EU Animal Health Law and Confined Establishments

FIRST EDITION, FEBRUARY 2024

Guidance Handbook to Implementation of AHL in Zoos

A collaborative project between:

EAZA — European Association of Zoos and Aquaria

easvo

FVE

EAZWV

First Edition

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This Handbook is a living document which will be updated as required.

For the latest version please visit www.eazwv.org/inf_handbook

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European Association of Zoo and Wildlife Veterinarians (EAZWV)
European Association of State Veterinary Officers (EASVO)
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Contributing authors

Allan Muir BVM&S, MSc (Wild Animal Health), MRCVS (**Main Author**)
European Association of Zoos and Aquaria
Plantage Middenlaan 45, 1018 DC Amsterdam, The Netherlands
Currently: Durrell Wildlife Conservation Trust,
Les Augrès Manor, Trinity, JE3 5BP Jersey, Channel Islands

Mads Bertelsen DVM, DVSc, Dipl. ACZM,
Dipl. ECZM (Zoo Health Management)
Copenhagen Zoo
Roskildevej 32, 2000 Frederiksberg, Denmark

Pavel Brávek MVDr
Association of Veterinarians of the Czech Republic
Head of Animal Health Departement-region Vysočina
Rantířovská 22, 586 01 Jihlava, the Czech Republic

Linda Bruins-van Sonsbeek DVM
Rotterdam Zoo
PO Box 532, 3000AM Rotterdam, The Netherlands

Montserrat Coll del Barco, DVM
Secció de Ramaderia i Sanitat Animal de Barcelona
Departament d'Acció Climàtica, Alimentació i Agenda Rural, Generalitat de Catalunya
Dr. Roux, 80,08017 Barcelona, Spain

Michael Fielding BVM&S, MRCVS
Zebra Foundation for Veterinary Zoological Education
7 Mansfield St, Marylebone, London W1G 9NQ, United Kingdom

Rafaela Fiúza DVM, MSci, GPCert, MRCVS
European Association of Zoo and Wildlife Veterinarians
c/o FVE, Avenue de Tervueren 12, B-1040 Brussels, Belgium

Gidona Goodman DVM, MSc (Wild Animal Health), MRCVS
European Association of Zoo and Wildlife Veterinarians
c/o FVE, Avenue de Tervueren 12, B-1040 Brussels, Belgium

Jan de Haan
Netherlands Food and Consumer Product Safety Authority (NVWA)
Catharijnesingel 59, 3511 GG Utrecht, The Netherlands

Sanna Hellström DVM, PhD
Korkeasaari Zoo
Mustikkamaanpolku 12, 00270 Helsinki, Finland

Mirosław Kalicki DVM, PhD
ZOO Gdańsk
Karwieńska 3, 80-328 Gdańsk, Poland

Pavel Kvapil, MVDr, PhD, Dipl. ECZM (Zoo Health Management)
Ljubljana Zoo
Večne pot 70, Ljubljana 1000, Slovenia

Arne Lawrenz DVM, PhD
Der Grüne Zoo Wuppertal
Hubertusallee 30, 42117 Wuppertal, Germany

Alexis Lécu DVM, Dipl. ECZM (Zoo Health Management)
Parc Zoologique de Paris
53 Avenue de Saint Maurice, 75012 Paris, France

William Magnone DVM
Parco Natura Viva
Località Quercia, 37012 Bussolengo VR, Italy

Baptiste Mulot DVM
ZooParc de Beauval
Avenue du Blanc, 41110 St Aignan, France

Alix Ortega DVM
Réserve Africaine de Sigean
19 Hameau du Lac D6009, 11130 Sigean, France

Frank O'Sullivan MVB, MSc
Dublin Zoo
Phoenix Park, Dublin 8, D08 AC98, Ireland

Bente Pedersen, DVM
Official Veterinarian
Veterinary Inspection Unit East
Ministry of Environment and Food of Denmark
The Danish Veterinary and Food Administration,
Stationsparken 31-33, DK 2600 Glostrup, Denmark

Ana Pereira do Vale DVM, MVetSci, PhD
University College Dublin
School of Veterinary Medicine, Veterinary Science Centre Belfield, Dublin 4, Ireland

Cornelia Rossi-Broy, DVM, Dr.
EASVO Board member
BbT (Bundesverband der beamteten Tierärzte-German Federal Association of Official Veterinarians)
Board member - International Affairs
Lentzeallee 97, D- 14195 Berlin, Germany

Contributing authors

Tomasz Rusek
European Association of Zoos and Aquaria
Plantage Middenlaan 45, 1018 DC Amsterdam, the Netherlands

Stephanie Sanderson MA, VetMB, MSc (Wild Animal Health), MRCVS
European Association of Zoo and Wildlife Veterinarians c/o FVE, Avenue de Tervueren 12, B-1040 Brussels, Belgium

Ditte-Mari Sandgreen DVM
Givskud Zoo- Zootopia
Løveparkvej 3, 7323 Give, Denmark

Endre Sós DVM, PhD, Dipl. ECZM (Zoo Health Management)
Budapest Zoo and Botanical Garden
H-1146 Budapest, Állatkerti krt. 6-12, Hungary

Job Stumpel DVM
Wildlands Adventure Zoo Emmen
Raadhuisplein 99, 7811 AP Emmen, Netherlands

Uta Westerhüs DVM
Opel-Zoo
Am Opel-Zoo 3, 61476, Kronberg im Taunus, Germany

Hermann Will DVM
Tiergarten Nürnberg
Am Tiergarten 30, 90480 Nürnberg, Germany

Foreword

Dr. Monique Eloit, Director General of the World Organisation for Animal Health (WOAH)

The World Organisation for Animal Health (WOAH formely OIE) is the intergovernmental organisation responsible for improving animal health worldwide. Under this general mandate, the WOAH is dedicated to ensuring transparency on the situation in relation to animal diseases worldwide, including diseases transmissible to humans; collecting, analysing and disseminating scientific information; providing expertise; and promoting international solidarity on the control of animal diseases. The organisation is also dedicated to guaranteeing the sanitary safety of international trade in animals and animal products; improving food safety from the farm to the abattoir; promoting domestic and wild animal welfare through a science-based approach; and improving the legal framework and resources of national Veterinary Services. Veterinarians have a key role to play in the surveillance and control of animal diseases worldwide, including those transmissible to humans.

Wildlife diseases are a major concern worldwide because shared pathogens not only threaten public and livestock health but also impact the health of wildlife and biodiversity. The surveillance of these diseases is essential in protecting both human and animal health, within the dark light of extant biodiversity crisis and habitat loss. Founded in 1994, the WOAH Working Group on Wildlife provides guidelines on the surveillance and control of wildlife diseases and advises the WOAH on threats to wildlife and biodiversity.

The European Association of Zoo and Wildlife Veterinarians (EAZWV) aims to promote the advancement and dissemination of veterinary knowledge as well as the practical in-the-field skills related to zoo and wild animal management, and in doing so aims to advance the health, welfare, husbandry and conservation of wild animals.

The activities of the EAZWV as well of those of the WOAH, specifically through its Working Group on Wildlife, are complementary, as both bodies have as a goal the improvement of knowledge on wildlife diseases globally, following the One Health Approach. The WOAH provides recommendations on a selected list of relevant diseases affecting wildlife, and encourages Member Countries to report the detection of these diseases thus improving situational awareness across the globe. The role of EAZWV in relation to this is important as it provides information to veterinary professionals and assists them in the detection and prevention of these pathogens.

The Transmissible Diseases Handbook, published for the first time by the EAZWV in 2002, provides an important tool, regularly updated and enhanced, on diseases affecting wildlife. The EAZWV has now partnered with the European Association of Zoos and Aquaria (EAZA) as well as the European Association of State Veterinary Officers (EASVO), a section of the Federation of Veterinarians of Europe (FVE), to deliver a complete overhaul of the legislation chapters in the handbook. The result is the present Guidance Handbook to Implementation of the Animal Health Law in Zoos.

This new contribution is welcome, as regulatory provisions are sometimes complex to interpret in their operational implementation. It is also a further opportunity to emphasize that animal health must be considered holistically, with a continuum between wild animals, domestic animals and their respective environments. In this way, WOAH advocates for better animal health that preserves both human health and biodiversity.

WOAH is delighted to be partnering with EAZWV, EAZA and EASVO for the Guidance Handbook to Implementation of the Animal Health Law in Zoos.

Dr. Monique Eloit, WOAH Director General

Preface

EAZA and EAZWV are proud to present this Guidance Handbook to Implementation of AHL in Zoos as a free resource to the wildlife conservation community and to official veterinarians who work alongside us. Wildlife conservation requires broad cooperation of stakeholders, across all fields and levels. Our two organizations have a proven track record of such collaboration, with Joint EAZA/EAZWV Working Groups contributing to several domains of ex-situ wildlife conservation.

Since the introduction of the EU Animal Health Law through Regulation (EU) 2016/429, our Joint Legislation Working Group has been dedicated to analysing, distilling and compiling the aspects of this new legal framework that impact the health and conservation of wildlife in human care. To ensure a high quality result, we enrolled the expertise of the European Association of State Veterinary Officers, an essential partner in implementation of such legislation.

The result of our collaboration is this Guidance Handbook, with contributions from 27 authors from the three organizations, led by Dr. Allan Muir, currently the Chair of the Joint EAZA/EAZWV Legislation Working Group. This Handbook is a living document that will evolve with the addition of new data, events and legislative changes. Whilst we offer this print version for your convenience and ease of information sharing, please be advised that the most current version of the Handbook's chapters can always be found at the online repository at https://www.eazwv.org/page/inf_handbook.

Endre Ákos Papp, DVM
Vice Director of Zoology, Nyíregyházi Állatpark Nonprofit Kft. (Sosto Zoo)
Chair, European Association of Zoos and Aquaria (EAZA)

MVDr. Pavel Kvapil, PhD, DECZM (ZHM)
Head veterinarian, Živalski vrt Ljubljana, (Ljubljana Zoo)
President, European Association of Zoo and Wildlife Veterinarians (EAZWV)

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Introduction to this Guidance Handbook

Modern zoos and aquariums are centres of education, recreation, research and biodiversity conservation[1], with around 140 million visits occurring annually to EAZA Member zoos and aquariums alone[2].

Within the EU, zoos and aquariums are subject to official veterinary controls which are laid down in EU veterinary legislation. Historically, these controls were primarily governed through Council Directive 92/65/EEC ("Balai Directive"). The Balai Directive set out the animal health conditions governing trade in and imports into the EU of animal species not covered by any other specific EU legislation. However, across EU Member States implementation of the Balai Directive was highly variable – and a 2016 European Commission audit report on five Member States highlighted deficiencies in processes applied as well as a lack of guidance for officials[3].

In March 2016, the EU Member States (EU Council) and the European Parliament adopted Regulation (EU) 2016/429 on transmissible animal diseases, "Animal Health Law" or AHL. The Regulation and its associated legal acts came into force in April 2021 and contain the principles and rules for competent authorities and animal keepers for the prevention and control of listed animal diseases[4]. These new rules repeal and replace much EU veterinary legislation, including the Balai Directive, providing an opportunity to improve understanding of this legislation and its specific requirements to the zoo and aquarium community, competent veterinary authorities and officials, to the benefit of all stakeholders and not least, the animals kept in these establishments.

Handbook aims:

- To improve understanding of Regulation (EU) 2016/429 and its associated legal acts and the requirements laid down for EU-based zoos and public aquariums.
- To facilitate and support coherent and harmonized implementation of Regulation (EU) 2016/429, and its associated legal acts, in the EU-based zoo and public aquarium community.
- To help establish, assist and guide collaborations and partnerships between relevant stakeholders involved in zoo animal health and legislative implementation, including establishment veterinarians, official veterinarians/competent authorities, zoo operators, zoo associations etc.

How to navigate and use this document:

This Handbook is divided into three Sections, which are further divided into Chapters. Most of the Chapters have a similar structure to assist readers in accessing the required information:

- **Chapter contents:** A brief overview of the information contained within that Chapter.
- **Key definitions within the AHL legislation:** A series of legal definitions taken from EU legislation which are of relevance for that Chapter or topic. Additional Handbook Chapters are highlighted where additional information may be found.
- **Guidance and additional recommendations:** Practical guidance on the legislation, its requirements and comments on how these may be implemented in the reality of an EU-based zoo or public aquarium. These parts of the Handbook contain the relevant legislative text for reference. Advice is provided on meeting the legislative requirements. Additional supplementary recommendations are provided in green text boxes.

- **Points for consideration of the competent authority/official veterinarian:** Present in some Chapters, these Handbook areas are designed to assist authorities that audit EU-based zoos and aquariums. These points for consideration are presented in a blue text box and are created to help the competent authority/official veterinarian check whether the legal requirements are met.
- **References:** Sources of further information.

About the Handbook project partners:

EAZA (European Association of Zoos and Aquaria):

Established in 1992, EAZA is the world's largest regional zoo and aquarium association, with over 400 Member institutions (over 330 zoos and aquariums, 12 national and sub-regional zoo associations, other affiliated organisations) in 47 countries, including in 25 EU Member States.

EAZA facilitates cooperation within the European and Western Asian zoo and aquarium community towards the goals of education, research and conservation, centred around the animals in our Members' care. Moreover, EAZA builds capacity in advocacy, lobby, and consultancy across the professional areas assigned to zoos by the EU Zoos Directive (Council Directive 199/22/EC). Membership in EAZA is based on strict accreditation requirements and binding Standards.

EAZWV (European Association of Zoo and Wildlife Veterinarians):

EAZWV is a membership organisation representing European veterinarians and committed to "help vets help wildlife" by improving the health, welfare and conservation of wildlife through advancements in zoo and wildlife medicine and promotion of the full and proper use of specialist wildlife veterinary expertise in the management of both captive and free-ranging wildlife. EAZWV has over 600 members representing 55 countries, mostly EU Member States.

FVE (Federation of Veterinarians of Europe):

FVE is the umbrella body for veterinary associations from 40 European Countries. FVE represents, through its Sections, veterinarians working in different fields of the profession, such as veterinary practitioners (UEVP), state officers (EASVO), food safety and veterinary public health (UEVH) and veterinarians working in education, research and industry (EVERI).

EASVO (European Association of State Veterinary Officers):

Founded in 1980, this FVE section represents veterinary inspectors, most of whom are employed in State Veterinary Services. They are involved in national disease eradication programmes, the protection of public health and food or animal inspection. Some are employed at border inspection posts, checking the health and certificates of imported and exported animals or products of animal origin. They may also help to elaborate or implement legislation regarding these domains or work in state veterinary laboratories. In this way, Veterinary Officers play an important role in the eradication and prevention of disease in animals and in

the protection of public health on a national and European level. They are also called to advise the government and work in conjunction with practicing veterinarians in case of notifiable disease outbreaks.

References

1. European Commission. *EU Zoos Directive Good Practices Document*. (2015). doi:10.2779/247108.
2. Gusset, M. & Dick, G. The global reach of zoos and aquariums in visitor numbers and conservation expenditures. *Zoo Biology* **30**, 566–569 (2011).
3. European Commission. *Overview report Animal Health Controls in Zoos and Laboratories*. (2016) doi:10.2772/56814.
4. Dries, L., Heijman, W., Jongeneel, R., Purnhagen, K. & Wesseler, J. *EU Bioeconomy Economics and Policies: Volume I*. vol. II (2019).

Section 1:

EU Animal Health Law and confined establishments

Chapter 1.1. The EU Animal Health Law

What is the EU Animal Health Law?

Regulation (EU) 2016/429 on transmissible animal diseases, also known as 'EU Animal Health Law', was adopted by the European Parliament and the Council in March 2016, and became applicable in all EU Member States on 21 April 2021.

Animal Health Law (AHL) is a single comprehensive framework law designed to support the EU animal sector towards competitiveness and safe and efficient movement of animals and their products. AHL repeals, streamlines, and replaces a large number of legal acts into a single law. Through this streamlining, the AHL aims to provide:

- Simpler and clearer rules to enable authorities and those having to follow the rules to focus on the key priorities of preventing and eradicating diseases,
- Clarified responsibilities for farmers, veterinarians and others dealing with and keeping animals,
- Rules that allow greater use of new technologies for animal health activities e.g., surveillance of pathogens, electronic identification and registration of animals,
- Better early detection and control of transmissible animal diseases, including emerging diseases and diseases which may be linked to climate change, will help to reduce the occurrence and effects of animal epidemics,
- More flexibility to adjust these rules to local circumstances and situations, and to emerging issues such as climate and social change.

What does the AHL cover?

AHL concerns transmissible animal diseases (i.e., infectious animal diseases that can pass from animal to animal or to humans) and where efforts need to be taken by the EU as a whole. It provides principles and rules for the prevention and control of such diseases in animals kept by humans, wild animals (i.e., free-living animals) and certain animal products.

These rules consist of requirements for disease prevention, awareness, surveillance, control and eradication; biosecurity; traceability of animals and animal products; movements within the EU and entry into the EU of animals and animal products; as well as emergency measures. These rules are aimed at diseases listed in the Regulation, as well as emerging diseases. Listed diseases can be found in Commission Implementing Regulation (EU) 2018/1882.

This AHL does not provide rules on animal welfare, although it does recognise that animal health and welfare are linked and requires that animal welfare is taken into account when considering the impacts of diseases and disease control measures. Other important areas such as EU veterinary expenditure, authorization and use of veterinary medicines or medicated feed, veterinary education, official controls are outside the scope of the AHL.

Delegated and Implementing Acts

The AHL empowers the European Commission to adopt a number of Delegated and Implementing Acts to make the new rules applicable in practice and to provide more details on specific areas of governance.

These Delegated and Implementing Acts are crafted with experts from all EU Member States and with input from stakeholder groups.

Delegated Acts supplement or amend basic EU laws, including AHL. These supplementations or amendments cannot change the essential elements of the law itself, and need to define the content, scope and objectives and duration of the delegated power.

Implementing Acts provide the uniform conditions and requirements for the implementation of the basic EU law by Member States.

It may be useful to view the AHL framework law as an umbrella, with the subsequent Delegated and Implementing Acts slotted under it, governing respective areas.

Important Delegated and Implementing Acts for confined establishments:

There are a number of Delegated and Implementing Acts, linked to the AHL, which are particularly important for confined establishment operators and their staff, as well as the competent authorities overseeing these establishments (for further information on the definition and work of confined establishments in the EU, see Chapter 1.2.):

- Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards **rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs.**

- Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards **animal health requirements for movements within the Union of terrestrial animals and hatching eggs.**

- 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.**

- Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the **approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals.**

- Commission Delegated Regulation (EU) 2020/691 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards **rules for aquaculture establishments and transporters of aquatic animals.**

- Commission Delegated Regulation (EU) 2020/990 of 28 April 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards **animal health and certification requirements for movements within the Union of aquatic animals** and products of animal origin from aquatic animals.

- **Commission Implementing Regulation (EU) 2021/403** of 18 March 2021 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards **model animal health certificates and model animal health/official certificates, for the entry into the Union and movements between Member States** of consignments of certain categories of **terrestrial animals and germinal products** thereof, official certification regarding such certificates and repealing Decision 2010/470/EU.

- **Commission Implementing Regulation (EU) 2018/1882** of 3 December 2018 on the application of certain disease prevention and control rules to **categories of listed diseases and establishing a list of species and groups of species** posing a considerable risk for the spread of those listed diseases.

Chapter 1.2. What is a confined establishment?

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Introduction

From their beginnings in the 18th century to the present day, European zoos and aquariums have transitioned and evolved from being menagerie-type attractions where a key focus was placed upon the exhibition of a diverse collection of animals, towards conservation centres working towards the missions of education and public awareness, science and research, and the conservation of biodiversity[1].

This development over time has shaped the community of zoos and aquariums based in the EU and further afield, as well as the ongoing collaboration, that exists between many institutions that we see today. In turn, legislation and policy, at both the national Member State and the EU level, has been formed and implemented to regulate and place controls on the work of zoos and aquariums in the EU. Asides from AHL, much further information on EU legislation relevant to the work of zoos and aquariums can be found in Chapter 1.3.

Zoo licenses are issued for the purposes of operation and being open to the public and are based upon the requirements laid down in the EU Zoos Directive (Council Directive 1999/22/EC). However, the number of zoos and aquariums present and operating within the EU, currently remains unquantified, as the Zoo Directive contains no EU or national reporting or recording mechanism. However, some groups estimate that up to 3,000 zoo-licensed facilities exist within the EU[2].

The European Association of Zoos and Aquaria (EAZA) is the world's largest regional zoo association. EAZA's membership is composed of approximately 340 zoological facilities, 240 of which are located in the European Union. Across the entire EAZA membership, some 2.4 million individual animals of approximately 9,800 different animal species are kept (data taken in October 2023 from the Zoological Information Management System (ZIMS), a centralized animal registry database provided by Species360 which is used by EAZA Members).

This chapter will focus on the definition of a confined establishment which keeps terrestrial animals, i.e., zoos, wildlife parks and safari parks, and introduce the work these institutions undertake within the EU. Chapter 2.2 covers the approval process and requirements for confined establishment status.

Key definitions from the AHL legislation

Term	Definition	Legal definition source	Where to find further information in this Handbook
'confined establishment'	means any permanent, geographically limited establishment, created on a voluntary basis and approved for the purpose of movements, where the animals are: a) kept or bred for the purposes of exhibitions, education, the conservation of species or research; b) confined and separated from the surrounding environment; and c) subject to animal health surveillance and biosecurity measures.	Def. 48, Art. 4 2016/429	Chapter 1.2

Guidance and additional recommendations

The following section provides further information on the work of the modern zoo community in Europe, with a focus on those institutions which are accredited by EAZA.

1. Confined establishment: an important definition

The definition of a confined establishment is an important one, analogous but not identical, to the definition of an '*approved body, institute or centre*' laid down in the previous, and now repealed Balai Directive (Council Directive 92/65/EEC).

It is important to realize that **not all EU-based licensed zoos, safari parks or wildlife parks are confined establishments** as per its definition. Approval is an essential part to the label of being a confined establishment, and this process is entirely voluntary on the part of the establishment. The approval procedures are described in Chapter 2.2 of this Handbook. In addition to approval, the confined establishment must be in a defined and fixed geographic location and cannot be transient or nomadic in nature.

Confined establishment status is linked to the ability to move kept terrestrial animals to confined establishments located in other EU Member States. This ability to move or transfer animals between confined establishments is key to the work and success of many e*x situ* population management programs (see EAZA Ex situ Programme section below).

The animals kept by the confined establishment also need to be kept with specific purpose or focus. This adds further nuance to this definition; they should only be kept for the purposes of exhibition, education, species conservation or research. Therefore, an establishment keeping animals for the human food chain cannot be considered a confined establishment.

The animals kept by the confined establishment need to be kept separated from the environment surrounding the facility and be subject to animal health surveillance and biosecurity controls (see Chapters 2.2 and 2.3 for more information on these areas).

2. Ex situ conservation

Ex situ conservation forms the basis of Article 9 of the Convention on Biological Diversity (CBD), which highlights that it should always be implemented as a complementary (and not as an alternative) approach to *in situ* conservation.

The IUCN Species Survival Commission Guidelines on the Use of Ex situ Management for Species Conservation define 'ex situ' as: *conditions under which individuals are spatially restricted with respect to their natural spatial patterns or those of their progeny, are removed from many of their natural ecological processes, and are managed on some level by humans*[3].

With this in mind, ex situ conservation has the potential to[3]:

- ***Address the causes of primary threats:*** *Ex situ* activities can help reduce primary threats such as habitat loss, exploitation, invasive species or disease when specifically designed conservation research, conservation training or conservation education activities directly and effectively impact the causes of these threats (e.g., training in the recognition of specific life stages or gender characteristics for preferential exploitation, education to limit the spread of an invasive species, or research into disease epidemiology or treatment).
- ***Offset the effects of threats:*** Ex situ activities can improve the demographic and/or genetic viability of a wild population by ameliorating the impacts of primary or stochastic threats on the population. Small populations that are vulnerable to primary threats and stochastic processes may require some form of intensive management of individuals and populations to improve demographic and genetic viability and avoid extinction. Challenges faced by small populations (e.g., reduced survival, reduced reproduction, decreased population size, and genetic isolation) can be counteracted by a range of population management options, such as head start programmes to address high juvenile mortality, or population reinforcement to balance age and sex distribution.
- ***Buy time:*** Establishment of a diverse and sustainable ex situ rescue or insurance population may be critical in preventing species extinction when wild population decline is steep and the chance of sufficiently rapid reduction of primary threats is slim or uncertain or has been inadequately successful to date. Examples include ex situ populations in response to severe disease threat, catastrophic events or continued habitat degradation.
- ***Restore wild populations:*** Once the primary threats have been sufficiently addressed, ex situ populations can be used for population restoration (reinforcement or reintroduction) or conservation introduction (assisted colonisation or ecological replacement). Such reintroductions should follow relevant codes of practice, such as IUCN Guidelines for Reintroductions and Other Conservation Translocations[4] and the OIE/IUCN Guidelines for Wildlife Disease Risk Analysis[5].

3. What is the European Association of Zoos and Aquaria (EAZA)?

EAZA was established in 1992, and today is the world's largest regional zoo and aquarium association. The membership of EAZA is comprised of over 400 institutions, made up of over 330 zoos and aquariums, 12 national and subregional zoo associations and other affiliated organisations. EAZA Members are based in and operate across some 47 countries, with 25 of these being EU Member States.

EAZA facilitates cooperation between the most progressive zoos and aquariums primarily located within Europe and Western Asia. Initial cooperation was based on population management of non-domestic

species (see EEP section below). Inter-institution collaboration has since grown and now encompasses many more aspects, including:

- Enabling the health, husbandry and welfare of the animals in EAZA Members care
- Protecting species through professional management of ex situ populations
- Contributing to in situ conservation through the provision of funding and expertise
- Providing a greater learning experience for visitors, and better sensitizing them to the need for sustainability and conservation
- Developing specialist skills through specialized sector-specific training
- Collaborating on research projects in zoology and other disciplines, both with other zoos and aquariums and with universities and other research partners

Work towards the primary goals of EAZA, i.e., facilitating research, education and biodiversity conservation, is centred around the animals in EAZA Members' care. Membership in EAZA, for those institutions keeping animals, is based upon a system of accreditation, on-site facility inspections as well as adherence to internal binding standards covering multiple zoo-related topics. These internal standards and procedures to which EAZA Members must comply to are freely available on the EAZA website.

