Annex 18

SECTION 4.

**DISEASE PREVENTION AND CONTROL**

**CHAPTER 4.X.**

**BIOSECURITY**

Article 4.X.1.

Introduction

*Biosecurity* is the cornerstone of animal health programmes and as such should be implemented to prevent and control diseases in *populations*. In addition to reducing the risk of disease, the benefits of *biosecurity* include a reduced ~~need for~~use of *veterinary medicinal products*; reduced *killing* of *animals* for disease control purposes; reduced economic losses; protection of livelihoods; ~~assurance of sustainability of~~improved animal production; improved food security and food safety; promotion of animal, human and environmental health; ~~, and assurance of~~ safe trade and business continuity.

Article 4.X.2.

Purpose and scope

This chapter provides general principles and recommendations to allow for a consistent approach that could be applied to implement *biosecurity* for a *population* or *subpopulation* irrespective of the settings or scale, such as at farm or non-production *establishment,*  *herd/flock*, *compartment*, *zone*, or country~~,~~ *~~zone~~*~~,~~ *~~compartment~~*~~,~~ *~~herd/flock~~*~~, farm or non-production establishment~~ level.

The purpose of this chapter is to provide guidance to the *Veterinary Authority* and other relevant actors, as described in Article 4.X.4., on the principles, implementation and evaluation of *biosecurity* to support disease prevention and control programmes. The chapter applies to *animals,* their gatherings and husbandry systems, to all components of animal keeping and transport, and to the interface between domesticated *animals*, *wildlife,* humans ~~and~~ *~~wildlife~~*and the environment.

More specifically, this chapter aims to:

− describe the general guiding principles of *biosecurity*;

− identify the roles and responsibilities of the different actors in *biosecurity*;

− describe the potential sources and pathways for entry of pathogenic agents into a *population* and the exposure of *animals* and factors for the transmission of pathogenic agents;

− describe the components of *biosecurity*;

− provide guidance on the design, application, monitoring*,* evaluation and training with regards to *biosecurity* and *biosecurity* *plans.*

The chapter does not apply to laboratories. ~~, whose a~~Approaches to laboratory biosecurity are addressed in the Terrestrial Manual.

Article 4.X.3.

General ~~guiding principles~~provisions

The desired objectives of *biosecurity* should be defined. To achieve ~~the~~ these objectives ~~of~~ *~~biosecurity~~*, the following should be considered:

1. The *population* for which *biosecurity* is to be implemented, including its context ~~and~~, size and its *animal health status*.
2. The identification of the *~~hazards~~*pathogenic agents of concern and from where and how they may be introduced, and how they may ~~the pathogenic agents may be introduced,~~ establish~~ed~~ ~~and spread~~ within ~~in~~ and spread from the *population.*
3. The factors and frequency of events that influence the introduction, establishment and spread of pathogenic agents.

4) Scientific evidence to assess the *risk.*

5) ~~and~~ P~~p~~roportionality of ~~to~~ the measures to manage the *risk*.

6)~~5)~~ Sustainability, adaptability~~,~~  and monitoring.

7)~~6)~~ Human behaviour to maximise compliance.

~~7) Evaluation of compliance built into the day-to-day operations.~~

1. Socio-economic impacts of *biosecurity*.
2. Impacts on other *populations* and the environment.
3. Development of a~~A~~ *biosecurity plan* that promotes consistent implementation of *biosecurity*.
4. Engagement with, training and awareness of, and communication with, all actors involved in *biosecurity*.

These ~~principles~~ general provisions ~~of~~ *~~biosecurity~~* apply to any type of activity (intensive, extensive, commercial or non-production); only the measures comprising the *biosecurity* should be adapted to the situation.

Article 4.X.4

Roles and responsibilities

The roles and responsibilities of different actors in *biosecurity* should be clearly defined and communicated ~~with consideration made~~and may vary depending on ~~to~~ the context (e.g. *establishment*, *compartment*, *zone*, or country ~~country,~~ *~~zone, compartment~~*~~,~~ *~~establishment~~*level), the scale and type of operations and existing public-private partnerships. Implementation of *biosecurity* requires engagement and collaboration among~~st~~ all actors involved.

