

OIE ACTIVITIES ON ZONING AND COMPARTMENTALIZATION

Communication from the World Organization for Animal Health (OIE)

The following communication, received on 19 January 2005, is being circulated at the request of the OIE.

Official recognition of disease status by the OIE

1. The OIE has a mandate to examine upon request from a member country its claims for a particular status with regard to four of the OIE listed diseases for terrestrial animals: foot and mouth disease (FMD), rinderpest, contagious bovine pleuropneumonia and bovine spongiform encephalopathy (BSE). With regard to BSE, Member Countries may apply to be recognized for only one of two categories of status (of the five in the current BSE chapter of the OIE Terrestrial Animal Health Code (the Terrestrial Code)) – free and provisionally free.
2. The OIE does not routinely classify its Member Countries with respect to their animal health status for other listed diseases. However, it publishes information received from the delegates of Member Countries with regard to their status for other listed diseases and for emerging diseases. Some Member Countries have suggested that the diseases for which the OIE officially recognises health status be increased to include avian influenza (AI) and classical swine fever (CSF).
3. The recognition procedure requires that the member country provide evidence that it complies with all the relevant provisions of the Terrestrial Code and Manual with respect to the disease for which free status is being sought, either for the whole country, or for a zone or compartment within the country.
4. As the procedure concludes with an official recognition by the OIE of the status of the member country for that disease (through a formal resolution adopted by the International Committee of the OIE at its General Session), other OIE Member Countries have an obligation to take that recognition into account when developing import health measures for commodities from that member country, to maximise the harmonisation of their measures with international standards.
5. Full details of the OIE process are provided in documents G/SPS/GEN/542 and G/SPS/GEN/542 Add1.

Zoning and compartmentalization

6. The *Terrestrial Code* chapter on zoning and compartmentalization provides general guidance to OIE Member Countries seeking to establish and maintain different animal subpopulations within their national boundaries using the procedures described. The chapter also outlines a process for trading partners to follow in achieving recognition of the health status of such subpopulations. These procedures are best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to disease outbreaks, rather than during outbreaks.

As well, specific requirements have been developed or are being developed for diseases for which the application of zoning or compartmentalization is considered appropriate; for example:

- The *Terrestrial Code* chapter on FMD gives detailed technical recommendations for a country or zone to be considered free from FMD, with or without vaccination. Recommendations for free compartments are under consideration but the manner in which the disease spreads presents difficulties.
- The *Terrestrial Code* chapter on avian influenza gives detailed technical recommendations for a country, zone or compartment to be considered free from all types of avian influenza or free from the highly pathogenic form only.
- The *Terrestrial Code* chapter on BSE gives detailed technical recommendations for a country, zone or compartment to be considered of negligible BSE risk or controlled BSE risk.
- The proposed revised *Terrestrial Code* chapter on classical swine fever (CSF) gives detailed technical recommendations for a country, zone or compartment to be considered as free from CSF, and addresses the disease in domestic and wild pigs.

7. It should be noted, however, that the application of zoning or compartmentalization is not mandatory, and should only be used when appropriate, taking into account the epidemiology of the disease and the particular factors applying in each situation. These particular factors may include environmental factors (e.g., the presence of natural boundaries), the level of surveillance for the disease, the quality of veterinary services or other competent authorities, and the ability to apply appropriate biosecurity measures.

OIE concept paper on compartmentalization

8. A provisional draft of an OIE concept paper on compartmentalization, which has been developed to enhance the understanding of Member Countries of the concept of compartmentalization and to suggest criteria and guidelines for the application of this concept, is attached.

Attachment

OIE CONCEPT PAPER ON COMPARTMENTALIZATION

A provisional draft for discussion at the General Session
of the OIE International Committee in May 2006

December 2005

Introduction

The objective of this document is to describe the concept of a “compartment” and to develop criteria and guidelines for the application of this concept.

