health certificates referred to in paragraph 1, where such electronic animal health certificates:

(a) contain all the information that the animal health certificate referred to in point (a) of paragraph 1 of this Article is required to contain in accordance with Article 238(1) and any rules adopted pursuant to Article 238(3);

(b) ensure the traceability of the consignments of animals, germinal products and products of animal origin concerned and link those consignments to the electronic animal health certificate.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) derogations from the animal health certificate requirements provided for in point (a) of paragraph 1 and paragraph 2 of this Article, for consignments of animals, germinal products and products of animal origin, and in specific rules for the animal health certification of those consignments, where the consignments in question pose an insignificant risk to animal health or public health within the Union, due to one or more of the following factors:

(i) the species and categories of animals, germinal products or products of animal origin concerned;

(ii) the methods of keeping and types of production of the animals, germinal products and products of animal origin concerned;

(iii) their intended use;

(iv) alternative risk-mitigation measures which are in place in the third countries or territories of origin or transit, or after their arrival into the territory of the Union, affording equivalent protection of animal health and public health within the Union as provided for in this Regulation;

(v) the provision by the third country or territory concerned of guarantees of compliance with the requirements for entry into the Union, demonstrated by means other than an animal health certificate;

(b) rules requiring consignments of animals, germinal products and products of animal origin entering into the Union to be accompanied by declarations or other documents needed to demonstrate that the animals, germinal products and products of animal origin in question meet the animal health requirements for entry into the Union laid down in rules adopted pursuant to Article 234(2).

Article 238

Content of animal health certificates

1. The animal health certificate referred to in point (a) of Article 237(1) shall contain at least the following information:

(a) the name and address of:

(i) the establishment or place of origin;

(ii) the establishment or place of destination;

(iii) where applicable, establishments for assembly operations or rest of the kept animals concerned;

(b) a description of the animals, germinal products or products of animal origin concerned;

(c) the number or volume of the animals, germinal products or products of animal origin concerned;

(d) where applicable, the identification and registration of the animals, germinal products or products of animal origin concerned;

(e) the information needed to demonstrate that the animals, germinal products and products of animal origin concerned fulfil the animal health requirements for entry into the Union provided for in Article 229 and Article 234(1) and in the rules adopted pursuant to Article 234(2) and Article 239.

2. The animal health certificate referred to in point (a) of Article 237(1) may include other information required under other Union legislation.

3. The Commission may, by means of implementing acts, lay down rules concerning:

(a) information to be contained in the animal health certificate referred to in point (a) of Article 237(1) in addition to that referred to in paragraph 1 of this Article;

(b) information to be contained in declarations or other documents as referred to in point (b) of Article 237(1);

(c) model forms for the animal health certificates, declarations and other documents referred to in Article 237(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4. Pending the establishment of rules in implementing acts adopted pursuant to paragraph 3, as regards a particular species and category of animal, germinal product or product of animal origin, Member States may, following an evaluation of the risks involved, apply national rules, provided those national rules comply with the conditions laid down in paragraph 1.

Section 6

Derogations and additional requirements in respect of certain categories of animals, germinal products and products of animal origin

Article 239

Derogations and additional requirements in respect of certain categories of animals, germinal products and products of animal origin

1. For certain specific types of entry of animals, germinal products and products of animal origin, the application of the rules set out in Article 229(1) and Articles 233 and 237 may not be adequate, and special rules may need to be adopted by the Commission through delegated acts which take into account the particular risks, the final destination, the type of final use and other circumstances.

2. The Commission shall adopt delegated acts in accordance with Article 264 concerning the special rules referred to in paragraph 1 of this Article regarding derogations from the requirements provided for in Article 229(1) and Articles 233 and 237 and imposing additional requirements for the entry into the Union of the following:

(a) animals:

(i) intended for circuses, events, exhibitions, display, shows and confined establishments;

(ii) intended to be used for scientific or diagnostic purposes;

(iii) for which the Union is not the final destination;

(iv) which originate in the Union and which are moved to a third country or territory, and are then moved back to the Union from that third country or territory;

(v) which originate in the Union and which are transported through a third country or territory en route to another part of the Union;

(vi) which are intended for grazing purposes on a temporary basis, in the vicinity of the Union's borders;

(vii) which pose an insignificant risk to the animal health status within the Union;

(b) products of animal origin:

(i) intended for personal use;

(ii) for consumption by the crew and passengers on means of transport arriving from third countries or territories;

(c) germinal products and products of animal origin:

(i) intended to be used as trade samples;

(ii) intended to be used as research and diagnostic samples;

(iii) for which the Union is not the final destination;

(iv) which originate in the Union and are moved to a third country or territory, and are then moved back to the Union from that third country or territory;

(v) which originate in the Union and are transported through a third country or territory en route to another part of the Union;

(vi) which pose an insignificant risk to the animal health status within the Union.

Those delegated acts shall take into account the matters referred to in Article 235 and 236.

3. The Commission may, by means of implementing acts, lay down rules:

(a) concerning model forms for the animal health certificates, declarations and other documents for the categories of animals, germinal products and products of animal origin referred to in paragraph 2 of this Article;

(b) indicating, for the products referred to in paragraph 1 of this Article, the codes from the Combined Nomenclature, where such codes are not provided for by other relevant Union rules.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 2

Entry into the Union of certain goods other than animals, germinal products and products of animal origin from third countries and territories

Article 240

Disease agents and delegated acts

1. Operators, veterinarians, aquatic animal health professionals and animal professionals bringing disease agents into the Union shall:

(a) take appropriate measures to ensure that the entry of those disease agents into the Union does not pose a risk to animal health or public health within the Union with regard to listed diseases referred to in point (d) of Article 9(1) and emerging diseases;

(b) take appropriate disease control and preventive measures to ensure that the entry of those disease agents into the Union does not present a risk of bioterrorism.

This paragraph shall also apply to any other natural or legal person bringing such agents into the Union intentionally.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 laying down requirements for the entry into the Union of disease agents concerning:

(a) the packaging of disease agents;

(b) other risk-mitigation measures required in order to prevent the release and spread of disease agents.

Article 241

Plant material and delegated and implementing acts

1. The Member States shall take measures to restrict the entry into the Union of consignments of plant material in the event of an unfavourable disease situation in third countries or territories concerning listed diseases as referred to in point (d) of Article 9(1) or emerging diseases, where this is required by the rules adopted in accordance with paragraph 3 of this Article.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the measures referred to in paragraph 1 of this Article, setting out:

(a) specific animal health requirements for the entry into the Union of plant material which acts as a path of transmission of listed or emerging diseases;

(b) requirements in relation to:

(i) animal health certification, taking into account the rules provided for in point (a) of Article 237(1) and Article 237(2) and (3); or

(ii) declarations or other documents, taking into account the rules provided for in point (b) of Article 237(1).

3. The Commission shall lay down the animal health requirements provided for in paragraph 2 on the basis of the following criteria:

(a) whether a listed or emerging disease that can be transmitted by means of plant material represents a serious risk to animal or to human health in the Union;

(b) the likelihood that animals of listed species for a particular listed disease or emerging disease will come into direct or indirect contact with the plant material referred to in paragraph 2;

(c) the availability and effectiveness of alternative risk-mitigation measures in relation to that plant material, which may eliminate or minimise the risk of transmission referred to in point (a).

4. The Commission may, by means of implementing acts, lay down rules indicating, for the plant material referred to in paragraph 2 of this Article, the codes from the Combined Nomenclature, where such indication is not provided for by other relevant Union rules.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 242

Means of transport, equipment, packaging materials, transport water and feed and fodder and delegated and implementing acts

1. Operators bringing animals and products into the Union shall take the appropriate and necessary disease prevention measures during transport, as provided for in Articles 125(1) and 192(1).

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) specific animal health requirements for the entry into the Union of:

(i) means of transport for animals and products;

(ii) equipment, packaging material or transport water for animals and products, or feed and fodder which may transmit animal diseases;

(b) requirements in relation to:

(i) animal health certification, taking into account the rules provided for in point (a) of Article 237(1) and Article 237(2) and (3); or

(ii) declarations or other documents, taking into account the rules provided for in point (b) of Article 237(1).

3. The Commission shall lay down the animal health requirements provided for in paragraph 2 of this Article in the event of a unfavourable disease situation concerning one or more listed diseases as referred to in point (d) of Article 9(1), or emerging diseases, which present a serious risk to animal and human health in the Union, in:

(a) a neighbouring third country or territory;

(b) the third country or territory of origin;

(c) a third country or territory of transit.

