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COMMISSION DELEGATED REGULATION (EU) 2020/689

of 17 December 2019

supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases

(Text with EEA relevance)

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PART I

GENERAL PROVISIONS

Article 1

Subject-matter and scope

1. This Regulation supplements the rules on surveillance, eradication programmes and disease-free status for certain listed and emerging diseases of terrestrial, aquatic and other animals as provided for in Regulation (EU) 2016/429.

2. Chapter 1 of Part II of this Regulation lays down the rules for surveillance of the diseases referred to in Article 9(1) of Regulation (EU) 2016/429 and the emerging diseases as defined in Article 6(2) of that Regulation in relation to:

(a) the design of the surveillance including the targeted animal population and the diagnostic methods;

(b) the disease confirmation and the case definition;

(c) Union surveillance programmes.

3. Chapter 2 of Part II of this Regulation lays down the rules for eradication programmes for the diseases of terrestrial animals referred to in points (b) and (c) of Article 9(1) of Regulation (EU) 2016/429 in relation to:

(a) the disease control strategy, the territory, the animal populations, the targets and the period of application;

(b) the obligations of operators and competent authorities;

(c) the disease control measures in the event of suspicion and of confirmation.

4. Chapter 3 of Part II of this Regulation lays down the rules for eradication programmes for the diseases of aquatic animals referred to in points (b) and (c) Article 9(1) of Regulation (EU) 2016/429 in relation to:

(a) the disease control strategy, the territory, the animal populations, the targets and the period of application;

(b) the obligations of operators and competent authorities;

(c) the disease control measures in the event of suspicion and of confirmation.

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5. Chapter 4 of Part II of this Regulation lays down the rules for disease-free status with regard to certain diseases of terrestrial and aquatic animals referred to in Article 9(1) of Regulation (EU) 2016/429 in relation to:

(a) the criteria for the approval of the disease-free status of Member States and zones;

(b) the criteria for the approval of the disease-free status for compartments keeping aquaculture animals;

(c) the criteria for the maintenance of the disease-free status;

(d) the suspension, the withdrawal and the restoration of disease-free status.

6. Part III of this Regulation lays down transitional and final provisions in relation to:

(a) the approval of the disease-free status of Member States, zones and compartments which are recognised disease-free under the legislation in force before the date of application of this Regulation;

(b) the approval of eradication programmes of Member States, zones and compartments which have an approved eradication or surveillance programme under the legislation in force before the date of application of this Regulation.

Article 2

Definitions

For the purpose of this Regulation, the following definitions shall apply:

(1) ‘category E disease’: means a listed disease for which there is a need for surveillance within the Union, as referred to in point (e) of Article 9(1) of Regulation (EU) 2016/429;

(2) ‘targeted animal population’ means the population of animals of listed species defined by species and, as appropriate, by categories, relevant for the surveillance activities, the eradication programmes or the disease-free status of a specific disease;

(3) ‘additional animal population’ means the population of kept or wild animals of listed species subjected to optional prevention, surveillance and disease control measures necessary to achieve or maintain the disease-free status of a targeted animal population;

(4) ‘category A disease’: means a listed disease that does not normally occur in the Union and for which immediate eradication measures must be taken as soon as it is detected, as referred to in point (a) of Article 9(1) of Regulation (EU) 2016/429;

(5) ‘category B disease’: means a listed disease which must be controlled in all Member States with the goal of eradicating it throughout the Union, as referred to in point (b) of Article 9(1) of Regulation (EU) 2016/429;

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(6) ‘category C disease’: means a listed disease which is of relevance to some Member States and for which measures are needed to prevent it from spreading to parts of the Union that are officially disease-free or that have eradication programmes for the listed disease concerned, as referred to in point (c) of Article 9(1) of Regulation (EU) 2016/429;

(7) ‘bovine animal’ or ‘animal of the bovine species’ means an animal of the species of ungulates belonging to the genera *Bison*, *Bos* (including the subgenera *Bos*, *Bibos*, *Novibos*, *Poephagus*) and *Bubalus* (including the subgenus *Anoa*) and the offspring of crossings of those species;

(8) ‘ovine animal’ or ‘animal of the ovine species’ means an animal of the species of ungulates belonging to the genus *Ovis* and the offspring of crossings of those species;

(9) ‘caprine animal’ or ‘animal of the caprine species’ means an animal of the species of ungulates belonging to the genus *Capra* and the offspring of crossings of those species;

(10) ‘travelling circus’ means an exhibition or fair that includes animals or animal acts which is intended to move between Member States;

(11) ‘animal acts’ means any act featuring animals kept for the purpose of an exhibition or fair, and which may form part of a circus;

(12) ‘porcine animal’ or ‘animal of the porcine species’ means an animal of the species of ungulates of family *Suidae* listed in Annex III to Regulation (EU) 2016/429;

(13) ‘means of transport’ means road or rail vehicles, vessels and aircrafts;

(14) ‘dog’ means a kept animal of the *Canis lupus* species;

(15) ‘cat’ means a kept animal of the *Felis silvestris* species;

(16) ‘ferret’ means a kept animal of the *Mustela putorius furo* species;

(17) ‘seasonally BTV-free area’ means the whole territory of a Member State or a zone thereof where the competent authority has established a temporary status of freedom from infection with bluetongue virus (serotype 1-24) (‘infection with BTV’) in accordance with Article 40(3) on the basis of a vector-free period and the demonstration of absence of the disease in listed animal species;

(18) ‘vector protected establishment’ means part or all facilities of an establishment that are protected against attacks from *Culicoides* by appropriate physical and management means, with a status of vector protected establishment being granted by the competent authority in accordance with Article 44;

(19) ‘well-boat’ means a vessel used by the aquaculture industry which has a well or tank for the storage and transport of live fish in water;

(20) ‘fallowing’ means, for disease management purposes, an operation where an establishment is emptied of aquaculture animals from listed species, and where feasible, of water;

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(21) ‘eligibility period’ means the period of time before the competent authority submits the application for disease-free status or, when relevant, before the provisional declaration referred to in point (a) of Article 83(1) is published electronically;

(22) ‘non-listed species’, means an animal species or group of animal species not listed in the Annex to Commission Implementing Regulation (EU) 2018/1882 for a particular disease;

(23) ‘flock’ means all poultry or captive birds of the same health status kept on the same premises or in the same enclosure and constituting a single epidemiological unit; in housed poultry includes all birds sharing the same airspace;

(24) ‘DIVA (differentiating infected from vaccinated animals) vaccination’ means a vaccination using vaccines that enable in conjunction with appropriate serological diagnostic methods, the detection of infected animals in a vaccinated population;

(25) ‘DIVA vaccinated animals’ means animals that have been vaccinated in the framework of a DIVA vaccination;

(26) ‘approved germinal product establishment’ means a semen collection centre, an embryo collection team, an embryo production team, a germinal product processing establishment or a germinal product storage centre, approved in accordance with Article 97(1) of Regulation (EU) 2016/429;

(27) ‘semen’ means the ejaculate of an animal or animals, either in the unaltered state or prepared or diluted;

(28) ‘oocytes’ means the haploid stages of the ootidogenesis including secondary oocytes and ova;

(29) ‘embryo’ means the initial stage of development of an animal while it is capable of being transferred to a recipient dam;

(30) ‘vector-free period’ means in a defined area the period of inactivity of *Culicoides* determined in accordance with Section 5 of Chapter 1 of Part II of Annex V;

(31) ‘honeybees’ means animals of the *Apis mellifera* species;

(32) ‘breeding poultry’ means poultry 72 hours old or more, intended for the production of hatching eggs;

(33) ‘random annual surveillance’ means a surveillance consisting of at least one survey of a targeted animal population organised during the year for which probability-based sampling methods are used to select units to examine.

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PART II

SURVEILLANCE, ERADICATION PROGRAMMES, DISEASE-FREE STATUS

CHAPTER 1

Surveillance

Section 1

Design of surveillance, Targeted animal population and diagnostic methods

Article 3

Design of surveillance

1. The competent authority shall design the surveillance for listed and emerging diseases of terrestrial animals and other animals taking into account:

(a) general surveillance requirements based on:

(i) notification as provided for in Article 18(1) of Regulation (EU) 2016/429;

(ii) appropriate veterinary investigation of increased mortalities and other signs of serious diseases or significantly decreased production rates with an undetermined cause;

(iii) investigation by the competent authority in the event of the suspicion of a category E disease or, if relevant, of an emerging disease;

(iv) targeted animal population for surveillance as provided for in Article 4;

(v) the contribution of official controls and other official activities as provided for in Article 7;

(b) specific surveillance requirements:

(i) in Union surveillance programme;

(ii) as a part of compulsory or optional eradication programmes;

(iii) for demonstrating and maintaining disease-free status;

(iv) as a part of disease control measures;

(v) in the context of approval of certain establishments;

(vi) for the movements of terrestrial animals within the Union or their entry into the Union.

2. The competent authority shall design the surveillance for listed and emerging diseases of aquatic animals taking into account:

(a) general surveillance requirements based on:

(i) notification as provided for in Article 18(1) of Regulation (EU) 2016/429;

(ii) appropriate veterinary investigation of increased mortalities and other signs of serious diseases or significantly decreased production rates with an undetermined cause;

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(iii) investigation by the competent authority in the event of the suspicion of a category E disease or, if relevant, of an emerging disease;

(iv) targeted animal population for surveillance as provided for in Article 4;

(v) the contribution of official controls and other official activities as provided for in Article 7;

(vi) disease control measures;

(b) specific surveillance requirements:

(i) as a part of the risk-based surveillance scheme set out in Chapter 1 of Part I of Annex VI, involving a risk ranking and regular animal health visits as provided for in Chapters 2 and 3 of Part I of Annex VI;

(ii) as a part of the eradication programmes provided for in Chapters 1 to 6 of Part II of Annex VI;

(iii) for demonstrating and maintaining disease-free status;

(iv) for demonstrating, in accordance with the surveillance programmes provided for in Chapters 1 to 6 of Part III of Annex VI, that establishments which are not participating in the eradication programme referred to in point (ii) or which have not obtained the disease-free status referred to in point (iii) are not infected;

(v) for the movements of aquatic animals within the Union or their entry into the Union.

Article 4

Targeted animal population

1. The competent authority shall specify the targeted animal population relevant to the surveillance referred to in Article 3 for each listed disease and, when relevant, for each emerging disease and shall include:

(a) kept animals of listed species;

(b) wild animals of listed species if:

(i) they are subject to a Union surveillance programme, or to a compulsory or an optional eradication programme or to the surveillance necessary for the granting or maintenance of a disease-free status;

(ii) the competent authority considers that they constitute a risk that may impair the health status of other species in a Member State, zone or compartment; or

(iii) surveillance is necessary to assess animal health requirements for entry into the Union or movements within the Union.

2. To ensure the early detection of an emerging disease in species other than those referred to in point (a) of paragraph 1, the competent authority shall include, in the targeted animal population, kept animals of species that are not listed for the purpose of the relevant listed disease if the following criteria apply:

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(a) they are moved to establishments in another Member State, zone or compartment; and

(b) due to the number of animals or the frequency of the movements, the competent authority considers the animals to constitute a risk that might impair the health status of other kept animals in another Member State, zone or compartment, should a disease emerge in that species.

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3. The competent authority shall include in the targeted animal population kept or wild animals of species that are not listed for the purpose of the relevant listed disease when the competent authority considers that they constitute a risk for animal and human health.

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Article 5

Exclusion of certain kept terrestrial animals from the targeted animal population

1. By way of derogation from point (a) of Article 4(1), the competent authority may limit the targeted animal population for the surveillance of a disease other than a category A disease to the categories of kept animals of listed species that are subject, for that disease, to:

(a) Union surveillance programmes;

(b) compulsory or optional eradication programmes or surveillance necessary for the granting or maintenance of a disease-free status; or

(c) surveillance-based animal health requirements for the movements within the Union or the entry into the Union.

2. The categories of kept animals referred to in paragraph 1 may be based on the animals' age, their sex, the location and type of production.

Article 6

Diagnostic methods

1. The competent authority shall ensure that the collection of samples, the techniques, validation and interpretation of the diagnostic methods for the purposes of surveillance shall comply:

(a) with the specific legislation adopted in accordance with Regulation (EU) 2016/429 and the relevant details and guidance made available on the websites of the European Union Reference Laboratories (EURL) and of the Commission;

(b) when not covered by the legislation, details and guidance referred to in point (a), with the collection of samples, the techniques, validation and interpretation of the diagnostic methods laid down in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE) ('the Terrestrial Manual' [1]) as amended or the Manual of Diagnostic Tests for Aquatic Animals of the OIE ('the Aquatic Manual' [2]) as amended;

[1] http://www.oie.int/en/standard-setting/terrestrial-manual/access-online/
[2] http://www.oie.int/en/standard-setting/aquatic-manual/access-online/

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(c) when not covered by points (a) and (b) of this paragraph, with the methods laid down in point (b) of Article 34(2) and Article 34(3) of Regulation (EU) 2017/625.

2. The diagnostic methods for granting and maintaining disease-free status are laid down in:

(a) Section 1 of Annex III for infection with *Brucella abortus, B. melitensis* and *B.suis*;

(b) Section 2 of Annex III for infection with *Mycobacterium tuberculosis* complex (*Mycobacterium bovis, M.caprae* and *M. tuberculosis*) (MTBC);

(c) Section 3 of Annex III for enzootic bovine leukosis (EBL);

(d) Section 4 of Annex III for infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis (IBR/IPV);

(e) Section 5 of Annex III for infection with Aujeszky's disease virus (ADV);

(f) Section 6 of Annex III for bovine viral diarrhoea (BVD);

(g) point 2 of Section 5 of Chapter 1 of Part II of Annex VI for viral haemorrhagic septicaemia (VHS);

(h) point 2 of Section 5 of Chapter 1 of Part II of Annex VI for infectious haematopoietic necrosis (IHN);

(i) point 2 of Section 5 of Chapter 2 of Part II of Annex VI for infection with highly polymorphic region deleted infectious salmon anaemia virus (HPR-deleted ISAV);

(j) point 2 of Section 5 of Chapter 3 of Part II of Annex VI for infection with *Marteilia refringens*;

(k) point 2 of Section 5 of Chapter 4 of Part II of Annex VI for infection with *Bonamia exitiosa*;

(l) point 2 of Section 5 of Chapter 5 of Part II of Annex VI for infection with *Bonamia ostreae*;

(m) point 2 of Section 5 of Chapter 6 of Part II of Annex VI for infection with white spot syndrome virus (WSSV).

Article 7

Contribution of official controls and other official activities to animal health surveillance

1. The competent authority shall, if relevant, include in the design of the surveillance referred to in Article 3 of this Regulation the outcome of the official controls and other official activities defined in Article 2 of Regulation (EU) 2017/625. These official controls and other official activities include:

(a) ante-mortem and post-mortem inspections;

(b) inspections at border control posts;

(c) official controls and other official activities at markets and assembly operations;

(d) official controls and other official activities during transport of live animals;

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(e) public health related inspections and sampling in establishments;

(f) any other official controls during which establishments, animals or samples are inspected or examined.

2. When the competent authority suspects a listed disease or an emerging disease in the context of official controls or other official activities referred to in paragraph 1, it shall ensure that all relevant authorities are informed. This shall be done:

(a) immediately in case of a category A disease or of an emerging disease;

(b) without delay for other diseases.

Section 2

Disease confirmation and case definitions

Article 8

Criteria for official confirmation of listed diseases, other than category A diseases, and certain emerging diseases and subsequent confirmation of outbreaks

1. The competent authority shall, on suspicion of listed diseases, other than category A disease, or of an emerging disease, conduct an investigation to confirm or to rule out the presence of that disease when:

(a) there is a need to determine the health status of the Member State, zone or compartment thereof; or

(b) there is a need to collect necessary information on the occurrence of the disease for any of the following purposes:

(i) to implement measures to protect animal or human health;

(ii) to implement animal health requirements for movements of animals or products; or

(iii) to comply with the requirements laid down in a Union surveillance programme.

2. The competent authority shall confirm an outbreak of any of the diseases referred to in paragraph 1 when it has classified an animal or a group of animals as a confirmed case of these diseases in accordance with Article 9(2).

Article 9

Case definitions

1. The competent authority shall classify an animal or a group of animals as a suspected case of a listed disease or of an emerging disease when:

(a) clinical, post-mortem or laboratory examinations conclude that clinical sign(s), post-mortem lesion(s) or histological findings are indicative of that disease;

(b) result(s) from a diagnostic method are indicating the likely presence of the disease in a sample from an animal or from a group of animals; or

(c) an epidemiological link with a confirmed case has been established.

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2. The competent authority shall classify an animal or a group of animals, as a confirmed case of a listed disease or of an emerging disease when:

(a) the disease agent, excluding vaccine strains, has been isolated in a sample from an animal or from a group of animals;

(b) an antigen or nucleic acid specific to the disease agent that is not a consequence of vaccination has been identified in a sample from an animal or from a group of animals showing clinical signs consistent with the disease or an epidemiological link with a suspected or confirmed case; or

(c) a positive result from an indirect diagnostic method that is not a consequence of vaccination has been obtained in a sample from an animal or from a group of animals showing clinical signs consistent with the disease or an epidemiological link with a suspected or confirmed case.

3. Disease specific definitions of a suspected case and a confirmed case of listed diseases are laid down for terrestrial animals in Annex I and for aquatic animals in point 3 of Section 5 of Chapters 1 to 6 of Part II of Annex VI.

4. In the absence of disease specific definitions as provided for in paragraph 3, the criteria laid down in paragraphs 1 and 2 shall apply to definitions of a suspected case and a confirmed case of listed diseases and, if relevant, emerging diseases.

Section 3

Union surveillance programme

Article 10

Criteria for and contents of Union surveillance programmes

1. A category E disease shall be subject to a Union surveillance programme in accordance with Article 28 of Regulation (EU) 2016/429 if it meets all of the following criteria:

(a) it poses a particular threat to animal and possibly human health on the whole Union territory with possible serious economic consequences for the farming community and the wider economy;

(b) it is susceptible to an evolution of the disease profile, in particular with regard to the risk for human health and animal health;

(c) infected wild animals pose a particular threat for the introduction of the disease into a part or the whole of the Union territory;

(d) it is fundamental to obtain, through surveillance, regularly updated information on the evolution of its circulation and on the characterisation of the disease agent, to assess those risks and adapt risk mitigating measures accordingly.

2. The competent authority shall implement Union surveillance programmes for the relevant disease in accordance with the contents set out in Annex II.

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Article 11

Information to be included in the submission of and reporting on Union surveillance programmes

1. The competent authority shall, when submitting a Union surveillance programme, include in that submission at least the following information:

(a) description of the epidemiological situation of the disease before the date of the beginning of the implementation of the programme and data on the epidemiological evolution of the disease;

(b) targeted animal population, epidemiological units and zones of the programme;

(c) organisation of the competent authority, supervision of the implementation of the programme, official controls to be applied during the implementation of the programme and the role of all relevant operators, animal health professionals, veterinarians, animal health laboratories and other natural or legal persons concerned;

(d) description and demarcation of the geographical and administrative areas in which the programme is to be implemented;

(e) indicators to measure the progress of the programme;

(f) diagnostic methods used, number of samples tested, frequency of testing and sampling patterns;

(g) risk factors to be considered for the design of a risk-based targeted surveillance.

2. The competent authority shall, when reporting on a Union surveillance programme, include in that report at least the following information:

(a) the description of the measures implemented and the results obtained based on the information referred to in point (b) and points (d) to (f) of paragraph 1; and

(b) the results of the follow-up of the epidemiological evolution of the disease in case of a suspected or confirmed case.

CHAPTER 2

Eradication programmes for category B and C diseases of terrestrial animals

Section 1

General provisions

Article 12

Disease control strategy for the eradication of category B and C diseases of terrestrial animals

1. The competent authority shall, when establishing a compulsory eradication programme for a category B disease or an optional eradication programme for a category C disease of terrestrial animals, base those programmes on a disease control strategy that includes for each disease:

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(a) the territory and animal population covered by the eradication programme as provided for in Article 13(1);

(b) the duration of the eradication programme as provided for in Article 15, including its final and intermediate targets as provided for in Article 14; and

(c) the disease specific requirements laid down:

(i) in Articles 16 to 31 for infection with *Brucella abortus, B. melitensis* and *B. suis*, infection with MTBC, EBL, IBR/IPV, infection with ADV and BVD;

(ii) in Articles 32 to 36 for infection with rabies virus (RABV);

(iii) in Articles 37 to 45 for infection with BTV.

2. The competent authority may include in the eradication programme coordinated measures at its common land or coastal border with other Member States or third countries to ensure that the objectives of the programme are achieved and that the results will last.

Where such coordination has not been established, the competent authority shall include in the eradication programme, if feasible, effective risk mitigating measures, including intensified surveillance.

Article 13

Territorial scope and animal populations

1. The competent authority shall determine the scope of the eradication programme, including:

(a) the territory covered; and

(b) the targeted animal population and, as necessary, additional animal populations.

2. The territory covered by the eradication programme referred to in point (a) of paragraph 1 shall be:

(a) the entire territory of the Member State; or

(b) one or several zones, provided that each zone corresponds to administrative unit(s) of at least 2 000 km^2 and includes at least one of the regions established in accordance with Article 21 of Regulation (EU) 2016/429.

3. By way of derogation from paragraph 2, the competent authority may define zones smaller than 2 000 km^2 taking into account:

(a) a minimum surface not significantly lower than 2 000 km^2; or

(b) the existence of natural barriers relevant to the disease profile.

Article 14

Final and intermediate targets

1. The competent authority shall include in the eradication programme qualitative and quantitative final targets that are covering all the disease specific requirements laid down in Article 72 for granting disease-free status.

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2. The competent authority shall include in the eradication programme qualitative and quantitative intermediate annual or multi-annual targets to reflect progress made towards the final targets. These intermediate targets shall include:

(a) all of the disease specific requirements referred to in paragraph 1; and

(b) if necessary, additional requirements that are not included in the criteria for granting disease-free status to assess progress towards eradication.

Article 15

Period of application

1. The competent authority shall include in the eradication programme the period of application taking into account the initial situation and the intermediate targets indicated in Article 14(2).

2. For category C diseases, the period of application of the eradication programme shall not exceed 6 years from the date of its initial approval by the Commission in accordance with Article 31(3) of Regulation (EU) 2016/429. In duly justified cases, the Commission may, upon request of Member States, extend the period of application of the eradication programme for an additional 6-year period.

Section 2

Requirements for eradication programmes based on granting disease-free status at the level of establishments

Article 16

Disease control strategy based on the disease-free status at establishment level

1. The competent authority shall design the disease control strategy of an eradication programme with respect to the targeted animal population kept in establishments for the following diseases of terrestrial animals:

(a) infection with *Brucella abortus, B. melitensis* and *B. suis*;

(b) infection with MTBC;

(c) EBL;

(d) IBR/IPV;

(e) infection with ADV;

(f) BVD.

2. Disease control strategies of eradication programmes referred to in paragraph 1 shall be based on:

(a) the implementation of disease specific measures laid down in Articles 18 to 31 until all relevant establishments reach disease-free status;

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(b) the granting, suspension and withdrawal by the competent authority of the disease-free status of all relevant establishments;

(c) the implementation of biosecurity and other risk mitigating measures;

(d) the optional implementation of vaccination programmes.

Article 17

Targeted and additional animal populations for eradication programmes for certain diseases

1. The competent authority shall apply a compulsory eradication programme to the following targeted animal populations:

(a) for infection with *Brucella abortus, B. melitensis* and *B. suis*, kept bovine animals, kept ovine animals and kept caprine animals;

(b) for infection with MTBC, kept bovine animals.

2. The competent authority shall apply the optional eradication programme to the following targeted animal populations:

(a) for EBL, kept bovine animals;

(b) for IBR/IPV, kept bovine animals;

(c) for infection with ADV, kept porcine animals;

(d) for BVD, kept bovine animals.

3. The competent authority shall include additional animal populations where it considers that such animals pose a significant risk to the health status of animals referred to in paragraphs 1 or 2.

