

ANNEX

GUIDELINES TO BE TAKEN INTO ACCOUNT FOR THE PURPOSE OF THE RISK-BASED ANIMAL HEALTH SURVEILLANCE SCHEMES PROVIDED FOR IN ARTICLE 10(1) OF DIRECTIVE 2006/88/EC

1. Purpose of these guidelines

The purpose of these guidelines is to provide Member States with guidance on the risk-based animal health surveillance schemes provided for in Article 10(1) of Directive 2006/88/EC (the risk-based animal health surveillance schemes).

2. Content of inspections

2.1. CHECKING OF RECORDS AND CLINICAL EXAMINATIONS

Each inspection of a farm or mollusc farming area should consist of an analysis of the records provided for in Article 8 of Directive 2006/88/EC, with particular attention being paid to the mortality records, in order to enable an assessment to be made of the health status track-record of the farm or mollusc farming area.

A representative selection of all epidemiological units should be inspected.

If available, a representative selection of recently dead and moribund aquaculture animals should be examined clinically, both externally and internally, for major pathological changes. That examination should, in particular, aim at detecting any infection with a disease listed in Part II of Annex IV to Directive 2006/88/EC (a listed disease).

If the outcome of that examination leads to any suspicion of the presence of such a disease, the aquaculture animals in the farm or mollusc farming area should be subjected to laboratory examination.

Detailed rules on actions to be taken in cases of suspicion and/or confirmation of a listed disease are laid down in Chapter V of Directive 2006/88/EC.

2.2. SAMPLING AND LABORATORY EXAMINATION

The taking of samples for laboratory examination is not necessary in all cases. In determining whether sampling is necessary, the information gained when checking the records of the farm or mollusc farming area and when inspecting the aquaculture animals, as well as other relevant information should be taken into account.

3. Choosing between the competent authority, private veterinarians and other qualified aquatic animal health service for carrying out the inspections

Member States should determine whether the inspections which are part of the risk-based animal health surveillance schemes are to be carried out by the competent authority or whether private veterinarians or other qualified aquatic animal health services should also be permitted to carry them out.

4. Frequency of inspections

Part B of Annex III to Directive 2006/88/EC sets out recommended frequencies for inspections of farms and mollusc farming areas. Those frequencies are determined by two factors:

- (a) the health status of the concerned Member State, zone or compartment in relation to non-exotic diseases listed in Part II of Annex IV to that Directive (listed non-exotic diseases);

(b) the risk level of the farm or mollusc farming area in relation to the contracting and spreading of diseases.

5. The health status of the farms and mollusc farming areas

Part B of Annex III to Directive 2006/88/EC differentiates between the following health status categories:

Category I	<p>(a) Declared disease-free in accordance with Article 49(1)(a) or (b) or Article 50(1)(a) or (b) of Directive 2006/88/EC. Such status is determined by the fact that:</p> <p>(i) none of the species susceptible to the disease(s) in question is present in the Member State, zone or compartment, and where relevant in the water source of that Member State, zone or compartment; or</p> <p>(ii) the pathogen is known not to be able to survive in the Member State, zone or compartment, and where relevant in the water source of that Member State, zone or compartment.</p> <p>(b) Declared disease-free in accordance with Article 49(1)(c) or Article 50(1)(c) of Directive 2006/88/EC. The status is based on targeted surveillance complying with the conditions laid down in Part II of Annex V to Directive 2006/88/EC.</p>
Category II	Not declared disease-free but subject to a surveillance programme approved in accordance with Article 44(1) of Directive 2006/88/EC.
Category III	Not known to be infected but not subject to surveillance programme for achieving disease-free status.
Category IV	Known to be infected but subject to an eradication programme approved in accordance with Article 44(2) of Directive 2006/88/EC.

Category V	Known to be infected. Subject to minimum control measures as provided for in Chapter V of Directive 2006/88/EC.
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Where appropriate, inspections carried out in the framework of a risk-based animal health surveillance scheme may be combined with:

- (a) inspections carried out in the framework of surveillance or eradication programmes approved in accordance with Directive 2006/88/EC (for zones or compartments falling within categories II or IV);
- (b) any surveillance carried out to maintain the disease-free status (for zones or compartments falling within category I – declared disease-free in accordance with Article 49(1)(a) or (b) or Article 50(1)(a) or (b) of Directive 2006/88/EC);
- (c) any surveillance carried out as part of control measures pursuant to Chapter V of Directive 2006/88/EC (for zones or compartments falling within category V).