4. The Commission may, by means of implementing acts, lay down rules indicating, for the goods referred to in point (a) of paragraph 2 of this Article, the codes from the Combined Nomenclature, where such indication is not provided for by other relevant Union rules.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 3

Export

Article 243

Export from the Union

1. Member States shall take the appropriate measures to ensure that the export and re–export from the Union to a third country or territory of animals and products takes place in accordance with the rules for the movement of animals and products between Member States provided for in Part IV (Articles 84 to 228), while taking into account the animal health status within the third country or territory of destination, or the relevant zone or compartment thereof, with regard to the listed diseases referred to in point (d) of Article 9(1) and emerging diseases.

2. By way of derogation from paragraph 1, if so requested by the competent authority of a third country or territory importing the animals and products in question, or if established by the legal and administrative procedures in force in that third country or territory, export and re–export from the Union may take place in accordance with the provisions in force in that third country or territory, provided that such exports or re-exports do not jeopardise public or animal health.

3. Where the provisions of a bilateral agreement concluded between the Union and a third country or territory are applicable, animals and products exported from the Union to that third country or territory shall comply with those provisions.

PART VI

NON–COMMERCIAL MOVEMENTS OF PET ANIMALS INTO A MEMBER STATE FROM ANOTHER MEMBER STATE OR FROM A THIRD COUNTRY OR TERRITORY

CHAPTER 1

General provisions

Article 244

Scope of Part VI

1. This Part shall apply to the non–commercial movement of pet animals into a Member State from another Member State or from a third country or territory.

2. It shall apply without prejudice to:

(a) Council Regulation (EC) No 338/97 ([1]);

(b) any national measures adopted, published and made available to the public by Member States to restrict the movement of certain species or breeds of pet animals on the basis of considerations other than those relating to animal health.

Article 245

General provisions

1. Non–commercial movements of pet animals that fulfil the animal health requirements laid down in this Part shall not be prohibited, restricted or impeded on animal health grounds other than those resulting from the application of this Part.

([1]) Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 61, 3.3.1997, p. 1).

2. Where the non–commercial movement of a pet animal is carried out by an authorised person, it may only take place within five days from the movement of the pet owner.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning requirements supplementing the rules laid down in paragraph 2 of this Article in relation to the following:

(a) documentation of the non–commercial movement of a pet animal carried out by an authorised person;

(b) granting of derogations from the period referred to in paragraph 2 of this Article.

4. The Commission may, by means of implementing acts, lay down requirements for the layout, languages and validity of the declaration authorising an authorised person in writing to carry out the non–commercial movement of a pet animal on behalf of the pet owner. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 246

Maximum number of pet animals

1. The number of pet animals of the species listed in Part A of Annex I which may be moved during a single non–commercial movement shall not exceed five.

2. By way of derogation from paragraph 1, the number of pet animals of the species listed in part A of Annex I may exceed five if the following conditions are fulfilled:

(a) the non–commercial movement in question is for the purpose of participating in a competition, exhibition or sporting event or training for such an event;

(b) the pet owner or the authorised person concerned submits written evidence that the pet animals are registered either to attend an event as referred to in point (a), or with an association organising such events;

(c) the pet animals are more than six months old.

3. In order to prevent commercial movements of pet animals of the species listed in Part B of Annex I from being fraudulently disguised as non–commercial movements, the Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules setting the maximum number of pet animals of those species which may be moved during a single non–commercial movement.

CHAPTER 2

Conditions applicable to non–commercial movements of pet animals into a Member State from another Member State

Article 247

Conditions applicable to non–commercial movements of pet animals of the species listed in Part A of Annex I

Pet animals of the species listed in Part A of Annex I shall not be moved into a Member State from another Member State unless:

(a) they are individually identified by a physical means of identification in accordance with the rules adopted pursuant to point (a) of Article 252(1);

(b) they fulfil the relevant prevention and risk-mitigation measures adopted pursuant to point (b) of Article 252(1) in relation to listed diseases as referred to in point (d) of Article 9(1);

(c) they are accompanied by an identification document duly completed and issued in accordance with the rules adopted pursuant to point (d) of Article 254.

Article 248

Conditions applicable to non–commercial movements of pet animals of the species listed in Part B of Annex I

1. In so far as the Commission has adopted a delegated act pursuant to point (b) of Article 252(1) with regard to pet animals of one of the species listed in Part B of Annex I, non-commercial movements of pet animals of that species into a Member State from another Member State shall be subject to compliance with the conditions laid down in paragraph 2 of this Article.

2. Pet animals of the species referred to in paragraph 1 may be moved into a Member State from another Member State only if:

(a) they are identified or described, either individually or in groups, in accordance with the rules adopted pursuant to point (a) of Article 252(1);

(b) they comply with the relevant prevention and risk-mitigation measures adopted pursuant to point (b) of Article 252(1) in relation to listed diseases as referred to in point (d) of Article 9(1);

(c) they are accompanied by an identification document duly completed and issued in accordance with the rules adopted pursuant to point (d) of Article 254;

3. Pending the adoption of the relevant delegated acts referred to in paragraph 1, Member States may apply national rules to non–commercial movements of pet animals of the species listed in Part B of Annex I into their territory from another Member State, provided that such rules are:

(a) applied proportionately to the risk to public or animal health associated with non–commercial movements of pet animals of those species; and

(b) not stricter than those applied to movements of animals of those species in accordance with Part IV.

CHAPTER 3

Conditions applicable to non–commercial movements of pet animals into a Member State from a third country or territory

Article 249

Conditions applicable to non–commercial movements of pet animals of the species listed in Part A of Annex I

1. Pet animals of the species listed in Part A of Annex I shall not be moved into a Member State from a third country or territory unless:

(a) they are individually identified by a physical means of identification in accordance with the rules adopted pursuant to point (a) of Article 252(1);

(b) they comply with the relevant prevention and risk-mitigation measures adopted pursuant to point (b) of Article 252(1) in respect of listed diseases as referred to in point (d) of Article 9(1);

(c) they are accompanied by an identification document duly completed and issued in accordance with the rules adopted pursuant to point (d) of Article 254.

2. Pet animals of the species listed in Part A of Annex I may be moved into a Member State from a third country or territory other than those listed pursuant to Article 253(1)(d) only through a point of entry listed for that purpose. Each Member State shall draw up a list of those points of entry within its territory and shall make that list available to the public.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the conditions for granting derogations from paragraph 2 of this Article.

Article 250

Conditions applicable to non–commercial movements of pet animals of the species listed in Part B of Annex I

1. In so far as the Commission has adopted a delegated act pursuant to point (b) of Article 252(1) with regard to pet animals of one of the species listed in Part B of Annex I, non–commercial movements of pet animals of that species into a Member State from a third country or territory shall be subject to compliance with the conditions laid down in paragraph 2 of this Article.

2. Pet animals of the species referred to in paragraph 1 may be moved into a Member State from a third country or territory only if:

(a) they are identified or described, either individually or in groups, in accordance with the rules adopted pursuant to point (a) of Article 252(1);

(b) they comply with the relevant prevention and risk-mitigation measures adopted pursuant to point (b) of Article 252(1) in relation to listed diseases as referred to in point (d) of Article 9(1);

(c) they are accompanied by an identification document duly completed and issued in accordance with the rules adopted pursuant to point (d) of Article 254;

(d) when coming from a third country or territory other than those listed pursuant to point (d) of Article 253(1), they enter through a point of entry listed for that purpose. Each Member State shall draw up a list of those points of entry within its territory and shall make that list available to the public.

3. Pending the adoption of the relevant delegated acts referred to in paragraph 1, Member States may apply national rules to non–commercial movements of pet animals of the species listed in Part B of Annex I into their territory from a third country or territory, provided that such rules are:

(a) applied proportionately to the risk to public or animal health associated with non–commercial movements of pet animals of those species; and

(b) not stricter than those applied to the entry into the Union of animals of those species in accordance with Part V.

Article 251

Derogation from the conditions applicable to non–commercial movements of pet animals between certain countries and territories

By way of derogation from Articles 249 and 250, non–commercial movements of pet animals between the following countries and territories may continue under the conditions laid down by the national rules of those countries and territories:

(a) San Marino and Italy;

(b) the Vatican and Italy;

(c) Monaco and France;

(d) Andorra and France;

(e) Andorra and Spain;

(f) Norway and Sweden;

(g) the Faeroe Islands and Denmark;

(h) Greenland and Denmark.