Article 18

Obligations of operators with respect to eradication programmes for certain diseases

1. The operators of establishments where animals from the targeted animal populations referred to in Article 17 are kept, other than slaughterhouses, shall comply with the following general and disease specific requirements to obtain and maintain the disease-free status of the establishments:

(a) general requirements:

(i) surveillance of the targeted and additional animal populations for the relevant disease as ordered by the competent authority pursuant to Article 3(1);

(ii) in the case of movement of animals from the targeted animal populations, ensuring that the health status of the establishments is not jeopardised due to transport or introduction into the establishments of animals of the targeted or additional animal populations or products thereof;

(iii) vaccination of the kept animals of targeted animal populations against the relevant disease;

(iv) disease control measures in the event the disease is suspected or confirmed;

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(v) any additional measures considered necessary by the competent authority that may include, if relevant, separation of animals according to their health status by physical protection measures and management measures;

(b) disease specific requirements laid down in:

(i) Chapters 1 and 2 of Part I of Annex IV for infection with *Brucella abortus, B. melitensis* and *B. suis*;

(ii) Chapter 1 of Part II of Annex IV for infection with MTBC;

(iii) Chapter 1 of Part III of Annex IV for EBL;

(iv) Chapter 1 of Part IV of Annex IV for IBR/IPV;

(v) Chapter 1 of Part V of Annex IV for infection with ADV;

(vi) Chapter 1 of Part VI of Annex IV for BVD.

2. The operators of slaughterhouses, where animals from the targeted animal populations referred to in Article 17 are kept and slaughtered shall comply with the general requirements laid down in points (a)(i), (iv) and (v) of paragraph 1.

Article 19

Derogation with regard to granting disease-free status to establishments

By way of derogation from Article 18 and provided that the relevant targeted animal populations comply with the general requirements laid down in point (a) of Article 18(1), the competent authority may decide that the obligations of operators to obtain and maintain disease-free status laid down in Article 18(1) do not apply to operators of the following establishments:

(a) confined establishments;

(b) establishments where animals are only kept for assembly operations;

(c) establishments where animals are only kept for the purpose of animal acts;

(d) travelling circuses.

Article 20

Obligation of the competent authority to grant, suspend and withdraw disease-free status

1. The competent authority shall grant disease-free status at establishment level according to the compliance of the establishments' operators with the requirements laid down in Article 18.

2. The competent authority shall suspend or withdraw disease-free status at establishment level when the conditions for suspension or withdrawal have been met. Those conditions are laid down in:

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(a) Sections 3 and 4 of Chapters 1 and 2 of Part I of Annex IV for infection with *Brucella abortus, B. melitensis* and *B. suis*;

(b) Sections 3 and 4 of Chapter 1 of Part II of Annex IV for infection with MTBC;

(c) Sections 3 and 4 of Chapter 1 of Part III of Annex IV for EBL;

(d) Sections 3 and 4 of Chapter 1 of Part IV of Annex IV for IBR/IPV;

(e) Sections 3 and 4 of Chapter 1 of Part V of Annex IV for infection with ADV;

(f) Sections 3 and 4 of Chapter 1 of Part VI of Annex IV for BVD.

3. The competent authority shall specify:

(a) the details of the testing regime, including as necessary, the disease specific requirements referred to in point (b) of Article 18(1) when the disease-free status is suspended or withdrawn; and

(b) the maximum period of time during which disease-free status may be suspended where there is a breach of the conditions referred to in paragraph 2.

4. The competent authority may attribute distinct health status to different epidemiological units of the same establishment provided that its operator:

(a) has submitted for the consideration of the competent authority the information about the different epidemiological units established within the establishment to be granted distinct health status prior to any suspicion or confirmation of the disease in accordance with Articles 21 and 24;

(b) has set up a system, to which the competent authority has access upon request, to trace the movements of animals and germinal products to, from and between the epidemiological units; and

(c) has separated the epidemiological units by physical and management means and complies with any risk mitigating measures requested by the competent authority for that purpose.

Article 21

Disease control measures in the event of suspicion of certain diseases

1. The competent authority shall, when it suspects a case of the relevant disease, conduct investigations, initiate an epidemiological enquiry and suspend the disease-free status of the establishment where the suspected case occurred until the investigations and the epidemiological enquiry are concluded.

2. Pending the outcome of the investigations and the epidemiological enquiry referred to in paragraph 1, the competent authority:

(a) shall prohibit movement of animals from the relevant targeted animal population out of the establishment unless it has authorised their immediate slaughter in a designated slaughterhouse;

(b) shall, when it considers it necessary for the control of the risk of spreading the disease:

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(i) where technically possible, order the isolation of the suspected cases in the establishment;

(ii) restrict the introduction of animals from the relevant targeted animal population into the establishment;

(iii) restrict the movement of products from the relevant targeted animal population from or to the establishment.

3. The competent authority shall maintain the measures referred to in paragraphs 1 and 2 until the presence of the disease has been ruled out or confirmed.

Article 22

Extension of disease control measures in the event of suspicion of certain diseases

1. The competent authority shall, when it considers it necessary, extend the measures laid down in Article 21 to:

(a) relevant additional animal populations kept in the establishment;

(b) any establishment which has an epidemiological link with the establishment where the suspected case occurred.

2. If the presence of the disease is suspected in wild animals, the competent authority shall, when it considers it necessary, extend to the establishments that are at risk of infection the measures laid down in Article 21.

Article 23

Derogations from disease control measures in the event of suspicion of certain diseases

1. By way of derogation from Article 21(1), based on duly justified grounds, the competent authority may decide not to suspend the disease-free status of the whole establishment when there are different epidemiological units as referred to in Article 20(4).

2. By way of derogation from point (a) of Article 21(2), the competent authority may authorise movement of animals from the relevant targeted animal population to an establishment under its official supervision provided that the following requirements are complied with:

(a) the animals shall only be moved by direct transport;

(b) in the establishment of destination, the animals shall be kept in closed facilities, with no contact with kept animals of a higher health status or with wild animals of listed species for the relevant disease.

3. By way of derogation from point (a) of Article 21(2), in the case of a category C disease, the competent authority may authorise movement of animals from the relevant targeted animal population provided that they are moved, if necessary by direct transport, to an establishment located in an area that is neither disease-free nor covered by an optional eradication programme.

4. When making use of the derogation laid down in paragraph 2, the competent authority shall:

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(a) suspend the disease-free status of the establishment of destination of the animals that are subject to the derogations, until the end of the investigations referred to in Article 21(1);

(b) prohibit, until the end of the investigations referred to in Article 21(1), the movement of animals from that establishment, unless it has authorised their direct transport to a designated slaughterhouse for immediate slaughter;

(c) in case of suspicion of infection with *Brucella abortus*, *B. melitensis* and *B. suis* or with MTBC, maintain the prohibition laid down in point (b) after the end of the investigation until all the animals that moved in the establishment following the derogation laid down in paragraph 2 have been slaughtered.

5. The competent authority may use the derogations provided for in paragraphs 1 to 3 only if operators of establishments of origin and of destination and transporters of the animals that are subject to the derogations:

(a) apply appropriate biosecurity and other risk mitigating measures necessary to prevent the spread of the disease; and

(b) provide the competent authority with guarantees that all the necessary biosecurity and other risk mitigating measures have been taken.

Article 24

Official confirmation of certain diseases and disease control measures

1. If a case is confirmed, the competent authority shall:

(a) withdraw the disease-free status of the infected establishment(s);

(b) adopt the measures laid down in Articles 25 to 31 in the infected establishment(s).

2. By way of derogation from point (a) of paragraph 1, the competent authority may limit the withdrawal of the disease-free status to the epidemiological units where a case was confirmed.

3. If the disease is confirmed in wild animals, the competent authority shall conduct, if necessary, an epidemiological enquiry and investigations as provided for in Article 25. If it considers it necessary in order to prevent the spread of the disease, it shall:

(a) order relevant disease control measures as provided for in Articles 21 to 25 and in Article 30 in establishments keeping the targeted animal population and the additional animal populations;

(b) conduct or order other proportionate and necessary prevention, surveillance and disease control measures with respect to the relevant wild animal population or in its habitat.

Article 25

Epidemiological enquiry and investigations in case of confirmation of certain diseases

1. When the disease is confirmed, the competent authority shall:

(a) conduct an epidemiological enquiry;

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(b) conduct investigations and apply the measures laid down in Article 21 in all epidemiologically linked establishments; and

(c) adapt the surveillance to the identified risk factors, taking into account the conclusions of the epidemiological enquiry.

2. The competent authority shall consider the need to conduct an investigation on wild animals from additional animal populations where the epidemiological enquiry reveals epidemiological links between kept and wild animals.

3. The competent authority shall as soon as possible inform about the situation:

(a) operators and relevant authorities from the Member States concerned by the epidemiological links with the confirmed case; and

(b) the competent authorities from other Member States or third countries that may be concerned by the epidemiological links with the infected establishment(s).

Article 26

Movement of animals to or from infected establishments

1. The competent authority shall prohibit movements of animals from targeted animal population out of the infected establishment unless it has authorised their immediate slaughter in a designated slaughterhouse.

2. When the competent authority considers it necessary in order to prevent the spread of the disease, it shall:

(a) order the isolation of the suspected and confirmed cases in the establishment where technically possible;

(b) restrict the movements of animals from targeted animal population within the establishment;

(c) restrict the introduction of animals from targeted animal population in the establishment;

(d) restrict the movement of products of animals from targeted animal population from and to the infected establishment.

3. The competent authority shall, when it considers it necessary, extend the measures in paragraphs 1 and 2 to animals and products from additional animal populations to prevent the spread of the disease.

Article 27

Testing and removal of animals from infected establishments

1. Following confirmation of the disease, the competent authority shall order that in infected establishments the following testing is conducted within a maximum period of time to be determined by it:

(a) testing of those animals whose testing is considered necessary to complete the epidemiological enquiry;

(b) testing to restore the disease-free status as laid down in:

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(i) Section 4 of Chapters 1 and 2 of Part I of Annex IV for infection with *Brucella abortus, B. melitensis and B. suis*;

(ii) Section 4 of Chapter 1 of Part II of Annex IV for infection with MTBC;

(iii) Section 4 of Chapter 1 of Part III of Annex IV for EBL;

(iv) Section 4 of Chapter 1 of Part IV of Annex IV for IBR/IPV;

(v) Section 4 of Chapter 1 of Part V of Annex IV for infection with ADV;

(vi) Section 4 of Chapter 1 of Part VI of Annex IV for BVD; and

(c) any additional testing it considers necessary to ensure the swift detection of infected animals that may contribute to the spreading of the disease.

2. By way of derogation from point (b) of paragraph 1, testing shall not be ordered when disease-free status is restored in accordance with:

(i) point 2 of Section 1 of Chapters 1 and 2 of Part I of Annex IV for infection with *Brucella abortus, B. melitensis* and *B. suis*;

(ii) point 2 of Section 1 of Chapter 1 of Part II of Annex IV for infection with MTBC;

(iii) point 2 of Section 1 of Chapter 1 of Part III of Annex IV for EBL;

(iv) point 2 of Section 1 of Chapter 1 of Part IV of Annex IV for IBR/IPV;

(v) point 2 of Section 1 of Chapter 1 of Part V of Annex IV for infection with ADV;

(vi) point 2 of Section 1 of Chapter 1 of Part VI of Annex IV for BVD.

3. The competent authority shall order that in infected establishments all animals recognised as confirmed cases and, if necessary, as suspected cases are slaughtered within a maximum period of time it determines.

4. The slaughtering of the animals referred to in paragraph 3 shall be carried out under official supervision in a designated slaughterhouse.

5. The competent authority may order the killing and destruction of some or all of the animals referred to in paragraph 3 instead of their slaughtering.

6. The competent authority shall extend the measures laid down in this Article to animals from additional animal populations when this is necessary to eradicate the disease in the infected establishments.

Article 28

Management of products from infected establishments

1. The competent authority shall in all establishments infected with *Brucella abortus, B. melitensis* and *B. suis* or with MTBC, order that:

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(a) milk from confirmed cases shall either be fed only to animals in the same establishment after it has been processed to ensure the inactivation of the disease agent, or it shall be disposed of;

(b) manure, straw, feed or any other matter and substance which has come into contact with a confirmed case or with contaminated material shall be either collected and disposed of as soon as possible or, following an appropriate risk assessment, stored and processed to reduce to an acceptable level the risk of spreading of the disease.

2. In the event of infection with *Brucella abortus, B. melitensis* and *B. suis,* the competent authority shall order that in all infected establishments foetuses, still-born animals, animals which have died from the disease after birth and placentae shall be collected and disposed of.

3. In the event of infection with a category C disease, the competent authority shall when it considers it necessary, order any appropriate measures provided for paragraphs 1 and 2.

4. The competent authority shall, when it considers it necessary, order the trace-back, the processing or the disposal of any products from infected establishments that may constitute a risk of spreading the disease or affect human health.

Article 29

Derogations from the restriction of movement of animals from infected establishments

1. By way of derogation from Article 26(1), the competent authority may authorise movement of clinically healthy animals, other than confirmed cases, to an establishment under its official supervision provided that the following requirements are complied with:

(a) the movement does not jeopardise the health status of animals at the establishment of destination or enroute to that destination;

(b) the animals shall only be moved by direct transport; and

(c) in the establishment of destination, the animals shall be kept, in closed facilities, with no contact with kept animals of a higher health status or with wild animals of listed species for the relevant disease.

2. By way of derogation from Article 26(1) in the case of a category C disease, the competent authority may authorise movement of clinically healthy animals from the relevant targeted animal population, other than confirmed cases, provided that:

(a) they are moved, if necessary by direct transport, to an establishment located in an area that is neither disease-free nor covered by an optional eradication programme; and

(b) the movement does not jeopardise the health status of targeted or additional animal populations at the establishment of destination or enroute to that destination.

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3. When making use of the derogation laid down in paragraph 1, the competent authority shall withdraw the disease-free status of the establishment of destination of the animals that are subject to the derogation and shall:

(a) order the movement of the animals by direct transport, within a maximum period of time it determines, from the establishment of destination to a designated slaughterhouse for immediate slaughter; or

(b) in case of a category C disease order the disease control measures laid down in Articles 26 to 30 until the disease-free status of the establishment is regained.

4. The competent authority may use the derogations provided for in paragraphs 1 and 2 only if operators of establishments of origin and of destination and transporters of the animals that are subject to the derogations:

(a) apply appropriate biosecurity and other risk mitigating measures necessary to prevent the spread of the disease; and

(b) provide the competent authority with the guarantees that all the necessary biosecurity and other risk mitigating measures have been taken.

Article 30

Cleaning and disinfection and other measures to prevent the spread of infection

1. The competent authority shall order the operators of all infected establishments and those receiving animals from infected establishments the cleaning and disinfection or, where relevant, the safe disposal of:

(a) all parts of the establishments that may have been contaminated after the removal of the confirmed and suspected cases and before repopulation;

(b) any feed, materials, substances, husbandry related equipment, medicinal equipment and production related equipment that may have been contaminated;

(c) any protective clothing or safety equipment used by operators and visitors;

(d) all means of transport, containers and equipment after the transport of animals or products from infected establishments;

(e) loading areas for animals after each use.

2. The competent authority shall approve the protocol for the cleaning and disinfection.

3. The competent authority shall supervise the cleaning and disinfection, or where relevant, the safe disposal and shall not restore or grant again disease-free status to the establishment until it considers that the cleaning and disinfection, or where relevant, the safe disposal, has been completed.

4. The competent authority may, based on a risk assessment, regard a pasture as contaminated and prohibit its use for kept animals of higher health status than that of the targeted animal population or, if epidemiologically

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relevant, additional animal populations, for a period of time sufficient to consider the risk of persistence of the disease agent to be negligible.

Article 31

Risk mitigating measures to prevent reinfection

Before or upon lifting of the disease control measures, the competent authority shall order proportionate risk mitigating measures to prevent the reinfection of the establishment taking into account relevant risk factors as indicated by the results of the epidemiological enquiry. These measures shall at least take account of:

(a) persistence of the disease agent in the environment or in wild animals; and

(b) biosecurity measures that are adapted to the specificities of the establishment.

Section 3

Provisions for eradication programmes for infection with RABV

Article 32

Disease control strategy of eradication programmes for infection with RABV

1. The competent authority shall, when establishing an eradication programme for infection with RABV, base it on a disease control strategy that includes:

(a) vaccination of the animals from the targeted animal population that it considers relevant;

(b) implementation of measures to reduce the risk of contact with infected animals;

(c) control of the risk of spread and introduction of the disease in the territory of its Member State.

2. The competent authority shall implement the eradication programme taking into account that it shall be:

(a) based on a risk assessment, updated, as necessary, according to the evolution of the epidemiological situation;

(b) supported by public information campaigns involving all relevant stakeholders;

(c) coordinated, if necessary, with relevant authorities in charge of public health, wild animal populations or hunting;

(d) scaled according to a territorial risk-based approach.

3. The competent authority may be involved in the implementation of eradication programmes for infection with RABV in a third country or territory, to prevent the risk of spread and introduction of RABV in the territory of its Member State.

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Article 33

Targeted animal population for eradication programmes for infection with RABV

1. The competent authority shall apply the eradication programme for infection with RABV to the following targeted animal population: kept and wild animals of species of the following families: Carnivora, Bovidae, Suidae, Equidae, Cervidae and Camelidae.

2. The competent authority shall address the measures in the eradication programme primarily to wild foxes, being the main reservoir of RABV.

3. The competent authority shall subject other targeted animal populations than wild foxes to the measures of the eradication programme when it considers that such animals pose a significant risk.

4. The competent authority may include wild animals of species of the order Chiroptera in the targeted animal population relevant to surveillance referred to in Article 4.

Article 34

Obligations of the competent authority in the context of eradication programmes for infection with RABV

1. The competent authority shall:

(a) conduct surveillance of infection with RABV for the purposes of:

(i) early detection of the infection; and

(ii) follow up of the trend in the number of infected animals, which shall include, according to a risk-based approach, the collection and testing of wild foxes and other wild carnivores found dead;

(b) carry out disease control measures in the event of suspicion or confirmation of infection with RABV as laid down in Articles 35 and 36;

(c) apply, if necessary, risk mitigating measures to prevent the spread of RABV by movements of dogs, cats and ferrets.

2. The competent authority shall, when it considers it necessary, order:

(a) vaccination, and the monitoring of the effectiveness of vaccination, in accordance with Section 2 of Chapter 1 of Part I of Annex V of wild foxes and, if relevant, of other animals referred to in Article 33(3);

(b) the identification and registration of dogs, cats and ferrets;

(c) movement restrictions of relevant kept animals of species referred to in Article 33(3) that are not vaccinated against infection with RABV in accordance with Section 1 of Chapter 1 of Part I of Annex V;

(d) the measures provided for in Article 35 when an animal of a listed species wounded a person or an animal without an understandable reason and in contradiction with its normal behaviour or presented an unexplained change in behaviour followed by death within 10 days.

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Article 35

Disease control measures in the event of suspicion of infection with RABV

When infection with RABV is suspected, the competent authority shall:

(a) conduct further investigations to confirm or rule out the presence of the disease;

(b) order relevant movement restrictions or killing of suspected cases to protect humans and animals against the risk of being infected pending the results of the investigations;

(c) order any risk mitigating measures justified to reduce the risk of further transmission of RABV to humans or to animals.

Article 36

Disease control measures in the event of confirmation of infection with RABV

When infection with RABV is confirmed, the competent authority shall take measures to prevent further transmission of the disease to animals and to humans, for which:

(a) it shall conduct an epidemiological enquiry, which shall include the identification of the RABV strain involved, to identify the likely source of the infection and epidemiological links;

(b) it shall, unless it considers further investigations are necessary, rule out an infection with RABV in animals with an epidemiological link when:

(i) a minimum period of 3 months has lapsed since the epidemiological link with the confirmed case occurred; and

(ii) no clinical signs have been detected in those animals;

(c) it shall, when it considers it necessary, take one or more of the measures laid down in Articles 34 and 35;

(d) it shall ensure that carcasses of confirmed cases of infected wild animals are disposed of or processed in accordance with the rules laid down in Article 12 of Regulation (EC) No 1069/2009.

Section 4

Provisions for eradication programmes for infection with BTV

Article 37

Disease control strategy of eradication programmes for infection with BTV

1. The competent authority shall, when establishing an optional eradication programme for infection with BTV, base the programme on a disease control strategy that includes:

(a) surveillance of infection with BTV in accordance with the requirements set out in Chapter 1 of Part II of Annex V;

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(b) vaccination of the relevant targeted animal population for eradicating the disease by means of regular vaccination campaigns to be implemented, as relevant, in accordance with a long-term strategy;

(c) movement restrictions of the targeted animal population in accordance with the requirements laid down in Articles 43 and 45;

(d) risk mitigating measures to minimise transmission of infection with BTV through vectors.

2. The competent authority shall implement the eradication programme taking into account that:

(a) it shall detect and eradicate all the serotypes 1-24 present in the territory covered by the eradication programme;

(b) the territory covered by the eradication programme shall be:

(i) the whole territory of the Member State; or

(ii) a zone or zones that include a territory within at least a 150-km radius of each infected establishment.

3. By way of derogation from point (b)(ii) of paragraph 2, the competent authority may adapt the zone(s) covered by the eradication programme in accordance with:

(a) the geographical situation of the infected establishment(s) and the boundaries of the corresponding administrative units;

(b) the ecological and meteorological conditions;

(c) the abundance, activity and distribution of the vectors present in the zone(s);

(d) the BTV serotype involved;

(e) the results of the epidemiological enquiry provided for in Article 42;

(f) the results of the surveillance activities.

Article 38

Targeted and additional animal populations for eradication programmes for infection with BTV

1. The competent authority shall apply the eradication programme for infection with BTV to the following targeted animal population: kept animals from species of families of Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Moschidae and Traguilidae.

2. The competent authority shall, when it considers it is necessary, apply the eradication programme to the following additional animal populations: wild animals from species of families of Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Moschidae and Traguilidae.

Article 39

Obligations of operators in the context of eradication programmes for infection with BTV

1. The operators of establishments, other than slaughterhouses, where animals from the targeted animal population referred to in Article 38(1) are kept shall:

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(a) comply with the requirements ordered by the competent authority as regards the surveillance of animals from the targeted animal population;

(b) comply with the requirements ordered by the competent authority as regards the entomological surveillance;

(c) have animals from the targeted animal population vaccinated following the orders of the competent authority;

(d) implement disease control measures in the event the disease is suspected or confirmed following the orders of the competent authority;

(e) comply with movement requirements following the orders of the competent authority;

(f) implement any additional measures considered necessary by the competent authority which may include, if relevant, protection of kept animals from attacks by vectors in accordance with the animals' health status.

2. The operators of slaughterhouses, where animals from the targeted animal population referred to in Article 38(1) are kept and slaughtered, shall:

(a) comply with the requirements ordered by the competent authority as regards the surveillance of animals from the targeted animal population;

(b) implement disease control measures in the event the disease is suspected or confirmed following the orders of the competent authority;

(c) implement any additional measures considered necessary by the competent authority which may include, if relevant, protection of kept animals from attacks by vectors in accordance with the animals' health status.

Article 40

Obligations of the competent authority in the context of eradication programmes for infection with BTV

1. The competent authority shall in the territory covered by an eradication programme for infection with BTV referred to in point (b) of Article 37(2):

(a) map the territory covered in a set of geographical units in accordance with point 1 of Section 4 of Chapter 1 of Part II of Annex V;

(b) conduct surveillance of infection with BTV in each geographical unit, as relevant with regard to the epidemiological situation, according to the requirements laid down in Chapter 1 of Part II of Annex V;

(c) apply the disease control measures laid down in Articles 41 and 42 in the event of suspicion or confirmation of the disease;

(d) order operators of establishments of bovine, ovine or caprine animals and, if necessary, other targeted animal populations to have their animals vaccinated; and

(e) apply the requirements laid down in Articles 43 and 45 to the movements of animals from the targeted animal population.

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2. By way of derogation from point (d) of paragraph 1, the competent authority may decide not to order operators to have their animals vaccinated if following a risk assessment, it duly justifies that the implementation of other measures is sufficient to eradicate the disease.

3. The competent authority shall, when it considers it necessary and if possible, establish a seasonally BTV-free area as provided for in Chapter 5 of Part II of Annex V. In that event, the competent authority shall make available to the Commission and to the other Member States:

(a) information demonstrating the fulfilment of the specific criteria for determining the seasonally BTV-free period;

(b) the start and end dates of the period;

(c) information demonstrating the cessation of the transmission of BTV in the area; and

(d) the delimitation of the area which complies with the minimum requirements laid down in Article 13.

Article 41

Disease control measures in the event of suspicion of infection with BTV

1. In the event of suspicion of infection with BTV, the competent authority shall conduct an investigation to confirm or rule out the disease.

2. Pending the outcome of the investigation referred to in paragraph 1, the competent authority shall:

(a) restrict movement of animals and germinal products from the targeted animal population from the establishment where they are kept unless authorised for the purpose of immediate slaughter;

(b) order relevant risk mitigating measures, when necessary and technically feasible, to prevent or reduce exposure of animals from the targeted animal population to attacks by vectors.