4. EAZA Ex-situ Programmes (EEPs)

EAZA Ex-situ programmes (EEPs) are defined as population management programmes that are endorsed by EAZA, for species that are managed by EAZA Members, aiming towards maintaining healthy populations of healthy animals.

EEPs have tailor-made conservation roles and goals. The acquisition of new animals and the regular exchange of animals between and beyond EAZA Members is essential when realizing healthy, demographically and genetically sustainable populations. All EEP animals leaving an EAZA accredited institution should go to appropriate facilities with professional standards e.g., under the care of skilled staff who are capable of ensuring adequate animal husbandry and welfare.

Figure 1: EAZA Ex situ Programme (EEP) logo

The very first EEPs were founded in 1985. Individual zoos participating in an EEP are given breeding or non-breeding recommendations for certain individuals in order to maintain genetic diversity in the population, avoid inbreeding and manage the population from a demographic perspective. Young animals bred at an institution are placed by the EEP in unrelated pairings or social groups to maximise the genetic diversity of their future offspring. Currently, approximately 400 different animal species form EEPs in EAZA, the majority of which are threatened by extinction within their home ranges[6].

As of January 2018, a new population management structure was implemented across EAZA, taking inspiration from the IUCN SSC Conservation Planning Specialist Group's 'One Plan Approach'[7] and the IUCN SSC Guidelines on the Use of Ex Situ Management for Species Conservation[3]. Briefly, this new framework in EAZA, is linked to three areas of work:

- **Regional Collection Planning (RCP)** – where species are evaluated and recommended, or otherwise, to be managed under an EEP, with each EEP then receiving precise and tailored conservation goals and roles e.g. insurance population, educational role, reintroduction population etc. This process involves

internal and external experts from across the *ex situ* and *in situ* conservation community that work together as intended in the One Plan Approach.

- **EAZA Ex situ Programmes (EEP)** – species that have a clear role(s) and goal(s), and where it is feasible for EAZA members to contribute to the delivery of these, will become part of an EEP. Well over 80% of the EEPs have at minimum one direct conservation role as described in the IUCN SSC Guidelines on the Use of Ex Situ Management for Species Conservation. An appointed EEP Coordinator and elected EEP Species Committee will take on responsibility to manage the population held across the membership. All EEPs must also appoint a veterinary advisor that is a member of the EEP Species Committee.
- **Long term Management Plans (LTMPs)** – at regular intervals an LTMP is produced for every established EEP. Following from the precise role(s) and the biological characteristics of the EEP as defined in the RCP, the LTMP more precisely defines the long term genetic and demographic goals for the programme and stipulates an action plan with all the strategies and activities (e.g. demographic and genetic management) to be implemented in a defined time period in order for the EEP to stay on target in reaching its roles and goals as defined in the RCP.

5. Zoo population health and the role of legislation

Animal Health Law and its associated legislative acts, when fully understood and implemented effectively, have the potential to form a basis for the harmonization and improvement of zoo animal health in the EU.

This improvement in health may be observed at different levels: for example, at the level of the individual confined establishment, at the level of confined establishments nationally within a Member State or more broadly at the EU level. This basis may then have subsequent positive indirect impacts on animal welfare and species conservation.

The Handbook authors would suggest the success of these outcomes are founded on several key principles:

- **Effective working relations** between the establishment veterinarian and the official veterinarian/competent authority. This should be founded upon good communication and transparency working towards shared common goals.
- **Acknowledging and understanding the different responsibilities** of each party involved, whether that be the operator of the confined establishment, the establishment veterinarian, and the official veterinarian/competent authority.
- **Effective communication within the confined establishment** between all responsible animal care staff and the establishment veterinarian.
- **Knowledgeable and experienced animal care staff** understanding the signs of ill health in the animals under their care.
- **Understanding the legislative requirements**, particularly surrounding
    - Approval (see Chapter 2.2)
    - Disease surveillance (see Chapter 2.3)
    - Animal movements (see Chapter 2.4)

References

1. Minteer, B. A., Maienschein, J. & Collins, J. P. Zoo and Aquarium Conservation : Past, Present and Future. In *The Ark and Beyond: the evolution of zoo and aquarium conservation* 1–12 (University of Chicago Press, 2018). Doi:10.7208/9780226538631.

2. Endcap. *The EU Zoo Inquiry 2011: an evaluation of the implementation and enforcement of EC Directive 1999/22, relating to the keeping of animals in zoos.* (2011).

3. IUCN/SSC. IUCN Species Survival Commission Guidelines on the Use of Ex Situ Management for Species Conservation. Version 2. 1–7 (2014).

4. IUCN/SSC. *Guidelines for Reintroductions and Other Conservation Translocations*. https://portals.iucn.org/library/sites/library/files/documents/2013-009.pdf (2013).

5. OIE/IUCN. *Guidelines for Wildlife Disease Risk Analysis.* https://portals.iucn.org/library/sites/library/files/documents/2014-006.pdf (2014).

6. EAZA. *EAZA Ex-situ Programme overview*. (2020).

7. Byers, O., Lees, C., Wilcken, J. & Schwitzer, C. The One Plan approach: The philosophy and implementation of CBSG's approach to integrated species conservation planning. *WAZA magazine* **14**, 2–4 (2013).

Chapter 1.3. Other EU legislation applicable to zoos

Chapter contents

Introduction

Zoos and aquariums located within the European Union are required to follow a number of EU laws in addition to those laid down by the Animal Health Law and its associated legal acts. These additional rules and requirements cover operation and work areas such as: zoo licensing to promote conservation and permit public admission, wildlife trade rules on those species whose survival is threatened by trade, and invasive alien species.

This chapter aims to briefly introduce these pieces of EU law with the aim of providing readers with a wider understanding of the rules applicable to EU zoos and aquariums.

Additional legislation

The following section provides further information on the other pieces of EU legislation which are applicable to zoos and aquariums.

1. EU Zoos Directive

Council Directive 1999/22/EC relating to the keeping of wild animals in zoos.

What are the aims of the Directive?

- It promotes wild animal species protection and conservation by strengthening the role of zoos in the conservation of biodiversity.
- It includes rules for the licensing and inspection of zoos to ensure they respect the required conservation and protection measures.

Key Points

Scope:

- A 'zoo' is defined as a permanent establishment where live wild animals are kept on public display for 7 days per year or more.
- EU countries can exempt certain establishments from the Directive if they do not display a significant number of animals or species to the public and if this exemption does not undermine the objectives of the Directive.

Conditions:

The Directive requires EU countries to take measures concerning the granting of licenses and the carrying out of regular inspections in zoos to check that the conditions required for their granting are met.

EU Member States must ensure that zoos:

- participate in research whose results benefit the preservation of species, and/or in training in relevant conservation skills and/or in exchange of information on the conservation of species and/or in reproduction in captivity (repopulation, reintroduction of species into the wild, etc.);
- promote public education and awareness in relation to the conservation of biodiversity, particularly by providing information about the species exhibited and their natural habitats;
- accommodate their animals under conditions that satisfy the biological and conservation requirements of the individual species by:
    - providing species-specific enrichment of the enclosures, and
    - maintaining a high standard of animal husbandry with developed programmes of preventive and curative veterinary care and nutrition;
- prevent animals from escaping to avoid possible ecological threats (e.g., invasive alien species) to indigenous species, as well as to prevent the intrusion of outside pests;
- keep up-to-date records of the animals in the establishment which vary according to the species.

Licensing and inspection:

- EU countries must adopt rules for licensing and inspecting zoos to ensure that the required conservation measures are met.
- All zoos must hold a valid license.
- Each license contains conditions to enforce the necessary conservation and protection measures.
- Member State competent authorities must carry out an inspection before granting, refusing, extending or substantially modifying a license.
- If a zoo does not completely or partially comply with the legal requirements, the competent authority must bar public access to the zoo in its entirety or to the part of it that is concerned.
- In the event of a partial or complete closure of a zoo, the animals involved must be treated or disposed of under conditions that the EU country concerned judges appropriate and compatible with the rules of the Directive.

Evaluation:

In 2015, the European Commission published the EU Zoos Directive Good Practices Document. This document, available in 22 EU languages, is designed to help EU countries improve compliance with the Directive through the sharing of experience and good practice.

In November 2018, the Commission published the results of a several-year long evaluation of the Directive. It declared that the Directive was still fit for purpose and provided EU added value – but it was not fully and equally implemented across Member States.

2. EU Wildlife Trade Regulation

Council Regulation 1997/338/EC on the protection of species of wild fauna and flora by regulating trade therein (base regulation) and additional implementing regulations.

What are the aims of the Regulation?

- The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) should be implemented uniformly in all EU countries, in view of the EU's single market and the absence of border controls.
- CITES is implemented in the EU through EU wildlife trade regulations. EU countries apply rules on the import and export of endangered species of animals and plants, and products derived from them.

Key Points

Trade controls:

- The import of specimens of endangered species into the EU requires a permit issued by an authority of the EU country of destination or an import notification.
- Export from the EU requires an export permit or a re-export certificate issued by an authority of the EU country in which the specimens are located.
- Categories of species are outlined in Annexes A to D of the regulation.
- Trade in species listed in Annex A are prohibited, while movement of live animals within the EU requires prior authorisation.
- Movement of a live specimen of a species listed in Annexes B and C, are subject to rules on certification and adequate housing and care, while Annex D covers other cases of the transit of live animals, whole skins and plant products.
- Further restrictions may be imposed in specific circumstances, and EU countries may have their own tougher rules.
- Special rules apply to specimens born and bred in captivity or that are the result of artificial reproduction, part of personal effects or destined for scientific institutions.

EU countries must:

- designate customs offices to carry out the checks;
- designate the management and scientific authorities responsible for implementation;
- monitor compliance and penalise infringements;
- draw up reports and exchange information on implementation and any permit rejections.

3. EU Invasive Alien Species (IAS) Regulation

Regulation (EU) 1143/2014 of the European Parliament and of the Council on the prevention and management of the introduction and spread of invasive alien species.

What is the aim of the Regulation?

- It sets out rules to prevent and manage the introduction and spread of invasive alien species in the EU.
- It seeks to minimise and mitigate the adverse effects of IAS on EU biodiversity and ecosystems, as well as on human health and the economy.
- It empowers the European Commission to adopt, with Member States' consent, a list of IAS of Union Concern.

Key Points

List of invasive alien species of Union concern

- On 13 July 2016, the European Commission adopted its first list of IAS of 'Union concern'.
- The list is based on scientific risk assessments, is updated regularly and reviewed at least every 6 years. The list has already been updated three times.
- Species on this list may not be intentionally brought into the EU's territory. Nor may they be kept, bred, transported to, from or within the EU, sold, grown or released into the environment.

Permits

- EU countries may issue permits to allow research, ex situ conservation and medicinal use of the species listed as IAS of EU concern. For any other uses, EU countries wishing to issue permits first need to seek the Commission's authorisation.
- The IAS in question must be kept and handled in contained holding and transported under conditions that preclude their escape.
- Within 3 years of the listing of a species, EU countries must establish and implement National Action Plans to address priority pathways. This is to prevent the unintentional introduction and spread of IAS of EU concern in their territory.

In addition, for further information on the role of European zoos and IAS, see the Council of Europe's Code of Conduct on 'Zoological gardens and aquaria and invasive alien species'.

4. EU Animal By-Products Regulation(s)

Regulation (EC) 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption, and,

Commission Regulation (EU) 142/2011 of 25 February 2011 implementing Regulation (EC) 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption.

What is the aim of the Regulation?

- It seeks to lay down public health and animal health rules for animal by-products and derived products.
- These rules are designed to prevent and minimise risks to human and animal health, and to ensure the food and feed chain is kept safe.

Key Points

The legislation applies to:

- animal by-products and derived products which, by law, may not be used for human consumption;
- animal-origin products which may be used for human consumption but are instead used for other purposes;

Zoo relevance:

- This Regulation prevents carcasses of zoo animals (Category 1 material) from entering the human food chain;
- It also permits, through a derogation, the feeding of zoo animal carcasses to other zoo animals, this feeding however is under the oversight of the competent authority and undertaken with the requirements laid down in Annex VI Chapter II Section 4 of Commission Regulation (EU) 142/2011.

Section 2:

Terrestrial animals, animal movements and approval of a confined establishment

Chapter 2.1. Terrestrial animals: defining species

Chapter contents

- Introduction
- Key definitions from the AHL legislation
- Guidance and additional recommendations
    1. What is a terrestrial animal?
    2. What is a kept animal?
    3. What parts of the AHL apply to terrestrial animals compared to taxon-specific requirements?

Introduction

European zoos and public aquariums keep a vast array of different animal species. This diversity of life encompasses species from the classes of Mammalia, Aves, Reptilia, Amphibia as well as bony, cartilaginous and jawless fishes (Osteichthyes, Chondrichthyes and Agnatha respectively) and invertebrate species.

This diversity can present some practical challenges when it comes to understanding which species fall inside and outside the scope of specific veterinary legislation. Additional confusion may exist for non-domestic zoo kept species which have domestic livestock relatives, for example banteng (*Bos javanicus*) and mouflon (*Ovis gmelini*).

This chapter aims to highlight and explain some key definitions in the Animal Health Law and when those definitions can be applied to animals kept within a confined establishment. Additionally, the animal species which fall outside of the Regulation will be described.

Future chapters of this Handbook will explain and provide guidance on the AHL terms 'aquatic animals' and 'confined aquaculture establishments'.

Key definitions from the AHL legislation

Term	Definition	Legal definition source	Where to find further information in this Handbook
'animals'	means vertebrate and invertebrate animals	Def. 1, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species
'terrestrial animals'	means birds, terrestrial mammals, bees and bumble bees	Def. 2, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species Chapter 2.2 Approval of confined establishments in the EU

'aquatic animals'	means animals of the following species, at all life stages, including eggs, sperm and gametes: a) fish belonging to the superclass *Agnatha* and to the classes *Chondrichthyes*, *Sarcopterygii* and *Actinopterygii*; b) aquatic molluscs belonging to the phylum *Mollusca*; c) aquatic crustaceans belonging to the subphylum *Crustacea*;	Def. 3, Art. 4 2016/429	Future chapter
'other animals'	means animals of species other than those falling within the definition of terrestrial or aquatic animals;	Def. 4, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species
'kept animals'	means animals which are kept by humans, including, in the case of aquatic animals, aquaculture animals;	Def. 5, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species
'wild animals'	means animals which are not kept animals;	Def. 8, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species
'bovine animal'	means an animal of the species of ungulates belonging to the genera *Bison*, *Bos* (including the subgenera *Bos*, *Bibos*, *Novibos*, *Poephagus*) and *Bubalus* (including the subgenus *Anoa*) and the offspring of crossings of those species	Def 4, Art. 3 2020/688	Chapter 2.4 Movements into and between confined establishments in the EU
'camelid animal'	means an animal of the species of ungulates belonging to the family *Camelidae* listed in Annex III to Regulation (EU) 2016/429	Def 15, Art. 3 2020/688	Chapter 2.4 Movements into and between confined establishments in the EU
'caprine animal'	means an animal of the species of ungulates belonging to the genus *Capra* and the offspring of crossings of those species	Def 12, Art. 3 2020/688	Chapter 2.4 Movements into and between confined establishments in the EU

'captive bird'	means any birds other than poultry that are kept in captivity for any reason other than those referred to in point (9), including those that are kept for shows, races, exhibitions, competitions, breeding or selling	Def 10, Art. 4 2016/429	Chapter 2.4 Movements into and between confined establishments in the EU
'cervid animal'	means an animal of the species of ungulates belonging to the family *Cervidae* listed in Annex III to Regulation (EU) 2016/429	Def 16, Art. 3 2020/688	Chapter 2.4 Movements into and between confined establishments in the EU
'equine animal'	means an animal of species of solipeds belonging to the genus *Equus* (including horses, asses, and zebras) and the offspring of crossings of those species	Def 14, Art. 3 2020/688	Chapter 2.4 Movements into and between confined establishments in the EU
'hatching eggs'	means eggs, laid by poultry or captive birds, intended for incubation;	Def. 44, Art. 4 2016/429	Chapter 3.1 Germinal products: collection, movement, and EU entry
'porcine animal'	means an animal of the species of ungulates belonging to the family *Suidae* listed in Annex III to Regulation (EU) 2016/429;	Def 13, Art. 3 2020/688	Chapter 2.4 Movements into and between confined establishments in the EU
'primates'	means animals of the species belonging to the order Primates excluding humans	Def. 12, Art. 2 2019/2035	Chapter 2.2 Approval of confined establishments in the EU
'ovine animal'	means an animal of the species of ungulates belonging to the genus *Ovis* and the offspring of crossings of those species	Def 11, Art. 3 2020/688	Chapter 2.4 Movements into and between confined establishments in the EU

Guidance and additional recommendations

The following section provides further information on some key processes and definitions associated with confined establishment approval.

1. What is a terrestrial animal?

A terrestrial animal is defined in the AHL legislation as 'birds, terrestrial mammals, bees and bumblebees'. This definition would therefore apply to the following orders of commonly kept zoological species:

- Primates
- Artiodactyla
- Perissodactyla
- Proboscidea
- Rodentia and Lagomorpha
- Carnivora
- Xenarthra
- Monotremes and marsupials
- All avian species
- Chiroptera
- Insectivora
- Bees and bumblebees (i.e., *Apis* and *Bombus* spp.)

However, this definition would **not** cover:

- Mammals living entirely within aquatic environments (e.g., Cetacea, Sirenia)
- Reptilian spp.
- Amphibian spp
- Terrestrial invertebrate spp.

Fish, crustaceans and molluscs will be considered separately in a future chapter to this Handbook, as these animals fall under the definition of an 'aquatic animal'.

Animal species outside of the scope of the definitions of a terrestrial animal and/or an aquatic animal, are termed a 'other animal' under the AHL.

Additional recommendations:

We would advise the inclusion of species of the order Pinnipedia (i.e., Odobenidae (walruses), Otariidae (fur seals and sea lions) and Phocidae (true seals) **within** the terrestrial animal definition, particularly with regards to the disease surveillance plan in the confined establishment.

2. What is a kept animal?

AHL makes a clear difference between those animals which are 'kept' and under the care of humans, and those which not – and are thus 'wild' or free-living. The definition of kept animal or wild animal does not relate to whether or not a species is domesticated, but whether it exists under free-living conditions or under human care.

Therefore, a chimpanzee (*Pan troglodytes*) kept in an EU-located confined establishment could fall under the AHL definition of being a 'kept animal', a 'terrestrial animal' and a 'primate' but not as a 'wild animal'. Whilst a West Indian manatee (*Trichechus manatus*) kept in an EU-located confined establishment would be a 'kept animal' but would fall into the category of being an 'other animal' and hence be outside the scope of the AHL requirements for a 'terrestrial animal' and 'aquatic animal'.

3. *What parts of the AHL apply to terrestrial animals compared to taxon-specific requirements?*

The following table summarises when an AHL-related process within a confined establishment is associated with all kept terrestrial animals or when specific species requirements are laid down:

AHL-related process	Do these requirements link to all 'terrestrial animal' species or are there species-specific requirements?		Further Handbook information
	Terrestrial animals	Species-specific	
Approval of a confined establishment in the EU	✓		Chapter 2.2 Approval of confined establishments in the EU
Design and implementation of a disease surveillance plan within a confined establishment	✓		Chapter 2.3 Disease surveillance planning in a confined establishment
Animal movement between two confined establishments located in different Member States	✓		Chapter 2.4 Movements into and between confined establishments in the EU
Animal movement from a non-approved source into a confined establishment in a different Member State		✓ Taxon-specific requirements laid down for: • Primates • Bovine animals • Ovine/caprine animals • Porcine animals • Equine animals • Carnivores • Other ungulate spp. • Camelids • Cervids • Captive birds/hatching eggs	Chapter 2.4 Movements into and between confined establishments in the EU Chapter 3.1 Germinal products: collection, movement, and EU entry (for hatching eggs from captive birds)
Animal movement from a third country confined establishment to an EU-based confined establishment		✓ Requirements only laid down for ungulate species	Chapter 2.7 Terrestrial animal entry into the EU
ID requirements of animals kept in a confined establishment	✓		Chapter 2.5 Terrestrial animal identification and record keeping
Record keeping obligations for animals kept in a confined establishment	✓		Chapter 2.5 Terrestrial animal identification and record keeping

Chapter 2.2. Approval of confined establishments in the EU

Chapter contents

Introduction

Approval of establishments, for the purposes of moving animals between different Member States, is an important concept within the EU Animal Health Law and its associated implementing and delegated acts. Historically, the approval system laid down by Council Directive 92/65/EEC has greatly facilitated the movement of and exchange of many non-domestic species whose conservation status is dependent on the work of the modern European zoo community (see Chapter 1.2). Approval under Animal Health Law contains some changes in terms of procedures and requirements when compared to Council Directive 92/65/EEC.

Competent veterinary authority approval is an intrinsic part of the Animal Health Law's definition of a 'confined establishment', however the decision to undergo approval is entirely voluntary on the part of the establishment operator and is not a legal obligation. Approval recognizes and requires establishments to have high levels of biosecurity, animal disease surveillance as well as appropriate facilities, policies, record keeping, and veterinary provision for the maintenance of animal health.

Approved confined establishments can trade and exchange animals with other EU-based confined establishments; these movements are subject to fewer official movement requirements, compared to the movement of domestic animal species from lower health or biosecurity status establishments. This closed system of exchanges within the confined establishment community, also provides for some guarantees on the health status of those animals living within and moving between different confined establishments, whether they are located within the same or different EU Member States. Approval importantly also grants a confined establishment the exclusive right to receive and send non-human primate species to other EU Member States.

This chapter will focus on the approval of confined establishments keeping terrestrial animals, i.e., zoos, wildlife parks and safari parks.

A future chapter will cover approval of public aquariums, which may fall under the AHL definition of a 'confined aquaculture establishment'.

Research facilities may also fall within the scope of the definition of a confined establishment in this legislation but are not covered within this Guidance Handbook.

Important note:

Establishments already approved under the Annex C requirements of Council Directive 92/65/EEC, so called Approved Bodies, Institutes or Centres (ABICs), do not need to seek approval under the Animal Health Law requirements in the short term, as regulated by Article 279 of Regulation (EU) 2016/429.

ABICs, provided they fulfil the previous requirements of Annex C, should consider themselves confined establishments from 21 April 2021. This status should apply until the next audit of the confined establishment by the competent authority. By the time of publication of this Handbook, all such audits should have taken place.

Key definitions from the AHL legislation

Term	Definition	Legal definition source	Where to find further information in this Handbook
'animals'	means vertebrate and invertebrate animals	Def. 1, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species
'competent authority'	means the central veterinary authority of a Member State responsible for the organisationo of official controls and any other official activities in accordance with this Regulation or any other authority to which that responsibility has been delegated	Def. 55, Art. 4 2016/429	Chapter 2.2 Approval of confined establishments in the EU
'confined establishment'	means any permanent, geographically limited establishment, created on a voluntary basis and approved for the purpose of movements, where the animals are: a) kept or bred for the purposes of exhibitions, education, the conservation of species or research; b) confined and separated from the surrounding environment; and c) subject to animal health surveillance and biosecurity measures;	Def. 48, Art. 4 2016/429	Chapter 1.2 What is a confined establishment? Chapter 2.2 Approval of confined establishments in the EU

'establishment veterinarian'	means a veterinarian responsible for the activities carried out at the quarantine establishment for kept terrestrial animals other than primates or at confined establishment as laid down in this Regulation	Def. 14, Art. 2 2019/2035	Chapter 2.2 Approval of confined establishments in the EU
'kept animals'	means animals which are kept by humans, including, in the case of aquatic animals, aquaculture animals	Def. 5, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species
'official control'	means any form of control carried out by a competent authority for the purpose of verifying compliance with this Regulation	Def. 33, Art. 4 2016/429	Chapter 2.2 Approval of confined establishments in the EU
'official veterinarian'	means a veterinarian authorized by the competent authority and appropriately qualified to perform official activities in accordance with this Regulation	Def. 53, Art. 4 2016/429	Chapter 2.2 Approval of confined establishments in the EU
'operator'	means any natural or legal person having animals or products under his responsibility, including for a limited duration of time, but excluding pet keepers and veterinarians	Def. 24, Art. 4 2016/429	Chapter 2.2 Approval of confined establishments in the EU
'primates'	means animals of the species belonging to the order Primates excluding humans	Def. 12, Art. 2 2019/2035	Chapter 2.2 Approval of confined establishments in the EU
'quarantine'	means the keeping of animals in isolation with no direct or indirect contact with animals outside the epidemiological unit, for the purpose of ensuring that there is no spread of one or more specified diseases while the animals in isolation are undergoing observation for a specified length of time and, if appropriate, testing and treatment;	Def. 38, Art. 4 2016/429	Chapter 2.2 Approval of confined establishments in the EU
'terrestrial animals'	means birds, terrestrial mammals, bees and bumble bees	Def. 2, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species
'unique approval number'	means a number assigned by the competent authority to an establishment approved by it in accordance with Articles 97 and 99 of Regulation (EU) 2016/429;	Def. 16, Art. 2 2019/2035	Chapter 1.2 What is a confined establishment?

Guidance and additional recommendations

The following section provides further information on some key processes and definitions associated with confined establishment approval.

1. Confined establishment approval procedures

Requirements from the legislation:

a) Becoming a confined establishment

Specific approval procedures will likely vary between Member State competent veterinary authorities; however, the core components of the required process can be summarized in Figure 2.

