Organisation Mondiale de la Santé Animale
World Organisation for Animal Health
Organización Mundial de Sanidad Animal

Annex 1

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MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION
Paris, 1–11 February 2022

PART B – Code Commission's work programme and texts circulated for comments

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EU comment

The EU would like to commend the OIE for its work under the current difficult circumstances and thank in particular the Code Commission for having taken into consideration EU comments on the Terrestrial Code submitted previously.

A number of general comments on this part B of the February 2022 meeting report of the Code Commission are inserted in the text below, while specific comments are inserted in the text of the respective annexes to the report.

The EU would like to stress once again its continued commitment to participate in the standard setting work of the OIE and to offer all technical support needed by the Code Commission and OIE ad hoc groups for future work on the Terrestrial Code.

The OIE Terrestrial Animal Health Standards Commission (the Code Commission) held its meeting electronically from 1 to 11 February 2022. The list of participants is attached as **Annex 1**.

To facilitate the 89th Annual General Session in semi-hybrid format, the February 2022 meeting report of the Code Commission is being distributed in two parts: **Part A** (available on the OIE website) provides information about the new and revised texts of the *Terrestrial Code* that will be proposed for adoption at the 89th General Session; and **Part B** (herewith) provides information about other topics discussed at the Commission's February 2022 meeting including texts circulated for comments and information.

The Code Commission thanked the following Members for providing comments: Argentina, Australia, Brazil, Canada, China (People's Rep. of), Chinese Taipei, Colombia, Japan, Mexico, New Caledonia, New Zealand, Norway, Saudi Arabia, South Africa, Switzerland, Thailand, the United Arab Emirates (UAE), the United Kingdom (UK), the United States of America (USA), Zimbabwe, the Member States of European Union (EU), the African Union Inter-African Bureau for Animal Resources (AU-IBAR) on behalf of African Members of the OIE. The Commission also thanked the following organisations for providing comments: the Global Alliance of Pet Food Associations (GAPFA), the International Meat Secretariat (IMS), the World Renderers Organization (WRO), the International Coalition for Animal Welfare (ICFAW) as well as various experts of the OIE scientific network.

The Code Commission reviewed all comments that were submitted prior to the deadline and supported by a rationale. The Commission made amendments to draft texts, where relevant, in the usual manner by 'double underline' and 'strikethrough'. In relevant annexes, amendments proposed at this meeting are highlighted with a coloured background to distinguish them from those made previously. Due to the large number of comments, the Commission was not able to provide a detailed explanation for the reasons for accepting or not each of the comments considered, and focused its explanations on significant issues. Where amendments were of an editorial nature, no explanatory text has been provided. The Commission wished to note that not all texts proposed by Members to improve clarity were accepted; in these cases, it considered the text clear as currently written.

The Code Commission encourages Members to refer to previous reports considering longstanding issues. The Commission also draws the attention of Members to those instances where the Scientific Commission for Animal Diseases (the Scientific Commission), the Biological Standards Commission (the Laboratories Commission), a

Working Group or an *ad hoc* Group have addressed specific comments or questions and proposed answers or amendments. In such cases the rationale is described in the reports of Scientific Commission, Laboratories Commission, Working Groups or *ad hoc* Groups and Members are encouraged to review these reports together with the report of the Code Commission. These reports are readily available on the OIE website.

To be considered by the Code Commission at its September 2022 meeting, all comments on relevant texts in this **Part B** must reach OIE Headquarters **by 15 July 2022**. Comments received after the due date will not be submitted to the Commission for its consideration. In addition, the Commission would like to highlight that comments should be submitted through the OIE Delegate of Member Countries or organisations, with which the OIE has a Cooperative Agreement.

All comments and related documents should be sent by email to the OIE Standards Department at **TCC.Secretariat@oie.int.**

The Code Commission again strongly encourages Members to participate in the development of the OIE's international standards by submitting comments on this report. Members are also reminded that comments should be submitted as Word files rather than pdf files because pdf files are difficult to incorporate into the working documents of the Commission. Comments should be submitted as specific proposed text changes, supported by a structured rationale or by published scientific references. Proposed deletions should be shown using '~~strikethrough~~' and additions using 'double underline'. Members should not use the automatic 'track-changes' function provided by word processing software as such changes are lost in the process of collating submissions into the Commission's working documents. Members are also requested **not** to reproduce the full text of a chapter as this makes it easy to miss comments while preparing the working documents.

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1. Introduction

The proposed agenda for the meeting was discussed, taking into consideration the priorities of the work programme and time availability. The adopted agenda of the meeting is attached as **Annex 2**.

Due to time constraints, the Code Commission did not discuss agenda items 5.1.8. Harmonisation of official recognition of status by the OIE: contagious bovine pleuropneumonia (Chapter 11.5.), African horse sickness (Chapter 12.1.) and 7.2.4. New chapter on infection with Trypanosoma Evansi (Non equine surra) (Chapter 8.X.). The Commission agreed to postpone these items until a future meeting.

2. Cooperation with other Specialist Commissions

2.1. Scientific Commission for Animal Diseases (Scientific Commission)

The OIE Secretariat updated the Code Commission on relevant ongoing activities of the Scientific Commission.

During the February 2022 meeting, the Bureaus (i.e. the President and the two Vice-Presidents) of the Code Commission and the Scientific Commission held a meeting chaired by OIE Deputy Director General, International Standards and Science (OIE DDG ISS), Dr Montserrat Arroyo Kuribreña. The purpose of the meeting was to inform the two Bureaus about the planning and coordination of relevant topics of common interest and, where necessary, prioritise them and agree on the process to manage these topics.

The Bureaus discussed the following topics:

- the importance of clearly defining the OIE offical status recognition process given that the revised Chapters 11.4., Bovine spongiform encephalopathy; 1.8., Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy; and 8.16., Infection with rinderpest virus will be proposed for adoption in May 2022 (refer to Part A of this report);

- the status of the ongoing assessments for listing or delisting of pathogenic agents;

- the work to develop or improve, where needed, the case definitions for some terrestrial animal listed diseases to support notification;

- the revised Chapter 8.8. Infection with foot and mouth disease virus.

Dr Arroyo informed the Bureaus about comments received on the OIE Standard Operating Procedure for determining if a disease should be considered as an emerging disease. Dr Arroyo noted that in March 2021 the OIE Headquarters developed a standard operating procedure (SOP) for determining if a disease meets the *Terrestrial Code* definition of an 'emerging disease' (ED SOP), and an accompanying guidance document. Both documents were published on the OIE website, and an informative article appeared in the June 2021 edition of the OIE *Bulletin* emphasising that SOPs are implementation tools that the OIE uses to give effect to international standards. The Bureaus discussed the concerns and discussed possible ways to address them, including whether there was a need to review either the SOP or the *Terrestrial Code*. The Bureaus did not agree with the proposal to amend the *Terrestrial Code*, and agreed on the need to review the SOP to ensure it was seen as a guidance process for notification, ensuring the involvement of delegates in the process. The Bureaus also agreed that it was needed to improve communications to promote the understanding of delegates on the identification and notification of emerging diseases (e.g. further disseminate the SOP and the guidance document, both of

which are currently available through the OIE website) and on the progress of the work for considering potential emerging diseases.

The Code Commission wished to thank the Scientific Commission for its collaborative work in providing opinions to support the consideration of relevant Member comments received. The Code Commission reminded Members that its consideration of the Scientific Commission contributions is noted under the relevant agenda items of this report.

2.2. Biological Standards Commission

The OIE Secretariat provided an update to the Code Commission on relevant activities of the Laboratories Commission, including chapters in the OIE *Manual of Diagnostic Tests and Vaccines for*

Terrestrial Animals (the *Terrestrial Manual*) that are being revised as well as other items of interest. The Code Commission acknowledged the relevant work of the Laboratories Commission and noted this was important information to ensure alignment of the two Commission's respective work plans regarding Code and Manual chapters.

The Commission wished to thank the Laboratories Commission for providing responses to questions to support the decisions of the Code Commission on relevant comments received. The Code Commission reminded Members that its consideration of the Laboratories Commission responses is noted under the relevant agenda items of its report and encouraged Members to read its report together with the reports of the Laboratories Commission.

The Code Commission expressed its interest in the Laboratories Commission's work to develop a new section that would describe the rationale for the selection of tests for different purposes given in a table in all disease chapters of the *Terrestrial Manual* and asked to be kept informed on this work.

Considering the complementarity of the *Terrestrial Code* and the *Terrestrial Manual*, and the need to ensure alignment between these two OIE standards, the Code Commission agreed that regular meetings between the Bureaus of both Commissions should be established as it would offer an excellent mechanism to ensure alignment of relevant items on the work programmes and agendas of both Commissions. The Commission requested the OIE Secretariat to convene a meeting for September 2022.

2.3. Aquatic Animal Health Standards Commission (Aquatic Animals Commission)

The Code Commission discussed with the OIE Secretariat the need to coordinate its revision of the glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' in the *Terrestrial Code* with the Aquatic Animals Commission's parallel work to revise these definitions in the glossary of the *Aquatic Animal Health Code* (the *Aquatic Code*).

The Code Commission emphasised the importance of working with the Aquatic Animals Commission to ensure alignment of these definitions in both Codes, except where differences can be justified.

Refer to Part A of this February 2022 Code Commission meeting report for its discussion on the revision of the Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Service'.

3. Code Commission's work programme not including texts circulated for comments

Comments were received from Japan, New Caledonia, South Africa, the UAE and the EU.

The Code Commission discussed ongoing priority topics on its work programme and considered new work requests, proposals and comments received. The Commission reminded Members that this programme outlines the current and planned work, to be undertaken to develop *Terrestrial Code* standards. The Commission strongly encouraged Members to provide feedback as to whether they agree with the topics being proposed, as well as their level of prioritisation, in addition to the specific discussions and annexes presented in the report.

The Code Commission noted a comment requesting recommendations from the OIE on Melioidosis and asked the OIE Secretariat to follow up on the issue to gather more information on the request.

In response to a comment to develop a disease-specific chapter for Crimean Congo haemorrhagic fever as it is a high priority zoonotic disease in Asia and Africa, the Commission noted that this was already included in their work programme and, noting that the Scientific Commission was developing a case definition for this listed disease, the Commission agreed to initiate this work once a draft case definition was available and recognised this item as a priority. The Commission noted that the Laboratories Commission is currently working to update the relevant *Terrestrial Manual* Chapter 3.1.5. (2022/2023 review cycle) and noted the need to undertake this work in conjunction and close collaboration with the Laboratory Commission.

In response to comments to review Chapter 10.9. Infection with Newcastle disease in line with the amendments adopted at the 88th OIE General Session in May 2021, for Chapter 10.4. Infection with high pathogenicity avian influenza viruses, the Commission noted that the revision of this chapter was already included in their work programme but agreed not to prioritize it for the moment given the extensive work that such revision would require. The Commission also acknowledged that, in September 2020, it had agreed that once the revised definition for "poultry" was adopted in the Glossary, any other definitions for poultry described in specific chapters would be deleted and decided to propose only this amendment in Article 10.9.1. at this time. (See item 4.5 of this report.

The Code Commission thanked Members for their comments expressing support to different items already included in its work programme and noted that even when not individually addressed in this report, they are taken into consideration for prioritisation purposes.

The Code Commission also thanked the Scientific Commission, the Laboratories Commission, the OIE Working Groups and all OIE *ad hoc* Groups for their contribution to the progress of the different topics.

3.1. Ongoing priority topics

The Code Commission discussed the progress of a number of ongoing priority topics for which no new or revised text is circulated in this report as below.

3.1.1. Collection and processing of semen of animals (Chapter 4.6.)

Background

At its September 2019 meeting, the Code Commission requested that an *ad hoc* Group be convened to revise Chapter 4.6. General hygiene in semen collection and processing centres and Chapter 4.7. Collection and processing of bovine, small ruminant and porcine semen, as well as provisions in relevant disease-specific chapters of the *Terrestrial Code* and the *Terrestrial Manual*. This work had been requested to resolve inconsistencies among the chapters and to ensure that the texts reflect the latest scientific evidence and best practices regarding risk mitigation measures in the collection and processing of semen of animals. The *ad hoc* Group was also requested to consider the inclusion of provisions to address equine semen in relevant chapters.

The *ad hoc* Group met virtually between November–December 2020 and May–July 2021 to review and revise Chapter 4.6. At its September 2021 meeting, the Code Commission considered the work of the *ad hoc* Group and supported the OIE Secretariat's suggestion to engage an expert to continue the revision of Chapter 4.6. given the limitations of the virtual modality to progress this work. A Commission member was nominated to work with the Secretariat and the expert to progress the development of the draft text.

Update

The OIE Secretariat informed the Code Commission that processes to engage an expert to incorporate recommendations from species-specific experts were underway. It is expected that revised draft of Chapter 4.6. will be presented for the Commission's review at its September 2022 meeting.

3.1.2. Revision of Section 4 Disease prevention and control (New chapter on biosecurity, revision of Chapter 4.13. on disposal of dead animals and Chapter 4.14. on disinfection)

Background

The Code Commission had agreed to develop some new chapters and to revise some existing chapters of Section 4. Disease prevention and control. To date, a new Chapter 4.18. Vaccination was adopted in 2018, and a revised Chapter 4.4. Zoning and compartmentalisation and a new Chapter 4.19. Official control programmes for listed and emerging diseases were adopted in 2021. Work on revising Chapter 4.6. General hygiene in semen collection and processing centres and Chapter 4.7. Collection and processing of bovine, small ruminant and porcine semen is in progress.

In September 2021, the Code Commission agreed that in addition to the ongoing work to revise Chapters 4.6. and 4.7., high priority should also be given to the revision of Chapter 4.13. Disposal of dead animals and Chapter 4.14. General recommendations on disinfection and disinsection as well as to the development of a new Chapter 4.X. Biosecurity. The Commission requested the OIE Secretariat to prepare the terms of reference for this work and to report back at its next meeting.

Discussion

The Code Commission considered the preparatory work presented by the OIE Secretariat and agreed that priority should be given to the elaboration of a new chapter on biosecurity and noted that the broad nature of this topic would likely influence the revisions of Chapters 4.13. and 4.14. The Commission noted that the consideration to develop a definition for swill should be included in this work.

The Commission requested that an *ad hoc* Group be convened to undertake this work and that the initial work of the *ad hoc* Group should be to define the scope and structure for the new chapter. The Commission highlighted that the Scientific Commission could provide valuable contributions to this work and proposed that a representative of the Code Commission together with a representative of the Scientific Commission participate in the *ad hoc* Group. The Commission requested the OIE Secretariat to initiate the work and present the initial outcomes from the *ad hoc* Group for its consideration to define the next steps.

The Commission reiterated that this was a high priority topic in its work programme and expressed its commitment to work closely with the OIE Secretariat to develop the terms of reference for the *ad hoc* Group to conduct this work.

3.1.3. Revision of Section 5 Trade measures, import/export procedures and veterinary certification (especially Chapters 5.4. to 5.7.)

Background

At its September 2017 meeting, the Code Commission agreed to include a review of Section 5 Trade measures, import/export procedures and veterinary certification in its work programme given that most of the chapters in this section have not been updated for some time and some are not adequate to support Members in managing the risks of introduction of diseases through the importation of commodities.

At its September 2021 meeting, the Code Commission reviewed the current chapters of Section 5 and agreed that a revision of Chapters 5.4. to 5.7. should be given priority. The Commission also discussed the scope of the revisions and requested that the OIE Secretariat further develop the scope of this work.

Discussion

With regard to the work to revise Chapters 5.4. to 5.7., the Code Commission reviewed the preparatory work of the OIE Secretariat and discussed a number of points, described below,

that it considered important to clarify to develop the terms of reference of the *ad hoc* Group to be convened to initiate this priority work.

a) Structure of the revised chapters

The Code Commission considered the structure of the four current chapters (5.4. to 5.7.) and agreed that whether to keep or change the current structure, the content and number of chapters should be discussed by the *ad hoc* Group.

b) Glossary definitions of 'border post' and 'quarantine station'

The Code Commission agreed that the *ad hoc* Group should consider the revision of two fundamental terms, 'border post' and 'quarantine station', which are defined in the Glossary in the *Terrestrial Code*, with a view of reassessing the relevance of each Glossary definition and clarifying the difference between these two terms and standardize their use in the Code. The Commission also requested that the *ad hoc* Group discuss whether there is a need to develop other definitions that may be relevant for the revised chapters.

c) Guidance/measures that should be included in the chapters

The Code Commission considered that the revised chapter(s) should provide general guidance, rather than disease-specific recommendations or specific recommendations on vector-borne diseases, which are currently included in some disease-specific chapters. The Commission agreed that the chapters should address the entire process of international trade, including measures taken at origin (from the farm/premises of origin) through to the final destination in the exporting country, in transit, and on arrival (import inspection and possible on-farm post-arrival follow-up). The Commission discussed a Member comment expressing its interests in examining the pathway of waste from international airports and seaports, and agreed that this pathway, as others as the *ad hoc* Group might find relevant, should be considered by the *ad hoc* Group.

The Code Commission agreed that the scope should not be limited to only animal health measures (which the current chapters focus on) but should address all measures relevant to trade in the *Terrestrial Code*.

The Code Commission also considered a Member request to develop recommendations on the management of quarantine stations, and agreed to request that this be considered by the *ad hoc* Group.

d) Scope of commodities to be covered

Noting that some of the current four chapters have insufficient provisions for some animal products, the Code Commission agreed that all commodities, as defined in the Glossary, should be addressed in the revised chapter(s), but that in doing so it is important to avoid duplication of, or discrepancies with, recommendations described in other chapters, such as Chapter 5.8. International transfer and laboratory containment of animal pathogenic agents and Chapter 5.9. Quarantine measures applicable to non-human primates.

e) To what extent risks posed by illegal or informal cross-border movement of commercial and non-commercial commodities should be considered

At its September 2021 meeting, the Code Commission agreed that risks posed by illegal or informal cross-border movement of commercial and non-commercial animal products, including products delivered via postal or courier services, should be considered during the revision because these pathways are a major cause of transboundary animal disease spread. The Commission considered that the inclusion of recommendations to address these risk pathways might be challenging but that could be addressed by developing general provisions to encourage collaborative activities with all relevant authorities and

stakeholders such as environment, customs and law enforcement authorities. The Commission agreed to request that this idea be discussed by the *ad hoc* Group.

f) Scope of diseases to be covered

The Code Commission agreed that the diseases which should be covered in the revised chapters should address not only animal infectious diseases but also zoonotic diseases and non-infectious diseases, as the OIE list of diseases already includes some and is always evolving.

The Code Commission strongly encouraged Members to submit comments on these points regarding the revision of Chapters 5.4. to 5.7. The Commission emphasised that Members active participation at this early stage of the work is important as it will ensure the development of revised chapters that are relevant for Members.

The Code Commission requested that the OIE Secretariat develop draft terms of reference which the Commission will consider, together with Member comments received, at its next meeting.

3.1.4. Responsible and prudent use of antimicrobial agents in veterinary medicine (Chapter 6.10.)

Background

At its February 2019 meeting, the Code Commission agreed to include in its work programme a review of Chapter 6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine, in response to comments received and in light of the revision of some definitions in Chapter 6.9. Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals, adopted in 2018. The Commission had requested the advice of the OIE Working Group on Antimicrobial Resistance. The Working Group considered this request at its 2019 meeting and recommended that a review of Chapter 6.10. not be undertaken until the relevant work by the Codex Alimentarius Task Force on Antimicrobial Resistance (TFAMR) had been progressed, in order to avoid inconsistencies.

At its February 2021 meeting, the Code Commission was informed that the Codex Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005) had been adopted at Step 5 by the Codex Alimentarius Commission (CAC) in November 2020. Noting the progress being made by Codex, the Commission requested that the Working Group review Chapter 6.10. and identify the main areas of the chapter that would benefit from an update, and the best way to progress this work, including whether to expand the scope to non-food producing animals.

At its September 2021 meeting, the Code Commission considered the Working Group's recommendations from its April 2021 meeting and requested that the Working Group progress work and also consider whether other AMR chapters (Chapters 6.7., 6.8., 6.9., or 6.11.) would need to be amended as a consequence of the proposed revision of Chapter 6.10.

Update

The Code Commission was informed that the revised Codex Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance had been adopted at the CAC in November 2021.

The Code Commission was also informed that the Working Group, at its October 2021 meeting, had agreed to work intersessionally to draft a revised Chapter 6.10. prior to its next meeting in April 2022, and that it would discuss the need to amend other AMR chapters at its April 2022 meeting. The Working Group report would be then considered by the Code Commission at its next meeting of September 2022.

The Code Commission commended the Working Group for its work and encouraged Members to read the Working Group's October 2021 report.

3.1.5. Transport of animals by land, sea and air (Chapters 7.2., 7.3. and 7.4.)

The OIE Secretariat provided an update on the work envisaged to revise the animal transport chapters. The Code Commission considered this work in light of other work in its work programme currently in progress, and agreed to postpone the start of this work until 2023 in order to prioritise the work on animal welfare chapters already underway.

3.1.6. Infection with foot and mouth disease virus (Chapter 8.8.)

Comments were received Australia, Brazil, Canada, China (People's Rep. of), Japan, Mexico, New Zealand, South Africa, Thailand, the UK, USA, the AU-IBAR, the EU and the IMS.

Background

A revised Chapter 8.8. Infection with foot and mouth disease virus has been circulated four times for comments, the last time in the Code Commission's September 2021 report.

At its September 2021 meeting, the Code Commission also considered recommendations of the joint Code Commission-Scientific Commission Taskforce, which met between June and July 2021 and a proposal from the OIE Secretariat on the harmonisation of requirements for official recognition and maintenance of free status and endorsement and maintenance of official control programmes to align with recently adopted revisions in Chapters 14.7. Infection with peste des petits ruminants virus and 15.2. Infection with classical swine fever virus.

Discussion

The Code Commission considered the comments received. It discussed selected comments and identified those comments which required further advice from experts, including the Laboratories Commission and the Scientific Commission. The Code Commission agreed to defer the review of the remaining comments until its September 2022 meeting so it could consider all comments together with expert inputs.

The Code Commission considered draft provisions for the importation of meat of susceptible captive wild animals and wild animals, and meat of domestic small ruminants and pigs from countries or zones infected with FMD virus, where an OIE endorsed official control programme for FMD exists, which were developed by the *ad hoc* Group on Foot and mouth disease virus (June 2020) and endorsed by the Scientific Commission at its February 2021 meeting. The Code Commission highlighted that at its February 2017 meeting, it had noted that the lack of recommendations for the importation of game meat or small ruminants from infected countries or zones was a significant gap in the chapter and requested that work be done to develop these provisions. The Code Commission considered that the proposed text by the *ad hoc* Group required further work, including its re-scoping, and agreed that between its February 2022 and September 2022 meetings, appointed members from the Commission will review the recommendations of the *ad hoc* Group to prepare a proposal to be considered by the Commission for incorporation into the revised chapter.

3.1.7. Infection with Mycobacterium tuberculosis complex (Chapter 8.11.)

Background

In May 2017, amendments to Chapter 8.11. Infection with *Mycobacterium tuberculosis* complex were adopted, which included *Mycobacterium bovis, M. caprae* and *M. tuberculosis.*

At its February 2019 meeting, the Code Commission considered the opinion of a panel of experts which had been requested to provide advice as to whether *M. caprae* and *M. tuberculosis* fulfil the listing criteria in Chapter 1.2. of the *Terrestrial Code*, and together with the opinion of the Scientific Commission, agreed that *M. tuberculosis* did not meet the

criteria for inclusion in Article 1.3.1. Consequently, the Code Commission proposed to delete *M. tuberculosis* from the chapter and to replace '*Mycobacterium tuberculosis* complex' with '*Mycobacterium bovis* and *M. caprae*' and circulated this for comment in its February 2019 report.

At its September 2019 meeting, the Code Commission together with the Scientific Commission considered the request submitted by some Members that *M. tuberculosis* be reinstated as part of the *Mycobacterium tuberculosis* complex. The two Commissions agreed that available scientific evidence regarding the transmission of *M. tuberculosis* from animals to humans or animal to animal does not provide a clear position, and therefore the delisting of *M. tuberculosis* will be deferred until new scientific information is available.

At its September 2020 meeting, the Code Commission noted that a Member had provided, as invited, some scientific evidence regarding transmission of *M. tuberculosis*, which was referred to the Scientific Commission for consideration.

The OIE Secretariat updated the Code Commission that in September 2020, the *ad hoc* Group on alternative strategies for the control and elimination of *Mycobacterium tuberculosis* complex infection in livestock had been requested to consider the new scientific evidence submitted and whether *M. tuberculosis* still met the listing criteria in Chapter 1.2.

At its February 2021 meeting, the Scientific Commission considered the *ad hoc* Group assessment that *M. tuberculosis* meets the listing criteria, and confirmed its previous position that it should not be delisted. The Scientific Commission also considered the *ad hoc* Group proposal to revise the case definition in Chapter 8.11. recommending that notification should not be restricted to *M. bovis*, *M. caprae*, and *M. tuberculosis sensu stricto*, but rather be expanded to include infections by any members of the M. tuberculosis complex (except vaccine strains) as described in the *Terrestrial Manual*, taking into account that none of the prescribed routine diagnostic techniques are able to differentiate amongst individual members of the M. tuberculosis complex.

At its February 2021 meeting, the OIE Secretariat informed the Code Commission that the Laboratories Commission is reviewing Chapter 3.4.6. Bovine tuberculosis of the *Terrestrial Manual* to broaden its scope to mammalian tuberculosis, including specific information on cattle, goats and camelids and recommended diagnostic tests, with a proposal for adoption in May 2022.

Discussion

The Code Commission considered the input from the Scientific Commission and the *ad hoc* Group, as well as the progress of work of the Laboratories Commission relevant for this chapter.

The Code Commission concurred with the Scientific Commission and agreed to retain *M. tuberculosis* in Chapter 8.11. as part of the M. tuberculosis complex. The Commission decided to withdraw the proposal to delete *M. tuberculosis* from the chapter.

The Code Commission did not agree with the proposal of the experts to expand the scope of Chapter 8.11. to include any mammalian tuberculosis agents. The Commission explained that the case definition in a disease-specific chapter should refer only to listed pathogenic agents, based on fulfilment of all the criteria in Chapter 1.2., including an assessment of the impact of the pathogenic agent, hence the fact that routine diagnostic tests do not allow for species differentiation was not sufficient. The Code Commission noted that molecular and genomic techniques are available to differentiate amongst the species and, although these could be cost prohibitive to some Members, this is also the case for some other OIE listed diseases.

In addition, given that the proposed revisions of Chapter 3.4.6. Bovine tuberculosis of the *Terrestrial Manual* will include recommendations on diagnostic tests for goats and camelids, the Code Commission proposed that the review of Chapter 8.11. also include measures for camelids and goats, as well as recommendations for the relevant pathogenic agents, host

species concerned, determination of animal health status, recovery of free status, surveillance and provisions on trade. The Commission also considered a comment requesting how to interpret point 1(b) of Article 8.11.4. The Commission acknowledged that the current text might be variously interpreted and agreed to address this point as part of the review, which is in its work plan.

3.1.8. West Nile fever

Background

In February 2021, after the implementation of the SOP for the process to be followed for assessing a pathogenic agent of terrestrial animals against the criteria in Chapter 1.2., the Code Commission had requested that the Scientific Commission undertake the assessments for pathogenic agents previously identified for assessment in the Code Commission's work programme (i.e. West Nile fever and paratuberculosis).

An expert consultation was conducted between February and September 2021 to undertake the assessment. At its September 2021 meeting, the Scientific Commission reviewed the collated expert consultation report and noted the opinion of the Laboratories Commission on criterion 3 of Article 1.2.2. The Scientific Commission agreed with the experts who were unanimous in their assessments against all criteria, and concluded that West Nile fever meets the criteria for listing.

Discussion

The Code Commission considered the opinion of the experts, the Laboratories Commission and the Scientific Commission, and agreed that West Nile fever meets the criteria for listing. Consequently, the Commission decided not to remove this disease from the OIE List at this stage.

3.1.9. Trichomonosis (Chapter 11.11.)

Comments were received from Canada, New Zealand, the USA, the AU-IBAR and the EU.

Background

At its September 2020 meeting, the Code Commission revised Articles 11.11.2., 11.11.3. and 11.11.4., to align with recommendations in Chapter 3.4.15. on 'Trichomonosis' of the *Terrestrial Manual*. The proposed amendments were based on the advice of the Reference Laboratory experts for Trichomonosis. The revised articles were circulated for comment twice, the last time in the Commission's September 2021 report.

In preparation for this meeting, the OIE Secretariat contacted two experts who had drafted the *Terrestrial Manual* chapter for advice on some comments received.

Discussion

The Code Commission considered comments received and discussed how to address several issues in these articles as well as comments requesting to review other aspects of these articles and the need to develop additional content for this chapter.

The Code Commission reminded Members that this revision was undertaken to align with recommendations in Chapter 3.4.15. on 'Trichomonosis' of the *Terrestrial Manual* and that the Commission, at its September 2021 meeting, had agreed not to expand the scope of the revision beyond this alignment.

However, after further discussion, and noting that Chapter 11.11. has not been revised since its first adoption in 1968, the Code Commission agreed to add to its work programme a broader revision of the chapter that would be subjected to prioritisation. Given this decision, the Commission agreed to postpone further work on this chapter.

The Code Commission also noted that the development of a case definition for Trichomonosis is on the list for the joint work with the Scientific Commission, and that it should be completed before commencing this work.

3.1.10. Scrapie (Chapter 14.8.)

Background

At its February 2021 meeting, the Code Commission noted that a revision of Chapter 14.8. Scrapie had been on its work programme for many years and therefore it needed to progress this work. The Commission requested the OIE Secretariat to collate all pending issues and to report back to the Commission so it could consider a way forward.

At its September 2021 meeting, the Code Commission reviewed the background document prepared by the Secretariat and recalled the previous discussions between the Code Commission and the Scientific Commission on this chapter, and noted that the main pending issue was the assessment of scrapie against the listing criteria in accordance with Chapter 1.2., as reported in the September 2014 report of the Scientific Commission. The Code Commission agreed that this assessment should be done before starting any work on Chapter 14.8. The Commission requested that an assessment be presented to the OIE DDG ISS in line with the Standard Operating Procedure for listing decisions for pathogenic agents of terrestrial animals.

Update

The OIE Secretariat informed the Code Commission that the OIE DDG ISS had considered the request for an assessment and concluded that an assessment was not justified. The Code Commission noted that the Scientific Commission was informed of this decision at its February 2022 meeting, and encouraged Members to refer to that report for more information.

3.1.11. Pet food as safe commodities

Background

At its February 2018 meeting, the Code Commission considered a request from the Global Alliance of Pet Food Associations (GAPFA) to recommence work on the development of provisions for pet food and appreciated the offer by GAPFA to gather scientific information that could inform the assessment of pet food products against the criteria on the safety of commodities in accordance with Chapter 2.2. Criteria applied by the OIE for assessing the safety of commodities.

During 2020 and 2021, GAPFA submitted to the OIE Secretariat summaries of scientific information it had collected to demonstrate that pet food could be considered as a safe commodity in a number of disease-specific chapters.

At its February 2021 meeting, the Code Commission noted that GAPFA had provided a description of two specific pet food (‘extruded dry pet food’ and ‘wet pet food in hermetically sealed containers’) as well as the internationally standardised processes and treatments involved in their production in order to facilitate the assessment of these commodities as safe commodities.

Update

The Code Commission thanked GAPFA for providing the OIE with its comprehensive analyses and processing information.

With regard to ‘extruded dry pet food’, the Code Commission reminded Members that, in discussing the recent revision of Chapter 10.4. Infection with high pathogenicity avian influenza, extruded dry pet food had been included as a safe commodity in Article 10.4.2.

With regard to ‘wet pet food in hermetically sealed containers’, the Code Commission reminded Members that ‘heat-treated meat products in a hermetically sealed container with an F0 value of 3 or above’, was included as a safe commodity in a number of disease-specific chapters. The Commission agreed that ‘heat-treated meat products in a hermetically sealed container with an F0 value of 3 or above’ was equivalent to ‘wet pet food in hermetically sealed containers’ and that ’heat-treated meat products in a hermetically sealed container with an F0 value of 3 or above’ would be the term used in the *Terrestrial Code*.

The Code Commission also agreed to consider the inclusion of ‘extruded dry pet food’ and ‘heat-treated meat products in a hermetically sealed container with an F0 value of 3 or above’ in the list of safe commodities each time a disease-specific chapter is reviewed.

3.1.12. Honey – definitions and provisions on importation

Background

At its February 2020 meeting, the Code Commission, in response to a comment, requested the OIE Secretariat to assess the need for a review of the recommendations regarding importation of honey, including the need for a Glossary definition for ‘honey’.

Update

The OIE Secretariat presented to the Code Commission a summary as to where and how honey is addressed in the bee disease-specific chapters (Chapters 9.1. to 9.6.) of the *Terrestrial Code*. Based on these considerations, and the fact that the common definition of honey is relevant for the use of the term in the *Terrestrial Code*, the Commission agreed that there were no gaps in the current recommendations for the importation of honey and consequently agreed not to initiate any further work on this matter.

3.1.13. Framework for the *Terrestrial Code* standards

Background

At its February 2021 meeting, the Code Commission agreed with the OIE Secretariat’s proposal to develop a framework for the development of disease-specific chapters of the *Terrestrial Code* that would define the structure and content of these chapters. The Commission agreed that having a consistent approach and harmonization (whenever feasible) to the structure and content of disease-specific chapters would improve the ability of Members to navigate the *Terrestrial Code*, especially given the importance of cross-referencing between chapters. The Commission also noted that this work would serve as a useful guide to ensure a consistent approach when undertaking work on the development or revision of a chapter.

Between the September 2021 and February 2022 meetings, the Code Commission members worked electronically with the OIE Secretariat to progress this work.

Update

The Code Commission noted that the framework has been shared with the Scientific Commission for its inputs and that it would consider this item at its next meeting in September 2022.

3.1.14. Standardised procedure to manage commodities’ names and their listing as “safe commodities” in *Terrestrial Code* chapters

Background

In September 2021, the Commission discussed a proposal from the OIE Secretariat on a draft Standard Operating Procedure (SOP) to be applied internally when assessing commodities for inclusion in the lists of safe commodities in disease-specific chapters of the *Terrestrial Code*.

The Code Commission agreed with the proposed approach and requested the OIE Secretariat to continue developing the SOP and report back at its next meeting.

Discussion

The Code Commission considered the proposal of the OIE Secretariat to include in the SOP the standardisation of names of commodities across the *Terrestrial Code*. The Commission agreed with the proposed approach, considered the SOP as final and requested to be informed if any points in the SOP requires further amendments.

3.2. New proposals / requests

The Code Commission considered the following proposals or requests for new developments or revisions of standards in the *Terrestrial Code*.

3.2.1. Request from Wildlife Working Group

Background

At its September 2021 meeting, the Code Commission discussed a proposal from the OIE Working Group on Wildlife (WGW) to develop a new chapter in the *Terrestrial Code* on surveillance of disease of wildlife (as reported in its December 2020 report). The Commission discussed this proposal and highlighted that wildlife disease surveillance is currently addressed in a number of chapters as part of surveillance system requirements (notably in Chapter 1.4. Animal Health Surveillance), and therefore a new chapter dedicated to surveillance of wildlife health could result in duplication or inconsistencies.

The Code Commission provided detailed feedback on the proposal and requested the Working Group on Wildlife to consider its comments.

Update

The Code Commission was informed that a consultant was being employed to analyse existing OIE Standards and OIE Guidelines to identify gaps and needs with regards to wildlife disease surveillance and health management, and to propose how to best address these needs. The WGW will review the consultant's report and consider the feedback from the Commission at its next meeting in June 2022, to further clarify the purpose and work.

The OIE Secretariat also presented a brief update on the work of the OIE *ad hoc* Group on Reducing the risk of disease spillover events at markets selling wildlife and along the wildlife supply chain, which had met several times in 2022. The Commission favourably noted the work of this *ad hoc* Group, and acknowledged that it could also provide valuable inputs to identify future work needed in the *Terrestrial Code* on these matters.

The Code Commission was informed that the OIE and CITES (Convention on International Trade in Endangered Species of Wild Fauna and Flora) have agreed to continue collaborating on wildlife trade and health in alignment with their respective mandates, and that both organisations have agreed to update their Cooperation Agreement.

The Code Commission requested the OIE Secretariat to report back at its next meeting on these two issues so that it can continue discussing the possible inclusion of new items related to wildlife health management in its work programme.

3.2.2. Chapter 7.Z. Animal welfare and laying hen production systems

Dr Arroyo, OIE DDG-ISS, informed the Code Commission that some Members and Partner Organisations had requested that the OIE continue the work on the proposed Chapter 7.Z. Animal welfare and laying hen production systems, given the importance of having a OIE standard that addresses the animal welfare of this production system. Dr Arroyo acknowledged that there is not a clear path forward at this moment because of divergent views regarding this

standard but that the OIE would explore the possibility to discuss with Members to define a way forward.

3.2.3. Rabbit haemorrhagic disease (Chapter 13.2.)

At its February 2021 meeting, the Code Commission noted recent outbreaks of rabbit haemorrhagic disease (RHD) in North America and West Africa and requested the opinion of the Scientific Commission as to whether the global epidemiological situation for RHD justifies the revision of Chapter 13.2.

The Code Commission noted that Chapter 13.2. Rabbit haemorrhagic disease of the *Terrestrial Code* was first adopted in 1992, and the most recent update was adopted in 2012, and that the corresponding *Terrestrial Manual* Chapter 3.7.2. Rabbit haemorrhagic disease was first adopted in 1991 as Viral haemorrhagic disease of rabbits, and the most recent update was adopted in 2021.

At this meeting, the Code Commission was informed that the Scientific Commission had recommended that Chapter 13.2. be revised as the current chapter does not contain a case definition nor provisions for recovery of free status. The Code Commission was also informed that the Scientific Commission had recommended that RHD be added to the next tranche of the case definition work.

Further, the OIE Secretariat informed the Code Commission that OIE Headquarters had recently received a question from a Member about the detection of RHD in imported rabbits that are sero-positive without any clinical signs, and whether they should be regarded as a case of the disease and the possible impact this may have on a country's free status.

Based on these considerations, the Code Commission agreed to add the revision of Chapter 13.2. Rabbit haemorrhagic disease to its work programme and requested the Scientific Commission to progress work on the development of a case definition in line with the *Terrestrial Manual*. The Code Commission reported that it would then revise Article 13.2.1. to include a case definition and develop a new article on recovery of free status and, if necessary, revise other articles, as appropriate.

3.2.4. Nipah virus encephalitis and Bovine viral diarrhoea

The OIE Secretariat informed the Code Commission that in September 2021 the Scientific Commission had endorsed draft case definitions developed by subject matter experts for Nipah virus encephalitis (NVE) and bovine viral diarrhoea (BVD) and that these had been placed on the OIE website to support Members to notify, when relevant. These case definitions were presented to the Code Commission to consider including the development of respective disease-specific chapters for the *Terrestrial Code* on its work programme.

The Code Commission highlighted that NVE and BVD are OIE listed diseases that are included in Chapter 1.3. but do not have a corresponding disease-specific chapter. The Commission noted that the development of disease-specific chapters for these two diseases have not been included in its work programme, as no request had been received. The Commission noted that the *Terrestrial Manual* includes chapters for both diseases: Chapter 3.1.14. Nipah and Hendra virus disease and Chapter 3.4.7. Bovine viral diarrhoea.

The Code Commission noted that the case definition endorsed by the Scientific Commission describes NVE as an infection of horses, pigs, dogs, and cats (animal hosts), while NVE is listed in Chapter 1.3. as a swine disease. The Code Commission noted that the case definition endorsed by the Scientific Commission describes BVD as an infection of suids, ruminants, and camelids, while in Chapter 1.3. it is listed as a cattle disease. The Commission also noted that the experts also proposed to change the name of 'Bovine viral Diarrhoea' to 'Infection with Bovine pestiviruses', which would imply the inclusion of a broader range of pathogenic agents.

The Code Commission reviewed the experts' reports and the Scientific Commission's opinion and considered that the rationale provided for these two case definitions was not sufficient to support commencing the work on these two OIE listed diseases. The Commission highlighted that if a change was to be proposed for either of these pathogenic agents or its hosts, that this should be done through an assessment against the criteria for the inclusion of diseases,

infections, and infestations in the OIE list in accordance with Chapter 1.2. The Commission requested the assessments be undertaken before including these items in its work programme.

The Code Commission also highlighted that the information contained in the general provisions of each disease-specific chapter of the *Terrestrial Code* to define a disease, the epidemiologically significant hosts, and its occurrence should be based on information in the corresponding chapter in the *Terrestrial Manual*. Noting that the *Terrestrial Manual* chapter for NVE is currently under revision and a revised chapter will be proposed for adoption in May 2022, and that the *Terrestrial Manual* chapter for BVD will be reviewed in the 2022/2023 review cycle, the Commission recommended that the assessments be undertaken in coordination with the update of the *Terrestrial Manual*, to ensure alignment and efficiency of the process.

The Code Commission requested the OIE Secretariat to report back on this proposal after the assessment against the criteria has been completed and both revised *Terrestrial Manual* chapters have been adopted.

Regarding the decision to place the case definitions on the OIE website to support Members notification, the Code Commission considered that these case definitions introduce a contradiction with the current OIE standards, which would impose an undue additional administrative burden on Members. Consequently, it requested the definitions to be removed from the OIE website until the work described above has been completed.

3.2.5. Request to clarify Glossary definition for Poultry

The Code Commission considered a comment received regarding the Glossary definition for 'poultry'. The Member asked for clarification as to whether populations of pet birds kept and bred for selling to hobby holdings, backyard holdings or pet bird owners were specifically addressed in the current definition, and whether this category of bird population may be considered 'poultry', depending on the epidemiological situation of each event.

The Code Commission agreed to include this in its work programme and discussed specific amendments to address the issue (See item 4.1 of this report).

3.2.6. Listed diseases names: Discrepancies between Chapter 1.3. and disease-specific chapters

The OIE Secretariat informed the Code Commission of some discrepancies observed between the names of some listed diseases in Chapter 1.3. and those in corresponding disease-specific chapters (i.e. Chapter 12.6., Chapter 12.8. and Chapter 10.5.).

The Code Commission discussed this issue and agreed to amend the disease names in the list to align with those in the disease-specific chapters as they had been adopted more recently. The Commission decided to propose the revised articles for adoption at the 89th General Session in May 2022, given that these amendments were of editorial nature (refer to Part A of this report).

The Code Commission also acknowledged the discrepancy between the listed disease 'haemorrhagic septicaemia' in Article 1.3.2. and Chapter 11.7. Haemorrhagic septicaemia (*Pasteurella multocida* serotypes 6:b and 6:e), but decided not to amend Article 1.3.2. for the time being, considering that the Scientific Commission was considering the possibility of expanding the scope of this disease to include other strains of *Pasteurella multocida*.

3.2.7. OIE Standard Operating Procedure for determining if a disease should be considered as an emerging disease

The Code Commission acknowledged a comment expressing concerns on the OIE Standard Operating Procedure for determining if a disease should be considered as an emerging disease, and requesting the Commission to consider whether amendments to the *Terrestrial Code* should be considered to address them. The Commission noted that similar comments received from some Members in the 88th OIE General Session were discussed at the meeting held by the Bureaus of the Code Commission and the Scientific Commission, together with possible ways to address them (See item 2.1 of this report).

The Code Commission noted that SOPs are documents developed by OIE Headquarters to guide internal processes and should be based on the standards, when relevant. The Commission considered there was no need to review the current standards related to Member's notification obligations and agreed not to include new work in this regard in its work programme at this stage.

3.3. Prioritisation of items in the Code Commission's work programme

Based on a number of considerations and the progress of the different topics since its last meeting, as well as the specific discussions during this meeting, the Code Commission discussed the prioritisation of ongoing and future work, and agreed to include and remove the items as presented below:

Added items:

- Revision of the Glossary definition for 'poultry'
- Revision of the use of the terms 'meat-and-bone meal' and 'greaves'
- Revision of selected disease names in Chapter 1.3. (to ensure alignment with disease-specific chapters)
- Revision of Chapter 13.2., Rabbit haemorrhagic disease

Removed items

- Delisting of Mycobacterium tuberculosis (in Mycobacterium tuberculosis complex)
- Delisting of West Nile fever

The Code Commission updated its work programme accordingly.

In addition to the recent changes introduced in the way the work programme is presented as an annex to provide more information to Members, the Code Commission wished to highlight the introduction of a new system to inform Members on the prioritisation of work on its programme. The Commission explained that the inclusion of an item in the work programme means there is an agreement of the Commission on the need to undertake a certain work, but does not mean that the work would be immediately initiated. This decision as to when to commence each work depends on an overall consideration of priorities, on the progress of ongoing work and on the resources available. This aims at providing a guide to plan and organise the work of the Commission and the OIE Secretariat, as well as to improve Members awareness of the progress of the different topics. The prioritisation order used in the work programme reflects the level of priority agreed by the Commission, through the rigorous assessment of each item, in terms of its necessity and urgency. Although the Commission reviews its work programme at each meeting and re-considers the prioritisation of items according to changes in necessity and urgency (e.g. in response to Member requests, changes in the epidemiological situation of diseases, etc.), the prioritisation reference would not be significantly modified frequently, because it implies underlying mid-to-long term work planning, in order to make the work of the Commission more efficient and predictable. The Commission also highlighted that the prioritisation order used in its work programme is not necessarily parallel to the progress of each work, which actually depends on the complexity of the specific tasks to be undertaken.

The updated work programme is presented as **Annex 3**, for Member comments.

EU comment

The EU fully support the revised work programme of the Code Commission and its prioritisation. Comments are inserted in the text of Annex 3.

4. Texts circulated for comments

4.1. Glossary definition for Poultry

The Code Commission agreed to consider a comment regarding the Glossary definition for 'poultry'. The Member asked for clarification as to whether populations of pet birds kept and bred for selling to hobby holdings, backyard holdings or pet bird owners were specifically addressed in the current definition, and whether this category of population may be considered 'poultry', depending on the epidemiological situation of each event.

The Code Commission noted that the definition for 'poultry' clearly states that pet birds are excluded, provided that they have no direct or indirect contact with poultry or poultry facilities, and therefore are not considered to be 'poultry' in the context of the *Terrestrial Code*. On the other hand, the Commission acknowledged that it is not clear whether populations of pet birds for breeding or selling are included. To address these concerns, the Commission agreed to amend the definition of 'poultry' by adding 'and companionship' at the end of the list of categories of birds excluded from the definition of poultry, and deleting 'as well as pet birds'.

The revised Glossary definition for 'poultry' is presented as part of **Annex 4**, for Member comments.

EU comment

The EU supports the proposed changes to the glossary definition of poultry.

4.2 Slaughter of animals (Chapter 7.5.)

Background

In February 2018, the Code Commission agreed to revise Chapter 7.5. Slaughter of animals and Chapter 7.6. Killing of animals for disease control purposes and requested that an *ad hoc* Group be convened to undertake this work. The *ad hoc* Group has been convened on several occasions since February 2018 to undertake a comprehensive review, starting with Chapter 7.5., and to consider feedback subsequently received. A revised chapter was circulated for comments in the Commission's February 2021 report.

At its September 2021 meeting, the Code Commission requested that the *ad hoc* Group be reconvened to consider comments and amend the revised chapter as appropriate, as well as the revised Glossary definitions for *death*, *euthanasia*, *slaughter* and *stunning* used in Chapter 7.5. and for *distress*, *pain* and *suffering* used in Chapter7.8. that have been proposed to be moved to the Glossary.

Discussion

The Code Commission considered the *ad hoc* Group's 2021 report including the revised Chapter 7.5. and the revised Glossary definitions for *death*, *euthanasia*, *slaughter*, *stunning*, *distress*, *pain* and *suffering*.

The Code Commission acknowledged and commended the very extensive work undertaken by the *ad hoc* Group to address the significant number of comments received and the detailed rationale that was provided in the *ad hoc* Group's report. The Commission encouraged Members to refer to the December 2021 *ad hoc* Group's report for the rationale for changes made in the revised chapter.

The Code Commission reviewed the revised Chapter 7.5 and did not make any additional amendments. The Commission agreed that the current structure based on how animals arrive at the slaughterhouse, i.e. 'free moving animal' and 'animals arriving in containers' was a good approach, and asked the *ad hoc* Group to clarify the species included in these two categories for the next revision of the text.

The revised Chapter 7.5. Animal welfare during slaughter, is presented as **Annex 6**, for Member comments.

EU comment

The EU thanks the OIE for having taken into consideration the majority of our comments submitted previously.

We welcome and in general support the adoption of this revised chapter.

Comments are inserted in the text of Annex 6.

The revised Glossary definitions for *death*, *euthanasia*, *slaughter* and *stunning* and for *distress*, *pain* and *suffering* are presented as part of **Annex 4**, for Member comments

EU comment

The EU welcomes and in general supports the proposed changes to the glossary. Comments are inserted in the text of Annex 4b.

4.3. Articles 8.14.6bis. and 8.14.7. of Chapter 8.14. Infection with rabies virus

Comments were received from Argentina, Australia, Canada, China (People's Rep. of), Chinese Taipei, New Caledonia, New Zealand, Norway, Switzerland, UK, Zimbabwe, the AU-IBAR and the EU.

Background

Following adoption of revised Chapter 8.14. Infection with rabies virus, in May 2019, the Code Commission, at its September 2019 meeting, acknowledged there was still some work pending on the chapter given that the priority had been to adopt amendments to support the global strategic plan to end human deaths from dog-mediated rabies by 2030 (i.e. the "Zero by 30 initiative"). The pending issues concerned the provisions for vaccination, testing and the shipment of animals (in Article 8.14.7.) and the provisions on risk mitigation measures for the importation of mammals outside of the Orders *Carnivora* and *Chiroptera* (in Articles 8.14.8. and 8.14.10.). In addition, the Code Commission and the Scientific Commission had agreed to seek advice on the relevance of including specific provisions on the control of rabies in wildlife, including oral vaccination.

At its September 2020 meeting, the Code Commission considered the advice of the October 2019 report of the *ad hoc* Group on Rabies and the Scientific Commission and agreed to add a new Article 8.14.6bis. on recommendations for the importation of dogs from countries or zones infected with rabies virus, and amend the title of Article 8.14.7. These texts were circulated for comments in the Code Commission's September 2020 report.

At its February 2021 meeting, the Code Commission considered the comments received on the new Article 8.14.6bis and the revised Article 8.14.7. and requested the advice of the Scientific Commission for some comments. The Code Commission also considered the recommendation of the Scientific Commission (September 2018) to amend Articles 8.14.8. to 8.14.10. and agreed not to work on this until new scientific evidence become available.

The Scientific Commission requested additional advice from the OIE Rabies Reference Laboratory network (RABLAB), which was sought between February and September 2021 and endorsed by the Scientific Commission at its September 2021 meeting (refer to its September 2021 report).

Discussion

The Code Commission considered the comments received on the new Article 8.14.6bis. and the revised Article 8.14.7., together with the advice from the RABLAB and the Scientific Commission. The Code Commission also considered a draft new article developed by the RABLAB experts providing provisions for the control of rabies in wildlife. The Commission also considered a new draft article on recommendations for implementing a rabies vaccination programme for dogs that had been endorsed by the Scientific Commission.

General comments

The Code Commission did not agree with comments not supporting the proposed reduction in the waiting period from 3 months to 30 days for the importation of vaccinated dogs from infected countries or zones, as no new scientific evidence was provided. The Code Commission, in agreement

with the Scientific Commission and the RABLAB experts, agreed that there was a strong scientific basis for the proposed amendment, and encouraged Members to refer to the recently published peer-reviewed scientific paper (Smith *et al.*, 2021). The Code Commission also encouraged Members to refer to the Scientific Commission's September 2021 report for more details.

The Code Commission reminded Members that if they wished to apply more stringent sanitary measures than those recommended in the *Terrestrial Code* they should conduct an import risk analysis in accordance with Chapter 2.1.

Article 8.14.6bis.

In point 2, in response to comments expressing practical concerns regarding unique numbering of dogs, the Code Commission replaced 'number' by 'code', to allow for different methods of individual identification to be applied.

In point 3(b), the Code Commission did not agree with a comment to amend the text so that isolation could be carried out outside a quarantine station (e.g. in an owner's home). The Commission noted that it would be difficult for a Veterinary Authority to certify isolation under such conditions. It also highlighted that this requirement on isolation is applicable only for unvaccinated dogs.

Article 8.14.7.

Comments received on this article were addressed by the responses provided to general comments and comments on Article 8.14.6bis.

New Article 8.14.11bis. Recommendations for dog-mediated rabies vaccination programmes

The Code Commission considered the draft new Article 8.14.11bis. and proposed further amendments.

While the Code Commission acknowledged that it is not standard practice to include provisions for the implementation of disease-specific vaccination programmes in the *Terrestrial Code*, the Commission agreed with its inclusion given that rabies vaccination programmes in dogs are essential for controlling and eradicating this disease of major public health concern. The Commission reminded Members that, in general, horizontal chapters of the *Terrestrial Code* provide the standards to be implemented by Members to define their national policies and programmes.

Recommendations for the control of rabies in wildlife

The Code Commission considered a proposed draft new article providing recommendations for an official control programme for wildlife-mediated rabies, which had been developed by the RABLAB with the support of wildlife rabies experts and endorsed by the Scientific Commission at its September 2021 meeting. The Commission considered that the proposed text, although scientifically sound, was too detailed and prescriptive for the *Terrestrial Code*, and that the establishment of an official control programme for wildlife-mediated rabies was not currently in the scope of the chapter. The Commission requested that the OIE Secretariat continue working on the proposal in collaboration with an appointed member of the Commission in preparation for its next meeting.

The revised new Article 8.14.6bis., the revised Article 8.14.7., and the new Article 8.14.11bis. are presented as **Annex 7**, for Member comments.

EU comment

The EU thanks the OIE for the latest version of the revised Chapter 8.14. on Infection with rabies virus and welcomes the new amendments introduced in the draft to address dog-mediated rabies vaccination programmes, as a complement to the recommendations of Chapter 7.7. on Dog population management.

However, the EU cannot support the proposed changes to this chapter as presented.

Comments are inserted in the text of Annex 7.

4.4. Infection with Rift Valley fever virus (Chapter 8.15.)

Comments were received from China (People's Rep. of), New Caledonia, New Zealand, Switzerland, Thailand, USA, the AU-IBAR and the EU.

Background

Proposed amendments to Chapter 8.15. Infection with Rift Valley fever virus were first circulated in the Code Commission's February 2019 report to clarify the obligations of Members to notify when there is an epidemic of Rift Valley fever (RVF) in an endemic country or zone. The revised chapter was circulated for the third time for comments in the Commission's February 2020 meeting report.

At its September 2020 meeting, the Code Commission acknowledged comments received and agreed to defer its discussion until it had received the Scientific Commission's opinion on selected comments.

At its February 2021 meeting, the Code Commission was informed that an *ad hoc* Group on Rift Valley fever would be convened to develop guidance for RVF surveillance during epidemic and inter-epidemic periods, as well as the consideration of other issues such as the development of provisions for the recovery of freedom in a country or zone previously free from RVF.

The *ad hoc* Group meeting was convened in June 2021 and the report was endorsed by the Scientific Commission at its September 2021 meeting.

Discussion

The Code Commission discussed the Member comments previously received, together with the report of the OIE *ad hoc* Group on Rift Valley fever. The Commission commended the *ad hoc* Group on its work and encouraged Members to refer to the report for detailed information.