The difficulty of establishing and maintaining a disease free status for an entire country, especially for diseases the entry of which is difficult to control at national boundaries, has been acknowledged. For many diseases, OIE Member Countries have traditionally applied the concept of zoning to establish and maintain an animal subpopulation with a different animal health status within national boundaries. Recently, the concept of compartmentalisation was introduced to the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) and the OIE *Aquatic Animal Health Code* as an alternative way to manage disease and pathogens in animal populations without unnecessarily disrupting trade. Regionalisation or zoning can be thought of as recognising animal subpopulations of differing health status based on geographical boundaries, while compartmentalisation is based primarily 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. Examples of such programmes include tuberculosis, brucellosis and pseudorabies. The intent of this document is to provide a structured framework for the application and recognition of compartments within countries or zones.

The fundamental requirement for application of either concept is that the animal population considered for trade maintains a functional separation through management or geographic boundaries that allow a clear epidemiological differentiation from populations of higher risk. For example, a confinement operation of poultry or swine might have biosecurity measures and management practices that result in virtually zero risk from diseases or agents in the same geographic area. On the other hand, a geographically isolated population of animals or birds might have substantial risk from travellers, tourists, or other long range epidemiological links. Thus the concept of a compartment extends the application of a “risk boundary” beyond that of a geographic interface and considers all epidemiological factors contributing to a functional separation that creates an effective boundary.

The main criterion for a compartment is that the animals contained in it are clearly recognisable as part of a unique subpopulation with limited or no epidemiological links to other populations of risk. The measures taken to ensure the identification of the sub-population and the recognition and maintenance of its health status should be documented in detail and must take into consideration the epidemiologic characteristics of the disease in question.

In disease control strategies the compartments should be defined prior to the occurrence of the outbreak. Following a disease outbreak, compartmentalisation may be able to take advantage of epidemiological linkages among groups of animals despite diverse geographical locations, to facilitate disease control.

For the purpose of international trade, compartments should be under the direct control and responsibility of the official *Veterinary Administration* in the country.

Definitions

The following definitions have been adopted for the Terrestrial Code (the definitions in the Aquatic Code are very similar):

Zone/region

means a clearly defined part of a country containing an animal subpopulation with a distinct health status with respect to a specific disease for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade.

Compartment

means one or more establishments under a common biosecurity management system containing an animal sub-population with a distinct health status with respect to a specific disease for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade.

Establishment

means the premises in which animals or birds are kept.

Seven factors for evaluation and recognition of a compartment

1. Definition of the compartment

A compartment is an animal subpopulation with a defined status in respect of the conditions of interest, a geographical identity and integrity in maintenance of its membership and status. The compartment must be clearly defined, indicating the functional relationships of all its components and their contribution to an epidemiological boundary between the animals in the compartment and populations of higher risk. The definition of compartment may revolve around common animal ownership or management, membership in associations, industry improvement plans or breed registries with prescriptive biosecurity guidelines, or similar functional demarcations.

The compartment may also be defined by disease specific factors. For example, a cattle population may be defined as a BSE free compartment dependent primarily on careful historical documentation of feed sources, animal movements and identification. Alternatively, a swine confinement operation might be defined by the ability of its biosecurity plan to exclude infectious agents on a day to day basis. In the poultry industry, a compartment may be defined on the basis of a slaughter plant and all the establishments that supply birds to it as well as those establishments that are vertically integrated with the operation.

In general, a compartment is defined by the factors common to a population that provide distinct disease risk separation from animals or birds at higher risk for the disease(s) in question.

2. Epidemiologic separation of the compartment from potential sources of infection

Epidemiological parameters comprise a major portion of the defining criteria for a compartment. These factors relate to pathways of disease transmission, mitigations to prevent exposure, disease specific factors, and environmental factors that affect exposure and propagation of the disease agent.

(a) Biosecurity in respect of health related issues

The biosecurity plan should address potential pathways for introduction and spread of infection into the compartment. In addition to detailing disease introduction pathways, a biosecurity plan should provide standard operating procedures that mitigate exposure from each pathway and describe a plan for the implementation and monitoring of compliance with the procedures. Finally, the plan should include means for education and training of workers to ensure that all persons involved in biosecurity are knowledgeable and informed.