CHAPTER 4

Identification and prevention and risk-mitigation measures

Article 252

Delegation of powers concerning the identification of pet animals and prevention and risk-mitigation measures

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) detailed species–specific requirements for:

(i) the means of identification of pet animals of the species listed in Annex I provided for in point (a) of Article 247, point (a) of Article 248(2), point (a) of Article 249(1) and point (a) of Article 250(2);

(ii) the application and use of those means of identification;

(b) detailed species–specific requirements for the prevention and risk-mitigation measures to ensure that pet animals do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) due to movements of pet animals of the species listed in Annex I as provided for in point (b) of Article 247, point (b) of Article 248(2), point (b) of Article 249(1) and point (b) of Article 250(2).

2. Where, in the case of emerging risks, imperative grounds of urgency so require, the procedure provided for in Article 265 shall apply to rules adopted pursuant to point (b) of paragraph 1 of this Article.

3. The species–specific prevention and risk-mitigation measures authorised by a delegated act adopted pursuant to point (b) of paragraph 1 of this Article shall be based on adequate, reliable and validated scientific information and applied proportionately to the risk to public or animal health associated with non–commercial movements of pet animals likely to be affected by listed diseases as referred to in point (d) of Article 9(1).

4. The delegated acts provided for in point (b) of paragraph 1 may also comprise the following:

(a) rules for the categorisation of Member States or parts thereof according to their animal health status and their surveillance and reporting systems with regard to certain diseases that are likely to be spread by movements of pet animals of the species listed in Annex I;

(b) the conditions that Member States are to fulfil in order to remain eligible for the application of the prevention and risk-mitigation measures referred to in point (b) of paragraph 1;

(c) the conditions for applying and documenting the prevention and risk-mitigation measures referred to in point (b) of paragraph 1;

(d) the criteria for granting and, where appropriate, documenting derogations in certain specified circumstances from the application of the prevention and risk-mitigation measures referred to in point (b) of paragraph 1;

(e) the criteria for granting and documenting derogations in certain specified circumstances from the conditions referred to in Articles 247 to 250.

Article 253

Implementing acts concerning prevention and risk-mitigation measures

1. The Commission shall, by means of implementing acts, as regards pet animals of the species listed in Part A of Annex I:

(a) lay down rules on the format, layout and languages of any documents required under points (c) and (d) of Article 252(4);

(b) adopt a list of Member States that comply with the conditions referred to in point (d) of Article 252(4) and remove Member States from that list should any change occur in relation to those conditions;

(c) adopt a list of Member States that comply with the rules for categorisation of Member States or parts thereof referred to in point (a) of Article 252(4) and remove Member States from that list should any change occur in relation to those rules;

(d) adopt a list of third countries and territories that comply with the conditions referred to in point (d) of Article 252(4) and remove third countries or territories from that list should any change occur in relation to those conditions.

2. The Commission may, by means of implementing acts, as regards pet animals of the species listed in Part B of Annex I, adopt a list of third countries and territories that comply with the conditions referred to in point (d) of Article 252(4) and remove third countries or territories from that list should any change occur in relation to those conditions.

3. The implementing acts referred to in paragraphs 1 and 2 of this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4. On duly justified imperative grounds of urgency relating to serious risks, the Commission shall adopt immediately applicable implementing acts updating the lists referred to in points (b) and (d) of paragraph 1 of this Article in accordance with the procedure referred to in Article 266(3).

CHAPTER 5

Identification documents

Article 254

Delegation of powers concerning identification documents

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

(a) entries for the insertion of the information to be included in the identification documents referred to in point (c) of Article 247, point (c) of Article 248(2), point (c) of Article 249(1) and point (c) of Article 250(2);

(b) the distribution of blank identification documents as referred to in point (c) of Article 247;

(c) the conditions for granting derogations in relation to the format of the identification documents provided for in point (c) of Article 247 and point (c) of Article 249(1);

(d) the issue, completion and, where applicable, endorsement of the identification documents provided for in point (c) of Articles 247, point (c) of Article 248(2), point (c) of Article 249(1) and point (c) of Article 250(2).

Article 255

Implementing acts concerning identification documents

1. The Commission shall adopt implementing acts laying down the model for identification documents as referred to in point (c) of Article 247 and point (c) of Article 249(1). That model shall contain the respective entries referred to in point (a) of Article 254, as well as requirements concerning the languages, layout, validity or security features of those identification documents.

2. The Commission may, by means of implementing acts, adopt:

(a) the model for identification documents as referred to in point (c) of Article 248(2) and point (c) of Article 250(2), which are to contain the respective entries referred to in point (a) of Article 254, as well as requirements concerning the languages, layout, validity or security features of those identification documents;

(b) the rules necessary for transition to the model identification document referred to in point (c) of Article 247.

3. The implementing acts referred to in paragraphs 1 and 2 of this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 6

Information obligations

Article 256

Information obligations

1. Member States shall provide the public with clear and easily accessible information concerning the animal health requirements applicable to non–commercial movements of pet animals, including:

(a) conditions for the grant of certain derogations referred to in point (d) of Article 252(4);

(b) conditions for the grant of derogations referred to in point (e) of Article 252(4);

(c) requirements for the application of the means of identification referred to in point (a)(ii) of Article 252(1);

(d) conditions applicable to non–commercial movements into Member States' territories of pet animals of the species referred to in Part B of Annex I, which are laid down by their national rules as provided for in Articles 248(3) and 250(3);

(e) conditions applicable to non–commercial movements into Member States' territories of pet animals from certain countries and territories laid down by their national rules as referred to in Article 251;

(f) any relevant information concerning certain prevention and risk-mitigation measures as referred to in point (b) of Article 252(1).

2. Member States shall establish internet–based information pages providing the information referred to in paragraph 1, and shall communicate the internet address of those pages to the Commission.

3. The Commission shall assist the Member States in making that information available to the public by providing on its internet page:

(a) links to the internet–based information pages of the Member States;

(b) the information referred to in points (a) and (d) of paragraph 1, and the information made available to the public as referred to in point (b) of Article 244(2) in additional languages, as appropriate.

PART VII

EMERGENCY MEASURES

Section 1

Emergency measures concerning movements of animals and products within the Union and means of transport and other material that may have come into contact with such animals and products

Article 257

Emergency measures to be taken by the competent authority of the Member State in the territory of which an outbreak of a listed disease or emerging disease, or a hazard occurred

1. In the event of an outbreak of a listed disease or emerging disease, or the occurrence of a hazard which is likely to constitute a serious risk to animal or public health, the competent authority of the Member State where it occurred shall, depending on the gravity of the situation and the disease or hazard in question, immediately take one or more of the following emergency measures to prevent the spread of the disease or hazard:

(a) for listed diseases:

(i) referred to in point (a) of Article 9(1), the disease control measures laid down in Chapter 1 of Title II of Part III (Articles 53 to 71);

(ii) referred to in point (b) of Article 9(1), the disease control measures laid down in Articles 72 to 75 and 77 to 81 of Chapter 2 of Title II of Part III;

(iii) referred to in point (c) of Article 9(1), the disease control measures laid down in Articles 76 to 78 and Articles 80 and 82 of Chapter 2 of Title II of Part III;

(b) for emerging diseases and hazards:

(i) restrictions on the movement of animals and products originating from the establishments, or, where relevant, the restricted zones or compartments, where the outbreak or the hazard occurred, and on means of transport and other material that may have come into contact with those animals or products;

(ii) quarantine of animals and isolation of products;

(iii) surveillance and traceability measures;

(iv) any emergency disease control measures provided for in Chapter 1 of Title II of Part III (Articles 53 to 71) that are appropriate;

(c) any other emergency measure which it deems appropriate in order to effectively and efficiently control and prevent the spread of the disease or hazard.

2. The competent authority referred to in paragraph 1 shall inform the Commission and the other Member States:

(a) immediately of any outbreak or the occurrence of a hazard as referred to in paragraph 1;

(b) without delay of the emergency measures taken pursuant to paragraph 1.