When drawing up risk-based animal health surveillance schemes, Member States should take account of the following:

- (a) for farms or mollusc farming areas situated in areas which have a health status falling within categories II and IV, the inspection frequency required by surveillance or eradication programmes approved in accordance with Directive 2006/88/EC is higher than the frequency recommended by Part B of Annex III to that Directive; it is therefore not necessary for Member States to lay down specific requirements concerning the inspection frequency for farms and mollusc farming areas situated in areas covered by such programmes;
- (b) the need for Member States to lay down specific requirements on the frequency of inspections under a risk-based animal health surveillance scheme exists mainly for farms or mollusc farming areas situated in areas which have a health status falling within categories I, III and V, depending on the particular circumstances and national measures;
- (c) consideration should be given to the fact that a farm or mollusc farming area may have a different health status in relation to different diseases; this may be the case for farms and mollusc farming areas keeping species which are susceptible to more than one of the listed non-exotic diseases⁽¹⁾.

6. The determination of the risk level of farms and mollusc farming areas

6.1. INTRODUCTION

The risk level of farms and mollusc farming areas varies, not only between areas having a different health status, but also within areas with the same health status⁽²⁾.

Section 6.2 gives guidance on the risk factors to be taken into account when determining the risk level of farms and mollusc farming areas.

Section 6.3 sets out a model which may be used for the classification of farms and mollusc farming areas as having a high, medium or low risk level. Member States may use other models to determine the risk level of farms and mollusc farming areas, if such models are considered more suited in a given situation.

These guidelines do not provide information concerning the way Member States should apply the model set out in Section 6.3. Member States may:

- (a) apply that model to each individual farm and mollusc farming area to determine its individual risk level; or
- (b) use the model to catalogue the different types of farms and mollusc farming areas on their territory and, on that basis, define which categories of farms and mollusc farming areas should be regarded as having a low, medium or high risk level.

6.2. RISK FACTORS

A wide range of factors are relevant in determining the risk level of a farm or mollusc farming area. Such factors may include, but are not limited to the following:

- (a) the direct spread of disease via water;
- (b) the movements of aquaculture animals;
- (c) the type of production;
- (d) the species of aquaculture animals kept;
- (e) the bio-security system, including staff competence and training;
- (f) the density of farms and mollusc farming areas and processing establishments in the area around the farm or mollusc farming area concerned;
- (g) the proximity of farms and mollusc farming areas having lower health status to the farm or mollusc farming area concerned;
- (h) the health status track record of the farm or mollusc farming area concerned and of other farms and mollusc farming areas situated in the area;
- (i) the presence of disease pathogens in wild aquatic animals in the area around the farm or mollusc farming area concerned;
- (j) the risk posed by human activities in the proximity of the farm or mollusc farming area concerned⁽³⁾;
- (k) predators or birds with access to the farm or mollusc farming area concerned.

The use of a complex system for the assessment of risk levels of farms and mollusc farming areas, taking into account all relevant risk factors, may provide a precise classification of farms and mollusc farming areas according to their risk level. However, such a system may also be time-consuming and not cost-efficient. In addition, the weighting of different factors in order to assess the overall risk is a complicated operation.

In view of the difficulties of using a complex system to classify farms and mollusc farming areas according to their risk level, it is appropriate in most cases to focus on the following risk factors:

- (a) the direct spread of disease via water and due to the geographical proximity of the farms and mollusc farming areas;
- (b) the movements of aquaculture animals.

Those two risk factors are relevant regardless of the type of production, of the species of aquaculture animals kept on the farm or mollusc farming area and of the diseases concerned.

6.3. MODEL TO DETERMINE THE RISK LEVEL OF FARMS AND MOLLUSC FARMING AREAS

This model to determine the risk level (high/medium/low) of farms or mollusc farming areas comprises three steps:

- Step I : Approximation of the likelihood of the contraction of disease on the farm or in the mollusc farming area;
- Step II : Approximation of the likelihood of the spread of disease from the farm or mollusc farming area;
- Step III : Combining the estimates of risk levels resulting from steps I and II.