General comments

The Code Commission agreed with the *ad hoc* Group to replace 'epizootic' with 'epidemic' throughout the chapter. Noting that consideration of the use of terms: enzootic/endemic/epizootic/epidemic is on its work programme, the Commission requested that the OIE Secretariat review the use of these terms in the *Terrestrial Code* and report back at its September 2022 meeting.

Article 8.15.1.

In point 2(c), the Code Commission noted the *ad hoc* Group's conclusion that it was not feasible to propose a uniform international standard for the establishment of a baseline for low RVFV activity, as there were too many epidemiological variations and different ecological situations between countries. In line with this, the Commission agreed to amend the definition for 'inter-epidemic period' and explained that the intention of the amendment was to encourage Members to notify RVF outbreaks to the OIE, emphasising that the transition from an inter-epidemic period to an epidemic complies with point 1(e) of Article 1.1.3. of Chapter 1.1. Notification of diseases and provision of epidemiological information. The Commission reminded Members that one of the objectives of the revision of this chapter was to address situations where infections in human are often notified to the World Health Organization without corresponding notifications of animal cases to the OIE, despite epidemiological knowledge that the occurrence of indigenous infections in humans would imply important ongoing virus circulation in the animal population. The Commission highlighted that some proposed amendments to Article 8.15.11. (see below) would help Members identify epidemics.

In points 4(b) and 4(c), in response to a comment that the inclusion of 'including in a human' would create an inconsistency with the case definition (i.e. RVF is defined as an infection of susceptible animals, not of humans) as described in point 3, the Code Commission proposed amendments to improve clarity.

Article 8.15.3.

In point 2(b), the Code Commission agreed with the *ad hoc* Group to amend this point given the importance to promote interactions with, and collaboration between, human and animal health sectors from the perspective of One Health approach. In the same point, in response to a comment to replace 'indigenous' with 'endogenous', the Commission explained that replacement of 'human cases' with 'infections in human' would also address this comment.

With regard to the request that the *ad hoc* Group develop an article on recovery of disease freedom, the Code Commission noted that the *ad hoc* Group had concluded that 'there was insufficient scientific evidence to support adding an article on fast recovery of freedom to the chapter', and agreed not to add an article.

Deleted Article 8.15.5.

In response to a comment to clarify the rationale of the deletion, the Code Commission explained that there was no difference in terms of RVF status between a 'country or zone infected with RVFV during the inter-epidemic period' and a 'country or zone infected with RVFV during an epidemic' (i.e. both are infected with RVFV).

Article 8.15.5. (renumbered)

In point 3, in response to a comment that insect-proof netting is just one of the protective measures and other effective measures should also be covered, the Code Commission proposed an amendment, taking into consideration relevant recommendations in other vector-borne disease chapters.

In the same point, the Code Commission agreed with the *ad hoc* Group to delete 'during dawn or dusk, or overnight', as RVFV vectors also show daylight activity.

In point 4, the Code Commission proposed to replace 'low risk' with 'lower risk' as it considered 'low' in absolute was not possible to assess and Members could only identify relatively lower risk ports and transport routes.

Article 8.15.6. (renumbered)

The Code Commission agreed with the *ad hoc* Group to delete point 2(c) to be consistent with proposed amendments to Article 8.15.7.

Article 8.15.7. and deleted Article 8.15.8. (renumbered)

The Code Commission agreed with the *ad hoc* Group that the risk mitigation measures for the importation of susceptible animals from a country or zone infected with RVFV should be in a single article, and should take into consideration the possible presence of epidemic areas even in inter-epidemic period. The Commission highlighted, in agreement with the *ad hoc* Group, that it was important to include in this article the requirement that animals did not originate from an epidemic area.

In point 3 of Article 8.15.7., the Code Commission did not agree with a comment to add 'RVFV' before 'epidemic area' as it was considered clear as written, since 'epidemic area' is defined in Article 8.15.1.

Article 8.15.8. (renumbered)

In point 2(a), the Code Commission did not agree with a comment to add 'in accordance with manufacturer recommendations' at the end as it considered it was clear as written and reminded Members that 'vaccination' is defined in the Glossary and includes a reference to manufacturer recommendations. Noting that there were some variations in this recommendation throughout the *Terrestrial Code*, the Commission requested the OIE Secretariat to review the variations and report back its findings at a future meeting.

The Code Commission did not agree with a comment to add a point requiring a DIVA test and noted that the *ad hoc* Group had reported that there was no evidence that the semen and embryos derived from seropositive animals following recovery from infection are still infective.

Article 8.15.9. (renumbered)

The Code Commission agreed with a comment to merge Article 8.15.10. with Article 8.15.10bis. and acknowledged that the addition of Article 8.15.10bis. had caused confusion.

In point 1(c), the Code Commission did not agree with a comment to replace 'submitted to maturation' with 'maturated' as it considered that certification can only address the process applied (i.e. treatment or test).

Article 8.15.10. (renumbered)

The Code Commission noted that the *ad hoc* Group had agreed that the current provisions are sufficient to ensure that milk and milk products are safe and indicated that any new information on the risk of RVFV in milk and milk products would be considered should this become available. Thus, the Commission agreed not to make amendments on this point.

Article 8.15.11. (renumbered)

The Code Commission noted that the *ad hoc* Group had proposed to revise Article 8.15.12., in response to a request that more detailed guidance for surveillance of RVF be developed. The Commission discussed the text proposed by the *ad hoc* Group and made some amendments for clarity and consistency with other chapters in the *Terrestrial Code*. In response to a comment querying why examining mosquito vectors for RVFV is not effective, the Commission encouraged Members to refer to the *ad hoc* Group's report.

The revised Chapter 8.15. Infection with Rift Valley fever virus is presented as **Annex 8**, for Member comments.

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. A comment is inserted in the text of Annex 8.

4.5. Infection with Newcastle disease virus (Article 10.9.1.)

In response to a comment, the Code Commission proposed to remove the definition of poultry from Chapter 10.9. Infection with Newcastle disease virus as reported in its September 2020 meeting report. While acknowledging that this chapter may benefit from other updates, the Commission wished to note that the current revision will be limited to addressing this change for consistency, and other aspects of the chapter will be considered for prioritisation in the future.

The revised Article 10.9.1. of Chapter 10.9. Infection with Newcastle disease virus is presented as **Annex 9**, for Member comments.

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter.

A comment is inserted in the text of Annex 9.

4.6 Contagious equine metritis (Chapter 12.2.)

Comments were received from Canada, Japan, New Caledonia, New Zealand, Switzerland, the UK and the EU.

Background

At its February 2019 meeting, the Code Commission agreed to amend Chapter 12.2. Contagious equine metritis to include requirements for the temporary movement of horses and it agreed that given this chapter had not been reviewed for some time, a comprehensive revision should be undertaken. The Commission requested that experts be convened to undertake this work.

An electronic expert consultation was conducted between September and December 2019 and its report, including the draft revised chapter, was endorsed by the Scientific Commission at its February 2020 meeting (refer to the Scientific Commission's February 2020 report). At its September 2020 meeting, the Code Commission considered the revised Chapter 12.2., made additional amendments, and circulated the revised chapter for comments.

At its February 2021 meeting, the Code Commission reviewed the comments received and agreed to defer its discussion until its September 2021 meeting, given that time constraints did not allow for a detailed discussion.

The OIE Secretariat sought the advice of the Scientific Commission and the Laboratories Commission on selected comments. The Scientific Commission asked for additional expert advice which was discussed at its September 2021 meeting.

Discussion

The Code Commission considered the comments received and the advice sought from the Scientific Commission, the Laboratories Commission and the subject-matter experts.

General comments

The Code Commission did not agree with a comment that the chapter should include specific provisions for country or zone freedom and requirements for maintenance of freedom after an incursion, as a requirement for a disease to be an OIE listed disease. The Commission highlighted that the criteria for listing were applied to assess diseases to determine if they should be included in the OIE List, and the existence of specific provisions to define freedom was not a prerequisite. The Code Commission considered the opinion of the Scientific Commission, but agreed with the experts' advice

that, due to the epidemiologic characteristics of the disease (i.e. stallions are asymptomatic carriers thus has life-long infective period), provisions for country or zone freedom from *T. equigenitalis* in the chapter would have to include such extremely strict requirements that it would be logistically and economically difficult to achieve for most Members. The Commission highlighted that the experts also emphasised that infection with *T. equigenitalis* is a concern mainly to the horse industry and that the disease is manageable at a smaller scale, i.e. at the establishment level. Hence, such recommendations would not present significant added value to manage the risks of the disease for most Members. The Commission agreed not to include such provisions in the chapter at this stage and reminded Members that the lack of provisions in a disease-specific chapter does not impede Members from implementing measures, e.g. to declare freedom at country or zone level, as long as they were in accordance with relevant horizontal chapters of the *Terrestrial Code*.

Article 12.2.1.

In the first paragraph, the Code Commission did not agree with a comment to add 'skin and' before 'mucous membrane', as it considered that the current text was clear as written and in line with the provisions in Chapter 3.6.2. Contagious equine metritis of the *Terrestrial Manual*.

In the same paragraph, the Code Commission did not agree with a comment to replace 'asymptomatic' with 'subclinical' as it considered that the meaning is different and, in this case, it refers to animals that show no sign at all of the disease. The Commission did not agree to replace 'male horses' with 'stallions' here, and explained that this paragraph aims to define the disease and, in this context, it should refer to all epidemiologically significant hosts, while 'stallions' refers to a specific practical context, which is considered in this chapter for risk management purposes.

In response to comments, the Code Commission agreed to delete 'antigen or' in point 2 and replace 'mare' with 'horse' and delete the whole point 3. The Commission agreed with comments that there

was no need to provide differentiated alternatives for ‘males’ and ‘mares’, and noted that according to the *Terrestrial Manual* chapter, antigenic tests were only considered suitable in very limited circumstances. The Commission highlighted that the only test recommended in the *Terrestrial Manual* chapter without limitations was the isolation of the pathogenic agent, and hence agreed to maintain the reference to ‘showing clinical or pathological signs consistent with infection with *T. equigenitalis* or epidemiologically linked to a confirmed or suspected case of infection with *T. equigenitalis*’ in point 2. The Commission noted that this would mean that if genetic material specific to *T. equigenitalis* was identified in a horse without clinical signs, pathological lesions or epidemiological links to a case, it should be confirmed by isolation.

In the fourth paragraph, the Code Commission agreed to delete the words ‘and vaccines’, given that there are no standards for vaccines in the *Terrestrial Manual* for this disease.

In the penultimate paragraph, the Code Commission deleted ‘for competition or cultural events excluding breeding,’ to harmonise the text with the other revised chapters where the meaning of ‘temporary importation’ of horses was described. The Commission noted that this text should be focused only on the conditions for the movement (i.e. short period, under special conditions ensured by the Veterinary Authorities, and defined conditions for exit) and not on the specific activities to be performed by the imported horses, and explained that the specific conditions to manage the risks for each disease were detailed in a specific article (in this case in Article 12.2.5.). The Commission also agreed that listing ‘exclusions' would not be accurate as it would be impossible to list all activities, and some terms such as ‘cultural events’ could be ambiguous.

Article 12.2.3.

In the title, the Code Commission agreed to replace ‘Establishment’ with ‘Herd’, as the status applies to the animals and not the premises. The Commission applied this change throughout the chapter, as relevant.

In point 2(c), the Code Commission agreed with a comment to amend the text for clarity.

In point 2(d), the Code Commission agreed with a comment to specify that stored semen should be subjected to a test for detection of genetic material of *T. equigenitalis*, as stored semen may contain antibiotics that could interfere with culture.

In point 4(b), the Code Commission did not agree with a comment that there was a discrepancy between the periods for recovery of freedom and the periods to qualify or maintain freedom. The Code Commission agreed with the opinion of the Scientific Commission that for other diseases the time frame for initial qualification and recovery of status are different.

In point 4(c), the Code Commission agreed with a comment from the Scientific Commission to amend the text to state that all stored semen from infected horses in the herd should be tested as the pathogenic agent would not be equally distributed in different aliquots.

Article 12.2.4.

In points 2(a) and 2(b)(i), the Code Commission agreed with a comment to amend the text for clarity.

In point 2(b)(ii), the Code Commission, in agreement with the opinion of the Laboratories Commission, proposed amendments to clarify that horses should be subjected to *T. equigenitalis* identification tests (culture for *T. equigenitalis* or molecular testing) with negative results.

In the same point, the Code Commission, in agreement with the Laboratories Commission, did not agree with a comment to replace ‘horses’ with ‘the donor stallion’ because this article covers both stallions and mares.

In the same point, the Code Commission agreed with a comment to include measures to manage the risks of infection during the period between testing and shipping, and added ‘have not been mated after sampling’ at the end of the paragraph.

Article 12.2.5.

In points 1(a) and 2, the Code Commission proposed to replace 'animals' with 'horses', for consistency with other text.

In point 2(a), the Code Commission agreed with a comment to delete 'stallion' after 'teaser' as not only stallions may be used as teasers (e.g. teaser mares to test stallions).

In point 2(b), the Code Commission agreed with a comment to amend the text to consider any practice that may represent a transmission risk other than genital examinations. The Commission noted that other practices might represent a risk, and that risks associated with genital examination could be managed if performed under adequate conditions by veterinarians.

Article 12.2.6.

In point 3(b), the Code Commission amended the text to align with amendments made in point 2 (b) of Article 12.2.4.

In point 3(b), the Code Commission agreed with a comment and amended the text in line with amendments made it point 2(b)(ii), to include measures to manage the risks of infection during the period between testing and shipping.

Article 12.2.8.

In the third paragraph, the Code Commission agreed with a comment to replace 'farmers' with 'owners, breeders' for clarity.

In point 4, in the first paragraph, the Code Commission did not agree with a comment to amend the text to provide further details on serological surveillance, as it considered that the text was clear as written and noted that further details are presented in the corresponding chapter of the *Terrestrial Manual*. The Commission agreed to replace 'culture' by 'agent identification' to align with the *Terrestrial Manual*.

The revised Chapter 12.2. Contagious equine metritis is presented as **Annex 10**, for Member comments.

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter.

Comments are inserted in the text of Annex 10.

4.7. Infection with equine influenza virus (Chapter 12.6.)

Comments were received from Argentina, Australia, China (People's Rep. of), Switzerland and the EU.

Background

At its February 2019 meeting, the Code Commission had proposed amendments to Article 12.6.6. of Chapter 12.6. Infection with equine influenza virus based on the outcomes of work by an OIE Reference Laboratory for equine influenza regarding equine influenza vaccination protocols prior to shipment of horses. The revised article has been circulated four times for comments, the last time in the Commission's September 2020 report.

At its February 2021 meeting, the Code Commission reviewed the comments received on the revised Article 12.6.6 and a proposal to revise the case definition which had been endorsed by the Scientific Commission at its February 2021 meeting. The Commission noted that the proposed amendments to the case definition would require consequential changes in other articles and agreed to defer its discussion until its September 2021 meeting.

At its September 2021 meeting, the Code Commission was not able to discuss this item due to time constraints.

Discussion

The Code Commission considered the comments received on the revised Article 12.6.6. circulated in its September 2020 report. In addition, it reviewed the entire chapter and proposed further amendments to include the proposed case definition endorsed by the Scientific Commission in February 2021 and align the text as necessary. The Code Commission also included recommendations for the temporary importation of horses in line with the new approach taken for the proposed revised Chapter 12.2. Contagious equine metritis and Chapter 12.7. Equine piroplasmosis.

Article 12.6.1.

In the first paragraph, the Code Commission added 'captive wild equids' to the definition of the disease as proposed in the case definition endorsed by the Scientific Commission, and added 'with equine influenza virus (EIV), i.e. influenza A viruses (H7N7 and H3N8)' to provide further precision regarding the pathogenic agent which was also in line with Chapter 3.6.7. Equine influenza (infection with equine influenza virus) of the *Terrestrial Manual*.

After the second paragraph, the Code Commission added new text to define the occurrence of infection with EIV.

The Code Commission deleted the paragraph defining 'isolation', as it considered that this concept would be covered by the changes made to address the new recommendations for the temporary importation of horses.

The Code Commission included a new paragraph describing the meaning of 'a temporary importation', in line with the text included in the proposed revised Chapter 12.2. and Chapter 12.7.

Article 12.6.2.

The Code Commission amended the text to ensure consistency with similar articles in the *Terrestrial Code*.

The Code Commission added 'meat and meat products from equids that have been slaughtered in a slaughterhouse/abattoir and have been subjected to ante- and post-mortem inspections with favourable results', as a 'safe commodity' and consequently proposed to delete Article 12.6.8.

Article 12.6.3.

In point 3), the Code Commission added 'and captive wild' after 'domestic', to align with the proposed changes in Article 12.6.1.

Article 12.6.4.

In the second paragraph, the Code Commission added 'captive wild' after 'domestic', to align with the proposed changes in Article 12.6.1.

In the third paragraph, the Code Commission added 'and be in accordance with relevant requirements and principles described in Chapter 4.4. and Chapter 4.5.' for consistency with other chapters in the *Terrestrial Code*.

New Article 12.6.4 bis.

The Code Commission proposed to add a new Article 12.6.4. 'Recovery of free status' for consistency with other chapters in the *Terrestrial Code*. The text was based on the recommendations contained in the last paragraph of current Article 12.6.4., which was consequently proposed to be deleted.

Article 12.6.5.

The Code Commission amended the title of the article to align with the proposed changes in Article 12.6.1.

Article 12.6.6.

The Code Commission amended the title to align with the proposed changes in Article 12.6.1. and for consistency with other chapters of the *Terrestrial Code*.

In point 3 (b), the Code Commission did not agree with a comment to remove the point, as it considered that there was sufficient data supporting the proposal which had also been endorsed by the Laboratories Commission and the Scientific Commission as noted in previous reports. The Commission reminded Members that countries wanting to apply more stringent requirements can do so if the requirements were justified by an import risk analysis conducted in accordance with Chapter 2.1.

In the last paragraph, the Code Commission did not agree with a comment requesting to replace the test on samples collected on two occasions by a single testing. The Commission noted that the specifications presented in the 'Table 1' of *Terrestrial Manual* chapter do not provide sufficient assurance. Additionally, in consultation with the Laboratories Commission, the Commission considered that the specific additional recommendations in the last paragraph would only be justified for rare cases, i.e. countries that are free from infection with EIV or are undertaking an eradication programme.

Article 12.6.7.

The Code Commission amended the title and text of the article from 'Recommendations for the importation of domestic equids which will be kept in isolation' to 'Recommendations for the temporary importation of domestic horses' to align with the approach being proposed in the revised Chapter 12.2. Contagious equine metritis and Chapter 12.7. Equine piroplasmosis.

The Code Commission also amended the content of the article to align with the new approach.

Article 12.6.8.

The Code Commission agreed to delete this article as a consequence of the proposal to include 'meat and meat products from animals that have been slaughtered in a slaughterhouse/abattoir and have been subjected to ante- and post-mortem inspections with favourable results' in the list of safe commodities in Article 12.6.2.

The revised Chapter 12.6. Infection with equine influenza virus is presented as **Annex 11**, for Member comments.

EU comment

The EU in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 11.

4.8. Equine piroplasmosis (Chapter 12.7.)

Comments were received from Australia, Canada, New Caledonia, New Zealand, Switzerland, Thailand, the USA, the AU-IBAR and the EU.

Background

At its February 2019 meeting, the Code Commission agreed to amend Chapter 12.7. Equine piroplasmosis to include requirements for the temporary movement of horses and it agreed that given this chapter had not been reviewed for some time, a comprehensive revision should be undertaken. The Commission requested that experts be convened to undertake this work.

An electronic expert consultation was conducted between September and December 2019 and its report, including the draft revised chapter, was endorsed by the Scientific Commission at its February 2020 meeting (refer to the Scientific Commission's February 2020 report).

At its September 2020 meeting, the Code Commission considered the revised draft Chapter 12.7., made additional amendments, and circulated the revised chapter for comments.

At its February 2021 meeting, the Code Commission reviewed the comments received and agreed to defer its discussion until its September 2021 meeting, given that time constraints did not allow for a detailed discussion.

The OIE Secretariat requested the advice of the Scientific Commission and the Laboratories Commission on selected comments. The Scientific Commission asked for additional expert advice and an OIE expert group on equine piroplasmosis and contagious equine metritis was consulted electronically between May and July 2021, the outcome of which was discussed in its September 2021 meeting.

Discussion

The Code Commission considered the comments received and the advice from the Scientific Commission, the Laboratories Commission and subject-matter experts.

Title of the chapter

The Code Commission did not agree with a comment to replace 'and' by 'or' for alignment with the text of Article 12.7.1. The Commission explained that the title of the chapter corresponds to the name of the OIE listed disease (whose reference in Chapter 1.3. will be updated when the chapter is proposed for adoption) and it covers both pathogenic agents *Theileria equi* and *Babesia caballi.* The text in Article 12.7.1., on the other hand, uses the word 'or' as it refers to animals infected with either of the two pathogenic agents.

Article 12.7.1.

In the first paragraph, in response to comments and a proposal from the expert group, the Code Commission agreed to amend the text for clarity and to expressly include asymptomatic infections in the scope of the chapter.

In the second paragraph, the Code Commission agreed with a comment to amend the text for clarity.

In the third paragraph, the Code Commission, in agreement with the opinion of the Scientific Commission and the expert group, did not agree with comments to include the genera *Ixodes* and *Haemaphysalis* as vectors for equine piroplasmosis. The Commission noted that these genera were not included in the *Terrestrial Manual* chapter. This response applies to similar comments received for other articles.

In response to a comment seeking clarification on the use of terms 'competent vectors' and 'competent tick vectors' in the *Terrestrial Code* and requesting the inclusion of genera or species of competent vectors in all relevant chapters, the Code Commission referred Members to the rationale presented in its February 2021 report where it had agreed that there was no added value in defining these terms for the purpose of the *Terrestrial Code*, and that it would not be feasible to provide a detailed and up-to-date list of competent vectors for every disease and that such a list may also vary by region. The Commission highlighted that the detailed provisions for surveillance of arthropod vectors is provided in Chapter 1.5. Surveillance for arthropod vectors of animal diseases.

In points 1, 2, and 3, in response to comments, and in agreement with the opinion of the Scientific Commission and the expert group, the Code Commission amended the text to take account of asymptomatic carriers.

In point 3, the Code Commission, in agreement with the Scientific Commission, did not agree with a comment that the text should include a requirement for a treatment history in presence of antibodies

specific to *T. equi* or *B. caballi*. The Commission did not consider that this was relevant for this text, as the detection of antibodies specific to *T. equi* or *B. caballi* in a sample from an equid, if associated with clinical or pathological signs consistent with infection with *T. equi* or *B. caballi* or epidemiologically linked to a confirmed or suspected case, should be considered a 'case' irrespective of whether the animal had been treated or not.

In the eighth paragraph, the Code Commission did not agree with a comment to specify different incubation periods for *T. equi* and *B. caballi*, as it considered that it was not relevant in this context, nor possible to differentiate the two diseases based on their clinical signs, and for safety reasons the longest incubation period should be retained.

In the penultimate paragraph, the Code Commission agreed to amend the text to harmonise it with the other revised chapters where the meaning of 'temporary importation' of horses was provided. The Commission noted that this text is aimed at clarifying that only horses destined to be exported at the end of the stay, for which the conditions are required to leave the country or zone, should be defined in advance. The fact that some of these animals may eventually be slaughtered as an exceptional outcome in the importing country does not have to be explicitly stated in the definition.

In the last paragraph, the Code Commission agreed with a comment to delete 'and vaccines', noting that there are no standards for vaccines for equine piroplasmosis described in the *Terrestrial Manual*.

Article 12.7.3.

In point 1, the Code Commission, in agreement with the Scientific Commission and the expert group, did not agree with comments requesting that countries should be able to claim historical freedom from *T. equi* or *B. caballi.* It considered that the vast majority of cases of infection with either pathogenic agent was asymptomatic and therefore it would not comply with provisions in Article 1.4.6.

In point 2(a)(i), the Code Commission, in agreement with the Scientific Commission and the expert group, did not agree with a comment requesting to reduce 'six years' to 'two years' for consistency with the provisions for theileriosis. The Commission encouraged Members to refer to the rationale provided by the experts in its 2021 report.

In points 2(a)(i) and (ii), the Code Commission did not agree with a comment to distinguish equine piroplasmosis due to iatrogenic transmission, illegal movement from endemic countries, and/or importation of illegal blood products, as it considered it was not relevant in the context of defining freedom.

In points 2(a)(ii) and (iii), in response to comments, and in agreement with the Scientific Commission and the expert group, the Code Commission amended the text to reflect that demonstration of the absence of competent vectors alone is not sufficient, and vector surveillance should be always carried out in conjunction with animal surveillance. The Commission encouraged Members to refer to the rationale provided by the experts in its 2021 report. This response also applied to other related comments.

In point 2(b), in response to comments, and in agreement with the Scientific Commission and the expert group, the Code Commission amended the text to clarify that the animal health status of a country or zone should not be affected by the temporary importation of seropositive or infective horses, provided the provisions in Article 12.7.6. are met and an epidemiological investigation has been conducted with favourable results ensuring that there had been no transmission of disease. The Commission encouraged Members to refer to the rationale provided by the expert group in its 2021 report.

In point 2(c), the Code Commission agreed with a comment to simplify the text and refer only to the specific provisions in Article 12.7.9.

Article 12.7.5.

In point 2(b)(i), in response to comments, and in agreement with the Laboratories Commission, the Code Commission amended the text to clarify that the requirement refers to both serological tests and

agent identification tests with molecular techniques for the detection of *T. equi* and *B. caballi*. The Commission noted that this recommendation is aligned with the respective *Terrestrial Manual* chapter and with previous opinions of the Laboratories Commission as reported in its February 2020 report.

In point 2(b)(ii), the Code Commission agreed with a comment to remove 'and throughout the transport to the destination country or zone', as it considered it was not possible for exporting countries to certify in advance about the compliance during transport to a destination country.

In the same point, the Code Commission agreed with comments to cover the risk of iatrogenic transmission of disease and amended the text in line with changes proposed elsewhere in the chapter.

The Code Commission did not agree with a comment to add a new point 2(b)(iii) requiring that the animals had never returned a positive test for *T. equi* and *B. caballi*, as it considered it was not proportionate to risk and would not be possible for exporting countries to certify.

Article 12.7.6.

In point 2(b), the Code Commission did not agree with a comment to include additional details on the need to identify ticks found during examinations, as it considered that was implicit in the current text.

The Code Commission did not agree with a comment to add a point 2(d) requiring that temporarily imported horses should be isolated from other horses during their stay in the country, as this was already covered by point 2(a).

Article 12.7.8.

In points 3 and 3(b), the Code Commission agreed with a comment to amend the text to clarify that the requirements apply to equids.

Article 12.7.9.

In the first paragraph of point 1, the Code Commission agreed with a comment to remove unnecessary details.

In the second paragraph of point 1, the Code Commission did not agree with a comment to remove the requirement for an active programme of surveillance of equids to detect evidence of infection with

T. equi and *B. caballi* because it was not justifiable for countries with a naive population. In agreement with the Scientific Commission and the expert group, the Code Commission considered that due to the high percentage of subclinical cases, even in a naive population, an active animal surveillance programme would be essential to detect infection with *T. equi* and *B. caballi*.

In point 3, in the first paragraph, the Code Commission did not agree with a comment to replace 'detect evidence' by 'demonstrate the absence', as the current wording was consistent with the requirements for country or zone freedom in Article 12.7.3.

The revised Chapter 12.7. Equine piroplasmosis is presented as **Annex 12**, for Member comments.

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 12.

4.9. New chapter on infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* (Chapter 14.X.) and revision of Article 1.3.3.

Comments were received from Canada, New Caledonia, South Africa, Switzerland, Thailand, AU-IBAR and the EU (on text circulated in the Code Commission's September 2017 report).

Background

A new Chapter 14.X. Infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* was first circulated for comment in the Code Commission's September 2017 report, following the work of the *ad hoc* Group on Theileriosis that met in February 2017. At the Code Commission's February 2018 meeting, in response to some comments which questioned the listing of some *Theileria* spp., the Commission agreed to seek expert advice regarding listing and to put on hold its review of comments received.

At its September 2019 meeting, the Code Commission was informed that *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* had been assessed by experts against the criteria for listing in accordance with Chapter 1.2. and were found to meet the criteria for listing (refer to Annex 19 of February 2019 report of the Scientific Commission).

At its September 2020 meeting, the Code Commission noted that there were no recommendations for diagnostic tests for these pathogenic agents in the *Terrestrial Manual*. As this would impact the case definition and appropriate diagnostic tests to be recommended in the chapter, the Code Commission agreed not to progress this work until the Laboratories Commission progressed the work on a new chapter for the *Terrestrial Manual*.

At its September 2021 meeting, the Code Commission was informed that the Laboratories Commission would circulate for comments a new chapter for the *Terrestrial Manual* that would be proposed for adoption in May 2022.

Discussion

Article 1.3.3.

Given that *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* met the criteria for listing in accordance with Chapter 1.2. and that the revised Article 1.3.2. (to replace 'Theileriosis' with 'infection with *Theileria annulata*, *Theileria orientalis* and *Theileria parva*') will be proposed for adoption in May 2022, the Code Commission agreed that 'Infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi*' should be added to Article 1.3.3.

New Chapter 14.X.

Given that a new chapter for the *Terrestrial Manual* would be proposed for adoption in May 2022, the Code Commission agreed to consider comments received on the proposed new Chapter 14.X. circulated in its September 2017 report.

Given the similarity in structure and contents between the new chapter and the revised Chapter 11.10. Infection with *Theileria annulata*, *T. orientalis* and *T. parva* which will be proposed for adoption in May 2022 (see Annex XVI of Part A of the report), the Code Commission proposed to amend Chapter 14.X. where appropriate to align with the revised Chapter 11.10. In this regard, the Commission encouraged Members to refer to the relevant discussions noted in its September 2020 and 2021 meeting reports for the detailed rationale of these amendments.

General comment on Chapter 14.X.

In response to comments to include all *Theileria* spp. in one chapter, the Code Commission reiterated that given the host specificity of different *Theileria* spp. and the respective epidemiological roles of host species, maintaining separate chapters was justified and would be easier for Members to understand the relevant recommendations for control and management of *Theileria* in different species, including surveillance. The Commission emphasised that this approach would also facilitate trade, by clarifying necessary information that should be certified on international veterinary certificates.

Article 14.X.1.

In the last paragraph, given that no commercial vaccines are available for infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* (in accordance with the draft Chapter 3.8.13. in the *Terrestrial Manual* which was circulated in September 2021 report of the Laboratories Commission), the Code Commission agreed to delete the reference to vaccines.

Article 14.X.5.

In point 4, given that all the serological tests are rated as 'not appropriate' method for individual animal freedom from infection prior to movement in the Table 1 of the draft Chapter 3.8.13. in the *Terrestrial Manual*, the Code Commission proposed to delete the reference to serological tests.

The revised Chapter 14.X. and the revised Article 1.3.3. are presented as **Annex 13** and **Annex 5** respectively, for Member comments.

EU comment

The EU thanks the OIE and in general supports the proposed new chapter 14.X. and the proposed changes to Article 1.3.3.

Comments are inserted in the text of Annex 13.

4.10. Middle East Respiratory Syndrome Coronavirus (MERS-CoV) (New Chapter X.X.)

Background

In September 2019 the Code Commission added the development of a disease-specific chapter for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) to its work programme and agreed to start work pending adoption of 'infection of dromedary camels with Middle East respiratory syndrome coronavirus' as an OIE listed disease in Chapter 1.3. and the adoption of a new corresponding chapter in the *Terrestrial Manual*.

An OIE *ad hoc* Group on MERS-CoV met in 2019 to develop the *Terrestrial Manual* chapter as well as a case definition which had been placed on the OIE website to facilitate notification by Members.

The inclusion of 'Infection of dromedary camels with Middle East respiratory syndrome coronavirus' in the OIE list of diseases (Article 1.3.9. of the *Terrestrial Code*) and the new Chapter 3.5.2., Middle East respiratory syndrome (infection of dromedary camels with MERS-CoV), in the *Terrestrial Manual* were adopted in May 2021.

Discussion

The Code Commission discussed the development of a new *Terrestrial Code* chapter for infection of dromedary camels with Middle East respiratory syndrome coronavirus and considered the recommendations of the *ad hoc* Group on MERS-CoV as well as the newly adopted *Terrestrial Manual* chapter.

The Code Commission noted that several studies had confirmed dromedary camels (*Camelus dromedarius*) as the natural host and zoonotic source of MERS-CoV infection in humans, and that MERS-CoV has been associated with mild upper respiratory signs in dromedary camels. The Commission agreed that while the impact of MERS-CoV on animal health is very low, human infections have a significant public health impact. The Commission noted that other species might be susceptible to infection with MERS-CoV, but their epidemiological significance has not yet been demonstrated.

The Code Commission reminded Members that the Code Commission and the Scientific Commission had agreed that there was a need to better understand the transmission dynamics in animal populations and mechanisms of zoonotic transmission to humans before recommending risk mitigation measures in the *Terrestrial Code*.

Based on these considerations, the Code Commission agreed to develop a new chapter for infection with MERS-CoV, but only include at this stage general provisions, including the definition of its occurrence.

The Code Commission noted that once this new chapter is adopted, possibly with changes accompanying the commenting process, the case definition on the OIE website should be either aligned or removed.

The Code Commission noted that, as the new chapter defines the susceptible hosts for the disease (i.e. human and dromedary camels), these should no longer be specified in the name of the listed disease in Article 1.3.9., and should be amended to 'Infection with Middle East Respiratory Syndrome Coronavirus (MERS-CoV)'. The Commission agreed to propose the amendments to Article 1.3.9. only after the proposed new chapter had undergone a few rounds of comments.

The proposed new Chapter X.X. Infection with Middle East respiratory syndrome coronavirus is presented as **Annex 14**, for Member comments.

EU comment

The EU thanks the OIE and in general supports this proposed new chapter. Comments are inserted in the text of Annex 14.

4.11. Leishmaniosis (New Chapter X.Y.)

Background

Leishmaniosis was included as an OIE listed disease in Article 1.3.9. of the *Terrestrial Code*.

In September 2020, the Code Commission agreed to include the development of a new disease-specific chapter on Leishmaniosis in its work plan, pending the review of amendments that were being proposed to the corresponding chapter in the *Terrestrial Manual*.

In February 2021, the Scientific Commission endorsed a case definition developed by subject matter experts which has been placed on the OIE website to support Members' notification. A revised Chapter 3.1.11. Leishmaniosis of the *Terrestrial Manual* was adopted in 2021.

Discussion

The Code Commission discussed the development of a new *Terrestrial Code* chapter for Leishmaniosis and considered the experts' recommendations and the newly adopted *Terrestrial Manual* chapter.

Based on these considerations, the Code Commission developed a new chapter on 'Infection with *Leishmania* spp.' but only included general provisions, including the definition of its occurrence.

The Code Commission noted that once this new chapter is adopted, possibly with changes accompanying the commenting process, the case definition on the OIE website should be either aligned or removed.

The Code Commission agreed that the name of the listed disease in Article 1.3.9, Leishmaniosis, should be amended to 'Infection with *Leishmania* spp.' in line with the current conventions for the *Terrestrial Code*. The Commission agreed to propose the amendments to Article 1.3.9. only after the proposed new chapter had undergone a few rounds of comments.

The proposed new Chapter X.Y. Infection with *Leishmania* spp. is presented as **Annex 15**, for Member comments.

EU comment

The EU thanks the OIE and in general supports this proposed new chapter. Comments are inserted in the text of Annex 15.

5. Other updates

5.1. OIE Observatory

The OIE Secretariat updated the Code Commission on the progress of the OIE Observatory. The Commission was informed that the OIE Observatory will evaluate the implementation of the OIE standards. To this end, information already collected by the OIE as well as data available from other international organisations such as the World Trade Organization will be used. The findings of the

Observatory will then be published in a format that maintains confidentiality of the involved parties. A pilot phase was undertaken during 2020 and 2021 to identify internal and external sources of information that could be used to monitor the implementation of OIE standards. The OIE Secretariat informed that, to this end, several prototypes were developed focusing on specific animal diseases and on horizontal topics, which allowed for the identification of possible indicators to develop an implementation review report that is planned to be published at the end of 2022. It also noted that the pilot phase had also informed on OIE processes that could be improved to better address Members' needs. Lastly, the OIE Secretariat informed that the OIE Panorama had published a special edition about the Observatory in December 2021, which provided further detail.

The Code Commission thanked the information and highlighted that the OIE Observatory would be a valuable source of information for the Commission to identify Members' needs, to continue ensuring that the *Terrestrial Code* standards remain fit for purpose to the realities of Members, and for the prioritisation of the Commission's work.

Moreover, the Code Commission noted that the OIE Observatory would provide important material to design targeted capacity-building activities for Members around the implementation of OIE standards.

The Code Commission expressed its commitment to further develop the liaison with this OIE programme and requested the OIE Secretariat to update the Commission on the progress and publication of the implementation review report to discuss further actions.

5.2. OIE Digitalisation strategy

The OIE Secretariat updated the Code Commission on the implementation of the OIE Digitalisation strategy. The OIE Secretariat informed the Commission that digital transformation was identified as a key objective in the OIE 7th Strategic Plan as an important response to trends and challenges arising from societal expectations for modern and agile organisations and the increasing application of information technologies to support regulation for animal health, animal welfare and veterinary public health.

The Secretariat noted that through Strategic Objective two 'Data governance' of the 7th Strategic Plan, the OIE would put in place a strong digital culture and drive innovative data use to transform how it worked digitally. It also highlighted that the OIE aims to leverage the opportunities that information technology offers to achieve concrete results to enhance the services it provides to its Members.

The Code Commission was briefed on different initiatives within the OIE Digitalisation strategy that would impact the way the Commission works. The Commission noted that some of the digitalisation work would require identifying key referential data within the *Terrestrial Code*, which are critical for its use and standardising this information in terms of structure, format, and content. The Commission noted that such key referential data would involve items such as: name of diseases, susceptible species, pathogenic agents, definition of occurrence/case, names of commodities including safe commodities, sanitary measures, among others, and highlighted that the Commission has already started working towards these goals with initiatives such as the development of a "Framework for Terrestrial Code standards" (see item 3.1.13. of this report) and the "SOP on Commodities" (see item 3.1.14. of this report), or the joint work with the Scientific Commission to develop missing or incomplete "case definitions".

The Code Commission expressed its commitment to contributing to the digital transformation of the OIE and stressed its availability to support the initiatives aiming at improving the access, use and understanding of the OIE standards and their setting process. The Commission requested the OIE Secretariat to be kept informed and involved, as relevant, of the progress of the relevant initiatives under the OIE digitalisation strategy.

5.3. GBADs - Global Burden of Animal Diseases

The OIE Secretariat informed the Code Commission that the Global Burden of Animal Diseases programme continues to work on developing methodologies to assess the economic burden of animal diseases in a systematic manner including net loss of production, expenditure and trade impacts. It noted that focus was on refining methodologies to enable initial estimates of disease burden, gathering data,

and advancing work on the prototype of an analytics platform. The Commission was briefed on the methodology development, initial outcomes from country case studies to test methods developed, recent publications, and activities of the first OIE Collaborating Centre of Animal Health. In addition, the Commission was also informed that an *ad hoc* Group on Economics of Animal Health would be established to undertake a high-level review of the proposed GBADs methodologies for estimating the Global Burden of Animal Health and develop a guideline, based on the review, for OIE Members with the intention of proposing a draft OIE standards on the matter.

The Code Commission expressed its interest in the matter and noted that the outcomes of this programme would be a critical input for the Commission to identify and prioritise this possible future work, and to understand not only the impact of diseases but also the impact of the measures provided in the *Terrestrial Code*. The Commission highlighted that the outcomes of GBADs should be a valuable tool to facilitate its considerations on the need and value of developing standards, such as the inclusion of diseases in the OIE list.

The Code Commission expressed its commitment to further liaison with this programme and offered the possibility for a member of the Commission to join the *ad hoc* Group on Economics of Animal Health when relevant.

6. Date of next meeting

The next meeting will be held from 13 to 22 September 2022.

WORK PROGRAMME FOR
THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

EU comment

The EU commends the OIE Code Commission for its continuous efforts to prioritise its heavy work programme, in coordination with other specialist commissions when relevant. We appreciate the opportunities for members to regularly comment on the work programme and thank the OIE for having taken into consideration comments submitted previously. We fully support the revised work programme of the Code Commission and its prioritisation.

In particular, the EU very much welcomes the new work just started on updating Code Chapter 6.10. on *Responsible and prudent use of antimicrobial agents in veterinary medicine*, in close cooperation with the OIE Working Group on AMR. The EU refers to the concrete text proposals we have submitted to the OIE in December 2018 regarding a revision of the chapter on Responsible and prudent use. We believe the time is right for the OIE to take bold and ambitious steps to include concrete principles and further recommendations as to the conditions of use in that Code chapter, in line with the recommendations of the 2nd Global Conference on AMR and prudent use of antimicrobial agents. Indeed, OIE standards should now significantly evolve on this important topic with a view to lead the way and help control the rise and spread of AMR at global level as an important effort to implement the Global Action Plan against AMR. The EU is ready to support OIE in every way possible in this endeavour, and we very much look forward to reviewing a first draft revised chapter by the end of this year.

The EU also fully supports plans to develop a new chapter on biosecurity in Section 4 *Disease prevention and control* of the Code. This is indeed a high priority in view of global challenges posed by diseases such as African swine fever, High Pathogenicity Avian Influenza (HPAI), potential serious zoonosis and other contagious diseases. Preventing introduction and spread of infectious diseases also reduces the need of antimicrobials and thereby also reduces the risk for the development of AMR. The EU is ready to offer support and its expertise to the OIE for this important endeavour.

Furthermore, the EU supports the Code Commission plans to embark on a revision of Section 5 of the Code, relating to *Trade measures, import/export procedures and veterinary certification*. We agree to prioritise Chapters 5.4. to 5.7. on trade measures and import/export procedures. Indeed, these chapters have not been revised for a very long time, yet these are crucial for safe international trade. This is particularly true for bilateral trade based on the concept of zoning applied in non-disease free countries: zoning has now become accepted between certain trade partners and will likely further gain importance compared to trade based on the concept of country freedom from certain diseases. What's more, the scope of these chapter should no longer be strictly limited to animal health, as experience has shown that other aspects such as animal welfare need to be addressed as well. Special attention in this regard should be given to veterinary procedures at border posts. The EU therefore supports giving priority to the revision of these chapters in the work programme of the Code Commission. Our experts are ready to support the OIE in this endeavour.

The EU also requests the Code Commission, in close collaboration with the Scientific Commission, to ensure that case definitions for listed diseases for which these do not yet

exist in the Code are developed and included in the Code as swiftly as possible, following the well-established OIE standard setting procedures that ensure member involvement and endorsement. Indeed, as indicated during the 89th OIE General Session in May 2022, the EU requests that instead of being published on the OIE website as guidance for purposes of notification without any prior information or consultation of members, case definitions for listed diseases always and exclusively be included in the OIE Code. This notwithstanding that it may lead to the adoption of new Code chapters with only a single article (as is the case for Chapters X.X. and X.Y. as presented in Annexes 14 and 15 of this report), or to a minimal revision of an existing Code chapter.

Finally, as indicated during the recent 89th General Session when the revised Chapter 1.3. was submitted for adoption, the EU queries whether *Mycoplasma gallisepticum*, *M. synoviae*, *M. meleagridis* and *M. iowae* should be assessed against the listing criteria, with a view to possible amendments of Code Chapters 1.3. and 10.5. Indeed, we noted that Code Chapter 10.5. Infection with *Mycoplasma gallisepticum* (Avian mycoplasmosis) does not cover infection with *Mycoplasma synoviae*, while both pathogens are listed separately in Chapter 1.3. What's more, Chapter 10.5. does not contain a case definition, and the articles refer to "avian mycoplasmosis" in general instead of to *Mycoplasma gallisepticum*. We also noted that the corresponding Manual chapter covers both pathogens (Chapter 3.3.5. Avian mycoplasmosis (*Mycoplasma gallisepticum*, *M. synoviae*), and in addition refers to *M. meleagridis* and *M. iowae*. This is somewhat confusing, especially as regards the concept of freedom from avian mycoplasmosis, referred to in several articles in Chapter 10.5.

Chapter	Issues	Status - February 2022		Priority order *
		Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	
N.A.	Use of terms: biosecurity / sanitary measures	Circulated for comments (proposed for adoption in May 2022)	Noted in Feb 2022 TAHSC report (Sep 2021/2)	1
	Use of terms: disease / infection / infestation	Preparatory work	Refer to Feb 2020 TAHSC report	2
	Use of terms: animal health status	Preparatory work	Refer to Feb 2020 TAHSC report	3
	Use of terms: animal-based measures / measurables	Preparatory work	Refer to Feb 2021 TAHSC report	2
	Use of terms: enzootic / endemic / epizootic / epidemic	Preparatory work	Refer to Feb 2021 TAHSC report	2
	Use of terms: notify / notifiable disease / report / reportable disease	Preparatory work	Refer to Feb 2019 TAHSC report	3

User's guide	Revision of the Users' guide (standing item)	Standing item		1
Glossary	'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'	Circulated for comments (proposed for adoption in May 2022)	Noted in Feb 2022 TAHSC report (Sep 2018/4)	1
	'Death', 'euthanasia', 'slaughter' and 'stunning'	Circulated for comments	Noted in Feb 2022 TAHSC report (Sep 2019/3)	2
	'Case'	Not started	Refer to Sep 2020 TAHSC report and Feb 2020 BSC report	3
	'Stray dog'	Circulated for comments (proposed for adoption in May 2022)	Noted in Feb 2022 TAHSC report (Sep 2021/2)	1
	'Poultry'	Circulated for comments	Noted in Feb 2022 TAHSC report (Feb 2022/1)	2
	New definition for 'protein meal'	Circulated for comments (proposed for adoption in May 2022)	Noted in Feb 2022 TAHSC report (Feb 2021/3)	1
	New definitions for 'distress', 'pain' and 'suffering'	Preparatory work	AHG to address Member comments (Sep 2019/2)	2
	New definitions for 'animal products', 'product of animal origin' and 'animal by-product'	Preparatory work	Refer to Feb 2020 TAHSC report	3
	New definition for 'swill'	Preparatory work	Noted in Sep 2021 TAHSC report	1
	Use of terms 'meat-and-bone meal' and 'greaves'	Preparatory work	Noted in Feb 2022 TAHSC report	2
Section 1				
1.3.	Revision of Chapter 1.3. (to ensure alignment with disease-specific chapters)	Circulated for comments (proposed for adoption in May 2022)	Noted in Feb 2022 TAHSC report (Feb 2022/1)	1
	Revision of Article 1.3.2. (Theileriosis)	Circulated for comments (proposed for adoption in May 2022)	Noted in Feb 2022 TAHSC report (Sep 2021/2)	1
	Listing of Infection with *T. lestoquardi*, *T. luwenshuni* and *T. uilenbergi* (Article 1.3.3.)	Circulated for comments	Noted in Feb 2022 TAHSC report	2

	Delisting of paratuberculosis	Preparatory work	Pending assessment by SCAD	3
1.8.	Application for official recognition by the OIE of free status for bovine spongiform encephalopathy	Circulated for comments (proposed for adoption in May 2022)	Noted in Feb 2022 TAHSC report (Sep 2019/5)	1
Section 3				
3.1., 3.2.	Introduction to recommendations on Veterinary Services (Ch 3.1.) and Quality of Veterinary Service (Ch 3.2.)	Circulated for comments (proposed for adoption in May 2022)	Noted in Feb 2022 TAHSC report (Sep 2021/2)	1
3.4.	Veterinary legislation	Circulated for comments (proposed for adoption in May 2022)	Noted in Feb 2022 TAHSC report (Sep 2021/2)	1
Section 4				
4.4.	Zoning and compartmentalisation	Preparatory work	Refer toSep 2021 TAHSC report	1
4.6.	Collection and processing of semen of animals	Expert consultation	Noted in Feb 2022 TAHSC report	1
4.7.	Collection and processing of bovine, small ruminant and porcine semen	Preparatory work	Pending progress of the work on Ch 4.6.	2
4.8.	Collection and processing of *in vivo* derived embryos from livestock and equids	Not started	Pending progress of the work on Ch 4.6. and Ch 4.7.	3
4.9.	Collection and processing of oocytes and *in vitro* produced embryos from livestock and horses	Not started	Pending progress of the work on Ch 4.6. and Ch 4.7.	3
4.13.	Disposal of dead animals	Preparatory work	Noted in Feb 2022 TAHSC report	2
4.14.	General recommendations on disinfection and disinsection	Preparatory work	Noted in Feb 2022 TAHSC report	2
4.X.	New chapter on biosecurity	Preparatory work	Noted in Feb 2022 TAHSC report	1
Section 5				
General	Revision of Section 5 Trade measures, import/export procedures and veterinary certification (especially Chs 5.4. to 5.7.)	Preparatory work	Noted in Feb 2022 TAHSC report	1

5.11.	Model veterinary certificate for international movement of dogs, cats and ferrets originating from countries considered infected with rabies	Preparatory work	Pending progress of the work on Ch 8.14.	3
5.12.	Model passport for international movement of competition horses	Preparatory work	Pending progress of the works on Chs on horse diseases	3
Section 6				
6.2.	The role of the Veterinary Services in food safety systems	Not started	Pending progress of the work on Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'	3
6.3.	Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection	Not started	Pending progress of the work on Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'	3
6.10.	Responsible and prudent use of antimicrobial agents in veterinary medicine	Preparatory work	Noted in Feb 2022 TAHSC report	1
6.12.	Zoonoses transmissible from non-human primates	Circulated for comments (proposed for adoption in May 2022)	Noted in Feb 2022 TAHSC report (Feb 2021/3)	1
Section 7				
General	Transport of animals by land, sea and air (Chs 7.2., 7.3. and 7.4.)	Preparatory work	Noted in Feb 2022 TAHSC report	3
7.5.	Slaughter of animals	Expert consultation	Noted in Feb 2022 TAHSC report	1
7.6.	Killing of animals for disease control purposes	Preparatory work	Refer to Feb 2021 TAHSC report	2
7.7.	Stray dog population control (Dog population management)	Circulated for comments (proposed for adoption in May 2022)	Noted in Feb 2022 TAHSC report (Sep 2020/3)	1
7.X.	New chapter on animal welfare and laying hen production system		Noted in Feb 2022 TAHSC report	2
Section 8				

8.5.	Infection with *Echinococcus granulosus* (Articles 8.5.1. and 8.5.3.)	Circulated for comments (proposed for adoption in May 2022)	Noted in Feb 2022 TAHSC report (Sep 2021/2)	1
8.8.	Infection with foot and mouth disease virus	Preparatory work	Noted in Feb 2022 TAHSC report (Sep 2015/3)	1
8.11.	Infection with *Mycobacterium tuberculosis* complex	Not started	Noted in Feb 2022 TAHSC report	3
8.13.	Paratuberculosis	Not started	Refer to Sep 2020 TAHSC report. Pending listing assesement	4
8.14.	Infection with rabies virus	Circulated for comments	Noted in Feb 2022 TAHSC report (Sep 2020/2)	1
8.15.	Infection with Rift Valley fever virus	Circulated for comments	Noted in Feb 2022 TAHSC report (Feb 2019/4)	1
8.16.	Infection with rinderpest virus	Circulated for comments (proposed for adoption in May 2022)	Noted in Feb 2022 TAHSC report (Sep 2020/4)	1
8.X.	New Chapter on Surra	Preparatory work	Postponed for Sep 2022	2
Section 10				
10.3.	Avian infectious laryngotracheitis	Not started	Refer to Sep 2020 TAHSC report	4
10.9.	Infection with Newcastle disease virus	Not started	Noted in Feb 2022 TAHSC report (Feb 2022/1)	3
Section 11				
11.4.	Bovine spongiform encephalopathy	Circulated for comments (proposed for adoption in May 2022)	Noted in Feb 2022 TAHSC report and Feb 2022 SCAD report (Sep 2019/5)	1
11.5.	Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia)	Preparatory work	Postponed until Sep 2022	2
11.10.	Theileriosis	Circulated for comments (proposed for adoption in May 2022)	Noted in Feb 2022 TAHSC report(Sep 2017/4)	1

11.11.	Trichomonosis	Expert consultation	Noted in Feb 2022 TAHSC report (Sep 2020/2)	3
Section 12				
12.1.	African horse sickness	Preparatory work	Postponed until Sep 2022	2
12.2.	Contagious equine metritis	Circulated for comments	Noted in Feb 2022 TAHSC report (Sep 2020/2)	1
12.3.	Dourine	Expert consultation	Refer to Feb 2019 TAHSC report and SCAD Sept 2021	2
12.4.	Equine encephalomyelitis (Eastern and Western)	Not started	Pending ongoing work on case definition	3
12.6.	Infection with equine influenza virus	Circulated for comments	Noted in Feb 2022 TAHSC report (Feb 2019/4)	1
12.7.	Equine piroplasmosis	Circulated for comments	Noted in Feb 2022 TAHSC report (Sep 2020/2)	1
12.11.	Venezuelan equine encephalomyelitis	Not started	Pending ongoing work on case definition	3
Section 13				
13.2.	Rabbit haemorrhagic disease	Not started	Noted in Feb 2022 TAHSC report	3
Section 14				
14.8.	Scrapie	Not started	Noted in Feb 2022 TAHSC report	3
14.X.	New Chapter on infection with *Theileria* in small ruminants	Circulated for comments	Noted in Feb 2022 TAHSC report (Sep 2017/2)	2
Section 15				
15.3.	Infection with porcine reproductive and respiratory syndrome virus (Article 15.3.9.)	Not started	Refer to Feb 2018 TAHSC report	4
15.4.	Infection with *Taenia solium* (Porcine cysticercosis) (Articles 15.4.1. and 15.4.3.)	Circulated for comments (proposed for adoption in May 2022)	Noted in Feb 2022 TAHSC report (Sep 2021/2)	1
Others				
X.X.	New Chapter on Crimean Congo haemorrhagic fever	Preparatory work	Noted in Feb 2022 TAHSC report Pending ongoing work on case definition	2

X.X.	New Chapter on infection with *Leishmania* spp. (Leishmaniosis)	Circulated for comments	Noted in Feb 2022 TAHSC report (Feb 2022/1)	2
X.X.	New Chapter on infection with Middle East respiratory syndrome coronavirus	Circulated for comments	Noted in Feb 2022 TAHSC report (Feb 2022/1)	2
X.X.	New Chapter on Camelpox	Not started	Refer to Sep 2020 TAHSC report Pending ongoing work on case definition	3

*** Description of priority order**	
1	- ***active work for the TAHSC*** - ***to be put forward for next meeting agenda***
2	- ***active work for the TAHSC*** - ***to be included in next meeting agenda if time allows, depending on other progress***
3	- ***not immediate work for the TAHSC*** - ***needs to progress before consideration for next meeting agenda***
4	- ***not active*** - ***not to be immediately started***

List of abbreviations	
AHG	***Ad hoc* Group**
BSC	**Biological Standards Commission**
Ch	**Chapter**
HQ	**OIE Headquarters**
SCAD	**Scientific Commission for Animal Diseases**
TAHSC	**Terrestrial Animal Health Standard Commission**

GLOSSARY

EU comment

The EU supports the proposed changes to the glossary.

For the purposes of the *Terrestrial Code*:

[...]

POULTRY

means all birds reared or kept in captivity for the production of any commercial animal products or for breeding for this purpose, fighting cocks used for any purpose, and all birds used for restocking supplies of game or for breeding for this purpose, until they are released from captivity.