Article 258

Emergency measures to be taken by a Member State other than the Member State where the outbreak or hazard occurred

1. The competent authority of a Member State other than the Member State where the outbreak or hazard referred to in Article 257(1) occurred shall, depending on the gravity of the situation and the disease or hazard in question, take one or more of the emergency measures referred to in Article 257(1) where it detects on its territory animals or products from the Member State referred to in Article 257(1) or means of transport or any other material that may have come into contact with such animals and products.

2. The competent authority referred to in paragraph 1 of this Article may, where a serious risk exists pending the adoption of emergency measures by the Commission in accordance with Article 259, take the emergency measures referred to in Article 257(1) on an interim basis, depending on the gravity of the situation with regard to animals or products originating from the establishments or other locations, or where relevant from the restricted zones of the Member State, where the disease or hazard referred to in Article 257(1) occurred, or means of transport or other material that may have come into contact with such animals.

3. A Member State may take measures as referred to in Article 257(1) in the event of an outbreak in a third country or territory bordering the Union of a disease referred to in point (a) of Article 9(1) or an emerging disease in such a third country or territory, in so far as those measures are necessary in order to prevent the spread of the disease into the territory of the Union.

4. The competent authority referred to in paragraph 1 and the competent authority of the Member State referred to in paragraph 3 shall inform the Commission and other Member States:

(a) immediately of the outbreak or occurrence of a hazard referred to in paragraph 1;

(b) without delay of the emergency measures taken pursuant to paragraphs 1 and 2.

Article 259

Commission emergency measures

1. In the event of an outbreak or the occurrence of a hazard as referred to in Article 257(1), and of emergency measures taken by the competent authorities of the Member States in accordance with Article 257(1) and Article 258(1), (2) and (3), the Commission shall review the situation and the emergency measures taken, and shall adopt, by means of an implementing act, one or more of the emergency measures provided for in Article 257(1) concerning the animals and products in question and means of transport and other material that may have come into contact with those animals or products, in any of the following cases:

(a) where the Commission has not been informed of any measures taken pursuant to Article 257(1) and Article 258(1), (2) and (3);

(b) where the Commission considers the measures taken pursuant to Article 257(1) and Article 258(1), (2) and (3) to be inadequate;

(c) where the Commission considers it necessary to approve or replace the measures taken by the competent authorities of the Member States pursuant to Article 257(1) and Article 258(1), (2) and (3) in order to avoid unjustified disruptions in the movement of animals and products.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

2. On duly justified imperative grounds of urgency relating to serious risks of the spread of a disease or a hazard, the Commission may adopt immediately applicable implementing acts in accordance with Article 266(3).

Section 2

Emergency measures concerning consignments of animals and products originating from third countries and territories, and means of transport and other material, that may have come into contact with such consignments

Article 260

Emergency measures to be taken by the competent authority

Where the competent authority of a Member State becomes aware of animals or products originating from a third country or territory, or of means of transport or materials, which may have come into contact with such animals and products, that are likely to constitute a serious risk in the Union due to possible infection or contamination by listed diseases or emerging diseases or hazards, it shall:

(a) immediately take one or more of the following emergency measures necessary to mitigate that risk, depending on the gravity of the situation:

  (i) destruction of the animals and products concerned;

  (ii) quarantine of animals and isolation of products;

  (iii) surveillance and traceability measures;

  (iv) any disease control measures referred to in Chapter 1 of Title II of Part III (Articles 53 to 71), where appropriate;

  (v) any other emergency measure which it deems appropriate to prevent the spread of the disease or hazard into the Union;

(b) immediately inform the Commission and the other Member States of the risks associated with the animals and products in question and of the origin of those animals and products by means of Traces, and without delay of the emergency measures taken pursuant to point (a).

Article 261

Commission emergency measures

1. Where a listed disease, an emerging disease or a hazard that is likely to constitute a serious risk occurs or spreads in a third country or territory, or if any other serious animal or public health reason so warrants, the Commission may, by means of an implementing act and acting on its own initiative or at the request of a Member State, adopt one or more of the following emergency measures, depending on the gravity of the situation:

(a) suspend the entry into the Union of consignments of animals and products, and means of transport or other material, that may have come into contact with such consignments, which may spread that disease or hazard into the Union;

(b) establish special requirements for the entry into the Union of animals and products, and of means of transport and other material that may have come into contact with such animals and products, which may spread that disease or hazard into the Union;

(c) take any other appropriate emergency disease control measures to prevent the spread of such disease or hazard into the Union.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

2. On duly justified imperative grounds of urgency relating to serious risks, the Commission shall, after consulting the Member State concerned, adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

Article 262

Emergency measures to be taken by Member States when the Commission does not act

1. Where a Member State has requested the Commission to take emergency measures in accordance with Article 261 and the Commission has not done so, that Member State:

(a) may, pending the adoption of emergency measures by the Commission in accordance with paragraph 2 of this Article, take one or more of the emergency measures referred to in point (a) of Article 260 on an interim basis in respect of animals and products, and any means of transport and other material that may have come into contact with such animals and products, originating from the third country or territory referred to in Article 261(1), depending on the gravity of the situation within its territory;

(b) shall inform the Commission and the competent authorities of the other Member States of such emergency measures without delay, giving the reason for their adoption.

2. The Commission shall review the situation and the emergency measures taken by the Member State concerned in accordance with paragraph 1 of this Article and shall, where necessary, adopt by means of an implementing act one or more of the emergency measures provided for in Article 261.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

3. On duly justified imperative grounds of urgency relating to serious risks, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

PART VIII

COMMON PROVISIONS

TITLE I

PROCEDURAL PROVISIONS

Article 263

Amendments to Annex III

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning amendments to Annex III, limited exclusively to taking into account changes in taxonomy.

Article 264

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. It is of particular importance that the Commission carry out consultations with experts, including Member States' experts, before adopting those delegated acts.

3. The power to adopt delegated acts referred to in Articles 3(5), 5(2) 5(4), 14(3), 16(2), 18(3), 20(3), 29, 31(5), 32(2), 37(5), 39, 41(3), 42(6), 47, 48(3), 53(2), 54(3), 55(2), 58(2), 63, 64(4), 67, 68(2), 68(3), 70(3), 72(2), 73(3), 74(4), 76(5), 77(2), 87(3), 94(3), 97(2), 101(3), 106(1), 109(2), 118, 119, 122(1), 122(2), 125(2), 131(1), 132(2), 135, 136(2), 137(2), 138(3), 139(4), 140, 144(1), 146(1), 147, 149(4), 151(3), 154(1), 156(1), 160(1), 160(2), 161(6), 162(4), 163(5), 164(2), 165(3), 166(3), 167(5), 168(3), 169(5), 176(4), 181(2), 185(5), 189(1), 192(2), 197(3), 200(3), 201(3), 202(3), 203(2), 204(3), 205(2), 211(1), 213(1), 214, 216(4), 218(3), 221(1), 222(3), 223(6), 224(3), 228(1), 230(3), 234(2), 237(4), 239(2), 240(2), 241(2), 242(2), 245(3), 246(3), 249(3), 252(1), 254, 263, 271(2), 272(2), 279(2), and 280(4) shall be conferred on the Commission for a period of five years from 20 April 2016.

The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

4. The delegation of power referred to in paragraph 3 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to the provisions listed in paragraph 3 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

7. The Commission shall allow a period of at least six months to elapse between the adoption of the respective initial delegated acts referred to in Articles 3(5), 14(3), 16(2), 20(3), 122(2), 164(2) and 228(1) and the date on which they start to apply.

Article 265

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 264(6). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council.

Article 266

Committee procedure

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

4. The Commission shall allow a period of at least six months to elapse between the adoption of the respective initial implementing acts referred to in Articles 25(3), 120, and 228(2), when those implementing acts relate to the implementation of Article 117, and the date on which they start to apply.

Article 267

Data protection

1. Member States shall apply Directive 95/46/EC of the European Parliament and of the Council [1] to the processing of personal data carried out in the Member States pursuant to this Regulation.

2. Regulation (EC) No 45/2001 of the European Parliament and of the Council [2] shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

TITLE II

PENALTIES

Article 268

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that those rules are implemented. The penalties provided for must be effective, proportionate and dissuasive.

The Member States shall notify those provisions to the Commission by 22 April 2022 at the latest and shall notify it without delay of any subsequent amendments affecting them.

