

## CHAPTER 4.3.

## ZONING AND COMPARTMENTALISATION

## Article 4.3.1.

**Introduction**

For the purposes of the *Terrestrial Code*, 'zoning' and 'regionalisation' have the same meaning.

Establishing and maintaining a disease free-status throughout the country should be the final goal for OIE Members. However, given the difficulty of establishing and maintaining a *disease* free status for an entire territory, especially for *diseases* the entry of which is difficult to control through measures at national boundaries, there may be benefits to a Member in establishing and maintaining a *subpopulation* with a distinct health status within its territory. *Subpopulations* may be separated by natural or artificial geographical barriers or, in certain situations, by the application of appropriate management practices.

Zoning and compartmentalisation are procedures implemented by a Member under the provisions of this chapter with a view to defining *subpopulations* of distinct health status within its territory for the purpose of *disease* control and/or *international trade*. While zoning applies to an animal *subpopulation* defined primarily on a geographical basis (using natural, artificial or legal boundaries), compartmentalisation applies to an animal *subpopulation* defined primarily by management and husbandry practices related to biosecurity. In practice, spatial considerations and good management including *biosecurity plans* play important roles in the application of both concepts.

A particular application of the concept of zoning is the establishment of a *containment zone*. In the event of limited *outbreaks* of a specified *disease* within an otherwise free country or *zone*, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*.

This chapter is to assist OIE Members wishing to establish and maintain different *subpopulations* within their territory using the principles of compartmentalisation and zoning. These principles should be applied in accordance with the measures recommended in the relevant *disease* chapter(s). This chapter also outlines a process through which trading partners may recognise such *subpopulations*. This process is best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to *outbreaks* of *disease*.

Before trade in *animals* or their products may occur, an *importing country* needs to be satisfied that its *animal health status* will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the *exporting country*, both at its borders and within its territory.

As well as contributing to the safety of *international trade*, zoning and compartmentalisation may assist *disease* control or eradication within a Member's territory. Zoning may encourage the more efficient use of resources within certain parts of a country and compartmentalisation may allow the functional separation of a *subpopulation* from other domestic or wild animals through biosecurity measures, which a *zone* (through geographical separation) would not achieve. Following a *disease outbreak*, the use of compartmentalisation may allow a Member to take advantage of epidemiological links among *subpopulations* or common practices relating to biosecurity, despite diverse geographical locations, to facilitate *disease* control and/or the continuation of trade.

## Annex 7 (contd)

Zoning and compartmentalisation cannot be applied to all *diseases* but separate requirements will be developed for each *disease* for which the application of zoning or compartmentalisation is considered appropriate.

To regain free status following a *disease outbreak* in a *zone* or *compartment*, Members should follow the recommendations in the relevant *disease* chapter in the *Terrestrial Code*.

### Article 4.3.2.

#### **General considerations**

The *Veterinary Services* of an *exporting country* which is establishing a *zone* or *compartment* within its territory for *international trade* purposes should clearly define the *subpopulation* in accordance with the recommendations in the relevant chapters in the *Terrestrial Code*, including those on *surveillance*, and the *identification* and *traceability* of live *animals*. The *Veterinary Services* of an *exporting country* should be able to explain to the *Veterinary Services* of an *importing country* the basis for claiming a distinct *animal health status* for the given *zone* or *compartment* under consideration.

The procedures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* ~~should be appropriate to the particular circumstances, and~~ will depend on the epidemiology of the *disease*, in particular, the presence and ~~importance~~ role of susceptible wildlife species ~~species, and~~ environmental factors, ~~and appropriate~~ on the application of biosecurity measures.

The authority, organisation and infrastructure of the *Veterinary Services*, including *laboratories*, should be clearly documented in accordance with the chapter on the evaluation of *Veterinary Services* of the *Terrestrial Code*, to provide confidence in the integrity of the *zone* or *compartment*. The final authority of the *zone* or *compartment*, for the purposes of domestic and *international trade*, lies with the *Veterinary Authority*.

In the context of maintaining the health status of a *population*, references to ‘import’, ‘importation’ and ‘imported animals/products’ found in the *Terrestrial Code* apply both to importation into a country and to the movement of *animals* and their products into *zones* and *compartments*. Such movements should be the subject of appropriate measures to preserve the *animal health status* of the *zone/compartment*.

The *exporting country* should be able to demonstrate, through detailed documentation provided to the *importing country*, that it has implemented the recommendations in the *Terrestrial Code* for establishing and maintaining such a *zone* or *compartment*.

An *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Terrestrial Code* are applied and the *Veterinary Authority* of the *exporting country* certifies that this is the case.

The *exporting country* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment* for *international trade* purposes. These include the human and financial resources, and the technical capability of the *Veterinary Services* (and of the relevant industry and production system, in the case of a *compartment*) including *disease surveillance* and diagnosis.