Birds that are kept in a single household, the products of which are used within the same household exclusively, are not considered *poultry*, provided that they have no direct or indirect contact with *poultry* or *poultry* facilities.

Birds that are kept in captivity for other reasons, including those that are kept for shows, racing, exhibitions, zoological collections, ~~and~~ competitions and companionship, and for breeding or selling for these purposes, ~~as well as pet birds,~~ are not considered *poultry*, provided that they have no direct or indirect contact with *poultry* or *poultry* facilities.

[...]

GLOSSARY

EU comment

The EU welcomes and in general supports the proposed changes to the glossary.

We would like to highlight that the translation of distress in the Spanish version is not always consistent. In addition, we would like to share a comment regarding the definition of death.

For the purposes of the *Terrestrial Code*:

DEATH

~~means the irreversible permanent loss of all vital functions brain activity demonstrable by the loss of brain stem reflexes. This may be confirmed through a combination of criteria such as dilated pupil and absence of corneal reflex, cardiac activity and breathing.~~

EU comment

We suggest keeping the definition of death.

Justification:

It is important to keep the definition of death in order to have criteria to confirm it and control it.

If we don't have such definition, this would need also to be reflected in Chapter 7.5 where the term "death" is used very often.

DISTRESS

means the state of an animal~~,~~ that has been unable to adapt to stressors~~,~~, that ~~and~~ ~~that~~ manifests ~~as~~ as abnormal physiological or behavioural responses or no signs. It can be acute or chronic and may result in pathological conditions.

EUTHANASIA

means *killing* of an *animal* ~~the act of inducing *death* using a method that causes a rapid and irreversible loss of consciousness~~ with the most rapid~~,~~ method and with the least *pain*~~less~~ and ~~*distress free*~~ *suffering* ~~method~~ possible ~~minimum pain and distress to *animal*~~.

PAIN

means an acutely or chronically unpleasant or aversive sensory and emotional ~~experience~~state of an animal associated with actual or potential tissue damage. ~~It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.~~

SLAUGHTER

means ~~any~~ *killing* ~~procedure that causes the *death* of an *animal* by bleeding~~ of an *animal*~~s~~ primarily intended for human consumption.

STUNNING

means any ~~mechanical, electrical, chemical or other~~ procedure that causes ~~rapid~~ ~~immediate~~ loss of consciousness with minimal pain ~~and other types of~~ and *suffering* for the purpose of killing; ~~when used before *slaughter*, the loss~~

~~of consciousness lasts until *death* from the *slaughter* process.; in the absence of *slaughter*, the procedure would allow the *animal* to recover consciousness.~~

SUFFERING

means an acutely or chronically unpleasant or aversive, ~~undesired~~ physical or ~~mental~~ emotional state of ~~being that is the outcome of the impact on~~ an animal, including *pain* and resulting from ~~of noxious~~ negative stimuli ~~and/~~or ~~the~~ absence of ~~important essential~~ positive stimuli. ~~It is the opposite of good welfare.~~

CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY THE OIE

EU comment

The EU supports the proposed changes to this chapter.

[…]

Article 1.3.3.

The following are included within the category of sheep and goat diseases and *infections*:

– Caprine arthritis/encephalitis

– Contagious agalactia

– Contagious caprine pleuropneumonia

– Infection with *Chlamydia abortus* (Enzootic abortion of ewes, ovine chlamydiosis)

– Infection with peste des petits ruminants virus

– Infection with *Theileria lestoquardi*, *Theileria luwenshuni* and *Theileria uilenbergi*

– Maedi–visna

– Nairobi sheep disease

– Ovine epididymitis *(Brucella ovis)*

– Salmonellosis (*S.* abortusovis)

– Scrapie

– Sheep pox and goat pox.

[…]

DRAFT CHAPTER 7.5.

ANIMAL WELFARE DURING SLAUGHTER

EU comment

The EU thanks the OIE for having taken into consideration the majority of our comments submitted previously.

We welcome and in general support the adoption of this revised chapter.

However, we would like to reiterate some comments that could improve the readability of the chapter as well as its practical use.

Article 7.5.1.

Introduction

Providing good welfare to the animals at *slaughter* is ethically and economically beneficial. The implementation of animal welfare measures in addition to giving value to the product directly for ethical reasons, contributes to the improvement of workers' health and safety and product quality~~, and is essential for~~ (including food safety) and consequently to the improvement of economic~~al~~ returns [Blokhuis *et al.*, 2008; Lara and Rostagno, 2018].

Article 7.5.2.

Scope

This chapter identifies potential *animal welfare hazards* during *slaughter* and provides recommendations for arrival and *unloading*, *lairage*, handling, *restraint*, *stunning* and bleeding of animals in *slaughterhouses/*~~*abattoirs*~~. It provides animal-based measures to assess the level of welfare and recommends remedial actions to be applied, when necessary.

This chapter applies to the *slaughter* in *slaughterhouses/abattoirs* of free-moving animals ~~the following domestic animals~~, e.g. ~~cattle, buffalo, bison, sheep, goats, horses, donkeys, mules,~~ruminants, equids and pigs, and animals in *containers* ~~(~~e.g. rabbits and most *poultry* species~~). hereafter referred as "animals". Recommendations consider whether animals arrive at the *slaughterhouse/abattoir* in *containers* or are free-moving.~~

This chapter should be read with the guiding principles for *animal welfare* provided in Chapter 7.1, Chapter 7.14. killing of reptiles for their skins, meat and other products and relevant provisions of Chapters 6.2. and 6.3.

The principles underpinning these recommendations ~~may~~ should also be applied ~~apply~~ to the *slaughter* of other species and those slaughtered in other places.

Article 7.5.3.

Definition for the purpose of this chapter

Bleeding means the act of severing major blood vessels that supply the brain, to ensure *death*.

Article 7.5.4.

Animal welfare hazards

Hazards to *animal welfare* during each of the pre-slaughter stages have a~~n additive~~ cumulative effect on the stress of the animals [Moberg and Mench, 2000].

At the *slaughterhouses/abattoirs*, animals are exposed to *animal welfare hazards* including ~~fasting~~feed and water deprivation, mixing of unfamiliar *animals*, handling by humans, exposure to a novel environment (e.g. noise, lighting, flooring), forced movement ~~physical exercise~~, limited space allowance, ~~extreme~~adverse weather conditions and ineffective ~~inadequate~~ *stunning* and bleeding. These *hazards* can have negative impacts on the welfare of the animals that can be assessed through animal-based measures. In absence of feasible animal-based measures, ~~In addition~~ resource-based measures and management-based measures may be used as a ~~substitute~~proxy. *Animal*

welfare hazards can be minimised by appropriate design of premises and choice of equipment, and through good management, training and competency of personnel.

Article 7.5.5.

Criteria (or measures)

The welfare of animals at *slaughter* should be assessed using ~~outcome~~animal-based measures. Although consideration should be given to the resources provided as well as the design and management of the system, animal-based criteria are preferential. However, key stunning parameters need to be considered alongside animal-based measures.

The routine use of these outcome-based measures and the appropriate thresholds should be adapted to the different situations in which animals are managed at a *slaughterhouse/abattoir*. It is recommended that target values or thresholds for *animal welfare* measurables be based on current scientific knowledge and appropriate national, sectorial or regional standards.

Article 7.5.6.

Management

The *slaughterhouse/abattoir* operator is responsible for the development and ~~enforcement~~implementation of a dedicated operating plan that should consider the following:

– training and competency of personnel;

– design of premises and choice of equipment;

– operating procedure and corrective actions;

– ~~training and competency of personnel;~~

– throughput (number of animals slaughtered per hour);

– maintenance and cleaning procedures;

– contingency plans;

– ~~operating procedure and corrective actions.~~

Article 7.5.7.

Training and competency of personnel

Animal handlers and other personnel have a crucial role to play in ensuring good *animal welfare* conditions from the time of arrival of the animals at the *slaughterhouse/abattoir* through to their *death*. Training for all personnel should emphasise the importance of *animal welfare* and their responsibility in contributing to the welfare of the animals that come through the *slaughterhouse/abattoir*.

Animal handlers should understand the species-specific behavioural patterns of the animals they are working with and the~~ir~~ underlying principles to carry out the required tasks whilst ensuring good *animal welfare*. They should be experienced and competent in handling and moving the animals with knowledge ~~about animal behaviour and physiology and able~~ to identify signs of distress, fear, pain and suffering. Personnel in charge of *restraint* and of *stunning* and bleeding operations should be familiar with the relevant equipment, their key working parameters and procedures. Personnel *stunning*, shackling and bleeding animals should be able to identify and take corrective actions in case of ~~in~~effective ~~*stunning* of the animal and signs of recovery of consciousness, should be able to detect if an animal is still alive prior to dressing or scalding and should be able to take corrective actions, if necessary~~ [EFSA, 2013a; EFSA 2013b].

a) ineffective *stunning* of the animal;

b) recovery of consciousness;

c) animal is still alive prior to dressing or scalding.

Competencies may be gained through a combination of formal training and practical experience. These competencies should be assessed by the *Competent Authority* or by an independent body recognised by the *Competent Authority*.

Only the personnel actively working ~~on the slaughter line~~in areas where live animals are handled should be present in these areas ~~where animals are handled~~. The presence of visitors or other personnel should be limited in those areas in order to prevent unnecessary noise, shouting, ~~or~~ movement or risk of accidents.

Article 7.5.8.

Design of premises and choice of equipment

The design of premises and the choice of equipment used in a *slaughterhouse/abattoir* have an important impact on the welfare of animals. They should consider the animals' needs, in terms of their physical comfort including:

– thermal comfort ~~conditions~~,

– ease of movement,

– protection from injury, ~~protection from sudden or excessive noise~~

– fear,

– ~~and~~ ability to perform natural and social behaviours, ~~as well as~~

– watering and feeding needs, including for the need of sick or injured animals.

Premises should be designed to eliminate distractions that may cause approaching animals to stop, baulk or turn back.

Flooring should be non-slip to prevent injury and stress due to slipping. Adequate quality and quantity of lighting allowing adequate ante-mortem inspection of animals and assisting the moving of animals utilising low-stress handling techniques.

The design of the *slaughterhouse/abattoir* and choice of equipment should take into consideration the species, categories, quantities, ~~and~~ size or weight and age of the animals. *Restraint*, *stunning* and bleeding equipment is critical for the welfare of an animal at the time of *slaughte*r. Appropriate back-up equipment should be available for immediate use in case of failure of the *stunning* equipment initially used.

Article 7.5.9.

Throughput (number of animals slaughtered per hour)

The throughput of the *slaughterhouse/abattoir* should never exceed the maximum specification of the design of the facilities or equipment. ~~and may~~ The *slaughterhouse/abattoir* operators should continuously monitor throughput and adjust it to any operational changes, such as staff numbers and experience or line breakdowns. ~~It~~Throughput may ~~also~~ need to be reduced ~~depending on their~~ welfare ~~outcomes~~ ~~are~~ is negatively impacted.

Personnel allocation should be adequate for the anticipated throughput and be sufficient to implement the *slaughterhouse/abattoir* operating plan as well as ante and post-mortem inspections.

Article 7.5.10.

Maintenance and cleaning procedures

All equipment should be clean and well maintained, including calibration, in accordance with manufacturer's instructions in order to ensure *animal welfare* ~~and safety of personnel~~.

Maintenance and cleaning of handling, *unloading*, *lairage* and moving facilities and equipment contribute to ensuring that animals are handled smoothly, preventing pain and fear.

Maintenance and cleaning of *restraining*, *stunning* and bleeding equipment are essential to ensure reliable and efficient *stunning* and *slaughter*, thereby minimising pain, fear and suffering.

Article 7.5.11.

Contingency plans

Contingency plans should be in place at the *slaughterhouse/abattoir* to protect the welfare of the animals in the event of an emergency. The contingency plans should consider the most likely emergency situations given the species slaughtered and the location of the *slaughterhouse/abattoir.*

Contingency plans should be documented and communicated to all responsible parties.

~~Each p~~Personnel who ~~has~~have a role to play in implementing contingency plans should be well trained on the tasks they have to perform in case of emergency.

Article 7.5.12.

Arrival of free-moving animals

On arrival at the *slaughterhouse/abattoir*, animals will already have been exposed to *hazards* that may have negative impacts on their welfare. Any previous *hazards* will have a cumulative effect that may affect the welfare of the animals throughout the *slaughter* process. Therefore, animals should be transported to the *slaughterhouse/abattoir* in a manner that minimises adverse animal health and welfare ~~outcomes~~, and in accordance with Chapters 7.2. and 7.3.

1. Animal welfare concerns:

   Delay in *unloading* of animals is a major ~~the main~~ *animal welfare* concern at arrival [NAMI, 2017].

   Animals in *vehicles* have smaller space allowances than on farm, undergo water and *feed* deprivation, may have suffered from an injury, ~~and~~ may be exposed to ~~thermal stress due to~~ adverse weather conditions and to stress and discomfort from social disturbance, noise, vehicle vibration and motion. In addition, stationary *vehicles* may have insufficient ventilation. Delays in *unloading* animals will prolong or exacerbate the impact of these *hazards*. Under these circumstances, injured or sick animals requiring urgent attention ~~will~~ may not be identified or dealt with appropriately and therefore the duration of their suffering will be increased.

2. Animal-based and other measurables include:

   It can be difficult to assess animal-based measures while animals are in the *vehicle*. Some measurables that may be assessed include animals with injuries, lameness and / or poor body condition or those that are sick or have died. Panting, shivering and huddling may indicate thermal stress. Drooling and licking may indicate prolonged thirst.

   Animals dead or emergency killed (see Article 7.5.19.) on arrival ~~or condemned on arrival~~ should be recorded and monitored as an indicator of *animal welfare* prior to and during transport.

   Time from arrival to *unloading* and the environmental temperature and humidity can be used to establish relevant thresholds for corrective action.

3. Recommendations:

   Animals should be unloaded promptly on arrival. This is facilitated by scheduling the arrival of the animals at the *slaughterhouse/abattoir* to ensure that there are sufficient personnel and adequate space in the *unloading* or *lairage* area.

   Consignments of animals assessed to be at greater risk of *animal welfare hazards* should be unloaded first. When no space is immediately available, creating space should be a priority. Provisions should be made to provide shelter, shade or additional ventilation during waiting periods, or animals should be transported to an alternative nearby location where such provision ~~i~~s available.

   Animals should be provided with water as soon as possible after *unloading*.

Special consideration should be given to animals that have undergone long or arduous journey times, injured animals, lactating or pregnant animals and young animals. These animals should be slaughtered as a priority. If this is not possible, arrangements should be made to mitigate or prevent suffering, in particular by: milking dairy animals at intervals of not more than 12 hours and providing appropriate conditions for suckling and the welfare of the newborn animal in the case of a female having given birth. Mortalities and injuries should be reported to the competent authority.

4. Species-specific recommendations:

Some species such as ~~P~~pigs and shorn sheep are especially sensitive to extreme temperatures and therefore special attention should be taken when dealing with delays in *unloading* ~~this species~~sensitive animals. This may include careful consideration of transport plans to time arrival and processing, provision of additional ventilation / heating, etc.

~~Shorn sheep might be especially sensitive to extreme temperatures and therefore special attention should be taken when dealing with delays in *unloading*.~~

Lactating animals should be given special attention and given priority when *unloading* and processing.

Unweaned animals are especially sensitive to extreme temperatures and can find it difficult to regulate their body temperature. They are ~~very~~more susceptible to dehydration, illness and stress after transportation and handling. These animals must be given special attention and be given priority when *unloading* and processing.

Article 7.5.13.

~~Displacements~~ Handling of free-moving animals

This article addresses the handling of animals during *unloading* and *lairage,* and in the killing area.

1. Animal welfare concerns:

During *unloading,* animals are exposed to similar *hazards* to those encountered when being loaded (see Chapters 7.2. and 7.3). Inappropriate equipment in the *vehicle* or the *slaughterhouse/abattoir*, such as a lack of lateral protection when *unloading*, excessively steep ramps, slippery surfaces, or an absence of foot battens, may result in animals slipping, falling or being trampled, causing injuries. The absence of ramps, ~~or~~ lifts or an unloading bay or dock could ~~can~~ result in animals being pushed or thrown off the vehicle. These *hazards* can also be associated with inappropriate handling and forced physical movement of animals that are unable to move independently as a result of weakness or injuries. Exposure to novel environments (e.g. noise, lighting, flooring, smell) will cause fear and reluctance to move, or turning back. Poorly designed facilities will increase the risk of such fear.

EU comment

We suggest adding *"and risk of injuries":*

"Poorly designed facilities will increase the risk of such fear and risk of injuries".

Justification:

Poorly designed facilities will not only increase fear, but also risk of injuries. This addition would be consistent with the sentence above, indicating that "Inappropriate equipment in the vehicle or the slaughterhouse/abattoir …. may result in … causing injuries".

2. Animal-based and other measurables include:

a) animals ~~running~~ slipping and falling;

b) animals with broken or otherwise injured limbs;

c) animals turning-back, attempting to escape and reluctant to move;

d) animal vocalisation ~~and frequency of~~ e.g. high pitched vocalisation for pigs ~~especially for pigs and cattle~~;

~~d~~ e) animals that are unable to move by themselves due to reasons other than those with broken or injured limbs;

~~e~~ f) animals that strike against the facilities;

~~f~~ g) ~~frequency of~~ use of excessive force by personnel;

~~g~~ h) ~~frequency of~~ use of electrical prods.

Animals are safely handled when these measures are below an acceptable threshold.

EU comment

We suggest adding the following:

'Animals are safely handled when these measures are below an acceptable threshold~~.~~, except for g where the use of excessive force is not acceptable.".

Justification:

Excessive force is never acceptable.

3. Recommendations:

Ramps or lifts should be provided and used. Ramps or lifts should be positioned so that the animals can be handled safely. There should be no gap between the *vehicle* and the ramp, the gradient should not be too steep preventing animals from voluntarily moving, and solid side barriers should be in place.

Design of the facilities should promote the natural movements of animals, and, as far as possible, with a ~~minimal~~minimise human interaction.

Preventive measures such as foot battens, rubber mats and deep groove flooring can help animals to avoid slipping.

The *unloading* area and raceways should be well lit so that animals can see where they are going.

The design of *unloading* areas and raceways should aim to minimise the potential for distractions that may cause animals to stop, baulk or turn back when being unloaded (e.g. shadows, changes in flooring, moving objects, loud or sudden noises). For details refer to Chapters 7.2. and 7.3.

Animals that are injured, sick or unable to rise require immediate action and, when necessary, emergency killing should be performed ~~euthanised~~ without moving them and without delay. Refer to Articles 7.5.19. and 7.5.2~~0~~1. Such animals should never be dragged, nor should they be lifted or handled in a way that might cause further pain, suffering or exacerbate injuries.

Personnel should be calm and patient, assisting the animals to move using a soft voice and slow movements. They should not shout, kick, or use any other means that is likely to cause fear or pain to the animals. Under no circumstances should *animal handlers* resort to violent acts to move animals (see Article 7.5.20.).

Personnel should not stand between an animal and where they want it to move to as this may cause the animal to baulk.

Mechanical aids ~~and electric goads~~ should be used in a manner to encourage and direct movement of the animals without causing distress and pain. Preferred mechanical aids include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and ~~metallic~~ rattles.

Electric goads should only be used ~~in extreme cases and not on a routine basis to move animals.~~ when other measures have been ineffective and there is room for the animal to move forward without obstruction (e.g. obstacles or other animals).

The use of electric goads should be limited to ~~battery-powered~~low voltage goads applied to the hindquarters of adult pigs and large ruminants, and never to sensitive areas such as the eyes, mouth, ears, ano-genital region or belly. Such instruments should not be used on equids, camelids, ratites, sheep and goats of any age, or on calves or piglets. Shocks shall not be used repeatedly if the animal fails to respond.

~~Mechanical~~ Other ~~H~~handling aids ~~and electric goads~~ should not be used as a substitute for good facility design and handling. They should not be used repeatedly if an animal fails to respond or move. In such cases it should be determined whether some physical or other impediment is preventing the animal from moving.

~~Electric goads should only be used in extreme cases and not on a routine basis to move animals.~~

~~The use of electric goads should be limited to battery-powered goads applied to the hindquarters of adult pigs and large ruminants, and never to sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.~~

The manual lifting of animals should be avoided; if it is necessary, animals should not be grasped or lifted in a manner which causes pain or suffering and physical damage (e.g. bruising, fractures, dislocations). (See Article 7.5.20.).

4. Species-specific recommendations:

None identified

Article 7.5.14.

Lairage of free-moving animals

1. Animal welfare concerns:

Animals during *lairage* may be exposed to several *animal welfare hazards* including:

a) food and water deprivation leading to prolonged hunger and thirst,

EU comment

The EU suggests replacing "food" with "feed":

"a) ~~food~~ feed and water deprivation leading to prolonged hunger and thirst,"

Justification:

In order to align the terminology in this chapter with that of e.g. chapter 7.10 on animal welfare and broiler chicken production systems.

b) absence of protection against ~~extremes~~ adverse ~~in~~ weather or climate conditions leading to thermal stress,

c) sudden or excessive noises, including from personnel, machinery, metal yards and gates, leading to fear,

d) insufficient space to lie down and move freely leading to fatigue and aggressive behaviour,

e) poor design and maintenance leading to distress and injuries,

f) mixing of unfamiliar animals leading to aggressive behaviour, or social stress,

g) limited access to resources (e.g. drinkers, bedding) leading to aggressive behaviour;

h) exposure to hard, sharp or abrasive surfaces leading to injury or lameness.

EU comment

We suggest the following revision:

"h) exposure to ~~hard, sharp or abrasive~~ surfaces leading to injury or lameness (e.g. sharp, abrasive etc.)."

Justification:

Moving the qualifiers at the end of the sentence would allow an open and not closed list, at the risk of forgetting some. The interpretation of the term "hard" may be problematic, in particular by excluding concrete floors, which represent a very large majority of existing constructions.

2. Animal-based and other measurables include:

   a) thermal stress (e.g. panting, sweating, shivering, huddling behaviour),

   b) space allowance,

   c) excessive soiling with faeces (e.g. coat cleanliness, dag score for sheep),

   d) injuries (e.g. lameness, open wounds, fractures),

   e) illness (e.g. ~~limping,~~ diarrhoea, coughing),

   f) aggressive behaviours (e.g. mounting, fighting),

   g) ~~frequency of~~animal vocalisation ~~especially~~ for pigs and cattle (e.g. hitch pitched vocalisation in pigs);

   h) restlessness (e.g. pacing, walking with continuous ear movements and frequency of snorts – especially for horses) [Micera *et al.*, 2010 and Visser *et al.*, 2008].

   i) carcass bruising.

3. Recommendations:

   Animals should have constant access to clean water. Water supply points should be designed according to the species and age of the animal, with environmental conditions that allow for effective consumption. The number and location of the water supply points should minimise competition.

   ~~Animals should be provided with *feed* in *lairage* if the duration between loading and expected time for *slaughter* exceeds 24 hours~~. Animals should be provided with *feed* in *lairage* if the duration between loading the last meal and expected time for *slaughter* exceeds a period appropriate for the species and age of animals. In absence of information on the transport duration in any case ~~A~~animals which are not expected to be slaughtered ~~after~~within 12 hours of arrival should be fed as appropriate for the age and species ~~and should be given moderate amounts of food at appropriate intervals~~.

   The *lairage* should provide animals with protection against adverse weather conditions including shade and shelter.

   Animals should be protected from excessive and sudden noise (e.g. ventilation fans, alarms, or other indoor or outdoor equipment).

   Lairage areas should be free from sharp edges and other *hazards* that may cause injury to animals.

   The *lairage* should provide enough space for all animals to lie down at the same time, to move freely and to move away in case of aggressive behaviours.

   Lairage areas should have adequate lighting levels to allow inspection of the animals.

   Animals from different groups (or different species) should not be mixed.

   Animals that can move freely but are injured, sick, very young or pregnant should be isolated to protect them from other animals and be slaughtered with priority.

4. Species-specific recommendations:

~~None identified.~~ Pigs should be kept in small groups (up to 15) when resting in lairage, when moving to the stunner and when stunned.

Bison and cervids need specific design and construction standards for the unloading and holding prior to slaughter.

Article 7.5.15.

Restraint for stunning or bleeding (free-moving animals)

1. Animal welfare concerns:

The purpose of *restraint* is to facilitate the correct application of the *stunning* or bleeding equipment. Incorrect *restraint* may not only lead to ineffective *stunning* or bleeding, but also cause pain and distress.

Other *hazards* include:

a) slippery ~~ing or falling of animals entering the~~ restraining area;

b) ~~struggling or escape attempts caused by~~ insecure *restraint*;

c) ~~injuries and pain caused by~~ excessive force of *restraint*;

d) ~~fear caused by~~ prolonged *restraint*, which may exacerbate insecure or excessive *restraint*.

EU comment

We suggest adding a point e) as follows:

"e) a restrainer that is not appropriate to the size of the animal."

Justification

It is important to ensure a proper restraint that the restrainer is or can be adjusted to the size of the animal. Especially, if the animal is too small and can move, there is a risk of an ineffective stunning.

In addition, *slaughter* without *stunning* increases the risk of pain and fear due to the need for robust *restraint* of conscious animals for neck cutting, especially if animals are turned on their sides or backs [von Holleben *et al.*, 2010; Pleiter, 2010].

2. Animal-based and other measurables include:

a) animal slipping or falling;

b) struggling;

c) escape attempts;

d) animal vocalisation ~~(cattle and pigs)~~(e.g. high pitched vocalisation in pigs);

e) reluctance to enter the restrainer;

f) frequency of use of electric goads.

3. Recommendations:

Where individual restraint is used, ~~T~~the restrainer should be narrow enough that the animals cannot move ~~either~~ backwards ~~or~~ ,forwards or turn around.

The restrainer being used should be appropriate to the size of the animals and the restrainer should not be loaded beyond its design capacity.

In case of *slaughter* without *stunning*, the restrainer should restrain the head ~~appropriately~~ and should support the body of the animal ~~appropriately~~.

The restrain~~ting~~ should be maintained until the animal is unconscious.

When restrainers are used that hold an animal with its feet off the floor, the animal must be held in a balanced, comfortable, upright position.

When a restrainer is used to rotate an animal from an upright position, the body and head must be securely held and supported to prevent struggling and slipping within the device.

Restrainers should not have sharp edges.

Non-slip flooring should be used to prevent animals from slipping or falling.

Flooring and handling that intentionally cause loss of balance, slip or fall - i.e. a box with a floor that rises on one side upon entry to the box – should not be used.

Distractions (e.g. movements of equipment or people, loose chains or objects, shadows, shiny surfaces or floors) should be minimised to prevent baulking ~~balking~~ and improve ease of entry into the restrainer.

No animals should enter the restrainer until equipment and personnel are ready to slaughter that animal.

No animals should be released from the restrainer until the operator has confirmed loss of consciousness.

Animals should not be left in conveyor style restrainers during work breaks, and in the event of a breakdown animals should be removed from the conveyor promptly.

The restrainer should be in a clean and non-slip condition.

4. Species-specific recommendations:

Gondolas for gas *stunning* of pigs should not be overloaded and pigs should be able to stand without being on top of each other.

Head *restraint* is recommended for cattle.

Specialised restraining equipment and methods are required for Bison and cervids as well as any species which may be processed with or without stunning.

Article 7.5.16.

EU comment

For the sake of clarity and easy reference, the EU suggests redrafting this section in order to separate the different stunning methods (mechanical, electrical and controlled atmosphere) as it is the case for animals in containers.

Justification

This approach was taken for animals containers and it would be consistent to keep the same structure for both parts.

Stunning of free-moving animals

1. Animal welfare concerns:

The main *animal welfare* concern associated with *stunning* is 'ineffective *stunning*' which results in pain,

distress or fear during induction of unconsciousness and possible recovery before *death*.

The most common methods for *stunning* are mechanical, electrical and exposure to controlled atmosphere.

Stunning prior to *slaughter* decreases or ~~avoid~~prevents pain and suffering to animals ~~and also improves workers' safety~~.

Mechanical *stunning* is divided into penetrative~~ng~~ ~~*stunning*~~ and ~~non-penetrating~~ non-penetrative percussive *stunning* applications. Both applications use different types of devices aimed to induce immediate loss of consciousness as the impact of the bolt on the skull results in concussion and disruption of normal brain function [Daly *et al.*, 1987; EFSA, 2004]. Penetrative *stunning* devices propel a bolt which penetrates the skull and enters the cranium damaging the brain. Non-penetrative percussive *stunning* devices propel a blunt bolt which does not penetrate the skull, but results in rapid loss of consciousness from impact. The main *hazards* preventing effective mechanical *stunning* are incorrect shooting position and incorrect direction of the impact. These may cause ineffective *stunning* and pain or short-lasting unconsciousness. Poor maintenance of the equipment or inadequate cartridge power or air line pressure (in pneumatic stunners) can result in low bolt velocity.. ~~Llow bolt velocity, misuse~~Inappropriate use of cartridge ~~Low bolt velocity~~, narrow bolt diameter or short length of bolt leading to shallow penetration~~,~~ may also affect the effectiveness of *stunning*. In ~~older~~ animals with a thicker skull, ~~low bolt velocity may result in~~there is an increased risk of an ineffective stun~~.~~, especially with ~~In non-penetrating~~ non-penetrative percussive *stunning* ~~applications, high bolt velocity may cause fracture of the skull and ineffective *stunning* [Gibson *et al.*, 2014]~~. If not applied correctly, fracture of the skull and ineffective *stunning* are more likely to occur with young animals such as calves, when a higher bolt velocity is used. Absence of or incorrect restraint can lead to an incorrect shooting position.

Electrical *stunning* involves application of an electric current to the brain of sufficient magnitude to induce immediate unconsciousness [EFSA, 2004; Grandin, 1980]. The main *hazards* preventing effective electrical *stunning* are: incorrect electrode placement, poor contact, electrical arcing, high contact resistance caused by wool or dirt on the animal surface, dirty or corroded electrode, low voltage/current or high frequency [EFSA, 2004].

Controlled atmosphere *stunning* methods involve the exposure to high concentrations of carbon dioxide (hypercapnia), low concentration of oxygen (hypoxia) or a combination of the two (hypercapnic hypoxia). Loss of consciousness is not immediate following exposure of animals to controlled atmosphere *stunning*. The main *hazards* causing increased distress during induction of unconsciousness are irritant or aversive gas mixtures (e.g. CO_2 in high concentrations), low gas temperature and humidity. The main *hazards* causing ineffective controlled atmosphere *stunning* are incorrect gas concentration and too short gas exposure time [Anon, 2018; EFSA, 2004; Velarde *et al.*, 2007].

~~Gases or gas mixtures that are painful to inhale should preferably not be used to stun or kill pigs.~~

2. Animal-based and other measurables include.:

Effectiveness of *stunning* should be monitored at different stages: immediately after *stunning*, just before and during bleeding until death ~~occurs~~is confirmed ~~neck cutting, and during bleed-out~~ [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

EU comment

We suggest that the paragraph above is deleted in this place and moved to section 3. Recommendations, where it should replace the second sentence in the fifth paragraph, as indicated.

Justification

The paragraph is a recommendation, and thus it should not be placed under animal-based and other measurables.

~~No single indicator should be relied upon alone~~. Multiple indicators should be used to determine whether a stun is effective and the animal is unconscious.

Mechanical *stunning:*

An effective stun is characterised by the presence of all the following signs: immediate collapse; apnoea; tonic seizure; absence of corneal reflex; absence of eye movements.

The presence of any of the following signs ~~may~~ indicates ~~an~~ a high risk of ineffective stun or recovery of consciousness: rapid eye movement or nystagmus, vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

EU comment

We suggest the following wording:

"The presence of any of the following signs ~~may indicates an a high risk of ineffective~~ after stun ~~or recovery of consciousness~~ should be considered as indicating ineffective or insufficient stun: rapid eye movement or nystagmus, vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing."

Justification:

The notion of "high risk" is not correct, because sometimes the signs indicated are signs of certain consciousness while others are signs that may be present in unconscious animals. The concept of insufficient stunning would be appropriate for both situations and all the signs described.

Electrical *stunning:*

An effective stun is characterised by the presence of all the following signs: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal reflex.

The presence of any of the following signs ~~may~~ indicates ~~an~~ high risk of ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

EU comment

We suggest revising as above:

"The presence of any of the following signs ~~may indicates an high risk of~~ after stun should be considered as indicating ineffective or insufficient stun ~~or recovery of consciousness~~: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing."

Justification:

As above, the notion of "high risk" is not correct, because sometimes the signs indicated are signs of certain consciousness while others are signs that may be present in unconscious animals. The concept of insufficient stunning would be appropriate for both situations and all the signs described.

Gas *stunning*:

An effective stun is characterised by the presence of all the following signs: loss of posture; apnoea; absence of corneal reflex; absence of muscle tone.

The presence of any of the following signs ~~may~~ indicates ~~an~~ high risk of ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; rghting reflex; presence of corneal reflex; rhythmic breathing.

EU comment:

Same suggestion as above:

"The presence of any of the following signs ~~may indicates an high risk of~~ after stun should be considered as indicating ineffective or insufficient stun ~~or recovery of consciousness~~: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing."

Justification:

As above, the notion of "high risk" is not correct, because sometimes the signs indicated are signs of certain consciousness while others are signs that may be present in unconscious animals. The concept of insufficient stunning would be appropriate for both situations and all the signs described.

3. Recommendations:

Animals should always be stunned as soon as they are restrained.

When a two-step electrical stun-kill method is used, the electrical current must ~~reach~~be applied to the brain before it reaches the heart otherwise the animal will experience cardiac arrest while still conscious.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system method. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Stunning equipment should be used, cleaned, maintained and stored following manufacturer's recommendations.

Regular calibration of the equipment according to the manufacturer's procedure ~~are~~is recommended. Effectiveness of the *stunning* should be monitored regularly.

EU comment

We suggest that the last sentence in the paragraph above is replaced by the first paragraph under section 2. Animal-based and other measurables: Effectiveness of stunning should be monitored at different stages: immediately after *stunning*, just before and during bleeding until death ~~occurs~~is confirmed ~~neck cutting, and during bleed-out~~ [EFSA, 2013a; EFSA, 2013b; AVMA, 2016] ~~Effectiveness of the stunning should be monitored regularly~~.

Justification

The inserted sentenced is moved from subsection 2 on animal-based and other measurables, as it is a recommendation. It should replace the original sentence, as it more appropriately addresses how effectiveness of stunning should be monitored.

*Slaughterhouses/abattoir*s should have standard operating procedures that define key operating parameters ~~or~~ and follow the manufacturer's recommendations for *stunning*, such as:

a) Mechanical:

– position and direction of the shot [AVMA, 2016];

– grain of the cartridge or air pressure ~~appropriate to the type of animal~~ (captive bolt) [Gibson *et al.*, 2015~~2014~~];

– length and diameter of the bolt (captive bolt);

– calibre and type of gun and ammunition (free bullet).

b) Electrical:

– shape, size and placement of the electrodes [AVMA, 2016];

– ~~pressure~~ contact between electrode and head;

– wetting point of contact;

– minimum exposure time;

– electrical parameters (current intensity(A), waveform type (AC and DC), voltage(V) and frequency(Hz));

EU comment

The EU suggests providing species-specific electrical parameters as it was done in the past version of the chapter or at least precise technical and scientific references for the competent authorities to determine effective electrical parameters.
As an indication, the following references could be added for head-only stunning:
1.25 to 1.28 A for cattle (EFSA Journal 2020;18(11):6275)
1.3 A for pigs (EFSA Journal 2020;18(6):6148)
1.0 A for small ruminants (EFSA Journal 2013;11(6):3249 and EFSA Journal 2015;13(2):4023)

Justification
The EU understands that establishing technical parameters is delicate in an international context. However, a range of values or references to external documents could be valuable for the competent authorities in order to determine these parameters until the OIE has adopted complementary guidance documents.

– visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors and displays duration of exposure, voltage and applied current.

c) Controlled atmosphere:

– gas concentrations and exposure time;

– temperature and humidity;

– ~~rate of decompression (law atmospheric pressure system for *stunning*);~~

– animal-based measures should be monitored during the induction phase, if possible, because this can be a point of highest welfare risk for animals.

– visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors gas concentration and temperature.

– ~~gases or gas mixtures that are painful to inhale should preferably not be used to stun or kill pigs~~

4. Species-specific recommendations:

Non-penetrativeng captive bolt should not be used in animals with thick skull (e.g. bison, water buffalo)~~mature cattle and pigs [Finnie, 1993 and Finnie *et al.*, 2003]~~.

The *Competent Authority* should determine effective electrical parameters, based on scientific evidence for different types of animals.

Where high electrical frequencies is used, the amperage should also be increased.

Gases or gas mixtures that are painful to inhale should preferably not be used to stun or kill pigs.

Article 7.5.17

Bleeding of free-moving animals

1. Animal welfare concerns:

The main *animal welfare* concern at the time of bleeding following *stunning* is the recovery of consciousness due to prolonged stun-to-stick interval or due to incomplete severance of the main blood vessels.

Bleeding without prior *stunning* increases the *risk* of animal suffering because the incision to sever blood vessels results in substantial tissue damage in areas well supplied with nociceptors. The activation of these nociceptors causes the animal to experience pain [Gregory, 2004; Gibson *et al.*, 2009]. Loss of consciousness due to bleeding is not immediate and there is a period during which the animal can feel fear, pain and distress [Gregory, 2004; Johnson *et al.*, 2015]. This period will be reduced by applying stunning immediately after neck cutting.

Absence of or ineffective *stunning* may result in animals being released from the *restraint*, shackled, and bled and or further processed while they are still conscious or have the potential to recover consciousness.

2. Animal-based and other measurables include:

The main animal-based measurable is the blood flow (rate and duration).For animal-based and other measurables of return of consciousness after *stunning*, see Article 7.5.16.

In cases of bleeding without *stunning* the animal-based and other measurables that indicate loss of consciousness include all the following: absence of muscle tone; absence of corneal reflex; absence of rhythmic breathing. In addition, cessation of bleeding after a continuous and rapid blood flow can be used as an indicator of *death*.

3. Recommendations:

a) both carotid arteries or the blood vessels from which they arise should be severed;

~~a~~ b) continuous and rapid blood flow should be assured after bleeding;

~~b~~ c) ~~cessation of blood flow~~ death should be assured before further processing;

~~c~~ d) bleeding knives should be sharpened for each animal.

EU comment

We propose amending as follows:

"d) bleeding knives should be sharpened ~~for each animal~~ as necessary to fulfill recommendation b)".

Justification

Sharpen bleeding knives for each animal at high throughputs would slow down the process, and is essential only for slaughter without prior stunning.

In addition, the following should be considered:

Slaughter with *stunning*:

a) the stun-to-stick interval should be short enough to ensure that the animal will ~~die before~~not recover~~ing~~ consciousness before it dies;

b) unconsciousness should be confirmed before bleeding.

Slaughter without *stunning*:

a) bleeding should be carried out by a single incision; any second intervention should be recorded and analysed to improve procedures.

b) Further processing may only be carried out when the death of the animal has been ascertained and no movement can be detected.

~~None identified.~~

Cattle are at risk of prolonged bleed out times and regaining consciousness if the bilateral vertebral arteries are not cut during a neck cut. ~~If~~As they are not cut, the vertebral arteries will continue to provide blood to the brain and ~~can cause~~any occlusion of the cut major arteries~~,~~ will slow~~ing~~ exsanguination. Therefore, bleeding with a cut of the brachiocephalic trunk should always be preferred in cattle.

Article 7.5.18.

Slaughter of pregnant free-moving animals

1. Animal welfare concerns:

Foetuses in the uterus are considered not to ~~cannot~~ achieve consciousness [EFSA, 2017; Mellor, D. J. *et al.*, 2005~~Diesch *et al.*, 2005~~]. However, if removed from the uterus the foetus may perceive pain or other negative impacts.

2. Animal-based and other measurables include:

~~None identified.~~ Signs of consciousness in the foetus, such as breathing [Mellor, 2003; Mellor, 2010; EFSA, 2017].

3. Recommendations:

Under ~~normal circumstances~~ OIE recommendations (Chapter 7.3. Animal transport by land), pregnant animals that would be in the final 10% of their gestation period at the planned time of *unloading* at the *slaughterhouse/abattoir* should be neither transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that pregnant females are handled separately.

The foetus should be left undisturbed in utero for at least 30 minutes after the *death* of the dam [EFSA, 2017; Anon, 2017]. The uterus could be removed as a whole, clamped and kept intact such that there is no possibility to the foetus to breathe.

In cases where the foetus is removed before 30 minutes has elapsed *euthanasia* ~~(captive bolt followed by bleeding)~~ should be carried out immediately.

4. Species-specific recommendations:

None identified.

Article 7.5.19.

Emergency killing of free-moving animals

EU comment

We suggest amending the title as follows:

"Other killing: Emergency killing and /or killing out of the slaughter line of free-moving animals",

If accepted, then "Emergency killing" needs to be replaced by "Other killing" in the rest of this article.

Justification

The exclusive concept "Emergency" means that we expect to deal with emergency situations only, but this is not the case, it would be appropriate to add "and killing out of the slaughter line. Proposal to define this paragraph as "other killing".

This article addresses animals that show signs of severe pain or other types of severe suffering before being unloaded or within the *slaughterhouse/abattoir*. These animals may correspond to animals unfit to travel as listed in Article 7.3.7. Principles described below may also apply to animals that are not suitable for *slaughter* for commercial reasons, even if they do not present signs of pain or suffering.

1. Animal welfare concerns:

Some animals can arrive at *slaughterhouses/abattoirs* with injuries or severe illnesses that can cause undue pain and suffering. This is more likely in animals of low economic value.

EU comment

We suggest that the first sentence of the paragraph above should be amended to:

"Some animals can arrive at *slaughterhouses/abattoirs* with injuries or severe illnesses that can cause ~~undue~~ pain and suffering."

Justification

The word 'undue' seem superfluous. This paragraph mentions the animal welfare concern. Injuries or severe illnesses can cause pain and suffering, and thus be a welfare concern. The next paragraph gives guidance on the conditions of an animal, which will require emergency killing.

2. Animal-based and other measurables include:

Animals requiring emergency *killing* are unable to walk independently or present severe injuries such as fractures, large open wounds, or prolapses. They may also present clinical signs of serious illness or being in a state of extreme weakness. New-born animals or animals that gave birth within the last 48 hours may also belong to this category.

3. Recommendations:

Animals should not be moved unless it can be done without causing ~~further~~ pain or suffering.

Animal handlers should euthanise the animal as soon as possible.

EU comment

We suggest replacing "euthanise" by "emergency kill", so that it reads:

"Animal handlers should ~~euthanise~~ emergency kill the animal as soon as possible'.

Justification:

The wording "emergency killing" includes both (emergency) slaughter and euthanasia and would be more suitable in this case.

Emergency *killing* should be systematically recorded and analysed in order to improve procedures and prevent recurrences.

4. Species-specific recommendations:

None identified.

Article 7.5.20.

Methods, procedures or practices unacceptable on animal welfare grounds for free-moving animals

1) ~~None of t~~The following practices for handling animals are unacceptable and should not be used:

a) crushing or breaking tails of animals;

b) applying pressure using an injurious object or applying an irritant substance ~~to sensitive areas such as eyes, mouth, ears, anogenital region or belly~~;

c) hitting animals with instruments such as large sticks, sticks with sharp ends, ~~metal~~ piping, stones, fencing wire or leather belts;

d) kicking, throwing or dropping animals;

e) grasping, lifting or dragging animals only by some body parts such as their tail, head, horns, ears, limbs, wool or hair;

f) dragging animals by any body part, by any means, including ~~with~~ chains, ~~or~~ ropes or by hand;

g) forcing animals to walk over other animals;

h) interfering with any sensitive area (e.g. eyes, mouth, ears, anogenital region or belly).

2) ~~None of t~~The following practices for restraining conscious animals are unacceptable and should not be used:

a) mechanical clamping of the legs or feet of the animals as the sole method of *restraint*;

b) breaking legs, cutting leg tendons or blinding animals;

c) severing the spinal cord, by using for example a puntilla or dagger;

d) applying electrical current that does not span the brain;

e) suspending or hoisting ~~conscious animals~~them by the feet or legs;

f) severing brain stem by piercing through the eye socket or skull bone;

g) forcing animals to ~~the ground~~sit or lay down by one or more handlers jumping on and lying across the animal's back.

3) Breaking the neck while the animal is still conscious during bleeding is also an unacceptable practice.

Article 7.5.21.

Arrival of animals in containers

On arrival at the *slaughterhouse/abattoir*, animals will already have been exposed to *hazards* that may have negative impacts on their welfare. Any previous *hazards* will have a cumulative effect that may impair the welfare of the animals throughout the *slaughter* process. Therefore, animals should be transported to the *slaughterhouse/abattoir* in a manner that minimises adverse animal health and welfare outcomes, and in accordance with Chapters 7.2. and 7.3.

1. Animal welfare concerns:

Animals in *containers* have smaller space allowances than on farm, undergo water and *feed* deprivation, and may be exposed to thermal stress due to adverse weather conditions and stress from social disturbance, noise, vehicle vibration and motion. In addition, stationary *vehicles* may have insufficient ventilation. Delays in *unloading containers* will prolong or exacerbate the impact of these *hazards*. Under these circumstances, injured or sick animals requiring urgent attention will not be identified and therefore the duration of their suffering will be increased.

2. Animal-based and other measurables include:

It can be difficult to assess animal-based measures while animals are in the *containers* and especially when the *containers* are on the vehicle or when many containers are stacked on top of each other. Some measurables that may be assessed include animals with injuries, or those that are sick or have died. Panting, reddening of the ears (heat stress in rabbits), shivering and huddling may indicate thermal stress. In rabbits drooling and licking may indicate prolonged thirst.

Time from arrival to *unloading* and slaughter, the environmental temperature and humidity (e.g. ambient, inside the vehicle) can be used to establish relevant thresholds for corrective action.

3. Recommendations:

Animals should be slaughtered as soon as they arrive at the *slaughterhouse/abattoir*. If not possible, *containers* should be unloaded, or vehicles should be placed in lairage or in sheltered and adequately ventilated area, promptly on arrival. This is facilitated by scheduling the arrival of the animals at the *slaughterhouse/abattoir* to ensure that there are sufficient personnel and adequate space in the *lairage* area. Time at lairage should be kept at a minimum.

Consignments of animals assessed to be at greater risk of *animal welfare hazards* (e.g. from long journeys, prolonged lairage, end of lay hens) should be unloaded first or should be considered for prioritised *slaughter*. When no available space is immediately available, creating space should be a priority. Provisions should be made to provide shelter, shade, cooling or heating systems or additional ventilation during waiting periods, or animals should be transported to an alternative nearby location where such provisions are is available. Mortalities and injuries should be reported to the competent authority.

4. Species-specific recommendations:

~~Poultry is especially sensitive to extreme temperatures and therefore special attention should be taken when dealing with delays in *unloading* this species in extreme temperatures.~~

Birds may get trapped or their wings or claws may get caught in the fixtures, mesh or holes in poorly designed, constructed or maintained transport systems. Similarly, rabbits may trap their paws in the fixtures mesh or holes in poorly designed, constructed or maintained transport systems. Under these situations, operators *unloading* birds or rabbits should ensure gentle release of trapped animals.

Article 7.5.22

Moving of animals in containers

This article addresses the handling of containerised animals during *unloading* and *lairage,* and into the killing area.

1. Animal welfare concerns:

During *unloading* and moving *containers* animals can be exposed to pain, stress and fear due to tilting, dropping or shaking of the *containers*.

2. Animal-based and other measurables include:

a) animals with broken limbs;

b) animals that strike against the facilities;

c) animals vocalizing;

d) body parts (i.e. wings, limbs, feet, paws or heads) stuck between *containers*;

e) animals injured by sharp projections inside *containers.*

3. Recommendations:

Containers in which animals are transported should be handled with care, moved slowly, and should not be thrown, dropped or knocked over. Where possible, they should be horizontal while being loaded or unloaded mechanically and stacked to ensure ventilation and prevent animals piling on one another. In any case, *containers* should be moved and stored in an upright position as indicated by specific marks.

Animals delivered in *containers* with perforated or flexible bottoms should be unloaded with particular care to avoid injury by crushing or jamming of body parts.

Animals that are injured, jammed or sick require immediate action and, when necessary, should be taken from the *containers* and euthanised without delay. Refer to Articles 7.5.8, 7.5.9., 7.6.8 and 7.6.17.

Staff should routinely inspect the *containers* and remove the broken *containers* that should not be re-used.

4. Species-specific recommendations:

None identified.

Article 7.5.23

Lairage of animals in containers

1. Animal welfare concerns:

Animals during *lairage* may be exposed to several *animal welfare hazards* including:

a) food and water deprivation leading to prolonged hunger and thirst,

EU comment

We suggest replacing "food" with "feed":

"a) ~~food~~ feed and water deprivation leading to prolonged hunger and thirst,"

Justification:

In order to align the terminology in this chapter with that of e.g. chapter 7.10 on animal welfare and broiler chicken production systems.

b) absence of protection against extremes in climate leading to thermal stress,

EU comment

We suggest replacing "extremes in climate" by "adverse weather or climate conditions", so that it reads as follows:

"b) absence of protection against ~~extremes in climate~~ adverse weather or climate conditions leading to thermal stress,"

Justification

"Adverse weather and climate conditions" would be better wording and in line with the wording in 7.5.14 (Lairage of free-moving animals). And thermal stress can occur also without the climate/weather being already extreme.

c) sudden or excessive noises, including from personnel, leading to fear,

d) insufficient space to lie down and move freely leading to fatigue and aggressive behaviour.

e) not being inspected or accessible for emergency killing when necessary.

2. Animal-based and other measurables include:

a) thermal stress (e.g. panting, shivering, huddling behaviour),

b) space allowance,

c) excessive soiling with faeces,

d) injuries (e.g. splay leg, open wounds, fractures),

e) dead animals.

3. Recommendations:

Animals should be slaughtered upon arrival at the *slaughterhouse/abattoir*.

Staff should routinely inspect and monitor containers while in the lairage to observe animals for signs of suffering and distress and take appropriate corrective action to address any concerns.

The *lairage* should provide animals with protection against adverse weather conditions.

Animals should be protected from sudden and excessive noise (e.g. ventilation fans, alarms, or other indoor or outdoor equipment).

4. Species-specific recommendations:

None identified.

Article 7.5.24.

Unloading animals from containers

1. Animal welfare concerns:

Animals are removed manually or automatically by tilting ~~(poultry)~~ from the transport *containers*.

When the *containers* with ~~birds~~animals are manually or mechanically emptied by tipping, animals fall on to conveyors. Dumping, piling up and shock might happen, especially for the last ~~birds~~animals which are often removed by manual or mechanical shaking of the *containers*.

Other *hazards* include:

a) narrow openings or doors of the *containers*;

b) *containers* placed too far away from the place of *stunning*;

c) handling and removal of animals from containers before stunning;

~~c~~d) incorrect design of tipping manually or using mechanical equipment that cause animals to fall~~ing~~ from height ~~and conveyor belts that are running too fast or too slow resulting in piling or injured animals~~;

e) conveyor belts that are running too fast or too slow resulting in piling or injury.

2. Animal-based and other measurables include:

a) animal falling;

b) struggling, including wing flapping;

c) escape attempts;

d) vocalisation;

e) injuries, dislocation, fractures;

f) pilling ~~off~~up of animals.

3. Recommendations:

Removal of animals from the *containers* in a way that cause pain, e.g. by one leg, wings, neck or ears, should be avoided.

EU comment

We suggest replacing "should be avoided" by "should not be applied", so that it reads as follows:

"Removal of animals from the containers in a way that cause pain, e.g. by one leg, wings, neck or ears, ~~should be avoided~~ should not be applied."

Justification

We think stronger wording is needed here than 'should be avoided'. We wish to make clearer that such ways of handling are not acceptable.

Animals should be removed from *containers* by the body or by both legs using both hands and one animal at a time. Animals should not be grabbed and lifted by one leg, the ears, wings or fur and they should not be thrown, swung or dropped.

Modular systems that involve tipping of live birds are not conducive to maintaining good animal welfare. These systems, when used, should be incorporated with a mechanism to facilitate birds sliding out of the transport system, rather than being dropped or dumped on top of each other ~~from heights of more than a metre~~.

4. Species-specific recommendations:

Any animal ~~Birds~~ with broken bones and/or dislocated joints should be ~~humanely~~emergency killed before being hung on shackles for processing.

Article 7.5.25.

Restraint for stunning animals from containers

1. Animal welfare concerns:

The purpose of *restraint* is to facilitate the correct application of the *stunning* and ~~or~~ bleeding procedures~~equipment~~. Incorrect *restraint* and handling cause pain, fear and distress and may lead to ineffective *stunning* and ~~or~~ bleeding.

Other *hazards* include:

a) Inversion can provoke compression of the heart and lungs or air sacs by the viscera and might compromise breathing and cardiac activity. This might will cause pain and fear in conscious birds and rabbits.

b) Shackling hanging birds upside down by inserting both legs into metal shackles. During shackling, the birds are also subjected to compression of their legs and wing flapping by their neighbour(s), leading to pain and fear.

c) Inappropriate shackling leads to pain and fear when shackles are too narrow or too wide, when the birds are hung by one leg, or when one bird is shackled on two different adjacent shackles. Line speed, without a concomitant increase in workforce, can contribute to poor shackling outcomes.

d) Drops, curves and inclination of shackle line or high speed of the slackline create fear and possible pain due to the sudden changes in position as well as increase effects of inversion.

2. Animal-based and other measurables include:

a) struggling;

b) escape attempts;

c) vocalisations of high frequency~~(poultry)~~;

d) injuries and pain caused by excessive force of restraint or shackling~~;~~.

~~e) fear caused by prolonged restraint, which may exacerbate insecure or excessive restraint.~~

3. Recommendations:

Stunning methods that avoid handling, shackling and inversion of conscious animals should always be preferred.

Where, not possible, ~~A~~animals should be handled and restrained to minimise ~~without provoking~~ struggle or attempts to escape.

~~Avoid inversion of conscious animals.~~

~~Avoid shackling of conscious animals but there is no real way to prevent or correct shackling, however, as it is a part of some of the *stunning* methods most commonly used in slaughter plants.~~

Shackle lines must be constructed and maintained so they do not jolt ~~birds~~animals as this is likely to stimulate flapping (poultry) or struggle. Shackle line speeds must be optimised so that they do not cause the birds to struggle.

To minimise wing flapping (poultry) or struggle, breast support should be provided to the birds from the shackling point up to the stunner.

Inappropriate shackling such as too narrow or too wide shackles, ~~birds~~animals being pushed into the shackles with force, ~~birds~~animals shackled by one leg, or shackled on two different adjacent shackles, should be avoided.

EU comment

Same as above, we suggest replacing "should be avoided" by "should not be applied":

"Inappropriate shackling such as too narrow or too wide shackles, animals being pushed into the shackles with force, animals shackled by one leg, or shackled on two different adjacent shackles, ~~should be avoided~~ should not be applied."

Justification

As above, we think stronger wording is needed here than "should be avoided". We wish to make clearer that such ways of handling are not acceptable.

Inappropriate shackling can be prevented by training staff to handle ~~birds~~animals with care and compassion, by an competent professional, shackle ~~birds~~animals gently by both legs and kill injured ~~birds~~animals before shackling, by rotating staff at regular intervals to avoid boredom and fatigue and by using shackles that are appropriate and adjustable for ~~to~~ the species and size of the ~~birds~~animals.