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[1] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

[2] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

TITLE III

MEMBER STATES' MEASURES

Article 269

Additional or more stringent measures by Member States

1. In addition to what follows from other provisions in this Regulation, allowing the Member States to adopt national measures, Member States may apply within their territories measures that are additional to, or more stringent than, those laid down in this Regulation, concerning:

(a) responsibilities for animal health as provided for in Chapter 3 of Part I (Articles 10 to 17);

(b) notification within Member States as provided for in Article 18;

(c) surveillance as provided for in Chapter 2 of Part II (Articles 24 to 30);

(d) registration, approval, record-keeping and registers as provided for in Chapter 1 of Title I (Articles 84 to 107), and Chapter 1 of Title II, of Part IV (Articles 172 to 190);

(e) traceability requirements for kept terrestrial animals and germinal products as provided for in Chapter 2 of Title I of Part IV (Articles 108 to 123).

2. The national measures referred to in paragraph 1 shall respect the rules laid down in this Regulation and shall not:

(a) hinder the movement of animals and products between Member States;

(b) be inconsistent with the rules referred to in paragraph 1.

PART IX

TRANSITIONAL AND FINAL PROVISIONS

Article 270

Repeals

1. Decisions 78/642/EEC, 89/455/EEC and 90/678/EEC, and Directives 79/110/EEC, 81/6/EEC, 90/423/EEC, 92/36/EEC and 98/99/EC are repealed.

2. The following acts are repealed as from 21 April 2021:

— Directive 64/432/EEC,

— Directive 77/391/EEC,

— Directive 78/52/EEC,

— Directive 80/1095/EEC,

— Directive 82/894/EEC,

— Directive 88/407/EEC,

— Directive 89/556/EEC,

— Directive 90/429/EEC,

— Directive 91/68/EEC,

— Decision 91/666/EEC,

— Directive 92/35/EEC,

— Directive 92/65/EEC,

— Directive 92/66/EEC,

— Directive 92/118/EEC,

— Directive 92/119/EEC,

— Decision 95/410/EC,

— Directive 2000/75/EC,

— Decision 2000/258/EC,

— Directive 2001/89/EC,

— Directive 2002/60/EC,

— Directive 2002/99/EC,

— Directive 2003/85/EC,

— Regulation (EC) No 21/2004,

— Directive 2004/68/EC,

— Directive 2005/94/EC,

— Directive 2006/88/EC,

— Directive 2008/71/EC,

— Directive 2009/156/EC,

— Directive 2009/158/EC,

— Regulation (EU) No 576/2013.

References to those repealed acts shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in Annex V hereto.

Article 271

Transitional measures related to the amendment of Regulation (EC) No 1760/2000 and the repeal of Regulation (EC) No 21/2004 and Directive 2008/71/EC

1. Notwithstanding Article 270(2) and Article 278 of this Regulation, Articles 1 to 10 of Regulation (EC) No 1760/2000, Regulation (EC) No 21/2004, and Directive 2008/71/EC, as well as the acts adopted on the basis thereof, shall continue to apply, instead of the corresponding Articles in this Regulation, until three years after the date of application of this Regulation or an earlier date to be determined in a delegated act adopted in accordance with paragraph 2 of this Article.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the earlier date referred to in paragraph 1 of this Article.

That date shall be the date of application of the corresponding rules to be adopted pursuant to the delegated acts provided for in Article 109(2) and Article 119 and the implementing acts provided for in Article 118 of this Regulation.

Article 272

Transitional measures related to the repeals of Directives 92/66/EEC, 2000/75/EC, 2001/89/EC, 2002/60/EC, 2003/85/EC and 2005/94/EC

1. Notwithstanding Article 270(2) of this Regulation, Directives 92/66/EEC, 2000/75/EC, 2001/89/EC, 2002/60/EC, 2003/85/EC and 2005/94/EC, as well as the acts adopted on the basis thereof, shall continue to apply, instead of the corresponding Articles in this Regulation, until three years after the date of application of this Regulation or an earlier date to be determined in a delegated act adopted in accordance with paragraph 2 of this Article.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the earlier date referred to in paragraph 1 of this Article.

That date shall be the date of application of the corresponding rules to be adopted pursuant to the delegated acts provided for in Article 47, Articles 48(3), 53(2), 54(3), 55(2) and 58(2), Article 63, Article 64(4), Article 67, and Articles 68(2) and 70(3) of this Regulation.

Article 273

Amendment of Regulation (EC) No 2160/2003

In Article 9(3) of Regulation (EC) No 2160/2003 the following wording is added:

'Those special measures shall include measures based on the provisions contained in Decision 95/410/EC in its last version prior to its repeal and Commission Decisions 2003/644/EC (*) and 2004/235/EC (**) in the versions thereof at the time of the repeal of Directive 90/539/EEC.

(*) Commission Decision 2003/644/EC of 8 September 2003 establishing additional guarantees regarding salmonella for consignments to Finland and Sweden of breeding poultry and day-old chicks for introduction into flocks of breeding poultry or flocks of productive poultry (OJ L 228, 12.9.2003, p. 29).

(**) Commission Decision 2004/235/EC of 1 March 2004 establishing additional guarantees regarding salmonella for consignments to Finland and Sweden of laying hens (OJ L 72, 11.3.2004, p. 86).'.

Article 274

Transitional measures related to the date of adoption of certain delegated and implementing acts

Without prejudice to the date of application provided for in Article 283, the Commission shall adopt the delegated acts referred to in the first subparagraph of Article 31(5), Articles 32(2), 39, 41(3), 54(3), 55(2), 58(2), 64(4), 67, 68(2), 74(4), 77(2) and 97(2), Article 122(2), and Articles 131(1), 132(2), 135, 137(2), 146(1), 149(4), 154(1), 162(3), 163(5), 166(3), 169(5), 181(2), 185(5), 213(1), 216(4), 221(1), 222(3), 224(3), 234(2), 239(1), and the implementing acts referred to in Articles 8 and 9, at the latest on 20 April 2019. In accordance with Article 283, those delegated and implementing acts shall apply from the date of application set out in that Article.

Article 275

Prior review and amendments of Annex II

The Commission shall, at the latest by 20 April 2019, review the list of diseases contained in Annex II. Should it be apparent from that review that an application of the rules set out in this Regulation requires amendments to be made to Annex II, by adding to or deleting from the list contained therein, such amendments shall be adopted by the Commission at the latest by the deadline referred to in the first sentence of this Article.

Article 276

Review

The Commission shall, by 20 April 2019 at the latest, review the existing legislation on the identification and registration of kept animals of the equine species.

The Commission shall take the results of that review into account in the framework of the application of Articles 118, 119 and 120.

Article 277

Transitional measures related to the repeal of Regulation (EU) No 576/2013 on the non–commercial movement of pet animals

Notwithstanding Article 270(2) of this Regulation, Regulation (EU) No 576/2013 shall continue to apply until 21 April 2026 in respect of non–commercial movements of pet animals, in place of Part VI of this Regulation.

Article 278

Amendments to Regulation (EC) No 1760/2000

Regulation (EC) No 1760/2000 is amended as follows:

(1) Articles 1 to 10 are deleted;

(2) Article 22 is replaced by the following:

'Article 22

1. Member States shall take all the necessary measures to ensure compliance with the provisions of this Regulation.

The controls provided for shall be without prejudice to any controls which the Commission may carry out pursuant to Article 9 of Regulation (EC, Euratom) No 2988/95.

Any penalties imposed by the Member State on an operator or organisation marketing beef shall be effective, dissuasive and proportionate.

2. Notwithstanding paragraph 1, where operators and organisations marketing beef have labelled beef without complying with their obligations laid down in Title II, Member States shall, as appropriate, and in accordance with the principle of proportionality, require the removal of the beef from the market. In addition to the penalties referred to in paragraph 1, Member States may:

(a) if the meat concerned conforms with relevant veterinary and hygiene rules, authorise that such beef:

(i) be placed on the market after being properly labelled in accordance with Union requirements; or

(ii) be sent directly for processing into products other than those indicated in point 1 of Article 12;

(b) order the suspension or withdrawal of the approval of the operators and organisations concerned.

3. Experts from the Commission, in conjunction with the competent authorities, shall:

(a) verify that Member States comply with the requirements of this Regulation;

(b) make on–the–spot checks to ensure that the checks are carried out in accordance with this Regulation.