Biosecurity and *surveillance* are essential components of zoning and compartmentalisation, and the arrangements should be developed through cooperation of industry and *Veterinary Services*.

Industry’s responsibilities include the application of biosecurity measures, documenting and recording movements of *animals* and personnel, quality assurance schemes, monitoring the efficacy of the measures, documenting corrective actions, conducting *surveillance*, rapid reporting and maintenance of records in a readily accessible form.

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The *Veterinary Services* should provide movement certification, and carry out documented periodic inspections of facilities, biosecurity measures, records and *surveillance* procedures. *Veterinary Services* should conduct or audit *surveillance*, reporting and *laboratory* diagnostic examinations.

## Article 4.3.3.

**Principles for defining and establishing a zone or compartment, including protection and containment zones**

In conjunction with the above considerations, the following principles should apply when Members define a *zone* or a *compartment*.

1. The extent of a *zone* and its geographical limits should be established by the *Veterinary Authority* on the basis of natural, artificial and/or legal boundaries, and made public through official channels.
2. A *protection zone* may be established to preserve the health status of *animals* in a free country or *zone*, from adjacent countries or *zones* of different *animal health status*. Measures should be implemented based on the epidemiology of the *disease* under consideration to prevent introduction of the pathogenic agent and to ensure early detection.

These measures should include intensified movement control and *surveillance* and may include:

- a) *animal identification* and *animal traceability* to ensure that *animals* in the *protection zone* are clearly distinguishable from other populations;
- b) vaccination of all or at risk susceptible *animals*;
- c) testing and/or vaccination of *animals* moved;
- d) specific procedures for sample handling, sending and testing;
- e) enhanced biosecurity including cleansing – *disinfection* procedures for transport means, and possible compulsory routes;
- f) specific *surveillance* of susceptible wildlife species and relevant vectors;
- g) awareness campaigns to the public or targeted at breeders, traders, hunters, *veterinarians*.

The application of these measures can be in the entire free *zone* or in a defined area within and/or outside the free *zone*.

3. In the event of limited *outbreaks* in a country or *zone* previously free of a *disease*, a *containment zone* may be established for the purposes of trade. Establishment of a *containment zone* should be based on a rapid response including:
  - a) appropriate standstill of movement of *animals* and other commodities upon notification of suspicion of the specified *disease* and the demonstration that the *outbreaks* are contained within this zone through epidemiological investigation (trace-back, trace-forward) after confirmation of *infection*. The primary *outbreak* has been identified and investigations on the likely source of the *outbreak* have been carried out ~~should be identified~~ and all *cases* shown to be epidemiologically linked.

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- b) A *stamping-out policy* or another effective control strategy aimed at eradicating the *disease* should be applied and the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*. Increased passive and targeted *surveillance* in accordance with Chapter 1.4. in the rest of the country or *zone* should be carried out and has not detected any evidence of *infection*.
  - c) Measures consistent with the disease specific chapter should be in place to prevent spread of the *infection* from the *containment zone* to the rest of the country or *zone*, including ongoing *surveillance* in the *containment zone*.
  - d) For the effective establishment of a *containment zone*, it is necessary to demonstrate that there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the last detected *case*.
  - e) The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The free status of these areas could be reinstated, once the *containment zone* is clearly established, irrespective of the provisions of the disease specific chapter.
  - f) The *containment zone* should be managed in such a way that it can be demonstrated that *commodities* for *international trade* can be shown to have originated outside the *containment zone*.
  - g) The recovery of the free status of the *containment zone* should follow the provisions of the disease specific chapter.
4. The factors defining a *compartment* should be established by the *Veterinary Authority* on the basis of relevant criteria such as management and husbandry practices related to biosecurity, and made public through official channels.
  5. *Animals* and *herds* belonging to such *subpopulations* need to be recognisable as such through a clear epidemiological separation from other animals and all things presenting a *disease risk*. For a *zone* or *compartment*, the *Veterinary Authority* should document in detail the measures taken to ensure the identification of the *subpopulation* and the establishment and maintenance of its health status through a *biosecurity plan*. The measures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and will depend on the epidemiology of the *disease*, environmental factors, the health status of *animals* in adjacent areas, applicable biosecurity measures (including movement controls, use of natural and artificial boundaries, the spatial separation of *animals*, and commercial management and husbandry practices), and *surveillance*.
  6. Relevant *animals* within the *zone* or *compartment* should be identified in such a way that their ~~history can be audited~~ movements are traceable. Depending on the system of production, identification may be done at the *herd, flock* lot or individual animal level. Relevant animal movements into and out of the *zone* or *compartment* should be well documented, and controlled ~~and supervised~~. The existence of a valid *animal identification system* is a prerequisite to assess the integrity of the *zone* or *compartment*.