3. The competent authority shall, when it considers it necessary, extend the measures provided for in paragraphs 1 and 2 to establishments where animals from the targeted animal population had a similar exposure to infectious vectors to that of the suspected cases.

4. The measures provided for in this Article may be withdrawn when the competent authority considers that they are no longer necessary to limit the risk of spreading the disease.

Article 42

Disease control measures in the event of confirmation of infection with BTV

1. In the event of confirmation of infection with BTV, the competent authority shall:

(a) confirm the outbreak and, if necessary, establish or extend the zone under eradication programme;

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(b) conduct an epidemiological enquiry, if necessary;

(c) restrict movement of animals of the targeted animal population from the establishment where they are kept unless authorised for the purpose of immediate slaughter;

(d) restrict movement of germinal products of animals from the targeted animal population from the establishment where they are kept;

(e) order relevant risk mitigating measures, when it considers it necessary and technically feasible, to prevent or reduce exposure of animals from the targeted animal population to attacks by vectors;

(f) apply the disease control measures provided for in Article 41 to all establishments having an epidemiological link with the confirmed case, including those keeping animals from the targeted animal population having a similar exposure to infectious vectors to that of the confirmed case.

2. In addition to measures laid down in paragraph 1 and in order to prevent the disease from spreading, the competent authority shall, when it considers it necessary:

(a) order operators of establishments of bovine, ovine or caprine animals and, if necessary, other targeted animal populations to have their animals vaccinated against the infection with the relevant BTV serotype(s) as provided for in point (d) of Article 40(1);

(b) investigate and monitor the health status of the targeted animal population in the proximity of the establishment where the confirmed case is kept.

3. The measures provided for in this Article may be withdrawn when the competent authority considers that they are no longer necessary to limit the risk of spreading the disease.

Article 43

Movement of kept animals and germinal products from the targeted animal population to Member States or zones covered by eradication programmes for infection with BTV

1. The competent authority shall only authorise the introduction of animals from the targeted animal population in the territory covered by an eradication programme for infection with BTV referred to in point (b) of in Article 37(2) if they comply with at least one of the requirements set out in points 1 to 4 of Section 1 of Chapter 2 of Part II of Annex V.

2. By way of derogation from paragraph 1, the competent authority may also authorise the introduction of animals from the targeted animal population in the territory covered by the eradication programme for infection with BTV if:

(a) it has assessed the risk that the introduction poses to the health status of the place of destination as regards infection with BTV, taking into account possible risk mitigating measures it may adopt at the place of destination;

(b) it prohibits the movement of these animals to another Member State:

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(i) for a period of 60 days after the introduction; or

(ii) until a negative polymerase chain reaction (PCR) test for BTV serotypes 1-24 was carried out on samples collected not earlier than 14 days after the introduction;

(c) it adapts, if necessary, the surveillance in accordance with point 6 of Section 4 of Chapter 1 of Part II of Annex V; and

(d) the animals comply with any one of the requirements set out in points 5 to 8 of Section 1 of Chapter 2 of Part II of Annex V.

3. The competent authority shall only authorise the introduction of germinal products from the targeted animal population in the territory covered by an eradication programme for infection with BTV referred to in point (b) of Article 37(2) if they comply with at least one of the requirements set out in points 1 to 3 of Section 2 of Chapter 2 of Part II of Annex V.

4. By way of derogation from paragraph 3, the competent authority may also authorise the introduction of germinal products from the targeted animal population in the territory covered by an eradication programme for infection with BTV if:

(a) it has assessed the risk that the introduction poses to the health status of the place of destination as regards infection with BTV, taking into account possible risk mitigating measures it may adopt at the place of destination;

(b) it prohibits the movement of these germinal products to another Member State; and

(c) the germinal products comply with the requirements set out in point 4 of Section 2 of Chapter 2 of Part II of Annex V.

5. When the competent authority receiving the animals or the germinal products uses the derogations provided for in paragraphs 2 or 4, it shall:

(a) inform the Commission thereof as soon as possible;

(b) accept animals or germinal products from the targeted animal population that comply with the requirements for the relevant derogation regardless of the Member State or zone of origin of the animal or germinal products.

6. When the competent authority receiving the animals or the germinal products no longer uses the derogations provided for in paragraphs 2 or 4, it shall inform the Commission as soon as possible.

Article 44

Vector protected establishment

1. The competent authority may, upon request by the operator, grant the status ‘vector protected establishment’ to establishments or facilities complying with the criteria laid down in Chapter 3 of Part II of Annex V.

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2. The competent authority shall verify at the appropriate frequency, but at least at the beginning, during and at the end of the required protection period, the effectiveness of the measures carried out by means of a vector trap inside the establishment.

3. The competent authority shall immediately withdraw the status vector protected establishment when the conditions referred to in paragraph 1 are no longer complied with.

Article 45

Movement of animals through Member States or zones covered by eradication programmes for infection with BTV

1. The competent authority shall only authorise movement of animals from the targeted animal population through the territory covered by an eradication programme for infection with BTV referred to in point (b) of Article 37(2) if:

(a) the animals from the targeted animal population comply with at least one of the requirements set out in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V; or

(b) the means of transport onto which the animals are loaded have been protected from attacks by vectors and the journey does not include the unloading of the animals for a period longer than 1 day, or the animals are unloaded for a period longer than 1 day in a vector protected establishment or during the vector-free period.

2. By way of derogation from paragraph 1, the competent authority may also authorise the movement of animals from targeted animal population through the territory covered by an eradication programme for infection with BTV if the requirements laid down in points (a), (c) and (d) of Article 43(2) are complied with.

CHAPTER 3

Eradication programmes for category B and C diseases of aquatic animals

Section 1

General provisions

Article 46

Disease control strategy for the eradication of category B and C diseases of aquatic animals

1. The competent authority shall, when establishing a compulsory eradication programme for a category B disease or an optional eradication programme for a category C disease of aquatic animals, base those programmes on a disease control strategy that includes for each disease:

(a) the type of surveillance requirements necessary to achieve the conditions for granting and maintaining disease-free status taking into account point (b)(ii) of Article 3(2);

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(b) the territory and animal population covered by the eradication programme as provided for in Articles 47 and 51;

(c) the duration of the eradication programme provided for in Article 49 including its final and intermediate targets as provided for in Article 48;

(d) the disease specific preventive and control measures laid down in Articles 55 to 65.

2. The competent authority may include in the eradication programme coordinated measures at its common land or coastal border with other Member States or third countries to ensure that the objective of the programmes are achieved and will last.

Where such coordination has not been established, the competent authority shall include in the eradication programme, if feasible, effective risk mitigating measures including intensified surveillance.

Article 47

Territorial scope and animal population

1. The competent authority shall determine the scope of the eradication programme including:

(a) the territory covered; and

(b) the targeted animal population and, if necessary, additional animal populations.

2. The territory covered by the eradication programme referred to in point (a) of paragraph 1 may be:

(a) the entire territory of the Member State;

(b) one or several zones; or

(c) the geographical location of the establishments of which the compartment or compartments are comprised.

3. All establishments located within the Member State, zone or compartment covered by the eradication programme shall be included in the eradication programme.

4. By way of derogation from paragraph 3 the competent authority may exclude from the eradication programme, aquaculture establishments which do not pose a significant risk to the success of that programme and which are exempted from the obligation to apply for approval.

Article 48

Final and intermediate targets

1. The competent authority shall include in the eradication programme qualitative and quantitative final targets that cover all the disease specific requirements laid down in Article 72 for granting disease-free status.

2. Where this is technically possible, the competent authority implementing an eradication programme shall also include in that programme qualitative and quantitative final targets based on the health status of wild animal populations that constitute a threat to the achievement of disease-free status.

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3. The competent authority shall include in the eradication programme qualitative and quantitative intermediate annual or multi-annual targets to reflect progress made towards the final targets. These intermediate targets shall include:

(a) all of the disease specific requirements referred to in paragraph 1 and the targets provided for in paragraph 2; and

(b) if necessary, additional requirements that are not included in the requirements for granting disease-free status to assess progress towards eradication.

Article 49

Period of application

1. The period of application of eradication programmes for listed aquatic animal diseases are laid down in Part II of Annex VI, specifically Sections 2 and 3 of:

(a) Chapter 1 for VHS and IHN;

(b) Chapter 2 for infection with HPR-deleted ISAV;

(c) Chapter 3 for infection with *Marteilia refringens*;

(d) Chapter 4 for infection with *Bonamia exitiosa*;

(e) Chapter 5 for infection with *Bonamia ostreae*;

(f) Chapter 6 for infection with WSSV.

2. For category C diseases, the period of application of an eradication programme shall not exceed 6 years from the date of its initial approval by the Commission in accordance with Article 31(3) of Regulation (EU) 2016/429. In duly justified cases, the Commission may, upon request of Member States, extend the period of application of the eradication programme for an additional 6-year period.

Section 2

Requirements for Eradication programmes

Article 50

Minimum requirements for an eradication programme

The competent authority shall base the eradication programme for a specific category B or C disease in a Member State, zone, or compartment on:

(a) the determination of the health status of the Member State, zone or compartment by ascertaining the health status of all establishments where animals from the listed species are kept;

(b) the implementation of disease control measures in all establishments where suspected and confirmed cases are detected;

(c) the implementation of biosecurity and other risk mitigating measures to reduce the risk of the listed species in an establishment becoming infected;

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(d) in certain cases, vaccination, as part of the eradication programme.

Article 51

Animal population to be included in eradication programmes for category B and C diseases

1. The competent authority shall apply the eradication programme to listed species kept in establishments within the territory of the Member State, the zone or compartment.

2. By way of derogation from paragraph 1, the competent authority may decide to exclude from the eradication programme, based on a risk assessment, establishments keeping only vector species referred to in the table set out in the Annex to Implementing Regulation (EU) 2018/1882.

3. Where technically feasible, the competent authority shall include in the eradication programme additional animal populations when such animals:

(a) pose a significant risk to the health status of animals referred to in paragraph 1;

(b) are included due to the small number of aquaculture establishments in the eradication programme and when their inclusion is necessary to obtain a satisfactory epidemiological coverage of the Member State, zone or compartment.

Article 52

Measures to be taken in Member States, zones or compartments covered by eradication programmes

1. In order to monitor the progress of eradication programmes, the competent authority shall classify the health status of all establishments where animals from the listed species are kept according to:

(a) the health status of each establishment as known at the time the eradication programme commences;

(b) the compliance with conditions for the introduction of animals from listed species into the establishment;

(c) the compliance by the operator with the obligation to notify the competent authority of any suspicion or detection of the disease;

(d) the fulfilment of disease control measures to be applied if the disease is suspected or confirmed;

(e) the vaccination regimes that may apply to animals from listed species kept in the establishment;

(f) any additional measures considered necessary by the competent authority.

2. The competent authority shall:

(a) commence, maintain, or withdraw the eradication programme according to the compliance or non-compliance of establishments with the requirements laid down in paragraph 1;

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(b) inform the operators of the relevant establishments about the evolution of the health status and the necessary measures for granting disease-free status.

3. Operators shall comply with the requirements set out in points (b) to (f) of paragraph 1 so that the eradication programme can be implemented until such time as it has been successfully completed or is withdrawn.

Article 53

Derogation from classification of the health status of confined establishments

By way of derogation from Article 52(1), the competent authority may decide not to classify the health status of confined establishments, if the animal population kept in these confined establishments is subjected to appropriate risk mitigating measures and disease control measures to ensure that it does not constitute a risk of spreading the disease.

Article 54

Vaccination

The competent authority may, include in eradication programmes under its official supervision:

(a) vaccination of listed species;

(b) vaccination of an additional animal population of kept animals;

(c) vaccination of an additional animal population of wild animals.

Article 55

Disease control measures in the event of suspicion of certain diseases

1. The competent authority shall, when it suspects a case of the relevant disease in an establishment, conduct the necessary investigation.

2. Pending the outcome of the investigation referred to in paragraph 1, the competent authority shall:

(a) prohibit the introduction of animals or products of animal origin into the establishment;

(b) where technically possible, order the isolation of units in the establishment where suspected animals are kept;

(c) prohibit the movement of animals and products of animal origin out of the establishment unless authorised by the competent authority for the purpose of immediate slaughter or processing in a disease control aquatic food establishment, or for direct human consumption in the case of molluscs or crustacea which are sold live for that purpose;

(d) prohibit the movement of equipment, feed and animal by-products from the establishment unless authorised by the competent authority.

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3. The competent authority shall maintain the measures referred to in paragraphs 1 and 2 until the presence of the disease has been ruled out or confirmed.

Article 56

Extension of disease control measures in the event of suspicion of certain diseases

1. The competent authority shall, when it considers it necessary, extend the measures laid down in Article 55 to:

(a) any establishment which due to hydrodynamic conditions, has an increased risk of contracting the disease from the suspected establishment;

(b) any establishment which has a direct epidemiological link with the suspected establishment.

2. If the presence of the disease is suspected in wild aquatic animals, the competent authority shall, when it considers it necessary, extend the measures laid down in Article 55 to the concerned establishments.

Article 57

Derogation from disease control measures in the event of suspicion of disease

1. By way of derogation from point (c) of Article 55(2) the competent authority may authorise the movement of aquaculture animals to an establishment under its official supervision provided that the following requirements are complied with:

(a) only animals showing no symptoms of disease are moved;

(b) the health status of aquaculture animals at the establishment of destination or aquatic animals enroute to that establishment is not jeopardised by the movement;

(c) in the establishment of destination they have no contact with aquaculture animals of a higher health status with respect to the relevant disease; and

(d) the animals are kept in the establishment of destination for a maximum period of time to be determined by the competent authority.

2. When making use of the derogation laid down in paragraph 1, the competent authority shall:

(a) re-classify the health status of the establishment of destination, if relevant, in accordance with the criteria laid down in Article 52(1), until the end of the investigation referred to in Article 55(1);

(b) prohibit the movement of animals from the establishment of destination until the end of the investigation, unless it has authorised their transport to a disease control aquatic food establishment for immediate slaughter or processing or for direct human consumption, in the case of molluscs or crustacea which are sold live for that purpose.

3. The competent authority may use the derogation provided for in paragraph 1 only if operators of establishments of origin and of destination and transporters of the animals that are subject to the derogation:

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(a) apply appropriate biosecurity and other risk mitigating measures necessary to prevent the spread of the disease;

(b) provide the competent authority with guarantees that all the necessary biosecurity and other risk mitigating measures have been taken; and

(c) provide the competent authority with guarantees that animal by-products as defined in point (1) of Article 3 of Regulation (EC) No 1069/2009 from the aquatic animals referred to in paragraph 1(c) of this Article are processed or disposed of as Category 1 or Category 2 material in accordance with Articles 12 or 13 of that Regulation.

Article 58

Official confirmation of certain diseases and disease control measures

1. If a case is confirmed, the competent authority shall:

(a) declare the establishment(s) infected;

(b) reclassify the health status of the infected establishment(s);

(c) establish a restricted zone which is of an appropriate size;

(d) adopt the measures laid down in Articles 59 to 65 in the infected establishment(s).

2. The minimum requirements that shall apply with regard to the establishment(s) of the restricted zone are set out in Part II of Annex VI, specifically in:

(a) point 1(a) of Section 3 of Chapter 1 for VHS and IHN;

(b) point 1(a) of Section 3 of Chapter 2 for infection with HPR-deleted ISAV;

(c) point 1(a) of Section 3 of Chapter 3 for infection with *Marteilia refringens*;

(d) point 1(a) of Section 3 of Chapter 4 for infection with *Bonamia exitiosa*;

(e) point 1(a) of Section 3 of Chapter 5 for infection with *Bonamia ostreae*;

(f) point 1(a) of Section 3 of Chapter 6 for infection with WSSV.

3. By way of derogation from point (c) of paragraph 1, the competent authority may decide not to establish a restricted zone:

(a) when an infected establishment does not discharge untreated effluent into surrounding waters; and

(b) where the biosecurity measures which exist at the establishment are of a standard which ensures that infection is fully contained within it.

4. The competent authority may take risk mitigating measures relating to the following activities in the restricted zone:

(a) the movement of well-boats through the restricted zone;

(b) fishing activities;

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(c) other activities that may pose a risk of disease spread.

5. If the disease is confirmed in wild aquatic animals, the competent authority may:

(a) develop and implement the prevention, surveillance and disease control measures that are necessary to prevent the spread of the disease to kept animals of listed species or to additional animal populations;

(b) apply intensified surveillance of wild aquatic animal populations and in establishments having a direct epidemiological link with the confirmed case;

(c) take measures to eradicate the disease from the relevant wild aquatic animal population, where feasible.

Article 59

Epidemiological enquiry and investigations in case of confirmation of certain diseases

1. When the disease is confirmed, the competent authority shall:

(a) conduct an epidemiological enquiry;

(b) conduct investigations and apply the measures laid down in Article 55(2) in all epidemiologically linked establishments;

(c) adapt the surveillance to the identified risk factors, taking into account the conclusions of the epidemiological enquiry.

2. The competent authority shall consider the need to conduct an investigation on wild animals where the epidemiological enquiry reveals epidemiological links between kept and wild animals.

3. The competent authority shall as soon as possible inform:

(a) operators and relevant authorities from the Member State concerned by the epidemiological links with the confirmed case; and

(b) the competent authorities from other Member States or third countries that may be concerned by the epidemiological links with the infected establishment(s).

Article 60

Movements to or from an infected establishment and any other establishment located in the restricted zone

1. The competent authority shall in all infected establishment(s) and any other establishment(s) located in the restricted zone:

(a) where technically possible, order the isolation of suspected and confirmed cases;

(b) prohibit the movement of animals or products of animal origin from the listed species for the relevant disease out of the establishment(s) unless authorised by the competent authority for immediate slaughter or processing in a disease control aquatic food establishment or for direct human consumption in the case of molluscs or crustacea which are sold live for that purpose;

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(c) prohibit the introduction of animals from the listed species for the relevant disease to the establishment(s) unless authorised by the competent authority on duly justified grounds;

(d) prohibit the movement of equipment, feed and animal by-products from the establishment(s) unless authorised by the competent authority.

2. The competent authority shall extend the measures in points (a) to (c) of paragraph 1 to kept animals from additional animal populations if they present a risk of spreading the disease.

Article 61

Derogations from the restriction of movement of animals and products of animal origin from infected establishments

1. By way of derogation from point (b) Article 60(1), the competent authority may authorise the movement of aquaculture animals to an establishment under its official supervision located within the same restricted zone provided that:

(a) only animals showing no symptoms of disease are moved;

(b) the health status of aquaculture animals at the establishment of destination or aquatic animals enroute to that establishment is not jeopardised by the movement;

(c) in the establishment of destination they have no contact with aquaculture animals of a higher health status with respect to the relevant disease;

(d) the animals are kept in the establishment of destination for a maximum period of time to be determined by the competent authority.

2. When making use of the derogation laid down in paragraph 1, the competent authority shall:

(a) re-classify the health status of the establishment of destination, if relevant, in accordance with the criteria laid down in Article 52(1);

(b) prohibit the movement of animals from the establishment of destination, unless it has authorised their transport to a disease control aquatic food establishment for immediate slaughter or processing or for direct human consumption, in the case of molluscs or crustacea which are sold live for that purpose. In all cases, animal by-products as defined in point (1) of Article 3 of Regulation (EC) No 1069/2009 shall be processed or disposed of as Category 1 or Category 2 material in accordance with Articles 12 or 13 of that Regulation.

(c) keep the establishment of destination under its official supervision until the completion of cleaning, disinfection and appropriate fallowing of the establishment.

3. By way of derogation from point (b) Article 60(1), the competent authority may authorise the movement of aquaculture animals to other infected establishments which are not implementing an eradication programme for that specific disease provided that:

(a) only animals showing no symptoms of disease are moved;

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(b) the health status of aquaculture animals at the establishment of destination or aquatic animals enroute to that establishment is not jeopardised by the movement; and

(c) the movement complies with the certification requirements set out in Article 208(2) of Regulation (EU) 2016/429.

4. By way of derogation from point (b) of Article 60(1), the competent authority may authorise the movement of aquaculture animals and products of animal origin to slaughtering and processing facilities other than disease control aquatic food establishments provided that:

(a) only animals showing no symptoms of disease are moved;

(b) the slaughtering and processing facility is not located in a Member State, zone or compartment which is implementing an eradication programme for that specific disease or which has been declared disease-free;

(c) the health status of aquatic animals enroute for the slaughtering and processing facility or in its vicinity is not jeopardised by the movement;

(d) the movement complies with the certification requirements set out in Article 208(2) of Regulation (EU) 2016/429.

5. By way of derogation from point (b) of Article 60(1), the competent authority may authorise the movement of animals and products of animal origin from additional animal populations from the infected establishment(s) to other establishments without further restrictions provided that:

(a) a risk assessment has been completed;

(b) risk mitigating measures are implemented, where necessary, to ensure that the health status of the aquatic animals at the establishment of destination or enroute to that destination is not jeopardised; and

(c) the movement complies with the certification requirements set out in Article 208(2) of Regulation (EU) 2016/429.

Article 62

Removal of infected animals

1. Following confirmation of the disease, the competent authority shall in all infected establishments order, within a maximum period of time to be determined by the competent authority, the following measures in relation to aquatic animals from listed species for the relevant disease:

(a) removal of all dead animals;

(b) removal and killing of all moribund animals;

(c) removal and killing of all animals showing symptoms of disease;

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(d) slaughtering for human consumption, or in the case of molluscs or crustacea which are sold live, removal from the water of the animals that remain at the establishment(s) after the measures in points (a) to (c) have been completed.

2. The competent authority may order, based on duly justified grounds, the slaughtering for human consumption, or in the case of molluscs or crustacea which are sold live, removal from the water of:

(a) all animals from listed species for the relevant disease in the infected establishment(s), without testing these animals;

(b) suspected animals which have an epidemiological link with a confirmed case.

3. Slaughtering for human consumption or removal from the water of the animals referred to in paragraph 1 shall be carried out under official supervision either in the infected establishment(s) with subsequent processing in a disease control aquatic food establishment, or in a disease control aquatic food establishment, as appropriate.

4. The competent authority shall extend the measures laid down in this Article to aquaculture animals of additional animal populations when it is necessary to control the disease.

5. The competent authority may order the killing and destruction of some or all the animals referred to in paragraph 1 and animals of non-listed species in the infected establishment(s) instead of their slaughter for human consumption.

6. All animal by-products from animals that are slaughtered or killed in compliance with this Article shall be processed or disposed of as Category 1 or Category 2 material in accordance with Articles 12 or 13 of Regulation (EC) No 1069/2009.

Article 63

Cleaning and disinfection

1. The competent authority shall for all infected establishments order the cleaning and disinfection of the following structures and items prior to repopulation:

(a) the establishments, in so far as this is technically possible, after the removal of the animals referred to in Article 62(1) and of all feed that may have been contaminated;

(b) any husbandry related equipment including but not limited to feeding, grading, treatment and vaccination equipment, and workboats;

(c) any production related equipment including but not limited to cages, netting, trestles, bags and longlines;

(d) any protective clothing or safety equipment used by operators and visitors;

(e) all means of transport including tanks and other equipment used to move infected animals or personnel who have been in contact with infected animals.

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2. The competent authority shall approve the protocol for the cleaning and disinfection.

3. The competent authority shall supervise the cleaning and disinfection and shall not restore or grant again disease-free status to the establishments until it considers that the cleaning and disinfection has been completed.

Article 64

Fallowing

1. The competent authority shall order the fallowing of all infected establishments. The fallowing shall be carried out following completion of the cleaning and disinfection process laid down in Article 63.

2. The duration of the fallowing shall be appropriate to the relevant pathogen and to the type of production system used in the infected establishments. Certain fallowing periods are laid down in Part II of Annex VI, specifically in:

(a) point 1(c) of Section 3 of Chapter 1 for VHS and IHN;

(b) point 1(c) of Section 3 of Chapter 2 for infection with HPR-deleted ISAV;

(c) point 1(c) of Section 3 of Chapter 3 for infection with *Marteilia refringens*;

(d) point 1(c) of Section 3 of Chapter 4 for infection with *Bonamia exitiosa*;

(e) point 1(c) of Section 3 of Chapter 5 for infection with *Bonamia ostreae*;

(f) point 1(c) of Section 3 of Chapter 6 for infection with WSSV.