1. ***Veterinary Authority*** or other relevant *Competent Authorities* should be responsible for the development and oversight of  ~~policy on and~~ legislative frameworks and general policies for *biosecurity*. These ~~policies~~ should include the relative contribution and roles of *veterinarians* and *veterinary paraprofessionals* in both the private and public sectors, promote and provide guidance for the implementation of *biosecurity*. When required ~~For~~ for international trade ~~purposes~~, the *Veterinary Authority* should have an active role in ~~enforcement,~~ oversight~~,~~ and verification of *biosecurity* and *biosecurity plans*.
2. ***Veterinary Services*** should execute and implement policies and legislation on *biosecurity* under the supervision of the *Veterinary Authority* or otherrelevant *Competent Authorities.*
3. ***Veterinarians* and *veterinary paraprofessionals* and other relevant advisors** should give advice on *biosecurity* and the *biosecurity* *plans*. This advice should be aligned with the policies and legislation*,* where available.
4. **Breeders, owners, managers, keepers, transporters, feed producers and other relevant actors** are responsible for developing, implementing and monitoring *biosecurity* and the *biosecurity plan* and should seek advice from *veterinarians,* *veterinary paraprofessionals* or other relevant advisors.
5. **Training entities** should provide training in *biosecurity* for relevant actors. Coordination between the *Veterinary Authority*, other relevant *Competent Authorities*, the *veterinary statutory body* and veterinary educational institutions may be required to ensure biosecurity training delivered to *veterinarians*, *veterinary paraprofessionals* and other relevant advisors meets relevant standards, especially the recommendations of Article 4.X.9.
6. **Farmer associations, veterinary and para-veterinary associations, and other relevant associations** should advocate and promote *biosecurity* among their members, and may become directly involved in leading and overseeing the biosecurity planning and implementation by their members.

Article 4.X.5.

Potential sources of pathogenic agents

Pathogenic agents can ~~be~~ spread ~~through~~ from different sources, which should be identified and considered when implementing *biosecurity* and developing a *biosecurity plan*. ~~The main~~ Potential sources of pathogenic agents ~~to be considered~~ include:

1) live *animals,*

2) *germinal products,*

3) secretions and excretions,

4) *animal products,*

5) dead *animals* and parts thereof and afterbirth materials,

6) arthropods such asmosquitoes, midges, flies, lice, ~~or~~ ticks or beetles,

7) fomites such as peoples’ clothing, boots, *vehicle*s, crates, bedding, or farm equipment,

8) *feed* and *feed ingredients* ~~including~~ such as forage, grazing pastures and swill,

9) water, soiland air,

10) *biological products,*

11) humans.

Article 4.X.6.

Transmission pathways

Transmission of pathogenic agents can occur either through *animal*-to-*animal* contact without an intermediate (direct transmission), or through an intermediate such as fomites, water, *feed*, *animal products*, *germinal products*, *biological products*, humans and the relevant animal environment (indirect transmission). Transmission pathways of pathogenic agents should be assessed based on scientific evidence and considered when implementing *biosecurity* or developing a *biosecurity plan.* Transmission pathways are not mutually exclusive and include:

1) Vertical transmission from parents to offspring *in ovo*, *in utero* or during birth.

2) Horizontal transmission from one *animal* to another that is not vertical.

3) Iatrogenic transmission.

4) Sexual transmission through reproductive secretions such as semen and vaginal fluids or transmitted directly between surfaces in contact during mating.

5) Vector-borne transmission via *vectors* including blood-feeding arthropods such as mosquitoes, flies, ticks, fleas and lice. *Vectors* may be mechanical with no biological association between the *vector* and pathogenic agent or biological where the pathogenic agent undergoes a multiplication or a developmental change within the *vector*, necessary for survival, transmission or host *infection*.

6) Droplets or airborne transmission ~~of pathogenic agents~~ through particles suspended in the air. Pathogenic agents may travel in particles of multiple sizes (droplets and droplet nuclei) that remain suspended in the air or deposited on surfaces. Airborne transmission may include short or long distances (which may be referred to as aerosol or wind-borne transmission, respectively).

7) Transmission though fomites, *germinal products*, *animal* *products* and *biological products*.

The relative importance of the different transmission pathways will vary depending on the epidemiological characteristics of pathogenic agents of concern.

Article 4.X.7.

Components of biosecurity

*Biosecurity* can be applied to any type of *population.* The components of *biosecurity* focus on reducing the likelihood~~risk~~ of transmission of pathogenic agents through interactions with elements outside the *population* (external *biosecurity*) and on reducing ~~risk~~ the likelihood of transmission of pathogenic agents within the *population* (internal *biosecurity).* The components of *biosecurity* aim at avoiding or breaking the transmission pathways described in Article 4.X.6*.* All relevant components of *biosecurity* should be appliedto address all potential sources of pathogenic agents of concern, transmission pathways as well as unexpectedevents, and may vary according to the *population*.