Annex 7 (contd)

7. For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant industry and the *Veterinary Authority*, and their respective responsibilities. It should also describe the routine operating procedures to provide clear evidence that the *surveillance* conducted, the live *animal identification* and *traceability* system, and the management practices are adequate to meet the definition of the *compartment*. In addition to information on animal movement controls, the plan should include *herd* or *flock* production records, feed sources, *surveillance* results, birth and *death* records, visitor logbook, morbidity and mortality history, medications, vaccinations, documentation of training of relevant personnel and any other criteria necessary for evaluation of *risk* mitigation. The information required may vary according to the species and *disease(s)* under consideration. The *biosecurity plan* should also describe how the measures will be audited to ensure that the *risks* are regularly re-assessed and the measures adjusted accordingly.

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## CHAPTER 4.4.

## APPLICATION OF COMPARTMENTALISATION

## Article 4.4.1.

**Introduction and objectives**

The recommendations in this chapter provide a structured framework for the application and recognition of *compartments* within countries or *zones*, based on the provisions of Chapter 4.3. with the objective to facilitate trade in *animals* and products of animal origin and as a tool for *disease* management.

Establishing and maintaining a disease free-status throughout the country should be the final goal for OIE Members. However, establishing and maintaining a *disease-free* status for an entire country may be difficult, especially in the case of *diseases* that can easily cross international boundaries. For many *diseases*, OIE Members have traditionally applied the concept of zoning to establish and maintain an animal *subpopulation* with a different animal health status within national boundaries.

The essential difference between zoning and compartmentalisation is that the recognition of *zones* is based on geographical boundaries whereas the recognition of *compartments* is based on management practices and biosecurity. However, spatial considerations and good management practices play a role in the application of both concepts.

Compartmentalisation is not a new concept for *Veterinary Services*; in fact, it has been applied for a long time in many *disease* control programmes that are based on the concept of *disease-free herds/flocks*.

The fundamental requirement for compartmentalisation is the implementation and documentation of management and biosecurity measures to create a functional separation of *subpopulations*.

For example, an animal production operation in an infected country or *zone* might have biosecurity measures and management practices that result in negligible *risk* from *diseases* or agents. The concept of a *compartment* extends the application of a 'risk boundary' beyond that of a geographical interface and considers all epidemiological factors that can help to create an effective *disease-specific* separation between *subpopulations*.

In *disease-free* countries or *zones*, *compartments* preferably should be defined prior to the occurrence of a *disease outbreak*. In the event of an *outbreak* or in infected countries or *zones*, compartmentalisation may be used to facilitate trade.

For the purpose of *international trade*, *compartments* should be under the responsibility of the *Veterinary Authority* in the country. For the purposes of this chapter, compliance by the Members with Chapters 1.1. and 3.1. is an essential prerequisite.

## Article 4.4.2.

**Principles for defining a compartment**

A *compartment* may be established with respect of a specific *disease* or *diseases*. A *compartment* should be clearly defined, indicating the location of all its components including *establishments*, as well as related functional units (such as feed mills, *slaughterhouses*, rendering plants, etc.), their interrelationships and their contribution to an epidemiological separation between the *animals* in a *compartment* and *subpopulations* with a different health status. The definition of *compartment* may revolve around *disease* specific epidemiological factors, animal production systems, biosecurity practices infrastructural factors and *surveillance*.

## Article 4.4.3.

**Separation of a compartment from potential sources of infection**

The management of a *compartment* should provide to the *Veterinary Authority* documented evidence on the following:

1. Physical or spatial factors that affect the status of biosecurity in a compartment

While a *compartment* is primarily based on management and biosecurity measures, a review of geographical factors is needed to ensure that the functional boundary provides adequate separation of a *compartment* from adjacent animal populations with a different health status. The following factors should be taken into consideration in conjunction with biosecurity measures and, in some instances, may alter the degree of confidence achieved by general biosecurity and *surveillance* measures:

- a) disease status in adjacent areas and in areas epidemiologically linked to the *compartment*;
- b) location, disease status and biosecurity of the nearest *epidemiological units* or other epidemiologically relevant premises. Consideration should be given to the distance and physical separation from:
  - i) *flocks* or *herds* with a different health status in close proximity to the *compartment*, including wildlife and their migratory routes;
  - ii) *slaughterhouses*, rendering plants or feed mills;
  - iii) *markets*, fairs, agricultural shows, sporting events, zoos, circuses and other points of animal concentration.