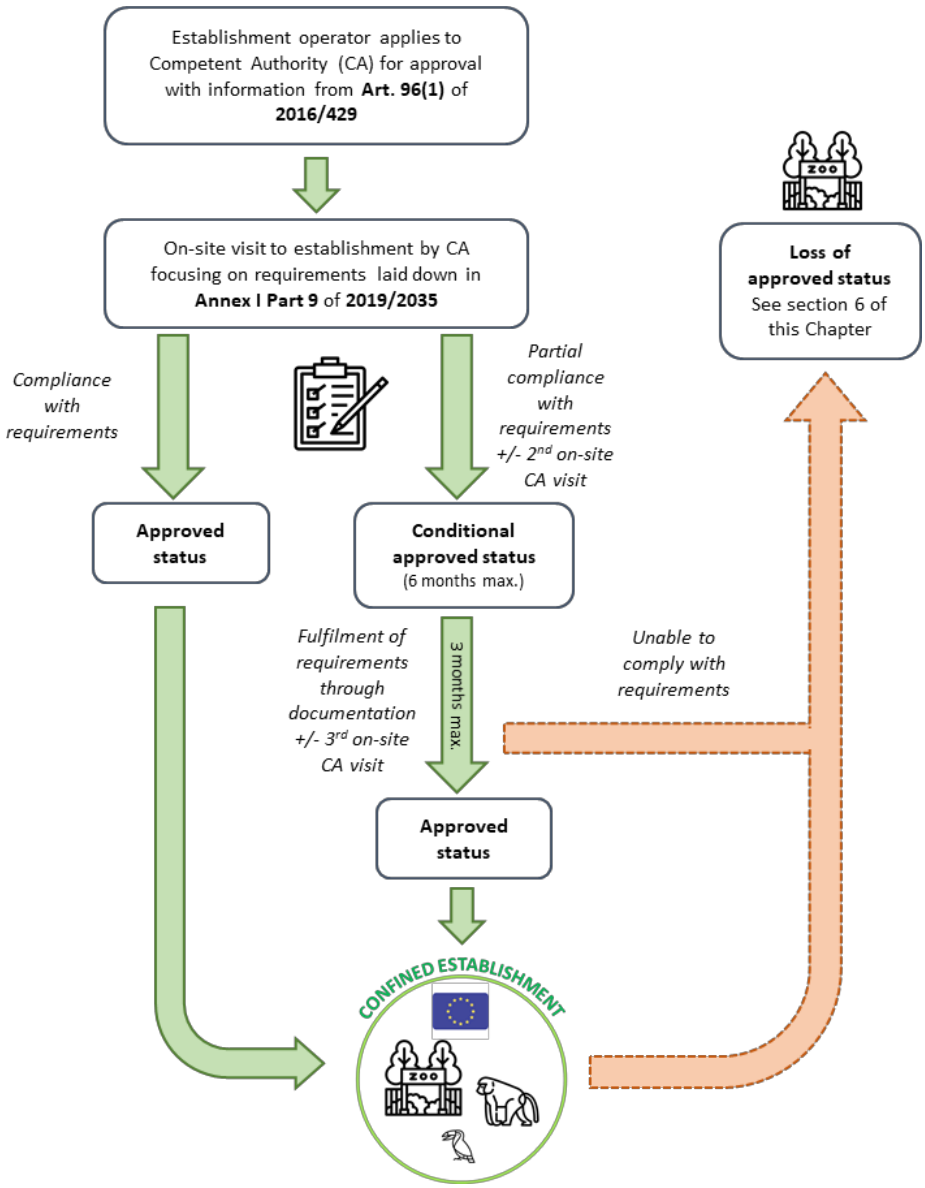

Figure 2: Diagram of confined establishment approval procedures as laid down in AHL for non-approved establishments.

b) Pre-existing Balai approved Body, Institute or Centre (ABICs)

Establishments already approved under the Annex C requirements of the Balai Directive (Council Directive 92/65/EEC), so called Approved Bodies, Institutes or Centres (ABICs) do not need to take immediate re-approval under the Animal Health Law requirements as regulated by Article 279 of 2016/429. Current ABICs, provided they fulfil the previous requirements of Annex C, should consider themselves confined establishments from 21 April 2021, and this status should apply until the confined establishments next annual audit by the competent authority. These audits should have taken place by the time of publication of this Handbook.

Under AHL, the competent authority must inspect the confined establishment at least annually, to ensure compliance with the approval requirements and so maintain the approval status. This is laid down in Commission Implementing Regulation (EU) 2022/160. This frequency is the same as was previously laid down in Council Directive 92/65/EEC.

Additional recommendations:

The inspection visits mentioned in the paragraph above, occurring at least annually, may contribute to, or entirely replace, the veterinary visits to all animal-keeping establishments required by AHL Article 25.

2. Establishment veterinarian

Art. 17 **Obligations on operators of confined establishments for terrestrial animals**	Operators of confined establishments for terrestrial animals referred to in Article 16 shall: […] b) secure by contract or by means of another legal instrument the services of an establishment veterinarian who shall be responsible for: i. supervising of the activities of the establishment and compliance with the requirements for approval laid down in Article 16; ii. ii. reviewing of the disease surveillance plan referred to in point 2(a) of Part 9 of Annex I whenever required and at least annually.

Requirements from the legislation:

The AHL definition of 'establishment vet' concerns a veterinarian working in two different contexts, either:

i. A veterinarian responsible for the activities at a quarantine establishment for kept terrestrial animals other than primates.

ii. A veterinarian responsible for the activities at a confined establishment.

This chapter solely focuses on the second of these options. The establishment veterinarian has a number of defined roles and responsibilities within the confined establishment and these are discussed below.

- Operators of confined establishments are responsible for putting in place an establishment veterinarian, whose services must be obtained and secured through a contract or another legal instrument.

- **The establishment veterinarian as a concept is similar but not identical to the concept of the 'approved veterinarian'** previously laid down in Annex C of Council Directive 92/65/EEC. One difference is that the appointment of the establishment veterinarian is solely down to the operator of the confined establishment and no longer subject to additional approval by the competent authority.
- The establishment veterinarian has several key roles to play with regards to approval, where they have responsibility for supervising the activities of the confined establishment, ensuring compliance with the approval requirements (Annex I Part 9 of Commission Delegated Regulation (EU) 2019/2035) and reviewing and updating the disease surveillance plan of the confined establishment at least annually (see Chapter 2.3).
- The establishment veterinarian must be a veterinarian possessing a full license to practice as required by national law.

Additional recommendations:

- The establishment veterinarian should understand the legal obligations placed upon them and the legislation from which these originate. Previous European Commission audits of Member State implementation of Council Directive 92/65/EEC have flagged this as an area of concern[4].
- Establishment veterinarians should also be familiar and keep up to date with advances in the field of zoological medicine, which may include relevant conference attendance, membership and involvement in relevant zoological medicine associations (e.g., EAZWV), undertaking research in zoological medicine, and pursuing study for additional post-graduate qualifications.

3. Terrestrial animals

Requirements from the legislation:

- The definition of a terrestrial animal in AHL covers all species of terrestrial mammals, all avian species as well as bumblebees and bees. However, this definition does not cover mammals living entirely within aquatic environments (e.g., Cetacea, Sirenia), or reptilian or amphibian species. See Chapter 2.1 above.
- All terrestrial animals kept within the confined establishment should be included in and subject to the disease surveillance plan for the confined establishment. For further guidance on this topic see Chapter 2.3.
- **Only terrestrial animals originating from another confined establishment may be introduced to a confined establishment without the need for a defined quarantine period under official control.** See below for further details.
- Some specific taxonomic groups of terrestrial animals are also subject to requirements for identification and registration under AHL. For further guidance on these measures and requirements and how they apply to kept animals within confined establishments, see Chapter 2.5.

Additional recommendations:

- Despite falling outside of the legal definitions of terrestrial animals, **we would recommend that amphibian and reptile species also be included in disease surveillance plans** so as to promote best practice and optimal animal health standards across all taxonomic groups kept within the confined establishment.
- We would advise the inclusion of species of the order Pinnipedia (i.e., seals, fur seals, sea lions and walruses) **within** the terrestrial animal definition, particularly with regards to the disease surveillance plan in the confined establishment.

4. Primates

Art. 47 **Requirements for movements of primates to other Member States**	Operators shall only move primates to another Member State when the animals either: 1. have been kept in a confined establishment and are transported to a confined establishment in the Member State of destination in accordance with the requirements in Article 64(1); or 2. come from an establishment other than a confined establishment and are transported to a confined establishment in the Member State of destination in accordance with the requirements of Article 63(2)(b).

Requirements from the legislation

- Confined establishments maintain the exclusive right to obtain and send non-human primates to other Member States, however these species may only be sent to other confined establishments.
- Primates originating from an establishment other than a confined establishment (i.e., a non-approved source) must be admitted to the confined establishment through a quarantine procedure at least as strict as the rules laid down in the WOAH (previously OIE) Terrestrial Animal Health Code, Article 6.12.4. of Chapter 6.12[1] of the 2018 edition.
- This quarantine period for primates from sources other than a confined establishment requires oversight of the official veterinarian/competent authority. Primate quarantine may only ever be undertaken in a confined establishment.
- Primates originating from another confined establishment, located in a different or the same Member State as the receiving confined establishment, do not need to undergo any official or statutory quarantine requirements. These movements are subject to the same requirements as for other terrestrial animals moving between confined establishments, laid down in Article 64 of Commission Delegated Regulation (EU) 2020/688 (see Chapter 2.4).

Additional recommendations:

For the quarantine of primates entering from non-approved sources we would recommend that the latest version of the WOAH (prev. OIE) Terrestrial Animal Health Code be used to ensure that the most up-to-date global standards are being applied. The latest version can be accessed on WOAH's website.

5. *Confined establishment approval requirements*

a) *Approval requirements related to quarantine, isolation and biosecurity measures (Annex I Part 9, Point 1a-c)*

Annex I PART 9 **Requirements for granting approval of confined establishments of kept terrestrial animals referred to in Article 16**	1. The requirements in relation to quarantine, isolation and biosecurity measures of confined establishments of kept terrestrial animals, as referred to in Article 16, shall be the following: a) they must only admit kept terrestrial animals which have been subject to a quarantine period appropriate to diseases relevant to the species, where those animals coming from establishment other than a confined establishment; b) they must only admit primates complying with the rules as strict as those referred to in Article 6.12.4 of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE), Edition 2018; c) where necessary, adequate facilities to quarantine kept terrestrial animals introduced from other establishments must be available

Requirements from the legislation:

- The AHL definition of 'quarantine' is strongly aligned with the World Association for Animal Health's (WOAH) current definition for a 'quarantine station'.

  WOAH defines a quarantine station as: *'an establishment under the control of the Veterinary Authority where animals are maintained in isolation with no direct or indirect contact with other animals, to ensure that there is no transmission of specified pathogenic agents outside the establishment while the animals are undergoing observation for a specified length of time and, if appropriate, testing or treatment.'*[2]

  One specific difference between the two definitions, is that in the AHL definition there is the concept of the 'epidemiological unit'.

  WOAH define an epidemiological unit as: *'a group of animals with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogenic agent. This may be because they share a common environment (e.g., animals in a pen), or because of common management practices. Usually, this is a herd or a flock. However, an epidemiological unit may also refer to groups such as animals belonging to residents of a village, or animals sharing a communal animal handling facility. The epidemiological relationship may differ from disease to disease, or even strain to strain of the pathogenic agent'.*

- Only terrestrial animals originating from another confined establishment may be introduced to a confined establishment without the need for a defined quarantine period under official control, see Figure 3.

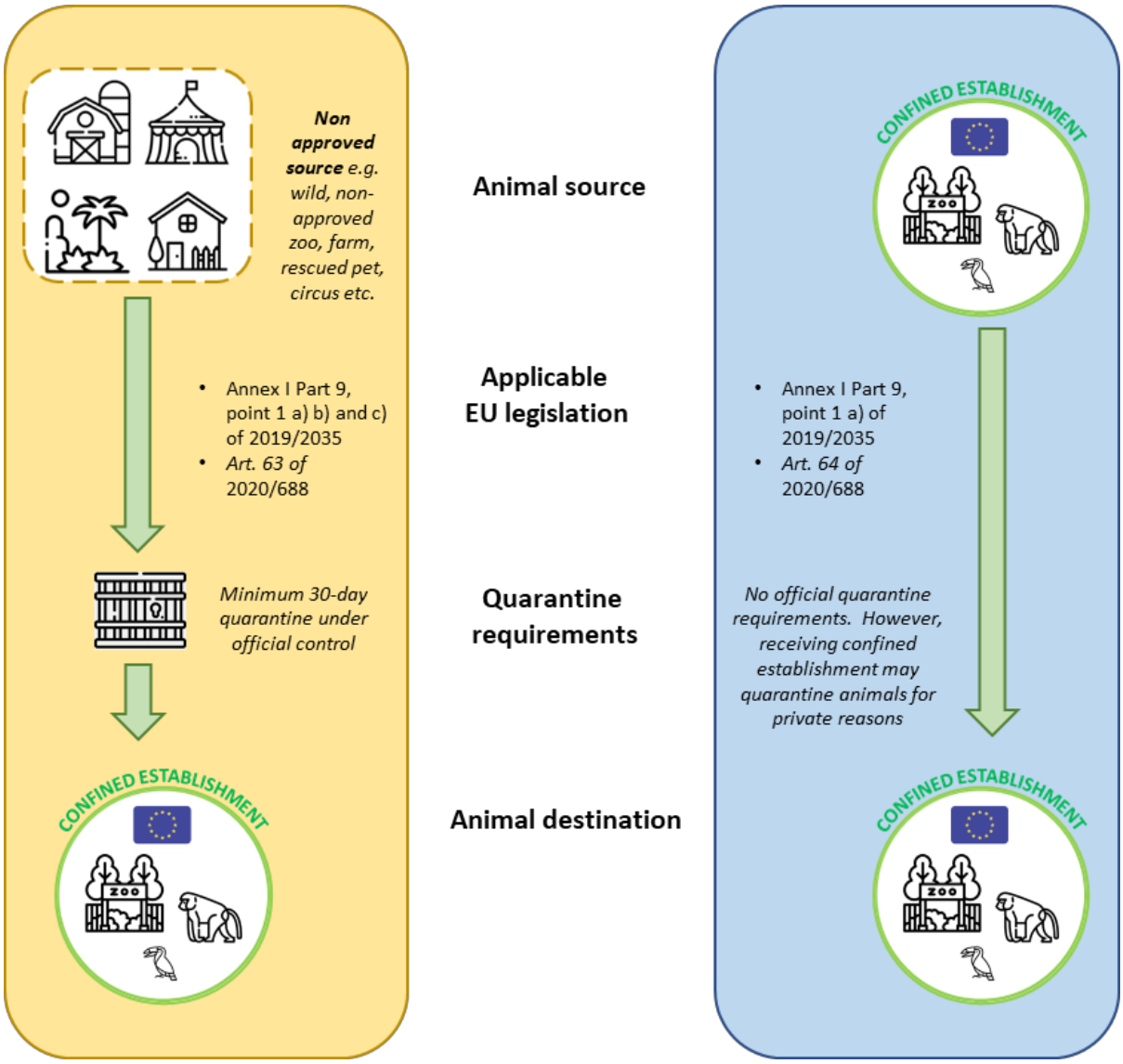

Figure 3: Diagram of quarantine requirements laid down in the AHL for terrestrial animal species entering a confined establishment from different sources.

- If a confined establishment only obtains terrestrial animals from other confined establishments, **there is no longer the approval requirement for the confined establishment to have dedicated quarantine or isolation facilities.**
- Where terrestrial animals are brought into a confined establishment from non-approved sources, these animals can undertake this quarantine period at three possible locations:

    i. At quarantine facilities of the receiving confined establishment

    ii. At quarantine facilities shared with another confined establishment (i.e., not on the site of the receiving confined establishment)

iii. At a designated quarantine establishment (except primate species) (a quarantine establishment is a new concept within the Animal Health Law, see Art. 14 of 2016/429)

To be able to quarantine terrestrial animals from non-approved sources at its own quarantine facility, the confined establishment does not need to obtain additional approval as a quarantine establishment (i.e., Art. 14 of Commission Delegated Regulation (EU) 2019/2035 does not apply to confined establishments). Approval as a confined establishment includes authorization to quarantine terrestrial animals, with these quarantine requirements being laid down in Art. 16 and Annex I Part 9, Point 1a-c of Commission Delegated Regulation (EU) 2019/2035.

Regardless of the location for the quarantine, for terrestrial animals from non-approved sources, this period must be completed under official control (i.e., under the oversight of the official veterinarian) before the animals are added to the confined establishment. This quarantine period should be appropriate for the diseases listed for the moved species, and be at least 30 days, as laid down in Article 63, point 1(a) of Commission Delegated Regulation (EU) 2020/688.

- During the quarantine period, terrestrial animals from non-approved sources may undergo testing for any listed or emerging disease that the establishment veterinarian and the competent authority consider appropriate. Additionally, for specific taxonomic groups of terrestrial animals entering the confined establishment from non-approved sources from other Member States, these animals may need to undergo specific disease testing requirements (see Chapter 2.4).

Additional recommendations:

During the quarantine period for animals entering the confined establishment from non-approved sources, the establishment veterinarian may also carry out specific testing for diseases which the confined establishment is concerned about, which are not listed or emerging, as per the definition in Commission Implementing Regulation (EU) 2018/1882.

When a quarantine or isolation facility is required by a confined establishment for the introduction of terrestrial animals from non-approved sources, the following recommendations may apply:

Structural requirements:

i. *Location*
The quarters should be physically separated from other animal accommodation by a reasonable distance, taking into account the species concerned and the ability of aerosol spread of relevant pathogens. This distance can be much reduced if the exhausted air is filtered (for animals originating from within the EU or from listed Third Countries the use of dust filters is sufficient, otherwise High Efficiency Particulate Extraction (HEPA) may be required).

ii. *Demarcation*
The limits of the isolation area should be clearly demarcated by walls or fences as appropriate. This does not preclude the possibility that specific areas or pens within the premises may be designated as isolation areas for a limited time and a particular purpose, provided that they meet the general requirements.

iii. *Access*
A double door system can be used to prevent escape at the entry/exit with sufficient space between the doors to allow one to be closed before the other is opened. Entry/exit doors must

be lockable and should display a notice stating: 'QUARANTINE: No Admission of Unauthorized Persons'.

iv. *Hygiene barrier*
Facilities should be available at the entry/exit point for attendants to change overalls, to change and disinfect boots, to wash hands, and if appropriate to shower.

v. *Loading/unloading*
Suitable facilities should be available to load or unload animals between transport crates and isolation pens without the risk of escape and under strict biosecurity measures.

vi. *Inspection*
The design of the pens or enclosures within the isolation area must be such that the animals may be visually inspected at any time, with adequate light and ease of access.

vii. *Disinfection*
The physical structure and all equipment must be made of such materials that they can be effectively cleaned and disinfected or destroyed after use.

viii. *Vermin*
The design must be suitable to minimize access by rodents, wild birds, and insects, as appropriate for the species in question. Rodent proof covers can be fitted to any present drains.

ix. *Feed storage*
The feed storage should be suitably protected from vermin.

x. *Waste disposal*
Adequate storage facilities should be available to contain the litter and animal waste produced during the isolation/quarantine period, and the storage facility should be bird and vermin proof. Consideration should be paid to the disposal of the waste either during or after the period which will ensure that there is no risk of the spread of disease.

xi. *Post-mortem*
Refrigeration facilities or equivalent may be available within the isolation area, or in a suitably disease-protected location nearby, to hold carcasses of animals that die until they can be subject to post-mortem examination. Procedures for conveying carcasses safely to the storage facility and the post-mortem facility should be laid down in writing by the establishment veterinarian.

<u>Quarantine biosecurity management procedures:</u>

i. *Surveillance*
Every animal requires to be visually inspected at least once a day by suitably competent staff. Any signs of illness should be recorded and reported immediately to the establishment veterinarian, who should make a further examination of the affected animals without any unreasonable delay.

ii. *Staff*
The confined establishment should have designated staff who are present on a sufficiently regular schedule to ensure surveillance of the animals on a daily basis, and more frequently if appropriate. These staff should take appropriate precautions to ensure that there is no risk of

transferring infection from the quarantine/isolation unit to any other kept animals the confined establishment, and the arrangements should be agreed in writing by the establishment veterinarian.

iii. Hygiene

Staff entering the premises should always change into protective clothing and footwear. On leaving, the protective clothing and footwear must be removed and left within the quarantine/isolation area, and the footwear must be disinfected. Hands must be washed, or otherwise disinfected, on entering and leaving.

iv. Equipment

None of the moveable items used in the isolation unit should be taken outside the unit, or used with other stock outside the unit, for the entire duration of the isolation period.

v. Waste

Litter and waste material must be collected regularly, stored in provided containers, and disposed of either during or after the isolation period in such a way that disease agents will not be spread.

vi. Disinfection

Premises must have an effective disinfection program, laid down in writing by the establishment veterinarian, for cleansing and disinfection after each isolation session. Approved disinfectants must be specified and used in the program; and an appropriate resting period (usually 7 days) must be specified after each cleansing and disinfection operation.

vii. Transport crates

Crates or cages used for transport, if to be re-used, must be made of materials which allow effective cleaning and disinfection, and this should be carried out within the isolation unit. If not re-used, the crates and cages must be destroyed in such a way that disease agents cannot be spread.

viii. All-in, all-out policy

An 'all-in, all-out' policy should be followed in the isolation unit. If it is necessary to add animals whilst others are already present in the unit, the isolation period of all of them must be extended until the latest completion date of any of the animals.

ix. Illness

If any animal becomes ill during isolation and the establishment veterinarian considers that the animal need to be moved to a specialized hospital facility for diagnosis or treatment, they must ensure that this is done under their personal supervision in such a way as to ensure no possible risk of disease spread. In particular, the approved establishment veterinarian must personally supervise the arrangements for maintaining isolation throughout the movement, and for disinfecting any vehicles, rooms, and equipment with which the animal has had contact with.

x. Disease and death

Any sign of any disease or death during isolation must be reported immediately to the establishment veterinarian. All suspicions of any infectious disease or listed diseases (see Chapter 2.3) and any deaths in isolation must be reported immediately to the competent authority. Carcasses of animals, which die during isolation (including stillbirths), and if necessary,

those that are dead on arrival, require a post-mortem examination without unreasonable delay.

xi. Visitors

Visitors must not be allowed to enter the isolation unit. If personnel apart from the designated attendants need to enter for essential maintenance etc., they must be required to wash thoroughly on leaving and wear protective clothing which shall be put on prior to entering and removed prior to leaving. There must be a visitor book to record the dates, names and contact details of any visitors.

xii. Records

The person in charge of the isolation unit must keep the following records, which should be retained for at least ten years:

- the date, number and identification of animals entering and leaving the isolation facility;
- copies of the export health certificates and border crossing certificates accompanying imported animals;
- significant health observations, cases of illness and deaths on a daily basis;
- dates and results of any testing;
- dates and types of any administered treatment;
- dates and names and addresses of persons entering the isolation unit.

<u>Additional requirements specifically for birds:</u>

i. Ventilation

Birds should always be isolated in buildings. There must be no possibility of access by wild birds or by mosquitoes, however taking into account different species, the competent authority may request different standards. As a general rule, windows should be kept closed, the isolation rooms should be ventilated, and the exhausted air should pass through a dust filter. If the isolation facility is more than 250m away from other bird enclosures, this requirement can be waived and ventilation through open windows can be permitted. In such case all ventilation openings must be covered with a double layer of wire mesh.

ii. Air space

If there are separate units within the isolation facility, each unit must occupy a separate airspace so as to be an isolated epidemiological unit. If this cannot be achieved, all the birds in the isolation facility must remain until the completion date of the last birds to enter.

<u>Additional requirements specifically for ungulates:</u>

i. Fencing

If the isolation area includes open paddocks, situations where there may be stock in adjacent paddocks must be avoided. The isolation paddocks must be surrounded by double fences allowing a suitable sanitary gap between the fences. A minimum gap of at least 3 meters should normally be satisfactory, but taking account of the species concerned, the competent authority may require different specific standards. Both fences must be escape-proof.

ii. Herds in isolation

If the isolation facility is intended to contain large groups of animals, there must be additional provision so that any individual that appears to be unwell can be separated and kept apart from the rest of the group, with facilities for testing and treatment as appropriate.

5. Confined establishment approval requirements (continued)

b) Approval requirements related to surveillance and control measures (Annex I Part 9, Point 2a-c)

Annex I PART 9 **Requirements for granting approval of confined establishments of kept terrestrial animals referred to in Article 16**	[…] 2. The requirements in relation to surveillance and control measures of confined establishments of kept terrestrial animals, as referred to in Article 16, shall be the following: a) the disease surveillance plan must include appropriate zoonoses control of the kept terrestrial animals, and must be implemented and updated according to the number and species of the kept terrestrial animals present in the establishment and to the epidemiological situation in and around the establishment as regards listed and emerging diseases; b) kept terrestrial animals suspected of being infected or contaminated by listed or emerging disease agents must be subject to clinical, laboratory or post-mortem testing; c) the vaccination and treatment of susceptible kept terrestrial animals against transmissible diseases must be carried out as appropriate.

Requirements from the legislation:

- One of the key roles of the establishment veterinarian is the creation, implementation and updating of the disease surveillance plan for the confined establishment. This plan is specific to the confined establishment and tailored to the terrestrial animals kept within the establishment as well as local epidemiological factors.
- The role of the disease surveillance plan is to quantify and qualify the disease risks posed by the terrestrial animals in the confined establishment, with particular focus on listed diseases and emerging diseases as defined by Commission Implementing Regulation (EU) 2018/1882.
- Should there be any suspicion of a case of a listed or emerging disease within the confined establishment, there must be immediate notification to the competent authority. This also includes suspicion of zoonoses that may notifiable under EU or national legislation.
- For more detailed guidance on the requirements and production of a disease surveillance plan for a confined establishment and appropriate management and mitigation of zoonosis risk, see Chapter 2.3.

5. Confined establishment approval requirements (continued)

c) Approval requirements related to facilities and equipment (Annex I Part 9, Point 3a-c)

Annex I PART 9 **Requirements for granting approval of confined establishments of kept terrestrial animals referred to in Article 16**	[…] 3. The requirements in relation to facilities and equipment of confined establishments of kept terrestrial animals, as referred to in Article 16, shall be the following: a) the establishments must be clearly demarcated and the access of animals and humans to animal facilities must be controlled; b) adequate means for catching, confining, where necessary restraining and isolating animals are available; c) animal accommodation areas shall be of a suitable standard and constructed in such way that: i. contact with animals on the outside is prevented and that inspection and any necessary treatment can be easily carried out; ii. floors, walls and all other material or equipment can be readily cleaned and disinfected.

Requirements from the legislation:

- The need for clear demarcation of the confined establishment's site, control of access of humans and animals to the animal facilities, and having animal accommodation of a suitable standard are aligned, although not identical, with some of the zoo licensing requirements laid down in Council Directive 1999/22/EC ('EU Zoos Directive'). Further information on correct implementation by zoos and competent authorities of Council Directive 1999/22/EC can be found in the EU Zoos Directive Good Practices document[3], available in 15 EU languages.