4. A Member State in whose territory an on–the–spot check is carried out shall provide the experts from the Commission with any assistance they may require in the performance of their tasks. The outcome of the checks made shall be discussed with the competent authority of the Member State concerned before a final report is drawn up and circulated. That report shall, where appropriate, contain recommendations for Member States on the improvement of compliance with this Regulation.';

(3) Article 22b is replaced by the following:

'*Article 22b*

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions under this Article.

2. The power to adopt delegated acts referred to in Articles 13(6), 14(4) and 15a shall be conferred on the Commission for a period of five years from 20 April 2016. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 13(6), 14(4) and 15a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Articles 13(6), 14(4) and 15a shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.';

(4) Article 23 is replaced by the following:

'*Article 23*

Committee procedure

1. The Commission shall be assisted for the implementing acts adopted pursuant to Article 13(6) of this Regulation by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council (*).

That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (**).

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the Committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time–limit for delivery of the opinion, the chair of the Committee so decides or a simple majority of committee members so requests.

(*) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

(**) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).'.

Article 279

Existing operators and establishments

1. Establishments and operators registered or approved in accordance with Directive 64/432/EEC, Directive 88/407/EEC, Directive 89/556/EEC, Directive 90/429/EEC, Directive 91/68/EEC, Directive 92/65/EEC, Regulation (EC) No 1760/2000, Regulation (EC) No 21/2004, Directive 2006/88/EC, Directive 2008/71/EC, Directive 2009/156/EC or Directive 2009/158/EC before the date of application of this Regulation shall be deemed to be registered or approved, as required, in accordance with this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules necessary to ensure a smooth transition from the rules existing prior to this Regulation referred to in paragraph 1 of this Article, in order in particular to protect acquired rights and legitimate expectations of natural and legal persons concerned.

Article 280

Existing disease–free Member States, zones and compartments and existing Member State eradication and surveillance programmes

1. Member States and zones with an approved disease–free status for one or more of the listed diseases referred to in points (b) and (c) of Article 9(1), for one or more of the relevant animal species, in accordance with Directive 64/432/EEC, Directive 91/68/EEC, Directive 92/65/EEC, Directive 2006/88/EC, Directive 2009/156/EC or Directive 2009/158/EC, shall be deemed to have an approved disease–free status in accordance with this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.

2. Member States and zones with an approved eradication programme or surveillance programme for one or more of the listed diseases referred to in points (b) and (c) of Article 9(1), for one or more of the relevant animal species, in accordance with Directive 64/432/EEC, Directive 91/68/EEC, Directive 92/65/EEC, Directive 2006/88/EC, Directive 2009/156/EC or Directive 2009/158/EC, shall be deemed to have an approved eradication programme in accordance with this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.

3. Approved compartments with an approved disease–free status for one or more of the listed diseases referred to in points (a), (b) or (c) of Article 9(1), in accordance with Directives 2005/94/EC and 2006/88/EC, shall be deemed to have a recognised disease-free status under Article 37 of this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules necessary in order to ensure a smooth transition from the rules existing prior to this Regulation referred to in paragraphs 1, 2 and 3.

Article 281

Relation with acts concerning official controls

In the event of any conflict between the provisions of this Regulation and the provisions of Regulation (EC) No 882/2004, Council Directives 89/608/EEC [1], 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/93/EC [2] and 97/78/EC and Decision 92/438/EEC, the provisions of this Regulation shall prevail.

Article 282

Evaluation

The Commission shall evaluate this Regulation together with the delegated acts referred to in Article 264 and submit the results of the evaluation in a report to the European Parliament and to the Council no later than 22 April 2026.

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[1] Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters (OJ L 351, 2.12.1989, p. 34).

[2] Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products (OJ L 13, 16.1.1997, p. 28).

Article 283

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 21 April 2021, except for Articles 270(1) and 274, which shall apply from the date of its entry into force.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 9 March 2016.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	J.A. HENNIS-PLASSCHAERT

ANNEX I

SPECIES OF PET ANIMALS

PART A

Dogs (*Canis lupus familiaris*)

Cats (*Felis silvestris catus*)

Ferrets (*Mustela putorius furo*)

PART B

Invertebrates (except bees, molluscs belonging to the phylum *Mollusca* and crustaceans belonging to the subphylum *Crustacea*)

Ornamental aquatic animals

Amphibians

Reptiles

Birds: specimens of avian species other than fowl, turkeys, guinea fowl, ducks, geese, quails, pigeons, pheasants, partridges and ratites (*Ratitae*).

Mammals: rodents and rabbits other than those intended for food production.

ANNEX II

LIST OF DISEASES

— Rinderpest (cattle plague)

— Sheep and goat plague

— Swine vesicular disease

— Bluetongue

— Teschen disease

— Sheep pox or goat pox

— Rift Valley fever

— Lumpy skin disease

— Vesicular stomatitis

— Venezuelan equine viral encephalomyelitis

— Haemorrhagic disease of deer

— Contagious bovine pleuropneumonia

— Newcastle disease

— Bovine tuberculosis

— Bovine brucellosis (*B. abortus*)

— Ovine and caprine brucellosis (*B. melitensis*)

— Anthrax

— Rabies

— Echinococcosis

— Transmissible spongiform encephalopathies (TSE)

— Campylobacteriosis

— Listeriosis

— Salmonellosis (zoonotic salmonella)

— Trichinellosis

— Verotoxigenic *E. coli*

— Viral haemorrhagic septicæmia (VHS)

— Infectious haematopoietic necrosis (IHN)

— Epizootic haematopoietic necrosis in fish (EHN)

— Epizootic ulcerative syndrome in fish (EUS)

— Infection with *Bonamia exitiosa*

— Infection with *Perkinsus marinus*

— Infection with *Microcytos mackini*

— Taura syndrome in crustaceans

— Yellowhead disease in crustaceans

— Koi herpes virus disease (KHV)

— Infectious salmon anaemia (ISA)

— Infection with *Marteilia refringens*

— Infection with *Bonamia ostreae*

— White spot disease in crustaceans

ANNEX III

SPECIES OF UNGULATES

Taxon		
Order	Family	Genera/Species
Perissodactyla	*Equidae*	*Equus* spp.
	Tapiridae	*Tapirus* spp.
	Rhinoceritidae	*Ceratotherium* spp., *Dicerorhinus* spp., *Diceros* spp., *Rhinoceros* spp.
Artiodactyla	*Antilocapridae*	*Antilocapra* ssp.
	Bovidae	*Addax* ssp., *Aepyceros* ssp., *Alcelaphus* ssp., *Ammelaphus* ssp., *Ammodorcas* ssp., *Ammotragus* ssp., *Antidorcas* ssp., *Antilope* ssp., *Arbitragus* ssp., *Beatragus* ssp., *Bison* ssp., *Bos* ssp.(including *Bibos, Novibos, Poephagus*), *Boselaphus* ssp., *Bubalus* ssp. (including *Anoa*), *Budorcas* ssp., *Capra* ssp., *Cephalophus* ssp., *Connochaetes* ssp., *Damaliscus* ssp.(including *Beatragus*), *Dorcatragus* ssp., *Eudorcas* ssp., *Gazella* ssp., *Hemitragus* ssp., *Hippotragus* ssp., *Kobus* ssp., *Litocranius* ssp., *Madoqua* ssp., *Naemorhedus* ssp. (including *Nemorhaedus* and *Capricornis*), *Nanger* ssp., *Neotragus* ssp., *Nilgiritragus* ssp., *Oreamnos* ssp., *Oreotragus* ssp., *Oryx* ssp., *Ourebia* ssp., *Ovibos* ssp., *Ovis* ssp., *Pantholops* ssp., *Philantomba* ssp., *Pelea* ssp., *Procapra* ssp., *Pseudois* ssp., *Pseudoryx* ssp., *Raphicerus* ssp., *Redunca* ssp., *Rupicapra* ssp., *Saiga* ssp., *Sigmoceros–Alecelaphus* ssp., *Strepticeros* ssp., *Sylvicapra* ssp., *Syncerus* ssp., *Taurotragus* ssp., *Tetracerus* ssp., *Tragelaphus* ssp. (including *Boocerus*).
	Camelidae	*Camelus* ssp., *Lama* ssp., *Vicugna* ssp.
	Cervidae	*Alces* ssp., *Axis–Hyelaphus* ssp., *Blastocerus* ssp., *Capreolus* ssp., *Cervus* ssp., *Dama* ssp., *Elaphodus* ssp., *Elaphurus* ssp., *Hippocamelus* ssp., *Hydropotes* ssp., *Mazama* ssp., *Megamuntiacus* ssp., *Muntiacus* ssp., *Odocoileus* ssp., *Ozotoceros* ssp., *Przewalskium* ssp., *Pudu* ssp., *Rangifer* ssp., *Rucervus* ssp., *Rusa* ssp.
	Giraffidae	*Giraffa* ssp., *Okapia* ssp.
	Hippopotamidae	*Hexaprotodon–Choeropsis* ssp., *Hippopotamus* ssp.
	Moschidae	*Moschus* ssp.
	Suidae	*Babyrousa* ssp., *Hylochoerus* ssp., *Phacochoerus* ssp., *Porcula* ssp., *Potamochoerus* ssp., *Sus* ssp.
	Tayassuidae	*Catagonus* ssp., *Pecari–Tayassu* ssp.
	Tragulidae	*Hyemoschus* ssp., *Tragulus–Moschiola* ssp.
Proboscidea	*Elephantidae*	*Elephas* ssp., *Loxodonta* ssp.