2. Infrastructural factors

Structural aspects of the *establishments* within a *compartment* contribute to the effectiveness of its biosecurity. Consideration should be given to:

- a) fencing or other effective means of physical separation;
- b) facilities for people entry including access control, changing area and showers;
- c) *vehicle* access including washing and *disinfection* procedures;
- d) *unloading* and *loading* facilities;
- e) isolation facilities for introduced *animals*;

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- f) facilities for the introduction of material and equipment;
- g) infrastructure to store feed and veterinary products;
- h) disposal of carcasses, manure and waste;
- i) water supply;
- j) measures to prevent exposure to living mechanical or biological vectors such as insects, rodents and wild birds;
- k) air supply;
- l) feed supply/source.

More detailed recommendations for certain *establishments* can be found in Sections 4 and 6 of the *Terrestrial Code*.

3. Biosecurity plan

The integrity of the *compartment* relies on effective biosecurity. The management of the *compartment* should develop, implement and monitor a comprehensive *biosecurity plan*.

The *biosecurity plan* should describe in detail:

- a) potential pathways for introduction and spread into the *compartment* of the agents for which the *compartment* was defined, including animal movements, rodents, fauna, aerosols, arthropods, *vehicles*, people, biological products, equipment, fomites, feed, waterways, drainage or other means. Consideration should also be given to the survivability of the agent in the environment;
- b) the critical control points for each pathway;
- c) measures to mitigate exposure for each critical control point;
- d) standard operating procedures including:
  - i) implementation, maintenance, monitoring of the measures,
  - ii) application of corrective actions,
  - iii) verification of the process,
  - iv) record keeping;
- e) contingency plan in the event of a change in the level of exposure;
- f) reporting procedures to the *Veterinary Authority*;
- g) the programme for educating and training workers to ensure that all persons involved are knowledgeable and informed on biosecurity principles and practices;
- h) the *surveillance* programme in place.

Annex 7 (contd)

In any case, sufficient evidence should be submitted to assess the efficacy of the *biosecurity plan* in accordance with the level of *risk* for each identified pathway. This evidence should be structured in line with the principles of Hazard Analysis and Critical Control Point (HACCP). The biosecurity risk of all operations of the *compartment* should be regularly re-assessed and documented at least on a yearly basis. Based on the outcome of the assessment, concrete and documented mitigation steps should be taken to reduce the likelihood of introduction of the disease agent into the *compartment*.

4. Traceability system

A prerequisite for assessing the integrity of a *compartment* is the existence of a valid *traceability* system. All *animals* within a *compartment* should be individually identified and registered in such a way that their history and movements can be documented and audited. In cases where individual identification may not be feasible, such as broilers and day-old chicks, the *Veterinary Authority* should provide sufficient assurance of *traceability*.

All animal movements into and out of the *compartment* should be recorded at the *compartment* level, and when needed, based on a *risk assessment*, certified by the *Veterinary Authority*. Movements within the *compartment* need not be certified but should be recorded at the *compartment* level.

Article 4.4.4.

**Documentation**

Documentation should provide clear evidence that the biosecurity, *surveillance*, *traceability* and management practices defined for a *compartment* are effectively and consistently applied. In addition to animal movement information, the necessary documentation should include *herd* or *flock* production records, feed sources, *laboratory* tests, birth and *death* records, the visitor logbook, morbidity history, medication and vaccination records, *biosecurity plans*, training documentation and any other criteria necessary for the evaluation of *disease* exclusion.

The historical status of a *compartment* for the *disease(s)* for which it was defined should be documented and demonstrate compliance with the requirements for freedom in the relevant *Terrestrial Code* chapter.

In addition, a *compartment* seeking recognition should submit to the *Veterinary Authority* a baseline animal health report indicating the presence or absence of OIE *listed diseases*. This report should be regularly updated to reflect the current animal health situation of the *compartment*.

Vaccination records including the type of vaccine and frequency of administration should be available to enable interpretation of *surveillance* data.

The time period for which all records should be kept may vary according to the species and *disease(s)* for which the *compartment* was defined.

All relevant information should be recorded in a transparent manner and be easily accessible so as to be auditable by the *Veterinary Authority*.

Article 4.4.5.

**Surveillance for the agent or disease**

The *surveillance* system should comply with Chapter 1.4. on surveillance and the specific recommendations for *surveillance* for the *disease(s)* for which the *compartment* was defined, if available.

Annex 7 (contd)

If there is an increased *risk* of exposure to the agent for which the *compartment* has been defined, the sensitivity of the internal and external *surveillance* system should be reviewed and, where necessary, increased. At the same time, biosecurity measures in place should be reassessed and increased if necessary.

1. Internal surveillance

*Surveillance* should involve the collection and analysis of *disease/infection* data so that the *Veterinary Authority* can certify that the animal *subpopulation* contained in all the *establishments* comply with the defined status of that *compartment*. A *surveillance* system that is able to ensure early detection in the event that the agent enters a *subpopulation* is essential. Depending on the *disease(s)* for which the *compartment* was defined, different *surveillance* strategies may be applied to achieve the desired confidence in *disease* freedom.