Additional recommendations:

- Adequate means for 'catching, confining and where necessary restraining' animals will vary significantly between confined establishments based on the terrestrial animals they keep, the design of the animal and veterinary facilities and the veterinary provisions on site. Such means may include, but are not limited to:

  i. Husbandry training of individual animals for veterinary procedures;
  ii. Chemical restraint (appropriate drugs for immobilization, suitably trained personnel, well-maintained equipment, darting equipment, gaseous anaesthesia etc.);
  iii. Nets of various sizes;
  iv. Crushes, chutes and restraint cages of various designs for different species.

- For further guidance on the requirements for isolating animals see above section 5) b) 'Approval requirements related to quarantine, isolation and biosecurity measures (Annex I Part 9, Point 1a c)'.

- Point 3(c)(i) requires that 'contact with animals on the outside is prevented'. Terrestrial animals living inside and outside of a confined establishment do represent a level of disease risk to one another. This disease risk should be viewed as a dynamic factor, which may increase or decrease over a given timeframe. Confined establishments can undertake a range of measures to quantify and mitigate the level of disease risk posed to their kept terrestrial animals from those external to the confined establishment (i.e., kept animals in neighbouring establishments or free-living 'wild' animals within or external to the confined establishment):

  i. Performing post-mortem examinations on any carcasses of free-living wild terrestrial animals found dead within or local to the confined establishment. With inclusion of the results of these opportunistic post-mortem examinations informing the confined establishment's disease surveillance plan.
  ii. Tailoring of the confined establishment's disease surveillance plan to local epidemiology, acknowledging disease emergence and endemism with input from the competent authority (see Chapter 2.3).
  iii. Risk assessments during high-risk periods or with respect to specific taxa or areas of the confined establishment (e.g., winter period and HPAI in migratory waterfowl).
  iv. Development of contingency plans specific for the confined establishment.

- Point 3(c)(ii) requires that animal accommodation has 'floors, walls, and all other material can be readily cleaned and disinfected'. This point, however, does not state when this cleaning or disinfection should occur, just that it is able to be performed. The responsibility for routine cleaning of animal accommodation is still the within the scope of the confined establishment's animal care staff. Additionally, this point does not suggest that hygiene and sanitation should be the primary deciding factor in the selection of substrate for a given species.

Additional national requirements

- Individual Member States may introduce additional approval requirements, related for instance to: fencing, DDD rules, treatment of waste water, storage and disposal of cadavers, identification and traceability of animals.

6. Loss of approved status

Art. 100 **Review, suspension and withdrawal of approvals by the competent authority**	1. The competent authority shall keep approvals of establishments granted in accordance with Articles 97 and 99 under review, at appropriate intervals based on the risk involved. 2. Where a competent authority identifies serious deficiencies in an establishment as regards compliance with the requirements laid down in Article 97(1) and the rules adopted pursuant to Article 97(2), and the operator of that establishment is not able to provide adequate guarantees that those deficiencies will be eliminated, the competent authority shall initiate procedures to withdraw the approval of the establishment. However, the competent authority may merely suspend, rather than withdraw, approval of an establishment where the operator can guarantee that it will eliminate those deficiencies within a reasonable period of time. 3. Approval shall only be granted after withdrawal or restored after suspension in accordance with paragraph 2 when the competent authority is satisfied that the establishment fully complies with all the requirements of this Regulation appropriate for that type of establishment

Requirements from the legislation:

- Article 100 of Regulation (EU) 2016/429 lays down the basis for a system for the withdrawal of an establishment's (including a confined establishment's) approval. Although outbreaks of listed disease are still reportable to the competent authority and measures are required by law to be put in place to prevent disease spread, **an outbreak of a listed disease is not a reason in itself for withdrawal of approval status**. This is an important change from the previous Council Directive 92/65/EEC.
- Approval is withdrawn by a competent authority when an establishment no longer meets the requirements as laid down for that type of establishment and the operator cannot guarantee that those deficiencies will be rectified.

Points for the competent authority/official veterinarian to consider:

The following section provides some points for the competent authority to consider during their on-site approval audit of a confined establishment. They are for consideration only and are based on the requirements of the AHL legislation. Additional layers of national specificities/requirements may also exist.

Consider:

- ✓ How does the terrestrial animal acquisition policy of the confined establishment take into account animal health?
- ✓ How does the confined establishment manage the entry of terrestrial animals from non-approved sources?
- ✓ How is the health of terrestrial animals entering from non-approved sources monitored and maintained during any quarantine period?
- ✓ How do any quarantine or isolation facilities used by the confined establishment meet the needs of terrestrial animals entering from non-approved sources?
- ✓ How is the entry of primate species into the confined establishment controlled?
- ✓ How does the establishment veterinarian demonstrate through the disease surveillance plan the monitoring of appropriate listed diseases based on the animal species kept in the confined establishment and the epidemiology within and local to the confined establishment?
- ✓ How does the establishment veterinarian review the disease surveillance plan annually?
- ✓ How is the control of entry of other animals and humans to the animal accommodation managed?
- ✓ How is contact with animals outside of the confined establishment and those animals kept within the confined establishment minimized and prevented?
- ✓ How does the construction and standard of the animal accommodation in the confined establishment take into account animal health and allow for potential veterinary interventions?

References

1. WOAH (prev. OIE). Zoonoses transmissible from non-human primates. in OIE Terrestrial Animal Health Code 1–5 (2019).
2. WOAH (prev. OIE). Glossary. in Terrestrial Animal Health Code 1–12 (2019).
3. European Commission. EU Zoos Directive Good Practices Document. (2015). doi:10.2779/247108.
4. European Commission. Overview report Animal Health Controls in Zoos and Laboratories. (2016) doi:10.2772/56814.

Chapter 2.3. Disease surveillance planning in a confined establishment

Chapter contents

Introduction

Disease surveillance as well as disease control and mitigation measures in a confined establishment should be appropriate and adapted to the local epidemiological situation. One central requirement for the approval of a confined establishment is the creation, implementation and at least annual review of a disease surveillance plan (as laid down in Article 17 of Regulation (EU) 2014/429 and further elaborated upon in Annex I, Part 9 of Commission Delegated Regulation (EU) 2019/2035). The disease surveillance plan plays an important role in the preventative healthcare for the confined establishment and the terrestrial animals it keeps. This document should be specific to that confined establishment and fine-tuned to the local circumstances, epidemiology and susceptible species kept on site.

Disease risk is an important concept for the drafting, implementation, and review of the disease surveillance plan. The WOAH (prev. OIE) definition of risk is '*the likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health*.'[1]. Understanding the disease risk posed both to and from the terrestrial animals within a confined establishment can be ascertained through effective use of disease surveillance planning[2].

The plan may form part of a broader, more holistic approach to preventative zoological medicine, potentially also covering diseases of non-regulatory concern, as well as linking to other internal animal health policies and practices in place at the confined establishment. However, the core function of the surveillance plan, when related to the approval of the confined establishment, is to help ascertain the health status of the confined establishment and the terrestrial animals kept by it with regards to diseases of EU regulatory concern which are classified as 'listed or emerging' by the EU Animal Health Law.

This chapter aims to introduce the topic of disease surveillance planning and provide guidance on the production of such a plan to aid both the establishment veterinarian and the official veterinarian/ competent authority.

Key definitions from the AHL legislation

Term	Definition	Legal definition source	Where to find further information in this Handbook
'biosecurity'	means the sum of management and physical measures designed to reduce the risk of the introduction, development and spread of diseases to, from and within: a) an animal population, or b) an establishment, zone, compartment, means of transport or any other facilities, premises or location;	Def. 23, Art. 4 2016/429	Chapter 2.2 Approval of confined establishments in the EU
'competent authority'	means the central veterinary authority of a Member State responsible for the organisation of official controls and any other official activities in accordance with this Regulation or any other authority to which that responsibility has been delegated;	Def. 55, Art. 4 2016/429	Chapter 2.2 Approval of confined establishments in the EU
'confined establishment'	means any permanent, geographically limited establishment, created on a voluntary basis and approved for the purpose of movements, where the animals are: a) kept or bred for the purposes of exhibitions, education, the conservation of species or research; b) confined and separated from the surrounding environment; and c) subject to animal health surveillance and biosecurity measures;	Def. 48, Art. 4 2016/429	Chapter1.2 What is a confined establishment?
'establishment veterinarian'	means a veterinarian responsible for the activities carried out at the quarantine establishment for kept terrestrial animals other than primates or at confined establishment as laid down in this Regulation	Def. 14, Art. 2 2019/2035	Chapter 2.2 Approval of confined establishments in the EU
'listed diseases'	means diseases listed in accordance with Article 5(1);	Def. 53, Art. 4 2016/429	Chapter 2.3 Disease surveillance planning in the confined establishment
'official veterinarian'	means a veterinarian authorised by the competent authority and appropriately qualified to perform official activities in accordance with this Regulation;	Def. 18, Art. 4 2016/429	Chapter 2.2 Approval of confined establishments in the EU
'terrestrial animals'	means birds, terrestrial mammals, bees and bumble bees	Def. 2, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species

Guidance and additional recommendations

The following section provides further information on the production and implementation of a disease surveillance plan within a confined establishment.

1. Confined establishment operator disease surveillance planning responsibilities

Art. 17 **Obligations on operators of confined establishments for terrestrial animals**	Operators of confined establishments for terrestrial animals referred to in Article 16 shall: a) put in place the necessary arrangements to perform veterinary post-mortem inspections in appropriate facilities in the establishment or in a laboratory; b) secure by contract or by means of another legal instrument the services of an establishment veterinarian who shall be responsible for i. supervising of the activities of the establishment and compliance with the requirements for approval laid down in Article 16 ii. reviewing of the disease surveillance plan referred to in point 2(a) of Part 9 of Annex I whenever required and at least annually

Art. 32 **Record-keeping obligations of operators of confined establishments**	Operators of approved confined establishments shall record the following additional information: […] c) details of the implementation and results of the disease surveillance plan provided for in point 2(a) of Part 9 of Annex I; d) the results of clinical, laboratory tests and post-mortem testing provided for in point 2(b) of Part 9 of Annex I; e) details of the vaccination and treatment of susceptible animals provided for in point 2(c) of Part 9 of Annex I; f) details of isolation or quarantine of incoming animals, instructions, if any, of the competent authority as regards isolation and quarantine and observations made during any isolation or quarantine period

<u>Requirements from the legislation</u>

- The operator of the confined establishment must meet a number of requirements which are distinct but linked to the disease surveillance plan and the understanding and improvement of the health status of the confined establishment:
    - An establishment veterinarian for the confined establishment must be appointed
    - Appropriate arrangements must be made for veterinary post-mortems to be undertaken in appropriate facilities, either in the confined establishment or externally in a laboratory

- The record-keeping obligations related to the disease surveillance plan and its implementation must be complied with (see Chapter 2.5 for more information on appropriate record keeping in the confined establishment)

- Fulfilment of the first two of these requirements is fundamentally linked to the approved status of the confined establishment (as per Article 16 of Commission Delegated Regulation (EU) 2019/2035), see Chapter 2.2 for more guidance on the other approval requirements and the responsibilities of the establishment veterinarian.

2a. Disease surveillance planning: general points

Annex I PART 9 **Requirements for granting approval of confined establishments of kept terrestrial animals referred to in Article 16**	[…] 2. The requirements in relation to surveillance and control measures of confined establishments of kept terrestrial animals, as referred to in Article 16, shall be the following: a) the disease surveillance plan must include appropriate zoonoses control of the kept terrestrial animals, and must be implemented and updated according to the number and species of the kept terrestrial animals present in the establishment and to the epidemiological situation in and around the establishment as regards listed and emerging diseases; b) kept terrestrial animals suspected of being infected or contaminated by listed or emerging disease agents must be subject to clinical, laboratory or post-mortem testing; c) c) the vaccination and treatment of susceptible kept terrestrial animals against transmissible diseases must be carried out as appropriate.

Requirements from the legislation

- The establishment veterinarian is responsible for the creation, implementation and review of the disease surveillance plan for the confined establishment. This review should occur at least annually.

- In addition to the annual review by the establishment veterinarian, the disease surveillance plan is also subject to auditing by the official veterinarian/competent authority on an annual basis, as mandated by Commission Implementing Regulation (EU) 2022/160.

- For the purposes of approval, the disease surveillance plan should consider primarily diseases of legislative concern, so called 'listed and emerging diseases'- see above definition and below sections for further guidance.

Additional recommendations:

- The disease surveillance plan may also consider other general measures as required by Article 3, point 4 of Council Directive 1999/22/EC (the 'EU Zoos Directive'), and the specific condition for a '*developed programme of preventative and curative veterinary care*'.
- Consultation with the official veterinarian/competent authority during the creation of the disease surveillance plan may be warranted to ascertain the disease risk and epidemiological situation surrounding and external to the confined establishment.
- The disease surveillance plan and the measures based thereon should be founded on a number of key principles, including:
    i. Immediate notification to the competent authority if there is any cause for suspicion that terrestrial animals may be affected by any listed or emerging disease, including zoonoses, that are notifiable under EU or national legislation.
    ii. Close observation of each terrestrial animal in the confined establishment by suitably qualified staff at least once per day under the direction of the establishment veterinarian.
    iii. Immediate notification to the establishment veterinarian from animal care staff of any terrestrial animal which appears unwell or is found dead.
    iv. Appropriate clinical, laboratory and/or post-mortem examination to establish the infective agent in any terrestrial animals that appear to be affected by an infectious disease.
    v. In the case of suspicion of a listed or emerging disease or a disease which is notifiable under national legislation, the official veterinarian must be informed immediately. The official veterinarian will be responsible for arranging disease control precautions and further investigation for diseases notifiable under national legislation, including the direction of appropriate samples to be taken and the submission of these to a designated laboratory.
    vi. Opportunistic examination and sample taking. These may be undertaken during physical restraint such as general anaesthesia or from animals trained for voluntary examination / sampling. Serum samples should be retained and stored at -80°C or below for future use.
    vii. Prompt post-mortem examination to identify the cause of death and/or significant pathology in every terrestrial animal which dies in the confined establishment. This recommendation extents to any aborted foetuses, free-living wild animals found dead within the confined establishment, and cases where there is no suspicion of the involvement of infectious agents (e.g., management euthanasia/culling of clinically healthy animals).
    viii. Appropriate record keeping of results of clinical, laboratory or post-mortem and other data relating to the disease surveillance plan and its implementation. Such data can easily be recorded and stored on '*ZIMS for Medical*', (see Chapter 2.5 for more information).

2b. Disease surveillance planning: which infectious diseases and species to consider?

Requirements from the legislation:

- Point 2(a) of Part 9 of Annex I of Regulation (EU) 2019/2035 highlights that the disease surveillance plan should focus primarily on 'listed and emerging diseases'. The definitions of these terms can be found above.
- Information on the listing process for animal diseases at EU level, can be found in Articles 5-7 of Regulation (EU) 2016/429, with listed diseases and susceptible species being found in Commission Implementing Regulation (EU) 2018/1882. Please check the legislation for the latest applicable list.
- At the time of the publication of this Handbook, the listed diseases and susceptible species of kept terrestrial animal, which the confined establishment's disease surveillance plan should take into consideration are:

Listed disease	**Susceptible species or group of species (taken from Regulation 2018/1882)**
Foot and mouth disease	Artiodactyla, Proboscidea
Infection with rinderpest virus	Artiodactyla
Infection with Rift Valley fever virus	Perissodactyla, Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Hippopotamidae, Moschidae, Proboscidea
Infection with *Brucella abortus*, *B. melitensis, B. suis*	*Bison* ssp., *Bos* ssp., *Bubalus* ssp., *Ovis* ssp., *Capra* ssp.
	Artiodactyla other than *Bison* ssp., *Bos* ssp., *Bubalus* ssp., *Ovis* ssp., *Capra* ssp.
	Perissodactyla, Carnivora, Lagomorpha
Infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae, M. tuberculosis*)	*Bison* ssp., *Bos* ssp., *Bubalus* ssp.
	Artiodactyla others than *Bison* ssp., *Bos* ssp., *Bubalus* ssp.
	Mammalia (terrestrial)
Infection with rabies virus	Carnivora, Bovidae, Suidae, Equidae, Cervidae, Camelidae
	Chiroptera
Infestation with *Echinococcus multilocularis*	Canidae
Infection with bluetongue virus (serotypes 1-24)	Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Moschidae, Tragulidae
Infection with epizootic haemorrhagic disease virus	Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Moschidae, Tragulidae
Anthrax	Perissodactyla, Artiodactyla, Proboscidea
Surra (*Trypanosoma evansi*)	Equidae, Artiodactyla
Ebola virus disease	Non-human primates (apes)
Paratuberculosis (*Mycobacterium avium* subsp. paratuberculosis)	*Bison* ssp., *Bos* ssp., *Bubalus* ssp., *Ovis* ssp., *Capra* ssp., *Camelidae*, Cervidae
Japanese encephalitis	Equidae
West Nile fever	Equidae, Aves
Q fever (*Coxiella burnetii*)	*Bison* ssp., *Bos* ssp., *Bubalus* ssp., *Ovis* ssp., *Capra* ssp.

Infection with lumpy skin disease virus	*Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia)	*Bison* ssp., *Bos* ssp., *Bubalus* ssp., *Syncerus cafer*
Infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis	*Bison* ssp., *Bos* ssp., *Bubalus* ssp.
	Camelidae, Cervidae
Bovine viral diarrhoea	*Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Bovine genital campylobacteriosis	*Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Trichomonosis	*Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Enzootic bovine leukosis	*Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Sheep pox and goat pox	*Ovis* ssp., *Capra* ssp.
Infection with *peste des petits ruminants* virus	*Ovis* ssp., *Capra* ssp., *Camelidae, Cervidae*
Contagious caprine pleuropneumonia	*Ovis* ssp., *Capra* ssp., *Gazella* ssp.
Ovine epididymitis (*Brucella ovis*)	*Ovis* ssp., *Capra* ssp.
African horse sickness	Equidae
Infection with *Burkholderia mallei* (Glanders)	*Equidae, Capra* ssp., *Camelidae*
Infection with equine arteritis virus	Equidae
Equine infectious anaemia	Equidae
Dourine	Equidae
Venezuelan equine encephalomyelitis	Equidae
Contagious equine metritis	Equidae
Equine encephalomyelitis (Eastern and Western)	Equidae
Classical swine fever	Suidae, Tayassuidae
African swine fever	Suidae
Infection with Aujeszky's disease virus	Suidae
Infection with porcine reproductive and respiratory syndrome virus	Suidae
Highly pathogenic avian influenza	Aves
Infection with Newcastle disease virus	Aves
Avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*)	*Gallus gallus, Meleagris gallopavo*
Infection with *Salmonella* Pullorum, *S.* Gallinarum, *S. arizonae*	*Gallus gallus, Meleagris gallopavo, Numida meleagris, Coturnix coturnix, Phasianus colchicus, Perdix perdix, Anas* spp.
Infection with low pathogenic avian influenza viruses	Aves
Avian chlamydiosis	Psittaciformes
Infestation with *Varroa* spp. (Varroosis)	*Apis*

Infestation with *Aethina tumida* (Small hive beetle)	*Apis, Bombus* ssp.
American foulbrood	*Apis*
Infestation with *Tropilaelaps* spp.	*Apis*
Infection with *Batrachochytrium salamandrivorans*	Caudata

Additional recommendations:

- Animals for the purpose of the disease surveillance programme mean those terrestrial animal species that are included in the table above and included in Regulation 2018/1882. In practice this means all terrestrial mammal species (including Pinnipedia spp.- see Chapter 2.1), all birds, and bee spp. of the groups *Apis* and *Bombus*, but not other invertebrates.
- Use of the OIE-WAHIS (OIE/WOAH-World Animal Health Information System) portal may assist in providing data on the national or regional epidemiological situation. OIE-WAHIS is a database through which information on the animal health situation worldwide is reported and disseminated. OIE-WAHIS data reflects the information gathered by the Veterinary Services from WOAH Members and non-Members Countries and Territories on WOAH-listed diseases in domestic animals and wildlife, as well as on emerging diseases and zoonoses[4]. The database can be accessed on https://wahis.oie.int
- Where terrestrial animals of the domestic species are kept within a confined establishment, for example in a children's petting zoo area, they will be regarded as part of the confined establishment animal collection and subject to all the same conditions as the rest of the collection as far as approval is concerned, including inclusion in the disease surveillance programme.
- It is important to note that domestic species kept within a confined establishment may be subject to additional disease surveillance and health requirements as laid down by the Member State competent authority in addition to inclusion within the confined establishment disease surveillance plan. Close consultation with the official veterinarian is recommended to fulfil such additional obligations.
- Whilst reptiles, amphibians and aquatic animals (e.g., fish, molluscs and crustaceans) fall outside the definition of a terrestrial animal species and are not subject to the disease surveillance plan linked to the approval of the confined establishment, inclusion of Caudata spp. and the fungal disease Bsal may be warranted, given its listed status.
- The disease surveillance plan should consider all the epidemiological elements within the confined establishment, for example, which species are kept that are susceptible to listed diseases, under which conditions the animals are kept, which diagnostic tests are available, which synergies can be made. The plan should form a disease risk assessment and consider the relative risks of a listed disease outbreak, as well as the mitigation and control measures in place at the confined establishment based on those risk levels.

- Disease surveillance plans of different confined establishments are likely to be quite varied in their approach and content. However, all disease surveillance plans should serve the same purpose: to understand the epidemiological situation within the confined establishment, with the surveillance planning considering the known and potential listed disease risks and explaining how those risks are taken into account. and addressed under the particular circumstances of the confined establishment.

2c. Disease surveillance planning: monitoring and control of zoonoses

Annex I PART 9 **Requirements for granting approval of confined establishments of kept terrestrial animals referred to in Article 16**	[…] 2. The requirements in relation to surveillance and control measures of confined establishments of kept terrestrial animals, as referred to in Article 16, shall be the following: a) the disease surveillance plan must include appropriate zoonoses control of the kept terrestrial animals, and must be implemented and updated according to the number and species of the kept terrestrial animals present in the establishment and to the epidemiological situation in and around the establishment as regards listed and emerging diseases;

Requirements from the legislation:

- Zoonoses control is an important requirement of the disease surveillance plan within the confined establishment. In addition to the listed diseases which may be zoonotic (e.g., avian chlamydiosis, rabies), focus should be given to zoonoses caused by other agents (e.g. *Salmonella* spp., *Campylobacter* spp., *E. coli* 0157).
- Other zoonotic agents which may be incorporated into the disease surveillance plan include those covered in national legislation as well as those listed in the 'EU Zoonoses Directive' (2003/99/EC).

Additional recommendations:

- When designing a zoonoses control programme for a confined establishment, the establishment veterinarian should focus on disease risk analysis and risk mitigation measures. Further information and guidance may be found in Chapter 7 of the UK's Zoo Expert Committee Handbook[3], accessible on www.gov.uk. Additionally, a zoonoses risk assessment template is included in section 2e) of this current Chapter.
- If it is felt necessary to screen for specific zoonotic disease agents then consideration for the implications of a positive result and what remedies, policy changes and reviews should take place upon the diagnosis of a specific agent.

- Focus should be placed upon managing the risk of zoonotic transmission instead of surveillance for specific zoonotic agents. Surveillance for specific zoonotic organisms may be misleading given the potential for intermittent shedding of some organisms (e.g., *Salmonella* spp., *Campylobacter* spp.) and that the presence of a specific agent does not correlate with clinical disease. Appropriate mitigation measures would include good personal and environmental hygiene and high animal welfare standards.
- A draft zoonoses risk assessment for activities carried out in a confined establishment where zoonoses mitigation and management is required can be found in section 2e of this Chapter.

2d. Disease surveillance planning: example proforma

The following pages contain an example proforma of a disease surveillance plan. This plan can be used for inspiration for establishment veterinarians and competent authorities on what a confined establishments disease surveillance plan may look like. Specific elements which are included in the proforma and may be useful in other plans include:

i. Contact details of the establishment veterinarian as well as the official veterinarian/competent authority.

ii. Dates of annual review for the establishment veterinarian and dates of approval for the official veterinarian/competent authority.

iii. Disease risk categories and definitions for these (those used in the proforma may be adapted, however these used are based upon two factors- the status of the listed disease in the surrounding area, zone or Member State in which the confined establishment is located and, the level of known or perceived listed disease within the European zoo population for a given species).

iv. Listed diseases of concern for the confined establishment based on the susceptible species kept as well as the population numbers within the confined establishment.

v. Surveillance and mitigation measures in place at the confined establishment based upon the disease risk given to the listed disease.

vi. Results of the surveillance and mitigation measures which have taken place over the previous 12 months and will inform the annual review of the current plan and formation of future disease surveillance planning.

Example proforma

Confined establishment name and address	
Approval number	
Establishment veterinarian and contact details	
Official veterinarian/competent authority and contact details	
Date(s) of disease surveillance plan review by establishment veterinarian	
Date(s) of approval by official veterinarian/competent authority	

Disease risk	**Description**
High	Listed disease present in zone/region in which confined establishment is located **and/or** listed disease endemic within European zoo population
Medium	Listed disease present in zone/region in which confined establishment is located but under control, **or** at high risk of entering/emerging in MS **and/or** some evidence of cases in European zoo population
Low	No evidence of listed disease within Member State **and/or** no evidence of disease within European zoo population

				Disease risk				
Listed disease	**Susceptible species (as per 2018/1882)**	**Kept susceptible species and numbers (m.f.u) in the confined establishment**	**EAZWV Transmissible Diseases Handbook link (c/signs, species susceptibility, prevention etc.)**	***High***	***Medium***	***Low***	**Surveillance and mitigation measures in place at the confined establishment**	**Annual results of surveillance and mitigation measures**
Foot and mouth disease	Artiodactyla Proboscidea	1.2.0 Eastern bongo *(Tragelaphus eurycerus isaaci)*) 2.2.0 Arabian oryx (*Oryx leucoryx*) 1.1 Okapi (*Okapia johnstoni*) 0.3.0 Asian elephant (*Elephas maximus*)	TDH Sheet 24 4th Edition			No cases in MS for the past X years.	Monitoring of animals for clinical signs. PME on all dead animals. Quarantine applied to incoming stock from non-approved sources. Known status of import confined establishment/MS known pre-movement.	No clinical signs observed in living collection. PME data on dead stock, past year (1.1. Eastern bongo, 0.2 Arabian oryx) had no evidence of FMD.