3. The competent authority shall order synchronous fallowing of the infected establishments within the protection zone or where no protection zone has been established, within the restricted zone. Synchronous fallowing may also be extended to other establishments based on risk assessment. The duration of the synchronous fallowing and the extent of the area within which such fallowing shall take place are laid down in Part II of Annex VI, specifically in:

(a) point 1 of Section 3 of Chapter 1 for VHS and IHN;

(b) point 1 of Section 3 of Chapter 2 for infection with HPR-deleted ISAV;

(c) point 1 of Section 3 of Chapter 3 for infection with *Marteilia refringens*;

(d) point 1 of Section 3 of Chapter 4 for infection with *Bonamia exitiosa*;

(e) point 1 of Section 3 of Chapter 5 for infection with *Bonamia ostreae*;

(f) point 1 of Section 3 of Chapter 6 for infection with WSSV.

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Article 65

Risk mitigating measures to prevent reinfection

Before or upon removal of the disease control measures, the competent authority shall order proportionate risk mitigating measures to prevent the reinfection of the establishment taking into account relevant risk factors as indicated by the results of the epidemiological enquiry. These measures shall at least take account of:

(a) persistence of the disease agent in the environment or in wild animals;

(b) biosecurity measures that are adapted to the specificities of the establishment.

CHAPTER 4

Disease-free status

Section 1

Approval of disease-free status of Member States and zones

Article 66

Criteria for the granting of disease-free status

Disease-free status may only be granted to Member States or zones thereof when the following general and specific criteria are complied with:

(a) general criteria:

(i) the territorial scope complies with the requirements laid down in Articles 13 or 47 as relevant;

(ii) the surveillance for the disease complies with the requirements laid down in paragraph 1 or 2 of Article 3 as relevant;

(iii) operators comply with obligations as regards biosecurity measures as laid down in Article 10 of Regulation (EU) 2016/429;

(iv) the disease control measures relevant to the disease in the event of a suspicion or confirmation of the disease comply with the requirements laid down for:

— infection with *Brucella abortus, B. melitensis* and *B. suis*, infection with MTBC, EBL, IBR/IPV, infection with ADV and BVD in Articles 21 to 31;

— infection with RABV in Articles 35 and 36;

— infection with BTV in Articles 41 and 42;

— VHS, IHN, infection with HPR-deleted ISAV, infection with *Marteilia refringens*, infection with *Bonamia exitiosa*, infection with *Bonamia ostreae* and infection with WSSV in Articles 55 to 65;

(v) the establishments were registered or approved, as relevant to the type of establishment;

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(vi) identification of animals from the targeted animal population and traceability of germinal products were ensured, as relevant for the type of animal;

(vii) when moved, the animals from the targeted animal population or products thereof complied with the animal health requirements for the movement within the Union and entry into the Union of those animals and products thereof;

(b) specific criteria for granting disease-free status based on Articles 67 to 71.

Article 67

Disease-free status based on the absence of listed species

1. The criteria to recognise the disease-free status of a Member State or of a zone because of the absence of the listed species for that disease are as follows:

(a) the general criteria laid down in point (a)(i) and (a)(ii) of Article 66 have been fulfilled for an eligibility period of at least 5 years and the disease was not detected; and

(b) the listed species relevant to the disease in question are absent from kept and wild animal populations.

2. The Member State shall provide documentary evidence to substantiate the fulfilment of the criteria in paragraph 1. The documentary evidence shall demonstrate the sustainability of disease-free status considering that:

(a) the likelihood of the presence of animals from listed species in the Member State's territory or a zone thereof was assessed and was found to be negligible; and

(b) the likelihood of introduction of animals from listed species into the Member State's territory or a zone thereof was found to be negligible.

Article 68

Disease-free status based on the disease agent's incapacity to survive

1. The criteria to recognise the disease-free status of a Member State or of a zone because of the disease agent's incapacity to survive are as follows:

(a) the general criteria laid down in points (a)(i) and (a)(ii) of Article 66 have been fulfilled for an eligibility period of at least 5 years and the disease was not detected;

(b) the disease has never been reported or, if reported, it has been demonstrated that the disease agent did not survive;

(c) the value of at least one critical environmental parameter that is not compatible with the survival of the disease agent is reached;

(d) the disease agent is exposed to that critical environmental parameter for a period of time that is sufficient to destroy it.

2. The Member State shall provide the following evidence to substantiate the fulfilment of the criteria in paragraph 1:

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(a) with respect to the fulfilment of the criteria set out in points (a) and (b) of paragraph 1, documentary evidence;

(b) with respect to the fulfilment of the criteria set out in points (c) and (d) of paragraph 1, scientific evidence.

Article 69

Disease-free status of terrestrial animals based on the incapacity to survive of listed vectors for listed diseases of terrestrial animals

1. The criteria to recognise the disease-free status of a Member State or of a zone because of the incapacity to survive of listed vectors for that listed disease are as follows:

(a) the general criteria laid down in points (a)(i) and (a)(ii) of Article 66 have been fulfilled for an eligibility period of at least 5 years and the disease was not detected;

(b) the disease has never been reported, or, if reported, it has been demonstrated that the disease agent has not been transmitted;

(c) the transmission of the disease agent is entirely dependent on the presence of listed vectors and no other mode of natural transmission is known to occur;

(d) the listed vectors are not naturally present in the Member State or zones thereof;

(e) the accidental or intentional introduction of listed vectors is unlikely to have occurred in the past or to occur in the future;

(f) the value of at least one critical environmental parameter that is not compatible with the survival of the listed vectors is reached;

(g) the listed vectors are exposed to that critical environmental parameter for a period of time that is sufficient to destroy it.

2. The Member State shall provide the following evidence to substantiate the fulfilment of the criteria in paragraph 1:

(a) with respect to the fulfilment of the criteria set out in points (a) and (b) of paragraph 1, documentary evidence;

(b) with respect to the fulfilment of the criteria set out in points (c) to (g) of paragraph 1, scientific evidence.

If the disease has occurred, the Member State shall provide documentary evidence that surveillance has demonstrated with a 95 % level of confidence that the prevalence rate of the disease was lower than 1 %.

Article 70

Disease-free status based on historical and surveillance data

1. The criteria to recognise the disease-free status of a Member State or a zone thereof based on historical and surveillance data are as follows:

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(a) the disease has never been reported in the Member State or in the zone thereof or it has been eradicated in the Member State or the zone thereof and not reported for at least 25 years;

(b) the disease has been reported in the past 25 years, it has been eradicated from the Member State or zone thereof and the disease specific requirements referred to in Article 72 are complied with.

2. A Member State wishing to obtain the approval of disease-free status for its entire territory or for a zone thereof on the basis of the provisions set out in point (a) of paragraph 1 shall have implemented the following measures for an eligibility period of at least 10 years:

(a) disease surveillance of kept animals of listed species;

(b) prevention to control the introduction of the disease agent;

(c) ban on vaccination against the disease unless it is compliant with the disease specific requirements referred to in Article 72;

(d) disease surveillance substantiating the fact that the disease is not known to be established in wild animals from listed species within the Member State or zone.

3. By way of derogation from point (b) of paragraph 1 the Commission may, for a period of two years following the entry of application of this Regulation, grant disease-free status to Member States or zones as regards:

(a) infection with RABV, if it was notifiable in accordance with Article 8 of Directive 64/432/EEC and, when necessary monitoring was implemented in accordance with Article 4 of Directive 2003/99/EC ([3]) of the European Parliament and of the Council, and no case was reported in listed animals species for the past two years;

(b) infection with BTV, if all restricted zones have been lifted in accordance with Article 6 of Regulation (EC) No 1266/2007 before the date of application of this Regulation.

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Article 71

Disease-free status based on eradication programmes

1. The criteria to recognise the disease-free status of a Member State or a zone based on eradication programmes are as follows:

([3]) Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31).

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(a) the competent authority has been running an approved eradication programme as referred to in Articles 12 or 46; and

(b) the competent authority has completed the eradication programme and submitted to the Commission an application for recognition of disease-free status that demonstrates that the disease specific requirements laid down in Article 72 are complied with.

2. By way of derogation from paragraph 1, in the case of aquatic animals where a zone covers less than 75 % of the territory of a Member State and is not shared with another Member State or third country, disease-free status may be achieved in accordance with Article 83.

Article 72

Disease specific requirements for disease-free status

Disease specific requirements for the granting of disease-free status to a Member State or to a zone are provided in:

(a) Section 1 of Chapter 3 of Part I of Annex IV for status free from infection with *Brucella abortus, B. melitensis* and *B. suis* in kept bovine animals and Section 1 of Chapter 4 of Part I of Annex IV for status free from infection with *Brucella abortus, B. melitensis* and *B. suis* in kept ovine and caprine animals;

(b) Section 1 of Chapter 2 of Part II of Annex IV for status free from infection with MTBC;

(c) Section 1 of Chapter 2 of Part III of Annex IV for status free from EBL;

(d) Section 1 of Chapter 2 of Part IV of Annex IV for status free from IBR/IPV;

(e) Section 1 of Chapter 2 of Part V of Annex IV for status free from infection with ADV;

(f) Section 1 of Chapter 2 of Part VI of Annex IV for status free from BVD;

(g) Section 1 of Chapter 2 of Part I of Annex V for status free from infection with RABV;

(h) Section 1 of Chapter 4 of Part II of Annex V for status free from infection with BTV;

(i) Section 1 of Part III of Annex V for status free from infestation with *Varroa* spp.;

(j) Section 1 of part IV of Annex V for status free from infection with Newcastle disease virus without vaccination;

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(k) Section 2 of Chapter 1 of Part II of Annex VI for status free from VHS;

(l) Section 2 of Chapter 1 of Part II of Annex VI for status free from IHN;

(m) Section 2 of Chapter 2 of Part II of Annex VI for status free from infection with HPR-deleted ISAV;

(n) Section 2 of Chapter 3 of Part II of Annex VI for status free from infection with *Marteilia refringens*;

(o) Section 2 of Chapter 4 of Part II of Annex VI for status free from infection with *Bonamia exitiosa*;

(p) Section 2 of Chapter 5 of Part II of Annex VI for status free from infection with *Bonamia ostreae*;

(q) Section 2 of Chapter 6 of Part II of Annex VI for status free from infection with WSSV.

Section 2

Approval of disease-free status for compartments keeping aquaculture animals

Article 73

Criteria for the granting of disease-free status to compartments keeping aquaculture animals

1. Disease-free status may only be granted to a compartment keeping aquaculture animals when the following general and specific criteria are complied with:

(a) general criteria:

(i) the territorial scope complies with point (c) of Article 47(2);

(ii) the surveillance for the disease complies with the requirements laid down in Articles 3(2), 4 and 6 to 9;

(iii) operators comply with obligations as regards biosecurity measures as laid down in Article 10 of Regulation (EU) 2016/429;

(iv) compliance with the disease control measures relevant to the disease in the event of a suspicion or confirmation;

(v) the establishments of which the compartment is comprised are approved;

(vi) traceability of the animals from the targeted animal population was ensured;

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(vii) when moved, the animals from the targeted animal population or products thereof complied with the animal health requirements for movement within the Union or for entry into the Union of those animals and products thereof;

(b) specific criteria for granting disease-free status based on the provisions of Articles 74 to 77.

2. The disease-free status referred to in paragraph 1 may be granted to:

(a) compartments which are independent of the health status of the surrounding natural waters; and

(b) compartments which are dependent on the health status of the surrounding natural waters but where conditions exist which create an effective disease specific separation between the compartment and other aquatic animal populations which may be infected.

3. In the case of the dependent compartments referred to in point (b) of paragraph 2, the competent authority shall:

(a) assess at least the following epidemiological factors:

(i) geographical location of each establishment in the compartment and the nature of the water supply;

(ii) health status of other aquaculture establishments in the water system;

(iii) the location of the establishments referred to in point (ii) and their distance from the dependent compartment;

(iv) production volume of the establishments referred to in point (ii) as well as their method of production and the source of their animals;

(v) presence and abundance of wild aquatic animals from relevant listed species in the water system and their health status;

(vi) details of whether the species referred to in point (v) are sedentary or migratory;

(vii) possibility of the wild aquatic animals referred to in point (v) entering the compartment;

(viii) general biosecurity measures in the compartment;

(ix) general hydrological conditions in the water system;

(b) classify all establishments in the compartment as high risk, in compliance with Chapter 1 of Part I of Annex VI;

(c) impose whatever measures are found to be necessary to prevent the introduction of disease.

4. When a disease-free declaration for a dependent compartment is made to the Commission in accordance with Article 83, the competent authority shall provide the assessment referred to in point (a) of

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paragraph 3 and details of any measure which were put in place to prevent the introduction of the disease into the compartment.

The competent authority shall communicate to the Commission without delay any subsequent changes to the epidemiological factors set out in point (a) of paragraph 3 and measures taken to mitigate their impact.

Article 74

Disease-free status based on the absence of listed species

1. The criteria to recognise the disease-free status of a compartment keeping aquaculture animals because of the absence of the listed species for that disease are as follows:

(a) the general criteria laid down in points (a)(i) and (a)(ii) of Article 73(1) have been fulfilled for an eligibility period of at least 5 years and the disease was not detected; and

(b) the listed species relevant to the disease in question are absent from kept and wild animal populations.

2. The Member State shall provide documentary evidence to substantiate the fulfilment of the criteria in paragraph 1. The documentary evidence shall demonstrate the sustainability of the disease-free status considering that:

(a) the likelihood of the presence of animals from listed species in the compartment was assessed and found to be negligible; and

(b) the likelihood of introduction of animals from listed species into the compartment was found to be negligible.

Article 75

Disease-free status based on the disease agent's incapacity to survive

1. The criteria to recognise the disease-free status of a compartment keeping aquaculture animals because of the disease agent's incapacity to survive are as follows:

(a) the general criteria laid down in points (a)(i) and (a)(ii) of Article 73(1) have been fulfilled for an eligibility period of at least 5 years and the disease was not detected;

(b) the disease has never been reported or if reported, it has been demonstrated that the disease agent did not survive;

(c) the value of at least one critical environmental parameter that is not compatible with the survival of the disease agent is reached;

(d) the disease agent is exposed to that critical parameter during a sufficient period of time to destroy it.

2. The Member State shall provide the following evidence to substantiate the fulfilment of the criteria in paragraph 1:

(a) with respect to the fulfilment of the criteria set out in points (a) and (b) of paragraph 1, documentary evidence;

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(b) with respect to the fulfilment of the criteria set out in points (c) and (d) of paragraph 1, scientific evidence.

Article 76

Disease-free status based on historical and surveillance data

1. The criteria to recognise the disease-free status of a compartment keeping aquaculture animals based on historical and surveillance data are as follows:

(a) the disease has never been reported in the compartment or it has been eradicated in the compartment and not reported for at least 25 years;

(b) the disease has been reported in the past 25 years, it has been eradicated from the compartment and the disease specific requirements referred to in Article 78 are complied with.

2. A Member State wishing to obtain the approval of disease-free status for the compartment on the basis of the provisions set out in point (a) of paragraph 1 shall have implemented the following measures for an eligibility period of at least 10 years:

(a) disease surveillance of kept animals of listed species;

(b) prevention to control the introduction of the disease agent;

(c) ban on vaccination against the disease unless it is compliant with the disease specific requirements referred to in Article 78;

(d) disease surveillance substantiating the fact that the disease is not known to be established in wild animals from listed species within the compartment.

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Article 77

Disease-free status based on eradication programmes

1. The criteria to recognise the disease-free status of a compartment keeping aquaculture animals based on eradication programmes are:

(a) the competent authority has been running an approved eradication programme as referred to in Article 46; and

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(b) the competent authority has completed the eradication programme and submitted to the Commission the final report that demonstrates that the disease specific requirements laid down in Article 78 are complied with.

2. By way of derogation from paragraph 1, where a compartment covers less than 75 % of the territory of a Member State and the water catchment supplying the compartment is not shared with another Member State or third country, disease-free status may be achieved in accordance with Article 83.

Article 78

Disease specific requirements for disease-free status

Disease-specific requirements for the granting of disease-free status to a compartment keeping aquaculture animals are provided in:

(a) Section 2 of Chapter 1 of Part II of Annex VI for status free from VHS;

(b) Section 2 of Chapter 1 of Part II of Annex VI for status free from IHN;

(c) Section 2 of Chapter 2 of Part II of Annex VI for status free from infection with HPR-deleted ISAV;

(d) Section 2 of Chapter 3 of Part II of Annex VI for status free from infection with *Marteilia refringens*;

(e) Section 2 of Chapter 4 of Part II of Annex VI for status free from infection with *Bonamia exitiosa*;

(f) Section 2 of Chapter 5 of Part II of Annex VI for status free from infection with *Bonamia ostreae*;

(g) Section 2 of Chapter 6 of Part II of Annex VI for status free from infection with WSSV.

Article 79

Specific requirements for compartments which are independent of the health status of the surrounding natural waters

1. In addition to the general criteria for granting disease-free status to compartments keeping aquaculture animals as set out in Article 73(1), a compartment which comprises one or more individual establishments where the health status regarding a specific disease is independent of the health status of the surrounding natural waters, may obtain disease-free status if it complies with paragraphs 2 to 6.

2. An independent compartment may comprise:

(a) an individual establishment which is considered a single epidemiological unit, as it is not influenced by the animal health status of the surrounding natural waters; or

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(b) more than one establishment where each establishment in the compartment complies with the criteria laid down in point (a) of this paragraph and paragraphs 3 to 6 but due to extensive movements of animals between establishments, they are considered as a single epidemiological unit, provided that all establishments operate a common biosecurity system.

3. An independent compartment shall be supplied with water:

(a) through a water treatment plant which inactivates the relevant disease agent; or

(b) directly from a well, a borehole or a spring.

Where such water supply originates from a source outside the establishment, the water shall be supplied directly to the establishment, and be channelled to the establishment by means which afford appropriate protection from infection.

4. There shall be natural or artificial barriers that prevent aquatic animals from entering each establishment in the compartment from the surrounding natural waters.

5. The compartment shall, where appropriate, be protected against flooding and infiltration of water from the surrounding natural waters.

6. The compartment shall comply with the disease-specific requirements referred to in Article 78.

Article 80

Special provisions for compartments which comprise individual establishments which commence or recommence aquaculture activities and where the health status regarding a specific disease is independent of the health status of the surrounding natural waters

1. A new establishment which is to commence aquaculture activities is considered to be disease-free when:

(a) it complies with point (a) of paragraph 2 and paragraphs 3 to 5 of Article 79; and

(b) it commences aquaculture activities with aquaculture animals from a disease-free Member State, zone or compartment.

2. An establishment which recommences aquaculture activities after a break and complies with paragraph 1 is considered to be disease-free without the surveillance referred to in point (a)(ii) of Article 73(1) provided:

(a) the health history of the establishment is known to the competent authority and there has been no confirmation in the establishment of a category B or category C disease;

(b) the establishment is cleaned, disinfected and fallowed, if necessary, prior to repopulation.

3. An establishment which recommences its activities after the confirmation of a category B or category C disease is considered to be disease-free from the confirmed disease, provided:

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(a) a representative sample of the animals which have been repopulated into the establishment from a disease-free Member State, zone or compartment following cleaning, disinfection and fallowing is tested for the relevant disease no sooner than 3 months and no later than 12 months after they have been exposed to conditions including water temperature, which are conducive to clinical expression of the disease;

(b) the sampling and diagnostic tests set out in the relevant Chapter of Part II of Annex VI are used and samples are taken from the number of animals that will ensure the detection of the relevant disease with a 95 % confidence if the targeted prevalence is 2 %;

(c) results of the testing described in point (b) are negative.

Section 3

Maintenance, suspension and withdrawal of disease-free status

Article 81

Specific criteria on surveillance and biosecurity measures for the maintenance of disease-free status

1. The Member States, zones or compartments thereof may maintain disease-free status only if, in addition to the criteria laid down in points (a) and (c) of Article 41(1) of Regulation (EU) 2016/429, they comply with:

(a) the undertaking of sufficient surveillance activities to enable the early detection of the disease and the demonstration of disease-free status;

(b) the biosecurity measures ordered by the competent authority based on the risks identified to prevent the introduction of the disease;

(c) the operational rules as referred to in points (a)(v), a(vi) and a(vii) of Article 66 or points (a)(v), a(vi) and a(vii) of Article 73(1).

2. In the case of aquatic animals, when a Member State is declared free from one or more of the listed diseases, it may discontinue targeted surveillance as referred to in points (k) to (q) of paragraph 3 and maintain its disease-free status provided that the risk of introduction of the relevant disease has been assessed and conditions conducive to clinical expression of the disease in question exist.

In disease-free zones or compartments in Member States which are not declared disease-free, or in all cases where conditions conducive to clinical expression of the disease in question do not exist, targeted surveillance shall be continued as referred to in points (k) to (q) of paragraph 3.

3. The disease specific requirements as regards surveillance and biosecurity measures are provided in:

(a) Section 2 of Chapter 3 of Part I of Annex IV for status free from infection with *Brucella abortus, B. melitensis* and *B. suis* as regards kept bovine animals or Section 2 of Chapter 4 of Part I of

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Annex IV for status free from infection with *Brucella abortus, B. melitensis* and *B. suis* as regards kept ovine and caprine animals;

(b) Section 2 of Chapter 2 of Part II of Annex IV for status free from infection with MTBC;

(c) Section 2 of Chapter 2 of Part III of Annex IV for status free from EBL;

(d) Section 2 of Chapter 2 of Part IV of Annex IV for status free from IBR/IPV;

(e) Section 2 of Chapter 2 of Part V of Annex IV for status free from infection with ADV;

(f) Section 2 of Chapter 2 of Part VI of Annex IV for status free from BVD;

(g) Section 2 of Chapter 2 of Part I of Annex V for status free from infection with RABV;

(h) Section 2 of Chapter 4 of Part II of Annex V for status free from infection with BTV;

(i) Section 2 of Part III of Annex V for status free from infestation with *Varroa* spp;

(j) Section 2 of Part IV of Annex V for status free from infection with Newcastle disease virus without vaccination;

(k) Section 4 of Chapter 1 of Part II of Annex VI for status free from VHS;

(l) Section 4 of Chapter 1 of Part II of Annex VI for status free from IHN;

(m) Section 4 of Chapter 2 of Part II of Annex VI for status free from infection with HPR-deleted ISAV;

(n) Section 4 of Chapter 3 of Part II of Annex VI for status free from infection with *Marteilia refringens*;

(o) Section 4 of Chapter 4 of Part II of Annex VI for status free from infection with *Bonamia exitiosa*;

(p) Section 4 of Chapter 5 of Part II of Annex VI for status free from infection with *Bonamia ostreae*;

(q) Section 4 of Chapter 6 of Part II of Annex VI for status free from infection with WSSV.

Article 82

Suspension, withdrawal and restoration of disease-free status

1. If the disease has been confirmed and therefore the conditions for maintaining the disease-free status of a Member State, a zone or compartment thereof are not fulfilled, the competent authority shall:

(a) apply without delay the relevant disease control measures;

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(b) conduct specific surveillance to assess the extent of the outbreak;

(c) order any necessary risk mitigating measures.

2. If the disease has not been confirmed, but there has been a breach of one of the conditions for maintaining the disease-free status of a Member State, a zone or compartment thereof, the competent authority shall take the appropriate corrective measures and assess the risk that the health situation has changed.

3. The competent authority may where necessary, as a transitional measure, suspend the disease-free status of the Member State, a zone or compartment thereof rather than the Commission withdrawing the disease-free status. During that suspension, the competent authority shall:

(a) adopt all necessary prevention, surveillance and control measures to manage the situation;

(b) inform without delay the Commission and the other Member States about the measures adopted; and

(c) inform regularly the Commission and the other Member States about the evolution of the situation, of its position as regards the restoration of the disease-free status, the prolongation of its suspension or its withdrawal by the Commission.

4. Subject to compliance with the provisions of paragraph 3 the competent authority may restore the disease-free status of the Member State, zone or compartment thereof by lifting the suspension.

Section 4

Derogations from approval by the Commission

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Article 83

Derogations from approval by the Commission for certain disease-free statuses and certain eradication programmes for aquatic animal diseases

1. By way of derogation from the requirement to submit eradication programmes to the Commission for approval as provided for in Article 31(1)(b) and Article 31(2) of Regulation (EU) 2016/429 or from the requirements to obtain approval by the Commission for disease-free status laid down in Article 36(4) and 37(4) of that Regulation, for aquatic animal diseases, such approval for zones or compartments which cover less than 75 % of the territory of a Member State, and where the water catchment supplying the zone or compartment is not shared with another Member State or third country, shall be gained in accordance with the following procedure:

(a) a Member State makes a provisional declaration of freedom or of the establishment of an eradication programme for the zone or compartment, which fulfils the requirements as set out in this Regulation;

(b) this provisional declaration is published electronically by the Member State, and the Commission and Member States are alerted to the publication;

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(c) 60 days after publication, the provisional declaration shall take effect and the zone or compartment referred to in this paragraph shall achieve disease-free status or have the eradication programme approved.