(b) Physical, spatial, or location factors that affect the status of biosecurity in the compartment

While a compartment is primarily based on biosecurity measures, a review of geographic factors is needed to ensure that the functional boundary provides adequate separation of the compartment from adjacent high risk animal populations. The following considerations are taken in conjunction with biosecurity measures and, in some instances, may alter the degree of confidence achieved by general biosecurity and surveillance measures.

- Disease or pest status in areas adjacent, or with unmanageable epidemiological links to the compartment.
- Location of nearest flocks or herds. Are the facilities within the compartment immediately adjacent to flocks or herds of higher risk or is there a buffer area that would preclude direct contact or aerosol spread?
- Consideration of environmental spread of the disease agent. Are aerosols a factor in the transmission of the disease-causing agent? Is the climate such that agent survivability would be extremely brief or extremely prolonged?

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. The compartment should periodically assess the biosecurity risk of all operations through a formal process using a survey instrument designed to identify high risk aspects. Based on the outcome, concrete and documented mitigation steps should be taken to reduce areas of high risk for introducing the agent.

(c) Identification and registration

A prerequisite to assess the integrity of the membership of the compartment is the existence of a valid traceability system. All animals within the compartment should be identified in such a way that their individual history can be audited. Depending on the system of production, identification may be done at the herd, flock, lot or individual animal level. All animal movements into and out of the compartment should be certified by the official veterinary service and documented.

Table 1. General considerations of compartmental biosecurity: pathways of entry of disease agents and responsive mitigations

Potential pathways of entry	Examples of responsive mitigations
Endemic compartments	No interactions with endemic compartments. Biosecurity practices protect farm site from neighbouring herds/flocks (also see employee policy).
Wild populations	Animals in the free compartment should be housed in a way that provides adequate separation from other wild populations (e.g. wild boars, wild birds)
Employees	Policy prohibiting employees' contact with high risk animals. e.g. in the poultry industry a policy preventing employees from owning or handling birds off farm or attending avian shows or exhibitions; shower, dedicated clothing/footwear Training
Service sectors (e.g. Catching/vaccination/cleaning crews/feed delivery/service personnel)	Require use of disposable or dedicated clothing/footwear Require that they not have been on another farm same day Require truck/equipment cleaned and disinfected before coming on farm
Congregation of sick/dead animals from multiple sources (e.g., rendering)	Compost, incinerate, or bury dead animals e.g. for poultry, covered barrel at perimeter of property – dead birds placed in bags in barrel
Vehicle traffic	Park away from animal housing, preferably outside farm perimeter Only essential vehicles enter premises (e.g., feed truck) Spray station at entrance – use on own vehicles as well as others
Visitors	Prohibit visitors in animal area Fences, signs, locked gates, or guards to discourage entry
Wild animals	No attractants such as garbage Fencing House production animals indoors
Aerosol	Prevention of possible aerosol-borne infection by distance or other specific measures such as air filtration systems.
Vectors	Vector proof housing. Verify the integrity of screens regularly.
Equipment	Do not share equipment with other farm sites, including same parent company Dedicated racks and flats (e.g., colour coded) – thoroughly cleaned and disinfected between uses
Downtime	Minimum downtime between flocks or litters? Cleaning and disinfection E.G for poultry: number of flocks before change litter?

3. Documentation of factors critical to the definition of compartment

Standard operating procedures should be in place to document all operations of the compartment. Documentation must provide clear evidence that the biosecurity, surveillance, traceability and management practices are adequate to meet the definition of the compartment. In addition to animal movement information, the necessary documentation should include herd or flock production records, feed sources, surveillance tests, birth and death records, visitor logbook, morbidity history, medications, vaccinations, biosecurity plans, documentation of training and any other criteria necessary for evaluation of disease exclusion.