Avian chlamydiosis	Psittaciformes	2.5.2 Moluccan cockatoo (*Cacatua moluccensis*) 2.3.2 Buffon's macaw (*Ara ambigua*) 1.1.0 Red-fronted macaw (*Ara rubrogenys*)	TDH Sheet 77 4th Edition		Disease present in MS. Also, 3 cases historically in this confined est. (2015)		If importing Psittaciformes, disease history of flock known before travel. Testing pre-travel required: including serological screen of blood and PCR swab (triple swab of conjunctiva, choana, cloaca and faeces per individual). Only trade with zoos with known test negative birds. Quarantine for up to 3 months when arrive repeat, sequential testing serology and PCR swabs once in confined establishment, reduce stress, avoid contact with public (**zoonotic potential**). Both macaw species kept in indoor aviaries, no contact with wild birds.	No clinical signs observed in living collection. No Psittaciforme imports into confined establishment in past year. Serology ran on all Psittaciformes undergoing GA (for this year n=6)- all negative. PME data on dead stock past year (1.1.0 Moluccan cockatoo), no signs splenomegaly and no evidence on histology.
African swine fever	Suidae	2.3.0 Red river hog (*Potamochoerus porcus*) 1.0.0 Babirusa (*Babyrousa babyrussa*)	TDH Sheet 4 4TH Edition EAZA 2019 ASF Guidance		Disease at risk of emergence in MS. No known ASF cases within the European zoo community.		Importation of Suidae only from other confined establishments. Repeat ASF serology of new arrivals into confined establishment, including internal quarantine procedure. No visitor feeding of Suidae and no visitor contact. Maintenance of confined establishment perimeter fence to prevent wild boar entry. All animal keepers educated on ASF risk and strict hygiene/biosecurity measures in place.	No clinical signs observed in living collection. No Suidae imports into confined establishment in past year.
Etc.								

2e. Disease surveillance planning: example zoonoses risk assessment proforma for visitors

DRAFT RISK ASSESSMENT guidance notes on completing the proforma are in italics.

Please note blue areas to be completed by zoo manager/health and safety officer and yellow areas to be completed by the establishment veterinarian.

Name of confined establishment	
Approval number	
Activity to be assessed	*Type of enclosure (including type of access)*
Location	*Specific enclosure name*
People at risk	*Include whether free or restricted access, supervised or unsupervised and likely numbers per day*
Kept terrestrial animal species involved	*Species or taxonomic groupings (may be multiple)*
Other animal risks	*e.g. rodent / invertebrate pests / free-ranging wildlife*

Possible infection sources	**Transmission route**	**Likelihood of occurrence**
For example: • *Body fluids (Blood, placenta, body parts)* • *Waste (faeces, urine, vomit)* • *Direct skin contact* • *Aerosol*	*For example:* • *Inhalation* • *Ingestion* • *Etc.*	*Low, medium or high risk, with this section should also give a brief justification for the score given*

Control Measures to minimise transmission risk	*Safe working practices that zoo managers should be able to come up with as a result of knowing the animals, their enclosure and assessing potential sources of infection and transmission routes alone*

Zoonotic agents of primary concern	**Source of infection**	**Harm to humans**	**Likelihood of occurrence at zoo**
Check relevant scientific literature/handbooks for each animal species being considered	*See above*	*Consider severity of disease caused in humans, whether it can be easily treated and whether it can spread easily from human to human*	*Vet should base this decision on factors such as the previous history of disease in the confined establishment and the wider zoo population, whether disease could be introduced into zoo animals etc.*

Control measures to minimize contamination risk	*Measures directed at reducing the likelihood of the animals contracting the organisms listed and to controlling spread / contamination of the enclosure if these agents are suspected/ confirmed. This should be within the capability of the establishment veterinarian who could fill this in without knowing the details of how the enclosure is managed.* *The zoo manager would not be able to fill in the yellow section as it requires specialist knowledge both microbiological and the disease history of the collection/animals concerned.*

Further information	**Any further notes (e.g. justification why things added or not included)**		
Assessor 1	*Two assessors required as in most zoos, no one person will have sufficient knowledge to complete both parts.*	**Assessor 2**	*Two assessors required as in most zoos, no one person will have sufficient knowledge to complete both parts.*
Date		**Date**	

<u>Completed example</u> zoonoses risk assessment proforma for visitors

Zoonoses Risk Assessment: indoor walk-through aviary

Name of confined establishment	
Approval number	
Activity to assessed	Public access to indoor walk-through Aviary
Location	Tropical House
People at risk	Visitors and staff, there is unrestricted access to public areas of this enclosure
Kept terrestrial animal species involved	**Passerines:** Blue-crowned laughingthrush (*Garrulax courtoisi*) Asian fairy-bluebird (*Irena puella*) Grosbeak starling (*Scissirostrum dubium*) **Columbiformes:** Pink-headed fruit dove (*Ptilinopus porphyreus*) Victoria crowned pigeon (*Goura victoria*) **Galliformes:** Collared hill partridge (*Arborophila gingica*) Roul roul partridge (*Rollulus roulroul*)
Other animal risks	Rodent/invertebrate pests

Possible infection sources	**Transmission route**	**Likelihood**
Bird faeces	Ingestion	Moderate: daily cleaning of areas visitors are most likely to come into contact with (e.g. hand-rails benches and signage) however cannot exclude possibility that birds may defecate on visitors as is a free flight area.
	Inhalation	Low: volume of building vs. number of birds is high and good ventilation system in use. Small size of birds in flight makes production of aerosol (e.g. feather dust from take-off) low.
Direct contact with birds	Skin contact	Unlikely: birds are not tame and are unlikely to approach visitors. No public feeding allowed. Visitors are restricted to the public pathway giving birds plenty of opportunity to escape. Any sick or recently fledged birds that might find their way onto a public path are quickly identified and removed.

Control Measures to minimise transmission risk	• Enclosure designed to keep visitors on designated pathways and there is plenty of space for the birds to retreat to. • Roost and feeding areas are out of reach of the path making soiling or direct contact much less likely. • Pathways and all furnishing visitors are likely to come in contact with are cleaned and disinfected daily and any obvious soiling removed. • Visitor feeding of animals is prohibited – signage, reinforced by staff • Visitors are asked not to eat or drink in the aviary – signage, reinforced by staff • Hand sanitising/washing facilities are provided at the exit to the enclosure. • Maintain good ventilation

Zoonotic agents of primary concern	**Source of infection**	**Harm to humans**	**Likelihood of occurrence at Zoo X**
Salmonella spp. Campylobacter spp. *Chlamydia psittaci* (Avian chlamydiosis)	All three agents are found in faeces of infected birds. *Chlamydia* can also be found in feather dust.	Salmonella and Campylobacter can cause diarrhoea, vomiting and fever. *Chlamydia* caught from birds causes flu-like illness which may lead to pneumonia and in severe cases death	Low – opportunistic screening has rarely isolated these organisms in tropical house. There have been no clinical cases of disease attributable to these infections in the last 5yrs.

Control measures to minimize contamination risk	• Prior to introduction to this aviary, all new birds receive a health check and laboratory screening specifically for the above zoonoses. • No birds suspected or confirmed as harbouring zoonotic diseases will be introduced. • All sick or dead birds from this enclosure will be screened for potential zoonotic disease. • Any bird diagnosed with a potentially zoonotic disease will be removed from the free flight enclosure and isolated until such time as is fully recovered and tests negative on microbiological screening and the establishment veterinarian and manager will undertake a risk assessment to determine whether any further action is required (e.g. decontamination of the enclosure /sampling in contact birds / restricting public access) • If removing the bird(s) is not possible, access to the enclosure will be restricted (commensurate with risk) until such time as the bird(s) is fully recovered and tests negative on microbiological screening. • Rodent and invertebrate pest control programme in place • Free ranging wildlife species are excluded from the building.

Further information/ notes	•		
Assessor 1		**Assessor 2**	
Date		**Date**	

Points for the competent authority/official veterinarian to consider:

The following section provides some points for the competent authority to consider during their on-site approval audit of a confined establishment linked to the disease surveillance planning.

These points are for consideration only and additional layers of national specificities/requirements may also exist.

Consider:

- ✓ How does the terrestrial animal acquisition policy of the confined establishment take into account animal health?
- ✓ How does the disease surveillance plan consider surveillance, control and mitigation of listed and emerging diseases (as listed in Regulation 2018/1882)?
- ✓ How is the disease surveillance plan kept up to date in terms of results, post mortem examination findings and the species kept within the confined establishment?
- ✓ How does the confined establishment undertake zoonoses control and management with regards to the kept terrestrial animals?
- ✓ How does the disease surveillance plan take into account variation in disease risk throughout the year (e.g., HPAI risk in winter months, BTV in summer months)?
- ✓ How is the annual review of the plan undertaken? Who is involved, what data is used and how does it help inform the surveillance plan for future years?
- ✓ How does the confined establishment record its animal health and medical data and how does this information then inform disease surveillance planning measures?

References

1. WOAH (prev. OIE). Glossary. in *Terrestrial Animal Health Code* 1–12 (2019).
2. European Commission. *Overview report Animal Health Controls in Zoos and Laboratories*. (2016) doi:10.2772/56814.
3. DEFRA. *Zoos Expert Committee Handbook*. https://www.gov.uk/government/publications/zoos-expert-committee-handbook (2012).
4. WOAH (prev. OIE). World Animal Health Information System (OIE-WAHIS). *https://wahis.oie.int/#/home* (2021).

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Chapter 2.4. Movements into and between confined establishments in the EU

Chapter contents

- Introduction
- Key definitions from the AHL legislation
- Guidance and additional recommendations
    1. Terrestrial animal movements from a confined establishment to a confined establishment located in a different Member State
    2. Terrestrial animal movements into and between confined establishments within a single Member State
    3. Terrestrial animal movements into a confined establishment from a non-approved source
    4. Confined establishment record keeping obligations for the movement of kept terrestrial animals
    5. Other applicable EU legislation
- References

Introduction

Animal movements into and between confined establishments in the EU, are a frequent occurrence in the European zoological community. Such movements, or transfers of animals form an integral part of cooperative population management programs, such as EAZA Ex Situ Programmes (EEPs) for many globally threatened and endangered species (see Chapter 1.2). Participation in such programs may contribute towards the zoo achieving the conservation measures required by Article 3 of the EU Zoos Directive[1].

Through the movement of specifically selected individual animals, such programs distribute a species amongst several institutions to lessen the risks of catastrophic loss, whilst creating a population which aims to have self-sustaining reproduction, and which can maintain genetic diversity and guard against inbreeding depression[2].

Moving animals between establishments, particularly those located in different Member States, however, does introduce a degree of risk with regards to the spread of transboundary infectious diseases. AHL recognizes the need to move animals between and into confined establishments but also provides a proportionate basis for mitigation measures to reduce the likelihood of disease events associated with such movements.

This chapter aims to introduce the mechanism for movements of animals between and into confined establishments based in the EU, as laid down by AHL and its associated acts.

A separate chapter will deal with movements of terrestrial animals into the EU from confined establishments located in third countries.

Key definitions from the AHL legislation

Term	Definition	Legal definition source	Where to find further information in this Handbook
'animals'	means vertebrate and invertebrate animals	Def. 1, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species
'bovine animal'	means an animal of the species of ungulates belonging to the genera *Bison*, *Bos* (including the subgenera *Bos*, *Bibos*, *Novibos*, *Poephagus*) and *Bubalus* (including the subgenus *Anoa*) and the offspring of crossings of those species	Def 4, Art. 3 2020/688	Chapter 2.1 Terrestrial animals: defining species Chapter 2.4 Movements into and between confined establishments in the EU
'camelid animal'	means an animal of the species of ungulates belonging to the family *Camelidae* listed in Annex III to Regulation (EU) 2016/429	Def 15, Art. 3 2020/688	Chapter 2.1 Terrestrial animals: defining species Chapter 2.4 Movements into and between confined establishments in the EU
'caprine animal'	means an animal of the species of ungulates belonging to the genus *Capra* and the offspring of crossings of those species	Def 12, Art. 3 2020/688	Chapter 2.1 Terrestrial animals: defining species Chapter 2.4 Movements into and between confined establishments in the EU
'captive bird'	means any birds other than poultry that are kept in captivity for any reason other than those referred to in point (9), including those that are kept for shows, races, exhibitions, competitions, breeding or selling	Def 10, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species Chapter 2.4 Movements into and between confined establishments in the EU
'cervid animal'	means an animal of the species of ungulates belonging to the family *Cervidae* listed in Annex III to Regulation (EU) 2016/429	Def 16, Art. 3 2020/688	Chapter 2.1 Terrestrial animals: defining species Chapter 2.4 Movements into and between

			confined establishments in the EU
'confined establishment'	means any permanent, geographically limited establishment, created on a voluntary basis and approved for the purpose of movements, where the animals are: a) kept or bred for the purposes of exhibitions, education, the conservation of species or research; b) confined and separated from the surrounding environment; and c) subject to animal health surveillance and biosecurity measures	Def. 48, Art. 4 2016/429	Chapter 1.2 What is a confined establishment? Chapter 2.2 Approval of confined establishments in the EU
'equine animal'	means an animal of species of solipeds belonging to the genus *Equus* (including horses, asses, and zebras) and the offspring of crossings of those species	Def 14, Art. 3 2020/688	Chapter 2.1 Terrestrial animals: defining species Chapter 2.4 Movements into and between confined establishments in the EU
'hatching eggs'	means eggs, laid by poultry or captive birds, intended for incubation;	Def. 44, Art. 4 2016/429	Chapters 2.1 Terrestrial animals: defining species Chapter 3.1 Germinal products: collection, movement, and EU entry
'kept animals'	means animals which are kept by humans, including, in the case of aquatic animals, aquaculture animals	Def. 5, Art. 4 2016/429	Chapter 1.2 What is a confined establishment?
'porcine animal'	means an animal of the species of ungulates belonging to the family *Suidae* listed in Annex III to Regulation (EU) 2016/429;	Def 13, Art. 3 2020/688	Chapter 2.1 Terrestrial animals: defining species Chapter 2.4 Movements into and between confined establishments in the EU

'operator'	means any natural or legal person having animals or products under his responsibility, including for a limited duration of time, but excluding pet keepers and veterinarians	Def. 24, Art. 4 2016/429	Chapter 1.2 What is a confined establishment?
'other carnivores'	means animals of the species belonging to the order Carnivora other than dogs, cats and ferrets	Def 32, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species
'other kept ungulates'	means kept ungulates other than bovine, ovine, caprine, porcine, equine, camelid and cervid animals	Def 17, Art. 3 2020/688	Chapter 2.1 Terrestrial animals: defining species Chapter 2.4 Movements into and between confined establishments in the EU
'ovine animal'	means an animal of the species of ungulates belonging to the genus *Ovis* and the offspring of crossings of those species	Def 11, Art. 3 2020/688	Chapter 2.1 Terrestrial animals: defining species Chapter 2.4 Movements into and between confined establishments in the EU
'primates'	means animals of the species belonging to the order Primates excluding humans	Def. 12, Art. 2 2019/2035	Chapter 2.1 Terrestrial animals: defining species Chapter 2.2 Approval of confined establishments in the EU
'terrestrial animals'	means birds, terrestrial mammals, bees and bumble bees	Def. 2, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species Chapter 2.2 Approval of confined establishments in the EU

Guidance and recommendations

The following section provides further information on some processes and definitions associated with movements of animals between confined establishments located in the EU.

1. Terrestrial animal movements from a confined establishment to a confined establishment located in a different Member State

CHAPTER 6 *Art. 64* **Requirements for movements of kept terrestrial animals from confined establishments into confined establishments in other Member States**	1. Operators shall only move kept terrestrial animals from a confined establishment to a confined establishment in another Member State if those animals do not pose a significant risk to the spread of diseases for which they are listed, based on the results of the surveillance plan covering those animals. 2. Operators shall only move kept animals belonging to the families of *Antilocapridae*, *Bovidae*, *Camelidae*, *Cervidae*, *Giraffidae*, *Moschidae* or *Tragulidae* to another Member State or zone thereof in compliance with at least one of the requirements for infection with Bluetongue virus (serotype 1-24) set out in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Commission Delegated Regulation (EU) 2020/689. 3. By way of derogation from paragraph 2, the competent authority of the Member State of origin may authorise the movement of such animals which do not fulfil at least one of the requirements laid down in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Commission Delegated Regulation (EU) 2020/689 to another Member State or zone thereof a) with a disease-free status or with an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised under the conditions referred to in Article 43(2) of Commission Delegated Regulation (EU) 2020/689, or b) without a disease-free status and without an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised. If the Member State of destination sets conditions for the authorisation of such movement, those conditions must be any one of the conditions referred to in points 5 to 8 of Section 1 of Chapter 2 of Part II of Annex V of Commission Delegated Regulation (EU) 2020/689.

<u>Requirements from the legislation</u>

- Article 64 of Commission Delegated Regulation (EU) 2020/688 lays down the health requirements for movements of **<u>all species of terrestrial animals</u>** i.e. all terrestrial mammal species (including primates), all avian species as well as bees and bumblebees, (as per the Article 4 definition of Regulation (EU) 2016/429) moving between confined establishments located in different EU Member States.

a) Disease surveillance plan

The disease surveillance plan and its implementation at both the sending and receiving confined establishments is key in establishing the disease risk associated with each movement of kept terrestrial animals.

Additional recommendations:

- Disease risks will vary between confined establishments, the kept animal species and local epidemiological factors, overall however through the approval of the confined establishment and the controls placed upon them by the competent authority, we should assume this disease risk for listed diseases in most instances to be low.
- For more detailed guidance on the creation and implementation of the confined establishment disease surveillance plan, see Chapter 2.3.

b) Bluetongue virus requirements for specific ungulate species

New requirements now exist for some ungulate species moving between confined establishments located in different Member States, these requirements are laid down in points 2 and 3 of Article 64 of Regulation (EU) 2020/688. See Figure 4 for a diagrammatic representation of these new requirements.

The requirements only apply to the following taxonomic families:

- Antilocapridae (i.e., pronghorn, *Antilocapra americana*)
- Bovidae (i.e., all bovine, antelope, sheep, goat, musk-ox spp.)
- Camelidae (camelid spp., i.e., *Camelus*, *Lama* or *Vicugna* spp.)
- Cervidae (all deer spp.)
- Giraffidae (giraffe spp., *Giraffa camelopardis* and okapi, *Okapia johnstoni*)
- Moschidae (musk deer spp., i.e., *Moschus* spp.)
- Tragulidae (chevrotain or mouse-deer spp., i.e., *Hyemoschus*, *Moschiola* or *Tragulus* spp.)

Additional recommendations:

Important note:

Ungulates originating in a confined establishment which is located in a Member State of zone covered by an official BTV eradication program, can travel provided they have met one of the requirements laid down in point 2 of Section 1, Chapter 2 of Part II of Annex V of Commission Delegated Regulation (EU) 2020/689.

However, point 2(c) states that should the ungulates be vaccinated against any reported BTV 1-24 serotypes that this should be 'within the immunity period guaranteed in the specifications of the vaccine', this poses a challenge for non-domestic ungulates which would be vaccinated using off-license products via the Prescription Cascade (i.e., Articles 112-115 of Regulation (EU) 2019/6).

Therefore, our recommendation given the diversity of ungulate species kept by confined establishments and the lack of BTV immunological data to BTV vaccination in these species, to preferentially look at the options laid down in 2 a), b) and d) instead, as shown in the diagram below.

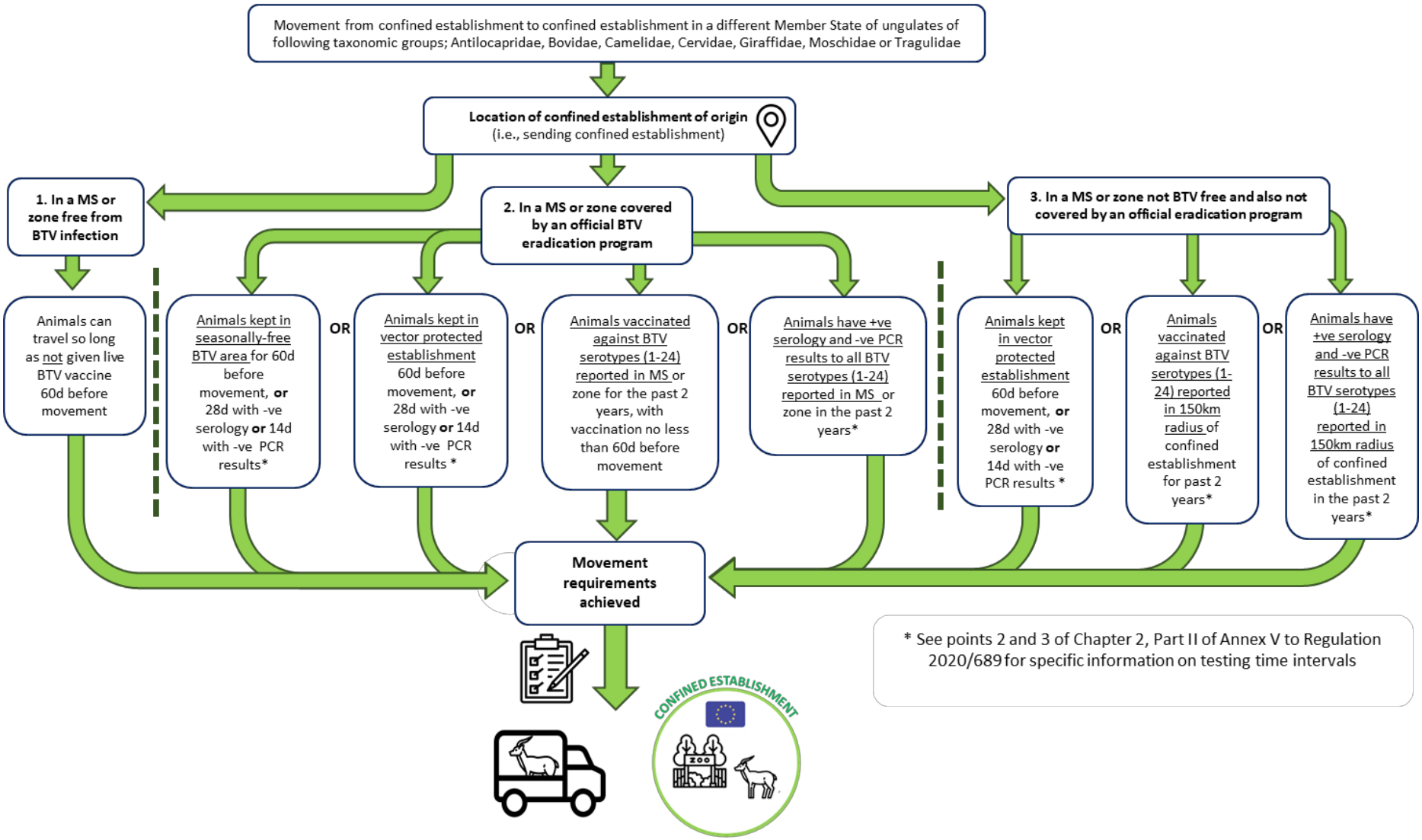


Figure 4: Diagram of pre-movement requirements for Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Moschidae and Tragulidae before moving between confined establishments located in different Member States

c) Primate movements between confined establishments

CHAPTER 5 Section 1 Primates Art 47 **Requirements for movements of primates to other Member States**	Operators shall only move primates to another Member State when the animals either: 1. have been kept in a confined establishment and are transported to a confined establishment in the Member State of destination in accordance with the requirements in Article 64(1), or 2. come from an establishment other than a confined establishment and are transported to a confined establishment in the Member State of destination in accordance with the requirements of Article 63(2)(b).
CHAPTER 6 Art. 64 **Requirements for movements of kept terrestrial animals from confined establishments into confined establishments in other Member States**	Operators shall only move kept terrestrial animals from a confined establishment to a confined establishment in another Member State if those animals do not pose a significant risk to the spread of diseases for which they are listed, based on the results of the surveillance plan covering those animals. […]

Primate species are subject to a higher level of control due the potential increased risk of zoonoses from these taxa. Primates which are to move between Member States can only do so when travelling between confined establishments or in the case of primates from a non-approved source, only with the prior authorization of both the Member State competent authorities of the origin and destination.

Once a primate has arrived at a confined establishment, from another confined establishment located in a different Member State, it is not required to undergo an official quarantine period. **Only kept terrestrial animals originating from non-approved sources are required to undergo an official quarantine period**, as per point 1(a) of Part 9 of Annex I of Commission Delegated Regulation (EU) 2019/2035.

d) Health certification

Terrestrial animal species, with the exception of captive birds, moving between two confined establishments located in different Member States should do so using the model heath certificate **'CONFINED-LIVE-INTRA'** (Chapter 58 of Annex I of Commission Implementing Regulation (EU) 2021/403). This certificate is also for use for primate species moving between confined establishments located in different Member States.

For captive birds moving between two confined establishments located in different Member States, the model health certificate 'CAPTIVE-BIRDS-INTRA' (Chapter 21 of Annex I of Commission Implementing Regulation (EU) 2021/403) should be utilized.

Health certificates for those species, outside of the definition of 'terrestrial animals' and 'aquatic animals', e.g., reptiles, should travel on model health certificates defined by the national legislation and requirements of the importing Member State.

For further information and guidance on the relevant model animal health certificates associated with AHL and confined establishments, see Chapter 2.6.

2. Terrestrial animal movements into and between confined establishments within a single Member State

Article 2, point 2, of Commission Delegated Regulation (EU) 2020/688 states that Article 63 of that Regulation also applies to movements of kept terrestrial animals moving within a single Member State. This means that the rules relating to movement of terrestrial animals into a confined establishment from a non-approved source, also apply to those movements within a Member State. Previously, the Balai Directive did not lay down such requirements for movements within a single Member State, as this would have fallen under national legislation.

For terrestrial animals moving between confined establishments in the same Member State, these movements are covered by the simple rules laid down in Article 137(1) of the AHL 2016/429. Here the basic criteria which must be met is that the animals being moved do not pose a significant risk for the spread of listed diseases or to categories of animals at the destination confined establishment, except where the movement in question is authorized for scientific purposes.

