Concept of compartmentalisation
(to be used by the Terrestrial Animal Health Standard Commission in revising Chapter 1.3.5 of the OIE Terrestrial Animal Health Code)

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Summary
The rationale for establishing trade regions and zones is based on principles of epidemiological science and risk analysis to assess and manage animal disease risks in a manner to allow safe trade. However, the boundaries of geographic regions and zones may readily be breached through numerous epidemiological pathways. The concept 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 fundamental requirement for application of either concept is that the population considered for trade maintains a functional separation through management or geographic boundaries allowing clear epidemiological differentiation from populations of higher risk. Seven factors are presented that an exporting country might use to guide the identification and documentation of a compartment. Additionally, the steps that would be undertaken to implement trade based on the compartmentalisation concept are discussed.

Keywords

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 as laid down in the OIE Terrestrial Animal Health Code (Terrestrial Code) concerning facilitation of trade in animals and products of animal origin.

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 Terrestrial Code and the OIE Aquatic Animal Health Code (Aquatic Code) as an alternative way to manage disease and pathogens in animal populations without unnecessarily disrupting trade. Regionalisation/zoning can be thought of as recognising animal subpopulations with a distinct 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 differing health status. 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 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 subpopulation 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 preferably should be defined prior to the occurrence of a disease 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 taking into account possible disease risk due to the outbreak.

For the purpose of international trade, compartments shall be under the direct control and responsibility of the 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 subpopulation with a distinct health status with respect to a specific disease or specific diseases for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade.

Establishment: means the premises in which animals are kept.
Seven factors for evaluation and recognition of a *compartment*

**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 with a different health status. 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 establishment 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.

**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.

**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.

**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 animal populations with a different health status. 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 a different health status 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 biosecurity risk of all operations of the compartment should be periodically reassessed 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.

**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 well documented, controlled, and supervised by the Veterinary Service (Table I).

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

<table>
<thead>
<tr>
<th>Potential pathways of entry</th>
<th>Examples of responsive mitigations</th>
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<tbody>
<tr>
<td>Endemic compartments</td>
<td>No interactions with endemic compartments. Biosecurity practices protect from neighbouring herds/flocks (also see employee policy)</td>
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<tr>
<td>Wild populations</td>
<td>Animals in the free compartment should be housed in a way that provides adequate separation from wild populations of risk for disease transmission (e.g. wild boars, wild birds)</td>
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<td>Employees</td>
<td>– 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 in biosecurity and disease prevention</td>
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<tr>
<td>Service sectors (e.g. catching/vaccination/cleaning crews/feed delivery/service personnel)</td>
<td>– Require use of disposable or dedicated clothing/footwear – Require that they not have been on another farm same day – Truck/equipment cleaned and disinfected before coming on farm</td>
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<td>Congregation of sick/dead animals from multiple sources (e.g. rendering)</td>
<td>Compost, incinerate, render, or bury dead animals e.g. for poultry, covered barrel at perimeter of property – dead birds placed in bags in barrel</td>
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<td>Vehicle traffic</td>
<td>– Park away from animal housing, preferably outside farm perimeter – Only essential vehicles enter premises (e.g., feed truck) – Disinfection facilities at entrance – own vehicles as well as others</td>
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<tr>
<td>Visitors</td>
<td>– Prohibit visitors in animal area – Fences, signs, locked gates, or guards to discourage entry</td>
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<tr>
<td>Wild animals or pets</td>
<td>– No attractants such as garbage; rodent control; fencing – House production animals indoors; no pets inside animal facility</td>
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<tr>
<td>Aerosol</td>
<td>Prevention of possible aerosol-borne infection by distance or other specific measures such as air filtration systems.</td>
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<tr>
<td>Feed</td>
<td>Processing and handling including storage to avoid introduction of disease agent or contamination</td>
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<tr>
<td>Vectors</td>
<td>Vector proof housing. Verify the integrity of screens regularly</td>
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<tr>
<td>Equipment</td>
<td>– Do not share equipment, including within the same company – Dedicated racks and flats (e.g., colour coded) – thoroughly cleaned and disinfected between uses</td>
</tr>
<tr>
<td>Downtime</td>
<td>– Minimum downtime between flocks or litters? – Cleaning and disinfection; number of flocks before changing litter?</td>
</tr>
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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, such historic feed records would be of little value for a highly contagious disease such as avian influenza.
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 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 Hazard Analysis Critical Control Points (HACCP) approach may be an appropriate tool with which to design and apply these measures.

The Veterinary Services with authoritative responsibility for international trade will provide movement certification, periodic inspections of facilities, biosecurity measures, records, surveillance, and sampling procedures. Veterinary Services should conduct surveillance and sampling and they should 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.

Surveillance for the agent or disease

a) Surveillance should involve the collection and analysis of disease/infection data such that the Veterinary Services have confidence that animals in the establishment 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 an establishment 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 to
the Veterinary Services by the compartment management and field veterinary officials
responsible for surveillance and monitoring of the disease.

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. Any laboratory
testing and procedures 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.

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 Administration 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 or other 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 (maximum of 60 days), 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 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 in animals and their products. Fundamental to its application is the 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/zoning.
All disease control approaches require the combined contributions of Veterinary Services and individual producers. Compartmentalisation 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 programmes (tuberculosis, brucellosis, pseudorabies) in which producers, under the 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; also taking into account any official recognition by the OIE, of whether its acceptable level of risk can be met during the commercial transaction.