The historical disease status of the compartment has to be documented, indicating the dates of last disease occurrence (if any), the number of outbreaks and the methods for disease control that were applied. Vaccination status for many diseases must be considered in regard to the interpretation of surveillance data. The type of vaccine and frequency of administration are needed in many cases to evaluate test results and to determine the risk of the disease in the population. Therefore, documentation of vaccine-related factors must be maintained for a period of time based on the disease, vaccine types and production cycles.

The information contained in the records may vary according to the species and disease(s) under consideration. For example, in a disease such as BSE that is strictly transmitted by feed, with a long incubation period, complete records of all feed sources for several years would be essential to recognise the compartment. On the other hand, historic feed records would be of little value for a highly contagious disease such as avian influenza.

4. Supervision and control of the compartment

The authority, organisation, and infrastructure of the veterinary services, including laboratories, must be clearly documented in accordance with the chapter on the evaluation of veterinary services of the OIE *Terrestrial Code*, to provide confidence in the integrity of the compartment

Official oversight of biosecurity and surveillance is an essential component of compartmentalisation. The supervision of the factors critical to maintenance of a compartment status should be developed through cooperation of industry and government veterinary services. The final authority for the purposes of domestic and international trade lies within the official *Veterinary Services*. All production within the compartment should be carried out according to a single standard of operation.

Industry's responsibilities in most cases will include the application of biosecurity measures, quality assurance schemes, monitoring the efficacy of the measures, documenting corrective actions, conducting surveillance sampling, rapid reporting and maintenance of records in a readily accessible form. A HACCP approach may be an appropriate tool with which to design and apply these measures.

The Official *Veterinary Services* with authoritative responsibility for international trade will provide movement certification, periodic inspections of facilities, biosecurity measures, records, surveillance, and sampling procedures. Official *Veterinary Services* should conduct surveillance and sampling and they will conduct or oversee laboratory diagnostic examinations. The extent of oversight and frequency of inspections must be adequate to provide reasonable confidence to trading partners that the measures defining the compartment are applied in a manner that meets the importing country's appropriate level of protection.

5. Surveillance for the agent or disease

- (a) Surveillance should involve the collection and analysis of disease/infection data such that the official *Veterinary Services* have confidence that the flocks or herds comply with the defined status of a compartment. A surveillance system that is able to ensure early detection in the event that the agent enters a flock or herd is essential. The surveillance system should comply with the General Guidelines for Surveillance in the *Terrestrial Code* and the specific guidelines for surveillance for the disease of interest.
- (b) Depending on the disease of interest, many different combinations of testing and surveillance may be applied to achieve the desired confidence in disease freedom. The surveillance methodology will usually follow OIE guidelines but may utilise a demonstrably equivalent method. Based on an assessment of risk factors, a country may choose to sample with greater intensity in areas of higher risk and less so in other areas that have a documented lower risk. In general, an appropriate combination of active (ongoing laboratory-based testing) and passive (voluntary intermittent reporting or testing) is necessary to achieve the surveillance goals described above. A system for reporting the results of surveillance testing must be documented and efficacious to inform veterinary officials and trading partners of positive tests, abnormal clinical signs and production observations that are included in the surveillance strategy. Surveillance information must be reported immediately by the compartment management and field veterinary officials responsible for surveillance and monitoring of the disease.

6. Diagnostic capabilities

Officially designated laboratory facilities complying with the OIE standards for quality assurance as defined by the *OIE Manual for diagnostic Tests and Vaccines* for terrestrial and aquatic animals should be available for sample testing. The laboratory tests and their use should be audited by the national authority. In particular, laboratories and personnel performing the tests should be trained and certified by the national reference laboratory as to competency. Periodically, the laboratories and personnel should complete a proficiency test to verify continuing competence. Reporting of test results should be transparent.

7. Emergency response, control, and notification capability

Rapid diagnosis, reporting, and notification of disease are critical to minimising risk from outbreaks. The structure of the compartment must be such that producers and their employees are aware of the notifiable diseases and procedures for reporting. Likewise, each laboratory that conducts surveillance testing must have systematic procedures in place for rapid reporting of disease results to authoritative government officials. The veterinary authority must then have standard operating procedures to inform the OIE and if necessary, other pertinent international bodies.