3. Terrestrial animal movements into a confined establishment from a non-approved source

Art. 63 **Requirements for movements of kept terrestrial animals from establishments other than confined establishments into a confined establishment**	1. Operators shall only move kept terrestrial animals other than primates coming from establishments other than a confined establishment into a confined establishment in compliance with the following requirements: a) the animals are subjected to quarantine for a period appropriate for the diseases listed for the species to be moved and in any case of at least 30 days and during this period they are kept, either: i. prior to their movement, in an approved quarantine establishment or in quarantine facilities of another confined establishment; or ii. after their movement, in a quarantine facility of the confined establishment of final destination; b) the animals show no clinical signs or suspicion of diseases listed for the species at the time of movement; c) the animals fulfil the requirements for identification laid down in Commission 9Delegated Regulation (EU) 2019/2035 relevant for the species; d) the animals fulfil the requirements for vaccination, treatment or testing laid down in this Regulation applicable for the movement of the animals.

	2. Operators shall only move kept primates to a confined establishment in compliance with rules that are at least as strict as those referred to in the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE), Edition 2018, in Articles 5.9.1 to 5.9.5 with regard to quarantine measures applicable to primates and in Article 6.12.4 with regard to quarantine requirements for primates from an uncontrolled environment, and such movement has been authorized a) in the case of movement within a Member State, by the competent authority of that Member State, or b) in the case of movement to another Member State, by an agreement of the competent authority of Member State of origin and the competent authority of Member State of destination.

The following section provides further information on the pre- and post-movement requirements laid down for terrestrial animals entering a confined establishment from a non-approved source (e.g., the wild, a non-approved zoo, private home, circus etc.):

a) Quarantine

All terrestrial animal species originating from non-approved sources must undergo a quarantine period under the oversight of the official veterinarian. Further details of this requirement and guidance on appropriate quarantine facilities can be found in Chapter 3.2 of this Handbook.

The quarantine period may be undertaken at the confined establishment of destination, in a quarantine facility of another confined establishment or within a designated quarantine establishment as laid down for in Commission Delegated Regulation (EU) 2019/2035.

b) Disease testing and additional health requirements

Specific disease testing and supplementary health requirements are also laid down for movements of specific taxa from non-approved sources, when these movements are between different Member States. It is important to note that these requirements also concern the movement of animals between two non-approved establishments, not just from non-approved into a confined establishment.

A summary of where to find the relevant requirements for relevant taxonomic groups can be seen in Figure 5 on the next page. Taxonomic groups of terrestrial animals not included in the diagram, fall outside of the scope of this part of the AHL legislation.

c) Health certification and animal identification

For information and guidance on the model animal health certificate to be used for the movement of different taxonomic groups from non-approved sources see Chapter 2.6.

For further information on the requirements of animal identification and confined establishments, see Chapter 2.5.

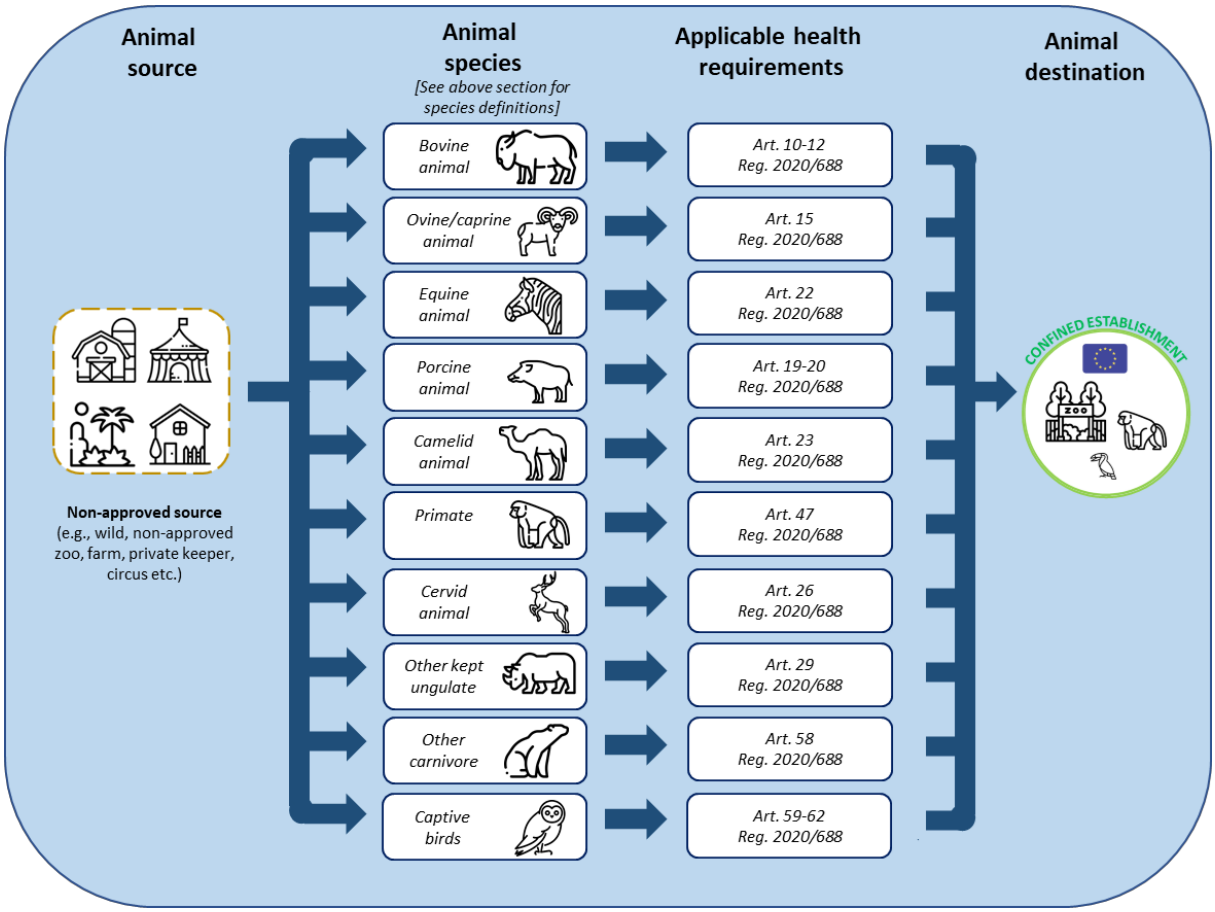


Figure 5: Diagram of the health requirements required of different animal species entering a confined establishment from a non-approved source located in a different Member State

d) Primate movements into a confined establishment from a non-approved source

CHAPTER 5 Section 1 Primates *Art 47* **Requirements for movements of primates to other Member States**	Operators shall only move primates to another Member State when the animals either: 1. have been kept in a confined establishment and are transported to a confined establishment in the Member State of destination in accordance with the requirements in Article 64(1) or 2. come from an establishment other than a confined establishment and are transported to a confined establishment in the Member State of destination in accordance with the requirements of Article 63(2)(b).
Art. 63 **Requirements for movements of kept terrestrial animals from establishments other than**	[…] Operators shall only move kept primates to a confined establishment in compliance with rules that are at least as strict as those referred to in the Terrestrial Animal Health Code of the World Organisation for Animal Health (WOAH), Edition 2018, in Articles 5.9.1 to 5.9.5 with regard to quarantine measures applicable to primates and in Article 6.12.4 with regard to quarantine

confined establishments into a confined establishment	requirements for primates from an uncontrolled environment, and such movement has been authorized: a) in the case of movement within a Member State, by the competent authority of that Member State, or b) in the case of movement to another Member State, by an agreement of the competent authority of Member State of origin and the competent authority of Member State of destination.

Primate species are subject to a higher level of control due the potential increased risk of zoonosis from these taxa. Primates which are to move between Member States can only do so when travelling between confined establishments or in the case of primates from a non-approved source, only with the prior authorization of both the Member State competent authorities of the origin and destination.

When primates do enter a confined establishment from a non-approved source, they must be admitted to the confined establishment through a quarantine procedure at least as strict as the rules laid down in the WOAH (prev. OIE) Terrestrial Animal Health Code, Article 6.12.4. of Chapter 6.123 of the 2018 or later editions (see Chapter 2.2 for further information).

4. Confined establishment record keeping obligations for the movement of kept terrestrial animals

Art. 32 **Record-keeping obligations of operators of confined establishments**	Operators of approved confined establishments shall record the following additional information: a) the estimated age and sex of animals kept on the establishment; b) the license plate number or registration number of the means of transport unloading and loading animals and the unique registration number of the transporter where available; c) details of the implementation and results of the disease surveillance plan provided for in point 2(a) of Part 9 of Annex I; d) the results of clinical, laboratory tests and post-mortem testing provided for in point 2(b) of Part 9 of Annex I; e) details of the vaccination and treatment of susceptible animals provided for in point 2(c) of Part 9 of Annex I; f) details of isolation or quarantine of incoming animals, instructions, if any, of the competent authority as regards isolation and quarantine and observations made during any isolation or quarantine period.

Article 32 of Commission Delegated Regulation (EU) 2019/2035 lays down a series of record-keeping requirements for operators of confined establishments, some of which are linked to the movements of terrestrial animals into the confined establishments. These records which are linked to movements include:

- the license plate number of registration number of the means of unloading transport;
- the unique registration number of the transported (where available);
- details of the implementation and results of the disease surveillance plan.

Further information on these record-keeping requirements and suitable record-keeping systems can be found in Chapter 2.5 of this Handbook.

5. Other applicable EU legislation

In addition to the requirements laid down in the AHL, there are a number of other pieces of EU legislation which may be applicable depending on the specificities of the animal movement. These include:

a) Regulation on Animal Welfare during Transport

Council Regulation (EC) 1/2005 on the protection of animals during transport:

This legislation regulates the transport of live animals (vertebrates) between EU countries and provides checks on animals entering or leaving the EU. The detailed rules aim to prevent injury or unnecessary suffering to the animals.

Key points:

- Transport arrangements must be made in advance to minimize the length of the journey and meet the animals' needs.
- The animals must be fit to travel.
- The means of transport, and loading and unloading facilities, must be designed, constructed, maintained and operated so as to avoid injury and suffering and ensure the animals' safety.
- People handling the animals must be properly trained and may not use any form of violence.
- Transportation to the destination must take place without delay and involve regular checks on the animals' welfare.
- Sufficient height and floor space must be available for the animals.
- Water, feed and rest must be provided when needed.
- Transporters must have authorization from the relevant national authority for all journeys over 65 km and provide documentation containing details such as the animals' origin and ownership, their destination and expected journey time.

b) Wildlife Trade Regulations

Council Regulation (EC) 338/97 on the protection of species of wild fauna and flora by regulating trade therein (base regulation) and additional implementing regulations:

As the EU is a single market without internal border controls, trade-related rules need to be implemented uniformly in all EU countries. This also applies to rules on the trade in endangered species, as regulated by CITES. The EU Wildlife Trade Regulations implement CITES in EU countries.

Key points:

- The import of specimens of endangered species into the EU requires a permit issued by an authority of the EU country of destination or an import notification.
- Export from the EU requires an export permit or a re-export certificate issued by an authority of the EU country in which the specimens are located.
- Categories of species are outlined in Annexes A to D of the regulation.
- Special rules apply to specimens born and bred in captivity or that are the result of artificial reproduction, part of personal effects or destined for scientific institutions.

References

1. European Commission. EU Zoos Directive Good Practices Document. (2015). doi:10.2779/247108.
2. Linhart, P., Adams, D. B. & Voracek, T. The international transportation of zoo animals: conserving biological diversity and protecting animal welfare. Veterinaria italiana 44, 49–57 (2008).
3. WOAH (prev. OIE). Zoonoses transmissible from non-human primates. in OIE Terrestrial Animal Health Code 1–5 (2019).

Chapter 2.5. Animal identification and record keeping obligations

Chapter contents

Introduction

The ability to identify the animals within a zoo or confined establishment is linked to record keeping and the traceability requirements of animals of certain taxa. Animal Health Law lays down a series of acceptable identification methods for specific species, namely bovine, ovine, caprine and porcine animals. Identification systems used within a zoo or confined establishment should be appropriate for the species in question, consider animal welfare as well as national legislation.

Additionally, it is important to note that specific animal identification requirements may exist beyond those discussed in this chapter, for example, for species listed in Annex A of the EU Wildlife Trade Regulations (Council Regulation (EC) No 338/97). A summary of these requirements for identification and marking can be found on https://environment.ec.europa.eu/topics/nature-and-biodiversity/wildlife-trade_en.

Good record keeping is a cornerstone of modern zoo animal management, contributing towards to the daily running of a facility as well as providing an important basis for contributing to the wider zoo goals of animal health, welfare, conservation, and research. Animal record keeping assists animal management staff to care for their animals, as well as the wider ex-situ management of species at the population level. In the context of the Animal Health Law, specific requirements for record keeping are laid down for operators of confined establishments.

It is important to note that appropriate record keeping obligations are also laid down for EU zoos through the fifth indent of Article 3 of the Zoos Directive (Council Directive 1999/22/EC), through the '*keeping of up-to-date records of the zoo's collection appropriate to the species recorded*'. Further information on the appropriate implementation of this point can found in the EU Zoos Directive Good Practices Document[1].

As a record keeping system, EAZA Member institutions are obliged to use the online central database Species360 ZIMS (Zoological Information Management Software). This database integrates both animal husbandry (ZIMS for Husbandry) and veterinary modules (ZIMS for Medical) obtained from participating institutions into a master dataset, comprising over 10 million individual animals, resulting in the largest keeping system, this greatly facilitates the collection, analysis, and transfer of records across international borders between collaborating confined establishments and zoos.

Key definitions from the AHL legislation

Term	Definition	Legal definition source	Where to find further information in this Handbook
'animals'	means vertebrate and invertebrate animals	Def. 1, Art. 4 2016/429	Chapter 2.1: Terrestrial animals: defining species
'bovine animal'	means an animal of the species of ungulates belonging to the genera *Bison*, *Bos* (including the subgenera *Bos*, *Bibos*, *Novibos*, *Poephagus*) and *Bubalus* (including the subgenus *Anoa*) and the offspring of crossings of those species	Def 4, Art. 3 2020/688	Chapter 2.1: Terrestrial animals: defining species
'camelid animal'	means an animal of species of ungulates of family *Camelidae* listed in Annex III to Regulation (EU) 2016/429;	Def 31, Art. 2, 2019/2035	Chapter 2.1: Terrestrial animals: defining species
'caprine animal'	means an animal of the species of ungulates belonging to the genus *Capra* and the offspring of crossings of those species	Def 12, Art. 3 2020/688	Chapter 2.1: Terrestrial animals: defining species
'cervid animal'	means an animal of the species of ungulates of family *Cervidae* listed in Annex III to Regulation (EU) 2016/429;	Def 32, Art. 2, 2019/2035	Chapter 2.1: Terrestrial animals: defining species
'confined establishment'	means any permanent, geographically limited establishment, created on a voluntary basis and approved for the purpose of movements, where the animals are: a) kept or bred for the purposes of exhibitions, education, the conservation of species or research; b) confined and separated from the surrounding environment; and c) subject to animal health surveillance and biosecurity measures	Def. 48, Art. 4 2016/429	Chapter 1.2: What is a confined establishment? Chapter 2.2: Approval of confined establishments in the EU
'equine animal'	means an animal of species of solipeds belonging to the genus *Equus* (including horses, asses, and zebras) and the offspring of crossings of those species;	Def 24, Art. 2, 2019/2035	Chapter 2.1: Terrestrial animals: defining species
'kept animals'	means animals which are kept by humans, including, in the case of aquatic animals, aquaculture animals	Def. 5, Art. 4 2016/429	Chapter 1.2: What is a confined establishment?
'porcine animal'	means an animal of the species of ungulates belonging to the family *Suidae* listed in Annex III to Regulation (EU) 2016/429;	Def 13, Art. 3 2020/688	Chapter 2.1: Terrestrial animals: defining species

Guidance and recommendations

The following section provides further information on the animal identification requirements and the record keeping obligations of confined establishments located in the EU.

1. Animal identification in the confined establishment

Requirements from the legislation:

- Commission Delegated Regulation (EU) 2019/2035 lays down the specific requirements for operators keeping bovine, ovine, caprine, porcine and equine animal to be able to identify each animal through use of a physical means of identification. These requirements may extend to non-domestic species kept in EU based confined establishments, and those animals entering the confined establishment from non-approved sources. For more details on the definitions of these taxa, see above or Chapter 2.1 of this Handbook.
- Commission Delegated Regulation (EU) 2019/2035 further specifies the acceptable methods of physical identification for each group of animals falling under the definition of bovine, ovine, caprine, porcine and equine animals, as well as camelids, cervids and Psittacidae. See Figure 6 below for more information.
- With regards to the approved methods of physical identification of bovine, ovine, caprine additional methods are approved for those individuals kept in a confined establishments, however use of this exemption and additional methods for operators of confined establishments, is subject to authorisation of the competent authority.
- Additionally, through Article 117 of Regulation (EU) 2016/429 (AHL), operators keeping terrestrial animals other than bovine, ovine, caprine, porcine and equine animals need to be able to identify each animal by physical means to ensure that when those individuals move to a different facility or Member State, that they do so with the correct identification and movement documentation. The methods of identification of these species is not specified in the AHL legislation and would be at the discretion of the confined establishment, the competent authority and any applicable national legislation.
- Regarding captive birds, specific requirements are laid down for species of Psittacidae, through Article 76 of Commission Delegated Regulation (EU) 2019/2035. These requirements for physical identification of the individual however are linked to the ability to move the bird to another EU Member State, not for identifications sake as the primary objective.
- It is also important that the timings or animal's age when the physical means of identification need to be in place by, are not specified in AHL. These may however be laid down in national legislation.

Additional recommendations:

The use of injectable transponders is common practice in the modern confined establishment for the identification of most kept terrestrial animals falling outside the definitions of bovine, ovine, caprine, porcine, equine, camelid and cervid animals. For welfare reasons, small avian species, typically weighing below 100g, may be subject to leg ring identification rather than injectable transponders.

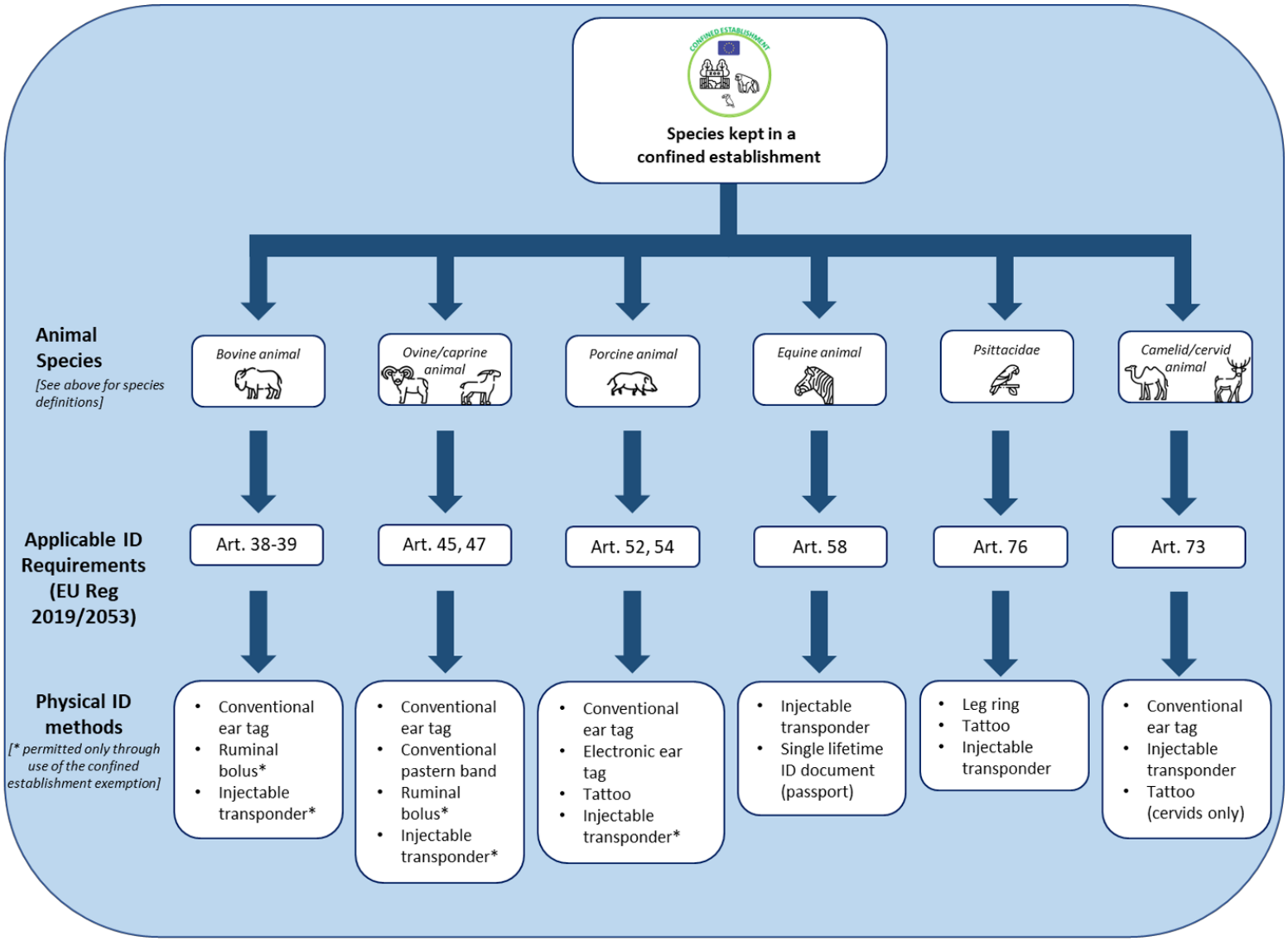


Figure 6: Approved methods of physical identification for kept ovine, caprine, porcine, equine, cervid and camelid animals as well as Psittacidae

2. Exemption from the requirements for the identification of bovine, ovine, caprine and porcine animals kept in confined establishments

a) Bovine animals

Art. 39 **Exemptions granted by the competent authority for operators of confined establishments and for operators to identify bovine animals kept for cultural, historical, recreational, scientific or sporting purposes**	1. The competent authority may exempt operators of confined establishments and operators keeping bovine animals for cultural, historical, recreational, scientific or sporting purposes from the identification requirements for bovine animals provided for in Article 38(1)(a). 2. When granting exemptions as provided in paragraph 1, the competent authority shall ensure that at least one of the means of identification listed in points (d) and (e) of Annex III is approved by the competent authority for the application of the means of identification of bovine animals kept by operators exempted in accordance with paragraph 1 of this Article. 3. The competent authority shall establish procedures for application by operators when requesting such an exemption as provided in paragraph 1 of this Article.

b) Ovine and caprine animals

Art. 47 **Exemptions from the requirements of Article 45(2) for operators of confined establishments and those keeping animals for cultural, recreational or scientific purposes**	1. The competent authority may exempt operators of confined establishments and operators keeping ovine and caprine animals for cultural, recreational or scientific purposes from identification requirements of Article 45(2) subject the conditions laid down in paragraph 2 of this Article. 2. The competent authority shall ensure that either a ruminal bolus as listed in points (d) of Annex III, or an injectable transponder as listed in point (e) of that Annex III, has been authorised by it for the identification of the ovine and caprine animals referred to in paragraph 1, and that such authorised means of identification complies with the requirements laid down in Article 48(3). 3. The competent authority shall establish procedures for application by operators when requesting such an exemption as provided in paragraph 1 of this Article.

c) Porcine animals

Art. 54 **Exemptions granted by the competent authority for operators of confined establishments and for operators to identify porcine animals kept for cultural, recreational or scientific purposes**	1. The competent authority may exempt operators of confined establishments and operators keeping porcine animals for cultural, recreational or scientific purposes from the identification requirements for porcine animals provided for in Article 52(1). 2. When granting exemptions as provided for in paragraph 1 of this Article, the competent authority shall ensure that an injectable transponder as listed in point (e) of Annex III, has been authorised by it for the identifications of porcine animals referred to in paragraph 1 of this Article, and that such authorised means of identification complies with the requirements of Article 55(1). 3. The competent authority shall establish procedures for application by operators when requesting such an exemption as provided in paragraph 1 of this Article.

Additional recommendations:

Use of the exemption for the above animals to be identified by an electronic transponder in the confined establishment should be considered normal practice. Additionally, the ability to identify these animals successfully should also be in place within the confined establishment through appropriate facilities and staff training.

3. Record keeping obligations for confined establishments

Art. 32 **Record-keeping obligations on operators of confined establishments**	Operators of approved confined establishments shall record the following additional information: […] a) the estimated age and sex of animals kept on the establishment; b) the licence plate number or registration number of the means of transport unloading and loading animals and the unique registration number of the transporter where available; c) details of the implementation and results of the disease surveillance plan provided for in point 2(a) of Part 9 of Annex I; d) the results of clinical, laboratory tests and post-mortem testing provided for in point 2(b) of Part 9 of Annex I; e) details of the vaccination and treatment of susceptible animals provided for in point 2(c) of Part 9 of Annex I; f) details of isolation or quarantine of incoming animals, instructions, if any, of the competent authority as regards isolation and quarantine and observations made during any isolation or quarantine period.

Requirements from the legislation:

- Record keeping obligations for confined establishments are also in place through Article 32 of Commission Delegated Regulation (EU) 2019/2035. These record keeping requirements are linked to the approval requirements of the confined establishment, and therefore focus on the biosecurity, animal traceability and disease surveillance planning in place at the confined establishment. For further information on the approval requirements of a confined establishment in the EU, see Chapter 1.2 of this Handbook.
- These records maintained by the operator of the confined establishment should be subject to checks and audits by the competent authority as required by Article 4 of Commission Delegated Regulation (EU) 2022/671.

Additional recommendations:

The online centralized database Species360 ZIMS provides a globally recognized solution to record keeping for non-domestic species in human care. Data from ZIMS can easily be extracted for audits by the competent authority and provide up to date information on the movement records into the confined establishment as well as an individual's age and gender and health status.

References

1. European Commission. *EU Zoos Directive Good Practices Document*. (2015). doi:10.2779/247108.

Section 2. AHL Legislation Annex

Regulation (EU) 2016/429

Art. 137 **Kept terrestrial animals intended for confined establishments and delegated acts**	1. Operators shall only move kept terrestrial animals to a confined establishment if the animals in question fulfil the following conditions: a. they originate from another confined establishment; b. they do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to listed species or to categories of animals at the confined establishment of destination, except where the movement in question is authorised for scientific purposes. 2. The Commission shall adopt delegated acts in accordance with Article 264 concerning: a. detailed rules for movements of kept terrestrial animals into confined establishments in addition to those provided for in paragraph 1 of this Article; b. specific rules for movements of kept terrestrial animals into confined establishments where the risk-mitigation measures in place guarantee that such movements do not pose a significant risk for the health of kept terrestrial animals within that confined establishment and the surrounding establishments.