1. Components of external biosecurity may include the following:

1. Introduction of *animals,* *animal products* and *germinal products* into a *population* should be limited to the extent necessary~~minimised~~ and if undertaken, the *animal health status* of the source *population* should be assessed.
2. ~~Whenever~~Before *animals* are newly introduced into the *population*, they should go through a monitored isolation period of sufficient length, during which measures such as test or treatment may be implemented to reduce~~mitigate~~ the ~~risk~~ likelihood of transmission of pathogenic agents.
3. Contact between *population*s of unknown or different *animal health status* should be avoided through segregation using managerial measures, physical or natural barriers.
4. Human access to the *population* should be controlled. When humans come in contact with *animals,* they should take measures to reduce~~mitigate~~ the *~~risk~~*likelihood of bi-directional transmission of pathogenic agents~~, which includes as a minimum wearing dedicated clothing and footwear, and hand hygiene~~. When humans come in contact with different *populations* subsequently, the order of the visits should be organised to minimise the likelihood of bi-directional transmission.
5. Equipment and clothing used to handle or care for *animals* should not be shared between different *population*s. If shared, equipment and clothing should undergo cleaning and *disinfection* at least before each use~~and after use~~.
6. Transport vehicles in contact with *animals* or their products should undergo cleaning and *disinfection* at least before each use~~and after use~~.
7. *Animal products*, faeces, manure or other waste materials should be handled in a way to ~~mitigate~~ minimise the spread of pathogenic agents. Special care should be taken to avoid contact with or attraction of other *animals* and arthropods.
8. Dead *animals* and parts thereof should be handled, stored and disposed of in a way to ~~mitigate~~ minimise the spread of pathogenic agents and to avoid contact with or attraction of other *animals* and arthropods.
9. *Feed* should be produced in accordance with Chapter 6.4. and should be~~,~~ stored and transported in dedicated equipment to minimise the contact with potential sources of pathogenic agents. Feeding of untreated swillshould be avoided.

j) Water should originate from low-risk sources or be treated to remove or inactivate pathogenic agents. The safety of the water ~~and~~ *~~feed~~* should be checked regularly.

k)~~j)~~ Contacts between the *population* and pets, birds, rodents, insects, and other *wildlife* or pests should be avoided by selecting an appropriate site and through using engineering, mechanical or chemical control.

l)~~k)~~ To minimise airborne transmission of pathogenic agents, sufficient distance or physical barriers between *populations* and ~~possible~~ potential sources of pathogenic agents should be considered. In some circumstances, air treatments might be considered.

m)~~l)~~ When cleaning and *disinfection* or other measures are not feasible or effectiveness is undetermined, an additional period of no contact between potential sources of pathogenic agents (e.g. humans, buildings, *vehicles*, equipment, materials, pastures) and the *population* may be applied. The effectiveness of this measure will depend on the specific circumstances and should be verified.

2. Components of internal biosecurity may include the following:

1. Sick *animals* should be isolated to prevent other *animals* from being exposed. Treatments should be administered ~~safely~~ to avoid iatrogenic transmission.
2. All-in all-out management should be applied, as appropriate, to all *animals* kept in the same space including cleaning and *disinfection* of the space between groups of *animals*.
3. Stocking densities that result in impaired health through increased transmission rates and higher virulence of pathogenic agents, or increased susceptibility to *infection*s, should be avoided.
4. Within the *population*, *units* with different characteristics impacting disease *risk* should be kept separately.
5. When the management of the *population* involves contact with different *units*, the workflow should be organised from the lowest to the highest risk of *infection*, considering transmission of pathogenic agents and susceptibility of the *units*. When moving between the *units*, measures to mitigate transmission of pathogenic agents should be applied.
6. Cleaning and *disinfection* of the equipment and surfaces should be applied between consecutive groups of *animals*.

Article 4.X.8.

Biosecurity plan

A *biosecurity plan* promotes consistent implementation of *biosecurity*.~~,~~ While remaining scientifically justifiable, ~~and~~ it should balance the objectives and intended benefits with the practicality, cost, regulatory requirements and should include necessary provisions for its maintenance and continuous improvement. The aim of a *biosecurity plan* is to organise, structure and document *biosecurity* including its evaluation.

The *biosecurity plan* should include the following sections:

1. Purpose and scope

This section should provide an overview of the plan, its purpose and scope. In addition, it should outline the goals and objectives of the plan, as well as the *population* characteristics, including animal husbandry systems, and epidemiological context.

1. Roles and responsibilities

Design, implementation, and monitoring is a shared responsibility. Therefore, it is essential to describe the roles and responsibilities of all actors for ensuring adherence and compliance with *biosecurity*.