2. External surveillance

The biosecurity measures applied in a *compartment* should be appropriate to the level of exposure of the *compartment*. External *surveillance* will help identify a significant change in the level of exposure for the identified pathways for *disease* introduction into the *compartment*.

An appropriate combination of active and passive *surveillance* is necessary to achieve the goals described above. Based on the recommendations of Chapter 1.4., targeted *surveillance* based on an assessment of *risk* factors may be the most efficient *surveillance* approach. Targeted *surveillance* should in particular include *epidemiological units* in close proximity to the *compartment* or those that have a potential epidemiological link with it.

Article 4.4.6.

**Diagnostic capabilities and procedures**

Officially-designated *laboratory* facilities complying with the OIE standards for quality assurance, as defined in Chapter 1.1.3. of the *Terrestrial Manual*, should be available for sample testing. All *laboratory* tests and procedures should comply with the recommendations of the *laboratory* for the specific *disease*. Each *laboratory* that conducts testing should have systematic procedures in place for rapid reporting of *disease* results to the *Veterinary Authority*. Where appropriate, results should be confirmed by an OIE Reference Laboratory.

Article 4.4.7.

**Emergency response and notification**

Early detection, diagnosis and notification of *disease* are critical to minimize the consequences of *outbreaks*.

In the event of suspicion of occurrence of the *disease* for which the *compartment* was defined, the free status of the *compartment* should be immediately suspended. If confirmed, the status of the *compartment* should be immediately revoked and *importing countries* should be notified **following the provisions of Article 5.3.7. Chapter 1.1.**

In case of an occurrence of any infectious *disease* not present according to the baseline animal health report of the *compartment* referred to in Article 4.4.4., the management of the *compartment* should notify the *Veterinary Authority*, and initiate a review to determine whether there has been a breach in the biosecurity measures. If a significant breach in biosecurity, even in the absence of *outbreak*, is detected, export certification as a free *compartment* should be suspended. Disease free status of the *compartment* may only be reinstated after the *compartment* has adopted the necessary measures to re-establish the original biosecurity level and the *Veterinary Authority* re-approves the status of the *compartment*.

Annex 7 (contd)

In the event of a *compartment* being at risk from a change, in the surrounding area, in the disease situation for which the *compartment* was defined, the *Veterinary Authority* should re-evaluate without delay the status of the *compartment* and consider whether any additional biosecurity measures are needed to ensure that the integrity of the *compartment* is maintained.

## Article 4.4.8.

**Supervision and control of a compartment**

The authority, organisation, and infrastructure of the *Veterinary Services*, including *laboratories*, should be clearly documented in accordance with the chapter on the evaluation of *Veterinary Services* of the *Terrestrial Code*, to provide confidence in the integrity of the *compartment*.

The *Veterinary Authority* has the final authority in granting, suspending and revoking the status of a *compartment*. The *Veterinary Authority* should continuously supervise compliance with all the requirements critical to the maintenance of the *compartment* status described in this chapter and ensure that all the information is readily accessible to the *importing countries*. Any significant change should be notified to the *importing country*.

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## CHAPTER 5.3.

**OIE PROCEDURES RELEVANT TO THE AGREEMENT  
ON THE APPLICATION OF SANITARY AND  
PHYTOSANITARY MEASURES OF  
THE WORLD TRADE ORGANIZATION**

## Article 5.3.1.

**The Agreement on the Application of Sanitary and Phytosanitary Measures and role and responsibility of the OIE**

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) encourages the Members of the World Trade Organization to base their *sanitary measures* on international standards, guidelines and recommendations, where they exist. Members may choose to adopt a higher level of protection than that provided by international texts if there is a scientific justification or if the level of protection provided by the relevant international texts is considered to be inappropriate. In such circumstances, Members are subject to obligations relating to *risk assessment* and to a consistent approach of *risk management*. The SPS Agreement encourages Governments to make a wider use of *risk analysis*: WTO Members shall undertake an assessment as appropriate to the circumstances of the actual *risk* involved.

The SPS Agreement recognises the OIE as the relevant international organisation responsible for the development and promotion of international animal health standards, guidelines, and recommendations affecting trade in live *animals* and animal products.

## Article 5.3.2.

**Introduction on the judgement of the equivalence of sanitary measures**

The importation of *animals* and animal products involves a degree of *risk* to the animal health status of an *importing country*. The estimation of that *risk* and the choice of the appropriate *risk management* option(s) are made more difficult by differences among the animal health and production systems in OIE Members. It is now recognised that significantly different animal health and production systems can provide equivalent animal and human health protection for the purpose of *international trade*, with benefits to both the *importing country* and the *exporting country*.