Commission Delegated Regulation (EU) 2020/688

CHAPTER 5 Section 1 Primates *Art 47* **Requirements for movements of primates to other Member States**	Operators shall only move primates to another Member State when the animals either: 1. have been kept in a confined establishment and are transported to a confined establishment in the Member State of destination in accordance with the requirements in Article 64(1); or 2. come from an establishment other than a confined establishment and are transported to a confined establishment in the Member State of destination in accordance with the requirements of Article 63(2)(b).
CHAPTER 6 *Art. 64* **Requirements for movements of kept terrestrial animals from confined establishments into confined establishments in**	2. Operators shall only move kept terrestrial animals from a confined establishment to a confined establishment in another Member State if those animals do not pose a significant risk to the spread of diseases for which they are listed, based on the results of the surveillance plan covering those animals. 3. Operators shall only move kept animals belonging to the families of *Antilocapridae*, *Bovidae*, *Camelidae*, *Cervidae*, *Giraffidae*, *Moschidae* or *Tragulidae* to another Member State or zone thereof in compliance with at least one of the requirements for infection with Bluetongue virus (serotype

other Member States	1-24) set out in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Commission Delegated Regulation (EU) 2020/689. 4. By way of derogation from paragraph 2, the competent authority of the Member State of origin may authorise the movement of such animals which do not fulfil at least one of the requirements laid down in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Commission Delegated Regulation (EU) 2020/689 to another Member State or zone thereof: a) with a disease-free status or with an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised under the conditions referred to in Article 43(2) of Commission Delegated Regulation (EU) 2020/689; or b) without a disease-free status and without an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised. If the Member State of destination sets conditions for the authorisation of such movement, those conditions must be any one of the conditions referred to in points 5 to 8 of Section 1 of Chapter 2 of Part II of Annex V of Commission Delegated Regulation (EU) 2020/689.
Art. 63 **Requirements for movements of kept terrestrial animals from establishments other than confined establishments into a confined establishment**	3. Operators shall only move kept terrestrial animals other than primates coming from establishments other than a confined establishment into a confined establishment in compliance with the following requirements: a) the animals are subjected to quarantine for a period appropriate for the diseases listed for the species to be moved and in any case of at least 30 days and during this period they are kept either: i. prior to their movement, in an approved quarantine establishment or in quarantine facilities of another confined establishment; or ii. after their movement, in a quarantine facility of the confined establishment of final destination; b) the animals show no clinical signs or suspicion of diseases listed for the species at the time of movement; c) the animals fulfil the requirements for identification laid down in Commission Delegated Regulation (EU) 2019/2035 relevant for the species; d) the animals fulfil the requirements for vaccination, treatment or testing laid down in this Regulation applicable for the movement of the animals. 4. Operators shall only move kept primates to a confined establishment in compliance with rules that are at least as strict as those referred to in the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE), Edition 2018, in Articles 5.9.1 to 5.9.5 with regard to quarantine

	measures applicable to primates and in Article 6.12.4 with regard to quarantine requirements for primates from an uncontrolled environment, and such movement has been authorized a) in the case of movement within a Member State, by the competent authority of that Member State, or b) in the case of movement to another Member State, by an agreement of the competent authority of Member State of origin and the competent authority of Member State of destination.

Commission Delegated Regulation (EU) 2020/689

Annex V Part II Chapter 2 Section 1	1. The animals originate from a Member State or a zone free from infection with BTV and have not been vaccinated with a live vaccine against infection with BTV in the last 60 days before the date of movement. 2. The animals originate from a Member State or a zone covered by the eradication programme and at least one of the following requirements is complied with: a) the animals have been kept in a seasonally BTV-free Member State or zone established in accordance with paragraph 3 of Article 40: i. for at least 60 days prior to the date of movement; ii. for at least 28 days prior to the date of movement and have been subjected to a serological test, with negative results, carried out on samples collected at least 28 days following the entry date of the animal into the seasonally BTV-free Member State or zone; or iii. for at least 14 days prior to the date of movement and have been subjected to a PCR test, with negative results, carried out on samples collected at least 14 days following the entry date of the animal into the seasonally BTV-free Member State or zone; b) the animals have been protected against attacks by the vectors during transportation to the place of destination and they have been kept protected against attacks by vectors in a vector protected establishment: i. for at least 60 days prior to the date of movement; or ii. for at least 28 days prior to the date of movement and have been subjected to a serological test, with negative results, carried out on samples collected at least 28 days following the date of the commencement of the period of protection against attacks by vectors; or iii. for at least 14 days prior to the date of movement and have been subjected to a PCR test, with negative results, carried out on samples collected at least 14 days following the date of

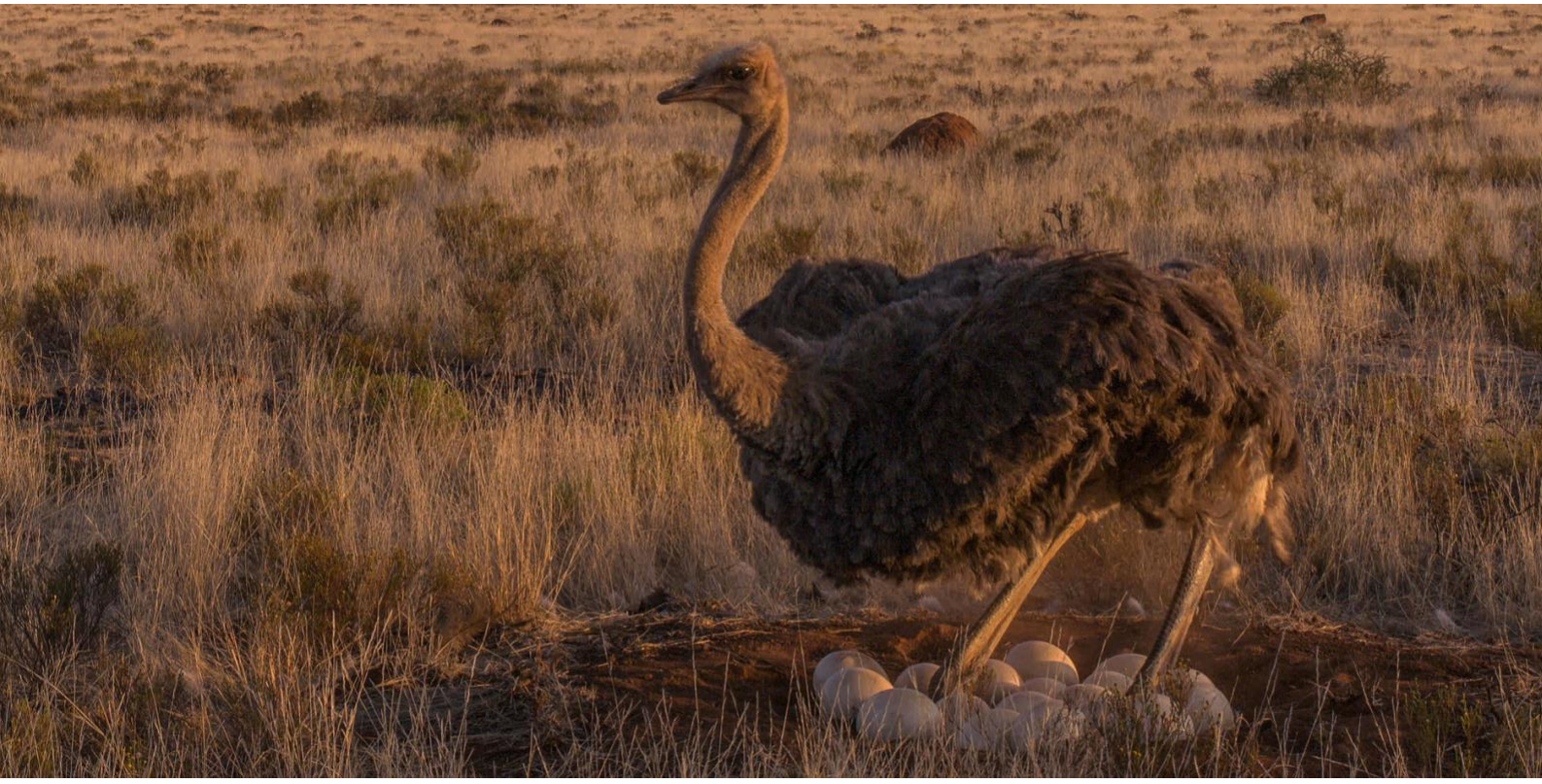
	commencement of the period of protection against attacks by vectors; c) the animals have been vaccinated against all serotypes 1-24 of BTV reported during the past 2 years in that Member State or zone, the animals are within the immunity period guaranteed in the specifications of the vaccine and meet at least one of the following requirements: i. they have been vaccinated more than 60 days before the date of movement; or ii. they have been vaccinated with an inactivated vaccine and subjected to a PCR test, with negative results on samples collected at least 14 days after the onset of the immunity set in the specifications of the vaccine. d) the animals have been subjected with positive results to a serological test able to detect specific antibodies against all serotypes 1-24 of BTV reported during the past 2 years in that Member State or zone and: i. the serological test has been carried out on samples collected at least 60 days before the date of movement; or ii. the serological test has been carried out on samples collected at least 30 days before the date of the movement and the animals have been subjected to a PCR test, with negative results, carried out on samples collected not earlier than 14 days before the date of movement. 3. The animals originate from a Member State or a zone neither BTV-free nor covered by an eradication programme for infection with BTV and: a) they comply with point 2(b); or b) the animals have been kept at least for the last 60 days prior to departure either in an area of at least 150 km radius from the establishment where they are kept, or in a Member State, where surveillance in compliance with the requirements laid down in Sections 1 and 2 of Chapter 1 have been carried out at least for the last 60 days prior to departure and: i. they have been vaccinated in accordance with point 2(c) against all serotypes 1-24 of BTV reported during the past 2 years in an area of at least 150 km radius centred on the place where the animals were kept; or ii. they have been immunised in accordance with point 2(d) against all serotypes 1-24 of BTV reported during the past 2 years in an area of at least 150 km radius centred on the place where the animals were kept.

Commission Delegated Regulation (EU) 2019/2035

Art. 32 **Record-keeping obligations of operators of confined establishments**	Operators of approved confined establishments shall record the following additional information: a) the estimated age and sex of animals kept on the establishment; b) the licence plate number or registration number of the means of transport unloading and loading animals and the unique registration number of the transporter where available; c) details of the implementation and results of the disease surveillance plan provided for in point 2(a) of Part 9 of Annex I; d) the results of clinical, laboratory tests and post-mortem testing provided for in point 2(b) of Part 9 of Annex I; e) details of the vaccination and treatment of susceptible animals provided for in point 2(c) of Part 9 of Annex I; f) details of isolation or quarantine of incoming animals, instructions, if any, of the competent authority as regards isolation and quarantine and observations made during any isolation or quarantine period.

Section 3:

Germinal products and confined establishments



Chapter 3.1. Germinal products: collection, movement, and EU entry

Chapter contents

Introduction

In recent decades the application of assisted reproductive techniques (ARTs) in non-domestic species kept in zoological facilities globally has increased and developed significantly. ARTs in zoo-kept species are increasingly commonplace and are viewed as an important tool in the population management of some endangered species1–7.

ARTs are currently not considered to be a replacement for natural reproduction of zoo animals, but rather a device to augment population management in specific circumstances; where natural breeding alone is insufficient to protect population sustainability[8,9], to facilitate reproduction between behaviorally incompatible animals, and to reduce the burden and requirements of transferring live animals between facilities for breeding purposes. ART can also improve the genetic diversity of a population by facilitating the introduction of genes from an unrelated or less related population, for example, from the wild or from zoos in another region globally.

The collection and movement of germinal products are key components for the use and further development of ARTs in zoo-kept species. In the context of a confined establishment, there is a number of important controls, laid down in Commission Delegated Regulation (EU) 2020/686, which need to be in place with regards to the health status of the donor animal and the traceability of any germinal products collected. These controls aim to reduce the likelihood and mitigate the impact of transmissible listed diseases, especially those which may be sexually transmitted within an animal population e.g., ovine epididymitis caused by *Brucella ovis* or contagious equine metritis (CEM).

Finally, it is important to introduce the concept and role of biobanking germinal products of zoo-kept species. Biobanking has been described as ex situ conservation resource to secure genetic material, enable conservation-directed research, improve the viability of small populations, and provide a backstop against extinction in certain cases10. In the EAZA community, biobanking is undertaken through a number of designated hub locations across Europe, with samples obtained from across EAZA Members. These

activities may include the banking of germinal products, but also genetic material from zoo-kept animals more widely. The relevant legislative text on the movement of germinal products to a gene bank is therefore highlighted in this Chapter.

Key definitions from the AHL legislation

Term	Definition	Legal definition source	Where to find further information in this Handbook
'animals'	means vertebrate and invertebrate animals	Def. 1, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species
'terrestrial animals'	means birds, terrestrial mammals, bees and bumble bees	Def. 2, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species Chapter 2.2 Approval of confined establishments in the EU
'germinal products'	means: a) semen, oocytes and embryos intended for artificial reproduction; b) hatching eggs;	Def. 28, Art. 4 2016/429	Chapter 3.1: Germinal products and EU-based confined establishments
'other animals'	means animals of species other than those falling within the definition of terrestrial or aquatic animals;	Def. 4, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species
'kept animals'	means animals which are kept by humans, including, in the case of aquatic animals, aquaculture animals;	Def. 5, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species
'wild animals'	means animals which are not kept animals;	Def. 8, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species
'bovine animal'	means an animal of the species of ungulates belonging to the genera *Bison*, *Bos* (including the subgenera *Bos*, *Bibos*, *Novibos*, *Poephagus*) and *Bubalus* (including the subgenus *Anoa*) and the offspring of crossings of those species	Def 4, Art. 3 2020/688	Chapter 2.4 Movements into and between confined establishments in the EU
'camelid animal'	means an animal of the species of ungulates belonging to the family *Camelidae* listed in Annex III to Regulation (EU) 2016/429	Def 15, Art. 3 2020/688	Chapter 2.4 Movements into and between confined establishments in the EU
'caprine animal'	means an animal of the species of ungulates belonging to the genus *Capra* and the offspring of crossings of those species	Def 12, Art. 3 2020/688	Chapter 2.4 Movements into and between confined establishments in the EU

'captive bird'	means any birds other than poultry that are kept in captivity for any reason other than those referred to in point (9), including those that are kept for shows, races, exhibitions, competitions, breeding or selling	Def 10, Art. 4 2016/429	Chapter 2.4 Movements into and between confined establishments in the EU
'cervid animal'	means an animal of the species of ungulates belonging to the family *Cervidae* listed in Annex III to Regulation (EU) 2016/429	Def 16, Art. 3 2020/688	Chapter 2.4 Movements into and between confined establishments in the EU
'equine animal'	means an animal of species of solipeds belonging to the genus *Equus* (including horses, asses, and zebras) and the offspring of crossings of those species	Def 14, Art. 3 2020/688	Chapter 2.4 Movements into and between confined establishments in the EU
'hatching eggs'	means eggs, laid by poultry or captive birds, intended for incubation;	Def. 44, Art. 4 2016/429	Chapter 2.1 Terrestrial animals: defining species
'porcine animal'	means an animal of the species of ungulates belonging to the family *Suidae* listed in Annex III to Regulation (EU) 2016/429;	Def 13, Art. 3 2020/688	Chapter 2.4 Movements into and between confined establishments in the EU
'primates'	means animals of the species belonging to the order Primates excluding humans	Def. 12, Art. 2 2019/2035	Chapter 2.2 Approval of confined establishments in the EU
'ovine animal'	means an animal of the species of ungulates belonging to the genus *Ovis* and the offspring of crossings of those species	Def 11, Art. 3 2020/688	Chapter 2.4 Movements into and between confined establishments in the EU
'gene bank'	means a repository of animal genetic material for ex situ conservation and sustainable use of genetic resources of kept terrestrial animals, held by a host institution authorised or recognised by the competent authority to fulfil these tasks;	Def 10, Art. 2 2020/686	Chapter 3.1: Germinal products and EU-based confined establishments
'confined establishment'	means any permanent, geographically limited establishment, created on a voluntary basis and approved for the purpose of movements, where the animals are: a) kept or bred for the purposes of exhibitions, education, the conservation of species or research; b) confined and separated from the surrounding environment; and	Def. 48, Art. 4 2016/429	Chapter 2.2 Approval of confined establishments in the EU

	c) subject to animal health surveillance and biosecurity measures.		
'operator'	means any natural or legal person having animals or products under his responsibility, including for a limited duration of time, but excluding pet keepers and veterinarians;	Def. 24, Art. 4 2016/429	Chapter 2.2 Approval of confined establishments in the EU

Guidance and additional recommendations

The following section provides further information on some key processes associated with germinal product collection in the EU-based confined establishment and the movements of germinal products between confined establishments.

1. Approval requirements

Requirements from the legislation:

- Recital 30 of Commission Delegated Regulation (EU) 2020/686 states that: 'This Regulation should […] provide for a possibility for operators of confined establishments to move to other Member States consignments of germinal products collected from animals kept at those establishments without a need for additional approval as germinal product establishment. High animal health requirements for the approval as a confined establishment, controlled management of animals at those establishments, specific surveillance requirements and targeted movement of consignments of germinal products to another confined establishment should provide for sufficient guarantees to prevent the spread of animal diseases.'
- Confined establishments are uniquely placed within the AHL legislation to be able to undertake collection and movements of germinal products to other Member States without the need for additional approval by the competent authority. Whilst there is no requirement for additional approval, specific requirements are laid down concerning the health of donor animals and the traceability and certification of germinal products originating from a confined establishment.

2. Movements of germinal products between confined establishments located in different EU Member States: bovine, porcine, ovine, caprine and equine animals

Art. 14 **Derogation for movements to other Member States of germinal products of bovine, porcine, ovine, caprine and equine animals kept at confined establishments**	By way of derogation from Article 12, operators of confined establishments may move to other Member States consignments of semen, oocytes and embryos collected at those establishments from bovine, porcine, ovine, caprine and equine animals, provided that those operators: a) only move consignments of those germinal products to another confined establishment; b) ensure that the donor animals: i. do not come from an establishment, nor have been in contact with animals from an establishment, situated in a restricted zone established due to the occurrence of a category A disease or of an emerging disease relevant for bovine, porcine, ovine, caprine or equine animals; ii. come from an establishment where none of the category D diseases relevant for bovine, porcine, ovine, caprine or equine animals have been reported for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos; iii. have remained in a single confined establishment of origin for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos; iv. have been clinically examined by the establishment veterinarian responsible for the activities carried out at confined establishment, and showed no symptoms suggesting the presence of any of the category D diseases referred to in point (ii) or of the emerging diseases or clinical signs of such diseases, on the day of collection of the semen, oocytes or embryos; v. as much as possible, were not used for natural breeding during a period of at least 30 days prior to the date of first collection and during the period of collection of the semen, oocytes or embryos intended for movement to another Member State; vi. are identified in accordance with requirements laid down in Commission Delegated Regulation (EU) 2019/2035; ▪ for bovine animals in Article 38; ▪ for porcine animals in Article 52(1) or 54(2); ▪ for ovine and caprine animals in Article 45(2) or (4), or Article 46(1), (2) or (3); ▪ for equine animals in Article 58(1) or 59(1) or 62(1); c) ensure that the germinal products have been marked in accordance with the requirements provided for in Article 10; d) ensure that the germinal products are transported in accordance with Articles 28 and 29.

Requirements from the legislation:

- The animal health requirements for donor animals of bovine, porcine, ovine, caprine and equine animal species are laid down in a specific derogation (Art. 14 of Commission Delegated Regulation (EU) 2020/686), if those animals are kept in a confined establishment. The definitions for these species can be found above, and does cover non-domestic species e.g. donor animals of Javan banteng (*Bos javanicus*) and red river hog (*Potamochoerus porcus*) would be classified as bovine and porcine animals respectively and be subject to the Article 14 requirements.
- Animal health requirements for donor animals kept in confined establishments are laid down with respect to the ability to move the collected germinal products to another EU Member State. If the germinal products were to be used within the confined establishment of collection or the same Member State, national legislation would apply.
- Category A and D diseases are laid down in Commission Implementing Regulation (EU) 2018/1882, with a **category A disease** being defined as a listed disease that does not normally occur in the Union and for which immediate eradication measures must be taken as soon as it is detected, as referred to in Article 9(1)(a) of Regulation (EU) 2016/429 and a **category D disease** being a listed disease for which measures are needed to prevent it from spreading on account of its entry into the Union or movements between Member States, as referred to in Article 9(1)(d) of Regulation (EU) 2016/429.
- For donor animals kept in confined establishments of bovine, porcine, ovine, caprine and equine species the following diseases are relevant for Art. 14, point (b)(i), (ii) and (iv):

Category A listed diseases of concern for donor animals of bovine, porcine, ovine, caprine and equine animals:	**Relevant listed susceptible species (as per Regulation (EU) 2018/1882):**
Foot and mouth disease	Artiodactyla of bovine, porcine, ovine, caprine animals
Infection with rinderpest virus	Artiodactyla of bovine, porcine, ovine, caprine animals
Infection with Rift Valley fever virus	Bovidae of the species *Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Infection with lumpy skin disease virus	*Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia)	*Bison* ssp., *Bos* ssp., *Bubalus* ssp., *Syncerus cafer*
Sheep pox and goat pox	*Ovis* ssp., *Capra* ssp.
Infection with peste des petits ruminants virus	*Ovis* ssp., *Capra* ssp.
Contagious caprine pleuropneumonia	*Ovis* ssp., *Capra* ssp.
African horse sickness	Equidae
Infection with *Burkholderia mallei* (Glanders)	Equidae, *Capra* ssp.
Classical swine fever	Suidae, Tayassuidae
African swine fever	Suidae

Category D listed diseases of concern for donor animals of bovine, porcine, ovine, caprine and equine animals:	**Relevant listed susceptible species (as per Regulation (EU) 2018/1882):**
Foot and mouth disease	Artiodactyla of bovine, porcine, ovine, caprine animals
Infection with rinderpest virus	Artiodactyla of bovine, porcine, ovine, caprine animals
Infection with Rift Valley fever virus	Bovidae of the species *Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Infection with *Brucella abortus, B. melitensis, B. suis*	*Bison* ssp., *Bos* ssp., *Bubalus* ssp., *Ovis* ssp., *Capra* ssp.
Infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae, M. tuberculosis*)	*Bison* ssp., *Bos* ssp., *Bubalus* ssp., *Ovis* ssp., *Capra* ssp.
Infection with rabies virus	Bovidae of the species *Bison* ssp., *Bos* ssp., *Bubalus* ssp., Suidae, Equidae,
Infection with bluetongue virus (serotypes 1-24)	Bovidae of the species *Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Infection with epizootic haemorrhagic disease virus	Bovidae of the species *Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Anthrax	Artiodactyla of bovine, porcine, ovine, caprine species, Equidae
Surra (*Trypanosoma evansi*)	Equidae, Artiodactyla of bovine, porcine, ovine, caprine species,
Infection with lumpy skin disease virus	*Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia)	*Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis	*Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Bovine viral diarrhoea	*Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Bovine genital campylobacteriosis	*Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Trichomonosis	*Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Enzootic bovine leukosis	*Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Sheep pox and goat pox	*Ovis* ssp., *Capra* ssp.
Infection with peste des petits ruminants virus	*Ovis* ssp., *Capra* ssp.
Contagious caprine pleuropneumonia	*Ovis* ssp., *Capra* ssp.,
Ovine epididymitis (*Brucella ovis*)	*Ovis* ssp., *Capra* ssp.,
African horse sickness	Equidae
Infection with *Burkholderia mallei* (Glanders)	Equidae
Infection with equine arteritis virus	Equidae

Equine infectious anaemia	Equidae
Dourine	Equidae
Venezuelan equine encephalomyelitis	Equidae
Contagious equine metritis	Equidae
Classical swine fever	Suidae, Tayassuidae
African swine fever	Suidae
Infection with Aujeszky's disease virus	Suidae
Infection with porcine reproductive and respiratory syndrome virus	Suidae

3. Movements of germinal products between confined establishments located in different EU Member States: terrestrial animal species other than bovine, porcine, ovine, caprine and equine animals

Art. 37 **Animal health requirements for movements to other Member States between confined establishments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine and equine animals**	Operators of confined establishments shall only move germinal products of terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at those establishments to confined establishments in other Member States when the donor animals: a) have been born and remained since birth in the Union, or have entered the Union in accordance with the requirements for entry into the Union; b) have remained in a single confined establishment of origin for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos; c) do not come from an establishment, nor have been in contact with animals from an establishment, situated in a restricted zone established due to the occurrence of a category A disease or of an emerging disease relevant for the species in those kept terrestrial animals; d) come from an establishment where no category D disease relevant for that species has been reported for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos; e) are identified and registered in accordance with the rules of that confined establishment; f) as much as possible, were not used for natural breeding during a period of at least 30 days prior to the date of first collection and during the period of collection of the semen, oocytes or embryos intended for movement to another Member State; g) have been clinically examined by the establishment veterinarian responsible for the activities carried out at confined establishment, and show no disease symptoms on the day the semen, oocytes or embryos are collected.