1. Identification of pathogenic agents, sources and transmission pathways

In addition to the identification of the potential pathogenic agents of concern, this section should include their potential sources and transmission pathways.

1. Description of biosecurity

This section should describe the relevant components of *biosecurity* in accordance with Article 4.X.7.

It should also includerelevant response procedures for emergencies.

1. Surveillance of pathogenic agents

The *biosecurity* *plan* should include the procedures for *surveillance* for early detection ~~to detect the presence~~ of pathogenic agents of concern, in accordance with Chapter 1.4.

1. Communication and reporting

This section should outline the procedures for communicating information about the *biosecurity plan* to all relevant actors. It should also include procedures for reporting incidents and sharing information with relevant authorities.

1. Training and education

This section should outline the training and education needs and identify programmes to ensure all relevant actors are aware of the *biosecurity* *plan* and clearly understand their roles and responsibilities to implement and maintain the *biosecurity* and the consequences of non-compliance.

1. Supporting documents

This section should outline the standard operating procedures ~~(SOPs)~~, checklists, and record-keeping templates which describe routine management processes and ensure that responsibilities and duties are consistently fulfilled and documented. It should also include relevant training materials for all actors involved in the implementation of the *biosecurity plan*.

1. Evaluation and continuous improvement

This section should describe the procedures for monitoring and evaluation of the *biosecurity plan* and its implementation in accordance with Article 4.X.10. Biosecurity Incidents and breaches in *biosecurity*, as well as corrective actions taken, should be documented. The *biosecurity plan* should be reviewed and updated regularly to ensure its relevance and effectiveness.

Article 4.X.9.

Training and awareness

1. Training

Regular training on *biosecurity* should be undertaken according to the needs identified and should include all relevant actors. Training should be provided by those with sufficient qualifications and experience. The training should be in line with legislative and policy frameworks. Such training may include:

− Principles of *biosecurity,*

− Sources of pathogenic agents, transmission pathways and relevant factors to susceptibility,

* Components and implementation of *biosecurity,* including emergency planning and response,

− Monitoring and evaluation of *biosecurity,*

− Purpose, development and implementation of a *biosecurity* *plan,*

− Competency-based training requirements should be identified and documented for each actor. The training achieved should be recorded and monitored to ensure the required level of competencies are obtained or maintained.

2. Awareness

All relevant actors described in Article 4.X.~~4~~. and the general public, when applicable, should be made aware of the importance of *biosecurity* (and the *biosecurity plan* if appropriate) at strategic places (e.g. *border inspection posts*, farm entrances, *markets*) and times (e.g. disease *outbreaks*, changes in the epidemiological situation). Raising awareness may be the responsibility of the *Veterinary Authority,* otherrelevant *Competent Authorities*~~,~~ or *Veterinary Services*~~,~~. ~~or p~~Producers~~,~~ or~~and~~ other relevant actors may also be responsible depending on the context and extent of the *risk.*

Article 4.X.10.

Evaluation and continuous improvement

The implementation of *biosecurity,* the compliance with the *biosecurity* *plan* and the effectiveness of implemented measures should be subjected to evaluation for continuous improvement.

1. The evaluation of implementation should be based on predefined scope and criteria, taking into consideration the expected scale of the operation and the characteristics of the *population* concerned. This will determine at which level of responsibility the evaluation should be conducted, and at which frequency. The frequency should be adapted to changing circumstances such as new *animal health status*, newly identified pathogenic agents or changes in epidemiological situation, previous evaluations, changes in production or changes in plan. The evaluation should determine the level of implementation of *biosecurity,* through collected evidence that may include documentation of procedures, other routine records, monitoring technologies, onsite audits as well as interviews with personnel. Based on these findings, the evaluation may allow the establishment of a risk-based *biosecurity* score as a whole or for each measure.
2. Compliance with the *biosecurity plan* should be evaluated routinely or following a change in the epidemiological situation. Documented evidence of compliance should be collected routinely and be provided for any evaluation. The evaluation of compliance with the *biosecurity plan* should be executed preferably by an independent party, in accordance with the policies and legislation*,* where available.
3. The effectiveness of the *biosecurity plan* should be evaluated routinely or following a change in production type, epidemiological situation, or other significant change, to ensure the *biosecurity plan* is complete, fit for purpose and up to date. The evaluation should be based on animal health or performance data. The outcomes of the evaluations should be communicated to all relevant actors and should inform if the plan needs to be modified, and which risk mitigation or corrective actions are needed so that the *biosecurity plan* can be updated accordingly.

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