ANNEX IV

CRITERIA FOR THE APPLICATION OF THE DISEASE PREVENTION AND CONTROL RULES REFERRED TO IN ARTICLE 9(1) TO DISEASES LISTED IN ACCORDANCE WITH ARTICLE 5

The scope of this Annex is to detail the criteria to be considered by the Commission when determining the disease prevention and control rules to be applied to the different categories of diseases listed in accordance with Article 5.

The process of categorisation shall take into account the profile of the disease in question, the level of the impact of that disease on animal and public health, animal welfare and the economy, and the availability, feasibility and effectiveness of the diagnostic tools and different sets of disease prevention and control measures provided for in this Regulation with respect to the disease.

Section 1

Criteria for the application of the disease prevention and control rules referred to in point (a) of Article 9(1)

The diseases for which the disease prevention and control rules referred to in point (a) of Article 9(1) apply shall be considered to have the most severe animal health, public health, economic, social or environmental impacts on the Union. Those diseases need to fulfil the following criteria:

(a) the disease in question is:

(i) not present in the territory of the Union;

(ii) present only in exceptional cases (irregular introductions); or

(iii) present in only in a very limited part of the territory of the Union;

and

(b) the disease in question is highly transmissible; in addition to direct and indirect transmission, there may also be possibilities of airborne, waterborne or vector–borne spread. The disease may affect multiple species of kept and wild animals, or a single species of kept animals of economic importance, and may result in high morbidity and significant mortality rates.

In addition to the criteria set out in points (a) and (b), those diseases need to fulfil one or more of the following criteria:

(c) the disease in question has a zoonotic potential with significant consequences for public health, including epidemic or pandemic potential or possible significant threats to food safety;

(d) the disease in question has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals;

(e) the disease in question has a significant impact on one or more of the following:

(i) society, with in particular an impact on labour markets;

(ii) animal welfare, by causing suffering to large numbers of animals;

(iii) the environment, due to the direct impact of the disease or due to the measures taken to control it;

(iv) in the long term, biodiversity or the protection of endangered species or breeds, including the possible disappearance of, or long-term damage to, those species or breeds.

Section 2

Criteria for the application of the disease prevention and control rules referred to in point (b) of Article 9(1)

The diseases for which the disease prevention and control rules referred to in point (b) of Article 9(1) apply shall be controlled in all Member States with the goal of eradicating them throughout the Union.

Those diseases need to fulfil the following criteria:

(a) the disease in question is endemic in nature and is present in the whole or part of the Union territory. However, several Member States or zones of the Union are free of the disease; and

(b) the disease is moderately to highly transmissible; in addition to direct and indirect transmission, there may also be possibilities of airborne, waterborne or vector–borne spread. It may affect single or multiple animal species and may result in high morbidity, with in general low mortality.

In addition to the criteria set out in points (a) and (b), those diseases need to fulfil one or more of the following criteria:

(c) the disease in question has a zoonotic potential with significant consequences for public health, including epidemic potential or possible significant threats to food safety;

(d) the disease in question has a significant impact on the economy of the Union causing substantial costs, mainly related to its direct impact on the health and productivity of animals;

(e) the disease has a significant impact on one or more of the following:

  (i) society, with in particular an impact on labour markets;

  (ii) animal welfare, by causing suffering to large numbers of animals;

  (iii) the environment, due to the direct impact of the disease or due to the measures taken to control it;

  (iv) in the long term, biodiversity or the protection of endangered species or breeds, including the possible disappearance of, or long-term damage to, those species or breeds.

A disease to which the measures referred to in point (a) of Article 9(1) apply, which has not been successfully and promptly eradicated in a part of the Union, and has, in that part of the Union, obtained an endemic character, may be subject to disease prevention and control measures under point (b) of Article 9(1), in that part of the Union.

Section 3

Criteria for the application of the disease prevention and control rules referred to in point (c) of Article 9(1)

The diseases for which the disease prevention and control rules referred to in point (c) of Article 9(1) apply are of relevance to some Member States and measures are needed to prevent them from spreading to parts of the Union that are officially disease-free or that have eradication programmes for the listed disease in question.

Those diseases need to fulfil the following criteria:

(a) in terrestrial animals, the disease in question is endemic in nature and is present in the whole or part of the Union territory; or in aquatic animals, several Member States or zones of the Union are free of the disease; and

(b) (i) in terrestrial animals, the disease in question is moderately to highly transmissible, mainly through direct and indirect transmission. The disease mainly affects multiple or single animal species, usually does not result in high morbidity, and has a negligible or no mortality rate. Often the most observed effect is production loss;

  (ii) in aquatic animals, the disease is moderately to highly transmissible, mainly through direct and indirect transmission. The disease affects multiple or single animal species and may result in high morbidity and usually low mortality. Often the most observed effect is production loss.

In addition to the criteria set out in points (a) and (b), those diseases need to fulfil one or more of the following criteria:

(c) the disease in question has a zoonotic potential with significant consequences for public health, or possible threats to food safety;

(d) the disease in question has a significant impact on the economy of parts of the Union, mainly related to its direct impact on certain types of animal production systems.

(e) the disease in question has a significant impact on one or more of the following:

(i) society, with, in particular, an impact on labour markets;

(ii) animal welfare, by causing suffering to large numbers of animals;

(iii) the environment, due to the direct impact of the disease or of the measures taken to control it;

(iv) in the long term, biodiversity or the protection of endangered species or breeds, including the possible disappearance of, or long-term damage to, those species or breeds.

Section 4

Criteria for the application of the disease prevention and control rules referred to in point (d) of Article 9(1)

The disease prevention and control rules referred to in point (d) of Article 9(1) shall apply to diseases that fulfil the criteria set out in Section 1, 2 or 3 and to other diseases fulfilling the criteria set out in Section 5 where the risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread.

Section 5

Criteria for the application of the disease prevention and control rules referred to in point (e) of Article 9(1)

The disease prevention and control rules referred to in point (e) of Article 9(1) shall apply to diseases that fulfil the criteria set out in Sections 1, 2 or 3 and to other diseases where surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment.