These recommendations are to assist OIE Members to determine whether *sanitary measures* arising from different animal health and production systems may provide the same level of animal and human health protection. They discuss principles which might be utilised in a judgement of equivalence, and outline a step-wise process for trading partners to follow in facilitating a judgement of equivalence. These provisions are applicable whether equivalence applies at the level of specific measures or on a systems-wide basis, and whether equivalence applies to specific areas of trade or *commodities*, or generally.

## Article 5.3.3.

**General considerations on the judgement of the equivalence of sanitary measures**

Before trade in *animals* or their products may occur, an *importing country* must be satisfied that its *animal health status* will be appropriately protected. In most cases, the *risk management* measures drawn up will rely in part on judgements made about the animal health and production system(s) in the *exporting country* and the effectiveness of sanitary procedures undertaken there. Systems operating in the *exporting country* may differ from those in the *importing country* and from those in other countries with which the *importing country* has traded. Differences may be with respect to infrastructure, policies and/or operating procedures, *laboratory* systems, approaches to the pests and *diseases* present, border security and internal movement controls.

International recognition of the legitimacy of different approaches to achieving the *importing country's appropriate level of protection* (ALOP) has led to the principle of equivalence being included in trade agreements, including the SPS Agreement of the WTO.

Benefits of applying equivalence may include:

1. minimising costs associated with *international trade* by tailoring animal health measures to local circumstances;
2. maximising animal health outcomes for a given level of resource input;
3. facilitating trade by achieving the required health protection through less trade restrictive *sanitary measures*; and
4. decreased reliance on relatively costly *commodity* testing and isolation procedures in bilateral or multilateral agreements.

The *Terrestrial Code* recognises equivalence by recommending alternative *sanitary measures* for many *diseases* and pathogenic agents. Equivalence may be gained, for example, by enhanced *surveillance* and monitoring, by the use of alternative test, treatment or isolation procedures, or by combinations of the above. To facilitate the judgement of equivalence, Members should base their *sanitary measures* on OIE standards, guidelines and recommendations.

It is essential to apply a scientific *risk analysis* to the extent practicable in establishing the basis for a judgement of equivalence.

## Article 5.3.4.

**Prerequisite considerations in a judgement of equivalence**1. Application of risk assessment

Application of the discipline of *risk assessment* provides a structured basis for judging equivalence among different *sanitary measures* as it allows a close examination to be made of the effect of a measure(s) on a particular step(s) in the importation pathway, and the relative effects of proposed alternative measure(s) on the same or related steps.

Annex 7 (contd)

A judgement of equivalence needs to assess the *sanitary measure* in terms of its effectiveness regarding the particular *risk* or group of *risks* against which the measure is designed to protect. Such an assessment may include the following elements: the purpose of the measure, the level of protection achieved by the measure and the contribution the measure makes to achieving the ALOP of the *importing country*.

2. Categorisation of sanitary measures

Proposals for equivalence may be in terms of a measure comprising a single component of a measure (e.g. an isolation procedure, a test or treatment requirement, a certification procedure) or multiple components (e.g. a production system for *commodity*), or a combination of measures. Multiple components or combinations of measures may be applied consecutively or concurrently.

*Sanitary measures* are those described in each chapter of the *Terrestrial Code* which are used for *risk* reduction and are appropriate for particular *diseases*. *Sanitary measures* may be applied either alone or in combination and include test requirements, processing requirements, inspection or certification procedures, quarantine confinements, and sampling procedures.

For the purposes of judging equivalence, *sanitary measures* can be broadly categorised as:

- a) infrastructure: including the legislative base (e.g. animal health law) and administrative systems (e.g. organisation of national and regional animal health authorities, emergency response organisations);
- b) programme design/implementation: including documentation of systems, performance and decision criteria, *laboratory* capability, and provisions for certification, audit and enforcement;
- c) specific technical requirement: including requirements applicable to the use of secure facilities, treatment (e.g. retorting of cans), specific test (e.g. ELISA) and procedures (e.g. pre-export inspection).

A *sanitary measure (s)* proposed for a judgement of equivalence may fall into one or more of these categories, which are not mutually exclusive.

In some cases, a comparison of specific technical requirements may suffice. In many instances, however, a judgement as to whether the same level of protection is likely to be achieved may only be able to be determined through an evaluation of all relevant components of an *exporting country's* animal health and production system. For example, a judgement of equivalence for a specific *sanitary measure* at the programme design/implementation level may require a prior examination of infrastructure while a judgement of equivalence for a specific measure at the specific technical requirement level may require that the specific measure be judged in its context through examination of infrastructure and programmes.

Article 5.3.5.

