Annex 26

SECTION 4.

DISEASE PREVENTION AND CONTROL

CHAPTER 4.X.

**BIOSECURITY**

Article 4.X.1.

Introduction

*Biosecurity* is the cornerstone of health programmes and as such should be implemented to prevent and control diseases. In addition to reducing the risk of disease, the benefits of *biosecurity* include a reduced need for *veterinary medicinal products*; reduced *killing* of *animals* for disease control purposes; reduced economic losses; protection of livelihoods; assurance of sustainability of 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

The purpose of this chapter is to provide guidance to the *Veterinary Authority* and other relevant actors, as described in Article 4.X.5., on the principles, implementation and evaluation of *biosecurity* to support disease prevention and control programmes.

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 sources and pathways and factors for the transmission of pathogenic agents;

− Describe the procedures and components of *biosecurity*;

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

The chapter applies to all animals including *wildlife*, to any type of animal gatherings and husbandry systems, to all components of animal production and commercial chains and to the interface between domesticated animals, humans and *wildlife*.

The chapter does not apply to laboratories, whose approaches to biosecurity are addressed in the Terrestrial Manual.

Article 4.X.3.

Definitions

For the purposes of this chapter:

**All-in all-out** is the management practice to remove all the *animals* prior to new *animals* entering a shared air space with the subsequent cleaning and decontamination of the space where the *animals* are housed to prevent the transmission of pathogenic agents between groups of *animals*.

**Fomite** is an inanimate object that can carry pathogenic agents.

**External *biosecurity*** also referred to as bio-exclusion or bio-containment, is a set of measures that aims at preventing pathogenic agents from entering or escaping a *population*.

**Internal *biosecurity*** also referred to as bio-management, is a set of measures that aims to reduce the spread of pathogenic agents within a *population*.

Article 4.X.4.

Guiding general principles

*Biosecurity* aims to break the cycle of *infection* by intervening at their source, during their transmission, or at the susceptible hosts. To achieve this, the following principles should be considered:

1. The *animal health status* of a *population* for which the *biosecurity* is being implemented should be known, to identify where improvements to the animal health and productivity may be required*.*
2. *Biosecurity* should be based upon *risk analysis* as described in Chapter 2.1. and be aligned with relevant legislative requirements.
3. *Risk assessments* applied to *biosecurity* should identify the *hazards* and how and where these *pathogenic agents* are introduced, spread and established in the *population.* The frequency of certain activities, which influence the entry, spread and establishment of *pathogenic agents*, should be considered in the *risk assessment*.
4. *Biosecurity* should be based on scientific evidence and proportional to the *risk*.
5. *Biosecurity* should be sustainable, adaptable, monitored and subjected to a documented routine and ongoing evaluation and should include long-term planning.
6. A *biosecurity plan* is essential for ensuring consistent implementation of *biosecurity*.
7. *Biosecurity* should be designed to account for human behaviour to maximise compliance.
8. Evaluation of compliance of *biosecurity* should be built into the day-to-day operations.
9. The socio-economic impacts of *biosecurity* and the context and size of the *population* to which the *biosecurity* is being applied should be considered.
10. Training of, and communication with, all actors involved in *biosecurity* is essential to successful outcomes.

Article 4.X.5.

Roles and responsibilities

The roles and responsibilities of different actors in *biosecurity* should be clearly defined and communicated with consideration made to the context (e.g. *establishment*, *compartment*, *zone,* country level), scale of operations, type of production and supply chain. Implementation of *biosecurity* requires engagement and collaboration amongst all actors involved.

1. ***Veterinary Authority***, in collaboration with other *Competent Authorities,* should be responsible for the development and oversight of policy on and legislative frameworks of *biosecurity*. These policies should include the relative contribution and roles of *veterinarians* and *veterinary paraprofessionals* in both the private and public sectors. For international trade purposes, the *Veterinary Authority* should have an active role in the development, implementation, 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 Authorities.*
3. ***Veterinarians* and *veterinary paraprofessionals* and other animal health advisors** should give advice to animal breeders, owners, and keepers on *biosecurity* which may include the design, and evaluation of *biosecurity* and *biosecurity* *plans* and training. This advice should be aligned with the policies and legislation set by the *Veterinary Authority*.
4. **Animal breeders, owners, keepers, transporters, feed producers** should seek advice from *veterinarians* and *veterinary paraprofessionals* and other animal health advisors and are responsible for implementing and monitoring *biosecurity* and the *biosecurity plan*.
5. **Training entities** should include training in *biosecurity* as part of the standard programmes and the training should be tailored for all actors. Coordination between the *Veterinary Authority*, the *Veterinary Statutory Body* and veterinary educational establishments may be required to ensure biosecurity training delivered to *veterinarians*, *veterinary paraprofessionals* and other advisors meets relevant standards.
6. **Farmer, veterinary and para-veterinary associations** should advocate and promote *biosecurity* among their members, including signposting to relevant training and advice.