4. Species-specific recommendations:

Rabbits:

Restraining for head-only electrical *stunning* is manual and involves holding the rabbit with one hand supporting its belly, and the other hand guiding the head into the *stunning* tongs or electrodes.

Rabbits should not be lifted or carried by the ears, head or one leg.

Poultry:

Shackling should not be used with heavy birds like parent *flocks,* turkeys or with birds that are more susceptible to fractures like end-of-lay hens.

Poultry should not be lifted or carried by the head, wings or one leg.

Article 7.5.26.

Head only electrical stunning

1. Animal welfare concerns:

Electrical *stunning* involves application of an electric current ~~to~~ across the brain of sufficient ~~magnitude~~ current and intensity to induce immediate unconsciousness [EFSA, 2004; Grandin, 1980]. The main *hazards* preventing effective electrical *stunning* are: incorrect electrode placement, poor contact, dirty or corroded electrode, inappropriate electrical parameters (low voltage/current or high frequency [EFSA, 2004]).

2. Animal-based and other measurables include:

Effectiveness of *stunning* should be monitored at different stages: immediately after *stunning*, just before and during bleeding until death ~~occurs~~ is confirmed [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

No indicator should be relied upon alone.

An effective stun is characterised by the presence of all the following signs: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal reflex.

The presence of any of the following signs indicate a high risk of ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal or palpebral reflex; rhythmic breathing~~.~~, spontaneous swallowing and head shaking.

3. Recommendations:

Animals should be stunned as soon as they are restrained.

To minimise any disturbance to birds during shackling, where shackles are wet to improve conductivity, they should be wet only prior to birds' legs being placed in them.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system or be immediately killed. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Stunning equipment should be used, cleaned, maintained and stored following manufacturer's recommendations.

Constant current stunners should always be preferred to constant voltage stunners since the first ones ensure that the minimum current is provided to the animal independently from individual impedance.

Regular calibration of the equipment according to the manufacturer's procedure are recommended. Effectiveness of the *stunning* should be monitored regularly.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters and~~or~~ follow the manufacturer's recommendations for *stunning*, such as:

– shape, size and placement of the electrodes [AVMA, 2016];

– contact between electrode and head;

– electrical parameters (current intensity(A), waveform type (AC and DC), voltage (V) and frequency (Hz));

EU comment

The EU suggests providing species-specific electrical parameters as it was done in the past version of the chapter or at least precise technical and scientific references for the competent authorities to determine effective electrical parameters.

As an indication, the following references could be added for head-only stunning (EFSA Journal 2019;17(11):5849):
240 mA for chicken
400 mA for turkeys

Justification
Same as for Article 7.5.16 (4).

– visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors and displays voltage and applied current.

4. Species-specific recommendations:

The *Competent Authority* should determine effective electrical parameters, based on scientific evidence for different types of animals.

Article 7.5.27.

Electrical water-bath stunning for poultry

1. Animal welfare concerns:

In electrical water-bath *stunning* poultry are inverted and hung by the legs from a shackle line. The bird's head has direct contact with the water-bath, and an electric current is passed from the water through the bird to the leg shackle. *Hazards* that may prevent effective electrical *stunning* are: lack of contact between head and water, differences in individual bird resistance pre-stun shocks due to wings contacting water before the head, and the use of inappropriate electrical parameters (low voltage/current or high frequency [AVMA 2016]).

Hazards that increase the likelihood of animals experiencing pre-stun shocks are: poor handling at shackling, line speed, physical contact between birds, incorrect angle of entry ramp, wet entry ramp, incorrect water-bath height, and shallow immersion.

Factors affecting individual bird resistance include the resistance between the shackle and the leg (leg/shackle interface), shackling on top of a severed foot, shackling by one leg, poor shackle position, incorrect shackle size, dry shackles, scale on the shackle surface, and keratinised skin on the legs (e.g. older birds).

Where inappropriate electrical stunning parameters (e.g. high frequency) are used, conscious animals are at risk of being electro-immobilized or paralysed causing pain and suffering.

2. Animal-based and other measurables include:

Effectiveness of *stunning* should be monitored at different stages: immediately after *stunning*, just before and during bleeding until death occurs [EFSA, 2019, EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

No indicator should be relied upon alone.

An effective stun is characterised by the presence of all the following signs: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal reflex.

EU comment

We suggest deleting "loss of posture":

"An effective stun is characterised by the presence of all the following signs: tonic-clonic seizures; ~~loss of posture;~~ apnoea; and absence of corneal reflex."

Justification

We think that "loss of posture" is not a good indicator for effectiveness of stunning for poultry, hanging shackled in a water bath. A sign of loss of posture seems to be very unclear for such a situation. We question if there is any relevant scientific source for mentioning loss of posture in case of electrical water-bath stunning. We couldn't find it in the references mentioned above.

The presence of any of the following signs indicate a high risk of ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex or palpebral reflex; rhythmic breathing spontaneous swallowing and head shaking.

3. Recommendations:

The height of the water-bath stunner must be adjusted so that the birds cannot pull themselves up and avoid the stunner. Avoid distractions such as people walking under the birds as this can cause birds to pull up.

Personnel should watch for short or stunted birds as these birds will not be able to make contact with the water and will not be stunned. These birds should be stunned in the slaughter line (e.g. penetrative captive bolt) or removed and euthanised.

The rail of the shackle line should run smoothly. Sudden movement such as jolts, drops or sharp curves in the line may cause birds to flap and avoid the stunner.

To minimise any disturbance to birds during shackling, where shackles are wet to improve conductivity, they could be wet only prior to birds' legs being placed in them.

Pre-stun shocks can be reduced by having a smooth shackle line and entry into the water-bath and by adjusting the water level of the bath.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Stunning equipment should be used. cleaned, maintained and stored following manufacturer's recommendations.

Constant current stunners should always be preferred to constant voltage stunners since the first ones ensure that the minimum current is provided to the animal independently from individual impedance.

Regular calibration of the equipment according to the manufacturer's procedure are recommended. Effectiveness of the *stunning* should be monitored regularly.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters or follow the manufacturer's recommendations for *stunning*, such as:

– water level;

– contact between water and head, as well as between the legs and the leg shackle;

– electrical parameters (current intensity(A), waveform type (AC and DC), voltage(V) and frequency(Hz));

EU comment

The EU suggests providing species-specific electrical parameters as it was done in the past version of the chapter or at least precise technical and scientific references for the competent authorities to determine effective electrical parameters.

As an indication, the following references could be added for waterbath stunning (EFSA Journal 2019;17(11):5849):
Frequency below 200 Hz
100 mA for chicken
250 mA for turkeys
130 mA for Ducks and geese
45 mA for quails
For frequency from 200 to 400 Hz
150 mA for chicken
400 mA for turkeys

For frequency from 400-600 Hz
200 mA for chicken
400 mA for turkeys
Ducks, geese and quails should not be stunned for frequency higher than 200 Hz.
Chicken and turkeys should not be stunned for frequency higher than 600 Hz.

Justification
Same as for Article 7.5.16 (4).
EFSA Journal 2019;17(11):5849

– visual or auditory warning system to alert the operator to proper or improper function, such as a device that monitors and displays voltage and applied current.

Ensure an optimum combination of voltage and frequency during electrical water bath *stunning* practices, to maximize the effectiveness of *stunning*.

Animal welfare hazards such as conscious inversion of birds, pre-stun shocks, and variability in electrical current delivered to each bird are inherent risks of electrical water-bath stunning. The use of electrical water-bath stunning should be avoided and replaced by stunning systems which avoid these associated animal welfare hazards.

4. Species-specific recommendations:

The *Competent Authority* should determine effective electrical parameters, based on scientific evidence for different types of birds.

Article 7.5.28.

Mechanical stunning

The mechanical methods described here are penetrative and non-penetrative captive bolt, ~~percussive blow to the head, cervical dislocation and decapitation~~.

Effective mechanical *stunning* requires a severe and immediate damage to the brain by the application of mechanical force. For that reason, cervical dislocation and decapitation cannot be considered as *stunning* methods.

1. Animal welfare concerns:

Mechanical methods required precision and often physical strength to restrain and stun the animals. A common cause for misapplication of these methods is the lack of proper skill and the operator fatigue.

Penetrative and non-penetrative cCaptive bolt

An incorrect shooting position or incorrect captive bolt parameters (not hitting the skull with sufficient force) will mis-stun~~ned~~ the animal leading to serious wounds and consequently pain, suffering, and fear.

Improper captive bolt parameters may be linked to the use of improper gun (bolt diameter), improper cartridges, overheated or badly maintained gun.

~~*Percussive blow to the head*~~

~~An incorrect application of the blow, by not hitting the brain with sufficient force will also mis-stunned the animals leading to serious wounds and consequently pain and fear.~~

~~In addition, the blow might not be consistently effective when delivered to an animal held upside down by its legs (part of the energy is dissipated by the movement of the body instead of damaging the brain).~~

Cervical dislocation and decapitation

Because neither method appl~~y~~ies to the brain, the loss of consciousness is not immediate and, in some cases, when the method is not properly applied risk of neck crushing and the pain and fear of the animal might be prolonged.

In addition, decapitation is associated with an open wound leading to intense pain.

EU comment

We suggest revising this paragraph as follows:

"Cervical dislocation ~~and decapitation~~

~~Because neither method applyies to the brain,~~ The loss of consciousness is delayed if there is no lesion of the cerebral trunk ~~not immediate~~ and, in some cases, when the method is not properly applied risk of neck crushing and the pain and fear of the animal might be prolonged.

~~In addition, decapitation is associated with an open wound leading to intense pain.~~"

Justification

As decapitation is only a bleeding method, and not a stunning method, it is suggested to delete the word "decapitation", and to delete the sentence: "In addition, decapitation is associated with an open wound leading to intense pain."

In addition, it would be more accurate to write "The loss of consciousness is delayed if there is no lesion of the cerebral trunk", rather than "Because neither method applies to the brain, the loss of consciousness is not immediate".

2. Animal-based and other measurables include:

Penetrative and non-penetrative ~~C~~captive bolt ~~and percussive blow to the head~~

~~With birds, s~~Severe convulsions (wing flapping (poultry) and leg kicking i.e. uncontrolled muscular movements) occur immediately after shooting or blowing. This is due to the loss of control of the brain over the spinal cord. Since mechanical *stunning* is applied on individual animals, its efficacy can be assessed immediately after the stun [Nielsen *et al.*, 2018].

Effectiveness of stunning should be monitored at different stages: immediately after stunning, just before and during bleeding until death occurs [EFSA, 2019; EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

An effective stun is characterised the following signs: the absence of corneal or palpebral reflex, the absence of rhythmic breathing and the presence of immediate collapse.

The presence of any of the following signs indicate a high risk of ineffective stun or recovery of consciousness: vocalisations; spontaneous blinking; righting reflex; presence of corneal or palpebral reflex; rhythmic breathing.

Cervical dislocation and decapitation

Death can be confirmed from several indicators: complete severance between the brain and the spinal cord (i.e. gap between neck vertebrae and base of skull), permanent absence of breathing, absence of corneal or palpebral reflex, dilated pupil, or relaxed carcass [EFSA, 2013a].

3. Recommendations:

Penetrative and non-penetrative ~~C~~captive bolt ~~and percussive blow to the head~~ should only be used as backup or for small-scale slaughtering as in small *slaughterhouses/abattoirs* or on-farm slaughter or for emergency killing.

Penetrative and non-penetrative ~~C~~captive bolt

The captive bolt gun should be used, cleaned, maintained and stored following manufacturer's recommendations.

Effectiveness of the *stunning* should be monitored regularly.

Because it requires precision, this method should only be applied with proper restrain of the head of the animal~~s~~. In addition, in the case of birds, they should be restrained in a bleeding cone to contain wing flapping.

The captive-bolt should be pointing perpendicularly on the parietal bones of birds.

Placement is different for birds with or without combs:

Without comb

The placement of the device should be directly on the midline of the skull and at the highest/widest point of the head with the captive bolt aimed directly down toward the brain [AVMA, 2020].

With comb

As far as captive bolt in chickens (and poultry with comb development) is concerned, the placement should be directly behind the comb and on the midline of the skull with the captive bolt aimed directly down towards the brain of the bird [AVMA, 2020].

The power of the cartridge, compressed air line pressure or spring should be appropriate for the species and size of birds. Cartridges should be kept dry and the gun regularly inspected and maintained.

This method should be dealt with a single sufficiently strong hit placed in the frontoparietal region of the head and should result resulted in loss of auditory evoked potentials when using an EEG in broilers and broiler breeders.

Fatigue of the operator can lead to inconsistency in application, creating concern that the technique may be difficult to apply humanely to large numbers of birds. It should not be done with the animal's head hanging down since inversion is stressful and part of the energy of the blow will be dissipated by the movement of the body.

It should not be used as a routine method and should be limited as a back-up method limited to small size animals (e.g. up to 3kg liveweight manually and up to 5 kg mechanical).

EU comment

We suggest deleting the two paragraphs above:
"~~Fatigue of the operator can lead to inconsistency in application, creating concern that the technique may be difficult to apply humanely to large numbers of birds. It should not be done with the animal's head hanging down since inversion is stressful and part of the energy of the blow will be dissipated by the movement of the body.~~

~~It should not be used as a routine method and should be limited as a back-up method limited to small size animals (e.g. up to 3kg liveweight manually and up to 5 kg mechanical).~~"

Justification

The 2 paragraphs above don't concern the usage of the 'captive bolt'. They seem to be old texts concerning 'percussive blow to the head' respectively 'cervical dislocation'.

Rabbits

The device should be placed in the centre of the forehead, with the barrel in front of the ears and behind the eyes. The device should be discharged twice in rapid succession at the pressure recommended for the age and size of the rabbit. [Walsh *et al.,* 2017].

The power of the cartridge, compressed air line pressure or spring should be appropriate for the animal ~~species and size of birds~~. Cartridges should be kept dry and the gun regularly inspected and maintained.

As an indication for broiler chickens, the appropriate specifications for captive bolt *stunning* are a minimum of 6-mm bolt diameter driven at an air pressure of 827 kPa to a penetration depth of 10 mm [Raj and O'Callaghan, 2001].

EU comment

We suggest deleting or redrafting this paragraph which should concern rabbits:

"~~As an indication for broiler chickens, the appropriate specifications for captive bolt *stunning* are a minimum of 6-mm bolt diameter driven at an air pressure of 827 kPa to a penetration depth of 10 mm [Raj and O'Callaghan, 2001].~~"

Justification

However, while this section is about rabbits in the text "broiler chickens" are mentioned.

There should be sufficient bolt guns such that they are allowed to cool between operations~~, and they should be cleaned and maintained according to manufacturer's instructions~~.

~~*Percussive blow to the head*~~

~~This method~~ The blow ~~should be dealt with a single sufficiently strong hit placed in the frontoparietal region of the head resulted in loss of auditory evoked potentials in broilers and broiler breeders.~~

~~Fatigue of the operator can lead to inconsistency in application, creating concern that the technique may be difficult to apply humanely to large numbers of birds. It should not be done with the animal's head hanging down since inversion is stressful and part of the energy of the blow will be dissipated by the movement of the body.~~

~~Considering that the application of this method is entirely manual and prone to error, percussive blow might be used only when no other *stunning* method is available and, by establishing a maximum number of animals per operator in time to avoid errors due to operator fatigue.~~

~~It should not be used as a routine method and should be limited as a back-up method limited to small size animals (e.g. up to 3kg liveweight manually and up to 5 kg mechanical).~~

~~This method should not be used in rabbits because of the difficulties to apply this method efficiently.~~

Cervical dislocation

Cervical dislocation should not be used in conscious birds under any circumstances. ~~avoided since it does not render the animal unconscious immediately~~.

EU comment

We suggest deleting this paragraph as it is not consistent with the rest of this section: "~~Cervical dislocation should not be used in conscious birds under any circumstances. avoided since it does not render the animal unconscious immediately.~~"

It should not be used as a routine method and should be limited as a back-up method limited to small size animals (e.g. up to 3kg liveweight manually and up to 5 kg mechanical).

Mechanical dislocation should be preferred to manual dislocation as the efficiency of the first is less dependent on the operator's strength than the later.

Cervical dislocation should not be undertaken with tools such as plyers as they cause neck crushing, rather than concussion, and consequently pain and fear.

Decapitation

Decapitation should not be used since it does not render the animal unconscious immediately.

EU comment

We suggest deleting as follows:

"~~Decapitation~~

~~Decapitation should not be used since it does not render the animal unconscious immediately.~~"

Justification

As decapitation is only a bleeding method, and not a stunning method, it is suggested to delete this reference to decapitation

4. Species-specific recommendations:

~~Because of their size, heavy animals such as turkeys, geese or mature rabbits should not be stunned through percussive blow to the head or cervical dislocation.~~

Turkeys and geese may be also properly stunned by non-penetrative captive bolt. [Walsh *et al.*, 2017; Woolcott *et al.*, 2018; Gibson *et al.*, 2019]

Article 7.5.29.

Controlled atmosphere stunning for poultry

Animals may be exposed to controlled atmosphere *stunning* methods either directly in crates or after being unloaded on a conveyor belt. Animals are not subject to restraint. Controlled atmosphere *stunning* includes exposure to carbon dioxide, inert gases, mixtures of carbon dioxide with inert gases or low atmosphere pressure (LAPS). The effectiveness and animal welfare impacts of LAPS are still being evaluated as it is a newer form of controlled atmosphere stunning in comparison to other methods, so far it has only been studied in poultry and therefore is not suitable for use in rabbits or other animals without further study.

1. Animal welfare concerns:

A common concern of all controlled atmosphere *stunning* methods is the risk of insufficient exposure of animals to the modified atmosphere, which can result in animals recovering ~~returning to~~ consciousness before bleeding and cause distress (respiratory), pain and fear. The insufficient exposure to modified atmosphere may be due to either a too short exposure time, a too low concentration of gas or a combination of these variables.

These variables are critical because animals being stunned in large groups need special attention to ensure unconsciousness prior to neck cutting. For this reason, the duration of unconsciousness induced needs to be longer than required by other *stunning* methods to ensure animals do not recover prior to being killed.

Furthermore, *hazards* causing increased distress during induction of unconsciousness are irritant or aversive gas mixtures, low gas temperature and humidity. In the case of exposure to carbon dioxide, there is a risk that animals are exposed to a too high concentration of this gas, leading to pain. Exposure of conscious animals to more than 40% carbon dioxide (CO_2) will cause painful stimulation of the nasal mucosa and aversive reactions.

Low atmospheric pressure systems (LAPS) should not be confused with decompression. LAPS utilise a slow removal of air where animals exhibit minimal to no aversive behaviours. Decompression is a fast process that is associated with induction of pain and respiratory distress.

2. Animal-based and other measurables include:

It may be difficult to monitor the effectiveness of controlled atmosphere *stunning* due to limited access to observation of animals during the *stunning* process. All chamber-type systems should have either windows or video cameras so that problems with induction can be observed. If problems are observed, there is a need to take immediate~~ly any~~ corrective measure that could alleviate the suffering of the animals concerned.

Therefore, it is essential that the death of animals is confirmed at the end of the exposure to the controlled atmosphere.

Death can be confirmed from permanent absence of breathing, absence of corneal or palpebral reflex, dilated pupils and relaxed carcass.

Since animal-based measures are difficult to monitor, resource-based measures should be used such as monitoring of gas concentration(s), exposure time, gas displacement rate, and ~~decompression~~ rate of air removal (for low atmosphere pressure).

3. Recommendations:

Conscious animals should not be exposed to carbon dioxide exceeding 40%. Any compressed gas should also be vaporised prior to administration and humidified at room temperature to prevent the risk of animals experiencing thermal shock.

The duration of exposure and the gas concentration should be designed and implemented in such a way that all animals are dead before being shackled.

Gas concentrations and exposure time, temperature and humidity must be monitored continuously at the level of the animal inside the chamber.

Stunning systems should have visual and auditory warning system to alert the operator to improper function, such as inappropriate gas concentration or decompression rate.

In case of low atmosphere pressure *stunning* ~~decompression~~ rate of air removal should be monitored continuously. The decompression rate should not be greater than or equivalent to a reduction in pressure from standard sea level atmospheric pressure (760 Torr) to 250 Torr in not less than 50 s. During a second phase, a minimum atmospheric pressure of 160 Torr shall be reached within the following 210 s.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

4. Species-specific recommendations:

Low atmosphere pressure *stunning* has only been scientifically studied on commercial broilers and therefore should not be used for other animals until further information is available.

The recommended CO_2 displacement rate for rabbits is 50-60% of the chamber or cage volume/min as this results in a significantly shorter time to insensibility and death (Walsh *et al.*, 2016, AVMA 2020). Exposure to CO_2 at high concentrations can reduce pre-stun handling and produce irreversible *stunning* in rabbits. With a stun to stick interval of up to 2 min, 200 s of exposure at 80%, 150 s at 90% and 110 s at 98% are recommended (Dalmau *et al.*, 2016). While there are advantages to high CO_2 exposure in rabbits, it is not without welfare concerns (aversion, vocalisation).

Article 7.5.30.

Bleeding ~~in~~ of animals arriving in containers

1. Animal welfare concerns

In poultry, the most common animal welfare concern at the time of bleeding is recovery of consciousness due to ineffective ~~electric water bath~~ *stunning* practices. There are a lot of factors that determine the efficacy of a *stunning* procedure such as type of chicken (broiler, breeder, layer), animal weight, voltage, frequency, impedance and duration of *stunning* or gas (mixture) concentration and exposure [Zulkifli *et al.*, 2013; Raj, 2006; Wotton & Wilkins, 2004].

Improper *stunning* practice leads to the risk of animal suffering fear, distress, and from pain, during and after *slaughter* if they regain consciousness. There is also an additional risk of injury ~~on~~ to bones (coracoid and scapula), wings and joints due to flapping if birds regain consciousness.

Bleeding without prior *stunning* increases the risk of animal suffering because the incision to sever blood vessels results in substantial tissue damage in areas well supplied with nociceptors. The activation of these nociceptors causes the animal to experience pain [Gregory, 2004; Gibson et al., 2009]. Loss of consciousness due to bleeding is not immediate and there is a period during which the animal can feel fear, pain and distress [Gregory, 2004; Johnson *et al.*, 2015].

In case of bleeding without *stunning*, higher cases of injury, bruises, haemorrhage and broken body parts are expected to occur due to wing flapping and violent muscular contractions [McNeal *et al.*, 2003).

Bleeding duration also plays an integral part in processing, where animals that have not undergone a sufficient bleeding period (min 40 sec), may still be alive upon reaching the scalding tank. Live and conscious birds, if not removed prior to scalding, will then be subjected to additional pain stimulators from the heat inside the scalding tank.

2. Animal-based and other measurables include:

The main animal-based measurable is the blood flow (rate and duration). For animal-based and other measurables of return of consciousness after *stunning*, see ~~Article 7.5.16~~Article 7.5.26. to Article 7.5.29.

One of the most common parameters in determining bleeding efficiency is the percentage of blood loss, where the amount of blood loss is estimated through the difference between pre-slaughter weight and post-slaughter weight [Velarde *et al.*, 2003; Sabow *et al.*, 2015].

For poultry, the presence of 'red-skin' carcasses may be the result of ineffective killing and live birds entering the scalding tank.

~~The effectiveness of a *stunning* procedure on birds can be seen through the following signs: absence of corneal reflex, loss of posture tonic-clonic seizures and apnoea. Presence of one or more signs during bleeding may be the result of ineffective *stunning* procedure.~~

3. Recommendations:

The *slaughterhouse/abattoir* operators should ensure that:

– qualified personnel take random samples of birds between the end of *stunning* and before bleeding to ensure birds are not showing signs of consciousness;

– qualified personnel right after bleeding check that the jugular veins, carotid artery and windpipe were cut thoroughly, guaranteeing a well bleeding process afterwards;

– the slaughter line speed allows a minimum bleeding period of 40 seconds (for chickens) so that there is minimum blood loss of 60 percent before reaching the scalding tank or other potentially painful operation;

– qualified personnel check that at the bleeding line, especially before scalding, birds are ~~completely~~ dead. Birds that are still alive need to be euthanized immediately ~~removed from shackle~~.

Decapitation should ~~not~~ be applied only in unconscious birds.. ~~used as a bleeding technique because it does not allow monitoring possible return of consciousness.~~

4. Species-specific recommendations

None identified.

Article 7.5.31

Emergency killing of~~n~~ animals arriving in containers

This article addresses animals that show signs of severe pain or other types of severe suffering before being unloaded or within the *slaughterhouse/abattoir*. These animals may correspond to animals unfit to travel as listed in Article 7.3.7. Principles described may also apply to animals that are not suitable for *slaughter* for commercial reasons, even if they do not present signs of pain or suffering.

1. Animal welfare concerns:

   Some animals can arrive at *slaughterhouses/abattoirs* with injuries or severe illnesses that can cause undue pain and suffering.

2. Animal-based and other measurables include:

   Animals requiring emergency *killing* are those~~, among others that present~~ ~~with~~ severe injuries such as fractures, bone dislocations, and large open wounds.

   They may also present clinical signs of serious illness or being in a state of extreme weakness.

3. Recommendations:

   Animal handlers should euthanise the animal as soon as they are identified at arrival, during lairage or at the time of shackling.

   Emergency *killing* should be systematically recorded and analysed to improve procedures and prevent recurrences.

4. Species-specific recommendations:

   None identified yet.

Article 7.5.32.

Methods, procedures or practices unacceptable on animal welfare grounds for animals arriving in containers

1) ~~None of t~~The following practices for handling animals are unacceptable and they should not be used:

   a) applying pressure using an injurious object or applying an irritant substance to any part of the body of the animal;

   b) hitting animals with instruments such as large sticks, sticks with sharp ends, ~~metal~~ piping, stones, fencing wire or leather belts;

   c) kicking, throwing or dropping animals;

   d) grasping, lifting or dragging animals only by ~~some~~ body parts such as their tail, head, ears, limbs, hair or feathers;

   e) dragging animals by any body parts.

2) ~~None of t~~The following practices for restraining animals are unacceptable and should not be used:

   a) mechanical clamping of the legs or feet of the animals as the sole method of restraint;

   b) breaking legs, cutting leg tendons or blinding animals;

   c) applying electrical current that does not span the brain; ~~such as the use of the electrical *stunning* method with a single application leg-to-leg~~;

   d) severing brain stem by piercing through the eye socket or skull bone;

e) neck crushing.

In poultry, electro-immobilisation for neck-cutting or preventing wing flapping during bleeding, or the method of brain piercing through the skull without prior *stunning*.

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CHAPTER 8.14.

INFECTION WITH RABIES VIRUS

EU comment

The EU thanks the OIE for the latest version of the revised Chapter 8.14. on Infection with rabies virus and welcomes the new amendments introduced in the draft to address dog-mediated rabies vaccination programmes, as a complement to the recommendations of Chapter 7.7. on Dog population management.

However, the EU cannot support the proposed changes to this chapter as presented.

Indeed, the EU regrets the position of the OIE to reduce the waiting period after the antibody titration test and prior to the international movement of dogs, from the current three months to 30 days, in Article 8.14.6bis.

This amendment is mainly based on a concept paper endorsed by the OIE Scientific Commission for Animals Diseases at its February 2020 meeting. This reduction of the waiting period has been assessed by the European Food Safety Authority (EFSA), together with its possible impact on the risk-mitigation system currently in force in the EU.

The EU recalls that the risk of transmission of rabies by dog movement is related to moving an animal incubating the disease. Rabies infection prior to vaccination protection cannot indeed be controlled by immunisation. A waiting period following primo-vaccination is recommended as the most efficient measure to reduce the risk of importing rabies-infected dogs.

The main conclusions of EFSA's scientific report are as follows:

"It was concluded with a 95% certainty that the maximum number of rabies-infected imported dogs following the regulations in the next 20 years could increase from 5 to 20 when decreasing the waiting period from 90 to 30 days

When the incubation period estimated based on field data was used, the average time it takes to import a RABV-infected dog fully compliant with the regulation was reduced 4.2 times if the waiting period was reduced from 90 to 30 days irrespective of the incidence in the region of origin and the numbers of dogs introduced.

The potential impact of even a small increase in probability means the risk is increased for a region like the EU where rabies has long been a focus for eradication, to protect human and animal health."

The EU is pleased to share the EFSA report with the Code Commission (https://www.efsa.europa.eu/en/efsajournal/pub/7350) and considers that, based on this assessment, it is necessary to maintain the current waiting period at a minimum of three months.

Further comments are inserted in the text below.

[…]

Article 8.14.6bis.

Recommendations for importation of dogs from countries or zones infected with rabies virus

Veterinary Authorities should require the presentation of an *international veterinary certificate* complying with the model of Chapter 5.11. attesting that the dogs:

1) showed no clinical signs of rabies the day prior to or on the day of shipment;

2) were permanently identified and their identification ~~number~~code stated in the certificate;

3) and either:

   a) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer, with a vaccine that was produced in accordance with the *Terrestrial Manual* and were subjected, not less than 30 days and not more than 12 months prior to shipment, to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5 IU/ml;

   or

   b) were kept in a *quarantine station* for six months prior to shipment.

Article 8.14.7.

Recommendations for importation of~~dogs~~, cats and ferrets from countries or zones infected with rabies virus

Veterinary Authorities should require the presentation of an *international veterinary certificate* complying with the model of Chapter 5.11. attesting that the animals:

1) showed no clinical signs of rabies the day prior to or on the day of shipment;

2) were permanently identified and their identification ~~number~~code stated in the certificate;

3) and either:

   a) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer, with a vaccine that was produced in accordance with the *Terrestrial Manual* and were subjected not less than 3 months and not more than 12 months prior to shipment to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5 IU/ml;

   or

   b) were kept in a *quarantine station* for six months prior to shipment.

Article 8.14.11bis.

Recommendations for dog-mediated rabies vaccination programmes

When developing and implementing *vaccination* programmes for dog-mediated rabies, in addition to provisions in Chapter 4.18., Member Countries should:

1. Prepare for the *vaccination* programme:

   a) consult with all relevant stakeholders, including target communities to define the most appropriate time to increase community participation and reduce the time required to complete *vaccination*;

   b) ensure safety of vaccination teams including training in humane dog capture and handling, and a strategy to manage exposure to suspect rabid animals.

2. Choose a vaccine and *vaccination* strategy:

   a) Priority should be given to vaccinating *free-roaming dogs*, including puppies, to immediately interrupt the rabies virus transmission cycle.

   b) *Vaccination* campaigns should be conducted recurrently (usually annually). More regular *vaccination* campaigns may be considered in especially high-risk areas, or to quickly interrupt the cycle of virus transmission.

c) *Vaccination* strategy should take into account simultaneous dog population management programmes as described in Chapter 7.7.

EU comment

The EU suggests inserting the word "The" before "vaccination strategy" (style).

3. Monitor the *vaccination* programme:

a) To monitor the *vaccination* coverage, vaccinated dogs should be identified and registered in a database.

EU comment

The EU suggests, for full coherence with the recommendations in Chapter 7.7. on Dog population management (version adopted in May 2022), to consider amending point 3(a) above to refer to "an animal identification system" rather than to "a database".

b) *Vaccination* certificates which state identification of the dog should be provided to dog owners as proof of *vaccination*.

c) *Vaccination* coverage should be monitored at the smallest administrative level possible.

CHAPTER 8.15.

INFECTION WITH RIFT VALLEY FEVER VIRUS

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. A comment is inserted in the text below.

Article 8.15.1.

General provisions

1) The aim of this chapter is to mitigate the animal and public health risks posed by Rift Valley fever (RVF) and to prevent its international spread.

2) For the purposes of this chapter:

a) 'epizooticepidemic area' means a part of a country or *zone* in which an epizooticepidemic of RVF is occurrings, and which does not correspond to the definition of *zone*;

b) 'epizooticepidemic of RVF' means a sudden and unexpected change in the distribution or increase in *incidence* of, or morbidity or mortality of RVF;

c) 'inter-epizooticepidemic period' means a period with low levels of *vector* activity and low rates of RVF virus (RVFV) transmission between two epidemics;

d) 'susceptible animals' means ruminants and dromedary camels.

32) Humans and many animal species are susceptible to *infection* can be affected by RVF. For the purposes of the *Terrestrial Code*, RVF is defined as an *infection* of ruminants 'susceptible animals' with Rift Valley fever virus Rift Valley fever virus ((RVFV)).

EU comment

The quotation marks in point 3 above ('susceptible animals') do not seem necessary, as the term is defined in point 2d, and no quotation marks are used elsewhere in the chapter when using that term (editorial).

43) The following defines the occurrence of *infection* with RVFV:

a) RVFV, excluding vaccine strains, has been isolated and identified as such from a sample from a ruminant susceptible animal; or

b) antigen or ribonucleic acid specific to RVFV, excluding vaccine strains, has been identified in a sample from a ruminant susceptible animal epidemiologically linked to a confirmed or suspected *case* of RVF, including in or to a human infected with RVFV, or giving cause for suspicion of association or contact with RVFV; or

c) antibodies to RVFV antigens which are not the consequence of *vaccination*, have been identified in a sample from a ruminant susceptible animal with either epidemiological links to a confirmed or suspected *case* of RVF, including in or to a human infected with RVFV, or giving cause for suspicion of association or contact with RVFV.

54) For the purposes of the *Terrestrial Code*, the *infective period* for RVF shall be 14 days and the *incubation period* shall be 7 days.

6) For the purposes of the *Terrestrial Code*, the *incubation period* for RVF shall be 7 days.

~~7~~6~~5~~) In areas where RVFV is present, ~~epizootic~~epidemics of RVF may occur following favourable climatic~~,~~ and other environmental conditions and availability of susceptible ~~host~~ animal and competent *vector* populations. ~~Epizootic~~Epidemics are separated by inter-~~epizootic~~epidemic periods. The transition from an inter-~~epizootic~~epidemic period to an ~~epizootic~~epidemic complies with point 1~~)(~~de) of Article 1.1.3. in terms of *notification*.

~~6) For the purposes of this chapter:~~

~~a) 'area' means a part of a country that experiences epizootics and inter-epizootic periods, but which does not correspond to the definition of *zone*;~~

~~b) 'epizootic of RVF' means the occurrence of *outbreaks* at an incidence substantially exceeding that during an inter-epizootic period or the occurrence of indigenous human cases;~~

~~c) 'inter-epizootic period' means the period of variable duration, often long, with intermittent low level of *vector* activity and low rate of virus transmission, which is often not detected;~~

~~d) ruminants include dromedary camels.~~

~~7) The historical distribution of RVF has been parts of the African continent, Madagascar, some other Indian Ocean Islands and the south-western Arabian Peninsula. However, *vectors*, environmental and climatic factors, land-use dynamics, and animal movements may modify the temporal and spatial distribution of the *infection*.~~

7~~8~~) When authorising importation or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.15.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the RVF status of the ~~ruminant~~ susceptible animal population of the *exporting country*.

8~~9~~) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.15.2.

Safe commodities

When authorising importation or transit of the following *commodities* ~~and any products made from them~~, *Veterinary Authorities* should not require any RVF-related conditions, regardless of the ~~RVF~~ health status of the ~~ruminant susceptible~~ animal population of the *exporting country* or *zone*:

1) hides and skins;

2) wool and fibre.

Article 8.15.3.

Country or zone free from RVF

A country or a *zone* may be considered free from RVF when *infection* with RVFV is notifiable in the entire country and either:

1) it meets the requirements for historical freedom in ~~point 1 *a)* of~~ Article 1.4.6.; or

2) meets the following conditions:

   a) an on-going pathogen-specific *surveillance* programme in accordance with Chapter 1.4. has demonstrated no evidence of *infection* with RVFV in ~~ruminants~~ susceptible animals in the country or *zone* for a minimum of ten years; and

   b) during that period no indigenous ~~human cases~~ infections in human ~~have occurred~~ has been reported by the public health authorities in the country or *zone*.

A country or *zone* free from RVF will not lose its free status through the importation of ~~ruminants~~ susceptible animals that are seropositive, so long as they are either permanently identified as such or destined for immediate *slaughter*.

Article 8.15.4.

Country or zone infected with RVFV ~~during the inter-epizootic period~~

A country or *zone* infected with RVFV~~, during the inter-epizootic period,~~ is one that does not ~~comply with~~ meet the requirements of Article 8.15.3. ~~in which virus activity is present at a low level but the factors predisposing to an epizootic are absent.~~

~~Article 8.15.5.~~

~~**Country or zone infected with RVFV during an epizootic**~~

~~A country or *zone* infected with RVFV, during an epizootic, is one in which *outbreaks* of RVF are occurring at an incidence substantially exceeding that of the inter-epizootic period; or one in which indigenous human cases of RVF are occurring even in the absence of detection of animal *cases*.~~

Article 8.15.~~6~~5.

Strategies to protect from vector attacks during transport

Strategies to protect animals from *vector* attacks during transport should take into account the local ecology and potential insecticide resistance of the *vectors*. ~~and potential r~~*Risk management* measures include:

1) treating animals and *vehicles/vessels* with insect repellents and insecticides prior to and during transportation;

2) *loading*, transporting and *unloading* animals at times of low *vector* activity;

3) ensuring *vehicles/vessels* do not stop en route ~~during dawn or dusk, or overnight,~~ unless the animals are ~~held behind insect-proof netting~~ protected from *vector* attacks;

4) using historical and current information to identify lower risk ports and transport routes.

Article 8.15.~~7~~6.

Recommendations for importation of susceptible animals from countries or zones free from RVF

~~For ruminants susceptible animals~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1) were kept in a country or *zone* free from RVF since birth or for at least 14 days prior to shipment;

AND

2) either:

   a) were vaccinated at least 14 days prior to leaving the free country or *zone*; or

   b) did not transit through an ~~epizooticepidemic~~ area ~~experiencing an epizootic during transportation to the *place of shipment*;, or~~

   ~~c) were protected from *vector* attacks when transiting through an epizootic area experiencing an epizootic~~.

Article 8.15.~~8~~7.

Recommendations for importation of susceptible animals from countries or zones infected with RVFV ~~during the inter-epizootic period~~

~~For ruminants susceptible animals~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1) showed no clinical signs of RVF on the day of shipment;

2) met one of the following conditions:

   a) were vaccinated against RVF at least 14 days prior to shipment ~~with a modified live virus vaccine~~; or

   b) were held for at least 14 days prior to shipment in a *vector*-protected *quarantine station*, which is located in an area of demonstrated low *vector* activity. During this period the animals showed no clinical sign of RVF;

AND

3) ~~either:~~

   ~~a)~~ did not originate or transit through an ~~area experiencing an epizooticepidemic~~ area ~~during transportation to the *place of shipment*; or~~

   ~~b) were protected from *vector* attacks when transiting through an area experiencing an epizootic area~~.

~~Article 8.15.98.~~

~~**Recommendations for importation of susceptible animals from countries or zones infected with RVFV during an epizootic**~~

~~For ruminants susceptible animals~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the susceptible animals: 1~~

~~1) showed no clinical signs of RVF on the day of shipment;~~

~~2) did not originate from an in the epizootic area of the epizootic;~~

~~3) were vaccinated against RVF at least 14 days prior to shipment;~~

~~4) were held for at least 14 days prior to shipment in a *vector* protected *quarantine station*, which is located in an area of demonstrated low *vector* activity outside the of an epizootic area of the epizootic. During this period the animals showed no clinical signs of RVF;~~

~~AND~~

~~5) either:~~

   ~~a) did not transit through an epizootic area experiencing an epizootic during transportation to the *place of shipment*; or~~

   ~~b) were protected from *vector* attacks when transiting through an epizootic area experiencing an epizootic.~~

Article 8.15.~~10~~98.

Recommendations for importation of semen and *in vivo* derived embryos of susceptible animals from countries or zones ~~not free from~~ infected with RVFV

~~For semen and *in vivo* derived embryos of ruminants susceptible animals~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the donor animals:

1) showed no clinical signs of RVF within the period from 14 days prior to and 14 days following collection of the semen or embryos;

AND

2) either:

a) were vaccinated against RVF at least 14 days prior to collection; or

b) were subjected to a serological test ~~demonstrated to be seropositive~~ on the day of collection, with positive result; or

c) were subjected to a serological test on two occasions with negative results on the day of collection and 14 days after collection ~~testing of paired samples has demonstrated that seroconversion did not occur within 14 days of~~ between ~~semen or embryo collection and 14 days after~~.

Article 8.15.~~11~~109.

Recommendations for importation of fresh meat and meat products ~~and meat products~~ from ~~ruminants~~ susceptible animals from countries or zones ~~not free from~~ infected with RVFV

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the entire consignment of *meat* or *meat products* comes from:

~~1~~a) ~~ruminants which~~ susceptible animals that showed no clinical signs of RVF within 24 hours before *slaughter*;

~~2~~b) ~~ruminants which~~ susceptible animals that were slaughtered in an approved *slaughterhouse/abattoir* and were subjected to ante- and post-mortem inspections with favourable results;

~~3~~c) carcasses ~~which~~ that were submitted to maturation at a temperature above 2°C for a minimum period of 24 hours following *slaughter*;

2) the necessary precautions were taken to avoid contact of the ~~products~~ *meat* or *meat products* with any potential source of RVFV.

~~Article 8.15.10bis.~~

~~**Recommendations for importation of meat products from susceptible animals from countries or zones infected with RVFV**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat products* comes from *meat* that complies with Article 8.15.10.~~

Article 8.15.~~12~~~~11~~10.

Recommendations for importation of milk and milk products of susceptible animals from countries or zones ~~not free from~~ infected with RVFV

~~For milk and milk products~~

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the consignment:

1) was subjected to pasteurisation; or

2) was subjected to a combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

Article 8.15.~~13~~~~12~~11.

Surveillance

Surveillance for RVF should be carried out in accordance with Chapter 1.4.

Surveillance for arthropod *vectors* should be carried out in accordance with Chapter 1.5., especially to determine areas of low *vector* activity.

Detection of RVFV in *vectors* has low sensitivity and therefore is not a recommended *surveillance* method.

An epidemic should be suspected in countries or *zones* infected with RVFV or countries or *zones* adjacent to a country or *zone* in which epidemics have been reported, when ecological conditions favour the breeding of large numbers of mosquito and other *vectors* with concurrent or consequent occurrence of increased number of abortions, and mortality particularly in new-born susceptible animals showing clinical signs or pathological lesions consistent with RVF, or reports of infection in humans.

Ecological conditions can be assessed through the sharing and analysis of meteorological data, and precipitation and water levels data, as well as the monitoring of *vector* activity. Clinical *surveillance* targeted at abortions and the use of sentinel *herds* can support detection of epidemics. Serological *surveillance* can also be used to assess the increase of number seroconversions.

~~1)~~ During an ~~epizootic~~epidemic, *surveillance* should be conducted to define the extent of the ~~affected area~~ epidemic area for the purpose of disease prevention and control as well of movements and trade of susceptible animals.

~~2)~~ During ~~the~~ inter-~~epizootic~~epidemic period:~~, *surveillance* and monitoring of climatic factors predisposing to an epizootic should be carried out in countries or *zones* infected with RVFV.~~

1) level of virus transmission should be assessed and determined by *surveillance* in sentinel *herds* of susceptible animals;

2) monitoring of ecological and meteorological factors should be carried out.

~~3)~~ Countries or *zones* adjacent to a country or *zone* in which ~~epizootic~~epidemics have been ~~reported~~ notified should determine their RVF status through an on-going specific *surveillance* programme.

~~To determine areas of low *vector* activity (see Articles 8.15.87. and 8.15.98.) *surveillance* for arthropod *vectors* should be carried out in accordance with Chapter 1.5.~~

~~Examination of *vectors* for the presence of RVFV is an insensitive *surveillance* method and is therefore not recommended.~~

The *Veterinary Authority* should coordinate in a timely manner with public health and other relevant authorities and share information to support the *surveillance* outcomes and the decision-making process for the prevention and control of RVF.

CHAPTER 10.9.

INFECTION WITH NEWCASTLE DISEASE VIRUS

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter.

A comment is inserted in the text below.

Article 10.9.1.

General provisions

1) For the purposes of the *Terrestrial Code*, Newcastle disease (ND) is defined as an *infection* of *poultry* caused by Newcastle disease virus (NDV), which is an avian paramyxovirus serotype 1 (APMV-1) that meets one of the following criteria for virulence:

   a) the virus has an intracerebral pathogenicity index (ICPI) in day-old chicks *(Gallusgallus)* of 0.7 or greater; or

EU comment

Editorial comment: the space seems to be missing in the parenthesis above (i.e. it should be "*Gallus gallus*" instead of "*Gallusgallus*").

   b) multiple basic amino acids have been demonstrated in the virus (either directly or by deduction) at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term 'multiple basic amino acids' refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the characteristic pattern of amino acid residues as described above would require characterisation of the isolated virus by an ICPI test.

   In this definition, amino acid residues are numbered from the N-terminus of the amino acid sequence deduced from the nucleotide sequence of the F0 gene, 113–116 corresponds to residues –4 to –1 from the cleavage site.'

2) ~~*Poultry* is defined as 'all domesticated birds, including backyard *poultry*, used for the production of *meat* or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.~~

   ~~Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions, or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.~~

~~3)~~ For the purposes of the *Terrestrial Code*, the *incubation period* for ND shall be 21 days.

43) This chapter deals with NDV *infection* of *poultry* as defined in point 2 above, in the presence or absence of clinical signs.

54) The occurrence of *infection* with NDV is defined as the isolation and identification of NDV as such or the detection of viral ribonucleic acid specific for NDV.

65) A Member Country should not impose bans on the trade in *poultry commodities* in response to information on the presence of any APMV-1 in birds other than *poultry*, including *wild* birds.

~~7~~6) Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. When the use of ND vaccines is appropriate, those vaccines should comply with the standards described in the *Terrestrial Manual*.

[...]

CHAPTER 12.2.

INFECTION WITH TAYLORELLA EQUIGENITALIS (CONTAGIOUS EQUINE METRITIS)

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter.

Comments are inserted in the text below.

Article 12.2.1.

General provisions

This chapter addresses the occurrence of clinical or asymptomatic *infection* of a mare caused by *Taylorella equigenitalis* as well as the presence of *T. equigenitalis* on the genital mucous membrane surface in the male horse.

For the purposes of the *Terrestrial Code,* the following defines *infection* with *T. equigenitalis:*

1) *T. equigenitalis* has been isolated and identified from a genital swab sample from a horse; or

EU comment

The EU does not support adding the words "and identified" in point 1 above. Indeed, isolation of *T. equigenitalis* already implies that the specific pathogen has been identified. Therefore, adding a reference to identification is superfluous and confusing in this context. The combination of "pathogenic agent" + "isolation" is a well-established practice in point 1 of the case definitions of other disease specific chapters and should be maintained consistently throughout the Code, also in this chapter.

2) ~~antigen or~~ genetic material specific to *T. equigenitalis* has been identified in a sample from a ~~mare~~ horse showing clinical or pathological signs consistent with *infection* with *T. equigenitalis* or epidemiologically linked to a confirmed or suspected *case* of *infection* with *T. equigenitalis*~~.~~;

~~3) genetic material specific to *T. equigenitalis* has been identified in a sample from a male horse.~~

For the purposes of the *Terrestrial Code*:

– due to long-term persistence of *T. equigenitalis* in horses, the *infective period* shall be lifelong;

– the *incubation period* in mares shall be 14 days.

Standards for diagnostic tests ~~and vaccines~~ are described in the *Terrestrial Manual*.

For the purposes of this chapter, a temporary importation refers to the introduction of a horse into a country or *zone*, ~~for competition or cultural events excluding breeding,~~ for a defined period of time, not exceeding 90 days, during which the *risk* of transmission of the *infection* is mitigated through specific measures under the supervision of the *Veterinary Authority*. Temporary imported horses are re-exported at the end of this period. The duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or *zone,* should be defined in advance.

EU comment

As the definition above is used in more than one horse disease specific chapter, OIE should consider moving it into the glossary.

When authorising import or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 12.2.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *T. equigenitalis* status of the *exporting country*, *zone* or ~~*establishment*~~*herd*.

Article 12.2.2.

Safe commodities

When authorising importation or transit of the following *commodities*, *Veterinary Authorities* should not require any *T. equigenitalis*-related conditions regardless of the ~~*T. equigenitalis infection*~~ health status of the *animal population* of the *exporting country*, *zone*, or ~~*establishment*~~*herd*:

1) geldings;

2) *milk* and *milk products*;

3) *meat* and *meat products*;

4) hides and skins;

5) hooves;

6) gelatine and collagen.

Article 12.2.3.

~~Establishment~~Herd free from infection with *T. equigenitalis*

1. Prerequisite

   Infection with *T. equigenitalis* has been a *notifiable disease* in the entire country for at least the past two years.

2. Qualification

   To qualify as free from *infection* with *T. equigenitalis*, a~~n establishment~~*herd* should satisfy the following conditions:

   a) it is under the control of the *Veterinary Authority;*

   b) no *case* has occurred for at least two years;

   c) all horses from the ~~*establishment*~~*herd* have been subjected to *T. equigenitalis* tests, with negative results. These tests should have been carried out on three occasions, within a 12-day period with an interval of no less than three days ~~apart~~ between each test. Horses must have not been treated with antibiotics for at least 21 days before the sampling;

EU comment

The EU queries what is meant by "all horses" in point c) above, i.e. should foals and other juvenile horses present in the herd be tested as well? If that should not be the case, a more accurate reference would be necessary (e.g. "all sexually mature horses" or similar). This comment is valid also for point 4b) of Article 12.2.3. below.

Furthermore, with reference to the Manual (Chapter 3.6.2., Section A point 1), the EU suggests adding in point c) above that horses that are to be tested should also not be locally washed with antiseptics as this may also hamper the test results. Therefore, please consider adding the words "nor subjected to antiseptic washing of affected sites" after "Horses have not been treated with antibiotics" (this comment is valid also for point 3 b) of Article 12.2.6. and for point 2 b ii) of Article 12.2.4 below).

d) stored semen was subjected to a test for detection of genetic material of ~~to detect~~ *T. equigenitalis* with negative results, carried out on an aliquot of the stored semen.

3. Maintenance of freedom

a) requirements in points 1 and 2(a) and 2(b) of Article 12.2.3. are met;

b) appropriate *surveillance*, capable of detecting *infection* with *T. equigenitalis* even in the absence of clinical signs, is in place; this may be achieved through a *surveillance* programme in accordance with Chapter 1.4. and this chapter;

c) the introduction of horses and their germplasm into the ~~*establishment*~~*herd* is carried out in accordance with the import conditions for these *commodities* listed in this chapter.

4. Recovery of freedom

When a *case* is detected in a previously free ~~*establishment*~~*herd* the free status ~~of the *establishment*~~ should be suspended until the following conditions are met~~in the affected *establishment*~~:

a) the *disinfection* of the *establishment* has been applied;

b) 21 days after the last removal or the last treatment of an infected horse, all horses have been subjected to a *T. equigenitalis* test, with negative results, on three occasions, within a 12-day period with an interval of no less than three days apart between each test;

c) stored semen from all infected horses in the *herd* ~~was~~ were subjected to a test to detect *T. equigenitalis* with negative results in accordance with Article 12.2.8.~~, carried out on an aliquot of the stored semen~~;

d) the introduction of horses and their germplasm into the ~~*establishment*~~*herd* is carried out in accordance with the import conditions for these *commodities* listed in this chapter.

Article 12.2.4.

Recommendations for importation of stallions or mares

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) mares showed no clinical sign of *infection* with *T. equigenitalis* on the day of shipment;

AND

2) horses have been kept ~~in an *establishment*~~:

a) since birth or for at least two years prior to shipment in a~~n *establishment*~~*herd* that has been free from *infection* with *T. equigenitalis* ~~since birth or for at least two years prior to shipment~~;

OR

b)

i) for at least the last 60 days in a~~n *establishment*~~*herd* in which no *case* has been reported during that period ~~the 60 days prior to shipment~~**;**

AND

ii) were subjected to tests for the detection of the agent ~~*T. equigenitalis* tests~~, with negative results, on three occasions, within a 12-day period with an interval of no less than three days apart between each test, being the last test carried out within the 30 days prior to shipment. Horses ~~must not~~ have not been treated with antibiotics for at least 21 days prior to sampling and have not been mated after sampling.

EU comment

Editorial comment: for clarity, please consider rewording point ii) above as follows: "[...], ~~being~~ with the last test carried out within the 30 days prior to shipment.".

Article 12.2.5.

Recommendations for temporary importation of horses

When importing on a temporary basis horses that do not comply with recommendations in Article 12.2.4. for purposes different than breeding and rearing, *Veterinary Authorities* should:

1) require:

   a) the ~~animals~~horses be accompanied by a passport in accordance with the model contained in Chapter 5.12. or be individually identified as belonging to a high health status *subpopulation* as defined in Chapter 4.17.;

   b) the presentation of *an international veterinary certificate* attesting that the mares showed no clinical sign of *infection* with *T. equigenitalis* on the day of shipment;

   c) the duration of the temporary importation period and the destination after this period, and the conditions required to leave the country or *zone* be defined;

2) ensure that during their stay in the country or *zone*, the ~~animals~~horses:

   a) are not used for breeding (including artificial insemination, semen collection, used as teaser ~~stallions~~) and do not have any sexual contact with other horses;

   b) ~~do not undergo any genital examinations~~are not subjected to any practice that may represent a risk of transmission of *infection* with *T. equigenitalis*;

   c) are kept and transported individually in stalls and *vehicles/vessels* which are subsequently cleaned and disinfected before re-use.

Article 12.2.6.

Recommendations for importation of semen of horses

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) semen was collected in an *approved* centre and collection, processing and storing was done in accordance with Chapter 4.6; and

EITHER

2) the donor stallion was kept in an ~~*establishment*~~*herd* free from *infection* with *T. equigenitalis*;

OR

3)

   a) the donor stallion was kept for at least 60 days prior to semen collection in an ~~*establishment*~~*herd* in which no *case* has been reported during that period~~the 60 days prior to semen collection~~; and

   b) the donor stallion was subjected to *T. equigenitalis* identification tests, with negative results, on three occasions, within a 12-day period with an interval of no less than three days apart between each test, being the last test carried out within the 30 days prior to shipment. ~~The donor stallion must not have been treated with antibiotics for at least 21 days prior to sampling~~ Horses have not been treated with antibiotics for at least 21 days prior to sampling and have not been mated after sampling;

OR

4) aliquots of fresh semen were subjected to culture and a test for detection of genetic material for *T. equigenitalis* with negative results, carried out immediately prior to processing and on an aliquot of semen collected within 15 to 30 days after the first collection of the semen to be exported;

OR

5) aliquots of frozen semen corresponding to the earliest and the most recent collection were subjected to culture and a test for detection of genetic material for *T. equigenitalis* with negative results.

EU comment

It is not clear what is meant by "earliest" in point 5) above. Please consider replacing with "oldest".

Article 12.2.7.

Recommendations for importation of oocytes or embryos of horses

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the oocytes and embryos were collected, processed and stored in *approved* centres following the general provisions in accordance with Chapters 4.9. and 4.10.;

2) the donor mare showed no clinical signs of *infection* with *T. equigenitalis* on the day of collection;

AND

for the importation of embryos:

3) the semen used for embryo production complied with Chapters 4.6. and 4.7.

Article 12.2.8.

Surveillance

1. General principles of surveillance

Surveillance for *infection* with *T. equigenitalis* is relevant for *establishments* seeking to achieve and demonstrate freedom from *infection*, as well as part of an *official control programme* in countries where the disease is endemic.

The *surveillance* strategy chosen should be adequate to detect the *infection* with *T. equigenitalis* even in the absence of clinical signs.