Requirements from the legislation:

- The definition of a terrestrial animal within AHL covers all species of terrestrial mammals, all avian species as well as bumblebees and bees. However, this definition does not cover mammals living entirely within aquatic environments (e.g., Cetacea, Serenia), or reptilian or amphibian species.
- Further guidance on the 'terrestrial animal' definition can be found in Chapter 2.1.
- Point a) of Art. 37 requires that donor animals of terrestrial animal species, have either lived in the EU since birth, or have entered the Union in accordance with the requirements (laid down in Commission Delegated Regulation (EU) 2020/692). It is important to note that harmonized EU rules for entry into the Union are only laid down for ungulate species and captive birds. For all other taxonomic groups, national Member State legislation and rules should be applied.
- For donor terrestrial animals of species other than bovine***, porcine, ovine, caprine and equine animals*****,** kept in confined establishments the following Category A and D listed diseases are relevant for Art. 37, point c) and d):

Category A listed diseases of concern for donor terrestrial animals of species other than bovine, porcine, ovine, caprine and equine animals:	**Relevant listed susceptible species (as per Regulation (EU) 2018/1882):**
Foot and mouth disease	Artiodactyla of species other than bovine, porcine, ovine, caprine animals, Proboscidea
Infection with rinderpest virus	Artiodactyla of species other than bovine, porcine, ovine, caprine animals
Infection with Rift Valley fever virus	Perissodactyla, Antilocapridae, Bovidae (other than species of *Bison* ssp., *Bos* ssp., *Bubalus* ssp.), Camelidae, Cervidae, Giraffidae, Hippopotamidae, Moschidae, Proboscidea
Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia)	African buffalo *Syncerus cafer*
Infection with peste des petits ruminants virus	Camelidae, Cervidae
Contagious caprine pleuropneumonia	*Gazella* ssp.
Infection with *Burkholderia mallei* (Glanders)	Camelidae
Highly pathogenic avian influenza	Aves
Infection with Newcastle disease virus	Aves

Category D listed diseases of concern for donor terrestrial animals of species other than bovine, porcine, ovine, caprine and equine animals:	**Relevant listed susceptible species (as per Regulation (EU) 2018/1882):**
Foot and mouth disease	Artiodactyla of species other than bovine, porcine, ovine, caprine animals, Proboscidea
Infection with rinderpest virus	Artiodactyla of species other than bovine, porcine, ovine, caprine animals
Infection with Rift Valley fever virus	Perissodactyla, Antilocapridae, Bovidae (other than species of *Bison* ssp., *Bos* ssp., *Bubalus* ssp.), Camelidae, Cervidae, Giraffidae, Hippopotamidae, Moschidae, Proboscidea
Infection with *Brucella abortus*, *B. melitensis, B. suis*	Artiodactyla of species other than *Bison* ssp., *Bos* ssp., *Bubalus* ssp., *Ovis* ssp., *Capra* ssp.
Infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae, M. tuberculosis*)	Artiodactyla of species other than *Bison* ssp., *Bos* ssp., *Bubalus* ssp.
Infection with rabies virus	Carnivora, Bovidae (of species other than *Bison* ssp., *Bos* ssp., *Bubalus* ssp), Cervidae, Camelidae
Infestation with *Echinococcus multilocularis*	Canidae
Infection with bluetongue virus (serotypes 1-24)	Antilocapridae, Bovidae (of species other than *Bison* ssp., *Bos* ssp., *Bubalus* ssp), Camelidae, Cervidae, Giraffidae, Moschidae, Tragulidae
Infection with epizootic haemorrhagic disease virus	Antilocapridae, Bovidae (of species other than *Bison* ssp., *Bos* ssp., *Bubalus* ssp), Camelidae, Cervidae, Giraffidae, Moschidae, Tragulidae
Anthrax	Perissodactyla (other than Equidae), Artiodactyla (of species other than *Bison* ssp., *Bos* ssp., *Bubalus* ssp., *Ovis* ssp., *Capra* ssp.), Proboscidea
Surra (*Trypanosoma evansi*)	Artiodactyla (of species other than *Bison* ssp., *Bos* ssp., *Bubalus* ssp., *Ovis* ssp., *Capra* ssp.)
Ebola virus disease	Non-human primates
Infection with Mycoplasma mycoides subsp. mycoides SC (Contagious bovine pleuropneumonia)	African buffalo *Syncerus cafer*
Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis	Camelidae, Cervidae
Infection with peste des petits ruminants virus	Camelidae, Cervidae
Contagious caprine pleuropneumonia	*Gazella* ssp.
Infection with *Burkholderia mallei* (Glanders)	Camelidae
Highly pathogenic avian influenza	Aves
Infection with Newcastle disease virus	Aves

Avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*)	Red junglefowl *Gallus gallus,* Turkey *Meleagris gallopavo*
Infection with *Salmonella Pullorum, S. Gallinarum, S. arizonae*	Red junglefowl *Gallus gallus,* Turkey *Meleagris gallopavo,* Helmeted guineafowl *Numida meleagris,* Common quail *Coturnix coturnix,* Common pheasant *Phasianus colchicus,* Grey partridge *Perdix perdix*, *Anas* spp.
Infection with low pathogenic avian influenza viruses	Aves
Avian chlamydiosis	Psittaciformes

- Animal health requirements for donor animals kept in confined establishments are laid down with respect to the ability to move the collected germinal products to another EU Member State. If the germinal products were to be used within the confined establishment of collection or the same Member State, national legislation would apply.

Additional recommendations

- Point (f) of Art. 37 requires that donor animals are not used for natural breeding '*as much as possible*' for 30 days prior and during the germinal product collection. In some circumstances, it may not be possible to separate the males and females of a terrestrial animal species in a confined establishment for 30 days prior to germinal product collection for practical, health or animal welfare reasons. Such reasons may include:
- Highly social or sensitive species, where separation may interrupt social group functionality
    - Bonded pairs of animals
    - Juvenile animals living within a social or family group
    - Where the confined establishment facilities are not conducive to 30-days of separation without significant compromise to animal welfare
    - To reduce stress on the donor animal and the potential need for repeated general anaesthesia, the clinical examination of donor animals required in Art. 37 point (g) in our opinion may be performed at the point of germinal product collection.
- Additional assurances for the health status of the donor animal, its group and the wider confined establishment may be obtained through assessing the disease surveillance plan (see Chapter 2.2).

4. Traceability of germinal products collected in an EU-based confined establishment

Art. 10 **Traceability requirements for germinal products of bovine, porcine, ovine, caprine and equine animals**	1. Operators collecting, producing, processing or storing germinal products of bovine, porcine, ovine, caprine or equine animals shall mark each straw or other package in which semen, oocytes or embryos, whether or not separated into individual doses, are placed, stored and transported, in such a way that the following information can be readily established: a) the date of collection or production of those germinal products; b) the species and identification of the donor animal(s); c) the unique approval number of the germinal product establishment of collection or production, processing and storage of those germinal products; d) any other relevant information. 2. In case of sex-sorting of semen at a germinal product processing establishment, the operator of the semen collection centre shall supplement the information referred to in paragraph 1 with information which permits the identification of the unique approval number of the germinal product processing establishment where that semen was sex-sorted. 3. Where a single straw or another package contains semen of bovine, porcine, ovine or caprine animals collected from more than one donor animal, the operator shall ensure that the information referred to in paragraph 1 permits the identification of all donor animals that have contributed to the dose of semen used for insemination. 4. By way of derogation from paragraph 1, where the semen of ovine or caprine animals is: a) frozen in pellets, the operator may mark the goblet containing the semen pellets of a single donor instead of marking each individual pellet in that goblet; b) fresh or chilled semen, the operator may mark the goblet containing the semen tubes or straws of a single donor instead of marking each individual tube or straw in that goblet. 5. By way of derogation from paragraph 1(c), the operator shall ensure that the marking of each straw or other package in which semen, oocytes or embryos are placed, stored and transported, is carried out in such a way that it permits the identification of: a) in the case of semen of ovine and caprine animals which has been collected at the establishment where the donor animals are kept as referred to in Article 13, the unique registration number of that establishment; or b) in the case of germinal products of bovine, porcine, ovine, caprine or equine animals which have been collected or produced at a confined establishment referred to in Article 14, the unique approval number of that confined establishment.

Art. 11 **Traceability requirements for germinal products of dogs and cats, terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments, and animals of the families Camelidae and Cervidae**	1. Operators collecting, producing, processing or storing germinal products of dogs or cats, terrestrial animals other than bovine, porcine, ovine, caprine or equine animals kept at confined establishments or of animals of the family *Camelidae* or *Cervidae* shall mark each straw or other package in which semen, oocytes or embryos, whether or not separated into individual doses, are placed, stored and transported in such a way that the following information can be readily established: a) the date of collection or production of those germinal products; b) the species, where necessary subspecies, and identification of the donor animal(s); c) one of the following: i. the address of the establishment of collection or production, processing and storage of those germinal products; ii. where the establishment of collection or production, processing and storage of those germinal products was assigned with a unique registration number, the unique registration number which shall include the ISO 3166-1 alpha-2 code of the country in which the establishment is registered; iii. where the establishment of collection or production, processing and storage of those germinal products is a confined establishment, the unique approval number which shall include the ISO 3166-1 alpha-2 code of the country in which the approval is granted; d) any other information 2. In case of sex-sorting of semen at an establishment other than the establishment of its collection or production, the operator of the establishment of collection or production of that semen shall supplement the information referred to in paragraph 1 with information which permits the identification of the establishment where that semen was sex-sorted. 3. By way of derogation from paragraph 1, where the semen of the animals referred to in paragraph 1 is frozen in pellets, the operator may mark the goblet containing semen pellets of a single donor instead of marking each individual pellet in that goblet. 4. Where a single straw or another package contains semen collected from more than one donor animal, the operator shall ensure that the information, referred to in paragraph 1, includes the identification of all donor animals.

Requirements from the legislation:

- The traceability requirements for germinal products collected at a confined establishment, are laid down in Articles 10 and 11 of Commission Delegated Regulation (EU) 2020/686, with the requirements varying depending on the taxa of the donor animal.
- Marking of germinal products remains a key component of ensuring the traceability, linking the collected semen, oocytes or embryos, to the confined establishment of collection and to the donor animal itself.

5. Animal health certification for germinal products collected in an EU-based confined establishment

Art. 39 **Rules concerning animal health certification**	[…] c) Before signing an animal health certificate for movements between Member States of consignments of germinal products of terrestrial animals other than bovine, porcine, ovine, caprine or equine animals kept at confined establishments, the official veterinarian shall carry out: a) a visual examination of the transport container in order to check: i. the seal and number applied by the establishment veterinarian responsible for the activities carried out at the confined establishment on the transport container; or ii. if necessary, germinal products placed in the transport container and to seal and number the transport container after that check b) a documentary check of the data submitted by the establishment veterinarian responsible for the activities carried out at confined establishment to ensure that: i. the information to be certified is supported by the records kept at the confined establishment ii. the mark on the straws or other packages, applied in accordance with Article 11, corresponds with the number provided in the animal health certificate and on the container in which they are transported iii. the requirements referred to in Article 37 have been fullfiled […] 4. The official veterinarian shall carry out the checks and examinations as provided for in paragraphs 1, 2 and 3 and issue the animal health certificate within the period of 72 hours preceding the time of dispatch of the consignment of germinal products. 5. The animal health certificate provided for in paragraphs 1, 2 and 3 shall be valid for 10 days from the date of issuing.

Requirements from the legislation:

- Germinal products being moved to another Member State, which were collected in a confined establishment should be moved in accordance with the issuance of an export health certificate based upon the model 'GP-CONFINED-INTRA', as laid down in Annex I Chapter 60 of Commission Implementing Regulation (EU) 2021/403. This model export certificate is for use for germinal products collected from all species of terrestrial animals, including bovine, porcine, ovine, caprine and equine animals kept in a confined establishment.
- The one exception from the above point, is the use of model export health certificate for hatching eggs from captive birds, where the use of certificate 'HE-CAPTIVE-BIRDS-INTRA', is foreseen. This model certificate can be found in Annex I Chapter 22 of Commission Implementing Regulation (EU) 2021/403.

6. Gene banks

Art. 45 **Additional rules for the granting of derogations by competent authorities for germinal products moved to gene banks in another Member State**	1. The competent authorities of the Member States of origin may grant derogations for movements to gene banks in another Member State of germinal products, provided that the operator of the establishment of dispatch has obtained the prior written consent of the competent authority of the Member State of destination to accept the consignment of germinal products, of: a) endangered breeds which do not fulfil the animal health requirements provided for in Chapter 1; or b) terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments which do not fulfil the animal health requirements provided for in Article 37 2. The competent authority of the Member State of destination shall only consent to accept the consignment of germinal products referred to in paragraph 1, provided that: a) the operator of the gene bank intended to receive those germinal products ensures that the germinal products are only used for the *ex situ* conservation and sustainable use of genetic resources of kept terrestrial animals for which the receiving gene bank was established; b) it has sufficient information, including information provided by the competent authority of the Member State of origin or results of testing, or carries out treatment of the germinal products enabling it to prevent the spread of foot-and-mouth disease, infection with rinderpest virus and other listed diseases.

Requirements from the legislation:

- Through Commission Delegated Regulation (EU) 2020/686, the concept of a gene bank is laid down, as a repository for animal genetic material used for ex-situ conservation. The concept and application of ex-situ conservation is further described in Chapter 1.2 of this Handbook.

- Germinal products may be moved from a confined establishment to a gene bank in another Member State for storage or further use. It is important to note that gene banks may also occur within a confined establishment (e.g., an EAZA Biobank Hub), however the establishment of a gene bank, and the movement of germinal products within a Member State to a gene bank is governed through national legislation.

7. Entry into the EU of germinal products intended for confined establishments

Requirements from the legislation:

- Commission Delegated Regulation (EU) 2020/692 governs the entry of germinal products into the EU. This Regulation lays down the entry requirements for germinal products intended for EU-based confined establishments from a range of different species.
- Figure 7 below summarizes those entry and animal health requirements and the Articles of Commission Delegated Regulation (EU) 2020/692 these are laid down in. The relevant Articles in full can be found in the Section Annex for reference.

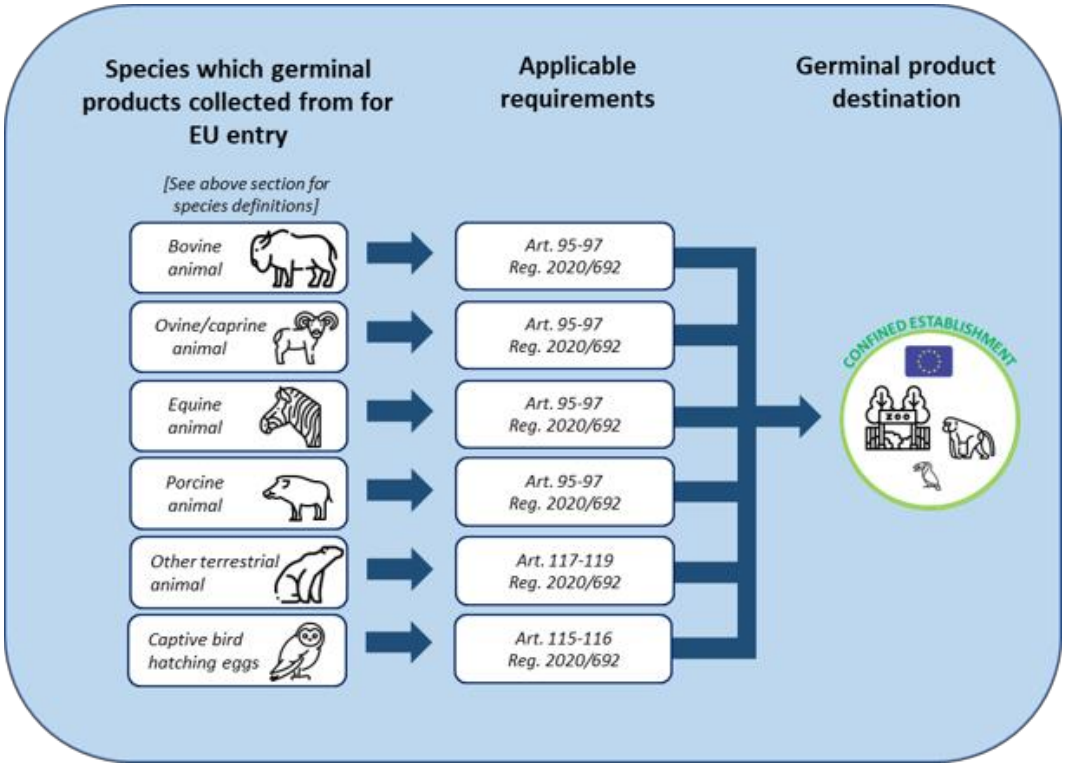


Figure 7: EU entry requirements for importation of germinal products of various taxa intended for a confined establishment.

Additional recommendations

- With the exception of hatching eggs from captive birds, all germinal products originating from terrestrial animals entering the Union, must originate from a third country confined establishment. The listing requirements for third country confined establishments are laid down in Article 29 of Commission Delegated Regulation (EU) 2020/692.
- EU-based confined establishments are uniquely placed in being able to receive germinal products from terrestrial animal species from third country confined establishments. This ability facilitates the transfer of genetic diversity between confined establishments located in EU and third countries without the need to transport live animals. Point (e) of Articles 96 and 118 requires that donor animals are not used for natural breeding 'as much as possible' for 30 days prior and during the germinal product collection. In some circumstances, it may not be possible to separate the males and females of a terrestrial animal species in a confined establishment for 30 days prior to germinal product collection for practical, health or animal welfare reasons. Such reasons may include:
    - Highly social or sensitive species, where separation may interrupt social group functionality
    - Bonded pairs of animals
    - Juvenile animals living within a social or family group
    - Where the confined establishment facilities are not conducive to 30-days of separation without significant compromise to animal welfare
- As stated above, to reduce stress on the donor animal and the potential need for repeated general anaesthesia, the clinical examination of donor animals required in Articles 96 and 118 point (d) in our opinion may be performed at the point of germinal product collection.
- Additional assurances for the health status of the donor animal, its group and the wider confined establishment may be obtained through assessing the disease surveillance plan (see Chapter 2.2).

References

1. Hermes, R., Göritz, F., Streich, W. & Hildebrandt, T. Assisted reproduction in female rhinoceros and elephants--current status and future perspective. *Reprod Domest Anim* **42 Suppl 2**, 33–44 (2007).
2. Thongtip, N. *et al.* Successful artificial insemination in the Asian elephant (*Elephas maximus*) using chilled and frozen-thawed semen. **8**, 1–8 (2009).
3. Hildebrandt TB, Hermes R, Saragusty J, Potier R, Schwammer HM, Balfanz F, Vielgrader H, Baker B, Bartels P, G. F. Enriching the captive elephant population genetic pool through artificial insemination with frozen-thawed semen collected in the wild. *Theriogenology* **78**, 1398/1404 (2012).
4. Portas, T. J. *et al.* Ovarian superstimulation , transrectal ultrasound-guided oocyte recovery , and IVF in rhinoceros. **72**, 959–968 (2009).
5. Howard, J. G. & Wildt, D. E. Approaches and efficacy of artificial insemination in felids and mustelids. *Theriogenology* **71**, 130–148 (2009).
6. Thomassen, R. & Farstad, W. Artificial insemination in canids: A useful tool in breeding and conservation. **71**, 190–199 (2009).

7. Howard, J. G., Lynch, C., Santymire, R. M., Marinari, P. E. & Wildt, D. E. Recovery of gene diversity using long-term cryopreserved spermatozoa and artificial insemination in the endangered black-footed ferret. (2004) doi:10.1111/acv.12229.

8. Herrick, J. R. Assisted reproductive technologies for endangered species conservation: Developing sophisticated protocols with limited access to animals with unique reproductive mechanisms. *Biology of Reproduction* vol. 100 1158–1170 (2019).

9. Andrabi, S. M. H. & Maxwell, W. M. C. A review on reproductive biotechnologies for conservation of endangered mammalian species. *Animal Reproduction Science* **99**, 223–243 (2007).

10. IUCN. IUCN motion 094: Linking in situ and ex situ efforts to save threatened species. (2021).

Section 3. AHL Legislation Annex

Articles relevant to the entry into the Union of germinal products originating from a bovine, ovine, caprine, porcine or equine animal destined for a confined establishment:

CHAPTER 6 ***Special rules for germinal products of ungulates intended for confined establishments*** *Art. 95* **Germinal products intended for confined establishments in the Union**	Consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals dispatched from confined establishments in third countries or territories listed in accordance with Article 29 shall only be permitted to enter the Union if they are dispatched to a confined establishment in the Union subject to compliance with the following requirements: a) an assessment was carried out by the competent authority of the Member State of destination of the risks associated with the entry into the Union of those germinal products; b) the donor animals of those germinal products originate from a confined establishment in the third country or territory of origin or zone thereof, which is included in a list established in accordance with Article 29 of confined establishments from which the entry of ungulates into the Union may be authorised; c) the germinal products are destined to a confined establishment in the Union, which is approved in accordance with Article 95 of Regulation (EU) 2016/429; d) (d) the germinal products are transported directly to the confined establishment referred to in point (c).
Art. 96 **Specific animal health requirements for donor animals kept in confined establishment**	Consignments of the germinal products referred to in Article 95 shall be only permitted to enter the Union if they were collected from donor animals that comply with the following requirements: a) the donor animals did not come from an establishment, nor been in contact with animals from an establishment, situated in a restricted zone established due to the occurrence of a category A disease or of an emerging disease relevant for the bovine, porcine, ovine, caprine or equine animals; b) the donor animals come from an establishment where none of the category D diseases relevant for bovine, porcine, ovine, caprine or equine animals have been reported for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos; c) the donor animals remained in a single confined establishment of origin for a period of at least 30 days prior to the date of collection of semen, oocytes or embryos intended for entry into the Union and during the period of that collection; d) the donor animals were clinically examined by the establishment veterinarian responsible for the activities carried out at confined establishment, and showed no disease symptoms on the day the semen, oocytes or embryos were collected;

	e) as much as possible, the donor animals were not used for natural breeding during a period of at least 30 days prior to the date of first collection of semen, oocytes or embryos intended for entry into the Union and during the period of that collection; f) the donor animals are identified in accordance with Article 21.
Art. 97 **The requirements for germinal products obtained in confined establishments**	Consignments of germinal products referred to in Article 95 shall only be permitted to enter the Union if they are: a) marked in accordance with the information requirements provided for in point (a) of Article 83; b) transported in accordance with Articles 84 and 85.

Articles relevant to the entry into the Union of germinal products originating from other terrestrial animals destined for a confined establishment:

Art. 117 **Requirements for entry into the Union of consignments of germinal products of animals other than those referred to in point (a) and (b) of Article 1(4) dispatched from confined establishments**	Consignments of semen, oocytes and embryos of animals other than those referred to in point (a) and (b) of Article 1(4) dispatched from confined establishments listed in accordance with Article 29 shall only be permitted to enter the Union if they are dispatched to a confined establishment located in the Union and provided that: a) an assessment has been carried out by the competent authority of the Member State of destination of the risks that the entry of those germinal products may present for the Union; b) the donor animals of those germinal products originate from a third country, territory or zone authorised for entry into the Union of the particular species and category of animals; c) the donor animals of those germinal products originate from a confined establishment in the third country, territory or zone of origin, which is included in a list established in accordance with Article 29 of confined establishments from which the entry of animals of specific species into the Union may be authorised; d) the germinal products are destined to a confined establishment in the Union, which is approved in accordance with Article 95 of Regulation (EU) 2016/429; e) the germinal products are transported directly to the confined establishment referred to in point (d).
Art. 118 **Specific animal health requirements for donor animals**	Consignments of semen, oocytes and embryos referred to in Article 117 shall only be permitted to enter the Union if they were collected from donor animals which comply with the following requirements: a) they do not come from an establishment, nor have been in contact with animals from an establishment, situated in a restricted zone established due

	to the occurrence of a category A disease or of an emerging disease relevant for the species of those kept terrestrial animals; b) they come from an establishment where no category D disease relevant for the species of those kept terrestrial animals has been reported for a period of at least the preceding 30 days; c) they have remained in a single confined establishment of origin for a period of at least 30 days prior to the collection of the semen, oocytes or embryos intended for entry into the Union; d) they have been clinically examined by the establishment veterinarian responsible for the activities of the confined establishment, and showed no disease symptoms on the day the semen, oocytes or embryos were collected; e) as much as possible, they were not used for natural breeding during a period of at least 30 days prior to the date of first collection and during the period of collection of semen, oocytes or embryos intended for entry into the Union; f) they are identified and registered in accordance with the rules of that confined establishment.
Art. 119 **The requirements for germinal products**	Consignments of semen, oocytes and embryos referred to in Article 117 shall only be permitted to enter the Union if they comply with the following requirements: a) they are marked in such a way that the following information can be readily established: i. the date of collection or production of those germinal products; ii. the species, where necessary subspecies, and identification of the donor animal(s); iii. the unique approval number of the confined establishment, which shall include the ISO 3166-1 alpha-2 code of the country in which the approval is granted; iv. any other relevant information; b) they are transported in the container which: i. is sealed and numbered prior to the dispatch from the confined establishment by the establishment veterinarian responsible for the activities of the confined establishment; ii. has been cleaned and either disinfected or sterilised before use, or is single-use container; iii. has been filled in with the cryogenic agent which not have been previously used for other products.

Articles relevant to the entry into the Union of hatching eggs originating from captive birds and destined for a confined establishment:

CHAPTER 7 **Specific animal health requirements for hatching eggs of captive birds** *Art. 115* **The hatching eggs of the consignment**	Consignments of hatching eggs of captive birds shall only be permitted to enter the Union if they were obtained from captive birds which comply with the requirements for entry into the Union set out in Articles 55 to 58.
Art. 116 **Handling of hatching eggs of captive birds following their entry into the Union and of captive birds hatched from those hatching eggs**	Operators at the establishment of destination shall: a) place the hatching eggs of captive birds which have entered into the Union from a third country or territory or zone thereof in separate incubators, including hatchers, from other hatching eggs; b) ensure that captive birds which are hatched from the hatching eggs of captive birds referred to in Article 115 are kept in an approved quarantine establishment in accordance with the requirements of Articles 59 to 61.

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The *European Union Animal Health Law* lays down a robust legal framework for the management of listed infectious disease risk in animals under human care. It also builds on extensive experience (primarily gained from the Balai Directive) to provide tailored mechanisms and procedures (e.g. through the Confined Establishment status) that ensure adequate prevention, mitigation and risk management of listed infectious diseases in non-domestic animal species housed in facilities such as zoos or other conservation institutions. This tailoring recognizes the unique requirements and constraints of keeping and breeding wildlife species for conservation purposes, and the capabilities of the professionals tasked with their care, and of the institutions that house them to ensure high standards of biosecurity, disease surveillance and control measures.

The *European Association of Zoos and Aquaria* (www.eaza.net) and the *European Association of Zoo and Wildlife Veterinarians* (www.eazwv.org) have partnered with the *European Association of State Veterinary Officers* (a section of the *Federation of Veterinarians of Europe*, www.easvo.fve.org) to produce this guidance document that distills and compiles the pieces of legislation in the AHL relevant for Confined Establishments. Guidance is provided on the processes and procedures that can be implemented to comply with the AHL by leveraging best practices in zoological medicine and management. We hope this guidance document will be of assistance to a range of stakeholders, including zoo animal managers, veterinary practitioners providing healthcare to non-domestic species and to official veterinarians working with zoo animal health controls.

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