STEP I

Approximation of the likelihood of the contraction of disease on the farm or in the mollusc farming area

Likelihood of the contraction of disease via water and due to the geographical proximity of farms and mollusc farming areas	Likelihood of the contraction of disease through movements of aquaculture animals	Level of risk
High	High	High
High	Low	Medium
Low	High	Medium
Low	Low	Low

STEP II

Approximation of the likelihood of the spread of disease from the farm or mollusc farming area

Likelihood of the spread of disease via water and due to the geographical proximity of farms and mollusc farming areas	Likelihood of the spread of disease through movements of aquaculture animals	Level of risk
High	High	High
High	Low	Medium
Low	High	Medium
Low	Low	Low

STEP III

Combining the estimates of risk levels resulting from steps I and II

Step I. Likelihood of the contraction of disease	High	M	H	H
	Medium	L	M	H
	Low	L	L	M

Status: This is the original version (as it was originally adopted).

		Low	Medium	High
		Step II. Likelihood of the spread of disease		

6.4. THE RISK LEVEL FOR CERTAIN FARMS AND MOLLUSC FARMING AREAS FALLING WITHIN HEALTH STATUS CATEGORY I

Farms and mollusc farming areas which do not keep species susceptible to any of the listed non-exotic diseases, or where the pathogen in question is known not to be able to survive in the Member State, zone or compartment and, where relevant, in its water source may, pursuant to Part B of Annex III to Directive 2006/88/EC, all be regarded as having a low risk level. It is therefore not necessary, in principle, for the risk-based animal health surveillance scheme to include different frequencies of inspections.

However, those farms and mollusc farming areas may have different levels of risk as regards the contraction and spread of listed non-exotic diseases or emerging diseases. Member States may therefore classify those farms and mollusc farming areas according to their risk level and thus differentiate their level of surveillance and inspection. In doing so, Member States may also take into account the need to optimise the use of resources.

6.5. APPROXIMATION OF THE LIKELIHOOD OF THE CONTRACTION AND THE SPREAD OF DISEASE VIA WATER AND DUE TO GEOGRAPHICAL PROXIMITY OF FARMS AND MOLLUSC FARMING AREAS

6.5.1. Introduction

Farms and mollusc farming areas have a low risk of the contraction and the spread of disease if the sources and outlet of water or the water environment in which the farm or mollusc farming area is located can be regarded as giving a certain level of protection from the introduction and spread of pathogens of diseases. The risk of the contraction and spread of a disease on and from a farm or a mollusc farming area via water and due to geographical proximity of the farms and mollusc farming areas varies greatly⁽⁴⁾.

The model set out in Section 6.3 only distinguishes between high and low likelihoods for the spread of diseases via water and due to the geographical proximity of farms and mollusc farming areas.

This section provides examples of situations that may be regarded as presenting a low likelihood for the contraction and spread of disease via water and due to the geographical proximity of farms and mollusc farming areas.

The list of examples provided in this section is not exhaustive. It should therefore not be concluded that farms and mollusc farming areas not covered by any of these examples present a high likelihood for the contraction or spread of diseases.

6.5.2. Examples of low risk for the contraction of disease via water and due to the geographical proximity of farms and mollusc farming areas:

- (a) farms and mollusc farming areas supplied with water through a borehole or spring;
- (b) farms and mollusc farming areas supplied with water which is disinfected or treated in order to prevent the introduction of pathogens;
- (c) farms and mollusc farming areas supplied with water from any other water source which:

- (i) are not connected to farms or mollusc farming areas, or processing establishments, keeping or processing species susceptible to the same diseases as the species kept in the farm or mollusc farming area concerned;
 - (ii) do not contain wild aquatic animals of susceptible species;
- (d) inland water basins, including ponds and lakes, which are isolated from other water sources; in determining whether the water basin should be regarded as isolated, consideration should be given to seasonal changes such as the possibility of contact with other water sources through flooding;
- (e) coastal farms and mollusc farming areas which are protected by a safe distance from other farms and mollusc farming areas and from processing establishments keeping or processing species susceptible to the same diseases as the species kept in the farm or mollusc farming areas concerned; what should constitute a safe distance needs to be determined by the competent authority, taking into account factors such as the ability of the relevant pathogens to survive in open waters, the water currents and the length of tidal excursions.