2. Within the 60-day period referred to in point (c) of paragraph 1, the Commission or Member States may seek clarification or additional information in relation to the supporting evidence provided by the Member State making the provisional declaration.

3. Where written comments are made by at least one Member State, or the Commission, within the period referred to in point (c) of paragraph 1 indicating concerns relating to the evidence which supports the declaration, the Commission, the Member State which made the declaration and where relevant, the Member State which has sought clarification or additional information, shall together examine the submitted evidence in order to resolve the concerns.

In such cases, the period referred to in point (c) of paragraph 1 shall be prolonged automatically for 60 days from the date on which the first concerns were raised. There shall be no further prolongation of this period.

4. Where the process referred to in paragraph 3 fails, the provisions laid down in Articles 31(3), 36(4) and 37(4) of Regulation (EU) 2016/429 shall apply.

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PART III

TRANSITIONAL AND FINAL PROVISIONS

Article 84

Transitional provisions concerning existing disease-free status

1. The Member States and zones thereof with an approved disease-free status before the date of application of this Regulation shall be deemed to have an approved disease-free status in accordance with this Regulation for the following statuses:

(a) free from infection with *Brucella abortus, B. melitensis, B.suis*:

(i) in bovine animal populations when the brucellosis-free status was granted in accordance with Directive 64/432/EEC;

(ii) in ovine and caprine animal populations, when the brucellosis-free (*B. melitensis*-free) status was granted in accordance with Directive 91/68/EEC;

(b) free from infection with MTBC, when the tuberculosis-free status was granted in accordance with Directive 64/432/EEC;

(c) free from EBL, when EBL-free status was granted in accordance with Directive 64/432/EEC;

(d) free from IBR/IPV, when IBR-free status was granted in accordance with Directive 64/432/EEC;

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(e) free from infection with ADV, when Aujeszky's disease-free-status was granted in accordance with Directive 64/432/EEC;

(f) free from infestation with *Varroa* spp., when *varroasis*-free status was granted in accordance with Council Directive 92/65/EEC ([4]);

(g) free from infection with Newcastle disease virus without vaccination when Newcastle disease non-vaccination status was granted in accordance with Directive 2009/158/EC;

(h) free from VHS, when VHS-free status was granted in accordance with Council Directive 2006/88/EC ([5]);

(i) free from IHN, when IHN-free status was granted in accordance with Directive 2006/88/EC;

(j) free from infection with HPR-deleted ISAV, when infection with HPR-deleted ISAV-free status was granted in accordance with Directive 2006/88/EC;

(k) free from infection with *Bonamia ostreae*, when infection with *Bonamia ostreae*-free status was granted in accordance with Directive 2006/88/EC;

(l) free from infection with *Marteilia refringens*, when infection with *Marteilia refringens*-free status was granted in accordance with Directive 2006/88/EC;

(m) free from infection with WSSV, when white spot disease–free status was granted in accordance with Directive 2006/88/EC.

2. The compartments in Member States with an approved disease-free status before the date of application of this Regulation shall be deemed to have an approved disease-free status in accordance with this Regulation for the following statuses:

(a) free from highly pathogenic avian influenza, when the compartment has been approved with respect to avian influenza in accordance with Commission Regulation (EC) No 616/2009 ([6]);

(b) free from VHS, when VHS-free status was granted in accordance with Directive 2006/88/EC;

(c) free from IHN, when IHN-free status was granted in accordance with Directive 2006/88/EC;

([4]) Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).

([5]) Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14).

([6]) Commission Regulation (EC) No 616/2009 of 13 July 2009 implementing Council Directive 2005/94/EC as regards the approval of poultry compartments and other captive birds compartments with respect to avian influenza and additional preventive biosecurity measures in such compartments (OJ L 181, 14.7.2009, p. 16).

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(d) free from infection with HPR-deleted ISAV, when infection with HPR-deleted ISAV-free status was granted in accordance with Directive 2006/88/EC;

(e) free from infection with *Bonamia ostreae*, when infection with *Bonamia ostreae*-free status was granted in accordance with Directive 2006/88/EC;

(f) free from infection with *Marteilia refringens*, when infection with *Marteilia refringens*-free status was granted in accordance with Directive 2006/88/EC;

(g) free from infection with WSSV, when white spot disease–free status was granted in accordance with Directive 2006/88/EC.

3. The Member States deemed to have an approved disease-free status in accordance with paragraph 1 or 2 shall ensure that the conditions of maintenance of the status conform with those laid down in this Regulation.

Article 85

Transitional provisions concerning existing eradication or surveillance programmes

1. The Member States and zones thereof with an approved eradication programme or an approved surveillance programme before the date of application of this Regulation shall be deemed to have an approved eradication programme in accordance with this Regulation for the following diseases for a period of six years from the date of application of this Regulation:

(a) IBR/IPV, when the IBR/IPV eradication programme was approved in accordance with Directive 64/432/EEC;

(b) infection with ADV, when the Aujeszky's disease eradication programme was approved in accordance with Directive 64/432/EEC;

(c) VHS, when the VHS surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;

(d) IHN, when the IHN surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;

(e) infection with HPR-deleted ISAV, when the infection with HPR-deleted ISAV surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;

(f) infection with *Bonamia ostreae*, when the infection with *Bonamia ostreae* surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;

(g) infection with *Marteilia refringens*, when the infection with *Marteilia refringens* surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;

(h) infection with WSSV, when the white spot disease eradication programme was approved in accordance with Directive 2006/88/EC.

2. The compartments in Member States with an approved eradication programme or an approved surveillance programme before the date of application of this Regulation shall be deemed to have an approved eradication programme in accordance with this Regulation for the following diseases for a period of six years from the date of application of this Regulation:

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(a) VHS, when the VHS surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;

(b) IHN, when the IHN surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;

(c) infection with HPR-deleted ISAV, when the infection with HPR-deleted ISAV surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;

(d) infection with *Bonamia ostreae*, when the infection with *Bonamia ostreae* surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;

(e) infection with *Marteilia refringens*, when the infection with *Marteilia refringens* surveillance *or* eradication programme was approved in accordance with Directive 2006/88/EC;

(f) infection with WSSV, when the white spot disease surveillance or eradication programme was approved in accordance with Directive 2006/88/EC.

3. The Member States deemed to have an approved eradication programme in accordance with paragraphs 1 or 2 shall ensure that the measures in the programme conform with those laid down for eradication programmes in this Regulation.

Article 86

Repeal

The following acts are repealed as from 21 April 2021:

— Decision 2000/428/EC;

— Decision 2002/106/EC;

— Decision 2003/422/EC;

— Decision 2006/437/EC;

— Regulation (EC) No 1266/2007;

— Decision 2008/896/EC;

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— Decision 2010/367/EU;

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— Implementing Decision (EU) 2015/1554.

References to those repealed acts shall be construed as references to this Regulation.

Article 87

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 21 April 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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ANNEX I

SPECIFIC CASE DEFINITION OF DISEASE OF TERRESTRIAL ANIMALS

Section 1

Highly pathogenic avian influenza (HPAI)

1. An animal or a group of animals must be considered, by the competent authority, as a suspected case of HPAI when it meets the criteria laid down in Article 9(1).

2. An animal or a group of animals must be considered, by the competent authority, as a confirmed case of HPAI when:

   (a) the disease agent responsible for HPAI, excluding vaccine strains, has been isolated in a sample from an animal or from a group of animals;

   (b) nucleic acid specific to the disease agent for HPAI, that is not a consequence of vaccination, has been identified in a sample from an animal or from a group of animals; or

   (c) positive result to an indirect diagnostic method, that is not a consequence of vaccination, has been obtained in a sample from a kept animal or from a group of kept animals showing clinical signs consistent with the disease or epidemiologically linked to a suspected or confirmed case.

3. For the purposes of this case definition, the disease agent responsible for HPAI must be either

   (a) an influenza A virus of H5 and H7 subtypes or any influenza A virus with an intravenous pathogenicity index (IVPI) greater than 1,2; or

   (b) an influenza A virus of H5 and H7 subtypes with a sequence of multiple basic amino acids present at the cleavage site of the haemagglutinin molecule (HA0) that is similar to that observed for other HPAI isolates.

Section 2

Infection with low pathogenic avian influenza viruses (LPAIV)

1. An animal or a group of animals must be considered, by the competent authority, as a suspected case of infection with LPAIV when it meets the criteria laid down in Article 9(1).

2. An animal or a group of animals must be considered, by the competent authority, as a confirmed case of infection with LPAIV when:

   (a) the disease agent responsible for infection with LPAIV, excluding vaccine strains, has been isolated in a sample from an animal or from a group of animals;

   (b) nucleic acid specific to the disease agent for infection with LPAIV, that is not a consequence of vaccination, has been identified in a sample from an animal or from a group of animals; or

   (c) positive result to an indirect diagnostic method, that is not a consequence of vaccination, has been obtained in a sample from a kept animal or from a group of kept animals showing clinical signs consistent with the disease or epidemiologically linked to a suspected or confirmed case.

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3. For the purposes of this case definition, the disease agent of infection with LPAIV must be any influenza A virus of H5 and H7 subtypes that are not HPAI viruses.

Section 3

Infection with Newcastle disease virus (NDV)

1. An animal or a group of animals must be considered, by the competent authority, as a suspected case of infection with NDV when it meets the criteria laid down in Article 9(1).

2. An animal or a group of animals must be considered, by the competent authority, as a confirmed case of infection with NDV when:

   (a) the disease agent responsible for infection with NDV, excluding vaccine strains, has been isolated in a sample from an animal or from a group of animals;

   (b) nucleic acid specific to the disease agent for infection with NDV, that is not a consequence of vaccination, has been identified in a sample from an animal or from a group of animals; or

   (c) positive result to an indirect diagnostic method, that is not a consequence of vaccination, has been obtained in a sample from a kept animal or from a group of kept animals showing clinical signs consistent with the disease or epidemiologically linked to a suspected or confirmed case.

3. For the purposes of this case definition, the disease agent responsible for infection with NDV must be any avian paramyxovirus type 1 (APMV-1) (avian *Avulavirus* type 1) that either:

   (a) has an intracerebral pathogenicity index (ICPI) of 0,7 or greater; or

   (b) presents multiple basic amino acids at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term ‘multiple basic amino acids’ refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the characteristic pattern of amino acid residues as described above would require characterisation of the isolated virus by an ICPI test. In this definition, amino acid residues are numbered from the N-terminus of the amino acid sequence deduced from the nucleotide sequence of the F0 gene (113–116 corresponds to residues –4 to –1 from the cleavage site).

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ANNEX II

UNION SURVEILLANCE PROGRAMME

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PART I

AVIAN INFLUENZA SURVEILLANCE IN ANIMALS

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Section 1

General approach and requirements

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1. TERRITORIAL SCOPE

Surveillance must be implemented in all Member States.

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2. PERIOD OF APPLICATION

Until revoked.

3. GENERAL APPROACH

The surveillance system must address the objectives provided for in Section 2 and must be built on a comprehensive approach including different components of surveillance activities complementing each other in poultry and wild bird populations:

— Early detection systems as provided for in Sections 3 and 4;

— Risk-based surveillance as provided for in Sections 5 and 6.

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Section 2

Objectives for Surveillance

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1. Early detection of highly pathogenic avian influenza (HPAI) in poultry.

2. Early detection of HPAI in wild birds providing for:

(a) an early warning for possible HPAI introduction into poultry, in particular when viruses enter the Union through migratory movements of wild birds;

(b) information for the assessment of risks for virus spread following findings of HPAI in wild birds.

3. Detection of HPAI in poultry species which generally do not show significant clinical signs.

4. Detection of circulating low pathogenic avian influenza viruses (LPAIV) that may easily spread between poultry flocks in particular in areas with a high density of poultry establishments in view of their potential to mutate to HPAI in order to:

(a) identify clusters of infection with LPAIV; and

(b) monitor the risk of spread of LPAIV by movements of poultry and by fomites in certain production systems at risk.

5. Contribution to increased knowledge on HPAI and LPAIV posing a potential zoonotic risk.

Section 3

Early detection of HPAI in poultry

1. The early detection systems for of HPAI in poultry must be part of the general surveillance requirements as provided for in point (a) of Article 3(1) and must be implemented throughout the poultry sector.

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2. The surveillance referred to in point 1 must at least include the early detection and investigation in establishments located in an area identified as being at heightened risk for HPAI introduction and spread, of:

   (a) any change in normal production and health parameters such as mortality rate, feed and water intake and egg production; and

   (b) any clinical sign or post-mortem lesion suggesting HPAI.

3. Regular testing of samples collected from dead and sick poultry in establishments located in an area identified as being at heightened risk for HPAI introduction and spread may also be relevant when an increased risk has been identified at national, EU or regional level due to outbreaks of HPAI in poultry and/or wild birds.

Section 4

Early detection of HPAI in wild birds

1. The early detection of HPAI in wild birds must be based on sampling and testing of birds that have been:

   (a) found dead;

   (b) found injured or sick;

   (c) hunted with clinical signs.

   This surveillance may need to be increased, when HPAI has been detected in wild birds, by monitoring systems using organised patrols for detecting and collecting dead and sick birds.

2. The design of this surveillance must be risk-based, taking into account at least relevant information on ornithology, virology, epidemiology and environmental matters.

3. The surveillance must apply to birds from targeted wild bird species, as provided for in Section 8. However, all suspected episodes of mortality in wild birds must be investigated to exclude HPAI.

   In addition to targeted wild bird species, additional wild bird species may also be included when their specific epidemiological relevance on the Member State's territory has been assessed.

4. In addition, the surveillance may include, at priority locations and key sites in particular those where birds of targeted wild birds species are entering the Union during their migratory movements, at least from North-East and Eastern routes, the sampling and testing of:

   (a) birds trapped;

   (b) hunted healthy birds;

   (c) sentinel birds.

5. Additional sources of information obtained from investigations of wild birds in the context of HPAI outbreaks in kept birds must be included in the results of the surveillance of HPAI in wild birds.

Section 5

Risk-based complementary surveillance for HPAI in poultry species which generally do not show significant clinical signs

1. The risk-based surveillance for infection with HPAI in poultry establishments keeping ducks, geese, poultry belonging to the species of *Anseriformes* for

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supplies of game or quails to be released into the wild must take into account at least the following risk factors:

(a) the historical and current epidemiological situation of the disease and its evolution over time in poultry and wild birds;

(b) the proximity of establishments to water bodies and other places where migratory birds, in particular water birds, may gather in higher numbers or have their stop-over places during their movements into and through the Union;

(c) the period of increased movements of migratory wild birds of targeted species into and through the Union;

(d) the structure of poultry farming including the broader sector involved in the different production systems;

(e) the geographical location of the establishments in an area with a high density of poultry;

(f) the biosecurity practices on the establishments;

(g) the type and frequency of movements of poultry, products and vehicles transporting poultry and trade patterns; and

(h) the risk assessments and scientific advice in relation to the relevance of the spread of HPAI by wild birds.

2. Based on scientific justifications, additional risk factors than those listed in points (a) to (h) of point 1 may be included and factors that are not relevant for the specific situation of the Member State may be omitted.

Section 6

risk-based surveillance in order to identify clusters of establishments infected with lpaiv and with continuous spread of LPAIV

1. The risk-based surveillance for the detection of circulating low pathogenic avian influenza viruses (LPAIV) that may easily spread between poultry flocks in particular in areas with a high density of poultry establishments, as referred to in point 4 of Section 2, must apply to poultry establishments for which the competent authority has assessed that clusters of infection with LPAIV have repeatedly occurred in the past or are deemed more likely to occur.

2. Such clusters are characterised by infection with LPAIV of groups of establishments related in time and geographical proximity.

3. The assessment for the selection of establishments for targeted surveillance must take into account the risk for lateral transmission of the virus due to the structure and complexity of the production system and functional connections between establishments, in particular when operating in areas with a high density of establishments.

4. In addition to the selection criteria for targeted surveillance of establishments referred to in point 3, the following risk factors must be taken into account at the establishment level:

(a) the kept species;

(b) the cycle and duration of production;

(c) presence of several poultry species;

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(d) presence of multi-age poultry flocks;

(e) presence of long-lived poultry;

(f) practice of all-in all-out principle;

(g) length of waiting period between batches; and

(h) biosecurity practices and housing conditions.

Section 7

Targeted poultry populations

1. Early detection systems for infection with HPAI referred to in Section 3 must apply to all poultry populations.

2. Complementary surveillance for infection with HPAI referred to in Section 5 in poultry species that do generally not display significant signs when infected with HPAI must apply to:

(a) breeding ducks

(b) breeding geese;

(c) fattening ducks;

(d) fattening geese;

(e) quails;

(f) poultry of species belonging to *Anseriformes* for supplies of game to be released into the wild.

3. In addition to the species and categories listed under point 2 the targeting of sampling and testing for infection with LPAIV referred to in Section 6 may apply to the following poultry species and production categories:

(a) laying hens including those kept in free-range;

(b) breeding turkeys;

(c) fattening turkeys;

(d) the poultry of species belonging to *Galliformes* for supplies of game to be released into the wild.

Section 8

Targeted Wild bird populations

Targeted wild birds species, in particular migratory water birds have shown to be at higher risk of becoming infected with, and transmitting HPAI.

The list of ‘wild bird targeted species’ compiled and updated in the light of the most recent knowledge is available on the website of the EURL.

Section 9

Sampling and laboratory testing methods

1. The number of poultry establishments to be sampled and the number of poultry to be tested per establishment and, as appropriate, by epidemiological unit (e.g. poultry flock, shed, etc.) on the concerned establishment must be based on a statistically valid sampling method. This method may be that used for representative sampling; i.e. an estimated prevalence to be detected according to a pre-defined level of confidence determined by the competent authority.

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2. Frequency and period for testing:

   (a) the frequency for sampling and testing of poultry establishments must be determined based on the outcome of a risk assessment by the competent authority;

   (b) the time period for sampling must coincide with seasonal production for each production category, but must not compromise the risk-based surveillance approach;

   (c) when relevant, the time period for sampling must take into account the period of heightened risk as referred to in point 3 of Section 3. Samples must be subjected to laboratory testing by virological methods, when taken for:

      (i) early detection of HPAI in poultry referred to in Section 3;

      (ii) early detection of HPAI in wild birds referred to in Section 4;

      (iii) complementary surveillance for HPAI in poultry species which generally do not show significant clinical signs of HPAI referred to in Section 5;

      (iv) follow-up of sero-positive findings referred to in point 4(b).

   For virological testing the prevalence and time window for detection of active infection must be taken into account.

3. Samples must be subjected to laboratory testing by serological methods, when taken for:

   (a) complementary surveillance for HPAI in poultry species which generally do not show significant clinical signs of HPAI referred to in Section 5 supplementing virological testing, as appropriate;

   (b) detection of clusters of LPAIV infected establishments referred to in Section 6. When for technical reasons or other duly justified reasons sampling for serology is not appropriate, virological testing must be performed.

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Section 10

Surveillance in species that are not listed for HPAI

HPAI surveillance must include surveillance activities in kept and wild animals of species not listed when the epidemiological situation indicates that those species may constitute a risk for animal and human health.

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ANNEX III

DIAGNOSTIC METHODS FOR THE GRANTING AND MAINTENANCE OF DISEASE-FREE STATUS FOR CERTAIN DISEASES OF TERRESTRIAL ANIMALS

Section 1

Infection with *Brucella abortus*, *B. melitensis* and *B. suis*

1. Serological tests

   (a) tests for blood samples

      (i) buffered *Brucella* antigen tests;

      (ii) complement fixation test (CFT)

      (iii) indirect enzyme-linked immunosorbent assay (I-ELISA)

      (iv) fluorescence polarisation assay (FPA)

      (v) competitive enzyme-linked immunosorbent assay (C-ELISA)

   (b) tests for milk samples

      (i) ring test (MRT)

      (ii) I-ELISA

2. Brucellin skin test (BST)

   For the testing as referred to in section 1 and 2 of Chapter 1 of Part I of Annex IV, Brucellin skin test (BST) shall only be used in ovine and caprine animals.

Section 2

Infection with mycobacterium tuberculosis complex

1. Tuberculin skin tests

   (a) the single intradermal tuberculin test (SITT)

   (b) the comparative intradermal tuberculin test (CITT)

2. Gamma-interferon assay

Section 3

Enzootic bovine leukosis

1. Serological tests

   (a) tests for blood samples

      (i) agar gel immuno-diffusion test (AGID)

      (ii) blocking enzyme-linked immunosorbent assay (B-ELISA)

      (iii) I-ELISA

   (b) tests for milk samples

      (i) I-ELISA

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Section 4

Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (IBR/IPV)

	Methods:	Matrix:
non-vaccinated bovine animals	BoHV-1 I-ELISA [a]	individual serum samples [d]
		milk samples
	gB B-ELISA [b]	individual serum samples [d]
		individual meat juice samples
DIVA vaccinated bovine animals with a gE-deleted vaccine	gE B-ELISA [c]	individual serum samples
		individual meat juice samples

[a] I-ELISA for the detection of antibodies against BoHV-1 whole virus. Pools of up to 50 milk samples (individual or bulk milk) may be used in tests for granting and up to 100 milk samples (individual or bulk milk) may be used in tests for the maintenance of the status free from IBR/IPV.

[b] B-ELISA for the detection of antibodies against BoHV-1-gB protein. When referred to tests for the detection of antibodies against whole BoHV-1 in Part IV of Annex IV this method may also be used.

[c] B-ELISA for the detection of antibodies against BoHV-1-gE protein. Individual milk samples may be used when testing to proof the maintenance of the status free from IBR/IPV. The samples may be pooled whereat the number of samples per pool may be chosen based on documented evidence that the test is under all circumstances of day to day laboratory work sensitive enough to detect one single positive sample in the pool.

[d] When testing is carried out to proof the maintenance of the status free from IBR/IPV individually collected samples may be pooled. The number of samples per pool may be modulated based on documented evidence that the test system is under all circumstances of day to day laboratory work sensitive enough to detect one weak positive sample in the pool of the modulated size.

Section 5

Infection with Aujeszky's disease virus (ADV)

	Methods:	Matrix:
non-vaccinated porcine animals	ADV ELISA [a]	individual or up to 5 pooled serum (or plasma) samples
		individual or up to 5 pooled filter paper samples
		individual meat juice samples
DIVA vaccinated porcine animals with a gE-deleted vaccine	gE ELISA [b]	individual serum samples

[a] ELISA for the detection of antibodies against whole ADV, ADV-gB protein or ADV-gD protein. For batch control of ADV-gB kits and ADV-gD kits or whole ADV kits, Community reference serum ADV 1, or sub-standards, must be scored positive at the dilution of 1:2. When referred to tests for the detection of whole ADV in Part V of Annex IV either of these tests may be used.

[b] ELISA for the detection of antibodies against ADV-gE protein. For batch control, Community reference serum ADV 1, or sub-standards, must be scored positive at the dilution 1:8.

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Section 6

Bovine viral diarrhoea (BVD)

1. Direct methods:
   (a) Real-time reverse transcription PCR
   (b) BVDV antigen detection ELISA
2. Serological tests:
   (a) I-ELISA
   (b) B-ELISA

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ANNEX IV

DISEASE-SPECIFIC REQUIREMENTS FOR THE GRANTING, MAINTENANCE, SUSPENSION AND WITHDRAWAL OF THE DISEASE-FREE STATUS AT THE LEVEL OF ESTABLISHMENTS AND DISEASE-SPECIFIC REQUIREMENTS FOR THE GRANTING AND MAINTENANCE OF THE DISEASE-FREE STATUS AT THE LEVEL OF MEMBER STATES OR ZONES

PART I

INFECTION WITH *BRUCELLA ABORTUS, B. MELITENSIS* AND *B. SUIS*

CHAPTER 1

Establishment free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination

Section 1

Granting of the status

1. The status free from infection with *Brucella abortus, B. melitensis* and *B. suis* without vaccination may only be granted to an establishment keeping bovine, ovine or caprine animals if:

(a) during the past 12 months there has been no confirmed case of infection with *Brucella abortus, B. melitensis* and *B. suis* in bovine, ovine or caprine animals kept in the establishment;

(b) during the past 3 years none of the bovine, ovine or caprine animals in the establishment has been vaccinated against infection with *Brucella abortus*, *B. melitensis* and *B. suis*;

(c) the entire bovine animals over 12 months of age and the entire ovine or caprine animals over 6 months of age present in the establishment at the time of sampling have tested negative to serological test, on two occasions as follows:

(i) the first test must be carried out on samples taken not earlier than 3 months after the removal of the last confirmed case and of the last animal that tested positive in an immunological test;

(ii) the second test must be carried out on samples taken not earlier than 6 months and not later than 12 months following the date of sampling referred to in point (i);

(d) animals showing clinical signs consistent with infection with *Brucella abortus*, *B. melitensis* and *B. suis*, such as abortions, have been subjected to investigations with negative results;

(e) since the beginning of the sampling referred to in point (c)(i) all bovine, ovine or caprine animals introduced into the establishment originate from establishments free from infection with *Brucella abortus, B. melitensis* and *B. suis* without vaccination, or free with vaccination and have not been vaccinated against infection with *Brucella abortus*, *B. melitensis* and *B. suis* during the past 3 years, and

(i) originate from a Member State or a zone free from infection with *Brucella abortus, B. melitensis* and *B. suis* for the relevant animal population;

(ii) are entire bovine animals over 12 months of age or entire ovine or caprine animals over 6 months of age and must have tested negative in a serological test carried out on a sample taken:

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— during the 30 days prior to their introduction into the establishment; or

— during the 30 days following their introduction provided they have been kept isolated during this period; or

(iii) are post-parturient females kept in isolation since their introduction into the establishment until they have tested negative in a serological test carried out on a sample taken not earlier than 30 days after parturition; and

(f) since the beginning of the sampling referred to in point (c)(i), all germinal products of bovine, ovine or caprine origin introduced into or used in the establishment originate from:

(i) establishments free from infection with *Brucella abortus, B. melitensis* and *B. suis* without vaccination; or

(ii) approved germinal product establishments.