The *Veterinary Services* should implement programmes to raise awareness among ~~farmers~~ owners, breeders and workers who have day-to-day contact with horses, as well as *veterinarians*, *veterinary paraprofessionals* and diagnosticians, who should report promptly any suspicion of *infection* with *T. equigenitalis* to the *Veterinary Authority.*

Under the responsibility of the *Veterinary Authority*, Member Countries should have in place:

a) a formal and ongoing system for detecting and investigating *cases*;

b) a procedure for the rapid collection and transport of samples from suspected *cases* to a *laboratory* for diagnosis;

c) a system for recording, managing and analysing diagnostic and *surveillance* data.

2. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs by close physical examination of horses and based on reproduction performance. However, clinical *surveillance* should be complemented by bacteriological and

molecular tests, as asymptomatic carriers play an important role in the maintenance and transmission of the *infection*.

3. Agent surveillance

An active programme of *surveillance* of horses to detect *case*s should be implemented to establish the status of a country, *zone* or ~~*establishment*~~*herd*. Culture for *T. equigenitalis* and molecular testing are the most effective methods of detection of the *case.*

Stored semen should be included in *surveillance* programmes. It represents a valuable source of material and may be very helpful in contributing to retrospective studies, including providing support for claims of freedom from *infection* and may allow certain studies to be conducted more quickly and at lower cost than other approaches. Samples can be gathered through representative sampling or following a *risk*-based approach.

4. Serological surveillance

Serological *surveillance* is not the preferred strategy for detecting *T. equigenitalis.* If used, serology should be used in conjunction with agent identification ~~culture~~ in assessing the status of a mare that may have been infected with *T. equigenitalis*. The usefulness of serological tests is further described in the *Terrestrial Manual*.

CHAPTER 12.6.

INFECTION WITH EQUINE INFLUENZA VIRUS

EU comment

The EU in general supports the proposed changes to this chapter. Comments are inserted in the text below.

Article 12.6.1.

General provisions

For the purposes of the *Terrestrial Code*, equine influenza (EI) is defined as an *infection* of domestic and c*aptive wild* equids with equine influenza virus (EIV), i.e. influenza A viruses (H7N7 and H3N8).

EU comment

The EU suggests slightly rewording the text above for clarity and alignment with the corresponding Manual chapter, as follows:

"[...] i.e. subtypes H7N7 and H3N8 of influenza A viruses ~~(H7N7 and H3N8)~~."

This chapter deals not only with the occurrence of clinical signs caused by *infection* with ~~equine influenza virus (~~EIV~~)~~, but also with the presence of *infection* with EIV in the absence of clinical signs.

The following defines the occurrence of *infection* with EIV:

1) EIV, excluding modified-live virus vaccine strains following recent *vaccination*, has been isolated from a sample from a domestic or *captive wild* equid; or

2) ribonucleic acid or antigen specific to EIV has been detected in a sample from a domestic or *captive wild* equid showing clinical signs or pathological lesions suggestive of equine influenza or epidemiologically linked to a suspected or confirmed *case* of equine influenza; or

3) seroconversion due to recent exposure to EIV virus, demonstrated by a significant increase in antibody titres which are not the consequence of *vaccination*, have been detected in paired samples from a domestic or *captive wild* equid showing clinical signs or pathological lesions consistent with equine influenza, or epidemiologically linked to a suspected or confirmed *case* of *infection* with EIV.

~~For the purposes of this chapter, isolation is defined as 'the separation of domestic equids from domestic equids of a different EI health status, utilising appropriate *biosecurity* measures, with the purposes of preventing the transmission of *infection*'.~~

For the purposes of the *Terrestrial Code*, the *infective period* for EI shall be 21 days.

For the purposes of this chapter, a temporary importation refers to the introduction of horses into a country or *zone*, for a defined period of time, not exceeding 90 days, during which the *risk* of transmission of the *infection* is mitigated through specific measures under the supervision of the *Veterinary Authority*. Temporarily imported horses are re-exported at the end of this period. The duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or *zone*, should be defined in advance.

EU comment

As the definition above is used in more than one horse disease specific chapter, OIE should consider moving it into the glossary.

When authorising import or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 12.6.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the EI status of the equine population of the *exporting country*, *zone* or *compartment*.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 12.6.2.

Safe commodities

When authorising the importation or transit of the following *commodities*, *Veterinary Authorities* should not require any EIV-related conditions, regardless of the ~~EI~~ health status of the ~~equine~~animal population of the *exporting country*, *zone* or *compartment*:

1) equine semen;

2) *in vivo* derived equine embryos collected, processed and stored in accordance with Chapters 4.8. and 4.10., as relevant ~~(under study).~~;

3) *meat* and *meat products* from equids that have been slaughtered in a *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 12.6.3.

Determination of the EI status of a country, a zone or a compartment

The EI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1) the outcome of a *risk assessment* identifying all risk factors and their historic relevance;

2) whether EI is notifiable in the whole country, an ongoing EI awareness programme is in place, and all notified suspect occurrences of EI are subjected to field and, where applicable, *laboratory* investigations;

3) appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in domestic and *captive wild* equids.

Article 12.6.4.

~~EI free c~~Country, zone or compartment free from EI

A country, *zone* or *compartment* may be considered free from EI provided ~~the disease~~ that *infection* with EIV is notifiable in the whole country and it shows evidence, through an effective *surveillance* programme, planned and implemented in accordance with the general principles in Chapter 1.4., that no *case* of ~~EI~~ *infection* with EIV occurred in the past two years. The *surveillance* may need to be adapted to parts of the country, *zone* or *compartment* depending on historical or geographical factors, industry structure, population data, movements of equids within and into the country, *zone* or *compartment*, *wild* equine populations or proximity to recent *outbreaks*.

A country, *zone* or *compartment* seeking freedom from EI, in which *vaccination* is practised, should also demonstrate that EIV has not been circulating in the population of domestic, *captive wild*, *feral*, and *wild* equids during the past 12 months, through *surveillance*, in accordance with Chapter 1.4. In a country in which *vaccination* is not practised, *surveillance* may be conducted using serological testing alone. In countries where *vaccination* is practised, the *surveillance* should include agent identification methods described in the *Terrestrial Manual* for evidence of *infection*.

A country, *zone* or *compartment* seeking freedom from EI should apply appropriate movement controls to minimise the risk of introduction of EIV in accordance with this chapter and be in accordance with relevant requirements and principles described in Chapter 4.4. and Chapter 4.5.

EU comment

In the report it is said the reference to Chapters 4.4. and 4.5. is added for consistency with other chapters. The EU queries what other disease specific chapters are meant, as no such reference could be found. We believe this reference is superfluous, as all chapters of the Code should be considered by members as a matter of principle.

~~If an *outbreak* of clinical EI occurs in a previously free country, *zone* or *compartment*, free status can be regained 12 months after the last clinical *case*, providing that *surveillance* for evidence of *infection* has been carried out during that twelve-month period in accordance with Chapter 1.4.~~

Article 12.6.4bis.

Recovery of free status

If a *case* of *infection* with EIV occurs in a previously free country, *zone* or *compartment*, free status can be regained 12 months after the last *case*, providing that *surveillance* in accordance with Chapter 1.4. has been carried out during that 12-month period, with negative results.

Article 12.6.5.

Recommendations for the importation of domestic and captive wild equids for immediate slaughter

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the domestic and *captive wild* equids showed no clinical sign of EI on the day of shipment.

Article 12.6.6.

Recommendations for the importation of domestic and captive wild equids ~~for unrestricted movement~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the domestic equids :

EU comment

The EU notes an inconsistency between the title of Article 12.6.6. (that includes also captive wild equids) and the chapeau sentence (that refers only to domestic equids). Preferably, both should be aligned.

1) came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid, information on its *vaccination* status should be included in the veterinary certificate;

OR

2) ~~came from a country, *zone* or *compartment* not known to be free from EI,~~ were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; ~~and~~

AND

EU comment

It should be clarified that the "AND" above relates to point 2 only, i.e. not to point 1. Indeed, point 1 would be a stand-alone option (free country, vaccination optional), while point 2 and 3 are parts of the second option (not-free country, vaccination mandatory). Preferably, points 2 and 3 should be combined into one single point, to avoid any possible confusion.

3) were ~~immunised~~vaccinated in accordance with the recommendations of the manufacturer with a vaccine complying with the standards described in the *Terrestrial Manual* and considered effective against the epidemiologically relevant virus strains, ~~between 21 and 90 days before shipment either with a primary course or a booster; information on their *vaccination* status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12.~~in accordance with one of the following procedures:

   a) between 14 and 90 days before shipment ~~either~~ with either a primary course or a booster; or

   b) between 14 and 180 days before shipment, if they are older than four years of age, ~~previously~~having received up to the date of this pre-shipment *vaccination*, at least four doses of ~~the same~~vaccine at intervals not greater than 180 days.

Information on the *vaccination* status should be included in the *international veterinary certificate* or the passport in accordance with Chapter 5.12. as relevant.

~~For additional security, c~~Countries that are free ~~of~~ from EI or undertaking an eradication programme may also request that the domestic equids were ~~tested negative for EIV by~~subjected to an agent identification test for EI described in the *Terrestrial Manual* with negative results, conducted on samples collected on two occasions~~, at 7 to 14 days~~four to six days after commencement of pre-export isolation and ~~less than 5 prior to~~ within four days ~~before of~~ prior to shipment.

Article 12.6.7.

Recommendations for the temporary importation of domestic ~~equid which will be kept in isolation (see Article 12.6.1.)~~ horses

EU comment

The word "domestic" in the title of Article 12.6.7. seems superfluous, as horses are *per se* domestic animals. Indeed, the text of the article simply refers to "horses".

If the importation of horses on a temporary basis does not comply with the recommendations in Article 12.6.6., *Veterinary Authorities* of *importing countries* should ~~require the presentation of an *international veterinary certificate* attesting that the domestic equids~~:

1) require that:

   a) the horses be accompanied by a passport in accordance with the model contained in Chapter 5.12. or be individually identified as belonging to a high health status *subpopulation* as defined in Chapter 4.17.;

   b) the presentation of an *international veterinary certificate* attesting that the horses:

EU comment

Point b) above should be reworded as follows (for better readability of the sentence):

"an *international veterinary certificate* be presented attesting that the horses:".

   ~~1~~i) came from a~~n EI free~~ country, *zone* or *compartment* free from EI, in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid, information on its *vaccination* status should be included in the veterinary certificate;

   OR

   ~~2~~ii) showed no clinical sign of EI in any premises in which the domestic equids had been resident for the 21 days prior to shipment nor on the day of shipment; and

   ~~3~~iii) were ~~immunised in accordance~~ vaccinated with ~~the recommendations of the manufacturer with~~ a vaccine complying with the standards described in the *Terrestrial Manual*; information on their *vaccination* status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12.;

2) ensure that during their stay in the country or *zone* domestic equids are kept separated from domestic and *captive wild* equids of a different EI health status through appropriate *biosecurity*.

~~Article 12.6.8.~~

~~**Recommendations for the importation of fresh meat of equids**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *fresh meat* came from equids which had been subjected to ante- and post-mortem inspections as described in Chapter 6.3.~~

CHAPTER 12.7.

~~EQUINE PIROPLASMOSIS~~ *INFECTION* WITH *THEILERIA EQUI* AND *BABESIA CABALLI* (EQUINE PIROPLASMOSIS)

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. Comments are inserted in the text below.

Article 12.7.1.

General provisions

The *infection* with ~~use of the term equine piroplasmosis indicates clinical diseases caused by the transmission of~~ *Theileria equi (T. equi)* or *Babesia caballi (B. caballi)* established after transmission of these pathogenic agents through competent ticks or iatrogenic practices may be asymptomatic or may cause a clinical disease known as equine piroplasmosis. Vertical transmission from mares to foals has also been reported. This chapter deals not only with ~~the occurrence of~~ clinical disease ~~signs caused by infection with T. equi or B. caballi~~, but also with asymptomatic infections ~~the presence of infection with T. equi or B. caballi in the absence of clinical signs~~.

Susceptible animals for *infection* with *T. equi* or *B. caballi* are primarily domestic and *wild* equids. Although old-world camelids are susceptible to *infection* and are potential reservoirs, they are not found to play a significant role in the epidemiology of the disease.

Equids infected with *T. equi* or *B. caballi* may remain carriers of these blood parasites for long periods, sometimes lifelong and act as sources of *infection* for competent tick *vectors* of the genera *Dermacentor, Rhipicephalus*, *Hyalomma* and *Amblyomma*.

For the purposes of the *Terrestrial Code*, the following defines *infection* with *T. equi* or *B. caballi*:

1) identification of the parasite by microscopic examination of a sample from an equid which may be showing clinical or pathological signs consistent with *infection* with *T. equi* or *B. caballi* or epidemiologically linked to a confirmed or suspected *case* of *infection* with *T. equi* or *B. caballi*; or

EU comment

The EU queries why, when the pathogenic agent has been identified, there is a need for additional criteria to be met (clinical or pathological signs, or epidemiological links), in point 1 above, which are the same as for points 2 and 3 below. This is not the case in other disease specific chapters, including parasitic diseases (e.g. draft Chapter 14.X.).

In addition, all index cases that are test positive (according to either of the 3 points of the case definition) but are currently asymptomatic and lack a reliable history (e.g. newly bought) will be missed with this definition.

Finally, it is not clear whether the words "which may be" in all 3 points of the case definition only refer to clinical or pathological signs, or also to the epidemiological links. In any case use of "which may be" is confusing and should be deleted.

2) antigen or genetic material specific for *T. equi* or *B. caballi* has been identified in a sample from an equid which may be showing clinical or pathological signs consistent with *infection* with *T. equi* or *B. caballi* or epidemiologically linked to a confirmed or suspected *case* of *infection* with *T. equi* or *B. caballi*; or

3) antibodies specific to *T. equi* or *B. caballi* have been identified in a sample from an equid which may be showing clinical or pathological signs consistent with *infection* with *T. equi* or *B. caballi* or epidemiologically linked to a confirmed or suspected *case* of *infection* with *T. equi* or *B. caballi.*

For the purposes of the *Terrestrial Code*, the *incubation period* of *infection* with *T. equi* or *B. caballi* in equids shall be 30 days and the *infective period* shall be lifelong.

For the purposes of this chapter, a temporary importation refers to the introduction of ~~equids~~horses into a country or *zone*, for a defined period of time, not exceeding 90 days, during which the *risk* of transmission of the *infection* is mitigated through specific measures under the supervision of the *Veterinary Authority.* Temporarily imported horses are re-exported ~~or slaughtered~~ at the end of this period. The duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or *zone*, should be defined in advance.

EU comment

As the definition above is used in more than one horse disease specific chapter, OIE should consider moving it into the glossary.

When authorising import or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 12.7.2. *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the status of *infection* with *T. equi* and *B. caballi* of the *exporting country* or *zone*.

Standards for diagnostic tests ~~and vaccines~~ are described in the *Terrestrial Manual*.

Article 12.7.2.

Safe commodities

When authorising importation or transit of the following *commodities*, *Veterinary Authorities* should not require any ~~conditions related with~~ *infection* with *T. equi* or *B. caballi* related conditions, regardless of the ~~*infection*~~ health status of the *animal population* of the *exporting country* or *zone*:

1) *milk* and *milk products*;

2) *meat* and *meat products*;

3) hides and skins;

4) hooves;

5) gelatine and collagen;

6) semen collected;

EU comment

Point 6 above seems incomplete (cf. point 8 below).

7) sterile filtered horse serum;

8) embryos collected, processed and stored in accordance with Chapters 4.9. and 4.10.

Article 12.7.3.

Country or zone free from infection with *T. equi* and *B. caballi*

1) Historical freedom as described in Chapter 1.4. does not apply to *infection* with *T. equi* and *B. caballi.*

2) A country or a *zone* may be considered free from *infection* with *T. equi* and *B. caballi* when:

   a) *infection* with *T. equi* and infection with *B. caballi* have been notifiable diseases in the entire country for at least the past 10 years and, in the country or *zone*:

      ~~EITHER:~~

i) there has been no *case* of *infection* with *T. equi* and no *case* of *infection* with *B. caballi* during the past six years; and

ii) a *surveillance* programme performed in accordance with Article 12.7.9. has demonstrated no evidence of *infection* with *T. equi* and no evidence of *infection* with *B. caballi* in the past six years and has considered the presence or absence of competent *vectors* in the epidemiological situation;

~~OR~~

~~iii) an ongoing *surveillance* programme performed in accordance with Article 12.7.9. has found no competent tick *vectors* for at least six years;~~

b) imports of equids into the country or *zone* are carried out in accordance with this chapter. A country or *zone* free from *infection* with *T. equi* and *B. caballi* in which an epidemiological investigation has been conducted with favourable results ~~ongoing *vector surveillance*, performed in accordance with Article 12.7.9., has found no competent tick *vector*~~ will not lose its free status through the introduction of seropositive or infective equids imported temporarily in accordance with Article 12.7.6.;

EU comment

The EU queries what exactly is meant with "an epidemiological investigation has been conducted with favourable results" in point b) above. For reasons of legal certainty and to avoid confusion, this needs to be clarified.

c) a country or *zone* free from *infection* with *T. equi* and *B. caballi* adjacent to an infected country or *zone* should include a high-risk area in which ~~continuous serological, agent and *vector*~~ *surveillance* is conducted in accordance with Article 12.7.9.

Article 12.7.4.

Recovery of a free status

When *infection* with *T. equi* or *B. caballi* is detected in a previously free country or *zone*, Article 12.7.3. applies.

Article 12.7.~~2~~5.

Recommendations for the importation of ~~equines~~ equids

Veterinary Authorities ~~of *importing countries*~~ should require the presentation of an *international veterinary certificate* attesting that ~~the animals~~:

1) the animals showed no clinical signs ~~equine piroplasmosis~~ of *infection* with *T. equi* or *B. caballi* on the day of shipment, and

2) EITHER:

a) the animals were kept in a country or *zone* free from *infection* with *T. equi* and *B. caballi* since birth;

OR

~~2) were subjected to diagnostic tests for equine piroplasmosis (Theileriaequi and Babesia caballi) with negative results during the 30 days prior to shipment;~~

b) i) were subjected to a serological ~~or~~ and agent identification test with molecular techniques for the detection of *T. equi* and *B. caballi* with negative results carried out on a blood sample taken within the 14 days prior to shipment; and

~~3) were maintained free from ticks, by preventive treatment when necessary, during the 30 days prior to shipment.~~

ii) were maintained free from competent ticks in accordance with Article 12.7.7. and not subjected to any practice that may present a risk of iatrogenic transmission of *infection* with *T. equi* or *B. caballi* during the 30 days prior to sampling and after sampling until shipment ~~and throughout the transport to the destination country or *zone*~~.

Article 12.7.~~3~~6.

Recommendations for the temporary importation of ~~equids~~ horses ~~of competition horses on a temporary basis~~

~~Veterinary Authorities of importing countries should consider the possibility of importing competition horses on a temporary basis and which are positive to the testing procedure referred to in point 2) of Article 12.7.2. under the following safeguards:~~

If the importation of ~~equids~~horses on a temporary basis does not comply with the recommendations in Article 12.7.5., *Veterinary Authorities* of *importing countries* should:

~~1.~~

1) require ~~that~~:

   a) ~~the horses are~~ the ~~animals~~horses be accompanied by a passport in accordance with the model contained in Chapter 5.12. or be individually identified as belonging to a high health status *subpopulation* as defined in Chapter 4.17.;

   ~~2.~~b) ~~the Veterinary Authorities of importing countries require~~ the presentation of *an international veterinary certificate* attesting that the ~~animals~~horses:

      ~~a.~~i) showed no clinical sign of ~~equine piroplasmosis~~ *infection* with *T. equi* or *B. caballi* on the day of shipment;

      ~~b) were treated against ticks within the seven days prior to shipment;~~

      ii) were maintained free from ticks in accordance with Article 12.7.7. during the 30 days prior to shipment and during transport;

   c) the duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or *zone,* be defined;

~~3) the horses are kept in an area where necessary precautions are taken to control ticks and that is under the direct supervision of the Veterinary Authority;~~

~~4) the horses are regularly examined for the presence of ticks under the direct supervision of the Veterinary Authority.~~

2) ensure that during their stay in the country or *zone*:

   a) the ~~animals~~horses are protected from ticks in accordance with Article 12.7.7.;

   b) ~~equids~~horses are examined daily for the presence of ticks of the genera *Dermacentor*, *Rhipicephalus*, *Hyalomma* and *Amblyomma* with particular attention to the ears, false nostrils, inter-mandibular space, mane, lower body areas, including the axillae, and inguinal region, and the perineum and tail, with negative results;

EU comment

The EU queries whether it is necessary to provide this level of detail in point b) above as regards the examination of horses for ticks.

   c) the ~~animals~~horses are not subjected to any practice that may represent a risk of iatrogenic transmission of *infection* with *T. equi* or *B. caballi*.

Article 12.7.7.

Protecting equids from ticks

Under the direct supervision of the *Veterinary Authority*:

1) equids are kept in tick-protected facilities and transported in protected ~~vehicles~~ *vehicles/vessels* according to Article 12.7.8.;

2) equids have been preventively treated according to the manufacturer's recommendations with an acaricide effective against the competent ticks.

Article 12.7.8.

Protecting facilities and transports from ticks

The *establishment* or facility should be approved by the *Veterinary Authority* and the means of protection should at least comprise the following:

1) measures to limit or eliminate habitats for competent tick *vectors* should be implemented for an appropriate time and over an appropriate distance in the vicinity of the area where equids are kept;

2) the facility and immediate surroundings of the stables and exercise or competition areas should be treated with an effective acaricide before the arrival of equids;

3) when transporting ~~animals~~ equids through infected countries or *zones*:

   a) the vehicle should be treated with an effective acaricide before transporting the animals;

   b) preventive treatment of the equids with an acaricide with an extended residual effect that lasts at least for the duration of any stopover during the trip should be conducted.

Article 12.7.9.

Surveillance strategies

1. General principles of surveillance

   A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with *T. equi* and the presence of *infection* with *B. caballi*, ~~even in the absence of clinical signs,~~ given the prevailing epidemiological situation in accordance with Chapter 1.4. and Chapter 1.5. and under the responsibility of the *Veterinary Authority*.

   An active programme of *surveillance* of equids to detect evidence of *infection* with *T. equi* and evidence of *infection* with *B. caballi* by serological or agent identification molecular testing is required to establish the status of a country or *zone* considering that asymptomatic carriers play an important role in the maintenance and transmission of the *infection*.

   The *Veterinary Services* should implement programmes to raise awareness among *veterinarians*, horse owners, riders and workers who have day-to-day contact with equids, as well as *veterinary paraprofessionals* and diagnosticians, who should report promptly any suspicion of *infection* with *T. equi* and any suspicion of *infection* with *B. caballi* to the *Veterinary Authority*.

   Under the responsibility of the *Veterinary Authority*, Member Countries should have in place:

   – a formal and ongoing system for detecting and investigating cases;

   – a procedure for the rapid collection and transport of samples from suspected cases of *infection* with *T. equi* or *B. caballi* to a laboratory for diagnosis;

   – a system for recording, managing and analysing diagnostic and surveillance data.

2. Clinical surveillance

   Clinical *surveillance* aims at detecting clinical signs by close physical examination of equids.

3. Serological and agent surveillance

   An active programme of *surveillance* of equids to detect evidence of *infection* with *T. equi* and evidence of *infection* with *B. caballi* by serological or agent identification test with molecular techniques is required to establish the status of a country or *zone* considering that asymptomatic carriers play an important role in the maintenance and transmission of the *infection*.

   The study population used for a serological survey should be representative of the population at risk in the country or *zone*.

4. Surveillance in high-risk areas

Disease-specific enhanced *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with an *infected* country or *zone*, based upon geography, climate, history of *infection* and other relevant factors. The *surveillance* should be carried out particularly over the border with that country or *zone* unless there are relevant ecological or geographical features likely to limit the spatial distribution and thereby prevent the *infestation* of equids from competent ticks and interrupt the transmission of *infection* with *T. equi* or *B. caballi*.

5. Vector surveillance

Infection with *T. equi* or *B. caballi* is transmitted between equine hosts by species of Ixodid ticks in the genera *Dermacentor*, *Rhipicephalus*, *Hyalomma,* and *Amblyomma.*

Vector surveillance is aimed at demonstrating the absence of tick *vectors* or defining high, medium and low-risk areas and local details of seasonality by determining the various species present in an area, their respective seasonal occurrence, and abundance. *Vector surveillance* has particular relevance to potential areas of spread. Long term *surveillance* can also be used to assess *vector* abatement measures or to confirm the continued absence of *vectors*.

Vector surveillance sampling should be scientifically based. The choice of the number and types of traps to be used in *vector surveillance* and the frequency of their use should consider the size and ecological characteristics of the area to be surveyed as well as the biology and behavioural characteristics of the local *vector* species of Ixodid ticks.

The use of a *vector surveillance* system to detect the presence of circulating *T. equi* or *B. caballi* is not recommended as a routine procedure. Animal-based *surveillance* strategies are preferred to detect *T. equi* or *B. caballi* transmission than entomological *surveillance*.

CHAPTER 14.X.

INFECTION WITH *THEILERIA LESTOQUARDI, T. LUWENSHUNI* AND *T. UILENBERGI*

EU comment

The EU thanks the OIE and in general supports this proposed new chapter. Comments are inserted in the text below.

Article 14.X.1.

General provisions

~~*Animals* susceptible to *infection* with *Theileria* are~~ Theileriosis is a disease of bovines (*Bos indicus*, *B. taurus* and *B. grunniens*), water buffaloes *(Bubalus bubalis)*, African buffaloes *(Syncerus caffer)*, sheep *(Ovis aries)*, goats *(Capra hircus),* camels (*Camel*lus *dromedarius* and *C. bactrianus*) and some *wild* ruminants.

~~*Infection* with Theileria~~Theileriosis can give rise to disease of variable severity and ~~to *Theileria* transmission. *Theileria*~~ the pathogenic agent may persist in ruminants for their lifetime. Such animals are considered carriers.

Only sheep and goats play a significant epidemiological role in the *infection* with *Theileria lestoquardi, T. luwenshuni* and *T. uilenbergi.*

For the purposes of the *Terrestrial Code*, *infection* with *Theileria lestoquardi, T. luwenshuni* and *T. uilenbergi* are defined as a tickborne *infection* of sheep and goats with *T. lestoquardi, T. luwenshuni* and *T. uilenbergi*.

For the purposes of this chapter, *Theileria* means *T. lestoquardi, T. luwenshuni* and *T. uilenbergi.*

The following defines the occurrence of *infection* with *Theileria*:

1) *Theileria* has been identified in a sample from a sheep or goat; or

2) antigen or nucleic acid specific to *Theileria* has been identified in a sample from a sheep or goat showing clinical signs consistent with *infection* with *Theileria*, or epidemiologically linked to a suspected or confirmed *case*, or giving cause for suspicion of previous association with *Theileria*; or

EU comment

The EU notes that due to the nature of the pathogenic agents, the well established wording "has been isolated from a sample" is not used in point 1 above, as in the other case definitions in disease specific chapters of the Code. However, simply referring to "identified" in both point 1 and point 2 is confusing. What would be the difference? For instance, PCR, one of the agent identification tests according to Manual Chapter 3.8.13. just adopted at the 89th OIE General Session in May 2022, could be used in both instances. Furthermore, the Manual recommends a combination of agent identification methods be applied on the same clinical sample (i.e. microscopic examination, PCR, nested PCR or RLB). Finally, there are no antigen tests described in the Manual.

We note that this comment is valid also for the revised Chapter 11.10. Infection with *Theileria annulata, T. orientalis* and *T. parva* that was just adopted in May 2022.

3) antibodies specific to *Theileria* have been detected in a sample from a sheep or goat ~~that either shows~~showing clinical signs consistent with *Theileria*, or ~~is~~ epidemiologically linked to a suspected or confirmed *case,* or giving cause for suspicion of previous association with *Theileria*.

For the purposes of the *Terrestrial Code*, the *incubation period* for *infection* with *Theileria* shall be 35 days.

Standards for diagnostic tests ~~and vaccines~~ are described in the *Terrestrial Manual*.

Article 14.X.2.

Safe commodities

When authorising the importation or transit of the following *commodities*, *Veterinary Authorities* should not require

any *Theileria*-related conditions regardless of the ~~*Theileria infection*~~ health status of the *animal population* of the *exporting country* or *zone*:

1) *meat* and *meat products*;

2) *casings*;

3) *milk* and *milk products*;

4) gelatine and collagen;

5) tallow;

6) semen and embryos;

7) hooves and horns;

8) bones.

Article 14.X.3.

Country or zone free from infection with *Theileria* in sheep and goats

1) A country or a *zone* may be considered free from *infection* with *Theileria* when the disease is notifiable in the entire country, importation of sheep and goats and their *commodities* is carried out in accordance with this chapter, and:

   a) the country or *zone* is historically free as described in Article 1.4.6.; or

   b) a *surveillance* programme in accordance with Chapter 1.4. has demonstrated no evidence of *infection* with *Theileria* in the country or *zone* for at least two years; or

   c) an ongoing *surveillance* programme in accordance with Chapter 1.5. has found no competent tick *vectors* for at least two years in the country or *zone*.

2) A country or *zone* free from *infection* with *Theileria* in which ongoing *vector surveillance*, performed in accordance with Chapter 1.5., has found no competent tick *vectors* will not lose its free status through the introduction of vaccinated, test-positive or infected sheep and goats from infected countries or *zones*.

3) A country or *zone* free from *infection* with *Theileria* will not lose its status as a result of introduction of seropositive or vaccinated sheep and goats or their *commodities*, provided they were introduced in accordance with this chapter.

EU comment

The EU notes that points 2 and 3 above refer to vaccinated animals, while reference to vaccines is deleted from Article 14.X.1. Indeed, Manual Chapter 3.4.15. does not contain standards for vaccines for the *Theileria* species covered by this Code chapter. This seems to be an inconcistency that merits review.

Or is it possible that sheep and goats are vaccinated with bovine *T. annulata* vaccines? Then also the case definition of Article 14.X.1. would need to be revised accordingly (adding "that are not a consequence of vaccination" to point 3, as is the case in the revised Chapter 11.10.).

Article 14.X.4.

Recommendations for importation of sheep and goats from countries or zones free from infection with *Theileria*

~~For sheep and goats~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1) showed no clinical sign of *infection* with *Theileria* on the day of shipment;

2) come from a country or *zone* free from *infection* with *Theileria*.

Article 14.X.5.

Recommendations for importation of sheep and goats from countries or zones not free from infection with *Theileria*

~~For sheep and goats~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1) showed no clinical sign of *infection* with *Theileria* and no *infestation* with tick *vectors* on the day of shipment;

2) were kept isolated for at least 35 days prior to shipment in an e*stablishment* where no *case* of *infection* with *Theileria* has occurred during the preceding two years;

3) were treated with a registered acaricide, the efficacy of which has been confirmed in relation to the area of origin of the *animals*, at the time of entry into the isolation *establishment* and then at regular intervals, according to manufacturer's instructions, allowing continuous protection against ticks until their shipment ~~48 hours prior to entry to the *establishment*, no more than two days after entering the *establishment* and three days prior to shipment~~;

4) were subjected to ~~serological and~~ agent detection tests with negative results on samples taken immediately prior to ~~on~~ entry and at least 25 days after entry into ~~to~~ the isolation *establishment* ~~and five days before shipment~~.

Article 14.X.6.

Recommendations for importation of hides and skins from countries or zones not free from infection with *Theileria*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products have been:

1) dry-salted or wet-salted for a period of at least 14 days prior to dispatch; or

2) treated for a period of at least seven days in salt (NaCl) with the addition of 2% sodium carbonate (Na_2CO_3); or

3) dried for a period of at least 42 days at a temperature of at least 20°C; or

4) frozen to at least -20°C for at least 48 hours.

Article 14.X.7.

Recommendations for importation of wool and fibre of sheep and goats from countries or zones not free from infection with *Theileria*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products were subjected to:

1) industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide or potassium hydroxide; or

2) industrial scouring, which consists of the immersion of wool in a water-soluble detergent held at 60–70°C.

Article 14.X.8.

Recommendations for importation of trophies derived from susceptible ~~wild~~ ruminants from countries or zones not free from infection with *Theileria*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products have been processed to ensure the destruction of tick *vectors*.

CHAPTER X.X.

INFECTION WITH MIDDLE EAST RESPIRATORY SYNDROME CORONAVIRUS

EU comment

The EU thanks the OIE and in general supports this proposed new chapter. Indeed, as indicated during the 89th OIE General Session, and in the EU comments inserted in Annex 3 "Work programme" of this report, the EU welcomes the drafting of new Code chapters for listed diseases, even if these chapters consist of only a single article with the case definition. This will provide the necessary legal certainty and will be very useful for consistent and transparent disease notification by members.

Comments are inserted in the text below.

Article X.X.1.

General provisions

Middle East respiratory syndrome (MERS) is a viral respiratory infection of humans and dromedary camels which is caused by a coronavirus called Middle East Respiratory Syndrome Coronavirus (MERS-CoV).

Dromedary camels (*Camelus dromedarius*) have been confirmed by several studies to be the natural host and zoonotic source of the MERS-CoV infection in humans. Other species may be susceptible to *infection* with MERS-CoV. However, their epidemiological significance has not been demonstrated.

EU comment

The EU suggests deleting the words "by several studies" in the paragraph above, as this type of information is not usually mentioned in the Code and is thus superfluous. Alternatively, the sentence could be further shortened to say "Dromedary camels (*Camelus dromedarius*) are the natural host [...]".

MERS-CoV has been associated with mild upper respiratory signs in some dromedary camels. While the impact of MERS-CoV on animal health is very low, human infections have a significant public health impact.

For the purposes of the *Terrestrial Code*, MERS is defined as an *infection* of dromedary camels with MERS-CoV.

The following defines the occurrence of *infection* with MERS-CoV:

1) MERS-CoV has been isolated from a dromedary camel, or

EU comment

The EU suggests inserting the words "<u>a sample from</u>" before "a dromedary camel", for consistency with other disease specific chapters.

2) nucleic acid specific to MERS-CoV has been identified in samples from a dromedary camel showing clinical signs or pathological lesions suggestive of MERS-CoV or epidemiologically linked to a suspected or confirmed *case* of MERS-CoV, or from a dromedary camel giving cause for suspicion of previous association or contact with MERS-CoV.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

CHAPTER X.Y.

INFECTION WITH *LEISHMANIA* SPP. (LEISHMANIOSIS)

EU comment

The EU thanks the OIE and in general supports this proposed new chapter. Indeed, as indicated during the 89th OIE General Session, and in the EU comments inserted in Annex 3 "Work programme" of this report, the EU welcomes the drafting of new Code chapters for listed diseases, even if these chapters consist of only a single article with the case definition. This will provide the necessary legal certainly and will be very useful for consistent and transparent disease notification by members.

A comment is inserted in the text below.

Article X.Y.1.

General provisions

For the purposes of the *Terrestrial Code*, *infection* with *Leishmania spp.* is defined as an *infection* of dogs and cats by parasites of the family *Trypanosomatidae*, order *Kinetoplastida*.

The *infection* is usually transmitted by the bite of an infected *Phlebotomus* sandfly.

The following defines the occurrence of *infection* with *Leishmania* spp.:

1) *Leishmania spp.* amastigotes have been observed in samples from a dog or a cat, or

EU comment

The EU queries whether the term "observed" in point 1 above is sufficiently clear. Perhaps "identified" or "detected" would be more pertinent (the latter is the term used in the Manual).

2) Nucleic acid specific to *Leishmania* spp. has been detected in a sample from a dog or a cat showing clinical signs or pathological lesions consistent with infection with *Leishmania* spp., or epidemiologically linked to a case, or giving cause for suspicion of previous association or contact with *Leishmania* spp., or

3) Antibodies specific to *Leishmania* spp. that are not the consequence of vaccination have been detected in a sample from a dog or a cat showing clinical signs or pathological lesions consistent with infection with *Leishmania* spp., or epidemiologically linked to a case, or giving cause for suspicion of previous association or contact with *Leishmania* spp.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

SCIENTIFIC REPORT

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Risks related to a possible reduction of the waiting period for dogs after rabies antibody titration to 30 days compared with 90 days of the current EU legislative regime

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Abstract

EFSA received a mandate from the European Commission to assess the risks related to a possible reduction of the waiting period after rabies antibody titration test to 30 days compared with 90 days of the current EU legislation, for dogs moving from certain non-EU countries to the EU. This Scientific Report assessed the probability of introduction of rabies into the EU through commercial and non-commercial movements of vaccinated dogs with a positive titration test ($\geq$ 0.5 IU/mL) if the waiting period decreases from 90 to 30 days. Assuming that all the legal requirements are complied with, the risk of transmission of rabies through the movement of a vaccinated dog is related to the risk of introducing an animal incubating rabies that was infected before the day of vaccination or shortly after vaccination but before the development of immunity (21 days post-vaccination). Using published data on the incubation period for experimental and field cases in dogs and considering the rabies incidence data in certain countries, the aggregated probability for the annual introduction of rabies through dogs was assessed. Considering the uncertainty related to the duration of the incubation period, the number of imported dogs, and the disease incidence in some countries it was concluded with a 95% certainty that the maximum number of rabies-infected imported dogs complying with the regulations in a 20-year period could increase from 5 to 20 when decreasing the waiting period from 90 to 30 days. Nevertheless, the potential impact of even a small increase in probability means the risk is increased for a region like the EU where rabies has long been a focus for eradication, to protect human and animal health.

Keywords: antibody titration test, dog, import, rabies, waiting period, vaccination

Requestor: European Commission

Question number: EFSA-Q-2022-00159

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Summary

The European Food Safety Authority (EFSA) received a mandate by the European Commission for scientific and technical assistance on the risks related to a possible reduction of the waiting time after rabies antibody titration to 30 days compared with the current EU legislative regime of 90 days. This reduction is indeed being considered at international level as a proposed change to the Rabies Chapter of the World Organisation for Animal Health (OIE) Terrestrial Animal Health Code.

Vaccination against rabies is currently required for dogs, cats and ferrets before entry into the European Union according to Commission Delegated Regulation (EU) 2020/692. Animals must be at least 12 weeks of age at vaccination using approved vaccines according to Annex III to Regulation (EU) 576/2013, and dispatch of the animal must only occur at least 21 days following primary vaccination. Vaccination should be specified in an animal health certificate; also, a virus neutralising antibody titration test (VNT) must be carried out for commercial movements of animals originating in countries or regions specified in column 5 of Annex VIII to Commission Implementing Regulation (EU) 2021/404 or from countries or regions not listed in Annex II to Commission Regulation (EU) No 577/2013. This test must be carried out by a veterinarian authorised by the competent authority on a blood sample taken at least 30 days after the primary vaccination, and the test should demonstrate neutralising antibodies in a concentration $\geq$ 0.5 IU/mL.

Rabies vaccination is considered effective in animals capable of mounting neutralising antibodies, and the test is carried out to demonstrate this vaccination. However, rabies vaccination is not effective in preventing the development of fulminant rabies in animals already incubating the disease at primary vaccination. Therefore, a waiting period from a positive titration test until import from certain non-EU countries is required for the commercial and non-commercial movements of dogs to the EU from certain no-EU countries where rabies is endemic. This period is currently 90 days (and thus in line with current OIE recommendations) but following a report by the OIE ad hoc Group on Rabies, OIE has proposed to be reduced to 30 days.

Therefore, the European Commission requested scientific advice for the assessment of the risks associated with the possible reduction of the waiting period following positive titration test before movement. Only the so-called Type A risk (EFSA AHAW Panel, 2007), in which an animal is incubating the disease at vaccination, was considered relevant; Type B risk characterised by failure to induce protective immunity following vaccination was not included, because these animals are expected to test negative for neutralising antibodies. In the vaccinated dogs with Type A risk, this likelihood of becoming infected was considered to include the days before vaccination and 21 days after vaccination, whereas the waiting period following this would be expected to capture those dogs incubating disease as part of Type A risk.

An Extensive Literature Review (ELR) was carried out by an external contractor to characterise the incubation period in experimental trials and natural infections, stratified by vaccinated and unvaccinated dogs. Furthermore, data on dog movements for commercial purposes from non-EU countries were collected from TRACES[1], the EU trade notification system. These data were used to characterise the import of dogs infected by Rabies Virus (RABV) and the total recorded imports of dogs for commercial purposes from non-EU countries.

Incubation with RABV causes a variable onset of clinical signs in dogs. The results of the ELR revealed the following distribution of the incubation periods for non-vaccinated dogs challenged intramuscularly: 90th percentile: 29 days, 95th percentile: 36 days, 99th percentile: 77 days, and maximum: 92 days. Recent field data indicate that incubation periods of $>$ 30, $>$ 60 and $>$ 120 days may occur in 41, 16 and 4% of infected dogs, respectively.

Neutralising antibodies are generally observed 5–21 days following experimental intramuscular inoculation, and 3–21 days following vaccination.

An average of 23,000 dogs per year were recorded in TRACES[1] as imported from non-EU countries into the EU for commercial purposes in the period 2019–2021 (Section 3.1.1.2 and Table C.1 of Appendix C). Of these, an average of 1,780 per year were from non-EU countries, for which the antibody titration test and the waiting period afterwards is mandatory. However, in general, the numbers of non-commercial movements of dogs into the EU are not registered.

[1] TRACES is the European Commission's online platform for sanitary and phytosanitary certification required for the importation of animals, animal products, food and feed of non-animal origin and plants into the European Union, and the intra-EU trade and EU exports of animals and certain animal products. Available online: https://ec.europa.eu/food/animals/traces_en

Specifically, for the period 2001–2021, based on the reports found in the ELR, 20 dogs were imported into the EU from non-EU countries and later confirmed to be RABV infected were identified (Table B.1 of Appendix B). Non-compliance with existing rules were identified in most cases.

The risk of introduction of rabies is dependent on the incidence in the country of origin. Recent estimates suggested an annual incidence of rabies in certain endemic countries between 100 and 500 infected dogs per 100,000 dogs, although this is likely to be an overestimate, so these along with an annual incidence of five infected dogs per 100,000 dogs were used. Using a deterministic approach, the probability of importing a dog incubating rabies but fully compliant with requirements (i.e. vaccination, positive titration test) and a waiting period of 30 days was estimated to 1.13×10^{-5}, in regions with high incidence rate (500/100,000), using an incubation period estimated based on experimental data. For a waiting period of 90 days, this probability would be zero, because no dogs in the experimental data had a sufficiently long incubation period. For the incubation period derived from field data, the probability of importing a dog incubating rabies, but fully compliant with legislation from a high incidence region (with 500 rabies cases per 100,000 dogs), would be 14.8×10^{-5} for a 30-day waiting period, while the probability with a 90-day waiting period would be 2.96×10^{-5}. These probabilities are lower for low prevalence regions. This implies that if 20,000 dogs are imported annually from high incidence regions and based on the incubation period as derived from the field data, then a dog incubating rabies will be imported every 0.34 years when applying a 30-day waiting period, and every 1.4 year if applying a 90-day waiting period. Because the estimates are very susceptible to the incubation period estimates, we also used data from experimental studies. These suggested that assuming the import of 20,000 dogs per year, one dog infected with rabies would be imported every 4.4 years if a waiting period of 30 days is applied; while for a waiting period of 90 days, import of a rabies-infected dog would not occur. When the incubation period estimated based on field data was used, the average time it takes to import a RABV-infected dog fully compliant with the regulation was reduced 4.2 times if the waiting period was reduced from 90 to 30 days irrespective of the incidence in the region of origin and the numbers of dogs introduced. This assessment was based on several assumptions subject to considerable uncertainty (number of dogs imported, incidence in the population of imported dogs, duration of the incubation period, etc.). Once the impact of all identified sources of uncertainty in the assessment was assessed collectively through expert judgement, it was concluded with a 95% certainty that the maximum number of RABV-infected dogs imported in the EU in a 20-year period from the countries considered in the assessment applying the current 90-day waiting period would be five, while this number could be up to 20 using the proposed 30-day waiting period.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Specific animal health requirements for entry into the Union of dogs, cats and ferrets are laid down in Commission Delegated Regulation (EU) 2020/692[2]. They mainly rely on preventing rabies from entering the EU territory from imported animals. To that end, the following conditions must be met:

Vaccination against rabies - dogs, cats and ferrets must be vaccinated against rabies as follows:

- the animals must be at least 12 weeks old at the time of vaccination;
- the vaccine must comply with the requirements set out in Annex III to Regulation (EU) No 576/2013[3];
- at the day of dispatch to the Union, at least 21 days must have elapsed since the completion of the primary vaccination against infection with rabies virus;
- a certified copy of the vaccination details must be attached to the animal health certificate.

Rabies antibody test - dogs, cats and ferrets coming from third countries or territories listed in Part I of Annex VIII to Commission Implementing Regulation (EU) 2021/404[4], for which the specific condition "rabies antibody titration test" applies, must undergo a rabies antibody test, meeting certain criteria. That test:

- must be carried out on a sample collected by a veterinarian authorised by the competent authority during the period commencing at least 30 days after the date of the primary vaccination, within a current valid vaccination series, and ending 3 months before the date of issue of the certificate;
- must measure a titre of neutralising antibody to rabies virus equal to or greater than 0.5 IU/mL;
- must be certified by an official report from the official laboratory as regards the result, and a copy of this report must be attached to the animal health certificate accompanying the animals to the Union;
- does not have to be renewed on an animal which, following the antibody rabies titration test with satisfactory results, has been revaccinated against rabies within the period of validity of the primary vaccination and all subsequent valid vaccinations in the series.

These measures largely reflect the recommendations provided by EFSA in an opinion adopted on 11 December 2006 and published on 15 February 2007 regarding an "Assessment of the risk of rabies introduction into the UK, Ireland, Sweden, Malta, as a consequence of abandoning the serological test measuring protective antibodies to rabies"[5]. In this opinion, EFSA points out that the risk of transmission of rabies by pet movement is related to moving an animal incubating the disease and that the primary means of removing an individual from the population at risk is by vaccination, as inactivated rabies vaccines are highly efficient and induce rapid protective immunity that prevents infection and subsequent transmission. On the other hand, it also highlights that infection prior to vaccination protection cannot be controlled by immunisation. Therefore, further requirements should be based on whether rabies occurs in the pet population or not. If rabies occurs in the pet population where pets reside before primo-vaccination, a waiting time following primo-vaccination is recommended as the most efficient measure to reduce the risk of importing rabies-infected pets. The higher is the actual prevalence, the longer should be the waiting time required in order to reach an acceptable level of risk. Finally, the opinion recognises that the implementation of serological testing or other risk-reducing measures may be considered when the required waiting time exceeds 100 days.

As indicated above, the waiting time legally required in the EU legislation for movements from countries with a higher prevalence/unknown status is of at least 3 months after the blood sampling, which has to be undertaken at least 30 days after rabies vaccination. This requirement is also in line

[2] Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin, OJ L 174, 3.6.2020, p. 379.

[3] 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.

[4] Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council, OJ L 114, 31.3.2021, p. 1.

[5] https://www.efsa.europa.eu/en/efsajournal/pub/436

with the current recommendations included in the OIE Terrestrial Animal Health Code Chapter 8.14 on rabies (29th edition 2021) (OIE, 2021).

As shown in EFSA Opinion (EFSA AHAW Panel, 2007), the waiting time between vaccination and import is crucial, because vaccination does not prevent disease developing in already infected animals. Blancou et al. (1989) demonstrated that vaccination in an already infected animal does not significantly alter the clinical picture or development time of the disease. Therefore, it is possible that an animal infected prior to rabies vaccination would continue to incubate the disease despite developing a significant antibody titre. Another risk of rabies introduction is linked to pets which are not fully protected by the vaccination, either because they were recently vaccinated or they mounted an insufficient antibody response, before being infected.

From a general point of view, the risk that an animal is incubating disease at the time of vaccination is the same as the risk that an unvaccinated animal is incubating disease when it is imported, thus, the overall risk is very sensitive to the waiting time. It is also very sensitive to compliance with requirements (e.g. shorter than required wait, incorrect or no vaccination, falsified test result) (Wilsmore et al., 2006).

The OIE ad hoc Group on Rabies has started to work on modifying Article 8.14.7 of the OIE Terrestrial Animal Health Code and reducing the waiting time after a positive antibody titration test from 90 to 30 days. A concept paper[6] of the OIE ad hoc group describing the scientific evidence to support those changes was released with the February 2020 OIE Scientific Commission for Animal Diseases ("OIE Scientific Commission") report[7] and was subsequently published in the scientific journal Vaccine[8]. The OIE Terrestrial Animal Health Standards Commission ("OIE Code Commission") amended Article 8.14.7 and circulated for OIE Members countries' (Members) comments after its September 2020 meeting. The OIE Scientific Commission agreed to consult subject-matter experts to address Member's concerns expressed after that round of consultation.

In December 2020, the European Union expressed concerns[9] that the presented data and drawn conclusions were not sufficient for a policy change and would request additional scientific evidence. To support its position, it submitted a scientific report prepared by experts of the European Union Reference Laboratory for Rabies (cf. p. 127–131 of the document under footnote 7[7]).

In September 2021, after careful analysis of the Member's concerns, the OIE Scientific Commission endorsed the expert opinion of the OIE Rabies Reference Laboratory network (RABLAB) which considered that the scientific basis for a 30-day post-titration waiting time was justified and that the conclusion of the 2019 OIE ad hoc Group on Rabies that reviewed dog importation standards should remain unchanged.

The OIE Scientific Commission opinion together with the experts' rationale were forwarded to the OIE Code Commission for consideration. It is therefore likely that these changes will be proposed for adoption by OIE member countries, possibly as early as at the General Session of the OIE in May [2022].

1.1.1. Terms of Reference

In the context of Article 31 of Regulation (EC) No 178/2002, the Commission asks EFSA for scientific and technical assistance on the risks related to a possible reduction of the waiting time after rabies antibody titration to 30 days compared to the current EU legislative regime, **taking into account:**

- the experience gained in the last years with the current waiting time laid down in the EU legislation;
- the possible risks/limitations including those identified by the experts of the EU Reference Laboratory for Rabies in their February 2021 opinion;
- newly available scientific information, and specifically the publication describing the scientific evidence to support the proposed changes released.

[6] Commentary in Vaccine, 39, 2496–2499. https://doi.org/10.1016/j.vaccine.2021.03.064
[7] https://www.oie.int/en/what-we-do/standards/standards-setting-process/scientific-commission/#ui-id-2
[8] Smith TG, Fooks AR, Moore SM, Freuling CM, Müller T, Torres G and Wallace RM, 2021. Negligible risk of rabies importation in dogs thirty days after demonstration of adequate serum antibody titer. Vaccine. https://doi.org/10.1016/j.vaccine.2021.03.064. (https://www.sciencedirect.com/science/article/pii/S0264410X21003686?via%3Dihub).
[9] https://ec.europa.eu/food/system/files/2020-12/ia_standards_oie_eu_comments_tahsc-report_202012.pdf

1.2. Interpretation of the Terms of Reference (if appropriate)

According to the background and terms of reference (ToRs) provided by the Commission, the request concerns the provisions for the dogs (*Canis lupus)* intended to be moved for commercial or non-commercial purposes into the EU territory from non-EU Countries to prevent the introduction of rabies in EU as described in Article 76 of the Commission Delegated Regulation (EU) 2020/692 in accordance with Article 8.14.7 of the OIE Terrestrial Code (last revised in 2019) (please refer to Appendix A).

More specifically, it concerns the waiting period from the neutralising antibody titration test and before dog shipment.

For this work, it is considered that all the requirements of EU legislation related to dog movements have been implemented. Specifically:

1) The dog **is individually identified** by means of an injectable transponder implanted that fulfils the technical requirements for means of identification (Article 74 Reg 2020/692) by a veterinarian, and the dog was individually identified before or at the time of primary vaccination (Annex III to the Regulation (EU) 576/2013) so the details correspond to those in the certificate or passport.
2) The dog **has been vaccinated** against rabies before shipment **with a vaccine that complies with the validity requirements** set out in Annex III to Regulation (EU) No 576/2013: (i) it is not a live modified vaccine and it is either an inactivated vaccine of at least one antigenic unit per dose (recommendation from the World Health Organisation); (ii) it has been granted an approval or a licence by the competent authority of the non-EU country and (iii) it meets at least the requirements laid down in the relevant part of the chapter concerning rabies in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health.
3) The dog **was at least 12 weeks old** at the date on which the **primary rabies vaccination** was administered (Article 76 of Regulation 2020/692).
4) The **period of validity of the vaccination** starts **from the establishment of protective immunity**, which shall not be less than 21 days from the completion of the vaccination protocol required by the manufacturer for the primary vaccination, **and continues until the end of the period of protective immunity,** as prescribed in the technical specification of the marketing authorisation referred to in point 1(b)[10] or the approval or licence referred to in point 1(c)[11] for the anti-rabies vaccine in the Member State or territory or non-EU country where the vaccine is administered [point 2(e) Annex III Regulation (EU) No 576/2013].
5) As p**rimary rabies vaccination** is considered the **first vaccination** and a**ny revaccination** if it was not carried out within the period of validity of the previous vaccination (point 2e of Annex III to Regulation (EU) No 576/2013).
6) The **vaccination has been conducted by an authorised veterinarian** (Annex III Regulation (EU) 576/2013) and therefore good veterinary practice related to vaccination has been implemented. This also implies that the dog was healthy at the day of vaccination (based on the results of the clinical examination) and there was no suspicion of any disease including rabies (based on the medical history of the dog for the last days prior to vaccination).
7) The vaccinated dog must, at the time of import, remain within the protective immunity period of the vaccines according to the manufacturer's instructions.
8) A certified copy of the vaccination details must be attached to the animal health certificate; the **date of administration of the vaccine** and the **period of validity of the vaccination** is indicated by an authorised veterinarian or an official veterinarian in the appropriate section of the identification document (article 76 Reg 2020/692, point 2(e) Annex III Regulation (EU) No 576/2013).
9) A rabies antibody titration test using a **virus neutralisation test** (VNT) to detect neutralising antibodies must be carried out on a blood sample collected not less than 3 months and not more than 12 months prior to the date of issue of the certificate for the

[10] Is referred to Point 1(b) of Annex III Regulation (EU) No 576/2013.
[11] Is referred to Point 1(c) of Annex III Regulation (EU) No 576/2013.

shipment. In case of primary vaccination, the samples should be collected at least 30 days after the date of primary vaccination course, within a current valid vaccination series. The sample should be collected by a veterinarian authorised by the competent authority.

10) The VNT must comply with the validity requirements set out in Annex XXI to Regulation (EU) 2016/429.
11) The VNT before entry should be performed in a laboratory authorised[12] by the ANSES-Nancy laboratory which is the European Union Reference Laboratory (EURL)[13] for rabies.
12) A neutralising antibody level ≥ 0.5 IU/mL is characterised as positive. Nevertheless, the test does not differentiate between infected and vaccinated animals and there are no laboratory tests able to differentiate between neutralising antibodies resulting from natural infection from those developed after vaccination.
13) The antibodies resulting from natural infection are only detectable when the animal is in the late stages and showing clinical signs, only dogs without clinical signs should travel, however only commercial consignments of dogs will be subject to a veterinary inspection before to travel.
14) Provided the VNT results are positive, the dogs are not allowed to travel immediately. A waiting period of at least 90 days (current regulation) and not more than 12 months, after the day of sampling for the antibody titration test, has been introduced to allow the clinical signs to manifest if animals were infected before vaccination or just after vaccination.
15) Once the dog is ready to travel, it should be clinically examined within a period of 48 h before to the time of loading for dispatch [article 13(3) of Reg 2020/692] and in the absence of clinical signs the shipment is allowed, and the certificate is provided. However, this is only applicable to commercial movements; for non-commercial movements, there is no such requirement.
16) Dogs from countries not listed in Annex II to 577/2013 and all commercial consignments from outside the EU will have to enter through a Traveller's Point of Entry (TPE) or a Border Control Post (BCP), respectively, where veterinary checks can be undertaken.