6.5.3. Examples of low risk for the spread of disease via water and due to the geographical proximity of farms and mollusc farming areas:

- (a) farms and mollusc farming areas with no discharge into natural waterways⁽⁵⁾;
- (b) farms and mollusc farming areas which disinfect, or in any other manner treat the water discharge, to prevent the spread of pathogens;
- (c) farms and mollusc farming areas which discharge their water into public sewage systems provided that the public sewage system contains a form of treatment of the sewage water; however, if the sewage water is discharged into natural water ways without any treatment, such farms and mollusc farming areas should not be regarded as constituting a low likelihood;
- (d) farms and mollusc farming areas with no discharge into waters with aquaculture or wild aquatic animals of species susceptible to the relevant listed disease(s);
- (e) inland water basins, including ponds and lakes, which are isolated from other water sources; in determining whether the water basin should be regarded as isolated, consideration should be given to seasonal changes such as the possibility of any contact with other water sources through flooding;
- (f) coastal farms and mollusc farming areas which are protected by a safe distance from other farms and mollusc farming areas keeping species which are susceptible to the same diseases as the species kept in the farm or mollusc farming areas concerned; what should constitute a safe distance needs to be determined by the competent authority taking into account factors such as the ability of the relevant pathogens to survive in open waters, the water currents, and the length of tidal excursions.

6.6. APPROXIMATION OF THE LIKELIHOOD OF THE CONTRACTION AND SPREAD OF DISEASE THROUGH MOVEMENTS OF AQUACULTURE ANIMALS

6.6.1. Introduction

Movements of live aquaculture animals into and out of farms and mollusc farming areas are a very important means for the transmission of disease.

In evaluating that factor, the following should be assessed:

- (a) the place of origin of the aquaculture animals;
- (b) the number of aquaculture animals supplied to the farm or mollusc farming area;
- (c) the number of different suppliers of aquaculture animals;
- (d) the frequency of movements of aquaculture animals into and out of farms and mollusc farming areas.

The model set out in Section 6.3 only recommends that farms be grouped together according to their high or low risk of the contraction and the spread of disease through movements of aquaculture animals. For the purposes of that model, it is therefore sufficient only to take account of whether the farm or mollusc farming area is supplied by or delivers live aquaculture animals (including eggs), and the place of origin of those animals.

This section provides examples of situations that may be regarded as presenting a low risk for the contraction and spread of disease through movements of aquaculture animals.

The list of examples provided in this section is not exhaustive. It should therefore not be concluded that farms and mollusc farming areas not covered by any of these examples present a high risk of the contraction and the spread of disease.

6.6.2. Examples of low likelihood of the contraction of disease through the supply of aquaculture animals to farms and mollusc farming areas:

- (a) farms and mollusc farming areas which are self sufficient with eggs or juveniles⁽⁶⁾;
- (b) cases where the aquaculture animals are supplied only from disease-free zones or compartments. For farms in health status Categories III and V there is no requirement under existing Community legislation that aquaculture animals be supplied from disease-free zones or compartments, and the fact that the farm chooses to obtain its animals from a disease-free zone or compartment distinguishes the farm from other farms in the same health status category. Farms in health status Category I should only receive animals from a disease-free place of origin. For these farms, it should therefore be required instead that the animals are either supplied from the same disease-free area or that the farm only has a limited number of suppliers of aquaculture animals;
- (c) cases where wild aquatic animals, released from quarantine and intended for further farming, are supplied;
- (d) cases where disinfected eggs are supplied; this is relevant only where scientific evidence or practical experience has shown that disinfection effectively reduces the risk of disease transmission to an acceptable level as regards the listed diseases to which the species on the farm or mollusc farming area are susceptible.

6.6.3. Examples of low likelihood of the spread of disease through the delivery of aquaculture animals to farms or mollusc farming areas:

- (a) farms and mollusc farming areas which do not deliver any animals for further farming, relaying or restocking;
- (b) fish farms which only deliver disinfected eggs; this is only relevant where scientific evidence or practical experience has shown that disinfection effectively reduces the risk of disease transmission to an acceptable level as regards the listed exotic or non-exotic diseases to which the species on the farm are susceptible.

Status: This is the original version (as it was originally adopted).

- (1) For example, a rainbow trout farm might be free of infectious salmon anaemia (Category I), be under Category II (under an approved surveillance programme) for viral haemorrhagic septicaemia and have unknown status as regards infectious haematopoietic necrosis (Category III).
- (2) For example, a farm which is declared free of a listed non-exotic disease, in general presents a low risk of spreading such a disease. However, a farm producing its own juveniles presents a much lower risk than a farm buying all its juveniles from one or more different suppliers.
- (3) Such as transport routes, ports (ballast water), angling.
- (4) For example, from a covered recirculation system with water sourced from a borehole and where the outlet water is disinfected (very low risk), to a sea cage farm with a large number of farms in its proximity (very high risk).
- (5) For example, inland farms which lead their outlet water into the ground or on the fields.
- (6) This could be the case for fish farms keeping their own brood stock and for mollusc farms and mollusc farming areas where the production is based on natural recruitment of spat.