Sequence of steps to be taken in defining a compartment

There is no single sequence of steps which must be followed in defining a zone or a compartment. The steps that the veterinary services of importing and exporting countries choose and implement will generally depend on the circumstances existing within a country and at its borders. The recommended steps are:

- based on discussions with the relevant enterprise/industry, the exporting country identifies within its territory one or more establishments or other premises owned by an enterprise(s) which operates under a common biosecurity management system, and which it considers contains an animal subpopulation with a distinct health status with respect to a specific disease/specific diseases;
- the exporting country assesses through a formal process compliance with the seven factors described above
- the exporting country identifies such an enterprise to be a free compartment, in accordance with the measures stipulated in the Terrestrial or Aquatic Code;
- the exporting country provides the information above to the importing country, and proposes that such an enterprise be treated as an epidemiologically separated compartment for international trade purposes;
- the importing country determines whether it may accept such an enterprise as a compartment for the importation of animals and animal products, taking into account:
 - an evaluation of the exporting country's Veterinary Services/competent authorities, according to the OIE Codes;
 - its own animal health situation with respect to the disease(s) concerned; and
 - other relevant OIE standards;
- the importing country notifies the exporting country of its determination and the underlying reasons, within a reasonable period of time, being either:
 - recognition of the compartment; in which case, the importing country and the exporting country may enter into a formal agreement defining the compartment;
 - request for further information; or
 - rejection of such an enterprise as a compartment for international trade purposes;

Official recognition of animal health status

The OIE has a mandate to examine upon request from a Member Country its claims for a particular status with regard to four of the OIE listed diseases: foot and mouth disease (FMD), rinderpest, contagious bovine pleuropneumonia and bovine spongiform encephalopathy (BSE). The OIE does not routinely classify its Member Countries with respect to their animal health status for other listed diseases.

The procedure requires that the Member Country provide evidence that it complies with all the relevant provisions of the Terrestrial Code and Manual with respect to the disease for which free status is being sought, either for the whole country, or for a zone or compartment within the country. While at present free status recognition is confined to countries and zones, as the use of the concept of compartmentalisation broadens within the Terrestrial and Aquatic Codes, official recognition of claims for free status of compartments will follow.

As the procedure concludes with an official recognition by the OIE of the status of the Member Country for that disease (through a formal resolution of the OIE International Committee), other OIE Member Countries have an obligation to take that recognition into account when developing import health measures for commodities from that Member Country.

Conclusion

OIE Member Countries have continuously striven to facilitate risk-based trade in the face of the challenges represented by disease prevalence in the livestock and poultry populations involved. In recent years, regionalisation/zoning was introduced as a means for trading from a sub-national area in an otherwise infected country. This requires that the official *Veterinary Services* exert control at the region/zone level equivalent or superior to that at the national level.

Compartmentalisation is a tool that may also be applied to facilitate trade. Fundamental to its application is the official *Veterinary Services'* control over the compartment and the free exchange of information necessary to convince importing countries that the risk of disease introduction from trade is minimised. Therefore, the procedures for establishing trade based upon the compartmentalisation concept should be similar to those practised for regionalisation or zoning.

All disease control approaches require the combined contributions of national veterinary services and individual producers. Compartmentalization requires a higher relative investment of resources per unit of animal production by the producers and the veterinary services than zoning or national disease control programs. A compartment is analogous to the initial phase in traditional national disease control programs (tuberculosis, brucellosis, pseudorabies) in which producers, under the official veterinary service supervision, decided for trade purposes to establish individual herd status superior to that to the general herd population.

The preceding guidelines provide a basis for establishing, evaluating and exchanging information on compartmentalised animal populations in the interest of international trade. As in the case of similar national or zoned/regionalised applications, the related trade decisions are ultimately determined by the importing country's assessment of whether its acceptable level of risk can be met during the commercial transaction.