Taking into consideration that all the above-mentioned requirements are implemented, the risk of transmission of rabies through the movement of a vaccinated dog is related to the risk of moving a vaccinated animal incubating the disease.

The question to be addressed by this Scientific Report is how much the risk of introduction of rabies into EU increases through the movement of vaccinated dogs with a positive titration test (≥ 0.5 IU/mL) if the waiting period from sampling to movement decreases from 90 to 30 days.

All other parameters are considered identical across both options in the assessment besides the difference in the length of the waiting period (Figure 1).

The length of the incubation period is considered the main epidemiological parameter for the purposes of this assessment.

[12] Approved rabies serology laboratories in EU and non-EU Countries: https://ec.europa.eu/food/animals/movement-pets/approved-rabies-serology-laboratories_en
[13] The link of the EURL: https://eurl-rabies.anses.fr/en/minisite/rabies/european-union-reference-laboratory-eurl-rabies

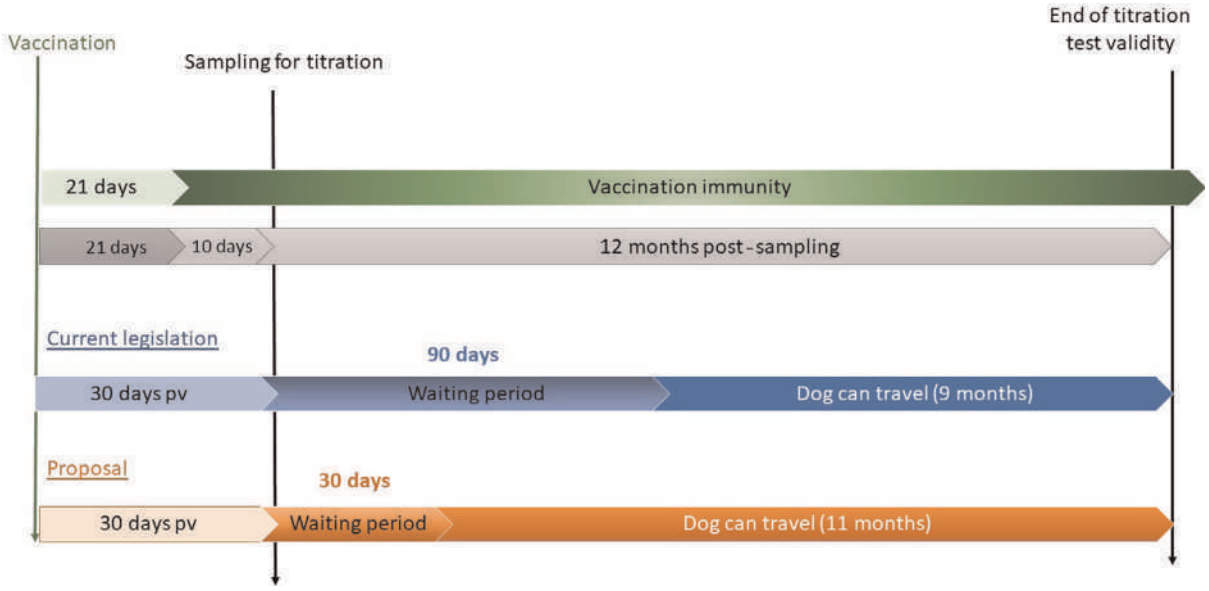


Figure 1: Schematic representation of the two options of the lengths of the waiting period (current of 90 days and proposed of 30 days) after the sampling and before travelling, given that the titration test is positive (≥ 0.5 IU/mL). In addition, some other time intervals are included for both options to support the comparison; pv: post-vaccination

To address the ToRs of the mandate, EFSA proposed and agreed with the European Commission that the assessment will be based on the results of an Extensive Literature Review (ELR), which would be conducted by an external contractor. The protocol of the literature review was shared and agreed with European Commission (Annex A; available under Supporting Information).

2. Data and methodologies

2.1. Data

Data on the incubation period were collected via an ELR conducted by an external contractor (OC/EFSA/ALPHA/2020/01) according to the ELR protocol in Annex A (available under Supporting Information), and following the overall methodology protocol agreed at the start of the process that is presented in Appendix D. This literature review included publications on experimental trials and natural infection in the field in unvaccinated and vaccinated dogs (please refer to Appendix B). Data were collected separately for vaccinated and unvaccinated dogs.

Experimental studies included purely experimental infection trials and vaccine trials in which the experimental infection preceded or followed the vaccination or was implemented to the control groups without vaccine administration.

Data on natural infection were obtained from publications, reports, and notification systems (e.g. ADIS, WAHIS) on dogs found infected after travelling from a non-EU country to the EU territory.

Data on dog movements for commercial purposes (imports) from non-EU countries into the EU territory were collected from TRACES online application[1] (Table C.1 of Appendix C). There are no consistent data collected on non-commercial dog movements in this database or in any other database at EU level and therefore official data are not available for this type of dog movements.

2.2. Methodologies

The main epidemiological parameter used for the assessment of the risk of rabies introduction to EU countries is the incubation period. The estimation of the length of the incubation period is based on the results of the literature review for which two different time intervals were considered: (i) the time from virus inoculation to the onset of clinical signs and/or death, for experimental infections and (ii) the time from entering the EU country of destination to the onset of clinical signs or death for natural infections in dogs moved from non-EU countries.

For the estimation of the incubation period in unvaccinated animals, data from control groups in vaccine studies were used together with those data from experimental infection studies in which dogs have not been subjected to any treatment for rabies. Data from non-EU countries of naturally infected dogs were also used to estimate the incubation period.

The ELR was carried out by an external contractor and the protocol is described in detail in Annex A (available under Supporting Information).

In a previous EFSA Opinion (EFSA AHAW Panel, 2007), two types of risk have been recognised for rabies transmission through dog movements: (i) Type A risk, related to the risk that an animal is already incubating rabies at the time of vaccination and (ii) Type B risk, related to the failure of inducing protective immunity following vaccination, and failure to correctly identify this condition.

Type B risk as described in the EFSA Opinion (EFSA AHAW Panel, 2007) is not as such relevant to this Scientific Report given that a positive titration test ($\geq$ 0.5 IU/mL) at least 30 days post-vaccination is a prerequisite for movement from countries where rabies is endemic or not controlled. The virus neutralising test is a managerial tool to minimise the risk of introducing rabies through dog movements.

A healthy dog with titration test undetectable or below the cut-off levels (i.e. $<$ 0.5 IU/mL) after vaccination cannot be considered as not having developed protective immunity as cellular immunity is mediated by vaccination as well. Nevertheless, this dog will not be allowed to travel. Conversely, a dog with immune system deficiencies that either fails to react to vaccination making the dog susceptible to infection, or when there was vaccine failure during the administration, will not reach a positive neutralising antibody titre $\geq$ 0.5 IU/mL within 30 days post-vaccination and will not be allowed to travel. Therefore, Type B risk, the risk of infection upon vaccination failure to develop protective immunity, used in the above-mentioned EFSA Opinion (EFSA AHAW Panel, 2007), is not considered relevant, because in the situation assessed here only dogs with a titre $\geq$ 0.5 IU/mL upon vaccination will be allowed to move into the EU.

In this Scientific Report, and for the purposes of the assessment, the following assumptions were applied:

- Vaccinated dogs without clinical signs, which show neutralising antibody titres $\geq$ 0.5 IU/mL at least 30 days post-vaccination, are fully protected against infection and this protection has been effective from day 21 post-vaccination (21dpv) onwards.
- The risk of infection before 21dpv is similar to Type A risk from a previous EFSA Opinion (EFSA AHAW Panel, 2007), and depends again on the incubation period, as the process of vaccination by an approved veterinarian constitutes a health check. These dogs can be infected either before vaccination or during the first 21 days (before the development of immunity) of the 30-day interval from vaccination to sampling for the titration test.
- The effectiveness of vaccination is 100% and a dog is fully protected from 21dpv. Given that the waiting period (30 or 90 days) starts from the blood sampling and that the blood is taken at least 30 days post-vaccination, the dogs are effectively protected 10 days before the start of the waiting period (from the 21dpv). For a 30-day waiting period, the dog is assumed protected and cannot be infected at least 40 days before movement (10 + 30), and accordingly 100 days (10 + 90) for a waiting period of 90 days (Figure 2).
- 100% of the dogs that show clinical signs of rabies before movement into EU are detected at border control or even before (sensitivity of clinical examination: $Se_{Clinical\ examination} = 1$) and the serological test (VNT) showing a titre $\geq$ 0.5 IU/mL is 100% specific ($Sp_{VNT} = 1$) (no false-positive results). The clinical inspection is systematically performed 48 h before leaving the country of origin in dogs moving for commercial purposes while for non-commercial movements clinical inspection is not always performed and the controls may be limited to document and identity checks.
- On each day before the 21dpv, it was assumed that a dog could be infected at the same incidence rate (IR; the incidence rate expressed per day in the region), as the IR in a region was assumed to be constant.

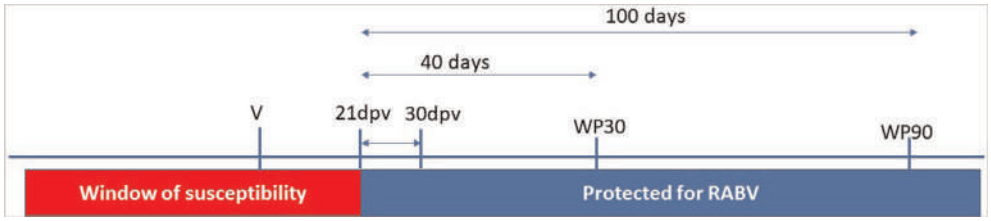


Figure 2: Timeline showing the window of susceptibility for RABV infection and the period when dogs are considered protected from RABV infection due to the development of the immunity in relation to the moment of vaccination (V) and the waiting period of 30 (WP30) and 90 days (WP90). Dogs are assumed to be protected against infection from day 21 post-vaccination (21dpv)

The methodology used to apply the question was based on a deterministic approach.

For each day before 21dpv, the probability of the incubation period exceeding the end of the waiting period, is derived from the distribution of the incubation period for the experimental data (extracted by the contractor via an ELR) and from a lognormal distribution fitted to field data according to Crozet et al. (2022) (please refer to Section 3.2). The earlier the infection occurs, the lower the probability that the incubation period will exceed the waiting period.

The probability of a single imported dog being infected with RABV having an incubation period exceeding the length of the waiting period (90 or 30 days) (while in compliance with the requirements of EU regulation) equals to:

$$P_{individual} = p \times IR/365,$$

where IR is the annual incidence rate in the region of origin and p is the sum of the probabilities of having an incubation period that will exceed the waiting period on each day before 21dpv. Specifically, $p = p_0 + p_1 + \ldots + p_d + \ldots + p_{20}$, where p_d is the probability that a dog infected at day 'd' post-vaccination but before day 21 has an incubation period exceeding or greater than 'WP – d', where WP is the waiting period.

The overall annual probability of introducing at least one RABV-infected dog incubating the RABV after the end of a certain waiting period (30 or 90 day) out of the total number of dogs (n) moved from a non-EU country to EU, can therefore be calculated as:

$$P_{overall} = 1 - (1 - P_{individual})^n.$$

2.3. Uncertainty

All sources of uncertainty identified during the assessment were recorded, and their impact on the scientific assessment was assessed collectively (the simplest option for this type of assessment; section 4.1 of EFSA Scientific Committee (2018)) after transforming the objective of the assessment into well-defined quantities of interest (QoIs). In particular, considering that the mandate requested scientific and technical assistance on the risks related to a possible reduction of the waiting time after rabies antibody titration to 30 days, compared with the current practice of 90 days, two QoIs were defined:

- QoI1: the number of RABV-infected dogs that will be moved from countries or regions either not listed in Annex II to Regulation (EU) 577/2013 for pet dogs, or listed in Regulation (EU) 2020/404 (Annex VIII column 5) for commercial and non-commercial movements compliant with the regulations (vaccinated as requested and passing a VNT test 30 days post-vaccination) in a 20-year period under the current waiting period of 90 days.
- QoI2: the number of RABV-infected dogs that will be moved from the same countries and conditions in the 20-year period assuming a 30-day waiting period is put in place.

The evidence included in this report and the sources of uncertainty identified during the assessment were summarised in an evidence dossier that was provided to the experts. A lower (0 dogs) and upper (50 dogs) bound delimiting the range of plausible values for both QoIs were then agreed within the Working Group during a meeting, and the Working Group experts were asked to provide their individual judgements on the most likely values for each QoI using the roulette method (EFSA, 2014). Individual judgements were then discussed and used to agree on the 95% percentile of

the distribution for each QoI (i.e. the value below which experts were 95% certain[14] that the QoI would be), which were used to quantify the increase in risk related to the reduction of the waiting period considering all uncertainties.

3. Assessment

Rabies is a viral zoonotic disease of mammals, including humans, which causes encephalomyelitis and if left untreated is invariably fatal. Rabies disease is induced by neurotropic viruses of the *Lyssavirus* genus, Rhabdoviridae family, rabies virus (RABV), serotype 1 of multiple strains. Each strain is identified by its reservoir host species. Other related Lyssaviruses can cause identical neurological disease, and include the European bat lyssaviruses in Phylogroup I, but this assessment is only concerned with classical RABV.

Classical rabies is present worldwide, with the exception of some islands and countries with strict wildlife and import controls. There is no official rabies free status recognition by the OIE, but an OIE member country can declare itself to be free of rabies based on the requirements of the OIE Code if there have been no autochthonous acquired cases in humans or animals during the previous 2 years, in the presence of adequate surveillance and import regulations.

The EU has over the last 20 years invested heavily and successfully in the pathway to freedom from rabies in wildlife, companion animals and livestock. This has been based not only on widespread rabies vaccination programmes in EU countries, but also on import controls to verify the implementation of a series of measures for dogs intended to travel from a non-EU country to EU territory: e.g. individual identification, mandatory vaccination and clinical examination before movement and in addition to (from some non-EU countries) positive titration test followed by a waiting period of 90 days post-titration and before movement.

The EU has for many years required import controls for dogs, cats and ferrets that includes vaccination as well as identification, health certificates and blood tests for some countries. However, many EU MS have been on a pathway to elimination of rabies in wildlife through annual oral vaccination programmes of the reservoir wildlife host (mostly the red fox) and monitoring/surveillance. As a result, most EU MS have not reported any rabies cases in wildlife and only a few MS have reported occasional cases in cats or dogs that have been illegally imported, having not been prepared properly for travel. Wildlife strains of rabies still occur as spill-over cases into domestic animals in some EU MS where wildlife vaccination programmes are in place.

Specific animal health requirements for entry into the European Union of dogs are laid down in European legislation. They mainly rely on preventing rabies from entering the EU territory from imported animals. Each one of the above-mentioned requirements verifies that some conditions are in place that are minimising the risk of rabies transmission through dog movement and there are several decisions to be made for each one (see Figure 3).

[14] % certainty is used in this Opinion to express the Panel's % probability for the more probable outcome, as recommended by EFSA's guidance on communication of uncertainty (EFSA, 2019).

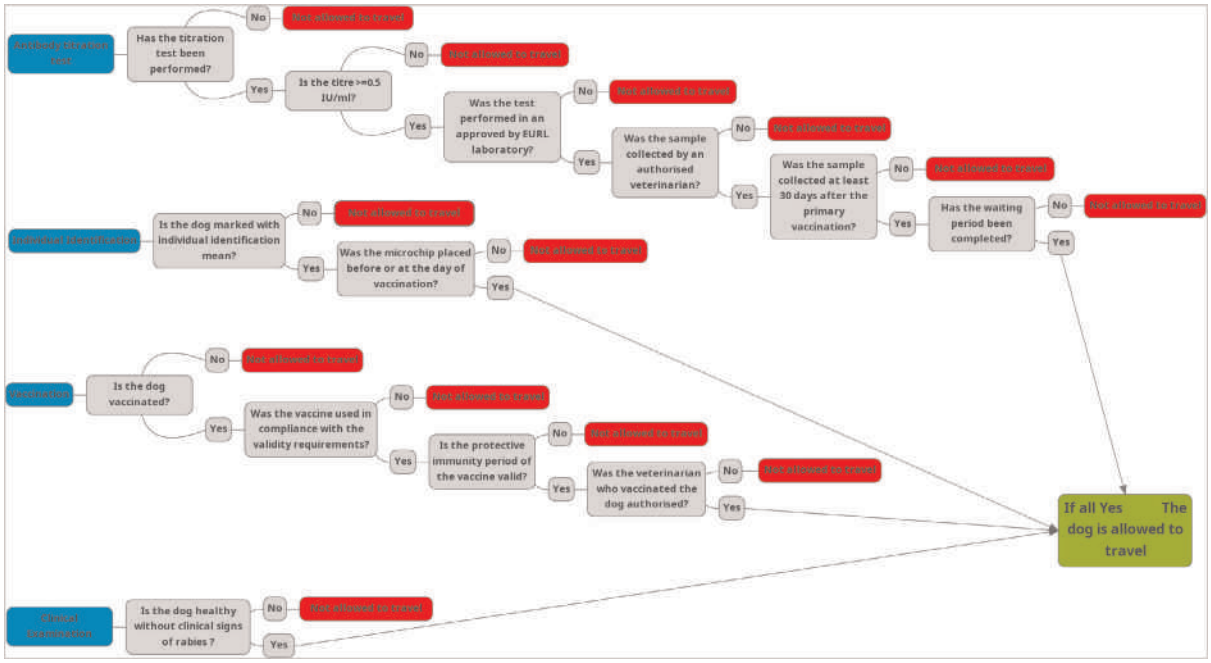


Figure 3: The process to be followed and the decisions to be taken in each step, for a dog to be allowed to enter the EU territory from non-EU countries for which the specific condition for rabies antibody titration test applies as per Part I of Annex VIII to Commission Implementing Regulation (EU) 2021/404. The box representing clinical examination is not applicable for non-commercial movements of dogs. MindMup app has been used to generate this figure

Dogs and also cats and ferrets that are moving for commercial purposes from certain non-EU countries or territories listed in Part I of Annex VIII of the Commission Implementing Regulation (EU) 2021/404, must undergo rabies antibody titration test before travel into the EU (map in Figure 4), whereas other non-EU countries may only apply a vaccination and the 21 days wait before entry into the EU. The criteria according to which the Countries are categorised into lists with different rules in terms of dog movements into EU territory, are not well described and are not based on epidemiological parameters. Those countries are approved for commercial movements of dogs with a certificate only are also approved for non-commercial movement of dogs under 576/2013, in which a derogation is applied for the blood test and the waiting period. For all other countries, non-commercial movements of dogs are allowed provided they apply the requirements (no derogations) in Regulations 576/2013 and 577/2013.

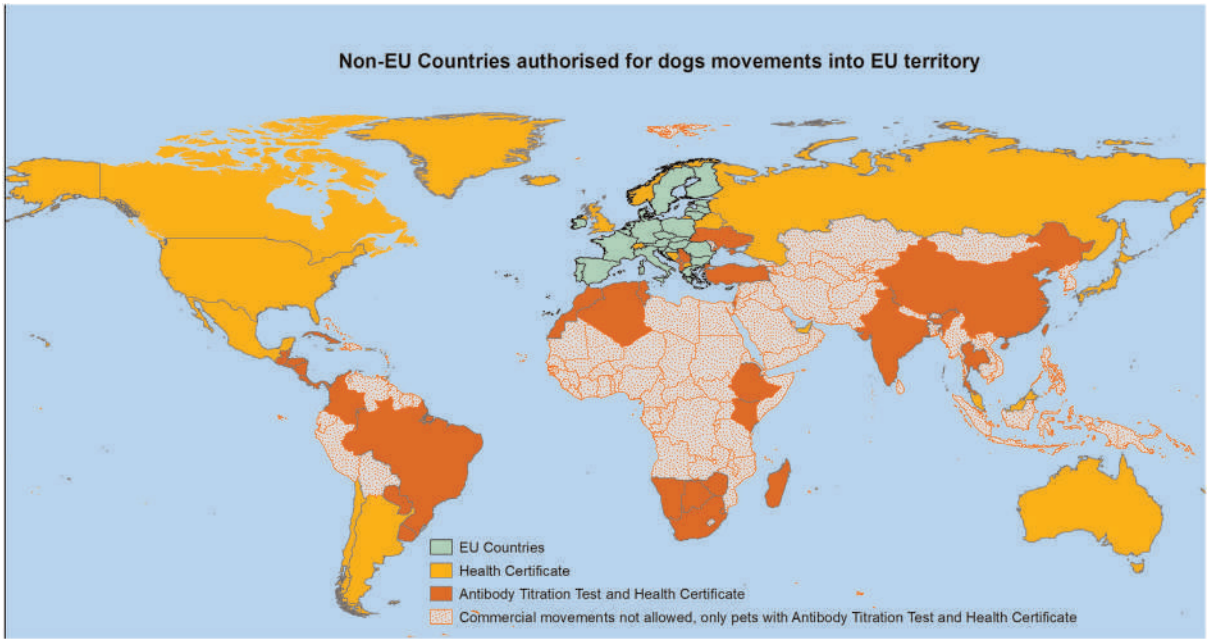


Figure 4: Map of non-EU Countries from which dogs are allowed to travel to EU territory either with health certificate (orange) or with health certificate and rabies antibody titration test (red) according to Part I of Annex VIII to Commission Implementing Regulation (EU) 2021/404. ArcMap was used to create this map

3.1. ELR results

Abstracts of 4,215 publications were reviewed by two reviewers according to the protocol of the literature review shown in Annex A (available under Supporting Information). As described in the exclusion criteria of this protocol, only those publications rejected by both reviewers were finally excluded. In total, 527 publications were subjected to full-text screening, and data were extracted from 124 publications. Data were collected to the highest level of detail available in the publication, and the results are summarised in the tables presented in Appendix B of this Scientific Report.

3.1.1. Incubation period

The data on the incubation period collected from experimental infections in unvaccinated (Table B.1 of Appendix B) and in vaccinated dogs (Table B.2 of Appendix B) and from naturally infected dogs travelling as non-commercial consignments (Table B.4 of Appendix B) to the EU territory are presented below (Table 1 and Figure 5) and in the tables in Appendix B.

3.1.1.1. Experimental trials

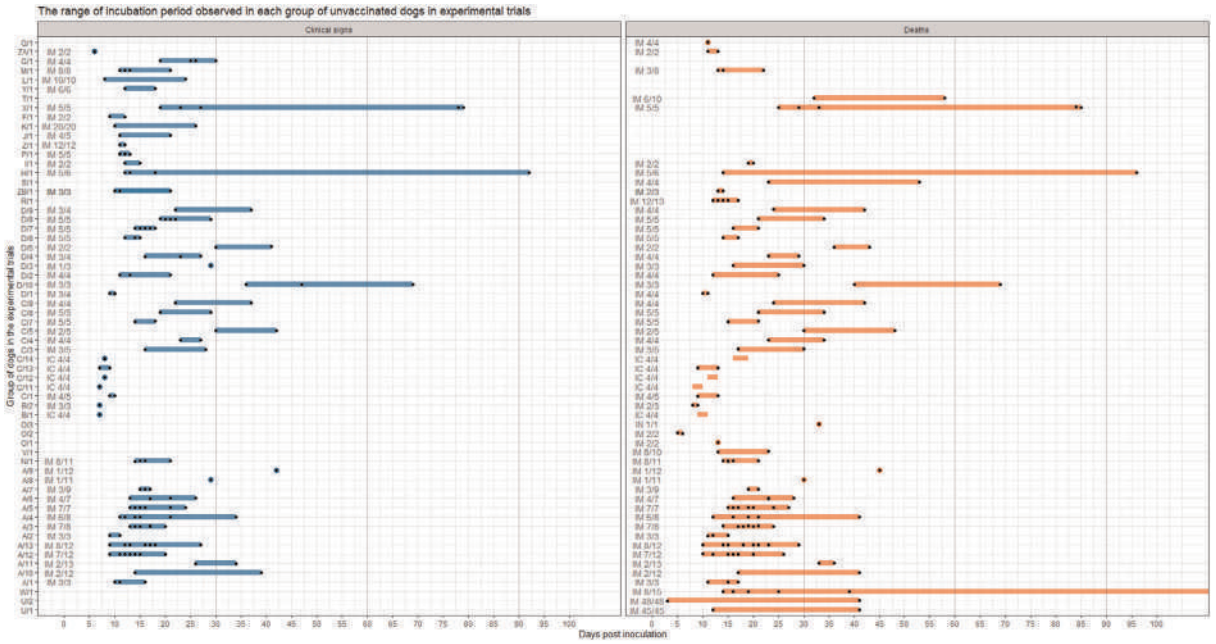
The experimental studies that were identified by the literature review were not harmonised in terms of the objectives and the level of details they included, their methodology and/or the presentation of the results. The dose of inoculation, the virus strains, and the route of inoculation (intramuscular, intracerebral, intranasal) varied in the different groups of animals.

Unvaccinated animals

In 27 experimental studies, 62 groups of dogs were identified as having been experimentally infected with various doses of different strains of RABV and through different routes of inoculation without being vaccinated or treated: 56 groups via intramuscular inoculation, 5 groups via intracerebral inoculation and 1 group via intranasal inoculation (Table B.1 of Appendix B).

Information on the onset of clinical signs and death at individual level was not available for all groups of dogs in all studies. Instead, the average or the range of the earliest and latest day of the onset of clinical signs or/and death in each group of dogs in the trial was provided. In some other groups, information was provided only for the onset of clinical signs or death but not for both.

The graph in Figure 5 presents the ranges from the time of inoculation to the time of the onset of the clinical signs and death, respectively, according to either the group of dogs in the studies or the days of the onset of the clinical signs in each dog when individual information was available.



Each group of dogs has a unique identification code and was inoculated with different doses of RABV through intramuscular (IM), intracerebral (IC) and intranasal (IN) route. Black dots indicate the time to the onset of clinical signs and death individually for each dog of the group. For the group with code number W/1, the last dog died 257 days post-inoculation but to maintain better visualisation of the whole graph the x-axis is not extended up to the value 257.

Figure 5: Range from the time of inoculation to the time of the onset of clinical signs (blue) and death (red), respectively, in each group of dogs of the experimental trial in studies retrieved from the literature review

One study provided the means for each group of dogs instead of ranges or individual information on the time from intramuscular virus inoculation to the onset of clinical signs or death (Soulebot et al., 1982). The means of the time between virus inoculation and the onset of clinical signs and death in the groups range from 9.5 to 19.7 days and from 13 to 24 days accordingly (Soulebot et al., 1982).

To estimate the incubation period, 48 groups of dogs from 25 studies that have been inoculated intramuscularly were used as the intramuscular inoculation is more similar to the natural route of infection compared with intranasal and intracerebral inoculation.

Vaccinated animals

Nine studies on experimental inoculation after vaccination were found through the literature review (Table B.2 of Appendix B). Clinical signs after immunisation were observed in three dogs in two studies, when non-commercial vaccines (two animals) and Rabisin (one animal) respectively were used. Dogs were challenged 60 days post-vaccination when non-commercial vaccines were used, with doses 106.5 $MICLD_{50}$/0.2 mL and 8,790 $MICLD_{50}$/0.2 mL. One of the vaccinated dogs died 19 days after the challenge inoculation, or 79 days after vaccination. The second dog died 173 days after the challenge inoculation, or 233 days after vaccination (Tierkel et al., 1949). It should be considered that this is a study with live virus vaccines and phenolised vaccines produced in the 1940s that probably do not meet today's international standards for market authorisation.

When Rabisin vaccine was used, the animal died after a 0.5 mL (104 DL50/mL) challenge dose, inoculation was performed 162 days after vaccination (Kallel et al., 2006). In the study conducted by Darkaoui et al. (2016), one dog out of eight died due to a mesenteric torsion accident after 58 days post-inoculation with 1 mL (105.6 MICLD50) challenge virus. The infection was carried out 121 days post-vaccination (Rabivac, two doses SC, days 0.30). No VNT titres were available for these studies, therefore it was not possible to extrapolate whether these animals would have been able to travel.

3.1.1.2. Cases imported into EU territory from infected non-EU Countries

Information about dogs imported from non-EU Countries and confirmed with rabies in the EU country of destination is summarised in Table B.4 of Appendix B.

For imported cases, no official positive serological testing of infected dogs before travel was reported. The infected dogs were either not tested or had no testing information reported. In one ProMED report, the animal was reported as 'RFFIT positive', but titres were not given. There have been no cases of imported dogs that have been prepared for travel to the EU according to the EU legislation, having been vaccinated and tested positive for neutralising antibodies ($\geq$ 0.5 IU/mL) that were then found to be infected with rabies once they have arrived in the EU.

Based on the literature review, in total 20 cases of RABV-infected dogs were imported into the EU territory, from 2001 to 2021 from Algeria, Azerbaijan, Bosnia and Herzegovina, Croatia (before becoming an EU Member State), Gambia, Morocco, Sri Lanka and Turkey. More than half of the records concerned France as the country of destination, with involved dogs mainly from Morocco (9/11 French imported cases). Germany is the country reporting the second highest number of imported rabid dogs with five cases since 2001.

The average importation frequency of rabid dogs into the EU amounts to one case every year. None of these cases complied with the regulations in force. Regarding the age of the dogs, more than half (65%) were under 6 months old and 5% were adult dogs over 1 year old.

Based on the available data from the literature review related to the imported cases (Table B.4 of Appendix B), the estimated period between the entry into the EU country of destination and the onset of first clinical signs ranged from 2 to 179 days, with an average of 33 days and a median of 16.5 days. In one case, the clinical signs started on the way from the country of origin (Morocco) to the country of destination (France) and was consequently excluded from this estimation. As the exact date of infection is not known, the incubation period cannot be defined accurately. Considering the rabies-free status of the country of destination and/or the sequencing studies of the rabies virus strains, it is assumed that the infection occurred at the country of origin before entering the EU territory. However, the period between the entry into the EU country of destination and the onset of first clinical signs is a good indicator and reflects how long an incubation could last following a natural infection even if systematically underestimated as the infection occurred before the arrival in the country of destination. Although underestimated, these estimations remain however longer than the estimations of incubation periods issued from experimental studies. It should be also noted that longer durations than the maximum of 179 days observed in the EU have been observed outside the EU, as documented for example in an imported dog having travelled from Cameroon to the USA with 288 asymptomatic days (more than 9 months) and found infected with a west African dog rabies strain (CDC, 1987) and for a 3-month-old vaccinated imported dog (dog vaccinated in the country of departure with a non-licensed rabies vaccine nor in Canada nor in the EU), in which the period between the entry into the country and onset of first clinical signs exceeded 7 months (Ministry of Agriculture Food and Rural Affairs of Canada, 2022).

Considering the impact on public health as a result of these illegal imports, for the 15 cases for which the information was available, 770 people that were in close contact, bitten or scratched by the infected animals were submitted for post-exposure treatment (PET) with vaccination or vaccination and human rabies immune globulin (HRIG).

3.1.1.3. Estimation from field data

Based on field data from previous published studies (Ribadeau-Dumas et al., 2016; Tojinbara et al., 2016) and the report from Great Britain by the Ministry of Agriculture Fisheries and Food (1971), Crozet et al. (2022) constructed a probability density (Figure 6) of the duration of the incubation period in which incubation $>$ 30, $>$ 60 and $>$ 120 days was estimated to have a respective probability of 0.41, 0.16 and 0.04.

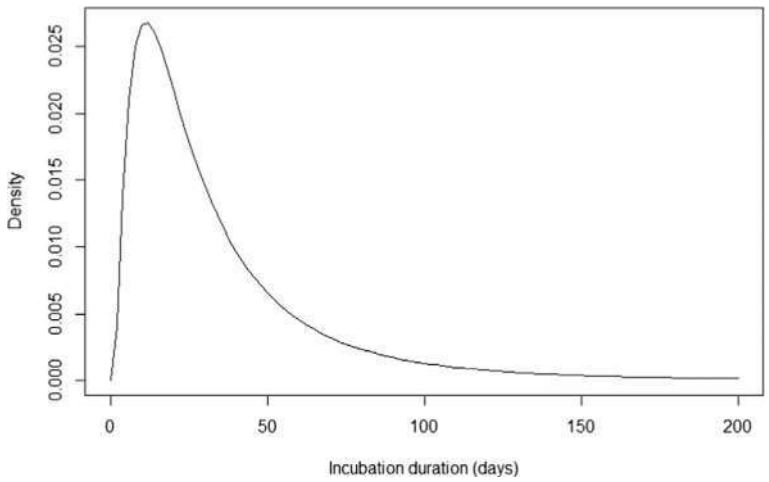


Figure 6: Probability density of the duration of the incubation period (Crozet et al., 2022)

Table 1: Summary of the results from literature review in relation to the incubation period from experimental studies and from cases imported into the EU. For experimental studies, the distribution for the onset of clinical signs and death is provided at group level in the trials (earliest and latest days of the ranges of the groups) and for the individual dogs as exact days

		CS/D	No. of studies	No. of groups	No. of animals	Earliest and latest day of the ranges	Distribution (days PI)			No. of limits of the ranges (earliest, latest) or no. of individual values exceeded			
								Max	Median (25th, 75th percentiles)	> 30 days	> 40 days	> 90 days	> 100 days
Ranges of onset of CS and D of the groups of dogs in experiments	**Experimental studies**	CS	19	46[(a)]	214[(a)]	Latest	6	92	**24** (17.25, 29.75)	11	6	1	0
						Earliest	6	42	**13** (10.25, 15.785)	2	1	0	0
		D	19	48[(a)]	288[(a)]	Latest	6	257	**28.5** (19.25, 41)	19	15	2	1
						Earliest	3	45	**14.5** (12, 23)	5	1	0	0
Individuals (dogs)	**Experimental studies**	CS	19	46[(a)]	159[(a)]		6	92	**15** (12, 21.5)	14	8	1	0
		D	19[(a)]	48[(a)]	152[(a)]		3	257	**17** (14, 25)	26	16	1	1
	Imported cases	CS			18[(b)]		2	179	**16.5** (6, 46)	6	5	2	2

PI = post-inoculation.
(a): Data on the onset of clinical signs (CS) and death (D) at individual level was not available for all groups of dogs in all studies. In some other groups information was provided only for the onset of CS or death or vice versa but not for both.
(b): The total number of imported infected dogs were 20, but for one there was no information on the onset of the CS and for another one the CS started during travelling before arriving at the EU country of destination.

3.1.2. Neutralising antibodies development

In human patients, neutralising antibody responses are usually only detectable at a late stage in the course of infection, by which point the infected individual has developed clinical signs and is unable to clear the virus (Gold et al., 2020). Some serological surveys in humans, dogs or wildlife do report the presence of anti-rabies antibodies in otherwise healthy people or animals, suggesting the existence of subclinical infections or recovery from a clinical infection (Gold et al., 2020). There is, however, still controversy to what extent these results represent true or false positives.

Serological studies in unvaccinated dogs that are experimentally challenged with RABV yield a variable picture from no seroconversion to very high neutralising antibody titres upon challenge (Table B.3, B.5–B.7 of Appendix B). The antibody response is most likely to depend on the size of the virus inoculum and the route of inoculation, but most available studies demonstrate some degree of seroconversion with the build-up of neutralising antibodies between 5 days and 3 weeks upon experimental inoculation.

In experimental infections and vaccine trials, there are few records of an individual dog in which a value of 0.5 IU/mL was measured before onset of clinical signs. Fekadu et al. (1982a) reported average values beyond 0.5 IU/mL (at 1.5 IU/mL) 7 days post-inoculation but 4 days prior the first onset of clinical signs in a vaccinated group in which five out of seven dogs showed clinical signs. However, there was no information on how these results were distributed in individual dogs.

Upon vaccination, most dogs seroconvert between 3 and 21 days. Antibody levels tend to reach a peak at 28–30 days post-vaccination with titres well above 0.5 IU/mL. Van Gucht and Le Roux (2008) analysed serology results of 28,412 canine blood samples submitted between 2000 and 2005 under the EU Pet Travel Scheme to check the neutralising antibody titre upon vaccination. The vast majority of dogs tested positive. Only 6.35% of canine blood samples tested negative 1–12 months after vaccination (< 0.5 IU/mL). Up to 14% of dogs between the age of 3 and 6 months tested negative upon vaccination. Approximately 8% of dogs between the age of 6 and 12 months tested negative. Above the age of 1 year, the percentage of negative test results varied at ~ 3%. The seemingly lower percentage of negative tests in dogs older than 1 year is most likely because young dogs have been vaccinated only once, whereas older animals have often received one or more additional vaccinations earlier in life. The probability of a positive test result was highest when the sample was taken 1–2 months after vaccination (4.42% negatives). Intervals of 3 months or more are associated with a significantly higher probability of a negative test result (8.81% negatives). Zanoni et al. (2010) found similar results with ~ 5% of dogs testing negative at 1–2 months after primary vaccination. Antibody titres were highest at 1 month post-vaccination and decreasing afterwards. At 7–12 months after the primary vaccination 30% of dogs tested negative. A double primary vaccination or repeat vaccination significantly increases the probability to reach a titre of ≥ 0.5 IU/mL.

3.1.3. Dogs imported into the EU territory from non-EU countries

The consignments of dogs imported into the EU territory for commercial purposes are registered into the TRACES system, therefore information on number of dogs according to the country of origin and destination are available. The total number of imported dogs from all non-EU countries and the number of dogs imported from the non-EU countries where the positive titration test has been a requirement for the last 3 years (2019–2021) are presented in Table C.1 of Appendix C.

The number of dogs imported from non-EU countries for non-commercial reasons (as pets accompanied by their owner or an authorised person) is not known.

There are no officially available data for the number of dog movements into the EU each year. According to the study conducted by (Norman et al., 2020) and based on the data collected using an online survey, the number of pets moving for non-commercial purposes was 10 times the number of commercial dogs, and the majority were from non-Eu countries for which no titration test is required or EU Member States, that is 300,000 vs. 31,000 (Norman et al., 2020).

3.2. Assessment

3.2.1. Probability of importing a RABV-infected dog from a country for which a titration test is mandatory

3.2.1.1. Based on the length of incubation period as derived from experimental studies

According to the results of the ELR, the inoculation dose used in experimental trials varied widely in the different groups of dogs (Table B.1 of Appendix B). For this risk assessment, 46 groups of dogs

inoculated by intramuscular route were selected from 19 experimental studies resulting in 214 infected dogs with clinical signs. The time from inoculation to the onset of clinical signs was considered as the incubation period. The incubation period was available at individual level for 35 groups of dogs, whereas for the other 11 groups only the range of the incubation period of each group of dogs was provided in the publication. The upper limit of each of these 11 ranges was below 40 days and the incubation period of each one of the individual dogs was therefore less than 40 days. Therefore, the incubation periods of 55 dogs were imputed in the dataset assuming a uniform distribution of the individual incubation periods over the range of the respective groups.

In total, for 159 dogs, the incubation period was available, whereas for the remaining 55 dogs the incubation periods were randomly imputed into the data set assuming a uniform distribution of cases over their respective incubation period range.

The overall distribution of the 214 dogs had a minimum incubation period of 6 days and a maximum incubation period of 92 days; in eight dogs the incubation period exceeded 40 days (Figure 7).

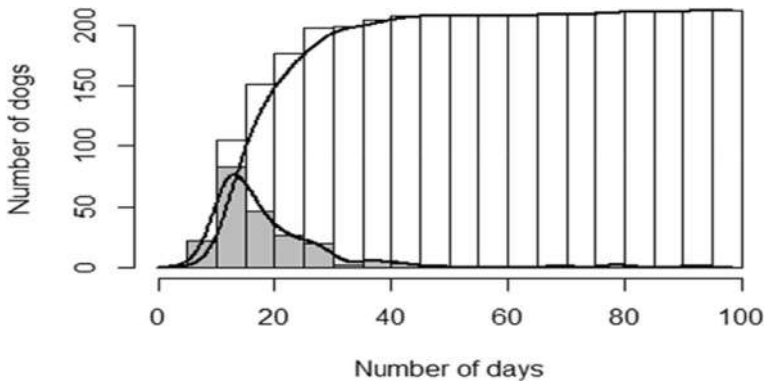


Figure 7: (Cumulative) Distribution of the number of days of the incubation period upon intramuscular challenge with rabies virus in unvaccinated dogs

In this data set, none of the incubation periods are long enough to reach WP90, as they would need to be longer than 100 days. Applying the methodology described in Section 2.2 to the available data the overall rate for a dog to be RABV infected and not present clinical signs before the end of WP30 equals $0.823 \times IR$, whereas this rate is $0.000 \times IR$ for WP90.

According to Crozet et al. (2020b), the annual incidence of rabies in dogs in non-EU countries, for which a blood test is required for dog movements either for commercial or non-commercial purposes, varies from 100 to 500 cases per 100,000 dogs.

This implies that from the high incidence regions (500 cases per 100,000 dogs per year) an imported dog that is fully compliant with legislation and had a waiting period of 30 days has a probability of 1.13×10^{-5} to be RABV infected, whereas this probability is 2.25×10^{-6} if imported from a low incidence region (100 cases per 100,000 dogs per year). For a region with a very low incidence (five cases per 100,000 dogs per year), the probability would be 1.13×10^{-7}.

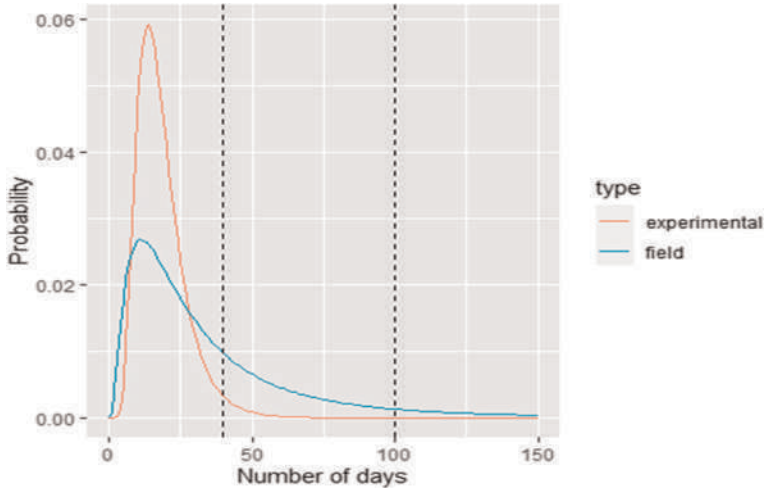


Figure 8: Distribution of the duration of the incubation period (days) of rabies derived from experimental data from the literature review (red) and field data from Crozet et al. (2022) (green line). A log normal distribution was fitted to the datasets

3.2.1.2. Based on the length of incubation period as derived from field data

Crozet et al. (2022) fitted a lognormal distribution [dlnorm(x, meanlog = 3.2132377, sdlog = 0.8908552)] to incubation periods from Ribadeau-Dumas et al. (2016), Tojinbara et al. (2016), and Appleton (1972). Figure 8 shows the comparison between this lognormal distribution and a lognormal distribution fitted to the data from Figure 7. Figure 8 shows that the field data contain longer incubation periods than those observed in experimental studies. According to this distribution, 29.6% of the incubation periods would exceed 40 days (WP30) and 5.9% would even exceed 100 days (WP90).

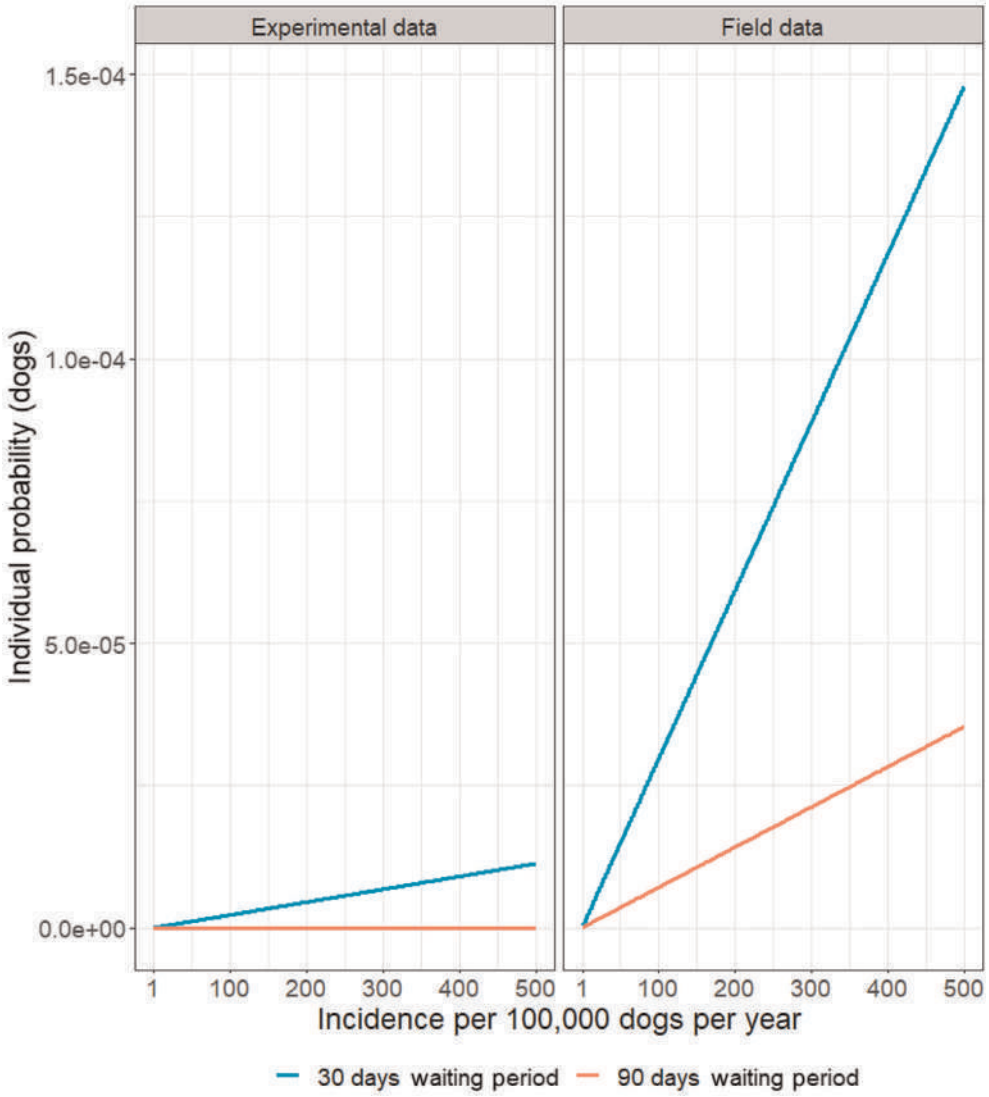
Using this distribution of the incubation periods in the method described above, the overall rate for a dog to be RABV infected and not develop clinical signs before the end of WP30 equals $10.8 \times IR$, whereas this is $2.58 \times IR$ for WP90 (Table 2 and Figure 9).

From high-incidence regions, the probability that an imported dog that is fully in compliance with legislation and had a waiting period of 30 days incubating RABV equals 14.8×10^{-5}, whereas this probability is 2.96×10^{-5} if imported from a low-incidence region and 14.8×10^{-7} if imported from a region with a very low incidence (Table 2 and Figure 9). For WP90, these probabilities are 3.53×10^{-5}, 0.707×10^{-5} and 3.53×10^{-7}, respectively (Table 2 and Figure 9).

Table 2 and Figure 9 show that the individual probability of an imported dog being infected and having an incubation period exceeding the waiting period, is higher when the dog has originated from regions with higher IR in both lengths of waiting periods (30 and 90 days). The linear relationship observed between the individual probability and the IR originates from the formula described in the Methodologies section.

Table 2: Probability of an individual dog being infected incubating rabies virus (RABV) and being moved to EU from a non-EU country, even if the movement is fully in compliance with the EU legislation, and having an incubation period exceeding the waiting period (WP) of 30 days and 90 days, respectively, as a function of the incidence rate of rabies in the regions of dog origin

Annual incidence rate (IR)	Probability of an imported dog incubating RABV based on the incubation period			
	Experimental data		Field data	
	WP 30 days	WP 90 days	WP 30 days	WP 90 days
High (500/100,000 dogs)	1.13×10^{-5}	0	14.8×10^{-5}	3.53×10^{-5}
Medium (250/100,000 dogs)	5.64×10^{-6}	0	7.4×10^{-5}	1.77×10^{-5}
Low (100/100,000 dogs)	2.25×10^{-6}	0	2.96×10^{-5}	0.707×10^{-5}
Very Low (5/100,000 dogs)	1.13×10^{-7}	0	14.8×10^{-7}	3.53×10^{-7}



The Incidence Rate (IR) is calculated as the number of infected dogs per 100,000 dogs per year. When the incubation period is derived from the experimental data and the waiting period is 90 days, the individual probability is zero regardless the value of the IR.

Figure 9: Probability of an individual dog imported being infected and having an incubation period exceeding the waiting period of 30 days and 90 days accordingly, as a function of the incidence rate of rabies in the regions of dog origin

3.2.2. Overall probability of RABV introduction from countries for which a titration test is mandatory

The estimation of the overall probability of RABV introduction from non-EU countries for which a titration test is mandatory, based on the probability of importing one RABV-infected dog and the number of dogs imported from such regions.

The total number of dogs moving into the EU from non-EU countries for which the titration test is mandatory is not known and cannot be calculated. Information on the number of dogs and the country of origin is available (in TRACES) only for commercial movements. For non-commercial movements of dogs this information is not available.

Based on the data from TRACES (Table C.1 of Appendix C) on commercial movements of dogs from non-EU countries for which a titration test is mandatory, in the period between 2019 and 2021, the average number of dogs imported per year equals 1,780.

For the non-commercial movements and based on the results of the study by Norman et al. (2020), the number of non-commercial dogs imported is assumed to be 10 times as high as the number of commercial movements; approximately 20,000.

Consequently, for the purposes of this assessment in the following examples, two indicative values were used for the number of animals moved from non-EU countries into EU per year; 1,780 and 20,000 (Table 3).

In addition, the dogs come from areas that vary in risk; from high risk (500 cases/100,000 dogs per year) to very low risk (5 cases/100,000 dogs per year) (Tables 2 and 3).

The probability of introduction of at least one RABV-infected dog per year and the average time (in years) it takes to introduce one RABV-infected dog have been calculated for both waiting periods (30 and 90 days) and are presented in Table 3. These probabilities have been estimated separately for dogs coming from areas of high, medium, low and very low risk using the length of incubation period as derived from experimental and field data.

3.2.2.1. Based on the length of incubation period as derived from experimental studies

90 days waiting period

In the 90-day waiting period scenario, the risk is zero according to the assessment based on experimentally derived incubation periods for both numbers of introduced dogs per year (1.780 and 20,000), because no incubation periods longer than 100 days were present in the data from experimental infections.

30 days waiting period

If the total number of imported dogs is 1,780 per year and assuming the dogs originate from a medium risk area, the likelihood for an individual dog to be RABV infected would be 5.64×10^{-6} (Table 2). This implies that the **annual probability** of importing at least one RABV-infected dog into EU after a 30-day waiting period, **equals 1.0%** ($1 - (1 - 5.64 \times 10^{-6})^{1,780}$) (Table 3). As a result, for a waiting period of 30 days, on average, once every 100 years a RABV-infected dog would be introduced into the EU.

If the total number of dogs is 20,000 per year and assuming the dogs originate from a medium risk area the annual probability of importing at least one RABV-infected dog after a 30-day waiting period would be 11% and, on average, one RABV-infected dog would be introduced into the EU every 9 years (Table 3).

3.2.2.2. Based on the length of incubation period as derived from field data

90 days waiting period

Assuming that the imported dogs originate from a medium risk area, the probability for an individual dog to be RABV infected after a 90-day waiting period would be 1.77×10^{-5} (Table 2). If the total number of imported dogs is 1,780 per year, this implies that the annual probability that one or more RABV-infected dogs are introduced to EU equals 3.1% ($1 - (1 - 1.77 \times 10^{-5})^{1,780}$) (Table 3). As a result, for a waiting period of 90 days, on average, once every 32 years one RABV-infected dog would be introduced into the EU.

If the total number of dogs is 20,000 per year, and assuming the dogs originate from a medium risk area, the probability of importing at least one RABV-infected dog is 29.8%, and on average, one RABV-infected dog would be imported every 2.8 years (Table 3).

30 days waiting period

If the total number of imported dogs is 1,780 per year and assuming the dogs originate from a medium risk area, the probability for an individual dog to be RABV infected after a 30-day waiting period would be 7.4×10^{-5} (Table 2).

This implies that the annual probability that one or more RABV-infected dogs are introduced to EU equals 12.3% ($1 - (1 - 7.4 \times 10^{-5})^{1,780}$) in the 30-day waiting period scenario (Table 2).

Phrased differently, the number of RABV-infected dogs introduced into the EU would increase from one dog every 32 years to one dog every 7.6 years when the waiting period is reduced from 90 to 30 days, respectively, (Table 3) even if the movement is in compliance with the EU regulation.

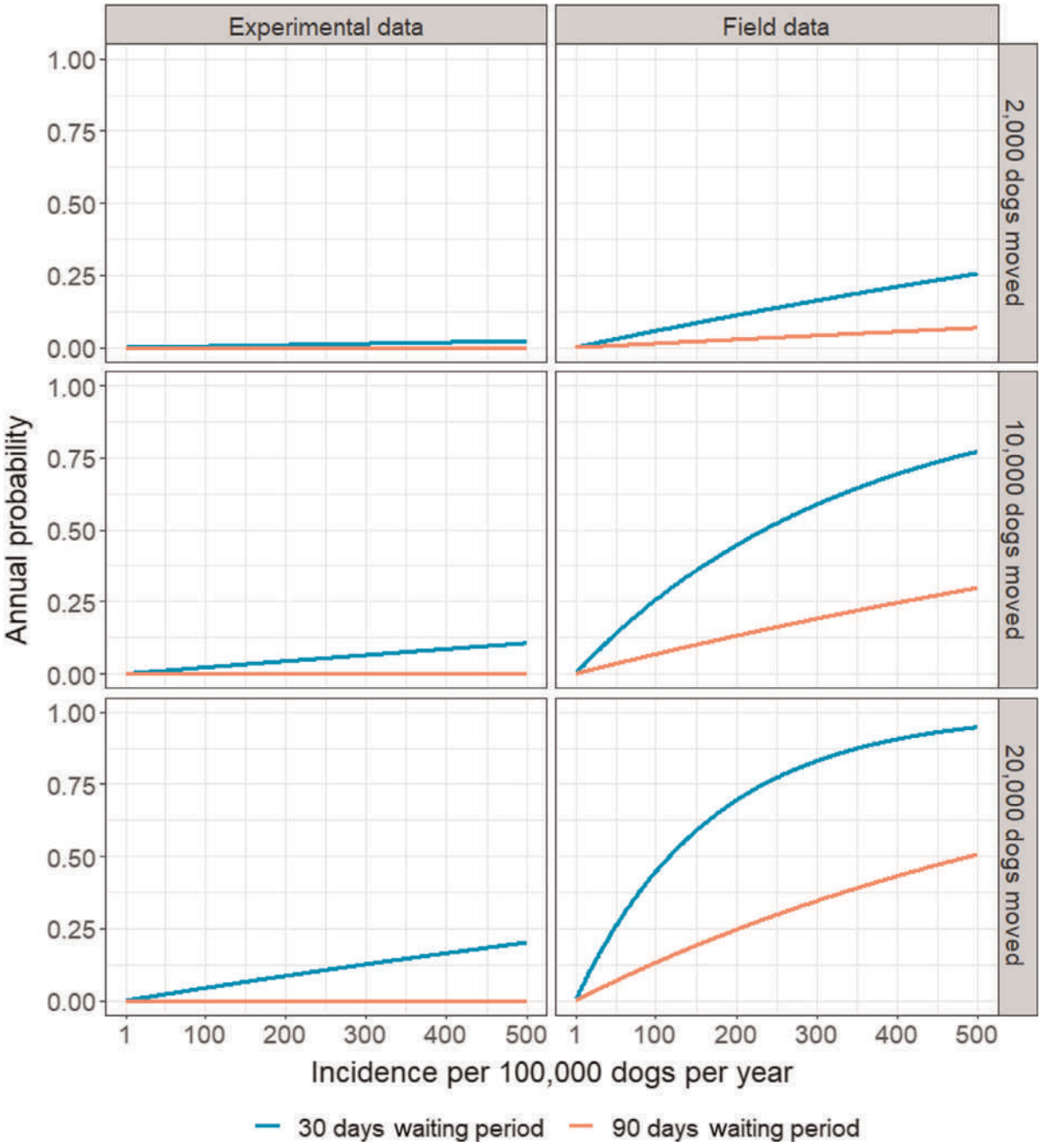
If the total number of dogs is 20,000 per year and assuming the dogs originate from a medium risk area, the probability of importing at least one RABV-infected dog is 77.2% for a waiting period of 30 days and on average one RABV-infected dog would be imported per 250 days (or 1.5 rabies-infected dogs per year) (Table 3).