ANNEX V

CORRELATION TABLE REFERRED TO IN ARTICLE 270 (2)

1. Directive 64/432/EEC

Directive 64/432/EEC	This Regulation
Article 1	—
Article 2	Articles 4 (partially), 21, 153(3) and 220(3)
Article 3(1)	Articles 124 and 126
Article 3(2)	Articles 124 (2), 126(1) and 149(3) and (4)
Article 4(1)	Article 126(1)(c)
Article 4(2) and (3)	Article 125(1) and (2)
Article 5(1)	Articles 143(1), 145 and 146
Article 5(2)	Article 149(3) and (4)
Article 5(2)(a)	Article 147(a)
Article 5(2)(b)	Article 144(1)(b)
Article 5(3)	—
Article 5(4)	Article 153(1) and (2)
Article 5(5)	Article 147(a)
Article 6	Articles 130, 131 and 132
Article 6a	—
Article 7	Articles 126(1)(c),132, 134(a) and 135
Article 8	Articles 18, 19, 20 and 23(a)
Article 9	Articles 31(1), (3)(a) and (5), 32, 33 and 36
Article 10	Articles 31(2) and (3)(b), 32, 33 and 36
Article 11(1)	Articles 94(1)(a), 97 and 98
Article 11(2)	Articles 102, 106 and 107
Article 11(3)	Articles 98 and 99
Article 11(4)	Article 100
Article 11(5) and (6)	Article 97(1)(d) and (2)(d)
Article 12(1)	Article 125
Article 12(2)	Articles 104 and 106
Article 12(3)	Article 125(1)(a) and (b)
Article 12(4)	Article 143
Article 12(5) and (6)	—
Article 13(1) and (2)	Articles 90, 92, 93(c), 94, 97, 98, 99, 102, 106 and 107
Article 13(3)	Article 100
Article 13(4)	—

Directive 64/432/EEC	This Regulation
Article 13(5) and (6)	Article 101
Article 14(1) and (2)	—
Article 14(3)A and B	—
Article 14(3)C	Article 109(1)(a) and (c)
Article 14(4) to (6)	—
Article 15(1)	Article 268
Article 15(2) to (4)	—
Article 16	—
Article 17	—
Article 17a	—
Article 18	Article 109(1)(a) and (c)
Article 19	—
Article 20	—

2. Directive 77/391/EEC

Directive 77/391/EEC	This Regulation
Article 1	—
Article 2(1)	Article 31(1)
Article 2(2)	Articles 32, 33 and 36(1)
Article 2(3)	Article 34
Article 2(4)	Articles 36 and 41
Article 3(1)	Article 31(1)
Article 3(2)	Articles 32, 33 and 36(1)
Article 3(3)	Article 34
Article 3(4)	Articles 36 and 41
Article 4	Articles 31(1), 32, 33, 34, 36 and 41
Article 5	—
Article 6	—
Article 7	—
Article 8	—
Article 9	—
Article 10	—
Article 11	—
Article 12	—
Article 13	—
Article 14	—
Article 15	—

3. Directive 78/52/EEC

Directive 78/52/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3(1)	Articles 31(1) and 32
Article 3(2)	—
Article 3(3)	—
Article 3(4)	Articles 31(1) and 32
Article 4	Articles 32, 35, 102(2) and (4) and 112
Article 5	Articles 18, 46 and 47
Article 6(1)	Articles 72 to 76
Article 6(2)	Articles 77 and 78
Article 6(3)	Articles 79 and 80
Article 7	Articles 79 and 80
Article 8	Articles 79 and 80
Article 9	Articles 79 and 80
Article 10	Articles 79 and 80
Article 11	Articles 79 and 80
Article 12	Articles 79 and 80
Article 13	Articles 18, 46 and 47
Article 14(1)	Articles 72 to 76
Article 14(2)	Articles 77 and 78
Article 14(3)	Articles 79 and 80
Article 15	Articles 79 and 80
Article 16	Articles 79 and 80
Article 17	Articles 79 and 80
Article 18	Articles 79 and 80
Article 19	Articles 79 and 80
Article 20	Articles 79 and 80
Article 21	—
Article 22	Articles 18, 19, 20, 46 and 47
Article 23	Articles 79 and 80
Article 24	Articles 79 and 80
Article 25	Articles 79 and 80
Article 26	Articles 79 and 80
Article 27	Articles 124(1) and 126(1)(c)
Article 28	—
Article 29	—
Article 30	—

4. Directive 80/1095/EEC

Directive 80/1095/EEC	This Regulation
Article 1	Articles 31(1) and 36
Article 2	Article 4 (partially)
Article 3	Articles 31(1) and 35
Article 3a	Articles 31(1) and 35
Article 4	Articles 32, 33 and 35
Article 4a	Articles 32, 33 and 35
Article 5	—
Article 6	Articles 31(1)(b), 31(3) and 32
Article 7	Articles 36, 39 and 40
Article 8	Articles 41 and 42
Article 9	—
Article 11	—
Article 12	—
Article 12a	—
Article 13	—

5. Directive 82/894/EEC

Directive 82/894/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 19, 21, 22 and 23
Article 4	Articles 19, 20, 21, 22 and 23
Article 5	Article 23
Article 6	—
Article 7	—
Article 8	—

6. Directive 88/407/EEC

Directive 88/407/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 159 and 160
Article 4	Article 160
Article 5	Articles 94, 97, 100 and 101
Article 6(1)	Articles 161 and 162
Article 6(2), (3) and (4)	Article 258
Article 8	Articles 229(1)(a) and 230
Article 9	Articles 229(1)(b) and 233

Directive 88/407/EEC	This Regulation
Article 10	Articles 229(1)(c), 234 and 236
Article 11	Articles 229(1)(d), 237 and 238
Article 12	Articles 260 to 262
Article 15	Articles 257 to 259
Article 16	—
Article 17	—
Article 18	—
Article 20	—
Article 21	—
Article 22	—

7. Directive 89/556/EEC

Directive 89/556/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Article 159, 160, 161
Article 5(1)	Articles 94 and 97
Article 5(2)	Article 101
Article 5(2a) and (3)	Articles 97, 98 and 100
Article 6	Articles 161 and 162
Article 7	Articles 229(1)(a) and 230
Article 8	Articles 229(1)(b) and 233
Article 9	Articles 229(1)(c), 234 and 236
Article 10	Articles 229(1)(d), 237 and 238
Article 11	Articles 260 to 262
Article 14	Articles 257 to 259
Article 15	—
Article 16	—
Article 17	—
Article 18	—
Article 19	—
Article 20	—
Article 21	—

8. Directive 90/429/EEC

Directive 90/429/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 159 and 160
Article 4	—

Directive 90/429/EEC	This Regulation
Article 5(1)	Articles 94, 97, 98 and 100
Article 5(2)	Article 101
Article 6(1)	Articles 161 and 162
Article 6(2)	Article 258
Article 7	Articles 229(1)(a) and 230
Article 8	Articles 229(1)(b) and 233
Article 9	Articles 229(1)(c), 234 and 236
Article 10	Article 229(1)(d), 237 and 238
Article 11(1)	Article 229
Article 11(2) and (3)	Article 260
Article 12	Article 237
Article 13	—
Article 14	—
Article 15	Articles 257 to 262
Article 16	—
Article 17	—
Article 18	—
Article 19	—
Article 20	—
Article 21	—
Article 22	—

9. Directive 91/68/EEC

Directive 91/68/EEC	This Regulation
Article 1	—
Article 2	Articles 4 (partially), 21, 153(3) and 220(3)
Article 3(1), (2), (3) and (5)	Articles 126(1)(b), 130 and 131
Article 3(4)	Article 139
Article 4(1)	Articles 124(2)(b), 126(1), 130, 131 and 149(3) and (4)(a) and (b)
Article 4(2)	Article 128
Article 4(3)	Article 131
Article 4a	Articles 130 and 131
Article 4b(1) and (2)	Articles 130 and 131
Article 4b(3)	Article 126(2)
Article 4b(4)	Article 133
Article 4b(5)	Article 132
Article 4b(6)	Articles 124(1), 125 and 126(1)(b)
Article 4c(1) and (2)	Articles 130 and 131

Directive 91/68/EEC	This Regulation
Article 4c(3)	Articles 133 and 135
Article 5	Article 131
Article 6	Articles 131 and 145(1)(e)
Article 7(1) to (3)	Articles 31, 32, 33 and 35
Article 7(4)	—
Article 8(1) to (3)	Articles 36, 39 and 40
Article 8(4)	—
Article 8a(1)	Articles 94(1)(a), 97, 98 and 134
Article 8a(2)	Article 102 and 106
Article 8a(3)	Articles 98, 99 and 101
Article 8a(4)	Article 100
Article 8a(5)	Article 97(1)(d) and (2)(d)
Article 8b(1)	Articles 84, 90, 92, 93(c), 94(1)(a), 97, 98, 102, 105 and 134
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12. Directive 92/65/EEC

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13. Directive 92/66/EEC

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14. Directive 92/118/EEC

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15. Directive 92/119/EC

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16. Decision 95/410/EC

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17. Directive 2000/75/EC

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18. Regulation (EC) No 1760/2000

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19. Directive 2001/89/EC

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20. Directive 2002/60/EC

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21. Directive 2002/99/EC

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22. Directive 2003/85/EC

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23. Regulation (EC) No 21/2004

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24. Directive 2004/68/EC

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25. Directive 2005/94/EC

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26. Directive 2006/88/EC

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27. Directive 2008/71/EC

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