**Principles for judgement of equivalence**

In conjunction with the above considerations, judgement of the equivalence of *sanitary measures* should be based on application of the following principles:

1. an *importing country* has the right to set the level of protection it deems appropriate (its ALOP) in relation to human and animal life and health in its territory; this ALOP may be expressed in qualitative or quantitative terms;

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2. the *importing country* should be able to describe the reason for each *sanitary measure* i.e. the level of protection intended to be achieved by application of the identified measure against a *hazard*;
3. an *importing country* should recognise that *sanitary measures* different from the ones it has proposed may be capable of providing the same level of protection;
4. the *importing country* should, upon request, enter into consultations with the *exporting country* with the aim of facilitating a judgement of equivalence;
5. any *sanitary measure* or combination of *sanitary measures* can be proposed for judgement of equivalence;
6. an interactive process should be followed that applies a defined sequence of steps, and utilizes an agreed process for exchange of information, so as to limit data collection to that which is necessary, minimise administrative burden, and facilitate resolution of claims;
7. the *exporting country* should be able to demonstrate objectively how the alternative *sanitary measure (s)* proposed as equivalent will provide the same level of protection;
8. the *exporting country* should present a submission for equivalence in a form that facilitates judgement by the *importing country*;
9. the *importing country* should evaluate submissions for equivalence in a timely, consistent, transparent and objective manner, and according to appropriate *risk assessment* principles;
10. the *importing country* should take into account any knowledge of and prior experience with the *Veterinary Authority* or other *Competent Authority* of the *exporting country*;
11. the *exporting country* should provide access to enable the procedures or systems which are the subject of the equivalence judgement to be examined and evaluated upon request of the *importing country*;
12. the *importing country* should be the sole determinant of equivalence, but should provide to the *exporting country* a full explanation for its judgement;
13. to facilitate a judgement of equivalence, OIE Members should base their *sanitary measures* on relevant OIE standards;
14. to allow the judgement of equivalence to be reassessed if necessary, the *importing country* and the *exporting country* should keep each other informed of significant changes to infrastructure, health status or programmes which may bear on the judgement of equivalence; and
15. an *importing country* should give positive consideration to a request by an exporting developing country for appropriate technical assistance that would facilitate the successful completion of a judgement of equivalence.

## Article 5.3.6.

**Sequence of steps to be taken in judgement of equivalence**

There is no single sequence of steps which must be followed in all judgements of equivalence. The steps that trading partners choose will generally depend on the circumstances and their trading experience. The interactive sequence of steps described below may be useful for all *sanitary measures* irrespective of their categorisation as infrastructure, programme design/implementation or specific technical requirement components of an animal health and production system.

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This sequence assumes that the *importing country* is meeting its obligations under the WTO SPS Agreement and has in place a transparent measure based either on an international standard or a *risk analysis*.

Recommended steps are:

1. the *exporting country* identifies the measure(s) for which it wishes to propose an alternative measure(s), and requests from the *importing country* a reason for its *sanitary measure* in terms of the level of protection intended to be achieved against a *hazard(s)*;
2. the *importing country* explains the reason for the measure(s), in terms which would facilitate comparison with an alternative *sanitary measure (s)* and consistent with the principles set out in these provisions;
3. the *exporting country* demonstrates the case for equivalence of an alternative *sanitary measure (s)* in a form which facilitates analysis by an *importing country*;
4. the *exporting country* responds to any technical concerns raised by the *importing country* by providing relevant further information;
5. judgement of equivalence by the *importing country* takes into account as appropriate:
  - a) the impact of biological variability and uncertainty;
  - b) the expected effect of the alternative *sanitary measure(s)* on all relevant *hazards*;
  - c) OIE standards;
  - d) application of solely qualitative frameworks where it is not possible or reasonable to conduct *quantitative risk assessment*;
6. the *importing country* notifies the *exporting country* of its judgement and the underlying reasons within a reasonable period of time:
  - a) recognition of the equivalence of the *exporting country*'s alternative *sanitary measure (s)*;
  - b) request for further information; or
  - c) rejection of the case for equivalence of the alternative *sanitary measure(s)*;
7. an attempt should be made to resolve any differences of opinion over judgement of a case, either interim or final, by using an agreed mechanism to reach consensus (e.g. the OIE informal procedure for dispute mediation), or by referral to an agreed expert;
8. depending on the category of measures involved, the *importing country* and the *exporting country* may enter into a formal equivalence agreement giving effect to the judgement or a less formal acknowledgement of the equivalence of a specific measure(s) may suffice.

An *importing country* recognising the equivalence of an *exporting country*'s alternative *sanitary measure(s)* needs to ensure that it acts consistently with regard to applications from third countries for recognition of equivalence applying to the same or very similar measure(s). Consistent action does not mean however that a specific measure(s) proposed by several *exporting countries* should always be judged as equivalent as a measure(s) should not be considered in isolation but as part of a system of infrastructure, policies and procedures.