2. By way of derogation from point 1, the status free from infection with *Brucella abortus, B. melitensis* and *B. suis* without vaccination may be granted to an establishment if all bovine, ovine or caprine animals originate from establishments free from infection with *Brucella abortus, B. melitensis* and *B. suis* without vaccination, or free with vaccination and have not been vaccinated during the past 3 years, and:

(a) originate from a Member State or a zone free from infection with *Brucella abortus, B. melitensis* and *B. suis* for the relevant animal population;

(b) are entire bovine animals over 12 months of age or entire ovine or caprine animals over 6 months of age and have tested negative in a serological test carried out on a sample taken:

— during the 30 days prior to their introduction into the establishment; or

— during the 30 days following their introduction into the establishment provided they have been kept isolated during this period; or

(c) are post-parturient females kept in isolation since their introduction into the establishment until they tested negative in a serological test carried out on a sample taken not earlier than 30 days after parturition.

3. By way of derogation from point 1, the status free from infection with *Brucella abortus, B. melitensis* and *B. suis* without vaccination may be granted to an establishment with the status free from infection with *Brucella abortus, B. melitensis* and *B. suis* with vaccination if:

(a) the requirements set out in points (a), (b), (d), (e) and (f) of point 1 are fulfilled; and

(b) the requirement set out in point (b)(i) of Section 2 is fulfilled.

Section 2

Maintenance of the status

The status free from infection with *Brucella abortus, B. melitensis* and *B. suis* without vaccination of an establishment keeping bovine, ovine or caprine animals may only be maintained if:

(a) the requirements set out in points (a), (b), (d), (e) and (f) of point 1 of Section 1 continue to be fulfilled; and

(b) serological testing is carried out with negative results on samples taken from:

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(i) all entire bovine animals over 12 months of age and all entire ovine or caprine animals over 6 months of age at appropriate intervals of not more than 12 months determined by the competent authority, taking into account the type of production, the situation of the disease and the identified risk factors; or

(ii) entire bovine animals over 12 months of age and entire ovine or caprine animals over 6 months of age kept in establishments located in a Member State or in a zone free from infection with *Brucella abortus, B. melitensis* and *B. suis*, in accordance with a testing regime set up by the competent authority, taking into account the type of production and the identified risk factors.

Section 3

Suspension and restoring of the status

1. The status free from infection with *Brucella abortus, B. melitensis* and *B. suis* without vaccination of an establishment keeping bovine, ovine or caprine animals must be suspended if:

(a) one or more of the requirements set out in Section 2 are not fulfilled; or

(b) a case of infection with *Brucella abortus, B. melitensis* and *B. suis* is suspected in a bovine, ovine or caprine animal kept in the establishment.

2. The status free from infection with *Brucella abortus, B. melitensis* and *B. suis* without vaccination may only be restored if:

(a) the requirements set out in points (b), (d), (e) and (f) of point 1 of Section 1 and in point (b) of Section 2 are fulfilled;

(b) the results of further investigations substantiate absence of infection with *Brucella abortus, B. melitensis* and *B. suis* and the status of all suspected cases has been determined.

Section 4

Withdrawal and regaining of the status

1. The status free from infection with *Brucella abortus, B. melitensis* and *B. suis* without vaccination of an establishment keeping bovine, ovine or caprine animals must be withdrawn if:

(a) one or more of the requirements set out in Section 2 are not fulfilled after the maximum period of time referred to in point (b) of Article 20(3) has lapsed since the status was suspended;

(b) the infection with *Brucella abortus*, *B. melitensis* and *B. suis* cannot be ruled out in accordance with point 2(b) of Section 3;

(c) a case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* has been confirmed in a bovine, ovine or caprine animal kept in the establishment; or

(d) it is justified by other needs to control infection with *Brucella abortus*, *B. melitensis*, *B. suis*.

2. If the status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination has been withdrawn in accordance with point 1(a), it may only be regained if the requirements laid down in Section 2 are fulfilled.

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3. If the status free from infection with *Brucella abortus, B. melitensis* and *B. suis* without vaccination has been withdrawn in accordance with point 1(b), 1(c) or 1(d), it may only be regained if all confirmed cases and all animals that have tested non-negative have been removed and the remaining bovine, ovine or caprine animals fulfil the requirements set out in point 1(c) of Section 1.

4. By way of derogation from point 3, where the infection with *B. suis* biovar 2 was confirmed in a single bovine, ovine or caprine animal kept in the establishment, the status may be regained after negative testing was obtained on samples taken in accordance with the requirements set out in point 1(c)(i) of Section 1.

CHAPTER 2

Establishment free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination

Section 1

Granting of the status

1. The status free from infection with *Brucella abortus, B. melitensis* and *B. suis* with vaccination may only be granted to an establishment keeping bovine, ovine or caprine animals if:

(a) the requirements set out in points (a), (c) and (d) of point 1 of Section 1 of Chapter 1 are fulfilled;

(b) since the beginning of the sampling referred to in point (c)(i) of point 1 of Section 1 of Chapter 1, all bovine, ovine, or caprine animals introduced into the establishment originate from establishments free from infection with *Brucella abortus, B. melitensis* and *B. suis* without vaccination or free from infection with *Brucella abortus, B. melitensis* and *B. suis* with vaccination and:

(i) originate from a Member State or a zone free from infection with *Brucella abortus, B. melitensis* and *B. suis* for the relevant animal population;

(ii) are entire bovine animals over 12 months of age or entire ovine or caprine animals over 6 months of age and have tested negative in a serological test on a sample taken

— during the 30 days prior to their introduction into the establishment; or

— during the 30 days following their introduction into the establishment provided they have been kept isolated during this period; or

(iii) are post-parturient females kept in isolation since their introduction into the establishment until they have tested negative in a serological test carried out on a sample taken not earlier than 30 days after parturition; and

(c) since the beginning of the sampling referred to in point (c)(i) of point 1 of Section 1 of Chapter 1, all germinal products of bovine, ovine or caprine origin introduced into or used in the establishment originate from:

(i) establishments free from infection with *Brucella abortus, B. melitensis* and *B. suis* without vaccination or free from infection with *Brucella abortus, B. melitensis* and *B. suis* with vaccination; or

(ii) approved germinal product establishments.

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2. By way of derogation from point 1, the status free from infection with *Brucella abortus, B. melitensis* and *B. suis* with vaccination may be granted to an establishment if all bovine, ovine or caprine animals originate from establishments free from infection with *Brucella abortus, B. melitensis* and *B. suis* without vaccination, or free with vaccination, and:

(a) originate from a Member State or a zone free from infection with *Brucella abortus, B. melitensis* and *B. suis* for the relevant animal population;

(b) are entire bovine animals over 12 months of age or entire ovine or caprine animals over 6 months of age and have tested negative in a serological test carried out on a sample taken:

(i) during the 30 days prior to their introduction into the establishment; or

(ii) during the 30 days following their introduction into the establishment provided they have been kept isolated during this period; or

(c) are post-parturient females kept in isolation since their introduction into the establishment until they have tested negative in a serological test carried out on a sample taken not earlier than 30 days after parturition.

Section 2

Maintenance of the status

The status free from infection with *Brucella abortus, B. melitensis* and *B. suis* with vaccination of an establishment keeping bovine, ovine or caprine animals may only be maintained if:

(a) the requirements set out in points (b) and (c) of point 1 of Section 1 of this Chapter and in points (a) and (d) of point 1 of Section 1 of Chapter 1 continue to be fulfilled; and

(b) serological testing is carried out with negative results on samples taken from all entire bovine animals over 12 months of age and all entire ovine or caprine animals over 6 months of age at appropriate intervals of not more than 12 months determined by the competent authority taking into account the type of production, the situation of the disease and the identified risk factors.

Section 3

Suspension and restoring of the status

1. The status free from infection with *Brucella abortus, B. melitensis* and *B. suis* with vaccination of an establishment keeping bovine, ovine or caprine animals must be suspended if:

(a) one or more of the requirements set out in Section 2 are not fulfilled; or

(b) a case of infection with *Brucella abortus, B. melitensis* and *B. suis* is suspected in a bovine, ovine or caprine animal kept in the establishment.

2. The status free from infection with *Brucella abortus, B. melitensis* and *B. suis* with vaccination may only be restored if:

(a) the requirements set out in point 1(d) of Section 1 of Chapter 1 and points (b) and (c) of point 1 of Section 1 and point (b) of Section 2 are fulfilled;

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(b) the results of further investigations substantiate absence of infection with *Brucella abortus, B. melitensis* and *B. suis* and the status of all suspected cases has been determined.

Section 4

Withdrawal and regaining of the status

1. The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination of an establishment keeping bovine, ovine or caprine animals must be withdrawn if:

(a) one or more of the requirements set out in Section 2 are not fulfilled after the maximum period of time referred to in point (b) of Article 20(3) has lapsed since the status was suspended;

(b) the infection with *Brucella abortus*, *B. melitensis* and *B. suis* cannot be ruled out in accordance with point 2(b) of Section 3;

(c) a case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* has been confirmed in a bovine, ovine or caprine animal kept in the establishment; or

(d) it is justified by other needs to control infection with *Brucella abortus*, *B. melitensis*, *B. suis*.

2. If the status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination has been withdrawn in accordance with point 1(a), it may only be regained if the requirements laid down in Section 2 are fulfilled.

3. If the status free from infection with *Brucella abortus, B. melitensis* and *B. suis* with vaccination has been withdrawn in accordance with point 1(b), 1(c) or 1(d), it may only be regained if all confirmed cases and all animals that have tested non-negative have been removed and the remaining bovine, ovine or caprine animals fulfil the requirements set out in point 1(c) of Section 1 of Chapter 1.

4. By way of derogation from point 3, where the infection with *Brucella suis* biovar 2 was confirmed in a single bovine, ovine or caprine animal kept in the establishment, the status may be regained after negative testing was obtained on samples taken in accordance with the requirements set out in point 1(c)(i) of Section 1 of Chapter 1.

CHAPTER 3

Member State or zone free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept bovine animals

Section 1

Granting of the status as regards kept bovine animals

The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept bovine animals may only be granted to a Member State or a zone if:

(a) for at least the past 3 years there has been no confirmed case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* in kept bovine animals;

(b) general surveillance requirements have been carried out for the past 3 years in accordance with point (a) of Article 3(1) for the early detection of infection with *Brucella abortus*, *B. melitensis* and *B. suis* in kept bovine animals, which included at least:

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(i) the regular submission of samples from abortion cases for laboratory testing;

(ii) the timely investigation of abortion cases that may have been caused by infection with *Brucella abortus*, *B. melitensis* and *B. suis*;

(c) during the past 3 years, at least 99,8 % of the establishments keeping bovine animals, representing at least 99,9 % of the bovine population, have maintained their status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination;

(d) vaccination of bovine animals against *Brucella abortus, B. melitensis* and *B. suis* has not taken place at least for the past 3 years and no bovine animal introduced into the Member State or zone has been vaccinated during the past 3 years prior to its introduction.

Section 2

Maintenance of the status as regards kept bovine animals

1. The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept bovine animals of a Member State or a zone may only be maintained if:

(a) the requirements set out in points (a), (b) and (d) of Section 1 continue to be fulfilled; and

(b) for the first 2 consecutive years following granting of the status, annual surveillance based on a representative sample of all establishments keeping bovine animals has been carried out that must allow at least for the detection, with a 95 % level of confidence, of infection with *Brucella abortus, B. melitensis* and *B. suis*, at a target prevalence rate of 0,2 % of the establishments keeping bovine animals or a target prevalence rate of 0,1 % of the bovine population;

(c) if no case of infection with *Brucella abortus, B. melitensis* and *B. suis* has been confirmed in kept bovine animals for 2 consecutive years following granting of the status, surveillance must be based on:

(i) random annual surveillance that must allow at least for the detection, with a 95 % level of confidence, of infection with *Brucella abortus, B. melitensis* and *B. suis*, at a target prevalence rate of 0,2 % of the establishments keeping bovine animals or a target prevalence rate of 0,1 % of the bovine population; or

(ii) risk-based annual surveillance to detect infection with *Brucella abortus, B. melitensis* and *B. suis* taking into account the systems of production and the risk factors identified, including spread of infection from other animals than kept bovine animals.

2. The status of a Member State or a zone free from infection with *Brucella abortus, B. melitensis* and *B. suis* as regards kept bovine animals is not affected by the confirmation of infection of *Brucella abortus, B. melitensis* and *B. suis* in an animal population other than kept bovine animals provided that effective measures have been implemented, and are periodically assessed, to prevent transmission of infection with *Brucella abortus, B. melitensis* and *B. suis* to kept bovine animals.

3. By way of derogation from point 1(a), the status free from infection with *Brucella abortus, B. melitensis* and *B. suis* as regards kept bovine animals of a Member State or a zone may be maintained in the event of the confirmation of a case of infection with *Brucella abortus, B. melitensis* and *B. suis* if:

(a) the establishment in which the infection with *Brucella abortus, B. melitensis* and *B. suis* was detected in kept bovine animals has been immediately subjected to the relevant disease control measures laid down in Article 24;

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(b) within 60 days after the first confirmation of the infection, the competent authority has conducted an epidemiological enquiry and investigations, as laid down in Article 25, to identify the likely source and the distribution of the infection and established conclusions on the likely source of infection and only a limited number of establishments were infected and those establishments are epidemiologically linked to the first detected outbreak;

(c) the relevant disease control measures laid down in Article 21 or Article 24 have been immediately implemented in each establishment identified with suspected or confirmed cases following implementation of the measures provided for in point (b) until their disease-free status is restored or regained;

(d) the surveillance referred to in point 1 has been adapted and has demonstrated that the incident has been resolved.

CHAPTER 4

Member State or zone free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept ovine and caprine animals

Section 1

Granting of the status as regards kept ovine and caprine animals

The status free from infection with *Brucella abortus, B. melitensis* and *B. suis* as regards kept ovine and caprine animals may only be granted to a Member State or a zone if:

(a) for at least the past 3 years there has been no confirmed case of infection with *Brucella abortus, B. melitensis* and *B. suis* in kept ovine and caprine animals;

(b) general surveillance requirements have been carried out for the past 3 years in accordance with point (a) of Article 3(1) for the early detection of infection with *Brucella abortus, B. melitensis* and *B. suis* in kept ovine and caprine animals, which included at least:

(i) the regular submission of samples from abortion cases for laboratory testing;

(ii) the timely investigation of abortion cases that may have been caused by infection with *Brucella abortus*, *B. melitensis* and *B. suis*;

(c) during the past 3 years, surveillance has been carried out on the ovine and caprine population and at least 99,8 % of the establishments keeping ovine or caprine animals, representing at least 99,9 % of the ovine and caprine population, have maintained their status free from infection with *Brucella abortus, B. melitensis* and *B. suis* without vaccination; and

(d) vaccination of ovine and caprine animals against *Brucella abortus, B. melitensis* and *B. suis* has not taken place for at least the past 3 years and no ovine or caprine animal introduced into the Member State or zone has been vaccinated during the past 3 years prior to introduction.

Section 2

Maintenance of the status as regards kept ovine and caprine animals

1. The status free from infection with *Brucella abortus, B. melitensis* and *B. suis* as regards kept ovine and caprine animals of a Member State or a zone may only be maintained if:

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(a) the requirements defined in points (a), (b) and (d) of Section 1 continue to be fulfilled; and

(b) for the first 2 consecutive years following granting of the status, annual surveillance based on a representative sample of all establishments where ovine or caprine animals are kept shall be carried out that must allow at least for the detection, with a 95 % level of confidence, of infection with *Brucella abortus, B. melitensis* and *B. suis* at a target prevalence rate of 0,2 % of the establishments keeping ovine or caprine animals or a target prevalence rate of 0,1 % of the ovine and caprine population;

(c) if no case of infection with *Brucella abortus, B. melitensis* and *B. suis* has been confirmed in kept ovine and caprine animals for 2 consecutive years following granting of the status, surveillance must be based on:

(i) random annual surveillance that must allow at least for the detection, with a 95 % level of confidence, of infection with *Brucella abortus, B. melitensis* and *B. suis* at a target prevalence rate of 0,2 % of the establishments keeping ovine or caprine animals or a target prevalence rate of 0,1 % of the ovine and caprine population; or

(ii) risk-based annual surveillance to detect infection with *Brucella abortus, B. melitensis* and *B. suis*, which takes into account the systems of production and the risk factors identified, including spread of infection from other animals than kept ovine and caprine animals.

2. The status of a Member State or a zone free from infection with *Brucella abortus, B. melitensis* and *B. suis* as regards kept ovine and caprine animals is not affected by the confirmation of infection of *Brucella abortus, B. melitensis* and *B. suis* in an animal population other than kept ovine and caprine animals provided that effective measures have been implemented, and are periodically assessed, to prevent transmission of infection with *Brucella abortus, B. melitensis* and *B. suis* to kept ovine and caprine animals.

3. By way of derogation from point 1(a), the status free from infection with *Brucella abortus, B. melitensis* and *B. suis* as regards kept ovine and caprine animals of a Member State or a zone may be maintained in the event of the confirmation of a case of infection with *Brucella abortus, B. melitensis* and *B. suis* if:

(a) the establishment in which the infection with *Brucella abortus, B. melitensis* and *B. suis* was detected in kept ovine and caprine animals has been immediately subjected to the relevant disease control measures laid down in Article 24;

(b) within 60 days after the first confirmation of the infection, the competent authority has conducted an epidemiological enquiry and investigations, as laid down in Article 25, to identify the likely source and the distribution of the infection and established conclusions on the likely source of infection and only a limited number of establishments were infected and those establishments are epidemiologically linked to the first detected outbreak;

(c) the relevant disease control measures laid down in Article 21 or Article 24 have been immediately implemented in each establishment identified with suspected or confirmed cases following implementation of the measures provided for in point (b) until their disease-free status is restored or regained; and

(d) the surveillance referred to in point 1 has been adapted and has demonstrated that the incident has been resolved.

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PART II

INFECTION WITH *MYCOBACTERIUM TUBERCULOSIS* COMPLEX

CHAPTER 1

Establishment free from infection with *Mycobacterium tuberculosis* complex

Section 1

Granting of the status

1. The status free from infection with *Mycobacterium tuberculosis* complex (*Mycobacterium bovis, Mycobacterium tuberculosis, Mycobacterium caprae*) (MTBC) may only be granted to an establishment keeping bovine animals if:

(a) during the past 12 months there has been no confirmed case of infection with MTBC in bovine animals kept in the establishment;

(b) the bovine animals over 6 weeks of age present in the establishment at the time of testing or sampling have tested negative to immunological test on two occasions as follows:

(i) the first test must be carried out on bovine animals or samples taken from bovine animals not earlier than 6 months after the removal of the last confirmed case and of the last animal that tested positive in an immunological test;

(ii) the second test must be carried out on bovine animals or on samples taken from bovine animals not earlier than 6 months and not later than 12 months following the date of testing of the bovine animal or taking of the samples referred to in point (i);

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(c) since the beginning of the testing or sampling referred to in point (b)(i), all bovine animals introduced into the establishment originate from establishments free from infection with MTBC and:

(i) originate from a Member State or a zone free from infection with MTBC; or

(ii) are bovine animals over 6 weeks of age and have tested negative in an immunological test:

during the 30 days prior to their introduction into the establishment; or

during the 30 days after their introduction provided they have been kept isolated during this period; and

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(d) since the beginning of the testing or sampling referred to in point (b)(i), all germinal products of bovine origin introduced into or used in the establishment originate from:

(i) establishments free from infection with MTBC; or

(ii) approved germinal product establishments.

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2. By way of derogation from point 1, the status free from infection with MTBC may be granted to an establishment if all bovine animals originate from establishments free from infection with MTBC and:

(a) originate from a Member State or a zone free from infection with MTBC; or

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(b) if they are bovine animals over 6 weeks of age, they have tested negative to an immunological test:

(i) during the 30 days prior to their introduction into the establishment; or

(ii) during the 30 days after their introduction provided they have been kept in isolation during this period.

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3. By way of derogation from points 1(c) and 2(b), the competent authority may not require the test if:

(a) the bovine animals introduced into the establishment:

(i) have tested negative in an immunological test carried out during the past 6 months; and

(ii) originate from establishments where the bovine animals have tested negative to a testing regime as provided for in points 1(c) or 2 of Section 2 carried out during the past 6 months; or

(b) the bovine animals introduced into the establishment:

(i) have tested negative in an immunological test carried out during the past 12 months; and

(ii) originate from establishments where the bovine animals have tested negative to a testing regime as provided for in point 2(b) or 2 (c) of Section 2 carried out during the past 12 months.

Section 2

Maintenance of the status

1. The status free from infection with MTBC of an establishment keeping bovine animals may only be maintained if:

(a) the requirements set out in points (a), (c) and (d) of point 1 of Section 1 continue to be fulfilled;

(b) any suspected case of infection with MTBC in a bovine animal kept on that establishment or introduced from that establishment into a slaughterhouse is notified to the competent authority and investigated; and

(c) an immunological test has been carried out, with negative results, on all bovine animals over 6 weeks of age, at intervals of not more than 12 months.

2. By way of derogation from point 1(c), the competent authority may modify the testing regime as follows:

(a) in a Member State or in a zone where the annual percentage, calculated on 31 December of each year, of establishments infected with MTBC is not more than 1 % during the last 24 months, the interval between tests may be extended to 24 months;

(b) in a Member State or in a zone where the annual percentage, calculated on 31 December of each year, of establishments infected with MTBC is not more than 0,2 % for the last 48 months, the interval between tests may be extended to 36 months;

(c) in a Member State or in a zone where the annual percentage, calculated on 31 December of each year, of establishments infected with MTBC is not more than 0,1 % for the last 72 months, the interval between tests may be extended to 48 months;

(d) in a Member State or a zone free from infection with MTBC, if the risk of transmission of MTBC from wild animals to bovine animals has been assessed by appropriate surveillance, the interval between tests may be based on the type of production and the risk factors identified, taking into account at least the following risks:

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(i) a location associated with suspected or confirmed infection with MTBC in wild animals;

(ii) a history of infection with MTBC within the last 5 years;

(iii) an epidemiological link with establishments in any of points (i) or (ii).

Section 3

Suspension and restoring of the status

1. The status free from infection with MTBC of an establishment keeping bovine animals must be suspended if:

   (a) one or more of the requirements laid down in Section 2 are not fulfilled; or

   (b) a case of infection with MTBC is suspected in a bovine animal kept in the establishment.

2. The status free from infection with MTBC may only be restored, if:

   (a) the requirements laid down in points 1(c) and 1(d) of point 1 of Section 1, 1(b), of Section 2 and, as relevant, in point 1(c) or in point 2 of Section 2 are fulfilled;

   (b) the results of further investigations substantiate absence of infection with MTBC and the status of all suspected cases has been determined. In case, suspected bovine animals are slaughtered in that context, investigations must include examination of samples with direct diagnostic methods.

Section 4

Withdrawal and regaining of the status

1. The status free from infection with MTBC of an establishment keeping bovine animals must be withdrawn if:

   (a) one or more of the requirements laid down in Section 2 are not fulfilled after the maximum period of time referred to in point (b) of Article 20(3) has lapsed since the status was suspended;

   (b) the infection with MTBC cannot be ruled out in accordance with point 2(b) of Section 3;

   (c) a case of infection with MTBC has been confirmed in a bovine animal kept in the establishment; or

   (d) it is justified by other needs to control infection with MTBC.