Article 4.X.6.

Potential sources of pathogenic agents

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

1) *animals,*

2) *germinal products,*

3) secretion and excretion,

4) *animal products,*

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

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

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

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

9) water, soil, surfaces and air,

10) *biological products,*

11) humans.

Article 4.X.7.

Transmission pathways

Transmission pathways of pathogenic agents should be considered when implementing *biosecurity* or developing a *biosecurity plan.* Transmission pathways are not mutually exclusive and include:

1. Direct transmission through *animal*-to-*animal* contact including their secretions and excretions without an intermediate. It includes contact between domesticated *animals* and *wildlife*.
2. Indirect transmission through an intermediate such as fomites, water, feed, germinal products and *animal* environment.
3. Vertical transmission of pathogenic agents from parents to offspring in ovo, in utero or during birth.
4. Horizontal transmissions from one *animal* to another that are not vertical.
5. Iatrogenic transmission through medical interventions.
6. Sexual transmission of pathogenic agents that are shed in reproductive secretions such as semen and vaginal fluids or transmitted directly between surfaces in contact during mating.
7. 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.
8. Airborne or droplets transmission of pathogenic agents through particles suspended in the air. Pathogenic agents may travel in particles of multiple size ranges (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).

Article 4.X.8.

Components of biosecurity

*Biosecurity* can be divided into: 1) external *biosecurity*, and 2) internal *biosecurity*. External *biosecurity* mainly focuses on interactions with elements outside the *population* (e.g. other farms, other regions) whereas internal *biosecurity* focuses on reducing risk of transmission between elements of the *population*. The distinction between external and internal *biosecurity* is not absolute and can vary depending on the scale considered (e.g. country, region, *herd*).

Several components of *biosecurity* may need to be applied to a *population* and *subpopulation* to address all transmission pathways, sources of *pathogenic agents* and unexpected *risks*. The components of *biosecurity* should be documented in a *biosecurity plan* when possible.

1. Components of external *biosecurity*:
2. Introduction of *animals,* animal products and germinal products should be minimised as much as possible and if undertaken, the health status of the *animal* and their source *population* should be assessed.
3. Whenever *animals* are introduced into a *population*, they should go through an isolation period of sufficient length, during which measures may be implemented to minimise the risk of transmission of pathogenic agents.
4. Direct contact between *population*s of unknown or different *animal health status* should be avoided through segregation using managerial measures, or physical or natural barriers.
5. The contact between humans and *animals* should be limited where possible but when required precautionary measures should be used to reduce the *risk* such as wearing farm specific clothing and footwear, and hand hygiene.
6. Equipment used to handle or care for *animals* should not be shared between different *population*s. If shared, equipment should undergo *disinfection*.
7. Transport vehicles in direct and indirect contact with *animals* or their products should undergo *disinfection* after use.
8. Faeces or manure should be handled in a way to mitigate the spread of pathogenic agents.
9. Dead animals and parts thereof should be handled and stored in specific containers, or in designated areas to avoid contact with or attraction of other *animals* in particular *wildlife* and arthropods.
10. Feed should be produced, stored and transported in dedicated equipment only for the purpose of feeding *animals*. Feeding of untreated swillshould be avoided. Water should originate from low-risk sources or be treated with pathogen inactivating agents prior to use. The safety of the water and feed should be checked regularly.
11. Direct and indirect contact between rodents, birds, pets, *wildlife*, pests and the *population* should be avoided using mechanical or chemical control.
12. Sufficient distance between *populations* and other possible sources of pathogenic agents should be considered. In some circumstances, air filtration might be considered when feasible and sufficient distance or other measures cannot be implemented to mitigate the risk of transmission.
13. When cleaning and *disinfection* or other measures are not feasible or effectiveness is undetermined, an additional period of no contact between potential carriers of pathogenic agents (e.g. people, buildings, *vehicles*, equipment, materials, pastures and air spaces) and the population can be applied. The effectiveness of this measure will depend on the specific circumstances.
14. Components of internal *biosecurity*:
15. Diseased *animals* should be isolated to prevent other *animals* being exposed. Treatments should be administered safely to avoid iatrogenic transmission.
16. All-in all-out management should be applied to all animals kept in the same air space.
17. Stocking densities that may result in increased transmission rates of pathogenic agents or increased susceptibility to *infection*s should be avoided.
18. *Animals* with different characteristics such as age and immune status should be kept separately.
19. It is advisable to organise the workflow according to disease risk starting at the lowest risk and ending with the highest risk. Whenever entering into contact with a new group or new animal category, *biosecurity* measures such as changing footwear and clothing and conducting hand hygiene should be considered. Dedicated equipment or material should be used in each group.
20. Cleaning and *disinfection* of the equipment and surfaces should be applied between consecutive groups of *animals*.