Table 3 and Figure 10 show that the annual probability of importing at least one RABV-infected dog into the EU and the number of years needed to import at least one infected dog increases as the number of dogs moving from the non-EU countries to the EU is increasing.

Table 3: Examples of the estimated overall probability of introducing at least one rabies-infected dog, and average number of years before this occurs, under different combinations of data source on incubation period, rabies incidence in non-EU countries of origin and number of dogs imported into the EU per year

Annual incidence rate in the non-EU country (IR)[a]	Incubation period	No. of imported dogs[b]	Waiting period			
			30 days		90 days	
			p	Years	p	Years
High (500/100,000)	Field data	1,780	0.23	3.8	0.061	16
		20,000	0.95	0.34	0.51	1.4
	Experimental data	1,780	0.02	50	0.000	N/A
		20,000	0.20	4.4	0.000	N/A
Medium (250/100,000)	Field data	1,780	0.12	7.6	0.031	32
		20,000	0.77	0.68	0.30	2.8
	Experimental data	1,780	0.010	100	0.000	N/A
		20,000	0.11	8.9	0.000	N/A
Low (100/100,000)	Field data	1,780	0.051	19	0.013	79
		20,000	0.45	1.7	0.13	7.0
	Experimental data	1,780	0.004	250	0.000	N/A
		20,000	0.044	22	0.000	N/A
Very low (5/100,000)	Field data	1,780	0.003	380	0.001	1,590
		20,000	0.029	34	0.007	141
	Experimental data	1,780	0.000	4,983	0.000	N/A
		20,000	0.002	443	0.000	N/A

p = probability of introducing at least one RABV-infected dog.
Years = average number of years to import one RABV-infected dog.
(a): The values for the Incident Rate (IR) used here are based on the publication of Crozet et al. (2020b) the low IR = 100/100,000 dogs, medium IR = 250/100,000 dogs, high IR = 500/100,000 dogs and for very low it was added to cover regions with lower IR.
(b): The total number of animals used here are based on the average number of dogs per year imported from non-EU countries for commercial purposes based on TRACES data for 2019–2021 (1,780); and on the assumption that the number of dogs imported into EU for non-commercial purposes would be 10 times as high as the number for the commercial purposes (20,000).



Incidence Rate (IR) is calculated as the number of infected dogs per 100,000 dogs per year. When the incubation period is derived from the experimental data for a waiting period of 90 days, the individual probability is zero regardless the value of the IR.

Figure 10: The overall annual probability of at least one RABV-infected dog with an incubation period exceeding the waiting period of 30 days and 90 days by the incidence rate of rabies in the regions of dog origin

Table 3 and Figure 10 show that using the incubation period as derived from the field data (Crozet et al., 2022), the average time it takes to import a RABV-infected dog incubating RABV, while fully compliant with the regulation, is reduced 4.2 times if the waiting period is reduced from 90 to 30 days, irrespective of the incidence in the region of origin and the numbers of dogs introduced.

Although this relative difference is stable, the absolute outcomes (probability of introducing at least one RABV-infected dog per year and the average number of years it takes to introduce one RABV-infected dog) are very sensitive to the incidence in the region of origin and the numbers of dogs

introduced from such regions. The median prevalence applies to certain regions in Africa and Asia mostly (Crozet et al., 2020b). For imports from countries where rabies is not endemic in the dog population, the very low incidence is more applicable. According to the assessment, the risk of importing a RABV-infected dog from a very low-risk region is much lower than from the median risk region as presented above (Table 2). Using the field-derived incubation periods, the average time it takes to import one dog fully compliant with the regulations from a region with very low risk is reduced from 141 years in WP90 to 34 years in WP30. Although the relative increase of the risk of changing from 90 to 30 days waiting period is stable for differences in IR and numbers of dogs imported, it strongly depends on the distribution of the incubation period, in particular those longer than 40 days and 100 days, respectively. Table 2 shows that while assuming the experimentally derived incubation period distribution, the risk is reduced considerably in comparison with the incubation periods derived from the field data.

3.3. Uncertainty analysis

The analysis presented above is based on several assumptions as described in the Methodology in Section 2.2 that lead to considerable uncertainty regarding its results. The approach is as follows:

- Uncertainty regarding the methodology used: the approach was based on a simple deterministic model and as such stochastic variability was not considered.
- Uncertainty on the number of dogs entering the EU from the countries considered in the assessment: although information on the number of dogs imported for commercial purposes is available, no data on the number of non-commercial movements exist, although it was estimated to be up to 10 times higher for some European countries. The assessment presented in Table 2 considered two scenarios (1,780 and 20,000), both of which can underestimate the true number of dogs imported from these countries every year. Conversely, only dogs subjected to their first vaccination or in which immunity has expired and therefore must be revaccinated could be incubating the disease while being imported and would thus be of interest for the assessment, but there is no information on what the proportion of those dogs may be among all imported from the countries considered in the assessment.
- Uncertainty on the incidence of rabies in the population of dogs travelling from these countries into the EU while complying with the regulations: although some estimates on the incidence of rabies in the countries of origin of imported dogs exist, no data on the actual incidence in the dogs that are actually imported are available. Available incidence estimates for countries of origin do not take into consideration differences in dog subpopulations (e.g. indoor, free-roaming and stray dog populations). Dogs travelling to the EU is more likely to be indoor well-cared pets, though an unknown proportion may also be formed by dogs found in the street, abandoned or coming from a rescue centre, that would be therefore subjected to a much higher risk of exposure than indoor animals.
- Uncertainty on the incubation period of naturally infected dogs: scientific articles retrieved through the literature review providing data on duration of the incubation period were mostly based on experimental infection, were typically very heterogeneous in terms of their objectives and methodology used (e.g. infection strain, dose and routes for experimental challenge studies, tests used, follow-up periods, etc.), and often did not provide sufficient information to assess the responses recorded in each individual animal considered in each study (and provided ranges of days from infection to clinical signs, death, etc.). Furthermore, incubation periods derived from experimental studies may not accurately reflect the situation in which natural exposure exists and may lead to artificially shorter periods. Differences in the incubation periods coming from experimental and field studies may be due to several reasons, e.g. the way of inoculation, the virus dose and the daily observation. Moreover, the duration of some of the experiments may not have been long enough to detect very long incubation periods. Conversely, in the field situation the actual moment of infection may be uncertain.
- Uncertainty on the degree of protection conferred by rabies vaccines and time between vaccination and development of a protective response: although in the report it was assumed that a dog with a titre > 0.5 IU/mL became fully protected (100% efficacy) 21 days post-vaccination (as by that time most of the vaccinated dogs will have fully seroconverted), the protective immunity induced by the vaccines is most likely to increase in a more gradual way after vaccination. Therefore, before 21 days post-vaccination some protection could be expected (i.e. not all vaccinated dogs will be fully susceptible), and therefore, the assumption

used in the report is likely to be an overestimation of the susceptibility of vaccinated dogs within the first weeks post-vaccination.

- Uncertainty on the sensitivity of clinical inspection at the EU borders: dogs entering the EU must have a health certificate verifying they are in good health, and if a dog is symptomatic, it is assumed that it would be detected at the border control (100% sensitivity), and therefore only fully asymptomatic infected dogs at import were considered at risk of remaining undetected. However, there are no estimates of the sensitivity of the inspection at border control regarding the detection of symptomatic animals; if it is not 100% it would be possible for an infected dog to enter the EU even if the incubation period was (slightly) shorter than the waiting period.

Because of these uncertainties in Table 2 different scenarios are presented, IR varying from high to low, number of dogs varying from the ones documented in TRACES to 20,000 dogs and a narrow range incubation period (experimental) to a wide range (field derived data).

After considering the overall impact of these sources of uncertainty in the assessment and discussing the individual judgements of the experts, it was concluded with a 95% certainty that the number of RABV-infected dogs that will be imported from countries or regions either not listed in Annex II to Regulation (EU) 577/2013 for pet dogs, or listed in Regulation (EU) 2020/404 (Annex VIII column 5) for commercial and non-commercial movements that are compliant with the regulations (vaccinated as requested and passing a VNT test 30 days post-vaccination) in a 20-year period under the current waiting period of 90 days (QoI1) would be equal or lower than 5. When the alternative scenario (waiting period of 30 days) was considered, it was concluded with a 95% certainty that this number would be equal or lower than 20. The difference between the QoIs was due to the much larger uncertainty on the possible effect of the factors listed above on the number of rabies-infected imported dogs that would remain undetected with a 30-day waiting period, with the effect leading to an increase of the risk in most cases. Therefore, even though the expected number of RABV-infected dogs that would enter the EU in a 20-year period in this alternative scenario was still low ($\leq$ 10) according to the judgements from most experts, it was not possible to rule out scenarios in which this number could be even twice as high.

4. Conclusions

1) Based on a review of published studies, in the experimental infections, the onset of clinical signs and deaths in dogs after intramuscular inoculation ranged from 6 to 92 and 3 to 257 days post-inoculation, respectively. Similarly, in infected dogs imported from non-EU countries not meeting EU requirements, the onset of clinical signs varied from 2 to 179 days after the arrival at the country of destination. Even if experimental infections might not reflect natural infection in the field, data from imported rabies cases in dogs suggest that the incubation period can be longer than 40 days and can exceed the 100 days, although rarely.
2) There is no official system at EU level requiring the registration of the non-commercial movements of dogs from non-EU countries to EU territory like TRACES for the commercial movements. Therefore, there are no available data on the number of dogs, and the countries of origin and destination to support the needs of the risk assessment.
3) No cases of imported RABV-infected dogs have been associated with non-commercial or commercial movements of dogs that have been correctly prepared for travel under EU rules. Cases of imported dogs that have been vaccinated, tested positive for neutralising antibodies ($\geq$ 0.5 IU/mL) and found to be infected with rabies virus have not been found by the literature review.
4) Most, but not all vaccinated dogs would develop neutralising antibodies by 2 weeks after primary vaccination reaching peak levels at ~ 4–8 weeks. Failure to mount an antibody response of $\geq$ 0.5 IU/mL occurs in 5–30% of dogs after primary vaccination, but less than 5% after repeat vaccination. Neutralising antibodies titres below 0.5 IU/mL following vaccination does not necessarily mean absence of protection as lower titres might be protective and cellular immunity might also play a role.
5) Based on the limited data from experimental infections of unvaccinated dogs, seroconversion was usually observed close to or after the onset of clinical signs. There is no way to distinguish the serological response induced by infection or vaccination, but it is reasonable to assume that dogs that test positive for neutralising antibodies ($\geq$ 0.5 IU/mL)

upon infection will develop clinical signs and die as a result of the infection within 1 or 2 weeks. The assumption that most dogs are protected against rabies virus infection by week 3 after primary vaccination seems reasonable and relatively conservative.

6) Reducing the waiting period from 90 days to 30 days would increase the probability of one or more RABV-infected dogs entering the EU, albeit to a small degree. Using an incubation period based on field data, the average time it would take to import a RABV-infected dog fully compliant with the regulations would decrease by a factor of 4.2 when reducing the waiting period from 90 to 30 days, regardless of the number of dogs imported and the incidence in the country of origin. The increase in absolute risk of rabies introduction will depend on the incidence rate in the country of origin and the number of dogs imported.
7) Reporting rabies cases to the OIE on a regular basis is not always done in a harmonised manner in all countries. Therefore, it is difficult to assess the incidence in individual countries.
8) The introduction of RABV-infected dogs has an impact on the public health sector. As an example, over 770 people have received PET in the EU following contact with 15 illegally imported infected dogs during the last 20 years. In addition, as rabies become less frequent in the EU, the awareness in the public, veterinary and medical sector decreases, and this might result in misdiagnoses and omission of preventive treatments in humans.
9) When all the sources of uncertainty were considered, it was concluded with a 95% certainty that under the current 90 days waiting period the number of rabies-infected dogs that will be imported from the countries or regions considered in this assessment in a 20-year period would be equal to or lower than 5. If the 30-day waiting period was implemented instead, it was concluded with a 95% certainty that this number would be equal or lower than 20. This difference was due to the much larger uncertainty on the number of RABV-infected imported dogs that would remain undetected under a 30-day waiting period.

5. Recommendations

A further assessment of the number of dogs that enter the EU under the commercial and non-commercial rules will reduce the uncertainty. In particular to focus on those dogs that do not have the same continual history of ownership or residency, have been mixing with animals of a different health status, including wildlife and therefore may be more likely to be exposed to rabies virus as a Type A risk.

The assessment of the countries or the regions regarding the risk of spread of RABV should be carried out based on epidemiological criteria to support the future risk management measures.

Further research with experimental and natural infection studies on the incubation period, the survival of infected animals and the development of antibodies will improve the evidence base and reduce the uncertainty of the analysis.

Awareness campaigns should be continued and focused on the risk of rabies introduction through dog movements from non-EU countries and the importance of the correct implementation of the requirements of EU legislation including vaccination and titration test.

The compliance with vaccine quality, OIE laboratory test validation, case reporting, clinical inspections of animals before travel and official controls at the borders should be maintained at high level.

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Abbreviations

CSF	cerebrospinal fluid
Dpv	days post-vaccination
GM	geometrical Mean
FAVN	fluorescent antibody virus neutralisation assay
HRIG	human rabies immune globulin
IC	Intracerebral
IM	Intramuscular
IN	Intranasal
IU	International Units
MS	Member State(s)
PET	post-exposure treatment
PI	post-inoculation
PV	post-vaccination
RABV	rabies virus
RFFIT	rapid fluorescent focus inhibition test
SC	subcutaneous
ToR	Term of Reference
VNT	virus neutralisation test
WP	waiting period

Glossary

Authorised veterinarian	Any veterinarian who has been authorised by the competent authority to carry out specific tasks in accordance with this Regulation or with acts adopted pursuant to this (Definitions in Regulation 576/2013)
Official veterinarian	Any veterinarian appointed by the competent authority (Definitions in Regulation 576/2013) A veterinarian authorised by the competent authority and appropriately qualified to perform official activities in accordance with this Regulation; (definition Animal Health Law)
Primary vaccination	The first vaccination and any revaccination if it was not carried out within the period of validity of the previous vaccination (point 2e of Annex III to Regulation (EU) No 576/2013).

Appendix A – Legislation

A. OIE Terrestrial Animal Health Code (29th edition – 2021) **Chapter 8.14 on Infection with rabies virus**

Article 8.14.7.: Recommendations for importation of dogs, cats and ferrets from countries or zones infected with rabies virus

Veterinary Authorities should require the presentation of an international veterinary certificate complying with the model of Chapter 5.11. attesting that the animals:

1) showed no clinical sign of rabies the day prior to or on the day of shipment;
2) were permanently identified and their identification number stated in the certificate;
3) and either:
    a) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer, with a vaccine that was produced in accordance with the Terrestrial Manual and were subjected not less than 3 months and not more than 12 months prior to shipment to an antibody titration test as prescribed in the Terrestrial Manual with a positive result of at least 0.5 IU/mL; or
    b) were kept in a quarantine station for six months prior to shipment.

B. Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin.

Article 76: The dogs, cats and ferrets

1) Consignments of dogs, cats and ferrets shall only be permitted to enter the Union if the animals of the consignment comply with the following requirements
    a) they have received a vaccination against infection with rabies virus that complies with the following conditions:
        i) the animals must be at least 12 weeks old at the time of vaccination
        ii) the vaccine must comply with the requirements set out in Annex III to Regulation (EU) No 576/2013 of the European Parliament and of the Council;
        iii) at the day of dispatch to the Union, at least 21 days must have elapsed since the completion of the primary vaccination against infection with rabies virus;
        iv) a certified copy of the vaccination details must be attached to the animal health certificate referred to in Article 3(1)(c)(i);
    b) they must have undergone a valid rabies antibody titration test, in accordance with point 1 of Annex XXI.
2) By way of derogation of paragraph 1(b), dogs, cats and ferrets originating in third countries or territories or zones thereof included in the list set out in Commission Implementing Regulation (EU) No 577/2013 shall be permitted to enter the Union without being subjected to the rabies titration test
3) Consignments of dogs shall be permitted to enter into a Member State with disease-free status for *Echinococcus multilocularis* or an approved eradication programme for infestation with that disease, if the animals of the consignment have been treated against this infestation in accordance with Part 2 of Annex XXI

Annex XXI to Regulation (EU) 2020/692:

Specific Requirements as Regards Dogs, Cats and Ferrets Intended For Entry Into The Union

1) Antibody Rabies Titration Test Requirements

a) must be carried out on a sample collected by a veterinarian authorised by the competent authority during the period commencing at least 30 days after the date of the primary vaccination, within a current valid vaccination series, and ending 3 months before the date of issue of the certificate;
b) must measure a titre of neutralising antibody to rabies virus equal to or greater than 0.5 IU/mL;

c) must be **certified by an official report** from the **official laboratory** as regards the result, and a copy of this report must be attached to the animal health certificate accompanying the animals to the Union;
d) does not have to be renewed on an animal which, following the antibody rabies titration test with satisfactory results, has been revaccinated against rabies within the period of validity of the primary vaccination referred to in point (a) and all subsequent valid vaccinations in the series.

C. 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:

Article 10: **Conditions applicable to the non-commercial movement 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 territory or a third country unless they fulfil the following conditions:

a) they are marked in accordance with Article 17(1);
b) they have received an anti-rabies vaccination that complies with the validity requirements set out in Annex III;
c) they have undergone a rabies antibody titration test that complies with the validity requirements set out in Annex IV;
d) they comply with any preventive health measures for diseases or infections other than rabies adopted pursuant to Article 19(1);
e) they are accompanied by an identification document duly completed and issued in accordance with Article 26.

Annex III to Regulation (EU) No 576/2013:
Validity requirements for anti-rabies vaccinations

1) The anti-rabies vaccine must

a) be a vaccine **other than a live modified vaccine** and fall within one of the following categories:

i) an **inactivated vaccine** of at least one antigenic unit per dose (recommendation from the World Health Organisation); or
ii) a recombinant vaccine expressing the immunising glycoprotein of the rabies virus in a live virus vector;

b) where it is administered in a Member State, it must have been granted a marketing authorisation in accordance with:
i) Article 5 of Directive 2001/82/EC; or
ii) Article 3 of Regulation (EC) No 726/2004;
c) where it is administered in a territory or a third country, have been granted an approval or a licence by the competent authority and meet at least the requirements laid down in the relevant part of the Chapter concerning rabies in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health.

2) An anti-rabies vaccination must fulfil the following conditions

a) the vaccine **was administered by an authorised veterinarian**;
b) the pet animal was at least 12 weeks old at the date on which the vaccine was administered;
c) the date of administration of the vaccine is indicated by an authorised veterinarian or an official veterinarian in the appropriate section of the identification document;
d) the date of administration referred to in point (c) does not precede the date of application of the transponder or tattoo or the date of reading of the transponder or the tattoo indicated in the appropriate section of the identification document;
e) the period of validity of the vaccination starts from the establishment of protective immunity, which shall not be less than 21 days from the completion of the vaccination protocol required by the manufacturer for the primary vaccination, and continues until the end of the period of protective immunity, as prescribed in the technical specification of the marketing authorisation referred to in point 1(b) or the approval or licence

referred to in point 1(c) for the anti-rabies vaccine in the Member State or territory or third country where the vaccine is administered.
The **period of validity of the vaccination** is indicated by an authorised veterinarian or an official veterinarian in the appropriate section of the identification document;

f) a revaccination must be considered a **primary vaccination** if it was not carried out within the period of validity referred to in point (e) of the previous vaccination.

Annex IV to Regulation (EU) No 576/2013:
Validity requirements for the rabies antibody titration test

1) The collection of the sample of blood necessary to carry out the rabies antibody titration test must be carried out and documented by an authorised veterinarian in the appropriate section of the identification document;
2) The rabies antibody titration test
   a) must be carried out on a sample collected at least 30 days after the date of vaccination and:
      i) not less than three months before the date of:
         – the non-commercial movement from a territory or a third country other than those listed in the implementing acts adopted pursuant to Article 13(1) or (2), or
         – the transit through such a territory or third country, where the conditions laid down in point (c) of Article 12 are not fulfilled, or
      ii) before the pet animal left the Union for movement to or transit through a territory or a third country other than those listed pursuant to Article 13(1) or (2); the identification document in the format provided for in Article 21(1) must confirm that a rabies antibody titration test was carried out with a favourable result before the date of movement;
   b) must measure a level of neutralising antibody to rabies virus in serum equal to or greater than 0.5 IU/mL and using a method prescribed in the relevant part of the Chapter concerning rabies in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health;
   c) must be performed in a laboratory approved in accordance with Article 3 of Decision 2000/258/EC;
   d) does not have to be renewed following a satisfactory result described in point (b), provided that the pet animal is revaccinated within the period of validity referred to in point 2(e) of Annex III to the previous vaccination.

Appendix B – Results from Literature Review

Incubation Period

Table B.1: Collected evidence regarding onset of clinical signs and time to death in ***unvaccinated*** dogs purposefully inoculated with rabies virus. This table includes data from experimental infection studies as well as unvaccinated (but challenged) control groups from vaccination studies

Reference	Route	Dose	Number of animals in groups	Number of animals with clinical signs	Clinical signs onset (days PI)	Number of dead animals	Death (days PI)
Schneider et al. (1965)	IM	–	11	8	14–21	8	14–21
Vaughn et al. (1965)	IM	4.4 Log_{10} of $MICLD_{50}$	3	3	10 to 16	3	11 to 17
		5.0 Log_{10} of $MICLD_{50}$	3	3	9 to 11	3	11 to 15
		4.9 Log_{10} of $MICLD_{50}$	8	7	13 to 20	7	14 to 24
		6.4 Log_{10} of $MICLD_{50}$	8	6	11 to 34	6	12 to 41
		5.2 Log_{10} of $MICLD_{50}$	7	7	13 to 24	7	15 to 27
		5.2 Log_{10} of $MICLD_{50}$	7	4	13 to 26	4	16 to 28
		3.6 Log_{10} of $MICLD_{50}$	9	3	15 to 17	3	19 to 21
		4.7 Log_{10} of $MICLD_{50}$	11	1	29	1	30
		4.4 Log_{10} of $MICLD_{50}$	12	1	42	1	45
		6.4 Log_{10} of $MICLD_{50}$	12	2	14 to 39	2	17 to 41
		6.5 Log_{10} of $MICLD_{50}$	13	2	26 to 34	2	33 to 36
		6.0 Log_{10} of $MICLD_{50}$	12	7	9 to 20	7	10 to 26
		5.7 Log_{10} of $MICLD_{50}$	12	8	9 to 27	8	10 to 29
Fekadu and Baer (1980)	IC	800,000 $MICLD_{50}$	4	4	7	4	9 to 11
	IM	800,000 $MICLD_{50}$	3	3	7	2	8 to 9
Botros et al. (1979)	IM	2 mL (6.6 Log_{10} $MICLD_{50}$/mL)	2	–	–	2	13
		2 mL (8.5 Log_{10} $MICLD_{50}$/mL)	2	–	–	2	5 to 6
	IN	2 mL (6.6 Log_{10} $MICLD_{50}$/mL)	1	–	–	1	33
Soulebot et al. (1982)[(b)]	IM	4.8 Log_{10} of $MICLD_{50}$	31		11.4 (average)	29	13 (average)
		3.8 Log_{10} of $MICLD_{50}$	34		14.2 (average)	30	15,9 (average)
		3.0 Log_{10} of $MICLD_{50}$	9		19.7 (average)	6	19,7 (average)
		6.0 Log_{10} of $MICLD_{50}$	5		9.5 (average)	3	13 (average)
		5.5 Log_{10} of $MICLD_{50}$	5		19.3 (average)	3	24 (average)
		4.8 Log_{10} of $MICLD_{50}$	5		14 (average)	4	15,5 (average)
		4.0 Log_{10} of $MICLD_{50}$	5		11 (average)	1	24 (average)
Fekadu et al. (1982a)	IC	8.3 Log_{10} of $MICLD_{50}$/mL	4	4	7	4	8 to 10
		6.3 Log_{10} of $MICLD_{50}$/mL	4	4	8	4	11 to 13
		5.9 Log_{10} of $MICLD_{50}$/mL	4	4	7 to 9	4	9 to 13
		4.0 Log_{10} of $MICLD_{50}$/mL	4	4	8	4	16 to 19
	IM	5.8 Log_{10} of $MICLD_{50}$/mL	5	4	9 to 10	4	9 to 13
		3.8 Log_{10} of $MICLD_{50}$/mL	5	3	16 to 28	3	17 to 30

Reference	Route	Dose	Number of animals in groups	Number of animals with clinical signs	Clinical signs onset (days PI)	Number of dead animals	Death (days PI)
		2.8 Log_{10} of $MICLD_{50}$/mL	4	4	23 to 27	4	23 to 34
		1.8 Log_{10} of $MICLD_{50}$/mL	5	2	30 to 42	2	30 to 48
		4.7 Log_{10} of $MICLD_{50}$/mL	5	5	14 to 18	5	15 to 21
		3.7 Log_{10} of $MICLD_{50}$/mL	5	5	19 to 29	5	21 to 34
		2.7 Log_{10} of $MICLD_{50}$/mL	4	4	22 to 37	4	24 to 42
Fekadu et al. (1982b)	IM	5.8 Log_{10} of $MICLD_{50}$/mL	4	3	9 to 10	4	10 to 11
		4.8 Log_{10} of $MICLD_{50}$/mL	4	4	11 to 21	4	12 to 25
		3.8 Log_{10} of $MICLD_{50}$/mL	3	1	29	3	16 to 30
		2.8 Log_{10} of $MICLD_{50}$/mL	4	3	16 to 27	4	23 to 29
		1.8 Log_{10} of $MICLD_{50}$/mL	2	2	30 to 41	2	36 to 43
		5.7 Log_{10} of $MICLD_{50}$/mL	5	5	12 to 15	5	14 to 17
		4.7 Log_{10} of $MICLD_{50}$/mL	5	5	14 to 18	5	16 to 21
		3.7 Log_{10} of $MICLD_{50}$/mL	5	5	19 to 29	5	21 to 34
		2.7 Log_{10} of $MICLD_{50}$/mL	4	3	22 to 37	4	24 to 42
		1.7 Log_{10} of $MICLD_{50}$/mL	3	3	36 to 69	3	40 to 69
Hanlon et al. (2002)	IM	0.5 mL (7 Log_{10} $MICLD_{50}$/mL)	5	5	11 to 13	11 to 13 euthanised	
McColl et al. (2007)	IM	0.2 mL (5 Log_{10} $TCID_{50}$)	2	2	9 to 12	9 to 12 euthanised	
Gnanadurai et al. (2015)	IM	0.3 mL (200 $MICLD_{50}$)	4	4	19 to 30	21 to 31 euthanised	
Wang et al. (2019)	IM	6×10^4 $MICLD_{50}$	4	–	–	4	11
Cho and Lawson (1989)	IM	$10^{6.3}$ $MICLD_{50}$	13	–	–	12	12 to 17
Haddad et al. (1994)	IM	$10^{3.7}$ $MICLD_{50}$/0.03 mL	4	4	–	4	23 to 53
Hammami et al. (1999)	IM	$< 10^4$ $MICLD_{50}$	6	5	12 to 92	5	14 to 96
Perrin et al. (1999)	IM	40,000 $MICLD_{50}$	2	2	12 to 15	2	19 to 20
Kallel et al. (2006)	IM	0.5 mL (10^4 DL_{50}/mL)	5	4	11 to 21	4	–
Hu et al. (2006)	IM	6×10^4 LD_{50}	20	20	10 to 26	10 to 26 euthanised	
Manickam et al. (2008)	IM	$10^{4.4}$ $MICLD_{50}$/0.03 mL	10			6 + (4 euthanised)	32 to 58 (90 euthanised)
Liu et al. (2012)	IM	6×10^4 LD_{50}	10	10	8 to 24		
Webster and Casals (1942)	IM	–	45	–	–	45	12 to 41
		0.25 mL of a 1:400 dilution	48	–	–	48	3 to 41
Fields et al. (1976)	IM	103.8 mouse LD_{50}/0.03 mL	10	–	–	8	13 to 23
Gnanadurai et al. (2013)	IM	100 mL viral suspension containing 200 $MICLD_{50}$	38	8	11 to 21	6	13 to 22
			5	5	13		
			4	0			

Reference	Route	Dose	Number of animals in groups	Number of animals with clinical signs	Clinical signs onset (days PI)	Number of dead animals	Death (days PI)
Tierkel et al. (1949)	IM	0.2 mL of 10% canine salivary gland suspension	15			8	14 to 39, and 257[(a)]
Fekadu et al. (1992)	IM	10^6.3 50% $MICLD_{50}$	6	–	–	6	–
Cliquet et al. (2007)	IM	100 $MICLD_{50}$	5	5	6–8 before death	5	25–85
(Cliquet et al., 2008)	IM	3,150 $MICLD_{50}$	6	6	12 to 18	Euthanised	
Rupprecht et al. (2005)	IM	$10^{7.4}$ $MICLD_{50}$/mL, 0.5 mL	12	12	11 to 12	–	–
Zhugunissov et al. (2017)	IM	105.0 $MICLD_{50}$	2	2	6	2	11 and 13
Blancou et al. (1989)	IM	107.6 $MICLD_{50}$	3	3	10, 11, 21	2	13, 14

IC: intracerebral; IM: intramuscular; IN: intranasal; $MICLD_{50}$: mice intracerebral lethal doses 50; LD_{50} or DL_{50}: median lethal dose; PI: post-inoculation.
(a): This unusually long time to death was specifically mentioned in the paper, and it is correctly registered here.
(b): Data are provided as averages because this is the information in the publication.

Table B.2: Collected evidence regarding onset of clinical signs and time to death **in vaccinated dogs** purposefully inoculated with rabies virus. The route of virus inoculation was intramuscular in all studies

Reference	Vaccine	Regimen	Inoculation		No. of animals in group	Clinical signs		Deaths		Study end (days PI/PV)
			Days PV	Dose		No. of animals	Onset (days PI)	No. of animals	Onset (days PI)	
Tierkel et al. (1949)	nonCOM	1-dose IM	60	105.20 $MICLD_{50}$/0.2 mL	9	–	–	0	–	–
				$10^{6.5}$ $MICLD_{50}$/0.2 mL	8	–	–	1	19	–
				$10^{6.25}$ $MICLD_{50}$/0.2 mL	8	–	–	0	–	–
				8.790 $MICLD_{50}$/0.2 mL	7	–	–	1	173	–
Fields et al. (1976)	Trimune	1-dose IM	1,080	103.8 MLD_{50}/0.03 mL	24	0	0	0	0	30/2,110
Kallel et al. (2006)	Rabisin	1-dose SC	162	0.5 mL (10^4 DL_{50}/mL)	5			1		150/312
	nonCOM	1-dose SC			5			0		
(Hu et al., 2006)	Nobivac	1-dose SC	175	60,000 LD_{50}	20	0	0	0	0	180/355
	nonCOM	1-dose SC			20	0	0	0	0	
	nonCOM	2-dose SC			13	0	0	0	0	
Bahloul et al. (2006)	Rabisin	2-dose IM Days 0, 21	1,400	10^4 LD_{50}/mL	4	–	–	0	0	120/1,520
		1-dose SC			3	–	–	0	0	
		1-dose SC			2	–	–	0	0	
Lodmell et al. (2006)	RabVac	1-dose IM	382	$10^{6.5}$ $MICLD_{50}$/0.03 mL	5	0	0	–	–	90/472
Liu et al. (2012)	nonCOM	1-dose IM	180	60,000 LD_{50}	10	0	0	–	–	270
	Nobivac				10	0	0	–	–	
Gnanadurai et al., (2013)	nonCOM	1-dose	28	200 $MICLD_{50}$	4	0	–	4 euthanised	30	30/58
Darkaoui et al. (2016)	Rabivac	2-dose SC Days 0, 30	121	1 mL ($10^{5.6}$ $MICLD_{50}$)	8	0	–	1 (not rabies)	58	70/191

IM: intramuscular; SC: subcutaneous; nonCOM: non-commercial vaccine; PI: post-inoculation; PV: post-vaccination; –: information not given in the publication; $MICLD_{50}$: Mice Intracerebral Lethal Doses 50; LD_{50} or DL_{50} or MLD_{50}: median lethal dose.
Notes: The route of virus inoculation was intramuscular in all studies. When it was explicitly reported that no animals were clinical or dead, the number of animals reported is zero.

Table B.3: Available information on the detection of virus neutralising antibodies in *unvaccinated* animals after challenge with rabies virus. All serological tests presented targeted virus neutralising antibodies and the type of test is given in the table

Reference	Tissue type	Test type	Serology testing day PI	No. of samples		Titre or concentration mean/range	Serology end (days PI)	Study end (days PI)
				Tested	Positive			
Fekadu and Baer (1980)	Serum	RFFIT	6–12 30 50	7 1 1	7 1 1	7–250 > 1,000 1,600	Single time point for dying dogs 50 days for surviving dogs	50
Fekadu and Shaddock (1984)	?	RFFIT	5	7	7	0.3–11 IU/mL	Single time point	
Hanlon et al. (2002)	Serum	RFFIT	0 3 7 11–13	5 5 5 5	5 5 5 5	< 5 < 5 < 5 to 7 13 to > 56	13	13
McColl et al. (2007)	Serum	RFFIT	7 12	2 2	2 2	1–3 IU/mL 6.3–30 IU/mL	12	42
Gnanadurai et al. (2015)	Serum	RFFIT	7 21	4 3	? ?	Mean = 0.12 IU/mL Mean = 0.32 IU/mL	21	90
Fekadu et al. (1992)	Serum	RFFIT	–49 –42 0 7 14	6 6 6 6 6		0.1 IU/mL 0.1 IU/mL 0.1 IU/mL 0.1 IU/mL 0.3 IU/mL	14	28
Hammami et al. (1999)	Serum	FAVN	–33 –26 –19 –12 0 7 160	6 6 6 6 6 6 1		0.04 to 0.14 IU/mL 0.03 to 0,18 IU/mL 0.02 to 0.06 IU/mL 0.02 to 0.05 IU/mL 0.02 to 0.14 IU/mL 0.02 to 0.08 IU/mL 0.04 IU/mL	160	160
Perrin et al. (1999)	Serum	RFFIT	–231 0	2 2		< 0.5 UI/mL < 0.5 UI/mL	0	20
Kallel et al. (2006)	Serum	RFFIT	–162 –147 –132 –102 0 150	5 5 5 5 5 1		0.26 IU/mL (GM) 0.24 IU/mL (GM) 0.28 IU/mL (GM) 0.25 IU/mL (GM) 0.27 IU/mL (GM) 11.27 IU/mL (GM)	150	150

Reference	Tissue type	Test type	Serology testing day PI	No. of samples		Titre or concentration mean/range	Serology end (days PI)	Study end (days PI)
				Tested	Positive			
Hu et al. (2006)	Serum	FAVN	–161	20		0 IU/mL	–161	180

RFFIT: rapid fluorescent focus inhibition test; FAVN: fluorescent antibody virus neutralisation assay.
Timeline is given as days post-inoculation (PI) (negative when before inoculation). All serological tests presented targeted virus neutralising antibodies and the type of test is given in the table.

Table B.4: Reports of imported dogs later confirmed infected with rabies are summarised

Country		Entry year	Dog age*	Vaccination certificate	Vaccination time to entry	Days post entry to		Non-compliance reported	No of people submitted to PET	References
Destination (last)	Origin					Clinical Signs	Confirmation			
Belgium	Morocco	2007	3.5 m	No	No	105 d	111 d	– Not titre tested – Not vaccinated	40	Van Gucht and Le Roux (2008)
France	Morocco	2001	3 m	No	–	49 d	51 d	– No vaccine certificate – Travel through Spain	5	WHO (2001b), Crozet et al. (2020a,b)
		2002	2.5 m	No	–	13 d	–	Health certificate	7	Crozet et al. (2020a)
		2004	4 y	–	–	–	5 d	– No passport – Travel through Spain	27	Crozet et al. (2020a)
		2004	4 m	No	–	37 d	46 d	Illegal travel through Spain	187 PET	Crozet et al. (2020a), Ribadeau-Dumas et al. (2016), Servas et al. (2005)
		2004	6 m	No	–	On the way to France	–	Illegal travel through Spain	11 PET	Crozet et al. (2020a), Ribadeau-Dumas et al. (2016)
		2007	adult	–	–	15 d to France (22 d to Spain)	Not tested	– Not titre tested Illegally introduced trough Spain and Portugal	152 vaccinated and several HRIG	Collective French multidisciplinary investigation team (2008), Crozet et al. (2020a)
	Gambia	2008	6 m	Confirmed	6 d	3 d France (9 d Belgium)	–	– Vaccine date falsified – Not titre tested – Travel through Belgium	32 PET	WHO (2008), Crozet et al. (2020a)
	Morocco	2008	3 m	Not vaccinated	–	18 d		Travel through Spain	25	Ribadeau-Dumas et al. (2016)
	Morocco	2011	3m	Not vaccinated	–	4 d	11 d	– Not vaccinated – No travel certificate – Illegal movement	5 vaccinated and 8 HRIG	Crozet et al. (2020a), Mailles et al. (2011)

Country		Entry year	Dog age*	Vaccination certificate	Vaccination time to entry	Days post entry to		Non-compliance reported	No of people submitted to PET	References
Destination (last)	Origin					Clinical Signs	Confirmation			
	Algeria	2015	6–7 m	–	–	7 d	11	– Illegal travel	24	Crozet et al. (2020a); ADIS
	Morocco	2020	3–5 m	Not vaccinated	–	54	97	– Not vaccinated – Illegally moved	7	Crozet et al. (2020a); ADIS
Germany	Azerbaijan	2002	2 m	Yes vaccinated	41 d	2 d	19 d	–		WHO (2001a)
	Morocco	2004	8 m	No	–	27 d	–	– No vaccination – No passport – No Health Certificate		Ribadeau-Dumas et al. (2016)
	Croatia(1)	2008	6 w	–	–	179 d	181 d	– No vaccine certificate		WHO (2009)
	Bosnia-Herzegovina	2010	2 m	Not vaccinated		22 d				Ribadeau-Dumas et al. (2016);
	Turkey	2021	8 w	–	no	6 d (died)	13 d	– Entered the country illegally via Bulgaria		PROMED-mail 2021-09-21; ADIS
Netherlands	Morocco	2012	2 m	Health Certificate	no	(11 d Spain) 3 d Netherlands	(15 d Spain) 4 d Netherlands	– Not vaccinated – No testing – Travelled via Spain	21 vaccinated, 21 vaccinated and HRIG	van Rijckevorse et al. (2012)
Spain	Morocco	2013	4 y	Vaccinated for the 1st time 11 days before entering Morocco from France	4,5 m	50 d	54 d	– No titre testing – Entered illegally – Vaccine waiting time not respected – the requirement for reintroduction not compliant	64 vaccinated, 118 vaccinated and HRIG	Perez de Diego et al. (2015); ADIS

Country		Entry year	Dog age*	Vaccination certificate	Vaccination time to entry	Days post entry to		Non-compliance reported	No of people submitted to PET	References
Destination (last)	Origin					Clinical Signs	Confirmation			
UK(2)	Sri Lanka	2008	2.5 m	–	2 d	6 d	8 d	In compliance, the dog was detected at the quarantine place	11 vaccination and HRIG	Catchpole et al. (2008)

HRIG: human rabies immune globulin; PET: post-exposure treatment.
(1): Croatia was not an EU MS in 2008.
(2): UK was an EU MS in 2008 and was applying 6 months quarantine.
*: dog age: m: months, w: weeks, y: years.

Antibodies production in unvaccinated animals after challenge

Table B.5: Available information on the detection of virus neutralising antibodies in ***unvaccinated*** animals **after challenge with rabies virus** All serological tests presented targeted virus neutralising antibodies

Reference	Tissue type	Test type	Serology testing day PI	Number of samples tested	Number of positive samples	Titre	Serology end (days PI)	Study end (days PI)
Fekadu and Baer (1980)	Serum	RFFIT	6–12 30 50	7 1 1	7 1 1	7–250 > 1,000 1,600	Single time point for dying dogs 50 days for surviving dog	50
	CSF	RFFIT	6–11 30 50	5 1 1	4 1 1	< 2–95 500 1,100		50
	Brain tissue	RFFIT	8–11	6	6	< 10–40		50
Fekadu and Shaddock (1984)	?	RFFIT	5	7	7	0.3–11 IU/mL	Single time point	
Hanlon et al. (2002)	Serum	RFFIT	0 3 7 11–13	5 5 5 5	5 5 5 5	< 5 < 5 < 5–7 13–> 56	13	13
McColl et al. (2007)	Serum	RFFIT	7 12	2 2	2 2	1–3 IU/mL 6.3–30 IU/mL	12	42
Gnanadurai et al. (2015)	Serum	RFFIT	7 (RFFIT) 21 (RFFIT)	4 3	? ?	Mean = 0.12 IU/mL Mean = 0.32 IU/mL	21	90
	CSF	RFFIT	7 21	4 4	0 0	0 IU/mL 0 IU/mL	21	90

CSF: cerebrospinal fluid; RFFIT: rapid fluorescent focus inhibition test.
Timeline is given as days post-inoculation (PI).

Table B.6: Available information on the detection of virus neutralising antibodies in ***unvaccinated*** animals belonging to the ***control group*** **of vaccine trial studies**, after **challenge with the rabies virus**. All serological tests presented targeted virus neutralising antibodies, and the type of test is given in the table

Reference	Tissue type	Test type	Serology testing day PI	Number of samples tested	Number Positive	Titre or concentration mean	Titre or concentration range	Serology end (days PI)	Study end (days PI)
Cho and Lawson (1989)	Serum	RFFIT	–49 –42 0 7 14	6 6 6 6 6		0.1 IU/mL 0.1 IU/mL 0.1 IU/mL 0.1 IU/mL 0.3 IU/mL		14	28
Haddad et al. (1994)	Serum	RFFIT	–120 0	4 4		0? 0.01?		0	53
Hammami et al. (1999)	Serum	FAVN	–33 –26 –19 –12 0 7 160	6 6 6 6 6 6 1			0.04–0.14 0.03–0.18 0.02–0.06 0.02–0.05 0.02–0.14 0.02–0.08 0.04	160	160
Perrin et al. (1999)	Serum	RFFIT	–231 0	2 2		< 0.5 UI/mL < 0.5 UI/mL		0	20
Kallel et al. (2006)	Serum	RFFIT	–162 –147 –132 –102 0 150	5 5 5 5 5 1		0.26 IU/mL (GM) 0.24 IU/mL (GM) 0.28 IU/mL (GM) 0.25 IU/mL (GM) 0.27 IU/mL (GM) 11.27 IU/mL (GM)		150	150
Hu et al. (2006)	Serum	FAVN	–161	20		0 IU/mL		–161	180
Lodmell et al. (2006)	Serum	RFFIT	–22 7 90	10 10 10		0.1 IU/mL (GM) 25 IU/mL (GM) 300 IU/mL (GM)		90	90

Reference	Tissue type	Test type	Serology testing day PI	Number of samples tested	Number Positive	Titre or concentration mean	Titre or concentration range	Serology end (days PI)	Study end (days PI)
Manickam et al. (2008)	Serum	RFFIT	7 14 28 90	10 10 10 4	0 1 2 3	0 1 1 1 to 2		90	90
Gnanadurai et al. (2013)	Serum	RFFIT	–28 2	8 8			0.05–9.85 UI/mL		90

FAVN: fluorescent antibody virus neutralisation assay; GM: geometric mean; RFFIT: rapid fluorescent focus inhibition test.
Timeline is given as days post-inoculation (PI) (negative when before inoculation). All serological tests presented targeted virus neutralising antibodies, and the type of test is given in the table.

Antibodies production in vaccinated animals after challenge

Vaccinated, not challenged

Table B.7: Virus neutralising antibodies titration in vaccination trials where animals were ***vaccinated, but not challenged with the rabies virus*** (sample specimen always serum)

Reference	Vaccine type	Vaccine regimen	Age group	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
						Tested	Positive				
Chomel et al. (1988)	Rabisin	1-dose SC	> 3 months	90	RFFIT	137	135	11.13 IU/mL (GM)		365	365
	Rabisin	1-dose SC	> 3 months	180	RFFIT	151	147	7.96 IU/mL (GM)		365	365
	Rabisin	1-dose SC	> 3 months	273	RFFIT	130	123	5.02 IU/mL (GM)		365	365
	Rabisin	1-dose SC	> 3 months	365	RFFIT	198	192	4.33 IU/mL (GM)		365	365
Tepsumethanon et al. (1991)	Rabdomun	1-dose IM	3–6 months	0 14 30 60 180 360	RFFIT	32 32 31 29 27 18		0.04 IU/mL (GM) 2.03 IU/mL (GM) 1.69 IU/mL (GM) 0.44 IU/mL (GM) 0.12 IU/mL (GM) 0.04 IU/mL (GM)	< 0.1 to 0.55 IU/mL < 0.1 to 17.66 IU/mL 0.08 to 16.18 IU/mL < 0.1 to 5.04 IU/mL < 0.1 to 2.31 IU/mL < 0.1 to 0.3 IU/mL	360	360
	Rabdomun	1-dose IM	6–12 months	0 14 30 60 180 360	RFFIT	14 14 14 14 11 9		0.04 IU/mL (GM) 1.67 IU/mL (GM) 2.78 IU/mL (GM) 0.39 IU/mL (GM) 0.05 IU/mL (GM) 0.03 IU/mL (GM)	< 0.1 to 0.27 IU/mL 0.24 to 49.77 IU/mL 0.6 to 19.23 IU/mL < 0.1 to 11.45 IU/mL < 0.1 to 1.64 IU/mL < 0.1 to 0.43 IU/mL	360	360
	Rabdomun	1-dose IM	> 12 months	0 14 30 60 180 360	RFFIT	7 7 7 7 5 4		0.03 IU/mL (GM) 4.3 IU/mL (GM) 3.6 IU/mL (GM) 1.99 IU/mL (GM) 0.32 IU/mL (GM) 0.03 IU/mL (GM)	< 0,1 to 0,25 IU/mL 1,02 to 19,24 IU/mL 0,39 to 17,64 IU/mL 0,18 to 9,64 IU/mL 0,15 to 0,63 IU/mL < 0,1 to 0,21 IU/mL	360	360
Sage et al. (1993)	Rabdomun	1-dose IM	> 3 months	0 14 30 60 180 360	RFFIT	24 25 21 26 23 16	0 25 21 19 17 11		< 0,1 IU/mL 0.75 to 10.06 IU/mL 1.06 to 9.64 IU/mL 0.29 to 4.38 IU/mL 0.25 to 6.39 IU/mL 0.26 to 7.17 IU/mL	360	360

Reference	Vaccine type	Vaccine regimen	Age group	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
						Tested	Positive				
	Rabdomun	2-dose IM days 0, 180	> 3 months	0 3 7	RFFIT	2 2 2	1 1 2		0.24 to 1.26 IU/mL 0.26 to 1.02 IU/mL 7.12 to 36.76 IU/mL	7	187
	Rabdomun	2-dose IM Days 0, 360	> 3 months	0 3 7	RFFIT	5 5 4	3 2 4		0.36 to 1.32 IU/mL 0.29 to 3.57 IU/mL 25.83 to 45.61 IU/mL	7	367
	Rabguard-TC	1-dose IM	Adult 15 animals measured at different times	3 months 5 months 7 months 8 months 9 months 11 months 12 months	RFFIT	1 2 2 1 2 3 4	1 1 1 0 2 2 2		0.66 IU/mL 0.2 to 0.53 IU/mL 0.31 to 0.72 IU/mL 0.37 IU/mL 0.69 to 0.82 IU/mL 0.31 to 1.5 IU/mL 0.34 to 1.26 IU/mL		
	Rabguard-TC	2 to 4-dose IM	Adult 17 animals measured at different times	2 years 3 years 4 years 5 years 6 years 7 years 8 years 9 years 10 years 11 years 12 years	RFFIT	2 2 1 2 1 2 2 1 2 1 1	2 2 1 2 0 2 2 1 2 1 1		2.31 to 2.6 IU/mL 0.85 to 1.38 IU/mL 1.32 IU/mL 2.69 to 5.99 IU/mL 0.34 IU/mL 0.97 to 1.6 IU/mL 3 to 5.26 IU/mL 2.07 IU/mL 2.58 to 4.15 IU/mL 1.64 IU/mL 1.9 IU/mL		
Sihvonen et al. (1995)	Madivak	1-dose SC		0 to 40 350 to 370	RFFIT	47 47 38	0 46 34	0.03 IU/mL (GM) 18.05 IU/mL (GM) 1.28 IU/mL (GM)	0.17 IU/mL 1.5 to 81 IU/mL 0.5 t 81 IU/mL	360	370
	Rabisin	1-dose SC		0 to 40 350 to 370	RFFIT	78 83 68	4 80 54	0.02 IU/mL 17.03 IU/mL 0.91 IU/mL	0.5 IU/mL 0.5 to 81 IU/mL	360	370

Reference	Vaccine type	Vaccine regimen	Age group	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
						Tested	Positive				
Benîšek et al. (1998)	Lyscelin	1-dose IM		14 28 60 90	Virus neutrali-sation in mice	6 6 6 6		153.3 ED50 153.3 ED50 98.2 ED50 92 ED50		90	90
	Rabisin	1-dose IM		14 28 60 90		6 6 6 6		162.1 ED50 162.1 ED50 90.9 ED50 105.1 ED50		90	90
Reddy and Srinivasan (1999)	Raksharab	1-dose SC	6–12 months	0 180 365 540 730 900 1095	RFFIT	30 24 24 19 15 12 12		< 0.12 IU/mL (GM) 7.2 IU/mL (GM) 5.4 IU/mL (GM) 3.8 IU/mL (GM) 2.9 IU/mL (GM) 1.8 IU/mL (GM) 1.2 IU/mL (GM)		1095	1095
Seghaier et al. (1999)	Rabirata	2-dose SC Days 0, 365	< 3 months	0 30 182 365 395	RFFIT	39 44 27 28 21	10 28 6 9 20			395	395
	Rabirata	2-dose SC Days 0, 365	3 months-1 year	0 30 182 365 395	RFFIT	81 68 49 54 43	15 44 10 24 43			395	395
	Rabirata	2-dose SC Days 0, 365	1–3 years	0 30 182 365 395	RFFIT	93 86 81 58 53	27 65 32 17 44			395	395

Reference	Vaccine type	Vaccine regimen	Age group	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
						Tested	Positive				
	Rabirata	2-dose SC Days 0, 365	> 3 years	0 30 182 365 395	RFFIT	74 69 60 43 48	41 58 37 16 45			395	395
HogenEsch et al. (2002)	Imrab	5-dose SC Days 112, 364, 728, 1092, 1456	8 weeks	112 364 378 728 742 1092 1104 1456 1470	RFFIT	5 5 5 5 5 5 5 5 5		400 0 3000 1000 3000 300 1000 500 2800		1470	1470
Reddy et al. (2003)	Megavac	2-dose IM Days 0, 30	9–16 weeks	0 90 180 360 540 720	RFFIT	10 10 8 8 8 8		< 0.12 IU/mL 6.6 IU/mL 5.1 IU/mL 4 IU/mL 3.6 IU/mL 2.9 IU/mL		720	720
Shimazaki et al. (2003)	Non-commercial	2-dose SC Days 0, 396	6–12 months	30 91 182 275 395 427 455	RFFIT	2 2 2 2 2 2 2		2 IU/mL (GM) 1.5 IU/mL (GM) 1.6 IU/mL (GM) 1.5 IU/mL (GM) 1 IU/mL (GM) 47 IU/mL (GM) 40 IU/mL (GM)		455	455
	Non-commercial	2-dose SC Days 0, 396	6–12 months	30 91 182 275 395 427 455	RFFIT	2 2 2 2 2 2 2		1.5 IU/mL (GM) 1 IU/mL (GM) 0.8 IU/mL (GM) 0.7 IU/mL (GM) 0.6 IU/mL (GM) 12 IU/mL (GM) 30 IU/mL (GM)		455	455

Reference	Vaccine type	Vaccine regimen	Age group	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
						Tested	Positive				
	Non commercial	2-dose SC Days 0, 396	6–12 months	30 91 182 275 395 427 455	RFFIT	2 2 2 2 2 2 2		1 IU/mL (GM) 0.6 IU/mL (GM) 0.7 IU/mL (GM) 0.5 IU/mL (GM) 0.4 IU/mL (GM) 45 IU/mL (GM) 35 IU/mL (GM)		455	455
Blancou et al. (1989)	Rabisin	1-dose SC	10 months	35 90 180 365 540 730 1400	RFFIT	4 4 4 4 4 4 2		8 IU/mL 0.6 IU/mL 0.9 IU/mL 1 IU/mL 0.5 IU/mL 0.5 IU/mL 0.1 IU/mL		1400	1400
Ramanna et al. (2007)	Rabivac	1-dose IM	3–48 months	0 30 180 360 540 720	RFFIT	60 60 45 30 15 15			< 0.5 to 1.75 0.75 to 1.75 0.75 to 1.75 0.75 to 1.75 1.25 to 2 1.25 to 1.75	720	720
Yuan et al. (2008)	Nobivak	1-dose IM	3 months	0 14 28 42 70 98 126 154 182	FAVN	6 6 6 6 6 6 6 6 6		0 IU/mL (GM) 0.83 IU/mL (GM) 4.52 IU/mL (GM) 6.59 IU/mL (GM) 9.61 IU/mL (GM) 8.75 IU/mL (GM) 8.28 IU/mL (GM) 7.06 IU/mL (GM) 6.97 IU/mL (GM)		182	182
Bender et al. (2009)	Denfensor 3	1-dose IM	> 5 months	0 13 27 61 82	RFFIT	16 16 16 16 16		0 IU/mL 0.65 IU/mL 0.65 IU/mL 0.61 IU/mL 0.6 IU/mL		82	82