2. If the status free from infection with MTBC has been withdrawn in accordance with point 1(a), it may only be regained if the requirements laid down in Section 2 are fulfilled.

3. If the status free from infection with MTBC has been withdrawn in accordance with point 1(b), 1(c) or 1(d), it may only be regained if:

   (a) all confirmed cases and all animals that have tested non negative in a immunological test have been removed; and

   (b) the remaining bovine animals fulfil the requirements set out in point 1(b) of Section 1.

4. By way of derogation from point 3(b), the status may be regained if:

   (a) all bovine animals over 6 weeks of age present in the establishment at the time of testing have tested negative in two immunological tests as follows:

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(i) the first test must be carried out on bovine animals or samples taken from bovine animals not earlier than 2 months after the removal of the last confirmed case and of the last animal that tested positive in an immunological test;

(ii) the second test must be carried out on bovine animals or on samples taken from bovine animals not earlier than 2 months and not later than 12 months following the date of testing or sampling of the bovine animal as referred to in point (i); and

(b) at least one of the following conditions apply:

(i) the conclusion of the epidemiological enquiry indicates that the infection is due to the introduction of one or more infected animals into the establishment during the past 12 months prior to the detection of the infection with MTBC; or

(ii) only a single case was confirmed or only a single bovine animal tested positive in an immunological test for MTBC since the detection of the infection with MTBC, and the status of the establishment has not been withdrawn during the past 3 years; or

(iii) bovine animals in the establishment have tested negative in an immunological test carried out less than 12 months prior to the detection of the infection with MTBC in accordance with point 1(c) or 2 of Section 2.

CHAPTER 2

Member State or zone free from infection with MTBC

Section 1

Granting of the status as regards kept bovine animals

The status free from infection with MTBC as regards kept bovine animals may only be granted to a Member State or a zone if:

(a) during the past 3 years at least 99,8 % of the establishments keeping bovine animals, representing at least 99,9 % of the bovine population, have maintained their status free from infection with MTBC and the incidence rate of establishments confirmed infected during the year did not exceed 0,1 %; and

(b) general surveillance requirements have been carried out for the past 3 years in accordance with point (a) of Article 3(1) for the detection of infection with MTBC in kept bovine animals and included at least:

(i) the systematic research of lesions of infection with MTBC in all bovine animals slaughtered through ante- and post-mortem surveillance;

(ii) the investigations of lesions that could be due to infection with MTBC.

Section 2

Maintenance of the status

1. The status free from infection with MTBC as regards kept bovine animals of a Member State or a zone may only be maintained if:

(a) the requirements in point (b) of Section 1 continue to be fulfilled; and

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(b) for the first 2 consecutive years following granting of the status random annual surveillance based on a representative sampling of all establishments where bovine animals are kept must be carried out to demonstrate with a 95 % level of confidence, that:

(i) at least 99,8 % of the establishments, representing at least 99,9 % of the bovine population are free from infection with MTBC;

(ii) the incidence rate of establishment confirmed infected during the year does not exceed 0,1 %;

(c) if the conditions in point (b) were fulfilled for 2 consecutive years, surveillance is based on:

(i) random annual surveillance to demonstrate at least with a confidence level of 95 %, that the incidence rate of establishments confirmed infected during the year does not exceed 0,1 %; or

(ii) risk-based annual surveillance carried out to detect infection with MTBC, taking into account the systems of production, the risk factors identified, including the spread of infection from other animals than kept bovine animals and increased surveillance in establishments associated with at least one of the specific risks referred to in point 2(d) of Section 2 of Chapter 1.

2. The status of a Member State or a zone free from infection with MTBC is not affected by the confirmation of infection with MTBC in the animal population other than kept bovine animals, provided that effective measures have been implemented, and are periodically assessed, to prevent transmission of infection with MTBC to kept bovine animals.

PART III

ENZOOTIC BOVINE LEUKOSIS

CHAPTER 1

Establishment free from enzootic bovine leukosis

Section 1

Granting of the status

1. The status free from enzootic bovine leukosis (EBL) may only be granted to an establishment keeping bovine animals if:

(a) during the past 24 months there has been no confirmed case of EBL in bovine animals kept in the establishment;

(b) during the past 12 months, bovine animals older than 24 months of age kept in the establishment have tested negative to a serological test, on at least two occasions at an interval of not less than 4 months;

(c) since the beginning of the sampling referred to in point (b), all bovine animals introduced into the establishment:

(i) originate from establishments free from EBL; or

(ii) originate from establishments where there has been no evidence of EBL either clinical, post-mortem, or as a result of a diagnostic test for EBL within the 24 months prior to their dispatch; and

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— if over 24 months of age,

they have been subjected to serological tests, with negative results, on two occasions at an interval of not less than 4 months while kept in isolation from other bovine animals of the establishment; or

they have been subjected to a serological test, with a negative result, within 30 days prior to their introduction provided all bovine animals have been tested in accordance with point (b);

— if less than 24 months of age,

they were born to dams, that have been subjected to a serological test for EBL, with negative results, carried out on samples taken during the past 12 months on two occasions at an interval of not less than 4 months; and

(d) since the beginning of the sampling referred to in point (b), all germinal products of bovine animals introduced into the establishment originate from:

(i) establishments free from EBL; or

(ii) approved germinal product establishments.

2. By way of derogation from point 1, the status free from EBL may be granted to an establishment if all bovine animals originate from establishments free from EBL located either in a Member State or zone free from EBL or in a Member State or zone covered by an approved eradication programme.

Section 2

Maintenance of the status

The status free from EBL of an establishment keeping bovine animals may only be maintained if:

(a) the requirements laid down in points (a), (c) and (d) of point 1 of Section 1 continue to be fulfilled; and

(b) serological testing for EBL is carried out, with negative results, on samples taken

(i) at intervals of not more than 36 months from all bovine animals over 24 months of age; or

(ii) in accordance with point (b) or (c) of Section 2 of Chapter 2, as relevant, if the establishment is located in a Member State or zone free from EBL.

Section 3

Suspension and restoring of the status

1. The status free from EBL of an establishment keeping bovine animals must be suspended if:

(a) one or more of the requirements laid down in Section 2 are not fulfilled;

(b) a case of EBL in a bovine animal that is kept on the establishment is suspected.

2. The status free from EBL may only be restored if:

(a) the requirements laid down in points (c) and (d) of point 1 of Section 1 and point (b) of Section 2 are fulfilled;

(b) the results of further investigations substantiate absence of EBL and the status of all suspected cases has been determined.

Section 4

Withdrawal and regaining of the status

1. The status free from EBL of an establishment keeping bovine animals must be withdrawn if:

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(a) one or more of the requirements laid down in Section 2 are not fulfilled after the maximum period of time referred to in point (b) of Article 20(3) has lapsed since the status was suspended; or

(b) a case of EBL has been confirmed in a bovine animal kept in the establishment.

2. If the status free from EBL has been withdrawn in accordance with point 1(a), it may only be regained if the requirements laid down in points (c) and (d) of point 1 of Section 1 and point (b) of Section 2 are fulfilled.

3. If the status free from EBL has been withdrawn in accordance with point 1(b), it may only be regained if:

(a) any bovine animal presenting a positive test result for EBL and all of their offspring younger than 24 months of age have been removed;

(b) all bovine animals over 12 months of age have been tested negative in a serological test, on two occasions at an interval of not less than 4 months, where the first test must be carried out on samples not taken earlier than 4 months after the removal of the last confirmed case.

4. By way of derogation from point (3)(a), the offspring of dams that have been tested positive in a serological test for EBL or which have shown lesions of EBL may be kept in the establishment if:

(a) they have been separated from the dam immediately after calving and tested negative in a PCR test, on two occasions, where the first sample must be taken within the period of 3 to 5 weeks and the second within 8 to 10 weeks postpartum; and

(b) they remain in the establishment until they are 24 months of age and are tested negative in a serological test, or they are sent before that test directly to the slaughterhouse in accordance with the requirements laid down in Article 27(4).

CHAPTER 2

Member State or zone free from EBL

Section 1

Granting of the status

The status free from EBL as regards kept bovine animals may only be granted to a Member State or a zone if:

(a) at least 99,8 % of the bovine establishments are free from EBL; and

(b) all bovine animals over 24 months of age slaughtered within this Member State or zone are subjected to an official post-mortem examination with samples from all animals with tumours that could be caused by EBL being subjected to laboratory examination to confirm or rule out the presence of EBL.

Section 2

Maintenance of the status

The status free from EBL as regards kept bovine animals of a Member State or a zone may only be maintained if:

(a) the requirements set out in Section 1 continue to be fulfilled; and

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(b) during the first 5 years after the granting of the status free from EBL, surveillance is carried out based on:

(i) annual random sampling to detect at least, with a 95 % level of confidence, establishments infected with EBL at a target prevalence rate of 0,2 %; or

(ii) serological testing of all bovine animals over 24 months of age on at least one occasion;

(c) following the first 5 years after the granting of the status free from EBL, surveillance is carried out to demonstrate the absence of infection, taking into account the systems of production and the risk factors identified.

PART IV

INFECTIOUS BOVINE RHINOTRACHEITIS/INFECTIOUS PUSTULAR VULVOVAGINITIS

CHAPTER 1

Establishment free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

Section 1

Granting of the status

1. The status free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (IBR/IPV) may only be granted to an establishment keeping bovine animals if:

(a) during the past 12 months there has been no confirmed case of IBR/IPV in bovine animals kept in the establishment;

(b) during the past 2 years none of the bovine animals kept in the establishment has been vaccinated against IBR/IPV;

(c) the bovine animals kept in the establishment have been subjected to at least one of the following testing regimes taking into account previous DIVA vaccinations, where serological tests for the detection of antibodies against whole BoHV-1 or, if necessary, antibodies against BoHV-1-gE have been carried out on:

(i) a blood, milk or meat juice sample taken from each bovine animal over a period of not more than 12 months; or

(ii) blood, milk or meat juice samples taken on at least two occasions at an interval of not less than 2 months and not more than 12 months from

— all female bovine animals over 12 months of age, and

— all male bovine animals used or intended for breeding over 12 months of age, and

— a random sample of male animals not intended for breeding over 12 months of age. The number of animals tested must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 10 %; or

(iii) in the case of an establishment in which at least 30 % of the bovine animals are lactating,

— bulk milk samples taken on at least three occasions at intervals of not less than 3 months from lactating female bovine animals representing all epidemiological units of the establishment, and

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— blood samples taken from all non-lactating female bovine animals over 12 months of age, and from all male bovine animals used or intended for breeding over 12 months of age, and

— a random blood or meat juice sample taken from male bovine animals not intended for breeding older than 12 months of age. The number of animals tested must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 10 %; or

(iv) in the case of an establishment in which less than 5 % of the kept bovine animals are male and at least 95 % of the female animals over 24 months are intended or used for milk production, bulk milk samples taken on at least six occasions at intervals of not less than 2 months from lactating female bovine animals representing all epidemiological units of the establishment;

(d) since the beginning of the sampling referred to in point (c) all bovine animals introduced into the establishment:

(i) originate from establishments free from IBR/IPV and, in case the establishments of origin are located in a Member State or zone that is neither free from IBR/IPV nor covered by an approved eradication programme, have tested negative in a serological test for the detection of antibodies against whole BoHV-1 or, if necessary, antibodies against BoHV-1-gE on a sample taken after their introduction and before the granting of the status free from IBR/IPV; or

(ii) have been subjected to quarantine prior to their introduction and have tested negative in serological test for the detection of antibodies against whole BoHV-1 on a sample taken not earlier than 21 days after the beginning of the quarantine; and

(e) since the beginning of the sampling referred to in point (c) all germinal products of bovine animals introduced into the establishment originate from:

(i) establishments free from IBR/IPV; or

(ii) approved germinal product establishments.

2. By way of derogation from point 1, the status free from IBR/IPV may be granted to an establishment if all bovine animals originate from establishments free from IBR/IPV located either in a Member State or zone free from IBR/IPV or in a Member State or zone under an approved eradication programme, provided they fulfil the requirements set out in points (c) and (d) of Section 2, as relevant.

Section 2

Maintenance of the status

The status free from IBR/IPV may only be maintained in an establishment keeping bovine animals if:

(a) the requirements laid down in points (a), (b) and (e) of point 1 of Section 1 continue to be fulfilled;

(b) serological testing for the detection of antibodies against whole BoHV-1 or, if necessary, antibodies against BoHV-1-gE is carried out taking into account previous vaccinations with a DIVA vaccine, with negative results,

(i) on blood, milk or meat juice samples taken annually from all bovine animals older than 24 months of age; or

(ii) in the case of an establishment, in which at least 30 % of the bovine animals are lactating, at least annually on:

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— bulk milk samples taken on at least three occasions at intervals of not less than 3 months from lactating female bovine animals representing all epidemiological units of the establishment, and

— blood samples taken from all breeding male bovine animals older than 24 months of age; or,

(iii) in the case of an establishment, in which less than 5 % of the kept bovine animals are male and at least 95 % of the female animals over 24 months are intended or used for milk production, at least annually on bulk milk samples taken on at least six occasions at intervals of not less than 2 months from lactating female bovine animals representing all epidemiological units of the establishment; or

(iv) provided the status free from IBR/IPV has been maintained for the past 3 consecutive years, annually on blood or milk samples taken from a number of bovine animals that must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 10 %; or

(v) if the establishment is located in a Member State or zone free from IBR/IPV, on samples taken in accordance with point 1(b) of Section 2 of Chapter 2 or point 3 of Section 2 of Chapter 2, if relevant.

(c) only bovine animals that have not been vaccinated against infection with IBR/IPV are introduced into the establishment if it is located in a Member State or zone:

(i) free from IBR/IPV; or

(ii) where a vaccination ban is in place as part of the eradication strategy under an approved eradication programme.

(d) all bovine animals that are introduced fulfil the requirements laid down in point 1(d)(ii) of Section 1 or originate from establishments free from IBR/IPV and have tested negative in a serological test for the detection of antibodies against whole BoHV-1 or, if necessary, antibodies against BoHV-1-gE on a sample taken in the establishments of origin within 15 days prior to their dispatch, in cases where:

(i) the establishment is located in a Member State or zone free from IBR/IPV and the establishments of origin are not located in a Member State or zone free from IBR/IPV; or

(ii) the establishment is located in a Member State or zone covered by an approved eradication programme and the establishments of origin are located in a Member State or zone that is neither free from IBR/IPV nor covered by an approved eradication programme.

Section 3

Suspension and restoring of the status

1. The status free from IBR/IPV of an establishment keeping bovine animals must be suspended if:

(a) one or more of the requirements laid down in Section 2 are not fulfilled;

(b) a case of IBR/IPV is suspected in a bovine animal kept in the establishment.

2. The status free from IBR/IPV may only be restored if:

(a) the requirements laid down in points 1(b) and (e) of Section 1 and points (b), (c) and (d) of Section 2 are fulfilled;

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(b) the results of further investigations substantiate absence of IBR/IPV and the status of all suspected cases has been determined.

Section 4

Withdrawal and regaining of the status

1. The status free from IBR/IPV of an establishment keeping bovine animals must be withdrawn if:

(a) one or more of the requirements laid down in Section 2 are not fulfilled after the maximum period of time referred to in point (b) of Article 20(3) has lapsed since the status was suspended;

(b) a case of IBR/IPV has been confirmed in a bovine animal kept in the establishment.

2. If the status free from IBR/IPV has been withdrawn in accordance with point 1(a), it may only be regained if the requirements laid down in points (b) and (e) of point 1 of Section 1 and points (b), (c) and (d) of Section 2 are fulfilled.

3. If the status free from IBR/IPV has been withdrawn in accordance with point 1(b), it may only be regained if:

(a) all confirmed cases have been removed;

(b) at least one of the testing regimes laid down in point 1(c) of Section 1 has been carried out with negative results on samples that have been taken not earlier than 30 days after the removal of the last confirmed case.

CHAPTER 2

Member State or zone free from IBR/IPV

Section 1

Granting of the status

The status free from IBR/IPV as regards kept bovine animals may only be granted to a Member State or a zone if

(a) vaccination against IBR/IPV has been prohibited for kept bovine animals; and

(b) at least 99,8 % of the establishments representing at least 99,9 % of the corresponding bovine population are free from IBR/IPV.

Section 2

Maintenance of the status

1. The status free from IBR/IPV as regards kept bovine animals of a Member State or a zone may only be maintained if:

(a) the requirements laid down in Section 1 continue to be fulfilled; and

(b) surveillance is carried out annually based on random sampling that must allow at least for the detection, with a 95 % level of confidence, of the infection of establishments with BoHV-1 at a target prevalence rate of 0,2 % of the establishments or of BoHV-1 infected bovine animals with a target prevalence rate of 0,1 % of the bovine population.

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2. By way of derogation from point 1(a), the use of DIVA vaccination may be authorised by the competent authority in the event of an outbreak, if:

(a) the result of the epidemiological enquiry and investigations according to Article 25 has demonstrated that only a limited number of establishments were involved in the outbreak;

(b) its use is limited to controlling this outbreak as deemed necessary by the competent authority;

(c) the bovine animals are DIVA vaccinated under the supervision of the competent authority and the use of DIVA vaccines is documented for each animal;

(d) the DIVA vaccinated bovine animals are only moved directly to a slaughterhouse or to an establishment in another zone or Member State where no vaccination ban is in place.

3. By way of derogation from point 1(b), surveillance may be carried out to demonstrate yearly the absence of infection with BoHV-1 taking into account the systems of production and the risk factors identified, provided no outbreaks have been detected for 5 consecutive years following the granting of the status free from IBR/IPV in this Member State or zone.

PART V

INFECTION WITH AUJESZKY'S DISEASE VIRUS

CHAPTER 1

Establishment free from infection with Aujeszky's disease virus

Section 1

Granting of the status

1. The status free from infection with Aujeszky's disease virus (ADV) may only be granted to an establishment keeping porcine animals if:

(a) during the past 12 months there has been no confirmed case of infection with ADV in porcine animals kept in the establishment;

(b) during the past 12 months none of the porcine animals kept in the establishment has been vaccinated against AD;

(c) during the past 12 months, the porcine animals kept in the establishment have been subjected to one of the following testing regimes taking into account previous DIVA vaccinations where serological tests for the detection of antibodies against ADV or, if necessary, antibodies against ADV-gE have been carried out, with negative results, on:

(i) a blood or meat juice sample taken from each porcine animal; or

(ii) blood or meat juice samples taken on two occasions at an interval of 2 to 3 months from a number of animals that must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 10 %.

(d) since the beginning of the sampling referred to in point (c), all porcine animals introduced into the establishment:

(i) originate from establishments free from infection with ADV and, in case the establishments of origin are located in a Member State or zone that is neither free from infection with ADV nor covered by an approved eradication programme, have tested negative in a serological

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test for the detection of antibodies against whole ADV or, if necessary, antibodies against ADV-gE after their introduction and before the granting of the status free from infection with ADV; or

(ii) have been subjected to quarantine for a period of at least 30 days prior to their introduction and have tested negative in a serological test for the detection of antibodies against whole ADV on two occasions at an interval of not less than 30 days between collection of each sample. The sample for the last test must be taken within 15 days prior to dispatch.

(e) since the beginning of the sampling referred to in point (c) all germinal products from porcine animals introduced into the establishment originate from:

(i) establishments free from infection with ADV; or

(ii) approved germinal product establishments.

2. By way of derogation from point 1, the status free from infection with ADV may be granted to an establishment if all porcine animals originate from establishments free from infection with ADV located either in a Member State or zone free from infection with ADV or in a Member State or zone covered by an approved eradication programme, provided they fulfil the requirements set out in point (d) of Section 2.

Section 2

Maintenance of the status

The status free from infection with ADV of an establishment keeping porcine animals may only be maintained if:

(a) the requirements laid down in points (a), (b) and (e) of point 1 of Section 1 continue to be fulfilled;

(b) serological testing is carried out, with negative results, on a representative number of blood or meat juice samples taken from the porcine animals kept in the establishment, to verify the absence of infection with ADV based on a testing regime that takes into account the production cycle and the risk of introduction of ADV:

(i) at least once a year, in case all kept porcine animals are not vaccinated against AD, with tests for the detection of antibodies against whole ADV; or

(ii) at least twice a year, with tests for the detection of antibodies against whole ADV and tests for the detection of antibodies against ADV-gE, if necessary;

(c) provided the establishment is located in a Member State or zone free from infection with ADV, the serological testing referred to in point (b) is carried out, as required, in accordance with the surveillance provided for in point 1(b) of Section 2 of Chapter 2 or point 4 of Section 2 of Chapter 2, if relevant;

(d) all porcine animals, that are introduced:

(i) fulfil the requirements set out in point 1(d)(ii) of Section 1; or

(ii) originate from establishments free from infection with ADV and have been subjected to a serological test for antibodies against whole ADV, with a negative result, on a sample collected in the establishments of origin within 15 days prior to their dispatch, in cases where:

— the establishment is located in a Member State or zone free from infection with ADV and the establishments of origin are not located in a Member State or zone free from infection with ADV; or

— the establishment is located in a Member State or zone covered by an approved eradication programme and the establishments of origin are located in a Member State or zone that is neither free from infection with ADV nor covered by an approved eradication programme.

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The number of porcine animals tested must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 10 %.

By way of derogation from the first subparagraph, for porcine animals less than 4 months old born to DIVA-vaccinated dams the serological test for the detection of antibodies against ADV-gE may be used.

Section 3

Suspension and restoring of the status

1. The status free from infection with ADV of an establishment keeping porcine animals must be suspended if:

   (a) one or more of the requirements laid down in Section 2 are no longer fulfilled;

   (b) a case of infection with ADV is suspected in a porcine animal kept in the establishment.

2. The status free from infection with ADV may only be restored if:

   (a) the requirements laid down in points (b) and (e) of point 1 of Section 1 and point (b) or (c), if relevant, and (d) of Section 2 are fulfilled;

   (b) the results of further investigations substantiate absence of infection with ADV and the status of all suspected cases has been determined.

Section 4

Withdrawal and regaining of the status

1. The status free from infection with ADV of an establishment keeping porcine animals must be withdrawn if:

   (a) one or more of the requirements laid down in Section 2 are not fulfilled after the maximum period of time referred to in point (b) of Article 20(3) has lapsed since the status was suspended;

   (b) a case of infection with ADV has been confirmed in a porcine animal kept in the establishment.

2. If the status free from infection with ADV has been withdrawn in accordance with point 1(a), it may only be regained if the requirements set out in points (b) and (e) of point 1 of Section 1 and point (b) or (c), if relevant, and (d) of Section 2 are fulfilled.

3. If the status free from infection with ADV has been withdrawn in accordance with point 1(b), it may only be regained, if all porcine animals of the establishment have been removed.

CHAPTER 2

Member State or zone free from infection with Aujeszky's disease virus

Section 1

Granting of the status

The status free from infection with ADV as regards kept porcine animals may only be granted to a Member State or a zone if:

(a) vaccination against AD has been prohibited for kept porcine animals for the previous 12 months;

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(b) surveillance has been carried out to demonstrate that no establishment in the respective Member State or zone has had any clinical, virological or serological evidence of infection with ADV for at least the previous 24 months; and

(c) in case, infection with ADV is known to be established in wild porcine animals, measures have been implemented to prevent any transmission of ADV from wild to kept porcine animals.

Section 2

Maintenance of the status

1. The status free from infection with ADV as regards kept porcine animals of a Member State or a zone may only be maintained if:

   (a) the requirements defined in points (a) and (c) of Section 1 continue to be fulfilled; and

   (b) surveillance is carried out annually based on random sampling to allow at least for the detection, with a 95 % level of confidence, of establishments infected with ADV at a target prevalence rate of 0,2 %. The number of blood or meat juice samples to be taken from the porcine animals kept in an establishment must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 20 %.

2. By way of derogation from point 1, the status free from infection with ADV in the porcine population of a Member State or zone may be maintained in the event of an outbreak, if:

   (a) all the porcine animals in the affected establishments have been removed;

   (b) an epidemiological enquiry and investigations including clinical examination and serological or virological testing has been carried out by the competent authority:

      (i) in all establishments keeping porcine animals that have been directly or indirectly in contact with the infected establishment to rule out infection; and

      (ii) in all establishments keeping porcine animals located within at least a 2-kilometre radius of an infected establishment, to demonstrate that these establishments are not infected. The number of blood or meat juice samples to be taken from porcine animals kept in these establishments must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 10 %; or

      (iii) in case a DIVA vaccination has been used, serological testing for antibodies against ADV-gE has been carried out on two occasions at an interval of 2 months in establishments keeping porcine animals located within the vaccinated radius from the infected establishment to demonstrate the absence of infection;

   (c) the result of the investigation according to point (b) has demonstrated that only a limited number of establishments were involved in the outbreak;

   (d) the relevant control measures as referred to in Article 24 have been immediately implemented in each establishment infected with ADV, including where necessary vaccination with DIVA vaccines.