Article 4.X.9.

Biosecurityplan

The purpose of a *biosecurity plan* is to document, organise and structure *biosecurity* including its evaluation.

*A biosecurity plan* should balance practicality, cost, and regulatory requirements and include necessary provisions for its maintenance.

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 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. Hazard identification and risk assessment

This section should include a summary of the relevant parts of *risk assessment* e.g. identification of the potential pathogenic agents (i.e. *hazard*s) and their transmission pathways.

1. Description of *biosecurity*

This section should outline the measures to reduce the risk of introduction, establishment and spread of pathogenic agents to, within and from the *population* in accordance with Article 4.X.8.

It should also includeemergency and response procedures for animal health events.

1. Surveillance and monitoring of pathogenic agents

The *biosecurity* *plan* should include the procedures for *monitoring* and *surveillance* to detect the presence of pathogenic agents in accordance with Chapter 1.4.

1. Communication and reporting

This section should outline the procedures for communicating information about the *biosecurity plan* to 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 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.

1. Evaluation and improvement

This section should describe the procedures for *monitoring* and evaluation of the *biosecurity plan* in accordance with Article 4.X.10. *Biosecurity* incidents, and corrective actions taken should be documented. The *biosecurity plan* should be updated regularly.

Article 4.X.10.

Training and awareness

1. Training

Regular training on *biosecurity* should be undertaken according to the needs identified and should include all 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,*

− *Biosecurity* *risk assessment,*

− Application and monitoring of *biosecurity*, including emergency response and contingency planning,

− *Biosecurity* implementation and evaluation,

− Purpose, development, implementation, monitoring and evaluation of a *biosecurity* *plan.*

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

1. Awareness

The general public and those in industry should be made aware of the importance of *biosecurity* (and the *biosecurity plan* if appropriate) at strategic places (e.g. *border posts*, farm entrances, *markets*) and times (e.g. during disease outbreak, high risk season). This may be the responsibility of the *Veterinary Authority*, *Veterinary Services* or even farmers depending on the context and extent of the *risk.*

Article 4.X.11.

Evaluation and improvement

The implementation of *biosecurity,* the compliance with the *biosecurity* *plan* and the effectiveness of implemented measures should be subjected to evaluation for 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 *hazards*, change in *risks*, previous evaluations, changes in production or changes in plan. The evaluation should determine the existence and level of implementation of *biosecurity,* through collected evidence that may include documentation of procedures and other routine records as well as interviews with personnel. Based on these findings, the evaluation may allow to establish 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 risks. Compliance should focus on critical control points as identified in the risk assessment and in the *biosecurity plan* itself. Documented evidence of compliance at these critical control points should be collected routinely and should be able to be provided for any evaluation, including formal audit. This could include checklists for routine procedures, log sheets, records of training and interviews with relevant actors. The evaluation of compliance to the *biosecurity plan* should be executed by an independent party.
3. The effectiveness of the *biosecurity plan* should be evaluated routinely or following a change in risks, to ensure the *biosecurity plan* is complete, fit for purpose and up to date. The evaluation should be based on animal health data from within and outside the *population* (such as mortality or morbidity rates related to the targeted hazards, results of laboratory tests on *animals* in the *population*, levels of antimicrobial use, cell count trends), and on animal production performance data (such as milk yield, growth rates, egg production).

The outcomes of the evaluations should be communicated to all relevant actors and should inform which risk mitigation or corrective actions are needed so that the *biosecurity plan* can be updated accordingly.