Reference	Vaccine type	Vaccine regimen	Age group	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
						Tested	Positive				
	Denfensor 3	1-dose IM	> 5 months	0 13 27 61 82	RFFIT	16 16 16 16 16		0.15 IU/mL 0.46 IU/mL 0.64 IU/mL 0.6 IU/mL 0.6 IU/mL		82	82
Minke et al. (2009)	Rabisin	1-dose SC	13–18 weeks	0 14 28 56 84 112 120	FAVN	15 15 15 15 15 15 15		0.06 IU/mL (GM) 2.53 IU/mL (GM) 2.03 IU/mL (GM) 1.07 IU/mL (GM) 0.61 IU/mL (GM) 0.51 IU/mL (GM) 0.4 IU/mL (GM)	0.06 to 0.66 IU/mL 0.17 to 1377 IU/mL 0.29 to 7.92 IU/mL 0.22 to 3.46 IU/mL 0.1 to 2.62 IU/mL 0.1 to 2.62 IU/mL 0.07 to 1.51 IU/mL	120	120
	Nobivac	1-dose SC	13–18 weeks	0 14 28 56 84 112 120	FAVN	15 15 15 15 15 15 15		0.06 IU/mL (GM) 1.26 IU/mL (GM) 0.74 IU/mL (GM) 0.11 IU/mL (GM) 0.11 IU/mL (GM) 0.16 IU/mL (GM) 0.11 IU/mL (GM)	0.06 to 0.13 IU/mL 0.5 to 4.56 IU/mL 0.66 to 1.99 IU/mL 0.06 to 0.22 IU/mL 0.06 to 0.29 IU/mL 0.06 to 0.5 IU/mL 0.06 to 0.5 IU/mL	120	120
David et al. (2010)	RabVac	2-dose? Days 0, 255	1 year	254 263	RFFIT	1 1	0 1		0.7 IU/mL 49.91 IU/mL		
Judit et al. (2010)	Mevak	1-dose IM	3–6 months	0 14 30 90 450	RFFIT	10 10 10 10 10		0.05 IU/mL 0.16 IU/mL 1.27 IU/mL 1.22 IU/mL 0.38 IU/mL	SD = 0.03 SD = 0.05 SD = 1.14 SD = 1.14 SD = 0.2	450	
	Mevak	1-dose IM	3–6 months	0 14 30 90 450	RFFIT	10 10 10 10 10		0.04 IU/mL 0.33 IU/mL 3.29 IU/mL 2.88 IU/mL 0.45 IU/mL	SD = 0.03 SD = 0.22 SD = 2.27 SD = 1.96 SD = 0.18	450	

Reference	Vaccine type	Vaccine regimen	Age group	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
						Tested	Positive				
	Mevak	1-dose IM	3–6 months	0 14 30 90 450	RFFIT	10 10 10 10 10		0.04 IU/mL 0.35 IU/mL 4.63 IU/mL 4.17 IU/mL 1.02 IU/mL	SD = 0.13 SD = 0.18 SD = 3.01 SD = 2.21 SD = 0.4	450	
Rad et al. (2010)	Rabdomun	1-dose IM	3–4 months	180 540	RFFIT	6 6		9.2 IU/mL 0.6 IU/mL		540	540
Durrani et al. (2012)	Rabisin	2-dose SC Days 0, 21	1–2 years	0 21 30 60 90 120 150 180 210 240 270 300	RFFIT	4 4 4 4 4 4 4 4 4 4 4 4		0 IU/mL 0.4 IU/mL 1.8 IU/mL 1.7 IU/mL 2.7 IU/mL 2.3 IU/mL 3.2 IU/mL 6.3 IU/mL 8.1 IU/mL 8.2 IU/mL 11 IU/mL 11 IU/mL		300	
	Hexadog DHP-LR	2-dose SC Days 0, 21	1–2 years	0 21 30 60 90 120 150 180 210 240 270 300	RFFIT	4 4 4 4 4 4 4 4 4 4 4 4		0 IU/mL 0.1 IU/mL 0.8 IU/mL 1.2 IU/mL 2.9 IU/mL 4.5 IU/mL 5.5 IU/mL 5.8 IU/mL 7.4 IU/mL 7.4 IU/mL 6.8 IU/mL 6.9 IU/mL		300	
	Rabisyva VP13	2-dose SC Days 0, 21	1–2 years	0 21 30	RFFIT	4 4 4		0 IU/mL 0.4 IU/mL 1.9 IU/mL		300	

Reference	Vaccine type	Vaccine regimen	Age group	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
						Tested	Positive				
				60		4		2.4 IU/mL			
				90		4		8.7 IU/mL			
				120		4		14 IU/mL			
				150		4		14 IU/mL			
				180		4		15 IU/mL			
				210		4		16 IU/mL			
				240		4		16 IU/mL			
				270		4		16 IU/mL			
				300		4		16 IU/mL			
Hurisa et al. (2013)	Ethiorab	1-dose SC	4–5 months	0	FAVN	6	0	1.55 IU/mL (GM)	1.55 to 2.05 IU/mL	90	120
				7		6	5	1.7 IU/mL (GM)	1.55 to 2.4 IU/mL		
				15		6	6	3.57 IU/mL (GM)	1.55 to 2.95 IU/mL		
				21		6	6	3.154 IU/mL (GM)	2.9 to 4.2 IU/mL		
				30		6	6		2.6 to 4.05 IU/mL		
				60		6	6		2.05 to 4.3 IU/mL		
				90		6	6				
Asokkumar et al. (2014)	Raksharab	1-dose IM	3–5 months	0	RFFIT	15	0	0.059 IU/mL	0.03 to 0.07 IU/mL	28	28
				14		15	12	1.059 IU/mL	0.41 to 1.55 IU/mL		
				28		15	15	2.034 IU/mL	1.6 to 2.44 IU/mL		
Liu et al. (2014)	Merial G52	1-dose SC	Adult	0	(not given by authors)	8		0 IU/mL (GM)		270	270
				41		8		3 IU/mL (GM)			
				21		8		4.5 IU/mL (GM)			
				60		8		5 IU/mL (GM)			
				120		8		4 IU/mL (GM)			
				180		8		3.5 IU/mL (GM)			
				240		8		2.6 IU/mL (GM)			
				270		8		2 IU/mL (GM)			
Shiraishi et al. (2014)	Commercial not specified	3-dose IM	13–24 months	0	FAVN	10	0		0 to 0 IU/mL	760	760
				14		10	10		1.3 to 10 IU/mL		
				21		10	10		1.25 to 8 IU/mL		
				28		10	10		1.2 to 12 IU/mL		
				40		10	10		40 to 700 IU/mL		
				47		10	10		53 to 1094 IU/mL		
				54		10	10		45 to 750 IU/mL		
				61		10	10		60 to 500 IU/mL		

Reference	Vaccine type	Vaccine regimen	Age group	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
						Tested	Positive				
				90		10	10		40 to 1100 IU/mL		
				120		10	10		0.7 to 1300 IU/mL		
				151		10	10		0.6 to 1300 IU/mL		
				181		10	10		0.9 to 10 IU/mL		
				213		10	10		0.9 to 20 IU/mL		
				243		10	10		0.7 to 30 IU/mL		
				274		10	10		0.7 to 50 IU/mL		
				305		10	10		0.7 to 50 IU/mL		
				335		10	10		1.05 to 30 IU/mL		
				365		10	10		0.9 to 50 IU/mL		
				395		10	10		1.05 to 50 IU/mL		
				426		10	10		20 to 800 IU/mL		
				549		10	10		8 to 300 IU/mL		
				671		10	10		10 to 400 IU/mL		
				760		10	10		5 to 200 IU/mL		
Morters et al. (2015)	Rabisin	1-dose SC	1–3 months	0	FAVN	2			0.06 IU/mL	30	30
				30		19			2.0 to 90.5 IU/mL		
	Nobivac	1-dose SC	2–3 months	0	FAVN	8			0.1 to 0.29 IU/mL	30	30
				30		8			> 5.9 IU/mL		
Asokkumar et al. (2016)	Raksharab	1-dose IM		0	RFFIT	8		0.51 IU/mL	SD = 0.17	28	28
				14		8		11.14 IU/mL	SD = 2.15		
				28		8		43.23 IU/mL	SD = 8.42		
	Raksharab	1-dose SC		0	RFFIT	8		0.17 IU/mL	SD = 0.04	28	28
				14		8		16.71 IU/mL	SD = 0.00		
				28		8		62.35 IU/mL	SD = 2.18		
	Raksharab	1-dose ID		0	RFFIT	8		0.91 IU/mL	SD = 0.11	28	28
				14		8		14.75 IU/mL	SD = 0.87		
				28		8		60.23 IU/mL	SD = 2.47		
	Raksharab	1-dose IM		0	RFFIT	8		0.07 IU/mL	SD = 0.00	28	28
				14		8		0.72 IU/mL	SD = 0.06		
				28		8		1.44 IU/mL	SD = 0.12		
	Raksharab	1-dose SC		0	RFFIT	8		0.07 IU/mL	SD = 0.00	28	28
				14		8		1.05 IU/mL	SD = 0.08		
				28		8		2.00 IU/mL	SD = 0.08		

Reference	Vaccine type	Vaccine regimen	Age group	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
						Tested	Positive				
	Raksharab	1-dose ID		0 14 28	RFFIT	8 8 8		0.07 IU/mL 0.57 IU/mL 1.84 IU/mL	SD = 0.00 SD = 0.06 SD = 0.08	28	28
	Rabivac	1-dose SC	> 3 months	0 30	FAVN	919 919	220 845		0.03 to 6.01 IU/mL 0.03 to 21826 IU/mL	30	30
Darkaoui et al. (2016)	Rabivac	1-dose SC	> 3 months	0 30	FAVN	919 919	220 845		0,03 to 6,01 IU/mL 0,03 to 218,26 IU/mL	30	30
Lankester et al. (2016)	Nobivac	1-dose SC		0 28	FAVN	50 50	0	< 0.5 IU/mL 1.8 IU/mL (GM)		28	
Niu et al. (2016)	Commercial not specified	2-dose SC Days 0, 14	6 months	14 28	FAVN	10 10		4 IU/mL (GM) 8 IU/mL (GM)		28	28
Zhang et al. (2016)	?	1-dose?	> 16 weeks	< 3 4–7 8–14 15–30 31–90 91–180 180–270 > 270	FAVN	5483 5483 5483 5483 5483 5483 5483 5483		0.02 IU/mL (GM) 1.65 IU/mL (GM) 2.66 IU/mL (GM) 2.7 IU/mL (GM) 1.86 IU/mL (GM) 0.86 IU/mL (GM) 0.75 IU/mL (GM)	0.01 to 0.06 IU/mL 1.01 to 2.69 IU/mL 2.31 to 3.06 IU/mL 2.57 to 2.85 IU/mL 1.75 to 1.99 IU/mL 0.75 to 0.98 IU/mL 0.59 to 0.97 IU/mL		
Giel-Moloney et al. (2017)	Commercial not specified	1-dose SC	4 months	−14 7 14 28 49 70 99 127 163 253	RFFIT	2 2 2 2 2 2 2 2 2 2		0 IU/mL (GM) 4.5 IU/mL (GM) 10 IU/mL (GM) 2.7 IU/mL (GM) 1.8 IU/mL (GM) 1.5 IU/mL (GM) 1 IU/mL (GM) 0.9 IU/mL (GM) 0.8 IU/mL (GM) 1 IU/mL (GM)		253	284
Pimburage et al. (2017)	Nobivac	1-dose IM	6 weeks–3 months	0 30 180 360	RFFIT	40	0 39 33 3	0.1 IU/mL (GM) 10.66 IU/mL (GM) 4.63 IU/mL (GM) 0.23 IU/mL (GM)	0.02 to 0.44 IU/mL 0.4 to 49.09 IU/mL 0.004 to 32.5 IU/mL 0.004 to 18 IU/mL	360	360

Reference	Vaccine type	Vaccine regimen	Age group	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
						Tested	Positive				
	Nobivac	1-dose IM	3 months–1 year	0 30 180 360	RFFIT	47	37 45 44 37	15.99 IU/mL (GM) 34.77 IU/mL (GM) 27.09 IU/mL (GM) 21.59 IU/mL (GM)	0.03 to 177.5 IU/mL 0.03 to 269.79 IU/mL 0.06 to 269.83 IU/mL 0.08 to 229 IU/mL	360	360
	Nobivac	1-dose IM	> 1 year	0 30 180 360	RFFIT	47	33 47 47 39	6.66 IU/mL (GM) 51.85 IU/mL (GM) 22.89 IU/mL (GM) 7.177 IU/mL (GM)	0.02 to 49.09 IU/mL 1.96 to 269.76 IU/mL 0.4 to 100.4 IU/mL 0.19 to 49.09 IU/mL	360	360
	Nobivac	1-dose IM	1–6 years	0 30 180 360	RFFIT	51	39 49 45 40	13.62 IU/mL (GM) 29.81 IU/mL (GM) 39.47 IU/mL (GM) 24.23 IU/mL (GM)	0.03 to 214.63 IU/mL 0.03 to 269.79 IU/mL 0.06 to 269.83 IU/mL 0.36 to 229 IU/mL	360	360
Wallace et al. (2017)	?	1-dose?	< 12 week	< 3 4–7 8–14 15–30 31–90 91–180 180–270 > 270	FAVN	290 290 290 290 290 290 290 290		1.42 IU/mL (GM) 4.14 IU/mL (GM) 2.51 IU/mL (GM) 1.21 IU/mL (GM) 0.55 IU/mL (GM) 2.05 IU/mL (GM) 1.46 IU/mL (GM)	0.27 to 7,39 IU/mL 2.89 to 5,93 IU/mL 1.99 to 3,16 IU/mL 0.87 to 1,68 IU/mL 0.28 to 1,12 IU/mL 1.58 to 2,66 IU/mL 0.67 to 3,19 IU/mL		
	?	1-dose?	12–16 weeks	< 3 4–7 8–14 15–30 31–90 91–180 180–270 > 270	FAVN	2238 2238 2238 2238 2238 2238 2238 2238		0.01 IU/mL (GM) 0.23 IU/mL (GM) 1.68 IU/mL (GM) 2.13 IU/mL (GM) 1.56 IU/mL (GM) 0.74 IU/mL (GM) 0.51 IU/mL (GM) 0.03 IU/mL (GM)	0 to 0.15 IU/mL 0 to 35.52 IU/mL 1 to 2.81 IU/mL 1.92 to 2.37 IU/mL 1.4 to 1.73 IU/mL 0.6 to 0.9 IU/mL 0.36 to 0.73 IU/mL 0 to 2.44 IU/mL		

Reference	Vaccine type	Vaccine regimen	Age group	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
						Tested	Positive				
	?	1-dose?	> 16 weeks	< 3 4–7 8–14 15–30 31–90 91–180 180–270 > 270	FAVN	5483 5483 5483 5483 5483 5483 5483 5483		0.02 IU/mL (GM) 1.65 IU/mL (GM) 2.66 IU/mL (GM) 2.7 IU/mL (GM) 1.86 IU/mL (GM) 0.86 IU/mL (GM) 0.75 IU/mL (GM)	0.01 to 0.06 IU/mL 1.01 to 2.69 IU/mL 2.31 to 3.06 IU/mL 2.57 to 2.85 IU/mL 1.75 to 1.99 IU/mL 0.75 to 0.98 IU/mL 0.59 to 0.97 IU/mL		
Bouvet et al. (2018)	Rabisin	1-dose SC	7–9 week	0 14 27 42 70 119 182 272 363	FAVN			0 IU/mL (GM) 8 IU/mL (GM) 16 IU/mL (GM) 11 IU/mL (GM) 3.5 IU/mL (GM) 8 IU/mL (GM) 9 IU/mL (GM) 10 IU/mL (GM) 3.5 IU/mL (GM)		363	363
	Rabisin	1-dose SC	7–9 week	0 14 27 42 70 119 182 272 363	FAVN			0 IU/mL (GM) 12 IU/mL (GM) 23 IU/mL (GM) 12 IU/mL (GM) 6 IU/mL (GM) 10 IU/mL (GM) 11 IU/mL (GM) 11,5 IU/mL (GM) 4 IU/mL (GM)		363	363
Devi et al. (2018)	Rabipur	2-dose? Days 0, 21	3–6 months	0 7 14 21 28	RFFIT	6 6 6 6 6		2 log 2 titer 12 log 2 titer 12 log 2 titer 12 log 2 titer 12 log 2 titer			

Reference	Vaccine type	Vaccine regimen	Age group	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
						Tested	Positive				
Zhang et al. (2016)	Commercial not specified	2-dose IM Days 0, 730	> 2 years	730 737 744 751 758	FAVN	5 5 5 5 5		1.2 IU/mL (GM) 1.5 IU/mL (GM) 2.3 IU/mL (GM) 2.3 IU/mL (GM) 2.5 IU/mL (GM)		758	758
	Commercial not specified	1-dose IM	3 months	14 28	FAVN	5 5		0.7 IU/mL (GM) 1.2 IU/mL (GM)		28	28
Arega et al. (2020)	Defensor 3	2-dose SC Days 0, 91	6 weeks	42 63 112	RFFIT	173 117 49		0.0064 IU/mL (GM) 1.47 IU/mL (GM) 2.73 IU/mL (GM)		112	112
Bommier et al. (2020)	Rabisin	1-dose SC	4.5–5 months	7 28	RFFIT	6 6	6 6	0.16 IU/mL (Med) 7.92 IU/mL (Med)	0.06 to 0.66 IU/mL 3.46 to 10.45 IU/mL	28	84
	Rabisin	1-dose SC	4.5–5 months	7 28	RFFIT	6 6	6 6	0.52 IU/mL (Med) 7.5 IU/mL (Med)	0.29 to 3.46 IU/mL 4.56 to 72.27 IU/mL	28	84
Paris et al. (2020)	Rabisin	1-dose SC	3.5–5.5 months	28	RFFIT	7		7 IU/mL (Med)	2 to 13.8 IU/mL	28	28
	Non-commercial	1-dose SC	3.5–5.5 months	28	RFFIT	6		1,6 IU/mL (Med)	0.2 to 13.8 IU/mL	28	28
	Non-commercial	1-dose SC	3.5–5.5 months	28	RFFIT	7		2 IU/mL (Med)	1.2 to 4.6 IU/mL	28	28
	Non-commercial	1-dose SC	3.5–5.5 months	28	RFFIT	6		1 IU/mL (Med)	0.3 to 13.8 IU/mL	28	28
	Non-commercial	1-dose SC	3.5–5.5 months	28	RFFIT	7		10.5 IU/mL (Med)	1.2 to 18.2 IU/mL	28	28
Lugelo et al. (2021)	Nobivac	1-dose SC	3–60 months	28	FAVN	163	139	1.8 IU/mL (GM)		28	28
	Nobivac	1-dose SC	3–60 months	28	FAVN	163	140	2.0 IU/mL (GM)		28	28
Molini et al. (2021)	Rabisin	1-dose?	?	28	RFFIT	2	2			28	28

FAVN: fluorescent antibody virus neutralisation assay; GM: geometric mean; RFFIT: rapid fluorescent focus inhibition test; PV: post-vaccination.
Timelines are given in relation to the first vaccination day. All serological tests presented targeted virus neutralising antibodies, and the type of test is given in the table.

Vaccinated and challenged

Table B.8: Virus neutralising antibodies titration in vaccination trials where animals were ***vaccinated, and later challenged with the rabies virus*** (sample specimen always serum)

Reference	Vaccine type	Vaccine regimen	Age group	Time to inoculation (days PV)	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
							Tested	Positive				
Tierkel et al. (1949)	Non-commercial	1-dose IM	6–51 months	60	0 22 43 60	Virus neutralisation test through injection in mice	3 2 3 2			< 1:2 to 1:6 1:25 to 1:105 1:20 to 1:70 1:15 to 1:50	60	60
	Non-commercial	1-dose IM	6–51 months	60	0 22 43 60		4 4 4 4			< 1:2 1:160 to 1:315 1:55 to 1:330 1:65 to 1:255	60	60
	Non-commercial	1-dose IM	6–51 months	60	0 22 43 60		3 3 3 3			1:2 to 1:10 1:30 to > 1:512 1:20 to 1:130 1:15 to 1:95	60	60
	Non-commercial	1-dose IM	6–51 months	60	0 22 43 60		4 3 3 4			< 1:2 to 1:3 1:20 to > 1:512 1:3 to > 1:512 1:4 to > 1:512	60	60
Fields et al. (1976)	Trimune	1-dose IM	> 12 month	1,080	0 30 330 720 1,080 1,110	Standard serum-dilution method	24 24 22 19 19 19		< 2 titre (median) 512 titre (median) 146 titre (median) 19 titre (median) 6 titre (median) 217 titre (median)	< 2 titre 165 to 789 titer 45 to 512 titre 3 to 194 titre < 2 to 458 titre 32 to 1,024 titre		
Cho and Lawson (1989)	Non-commercial	1-dose IM	1–3 years	56	7 14 35	RFFIT	7 7 7		0.1 IU/mL 0.1 IU/mL 0.1 IU/mL			130

Reference	Vaccine type	Vaccine regimen	Age group	Time to inoculation (days PV)	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
							Tested	Positive				
					56		7		0.1 IU/mL			
					63		7		0.3 IU/mL			
					70				1.5 IU/mL			
					84				1.5 IU/mL			
	Non-commercial	1-dose IM	1–3 years	56	7	RFFIT	5		0.3 IU/mL			130
					14		5		1.5 IU/mL			
					35		5		1.5 IU/mL			
					56		5		1.5 IU/mL			
					63		5		37 IU/mL			
					70		5		37 IU/mL			
					84		5		37 IU/mL			
	Non-commercial	1-dose IM	1–3 years	56	7	RFFIT	5		0.1 IU/mL			130
					14		5		1.5 IU/mL			
					35		5		1.5 IU/mL			
					56		5		1.5 IU/mL			
					63		5		37 IU/mL			
					70		5		37 IU/mL			
					84		5		37 IU/mL			
Kallel et al. (2006)	Rabisin	1-dose SC	5–6 months	162	0	RFFIT	5		0.29 IU/mL (GM)		312	312
					15		5		6.1 IU/mL (GM)			
					30		5		5 IU/mL (GM)			
					60		5		2.8 IU/mL (GM)			
					162		5		1.06 IU/mL (GM)			
					312		4		3.62 IU/mL (GM)			
Hu et al. (2006)	Nobivac	1-dose SC	75–100 days	175	14	FAVN	20		10.36 IU/mL		112	355
					28		20		26.3 IU/mL			
					112		20		14.2 IU/mL			
Bahloul et al. (2006)	Rabisin	2-dose IM Days 0, 21	10 months	1,400	35	RFFIT	4		38 IU/mL		1,400	1,520
					90		4		1.6 IU/mL			
					180		4		1.4 IU/mL			
					365		4		1.3 IU/mL			
					540		4		1.2 IU/mL			
					730		4		1.1 IU/mL			
					1,400		2		0.3 IU/mL			

Reference	Vaccine type	Vaccine regimen	Age group	Time to inoculation (days PV)	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
							Tested	Positive				
	Rabisin	1-dose SC	2 months	1,400	0 27 90 1,400	RFFIT	3 3 3 3		0.5 IU/mL 7.1 IU/mL 3.6 IU/mL 0.2 IU/mL		1,400	1,520
	Rabitun	1-dose SC	2 months	1,400	0 27 90 1,400	RFFIT	3 3 3 2		0.5 IU/mL 0.9 IU/mL 0.4 IU/mL 0.25 IU/mL		1,400	1,520
Lodmell et al. (2006)	RabVac	1-dose IM	12–14 months	382	60 120 180 240 300 360 389 472	RFFIT	5 5 5 5 5 5 5 5		240 IU/mL (GM) 150 IU/mL (GM) 120 IU/mL (GM) 90 IU/mL (GM) 110 IU/mL (GM) 90 IU/mL (GM) > 1,000 IU/mL (GM) 900 IU/mL (GM)		472	472
Manickam et al. (2008)	Nobivak	5-dose IM Days 0, 3, 7, 14, 28	8–12 months	0	3 7 14 21 28 90	RFFIT	10		< 0.5 IU/mL 2.2 IU/mL 1.8 IU/mL 6.3 IU/mL 11.2 IU/mL 2.3 IU/mL	SD = 2,3 SD = 2,2 SD = 4,8 SD = 5,3 SD = 1,3	90	90
	Rabisin	5-dose IM Days 0, 3, 7, 14, 28	8–12 months	0	3 7 14 21 28 90	RFFIT	10		< 0.5 IU/mL 1.3 IU/mL 6.3 IU/mL 9.6 IU/mL 12.4 IU/mL 3.4 IU/mL	SD = 1.1 SD = 5.7 SD = 5.7 SD = 8.1 SD = 1.9	90	90
	Nobivak	3-dose IM Days 0, 5, 28	8–12 months	0	7 14 21 28 90	RFFIT	10		1.5 IU/mL 6.2 IU/mL 14.6 IU/mL 20.0 IU/mL 2.5 IU/mL	SD = 1.4 SD = 5.5 SD = 10.8 SD = 11.3 SD = 2.1	90	90

Reference	Vaccine type	Vaccine regimen	Age group	Time to inoculation (days PV)	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
							Tested	Positive				
Liu et al. (2012)	Non-commercial	1-dose IM	3–4 months	180	0 30 60 90 120 150 180	FAVN	10 10 10 10 10 10 10		0 IU/mL (GM) 11.5 IU/mL (GM) 9.5 IU/mL (GM) 8 IU/mL (GM) 7.8 IU/mL (GM) 7.6 IU/mL (GM) 7.5 IU/mL (GM)		180	270
	Nobivac	1-dose IM	3–4 months	180	0 30 60 90 120 150 180	FAVN	10 10 10 10 10 10 10		0 IU/mL (GM) 12 IU/mL (GM) 11 IU/mL (GM) 10,5 IU/mL (GM) IU/mL (GM)10 9 IU/mL (GM) 8 IU/mL (GM)		180	270
Gnanadurai et al. (2013)	Non-commercial	1-dose IM	5 months	28	0 30	RFFIT	4 4	4 4		9.85 to 29.6 IU/mL 0.2 to 2.9 IU/mL	30	
	Non-commercial	1-dose IM	5 months	28	0 30		4 4	0		0 IU/mL	30	
Darkaoui et al. (2016)	Rabivac	2-dose SC Days 0, 30	3–6 months	121	1 7 14 21 28 35 49 56 64 70 77 84 91 98 105	FAVN	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	0 7 8 8 7 8 8 8 8 7 7 6 6 7 6	0.04 IU/mL (GM) 1.41 IU/mL (GM) 3.34 IU/mL (GM) 5.51 IU/mL (GM) 4.36 IU/mL (GM) 7.16 IU/mL (GM) 18.3 IU/mL (GM) 5.42 IU/mL (GM) 3.54 IU/mL (GM) 3.29 IU/mL (GM) 1.29 IU/mL (GM) 1.07 IU/mL (GM) 0.71 IU/mL (GM) 0.57 IU/mL (GM) 0.39 IU/mL (GM)	0.04 to 0.06 IU/mL 0.17 to 4.56 IU/mL 0.5 to 10.45 IU/mL 1.99 to 18.15 IU/mL 0.04 to 13.77 IU/mL 1.51 to 23.93 IU/mL 1.15 to 54.82 IU/mL	119	120

Reference	Vaccine type	Vaccine regimen	Age group	Time to inoculation (days PV)	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
							Tested	Positive				
					112 119		8 8	7 6	0.77 IU/mL (GM) 0.71 IU/mL (GM)	0.29 to 18.15 IU/mL 0.29 to 10.45 IU/mL 0.17 to 10.45 IU/mL 0.22 to 4.56 IU/mL 0.13 to 3.46 IU/mL 0.04 to 1.99 IU/mL 0.07 to 1.99 IU/mL 0.07 to 1.15 IU/mL 0.06 to 2.62 IU/mL 0.04 to 1.99 IU/mL		
Zhang et al. (2016)	PCEV	4-dose IM Days 0, 7, 14, 28		0	0 7 14 21 28	FAVN	15 15 15 15 15		0 IU/mL 0.5 IU/mL 3 IU/mL 3.5 IU/mL 4 IU/mL		28	45
	PIKA-RV	4-dose IM Days 0, 7, 14, 28		0	0 7 14 21 28	FAVN	15 15 15 15 15		0 IU/mL 0.5 IU/mL 6 IU/mL 11.5 IU/mL 16 IU/mL		28	45
	PCEV	4-dose IM Days 0, 7, 14, 28		0	0 7 14 21 28	FAVN	15 15 15 15 15		0 IU/mL 0.5 IU/mL 4 IU/mL 6 IU/mL 10 IU/mL		28	45

Reference	Vaccine type	Vaccine regimen	Age group	Time to inoculation (days PV)	Serology testing day (PV)	Test type	Number of animals		Titre or concentration mean	Titre or concentration range	Serology end (days PV)	Study end (days PV)
							Tested	Positive				
	PIKA-RV	4-dose IM Days 0, 7, 14, 28		0	0 7 14 21 28	FAVN	15 15 15 15 15		0 IU/mL 0.5 IU/mL 7 IU/mL 12 IU/mL 16 IU/mL		28	45

FAVN: fluorescent antibody virus neutralisation assay; GM: geometric mean; PV: post-vaccination; RFFIT: rapid fluorescent focus inhibition test; Vaccine regimen; IM: intramuscular, SC: subcutaneous.
Timelines are given in relation to the first vaccination day. All serological tests presented targeted virus neutralising antibodies, and the type of test is given in the table.

Appendix C – Dogs imported into EU countries from non-EU countries and from listed non-EU countries for commercial purposes

Table C.1: Number of dogs imported from non-EU countries in 2019–2021 as registered in TRACES

EU country of destination	Number of dogs imported from non-EU countries for commercial purposes per year							
	All non-EU countries from which dogs imports are allowed				Non-EU countries for which the antibody titration test and the waiting period afterwards is mandatory			
	2019	2020	2021	Mean	2019	2020	2021	Mean
Austria	288	261	528	359	124	72	130	109
Belgium	241	448	2,059	916	34	30	86	50
Bulgaria	50	52	273	125	10	22	9	14
Croatia	39	25	143	69	1	12	105	39
Cyprus	326	103	179	203	7	15	19	14
Czechia	39	79	653	257	7	10	13	10
Denmark	218	767	950	645	31	14	34	26
Estonia	32	631	1,849	837	10	8	3	7
Finland	1,127	756	1,315	1,066	69	64	38	57
France	2,375	2,276	4,575	3,075	91	89	248	143
Germany	3,701	5,968	10,599	6,756	309	344	410	354
Greece	31	45	80	52	2	8	3	4
Hungary	253	249	506	336	1	24	71	32
Ireland	477	501	795	591	172	116	168	152
Italy	839	1,097	1,945	1,294	75	78	100	84
Latvia	9	523	913	482	0	3	0	1
Lithuania	9	100	1,183	431	0	0	0	0
Luxembourg	21	24	39	28	4	5	20	10
Malta	32	29	118	60	18	5	25	16
Netherlands	648	1,281	2,370	1,433	105	207	297	203
Poland	61	196	3,814	1357	22	24	25	24
Portugal	347	301	543	397	277	202	296	258
Romania	15	457	1,825	766	3	4	15	7
Slovakia	7	162	22	64	2	3	3	3
Slovenia	7	8	64	26	4	0	1	2
Spain	472	526	1,318	772	107	68	155	110
Sweden	610	921	1,758	1,096	33	41	79	51
Total	**12,274**	**17,786**	**40,416**	**23,492**	**1,518**	**1,468**	**2,353**	**1,780**

Appendix D – Protocol for the assessment

Assessment of the risk of importing to EU infected with rabies dogs related to a possible reduction of the waiting time after rabies antibody titration from 90 days to 30 days.

Background as provided by the requestor

Specific animal health requirements for entry into the Union of dogs, cats and ferrets are laid down in Commission Delegated Regulation (EU) 2020/692[2]. They mainly rely on preventing rabies from entering the EU territory from imported animals. To that end, the following conditions must be met:

Vaccination against rabies - dogs, cats and ferrets must be vaccinated against rabies as follows:

- the animals must be at least 12 weeks old at the time of vaccination;
- the vaccine must comply with the requirements set out in Annex III to Regulation (EU) No 576/2013[15];
- at the day of dispatch to the Union, at least 21 days must have elapsed since the completion of the primary vaccination against infection with rabies virus;
- a certified copy of the vaccination details must be attached to the animal health certificate.

Rabies antibody test - dogs, cats and ferrets coming from third countries or territories listed in part I of Annex VIII to Commission Implementing Regulation (EU) 2021/404[16] for which the specific condition 'rabies antibody titration test' applies must undergo a rabies antibody test, meeting certain criteria. That test:

- must be carried out on a sample collected by a veterinarian authorised by the competent authority during the period commencing at least 30 days after the date of the primary vaccination, within a current valid vaccination series, and ending 3 months before the date of issue of the certificate;
- must measure a titre of neutralising antibody to rabies virus equal to or greater than 0.5 IU/mL;
- must be certified by an official report from the official laboratory as regards the result, and a copy of this report must be attached to the animal health certificate accompanying the animals to the Union;
- does not have to be renewed on an animal which, following the antibody rabies titration test with satisfactory results, has been revaccinated against rabies within the period of validity of the primary vaccination and all subsequent valid vaccinations in the series.

These measures largely reflect the recommendations provided by EFSA in an opinion adopted on 11 December 2006 and published on 15 February 2007 regarding an 'Assessment of the risk of rabies introduction into the UK, Ireland, Sweden, Malta, as a consequence of abandoning the serological test measuring protective antibodies to rabies'.[9] In this opinion, EFSA points out that the risk of transmission of rabies by pet movement is related to moving an animal incubating the disease and that the primary means of removing an individual from the population at risk is by vaccination, as inactivated rabies vaccines are highly efficient and induce rapid protective immunity that prevents infection and subsequent transmission. On the other hand, it also highlights that infection prior to vaccination protection cannot be controlled by immunisation. Therefore, further requirements should be based on whether rabies occurs in the pet population or not. If rabies occurs in the pet population where pets reside before primo-vaccination, a waiting time following primo-vaccination is recommended as the most efficient measure to reduce the risk of importing rabies-infected pets. The higher is the actual prevalence, the longer should be the waiting time required in order to reach an acceptable level of risk. Finally, the opinion recognises that the implementation of serological testing or other risk-reducing measures may be considered when the required waiting time exceeds 100 days.

As indicated above, the waiting time legally required in the EU legislation for movements from countries with a higher prevalence/unknown status is of at least 3 months after the blood sampling, which has to be undertaken at least 30 days after rabies vaccination. This requirement is also in line

[15] 2 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.

[16] 3 Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council, OJ L 114, 31.3.2021, p. 1.

with the current recommendations included in the OIE Terrestrial Animal Health Code Chapter 8.14 on rabies (29th edition 2021).

As shown in EFSA 2007 opinion, the waiting time between vaccination and import is crucial, because vaccination does not prevent disease developing in already infected animals. Blancou et al. (1989) demonstrated that vaccination in an already infected animal does not significantly alter the clinical picture or development time of the disease. Therefore, it is possible that an animal infected prior to rabies vaccination would continue to incubate the disease despite developing a significant antibody titre. Another risk of rabies introduction is linked to pets which are not fully protected by the vaccination, either because they were recently vaccinated or they mounted an insufficient antibody response, before being infected.

From a general point of view, the risk that an animal is incubating disease at the time of vaccination is the same as the risk that an unvaccinated animal is incubating disease when it is imported, thus, the overall risk is very sensitive to the waiting time. It is also very sensitive to compliance with requirements (e.g. shorter than required wait, incorrect or no vaccination, falsified test result) (Wilsmore et al., 2006).

The OIE ad hoc Group on Rabies has started to work on modifying Article 8.14.7 of the OIE Terrestrial Animal Health Code and reducing the waiting time after a positive antibody titration test from 90 to 30 days. A concept paper of the OIE ad hoc group describing the scientific evidence to support those changes was released with the February 2020 OIE Scientific Commission for Animal Diseases ('OIE Scientific Commission') report[7] and was subsequently published in the scientific journal Vaccine[17]. The OIE Terrestrial Animal Health Standards Commission ('OIE Code Commission') amended Article 8.14.7 and circulated for OIE Members Countries' (Members) comments after its September 2020 meeting. The OIE Scientific Commission agreed to consult subject-matter experts to address Member's concerns expressed after that round of consultation.

In December 2020, the European Union expressed concerns[9] that the presented data and drawn conclusions were not sufficient for a policy change and would request additional scientific evidence. To support its position, it submitted a scientific report prepared by experts of the European Union Reference Laboratory for Rabies (cf. p. 127-131 of the document under footnote 7[7]).

In September 2021, after careful analysis of the Member's concerns, the OIE Scientific Commission endorsed the expert opinion of the OIE Rabies Reference Laboratory network (RABLAB) which considered that the scientific basis for a 30-day post-titration waiting time was justified and that the conclusion of the 2019 OIE ad hoc Group on Rabies that reviewed dog importation standards should remain unchanged.

The OIE Scientific Commission opinion together with the experts' rationale were forwarded to the OIE Code Commission for consideration. It is therefore likely that these changes will be proposed for adoption by OIE member countries, possibly as early as at the General Session of the OIE in May 2022.

ToRs as provided by the requestor

In the context of Article 31 of Regulation (EC) No. 178/2002, the Commission asks EFSA for scientific and technical assistance on the risks related to a possible reduction of the waiting time after rabies antibody titration to 30 days compared to the current EU legislative regime, **taking into account:**

- the experience gained in the last years with the current waiting time laid down in the EU legislation;
- the possible risks/limitations including those identified by the experts of the EU Reference Laboratory for Rabies in their February 2021 opinion;
- newly available scientific information, and specifically the publication describing the scientific evidence to support the proposed changes released.

Problem formulation

Here, a summary of the initial considerations taken to deliver on the mandate are described. With this mandate the EC requests EFSA's support in assessing the excess risk associated with a potential

[17] Smith TG, Fooks AR, Moore SM, Freuling CM, Müller T, Torres G and Wallace RM, 2021. Negligible risk of rabies importation in dogs thirty days after demonstration of adequate serum antibody titer. Vaccine. https://doi.org/10.1016/j.vaccine.2021.03.064. (https://www.sciencedirect.com/science/article/pii/S0264410X21003686?via%3Dihub)

delay in the waiting period prior to the importation of dogs from non-EU countries. The request concerns the provisions for the dogs (*Canis lupus)* intended to be moved as non-commercial pets or imported as commercial dogs into the EU territory from non-EU countries to prevent the introduction of rabies in EU as described in Article 76 of the Commission Delegated Regulation (EU) 2020/692 in accordance with the article 8.14.7 of the OIE Terrestrial Code (last revised in 2019) (please refer to Appendix A).

For this work it is considered that all the requirements of EU legislation related to dog movements have been implemented. Specifically:

1) the dog **is individually identified** by means of an injectable transponder implanted which fulfils the technical requirements for means of identification (Article 74 Reg 2020/692) by a veterinarian, and the dog was individually identified before or at the time of primary vaccination (Annex III to the Regulation (EU) 576/2013) so the details correspond to those in the certificate or passport.
2) the dog **has been vaccinated** against rabies before shipment **with a vaccine that complies with the validity requirements** set out in Annex III to Regulation (EU) No 576/2013: (i) it is not a live modified vaccine and it is either an inactivated vaccine of at least one antigenic unit per dose (recommendation from the World Health Organisation); (ii) it has been granted an approval or a licence by the competent authority of the third country; and (iii) it meets at least the requirements laid down in the relevant part of the chapter concerning rabies in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health.
3) the dog **was at least 12 weeks old** at the date on which the **primary rabies vaccination** was administered (Article 76 Reg 2020/692).
4) the **period of validity of the vaccination** starts **from the establishment of protective immunity**, which shall not be less than 21 days from the completion of the vaccination protocol required by the manufacturer for the primary vaccination, **and continues until the end of the period of protective immunity,** as prescribed in the technical specification of the marketing authorisation referred to in point 1(b)[10] or the approval or licence referred to in point 1(c)[11] for the anti-rabies vaccine in the Member State or territory or third country where the vaccine is administered (point 2(e) Annex III Regulation (EU) No 576/2013).
5) as **primary rabies vaccination** is considered the **first vaccination** and **the any revaccination** if it was not carried out within the period of validity of the previous vaccination (point 2e of Annex III to Regulation (EU) No 576/2013.
6) the **vaccination has been conducted by an authorised veterinarian** (Annex III Regulation (EU) 576/2013) and therefore good veterinary practice related to vaccination has been implemented. This also implies that the dog was healthy at the day of vaccination (based on the results of the clinical examination) and there was no suspicion of any disease including rabies (based on the medical history of the dog for the last days prior to vaccination).
7) the vaccinated dog must, at the time of import, remain within the protective immunity period of the vaccines according to the manufacturer's instructions
8) a certified copy of the vaccination details must be attached to the animal health certificate; the **date of administration of the vaccine** and the **period of validity of the vaccination** is indicated by an authorised veterinarian or an official veterinarian in the appropriate section of the identification document (article 76 Reg 2020/692, point 2(e) Annex III Regulation (EU) No 576/2013).
9) a rabies antibody titration test using a **virus neutralisation test** (VNT) to detect neutralising antibodies must be carried out on a blood sample collected not less than 3 months and not more than 12 months prior to the date of issue of the certificate for the shipment. In case of primary vaccination, the samples should be collected at least 30 days after the date of primary vaccination course, within a current valid vaccination series. The sample should be collected by a veterinarian authorised by the competent authority.
10) the VNT must comply with the validity requirements set out in Annex XXI to Regulation (EU) 2016/429.
11) the VNT before entry should be performed in a laboratory authorised[12] by the ANSES-Nancy laboratory which is the European Union Reference Laboratory (EURL)[13] for rabies.

12) a neutralising antibody level ≥ 0.5 IU/mL is characterised as positive. Nevertheless, the test does not differentiate between infected and vaccinated animals and there are no laboratory tests able to differentiate between neutralising antibodies resulting from natural infection from those developed after vaccination.
13) as antibodies resulting from natural infection are only detectable when the animal is in the late stages and showing clinical signs, only healthy animals should travel, however only commercial consignments of dogs will be subject to a veterinary inspection prior to travel.
14) provided the results are positive, the dogs are not allowed to travel immediately. A waiting period of at least 90 days (current regulation) and not more than 12 months, after the day of sampling for the antibody titration test, has been introduced to allow the clinical signs to manifest if animals were infected before vaccination or just after vaccination.
15) once the dog is ready to travel, it should be clinically examined within a period of 24–48 h prior to the time of loading for dispatch (article 13(3) of Reg 2020/692) and in the absence of clinical signs the shipment is allowed, and the certificate is provided. However, this is only applicable to commercial movements; for non-commercial movements, there is no such requirement.
16) dogs from countries not listed in Annex II to 577/2013 and all commercial consignments from outside the EU will have to enter through a Traveller's Point of Entry (TPE) or a Border Control Point (BCP), respectively, where veterinary checks can be undertaken.

Taking into consideration that all the above-mentioned requirements are implemented, the risk of transmission of rabies through the movement of a vaccinated dog is related to the risk of moving a vaccinated animal incubating the disease.

Clarifications of the scope of the request: framework, population and geographical area of concern, definitions

Scope: Recommendations for importation of dogs from countries or zones infected with rabies virus
Geographical area:

- Countries of dog origin: countries or zones infected with rabies virus (OIE) or coming from third countries or territories listed in part I of Annex VIII to Commission Implementing Regulation (EU) 2021/404 for which the specific condition 'rabies antibody titration test' applies.
- Countries of destination: EU countries

Population: **Dogs** over 12 weeks of age, intended to be exported from countries or zones infected with rabies virus and have been subjected (at least 30 days post-vaccination and not more than 12 months prior to shipment, to **antibody titration test** with a positive result of at least 0.5 IU/mL.

Translation of ToRs into assessment questions and subquestions

The main question to be addressed by this Scientific Report is: 'How much does the risk of introduction of rabies into EU increase through the movement of vaccinated dogs with a positive titration test (≥ 0.5 IU/mL) if the waiting period from sampling to movement decreases from 90 to 30 days?'.

The ToRs have been translated into three subquestions, and these subquestions have been further broken into more specific questions:

Subquestion 1: How can we identify vaccinated dogs, with positive results (≥ 0.5 IU/mL) to virus neutralisation test that are incubating rabies before their movement?

Within this subgroup, questions to be discussed and addressed are:

- When do clinical signs of rabies (including death) appear and can be identified through clinal examination? This should be considered after natural and experimental infection, and before and after vaccination.
- When does the production of the neutralising antibodies start following vaccination and natural and experimental infection? How does the titre change over time?
- Are there any reports of dogs with a titre of neutralisation antibodies ≥ 0.5 IU/mL appearing with clinical signs of rabies?

- What is the effect of different vaccination schemes (in terms of the types of the vaccines, the times of vaccination shots and the age of the dogs (e.g. vaccination in puppies < 16 weeks old) on the development of neutralising antibodies in dogs following vaccination?

Method/data: The subquestions can be addressed through literature review including plausible grey literature, and data retrieved from endemic countries that could help with the questions related to natural infection. Expert knowledge from WG members will also be used for answering the questions.

Subquestion 2: Are the results presented in the February 2020 OIE Scientific Commission report, and published in the scientific journal Vaccine, valid?

Within this subgroup, questions to be discussed and addressed are:

- Is the methodology used for the review appropriate (e.g., terms of search, criteria of inclusion and exclusion)?
- Were all relevant publications included in the assessment?
- What are the limitations and strengths of the evidence provided?

Method/data: By a critical appraisal of evidence provided by OIE in the February 2020 OIE Scientific Commission report and published in the scientific journal Vaccine. By including experts contributing to this publication in the WG (as Hearing Experts), EFSA can retrieve further information on the methodology followed in the OIE report.

Subquestion group 3: Were there any cases of infected dogs imported into the EU during the period while the measures described in the EU legislation were in place?

Sub questions:

- Were there any cases of infected dogs imported into the EU after the implementation of these measures?
- Are there any records of the number of dogs imported to EC?
- How many cases of vaccinated and tested for antibodies imported dogs were found to be infected with rabies?
- Are there any cases in the literature of vaccinated and tested positive for neutralising antibodies imported dogs found to be infected with rabies?

Method/data: by analysis of documented/reported cases of rabies in dogs imported into EU in the period between 2019 and 2021. Aside, a literature review of publications on cases of imported infected dogs will be carried out.

Assessing and synthesising evidence (including uncertainty analysis)

Details of the methodology used for the analysis of the data retrieved by the literature review as well as data from other sources will be provided in the methodology section of the opinion.

All sources of uncertainty identified during the assessment will be recorded, and their impact on the scientific assessment will be assessed collectively (the simplest option for this type of assessment (section 4.1 of EFSA Scientific Committee (2018)) after transforming the objective of the assessment into one or several well-defined quantities of interest (QoI). Evidence dossiers will be provided to the experts for their assessment. A lower and upper bound delimiting the range of plausible values for the QoIs will be agreed within the Working Group during a meeting, and the Working Group experts will be asked to provide their individual judgements on the most likely values for each QoI using the roulette method (EFSA, 2014). Individual judgements will be then discussed and used to agree on the 95% percentile of the distribution for each QoI.

Annex I – Legal Requirements

A. OIE Terrestrial Animal Health Code (29th edition 2021) Chapter 8.14 on rabies (version adoption in 2019as they described in article 8.14.7 of Terrestrial Code.

Article 8.14.7.: Recommendations for importation of dogs, cats and ferrets from countries or zones infected with rabies virus.

Veterinary Authorities should require the presentation of an international veterinary certificate complying with the model of Chapter 5.11. attesting that the animals:

1) showed no clinical sign of rabies the day prior to or on the day of shipment;
2) were permanently identified and their identification number stated in the certificate;
3) and either:
    a) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer, with a vaccine that was produced in accordance with the Terrestrial Manual and were subjected not less than 3 months and not more than 12 months prior to shipment to an antibody titration test as prescribed in the Terrestrial Manual with a positive result of at least 0.5 IU/mL; or
    b) were kept in a quarantine station for six months prior to shipment.

B. Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin.

Article 76: The dogs and the cats

1) Consignments of dogs, cats and ferrets shall only be permitted to enter the Union if the animals of the consignment comply with the following requirements:
    a) they have received a vaccination against infection with rabies virus that complies with the following conditions:
        i) the animals must be at least 12 weeks old at the time of vaccination
        ii) the vaccine must comply with the requirements set out in Annex III to Regulation (EU) No 576/2013 of the European Parliament and of the Council (21);
        iii) at the day of dispatch to the Union, at least 21 days must have elapsed since the completion of the primary vaccination against infection with rabies virus;
        iv) a certified copy of the vaccination details must be attached to the animal health certificate referred to in Article 3(1)(c)(i);
    b) they must have undergone a valid rabies antibody titration test, in accordance with point 1 of Annex XXI.
2) By way of derogation of paragraph 1(b), dogs, cats and ferrets originating in third countries or territories or zones thereof included in the list set out in Commission Implementing Regulation (EU) No 577/2013 (22) shall be permitted to enter the Union without being subjected to the rabies titration test.
3) Consignments of dogs shall be permitted to enter into a Member State with disease-free status for Echinococcus multilocularis or an approved eradication programme for infestation with that disease, if the animals of the consignment have been treated against this infestation in accordance with Part 2 of Annex XXI.

Annex XXI:
Specific Requirements As Regards Dogs, Cats And Ferrets Intended For Entry Into The Union

1) Antibody Rabies Titration Test Requirements:

a) must be carried out on a sample collected by a veterinarian authorised by the competent authority during the period commencing at least 30 days after the date of the primary vaccination, within a current valid vaccination series, and ending 3 months before the date of issue of the certificate;
b) must measure a titre of neutralising antibody to rabies virus equal to or greater than 0,5 IU/mL;

c) must be **certified by an official report** from the **official laboratory** as regards the result, and a copy of this report must be attached to the animal health certificate accompanying the animals to the Union;
d) does not have to be renewed on an animal which, following the antibody rabies titration test with satisfactory results, has been revaccinated against rabies within the period of validity of the primary vaccination referred to in point (a) and all subsequent valid vaccinations in the series.

C. Regulation (EU) 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals:

***Article 10*: Conditions applicable to the non-commercial movement 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 territory or a third country unless they fulfil the following conditions:

a) they are marked in accordance with Article 17(1);
b) they have received an anti-rabies vaccination that complies with the validity requirements set out in Annex III;
c) they have undergone a rabies antibody titration test that complies with the validity requirements set out in Annex IV;
d) they comply with any preventive health measures for diseases or infections other than rabies adopted pursuant to Article 19(1);
e) they are accompanied by an identification document duly completed and issued in accordance with Article 26.

1. Annex III:
2. Validity requirements for anti-rabies vaccinations

1) The anti-rabies vaccine must:

a) be a vaccine **other than a live modified vaccine** and fall within one of the following categories:

i) an **inactivated vaccine** of at least one antigenic unit per dose (recommendation from the World Health Organisation); or
ii) a **recombinant vaccine expressing the immunising glycoprotein** of the rabies virus in a live virus vector;

b) where it is administered in a Member State, it must have been granted a marketing authorisation in accordance with:

i) Article 5 of Directive 2001/82/EC; or
ii) Article 3 of Regulation (EC) No 726/2004;

c) where it is administered in a territory or a third country, have been granted an approval or a licence by the competent authority and meet at least the requirements laid down in the relevant part of the Chapter concerning rabies in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health.

2) An anti-rabies vaccination must fulfil the following conditions:

a) the vaccine **was administered by an authorised veterinarian**;
b) the pet animal was at least 12 weeks old at the date on which the vaccine was administered;
c) the date of administration of the vaccine is indicated by an authorised veterinarian or an official veterinarian in the appropriate section of the identification document;
d) the date of administration referred to in point (c) does not precede the date of application of the transponder or tattoo or the date of reading of the transponder or the tattoo indicated in the appropriate section of the identification document;
e) the period of validity of the vaccination starts from the establishment of protective immunity, which shall not be less than 21 days from the completion of the vaccination

protocol required by the manufacturer for the primary vaccination, and continues until the end of the period of protective immunity, as prescribed in the technical specification of the marketing authorisation referred to in point 1(b) or the approval or licence referred to in point 1(c) for the anti-rabies vaccine in the Member State or territory or third country where the vaccine is administered.
The **period of validity of the vaccination** is indicated by an authorised veterinarian or an official veterinarian in the appropriate section of the identification document;

f) a revaccination must be considered a **primary vaccination** if it was not carried out within the period of validity referred to in point (e) of the previous vaccination.

Annex IV: Validity requirements for the rabies antibody titration test

1) The collection of the sample of blood necessary to carry out the rabies antibody titration test must be carried out and documented by an authorised veterinarian in the appropriate section of the identification document;
2) The rabies antibody titration test:
    a) must be carried out on a sample collected at least 30 days after the date of vaccination and:
        i) not less than three months before the date of:
            - the non-commercial movement from a territory or a third country other than those listed in the implementing acts adopted pursuant to Article 13(1) or (2), or
            - the transit through such a territory or third country, where the conditions laid down in point (c) of Article 12 are not fulfilled, or
        ii) before the pet animal left the Union for movement to or transit through a territory or a third country other than those listed pursuant to Article 13(1) or (2); the identification document in the format provided for in Article 21(1) must confirm that a rabies antibody titration test was carried out with a favourable result before the date of movement;
    b) must measure a level of neutralising antibody to rabies virus in serum equal to or greater than 0,5 IU/mL and using a method prescribed in the relevant part of the Chapter concerning rabies in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health;
    c) must be performed in a laboratory approved in accordance with Article 3 of Decision 2000/258/EC;
    d) does not have to be renewed following a satisfactory result described in point (b), provided that the pet animal is revaccinated within the period of validity referred to in point 2(e) of Annex III to the previous vaccination.

Annex II: Documents

OIE Terrestrial Animal Health Code (29th edition 2021) Chapter 8.14 on rabies (version adoption in 2019) (https://www.oie.int/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/)

OIE Terrestrial Manual Chapter, Chapter 3.1.17. on Rabies (version adoption in May 2018) https://www.oie.int/en/what-we-do/standards/codes-and-manuals/terrestrial-manual-online-access/

Commission Delegated Regulation (EU) 2020/6921: Rules for import into the EU (https://eur-lex.europa.eu/eli/reg_del/2020/692/oj)

Commission Delegated Regulation (EU) 2020/689: Rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (https://eur-lex.europa.eu/legal-ontent/EN/TXT/?uri=CELEX%3A32020R0689&qid=1643032540018)

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 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0576&qid=1643032787787)

Commission Delegated Regulation (EU) 2021/404: lists of third countries, territories or zones from which import of products and animals is permitted (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0404&qid=1643224144905)

EFSA Opinion of the Scientific Panel on Animal Health and Welfare (AHAW) on a request from the Commission regarding an assessment of the risk of rabies introduction into the UK, Ireland, Sweden, Malta, as a consequence of abandoning the serological test measuring protective antibodies to rabies. (https://www.efsa.europa.eu/en/efsajournal/pub/436)

Report of the meeting of the OIE Scientific Commission for Animal Diseases (the Commission) 3–7 February 2020 https://www.oie.int/en/what-we-do/standards/standards-setting-process/scientific-commission/#ui-id-2

Report of the meeting of the OIE Terrestrial Animal Health Standards Commission (SCAD) 1-10 September 2020 (https://ec.europa.eu/food/system/files/2020-12/ia_standards_oie_eu_comments_tahsc-report_202012.pdf) https://www.oie.int/en/what-we-do/standards/standards-setting-process/scientific-commission/#ui-id-2

Report of the meeting of the OIE Scientific Commission for Animal Diseases (the Commission) 13–14 September 2021 https://www.oie.int/en/what-we-do/standards/standards-setting-process/scientific-commission/#ui-id-2

Annex A – Literature Review protocol as provided by the contractors

Annex A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2022.7350