

ANNEX V

Requirements for declaring a Member State, zone or compartment disease-free

PART I

Disease-free Member State

1. On historical grounds

1.1. A Member State where susceptible species are present, but where there has not been any observed occurrence of the disease for at least for a period of 10 years before the date of application for the disease-free status despite conditions that are conducive to its clinical expression may be considered disease-free where:

- (a) basic biosecurity measure conditions have been in place continuously for at least a period of 10 years before the date of application for the disease-free status;
- (b) infection is not known to be established in wild populations;
- (c) the implementation of trade and imports conditions to prevent the introduction of the disease into the Member State is effective.

A Member State wishing to benefit from a disease-free status, shall submit an application in accordance with Article 49 before 1 November 2008. After this date, disease-free status may only be granted in accordance with Part I.2.

1.2. The basic biosecurity measures referred to in point 1.1(a) shall consist, as a minimum, of the following:

- (a) the disease is compulsorily notifiable to the competent authority, including notification of suspicion;
- (b) an early detection system is in place throughout the Member State, enabling the competent authority to undertake effective disease investigation and reporting, and ensuring in particular:
 - (i) the rapid recognition of any clinical signs consistent with the suspicion of a disease, emerging disease, or unexplained mortality in farms or molluscs farming areas, and in the wild;
 - (ii) the rapid communication of the event to the competent authority with the aim to activating diagnostic investigation with minimum delay.

1.3. The early detection system referred to in point 1.2(b) shall include at least the following:

- (a) broad awareness, among the personnel employed in aquaculture businesses or involved in the processing of aquaculture animals, of any signs consistent with the presence of a disease, and training of veterinarians or aquatic animal health specialists in detecting and reporting unusual disease occurrence;

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- (b) veterinarians or aquatic animal health specialists trained in recognising and reporting suspicious disease occurrence;
- (c) access by the competent authority to laboratories with the facilities for diagnosing and differentiating listed and emerging diseases.

2. Based on targeted surveillance

A Member State where the last known clinical occurrence was within 10 years before the date of application for the disease-free status or where the infection status prior to targeted surveillance was unknown, for example because of the absence of conditions conducive to clinical expression, may be considered free of the specific disease where:

- (a) the Member State meets the basic disease control conditions laid down in point 1.2;
- and
- (b) targeted surveillance in accordance with methods adopted pursuant to Article 49(3), has been in place for at least a period of two years without detection of the disease agent on farm, or in mollusc farming areas that rears any of the susceptible species.

Where there are parts of the Member State in which the number of farms, or molluscs farming areas is limited, and consequently targeted surveillance in these parts do not provide sufficient epidemiological data, but in which there are wild populations of any of the susceptible species, those wild populations shall be included in the targeted surveillance.

PART II

Disease-free zone or compartment

1. Zones

1.1. A zone may comprise:

- (a) an entire water catchment area from its source to its estuary;
- or
- (b) part of a water catchment area from the source(s) to a natural or artificial barrier that prevents the upward migration of aquatic animals from lower stretches of the water catchment area;
- or
- (c) more than one water catchment area, including their estuaries, due to the epidemiological link between the catchment areas through the estuary.

The geographical demarcation of the zone shall be clearly identified on a map.

1.2. Where a zone extends over more than one Member State, it may not be declared a disease-free zone unless the conditions outlined in points 1.3,

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1.4 and 1.5 apply to all areas of that zone. In that case both Member States concerned shall apply for approval for the part of the zone situated in their territory.

- 1.3. A zone where susceptible species are present, but where there has not been any observed occurrence of the disease for at least a period of 10 years before the date of application for the disease-free status, despite conditions that are conducive to its clinical expression, may be considered disease-free if it complies *mutatis mutandis* with the requirements laid down in Part I.1.

A Member State wishing to benefit from a disease-free status shall notify its intention in accordance with Article 50(2) before 1 November 2008. After this date, disease-free status may only be granted in accordance with Part I.2.

- 1.4. A zone where the last known clinical occurrence was within a period of 10 years before the date of application for the disease-free status or where the infection status prior to targeted surveillance was unknown, for example because of the absence of conditions conducive to clinical expression, may be considered disease-free where it complies *mutatis mutandis* with the requirements laid down in Part I.2.
- 1.5. A buffer zone in which a monitoring programme is carried out shall be established, as appropriate. The demarcation of the buffer zones shall be such that it protects the disease-free zone from passive introduction of the disease.