Annex 7 (contd)

## Article 5.3.7.

**Sequence of steps to be taken in establishing a zone/compartment and having it recognized for international trade purposes**

There is no single sequence of steps which should be followed in establishing a *zone* or a *compartment*. The steps that the *Veterinary Services* of the *importing country* and the *exporting country* choose and implement will generally depend on the circumstances existing within the countries and at their borders, and their trading history. The recommended steps are:

1. For zoning

- a) The *exporting country* identifies a geographical area within its territory, which it considers to contain an animal *subpopulation* with a distinct health status with respect to a specific *disease* /specific *diseases*, based on *surveillance*.
- b) The *exporting country* describes in the *biosecurity plan* for the *zone* the measures which are being, or will be, applied to distinguish such an area epidemiologically from other parts of its territory, in accordance with the recommendations in the *Terrestrial Code*.
- c) The *exporting country* provides:
  - i) the above information to the *importing country*, with an explanation of why the area can be treated as an epidemiologically separate *zone* for *international trade* purposes;
  - ii) access to enable the procedures or systems that establish the *zone* to be examined and evaluated upon request by the *importing country*.
- d) The *importing country* determines whether it accepts such an area as a *zone* for the importation of *animals* and animal products, taking into account:
  - i) an evaluation of the *exporting country*'s *Veterinary Services*;
  - ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
  - iii) its own animal health situation with respect to the *disease (s)* concerned; and
  - iv) other relevant OIE standards.
- e) The *importing country* notifies the *exporting country* of its determination and the underlying reasons, within a reasonable period of time, being:
  - i) recognition of the *zone*; or
  - ii) request for further information; or
  - iii) rejection of the area as a *zone* for *international trade* purposes.
- f) An attempt should be made to resolve any differences over recognition of the *zone*, either in the interim or finally, by using an agreed mechanism to reach consensus such as the OIE informal procedure for dispute mediation (Article 5.3.8.).

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- g) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognizing the *zone*.

2. For compartmentalisation

- a) Based on discussions with the relevant industry, the *exporting country* identifies within its territory a *compartment* comprising an animal *subpopulation* contained in one or more *establishments* or other premises operating under common management practices related to biosecurity. The *compartment* contains an identifiable animal *subpopulation* with a distinct health status with respect to specific *disease (s)*. The *exporting country* describes how this status is maintained through a partnership between the relevant industry and the *Veterinary Authority* of the *exporting country*.
- b) The *exporting country* examines the *compartment's biosecurity plan* and confirms through an audit that:
- i) the *compartment* is epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its *biosecurity plan*; and
  - ii) the *surveillance* and monitoring programme in place is appropriate to verify the status of such a *subpopulation* with respect to such *disease(s)*.
- c) The *exporting country* describes the *compartment*, in accordance with the recommendations in the *Terrestrial Code*.
- d) The *exporting country* provides:
- i) the above information to the *importing country*, with an explanation of why such a *subpopulation* can be treated as an epidemiologically separate *compartment* for *international trade* purposes; and
  - ii) access to enable the procedures or systems that establish the *compartment* to be examined and evaluated upon request by the *importing country*.
- e) The *importing country* determines whether it accepts such a *subpopulation* as a *compartment* for the importation of *animals* and animal products, taking into account:
- i) an evaluation of the *exporting country's Veterinary Services*;
  - ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
  - iii) its own animal health situation with respect to the *disease (s)* concerned; and
  - iv) other relevant OIE standards.
- f) The *importing country* notifies the *exporting country* of its determination and the underlying reasons, within a reasonable period of time, being:
- i) recognition of the *compartment*; or
  - ii) request for further information; or
  - iii) rejection of such a *subpopulation* as a *compartment* for *international trade* purposes.

Annex 7 (contd)

- g) An attempt should be made to resolve any differences over recognition of the *compartment*, either in the interim or finally, by using an agreed mechanism to reach consensus such as the OIE informal procedure for dispute mediation (Article 5.3.8).
- h) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognising the *compartment*.
- i) The *Veterinary Authority* of the *exporting country* should promptly inform *importing countries* of any occurrence of a *disease* in respect of which the *compartment* was defined.

Article 5.3.8.

### The OIE informal procedure for dispute mediation

OIE shall maintain its existing voluntary in-house mechanisms for assisting OIE Members to resolve differences. In-house procedures which will apply are that:

1. Both parties agree to give the OIE a mandate to assist them in resolving their differences.
2. If considered appropriate, the Director General of the OIE recommends an expert, or experts, and a chairman, as requested, agreed by both parties.
3. Both parties agree on the terms of reference and working programme, and to meet all expenses incurred by the OIE.
4. The expert or experts are entitled to seek clarification of any of the information and data provided by either country in the assessment or consultation processes, or to request additional information or data from either country.
5. The expert or experts shall submit a confidential report to the Director General of the OIE, who will transmit it to both parties.

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