2. Compartments comprising one or more farms or mollusc farming areas where the health status regarding a specific disease is dependent on the health status regarding that disease of surrounding natural waters

- 2.1. A compartment may comprise one or more farms, a group or cluster of farms or a mollusc farming area that may be considered as one epidemiological unit due to its geographical localisation and distance from other groups or clusters of farms or mollusc farming areas, provided that all farms comprising the compartment fall within a common biosecurity system. The geographical demarcation of a compartment shall be clearly identified on a map.
- 2.2. A compartment where susceptible species are present, but where there has not been any observed occurrence of the disease for at least a period of 10 years before the date of application for the disease-free status despite conditions that are conducive to its clinical expression, may be considered disease-free if it complies *mutatis mutandis* with the requirements in Part I.1 of this Annex.

Member States wishing to benefit from this provision shall notify their intention in accordance with Article 50(2) before 1 November 2008. After this date, disease-free status may only be granted in accordance with Part I.2.

- 2.3. A compartment where the last known clinical occurrence was within 10 years before the date of application for the disease-free status, or where the infection status in the compartment or in the waters surrounding the compartment prior to targeted surveillance was unknown, for example because of the absence of conditions conducive to clinical expression, may be considered disease-free if it complies *mutatis mutandis* with the requirements laid down in Part I.2.

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- 2.4. Each farm or mollusc farming area in a compartment shall be subject to additional measures imposed by the competent authority, when considered necessary to prevent the introduction of diseases. Such measures may include the establishment of a buffer zone around the compartment in which a monitoring programme is carried out, and the establishment of additional protection against the intrusion of possible pathogen carriers or vectors.
3. Compartments comprising one or more individual farms where the health status regarding a specific disease is independent of the health status regarding that disease of the surrounding natural waters.
 - 3.1. A compartment may comprise:
 - (a) an individual farm which may be considered a single epidemiological unit, as it is not influenced by the animal health status in the surrounding waters;
or
 - (b) more than one farm where each farm in the compartment complies with the criteria laid down in point 3.1(a) and points 3.2 to 3.6, but, due to extensive movement of animals between farms, shall be considered as a single epidemiological unit, provided that all farms are under a common biosecurity system.
 - 3.2. A compartment shall be supplied with water:
 - (a) through a water treatment plant inactivating the relevant pathogen in order to reduce the risk of the introduction of the disease to an acceptable level;
or
 - (b) directly from a well, a borehole or a spring. Where such water supply is situated outside the premises of the farm, the water shall be supplied directly to the farm, and be channelled through a pipe.
 - 3.3. There shall be natural or artificial barriers that prevent aquatic animals from entering each farm in a compartment from the surrounding watercourses.
 - 3.4. The compartment shall, where appropriate, be protected against flooding and infiltration of water from the surrounding watercourses.
 - 3.5. The compartment shall comply, *mutatis mutandis*, with the requirements laid down in Part I.2.
 - 3.6. A compartment shall be subject to additional measures imposed by the competent authority, when considered necessary to prevent the introduction of diseases. Such measures may include the establishment of additional protection against the intrusion of possible pathogen carriers or vectors.
 - 3.7. Implementing measures concerning point 3.2(a) shall be laid down in accordance with the procedure referred to in Article 62(2).
4. Special provisions for individual farms which commence or recommence their activities

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- 4.1. A new farm, which meets the requirements referred to in points 3.1(a) and 3.2 to 3.6, but which commences its activities with aquaculture animals from a compartment declared disease-free may be considered disease-free without undergoing the sampling required for approval.
- 4.2. A farm which recommences its activities after a break with aquaculture animals from a compartment declared disease-free, and meets the requirements referred to in points 3.1(a) and 3.2 to 3.6, may be considered disease-free without undergoing the sampling required for approval, provided that:
 - (a) the health history of the farm over the last four years of its operation is known to the competent authority; however, if the farm concerned has been in operation for less than four years, the actual period in which it has been in operation will be taken into account;
 - (b) the farm has not been subject to animal-health measures in respect of the diseases listed in Part II of Annex IV and there have been no antecedents of those diseases on the farm;
 - (c) prior to the introduction of the aquaculture animals, eggs or gametes, the farm is cleaned and disinfected, followed, as necessary, by a period of fallowing.