3. By way of derogation from point (a) of Section 1, the use of DIVA vaccination may be authorised by the competent authority in the event of an outbreak referred to in point 2, if:

   (a) its use is limited to control this outbreak as deemed necessary by the competent authority;

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(b) the porcine animals are DIVA vaccinated under the supervision of the competent authority and the use of DIVA vaccines is documented for each animal;

(c) the DIVA vaccinated porcine animals are only moved directly to a slaughterhouse or to an establishment in another Member State or zone where no vaccination ban is in place.

4. By way of derogation from point 1(b), surveillance may be carried out to demonstrate annually the absence of ADV infection taking into account the systems of production and the risk factors identified, provided no outbreaks have been detected for 2 consecutive years following the granting of the status free from infection with ADV in this Member State or zone.

PART VI

BOVINE VIRAL DIARRHOEA

CHAPTER 1

Establishment free from bovine viral diarrhoea

Section 1

Granting of the status

1. The status free from bovine viral diarrhoea (BVD) may only be granted to an establishment keeping bovine animals if:

(a) during the past 18 months there has been no confirmed case of BVD in a bovine animal kept in the establishment;

(b) the bovine animals kept in the establishment have been subjected to at least one of the following testing regimes taking into account possible previous vaccinations:

(i) tests for the detection of BVD virus (BVDV) antigen or genome have been carried out, with negative results, on samples of all bovine animals.

At least from all calves born in the previous 12 months, the samples must have been taken after or at the same time as official identification, but not later than 20 days postpartum. The dams of those calves with negative test results do not need to be tested;

(ii) serological tests for the detection of antibodies against BVDV have been carried out, with negative results, on samples taken over a period of not less than 12 months on at least three occasions at intervals of not less than 4 months from bovine animals which have been kept in the establishment for at least 3 months prior to testing.

The number of animals tested must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 50 % and must be at least five animals or all the animals if there are fewer than five animals kept.

In case the bovine animals of the establishment are kept in separate groups without direct contact with each other, a respective number of animals of each group must be tested;

(iii) a combination of the testing regimes set out in points (i) and (ii) has been applied over a period of not less than 12 months.

The capacity of the combined testing regime to detect the disease must be equivalent to that of the testing regimes referred to in points (i) and (ii);

(c) since the beginning of the sampling referred to in point 1(b), all bovine animals introduced into the establishment:

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(i) originate from establishments free from BVD located in a Member State or zone free from BVD; or

(ii) originate from establishments free from BVD, where

— serological tests referred to in point 1(c) (ii) or (iii) of Section 2 of Chapter 1 have been carried out, with negative results, within the past 4 months; or

— prior to their dispatch, they have been tested individually to exclude BVDV transmission into the establishment of destination taking into account the testing history and, if relevant, the animal's stage of gestation; or

(iii) have tested negative in a test for BVDV antigen or genome, and

— have been subjected to quarantine for a period of at least 21 days prior to their dispatch and, in case of pregnant dams, have tested negative for antibodies against BVDV on samples taken after not less than 21 days of quarantine; or

— have tested positive for antibodies against BVDV either prior to their dispatch or, in case of pregnant dams, before insemination preceding the current gestation;

(d) since the beginning of the sampling referred to in point 1(b) all germinal products of bovine animals introduced into the establishment originate from:

(i) establishments free from BVD; or

(ii) approved germinal product establishments.

2. By way of derogation from point 1, the status free from BVD may be granted to an establishment if:

(a) all bovine animals originate from establishments free from BVD located in a Member State or zone free from BVD or in a Member State or zone covered by an approved eradication programme and fulfil the requirements laid down in point 1(c), if relevant; or

(b) all bovine animals originate from establishments free from BVD, are not intended for breeding and the status free from BVD of the establishment is maintained in accordance with point 2 of Section 2.

Section 2

Maintenance of the status

1. The status free from BVD of an establishment keeping bovine animals may only be maintained if:

(a) the requirements laid down in point (a), (c) and (d) of point 1 of Section 1 continue to be fulfilled;

(b) no bovine animal has been vaccinated against BVD since the status free from BVD was granted to the establishment;

(c) at least one of the following testing regimes is carried out with negative results:

(i) each new-born calf is tested negative for BVDV antigen or genome on a sample taken after or at the same time as official identification, but not later than 20 days postpartum;

(ii) serological tests for the detection of antibodies against BVDV are carried out at least annually on samples taken from bovine animals that have been kept in the establishment for at least 3 months prior to testing.

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The number of animals tested must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 50 % and must be at least five animals or all the animals if there are fewer than five animals kept;

In case the bovine animals of the establishment are kept in separate groups without direct contact with each other, a respective number of animals of each group must be tested;

(iii) a combination of the testing regimes laid down in points (i) and (ii) is applied.

The capacity of the combined testing regime to detect the disease must be equivalent to that of the testing regimes referred to in points (i) and (ii);

(iv) if the establishment is located in a Member State or zone free from BVD, tests are carried out on samples taken in accordance with point 1(b) of Section 2 of Chapter 2 or point 3 of Section 2 of Chapter 2, if relevant;

(d) only bovine animals that have not been vaccinated against BVD are introduced into the establishment if it is located in a Member State or zone free from BVD.

2. By way of derogation from point 1, the status free from BVD of an establishment keeping bovine animals referred to in point 2(b) of Section 1 may be maintained without testing the bovine animals in accordance with point 1(c) if:

(a) the requirements laid down in point 2(b) of Section 1 continue to be fulfilled;

(b) they are not used for breeding;

(c) they have no contact with animals that are intended or used for breeding and are moved from this establishment to a slaughterhouse,

(i) directly, or;

(ii) via an assembly operation, which is carried out in the same Member State or zone, and where only animals that comply with the requirements laid down in points (b) and (c) and originate from establishments that comply with the requirement laid down in point (a) are assembled.

Section 3

Suspension and restoring of the status

1. The status free from BVD of an establishment keeping bovine animals must be suspended if:

(a) one or more of the requirements laid down in Section 2 are not fulfilled;

(b) a case of BVD is suspected in a bovine animal kept in the establishment.

2. The status free from BVD may only be restored if:

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(a) the requirements laid down in point 1(c) and (d) of Section 1 and point 1(b)(c) and (d) and, if relevant, point 2 of Section 2 are fulfilled.

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(b) the results of further investigations substantiate absence of BVD and the status of all suspected cases has been determined.

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Section 4

Withdrawal and regaining of the status

1. The status free from BVD of an establishment keeping bovine animals must be withdrawn if:

   (a) one or more of the requirements laid down in Section 2 are not fulfilled after the maximum period of time referred to in point (b) of Article 20(3) has lapsed since the status was suspended;

   (b) a case of BVD has been confirmed in a bovine animal kept in the establishment.

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2. If the status free from BVD has been withdrawn in accordance with point 1(a), it may only be regained if the requirements laid down in point 1(c) and (d) of Section 1 and point 1(b), (c) and (d) and, if relevant, point 2 of Section 2 are fulfilled.

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3. If the status free from BVD has been withdrawn in accordance with point 1(b), it may only be regained if:

   (a) all animals tested positive for BVDV have been removed;

   (b) the status in relation to infection with BVDV of each bovine animal kept in the establishment has been determined;

   (c) all calves that might have been infected in utero with BVDV were born and kept in isolation until they tested negative for BVDV antigen or genome.

CHAPTER 2

Member State or zone free from bovine viral diarrhoea

Section 1

Granting of the status

The status free from BVD as regards kept bovine animals may only be granted to a Member State or a zone if:

(a) vaccination against BVD has been prohibited for kept bovine animals;

(b) no case of BVD has been confirmed in a kept bovine animal for at least the previous 18 months; and

(c) at least 99,8 % of the establishments representing at least 99,9 % of the bovine population are free from BVD.

Section 2

Maintenance of the status

1. The status free from BVD as regards kept bovine animals of a Member State or a zone may only be maintained if:

   (a) the requirements laid down in point (a) and (c) of Section 1 continue to be fulfilled; and

   (b) surveillance is carried out annually that must allow at least for the detection, with a 95 % level of confidence, of establishments infected with BVDV at a target prevalence rate of 0,2 % of the establishments or of BVDV infected bovine animals with a target prevalence rate of 0,1 % of the bovine population.

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2. By way of derogation from point 1(a), the use of vaccination may be authorised by the competent authority in the event of an outbreak, if:

   (a) the results of the epidemiological enquiry and investigations according to Article 25 have demonstrated that only a limited number of establishments were involved in the outbreak;

   (b) only a limited number of bovine animals deemed necessary by the competent authority to control this outbreak are vaccinated under the supervision of the competent authority and the use of vaccination is documented for each animal.

3. By way of derogation from point 1(b), surveillance may be carried out to demonstrate annually the absence of BVD taking into account the systems of production and the risk factors identified, provided no outbreaks have been detected for 5 consecutive years following the granting of the status free from BVD in this Member State or zone.

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ANNEX V

DISEASE SPECIFIC REQUIREMENTS FOR THE GRANTING AND MAINTENANCE OF THE DISEASE-FREE STATUS AT THE LEVEL OF MEMBER STATES OR ZONES

PART I

INFECTION WITH RABIES VIRUS

CHAPTER 1

Technical requirements for the vaccination against rabies

Section 1

Vaccination of kept animals

1. For the purpose of eradication programmes for infection with rabies virus (RABV), anti-rabies vaccination must only be carried out on pet animals that are identified and must fulfil the requirements laid down in Annex III to Regulation (EU) No 576/2013 of the European Parliament and of the Council ([1]).

2. For the purpose of eradication programmes for infection with RABV, anti-rabies vaccination of kept animals, other than those referred to in the first paragraph, must be risk-based and carried out with the purpose of protecting humans from being exposed to rabies virus, using vaccines that meet the requirements laid down in points (1)(a) and (1)(b)of Annex III to Regulation (EU) No 576/2013 of the European Parliament and of the Council.

Section 2

Vaccination of wild animals

1. For the purpose of eradication programmes for infection with RABV the oral vaccination against infection with RABV of wildlife must:

   (a) be organised and implemented as regular planned or emergency campaigns taking into account the risk assessment provided in point (a) of Article 32(2);

   (b) be subjected to an adequate vaccine distribution in terms of timing and coverage of the vaccination area, taking into account the biology of the targeted animal population, the epidemiological situation and the topography of the area;

   (c) be subjected, with the support of geographical information systems, to assessment of the correct geographical distribution of vaccine baits with a frequency that allows, if necessary, the adoption of corrective measures; and

   (d) be subjected to monitoring of vaccination effectiveness, that may include the detection of the presence of biomarker and serological testing in dead animals from the targeted animal population for the vaccination.

2. For the purpose of eradication programmes for infection with RABV the vaccination against infection with RABV of stray dog populations must:

([1]) Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) N0 998/2003 (OJ L 178, 28.6.2013, p. 1).

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(a) be organised and implemented, if necessary, as part of control and management measures of stray dog populations, taking into account the risk assessment provided for in point (a) of Article 32(2);

(b) comply with the requirements of Section 1.

CHAPTER 2

Member State or zone free from infection with rabies virus

Section 1

Granting of the status

1. The status free from infection with RABV may only be granted to a Member State or a zone if:

(a) surveillance has been implemented in accordance with the requirements laid down in Article 3(1) at least for the past 24 months; and

(b) no case of infection with RABV has been confirmed during the past 24 months in the targeted animal population.

2. By way of derogation from point 1(b), if a case of infection with RABV has been confirmed, the status may be granted if the infection of the case did not occur in the Member State or in the zone; and

(a) the case has been officially confirmed and no epidemiological link may have occurred and resulted in any additional case, which includes detection of the case at a border control post, or in a quarantine establishment or the quarantine facilities of a confined establishment; or

(b) epidemiological link may have occurred and no additional case was detected by increased surveillance and epidemiological enquiry and investigations during the 6 months following the death of the case.

Section 2

Maintenance of the status

The status free from infection with RABV of a Member State or a zone may only be maintained if:

(a) surveillance is implemented in accordance with the requirements laid down in Article 3(1) with the objective of an early detection of the disease; and

(b) no case of infection with RABV has been confirmed in the targeted animal population or a case occurred and the conditions laid down in point 2 of Section 1 were complied with.

PART II

INFECTION WITH BLUETONGUE VIRUS (SEROTYPES 1-24)

CHAPTER 1

Minimum requirements for the surveillance

Section 1

Surveillance for the detection of serotypes of Bluetongue virus not reported in the previous 2 years

1. The surveillance of infection with bluetongue virus (serotypes 1-24) (infection with BTV) to ensure early detection of introduction or recurrence

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of infection with any of the serotypes 1-24 of BTV that were not reported during the previous 2 years must include:

(a) general surveillance requirements as provided for in point (a) of Article 3(1);

(b) active surveillance as provided for in Section 4.

2. The design of the surveillance provided for in point 1 must address:

(a) the risk of infection with limited clinical manifestations;

(b) the risk of introduction of BTV serotypes associated with the circulation of any of the serotypes 1-24 of BTV in the vicinity; and

(c) any other identified relevant risk factor for introduction of any of the serotypes 1-24 of BTV not reported in the previous 2 years.

3. The surveillance in an area(s) adjacent to any infected Member State, zone or third country must be increased in an area of up to 150 km from the limit with the Member State, zone, or third country. The demarcation of the area of increased surveillance may be adapted to relevant ecological or geographical features likely to facilitate or interrupt the transmission of BTV or adapted due to the implementation of disease control measures that supports the choice between a greater or lesser distance.

4. The surveillance provided for in point 1(b) and point 3 must have the capacity at least to detect, with a 95 % level of confidence, the infection in the targeted animal population at a target prevalence rate of 5 %, unless otherwise specified in Section 2 of Chapter 4.

Section 2

Surveillance to determine the extent of infection with BTV

1. The surveillance of infection with BTV to ensure the timely demarcation of the spread of the infection when one or more serotypes of BTV is present and, if necessary, to monitor the prevalence rate must include:

(a) general surveillance requirements as provided for in point (a) of Article 3(1); and

(b) active surveillance as provided for in Section 4.

2. The design of the surveillance provided for in point 1 must take into account: all available information on the epidemiology of the disease and biology of the vector that prevail on the territory.

3. The target prevalence rate of the surveillance provided for in point 1 must be adapted to the epidemiological situation, taking into the main risk factors such as the targeted animal population and the vector population.

Section 3

Surveillance to demonstrate absence of infection with BTV

1. The surveillance of infection with BTV to demonstrate the absence of infection with any of the serotypes 1-24 that has been previously detected in the territory must include:

(a) general surveillance requirements as provided for in point (a) of Article 3(1); and

(b) active surveillance as provided for in Section 4.

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2. The design of the surveillance provided for in point 1 must address:

   (a) the risk of infection with limited clinical manifestations;

   (b) all available information on the epidemiology of the disease and biology of the vector that prevail on the territory; and

   (c) any specific risk of persistence of the infection identified.

3. The surveillance provided for in point 1(b) must have the capacity at least to detect, with a 95 % level of confidence, the infection in the targeted animal population at a target prevalence rate of 1 %.

Section 4

Requirements for the active surveillance of infection with BTV

1. The geographical units referred to in point (a) of Article 40(1) must be based on a grid of 45 km by 45 km and can be adapted to:

   (a) the epidemiological situation, how fast the infection is spreading and the shape and size of the zones covered by the eradication programme in the event of confirmation of the infection; and

   (b) the zones in accordance with point (b) of Article 13(2).

2. Active surveillance must be based on one or a combination of the following activities:

   (a) monitoring of sentinel animals using serological or virological testing; and

   (b) structured prevalence surveys, based on a random or risk-based sampling strategy using serological or virological testing.

3. The frequency of the sampling must:

   (a) at least be annual, in the period of the year when infection or seroconversion is most likely to be detected; and

   (b) be monthly during the vector activity season where regular information is needed due to the risk of the infection spreading.

4. The animals sampled must:

   (a) not be vaccinated against the serotype(s) of BTV targeted for surveillance;

   (b) no longer be covered by maternal immunity in case their mother was vaccinated or infected;

   (c) be resident for a sufficient time in the relevant geographical unit and not have been protected from exposure to the vector;

   (d) be representative for the geographical distribution of the targeted animal population in the relevant geographical unit; and

   (e) be initially seronegative when surveillance is based on serological testing of sentinels.

5. The sample size in each geographical unit must be calculated in accordance with the target prevalence rate based on the objectives assigned in Sections 1-3.

6. When surveillance must be adapted as provided for in point (c) of Article 43(2), it must at least include a survey:

   (a) on the introduced animals that:

      (i) must be based on the sampling and testing of all introduced animals;

      (ii) must take place as soon as possible after their introduction; or

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(b) on the targeted animal population the most at risk due to the possible circulation of the virus that:

(i) must have a capacity at least to detect, with a 95 % level of confidence, infection with BTV at a target prevalence rate of 5 %;

(ii) must either:

— not take place before 21 days has elapsed after the introduction of animals if it is a one-shot survey; or

— must be conducted with a frequency adapted to the frequency of the movements of the animals that may jeopardise the health status.

This survey is not required if the frequency of the sampling is carried out in accordance with point 3(b).

Section 5

Entomological surveillance

1. Entomological surveillance must consist of at least an active annual programme of vector catching by means of permanently sited aspiration traps intended to determine the population dynamics of the vector and, where relevant, the vector-free period.

2. Aspiration traps equipped with ultraviolet light must be used in accordance with pre-established protocols; the traps must be operated throughout the night and operate at least:

(a) one night per week during the month before the expected beginning and during the month before the expected end of the vector-free period; and

(b) one night per month during the vector-free period.

On the basis of the evidence obtained in the first 3 years of operating the aspiration traps, the frequency of operation of those traps may be adjusted.

3. At least one aspiration trap must be placed in each geographical unit referred to in point (a) of Article 40(1) throughout the seasonally BTV-free zone. A proportion of the midges collected in the aspiration traps must be sent to a specialised laboratory capable of counting and identifying the suspected vector species or complexes.

4. When entomological surveillance is organised in the context of determination of a vector-free period, a maximum threshold of *Culicoides* species must be defined for the interpretation of the results. In the absence of sound evidence supporting the determination of the maximum threshold, total absence of *Culicoides imicola* specimens and less than five parous *Culicoides* per trap must be used as maximum threshold.

CHAPTER 2

Movement of animals and germinal products

Section 1

Movement of animals

1. The animals originate from a Member State or a zone free from infection with BTV and have not been vaccinated with a live vaccine against infection with BTV in the last 60 days before the date of movement.

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2. The animals originate from a Member State or a zone covered by the eradication programme and at least one of the following requirements is complied with:

(a) the animals have been kept in a seasonally BTV-free Member State or zone established in accordance with paragraph 3 of Article 40:

(i) for at least 60 days prior to the date of movement;

(ii) for at least 28 days prior to the date of movement and have been subjected to a serological test, with negative results, carried out on samples collected at least 28 days following the entry date of the animal into the seasonally BTV-free Member State or zone; or

(iii) for at least 14 days prior to the date of movement and have been subjected to a PCR test, with negative results, carried out on samples collected at least 14 days following the entry date of the animal into the seasonally BTV-free Member State or zone;

(b) the animals have been protected against attacks by the vectors during transportation to the place of destination and they have been kept protected against attacks by vectors in a vector protected establishment:

(i) for at least 60 days prior to the date of movement; or

(ii) for at least 28 days prior to the date of movement and have been subjected to a serological test, with negative results, carried out on samples collected at least 28 days following the date of the commencement of the period of protection against attacks by vectors; or

(iii) for at least 14 days prior to the date of movement and have been subjected to a PCR test, with negative results, carried out on samples collected at least 14 days following the date of commencement of the period of protection against attacks by vectors;

(c) the animals have been vaccinated against all serotypes 1-24 of BTV reported during the past 2 years in that Member State or zone, the animals are within the immunity period guaranteed in the specifications of the vaccine and meet at least one of the following requirements:

(i) they have been vaccinated more than 60 days before the date of movement; or

(ii) they have been vaccinated with an inactivated vaccine and subjected to a PCR test, with negative results on samples collected at least 14 days after the onset of the immunity set in the specifications of the vaccine.

(d) the animals have been subjected with positive results to a serological test able to detect specific antibodies against all serotypes 1-24 of BTV reported during the past 2 years in that Member State or zone and:

(i) the serological test have been carried out on samples collected at least 60 days before the date of movement; or

(ii) the serological test have been carried out on samples collected at least 30 days before the date of the movement and the animals have been subjected to a PCR test, with negative results, carried out on samples collected not earlier than 14 days before the date of movement.

3. The animals originate from a Member State or a zone neither BTV-free nor covered by an eradication programme for infection with BTV and:

(a) they comply with point 2(b); or

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(b) the animals have been kept at least for the last 60 days prior to departure either in an area of at least 150 km radius from the establishment where they are kept, or in a Member State, where surveillance in compliance with the requirements laid down in Sections 1 and 2 of Chapter 1 have been carried out at least for the last 60 days prior to departure and:

(i) they have been vaccinated in accordance with point 2(c) against all serotypes 1-24 of BTV reported during the past 2 years in an area of at least 150 km radius centred on the place where the animals were kept; or

(ii) they have been immunised in accordance with point 2(d) against all serotypes 1-24 of BTV reported during the past 2 years in an area of at least 150 km radius centred on the place where the animals were kept.

4. The animals originate from a Member State or a zone not BTV-free, are destined for immediate slaughter and the following requirements apply:

(a) no case of infection with BTV has been reported in the establishment of origin for a period of at least 30 days prior to the date of movement;

(b) the animals are transported directly from the Member State or zone of origin to the slaughterhouse of destination where they are slaughtered within 24 hours of arrival;

(c) the operator of the establishment of origin have informed the operator of the slaughterhouse of destination of the movement at least 48 hours prior to the loading of the animals.

5. The animals originate from a Member State or a zone neither BTV-free nor covered by an eradication programme for infection with BTV and the animals comply with the requirements set out in point 2(a).

6. The animals originate from a Member State or a zone not BTV-free and:

(a) they have been protected from vector attacks by insecticides or repellents for at least 14 days prior to the date of movement; and

(b) they have been subjected during that period to a PCR test, with negative results, carried out on samples collected at least 14 days following the date of protection from vector attacks.

7. The animals comply with specific animal health requirements defined by the competent authority to ensure they have sufficient immunological protection prior to departure.

8. The animals comply with any of the requirements provided for in points 2, 3 5, 6 or 7 only for the serotypes of BTV reported for the past 2 years in the Member State or zone of origin and not in the Member State or zone of destination during the same period.

Section 2

Movement of germinal products

1. The donor animals have been kept at least for a period of 60 days prior to and during the collection of germinal products in a Member State or a zone free from infection with BTV.

2. The germinal products originate from a Member State or a zone covered by the eradication programme for infection with BTV and at least one of the requirements set out in point (a) for semen, point (b) for in vivo derived embryos of bovine animals or point (c) for embryos other than in vivo derived embryos of bovine animals and oocytes is complied with:

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(a) semen have been obtained from donor animals that comply with at least one of the following requirements:

(i) they have been protected against attacks by vectors in a vector protected establishment for a period of at least 60 days before commencement of collection and during collection of the semen;

(ii) they have been kept in a seasonally BTV-free Member State or zone for a period of at least 60 days before commencement of collection and during collection of the semen;

(iii) they have been subjected to a serological test, with negative results, on samples collected between 28 and 60 days from the date of each collection of the semen;

(iv) they have been subjected, with negative results, to a direct diagnostic method carried out on samples collected:

— at commencement and final collection of the semen to be consigned; and

— during the period of semen collection: at least every 7 days in the case of a virus isolation test, or at least every 28 days, in the case of a PCR test;

(b) in vivo derived embryos of bovine animals have been obtained from donor animals that do not show any clinical signs of infection with BTV on the day of collection and are collected, processed and stored in accordance with Part 2 of Annex III of Commission Delegated Regulation (EU) 2020/686 ([2]);

(c) embryos other than in vivo derived embryos of bovine animals and oocytes have been obtained from donor animals that comply with at least one of the following requirements:

(i) they have been protected against attacks by vectors in a vector protected establishment for at least 60 days before commencement of collection and during collection of the embryos/oocytes;

(ii) they have been subjected to a serological test, with negative results, on samples collected between 28 and 60 days from the date of each collection of the embryos/oocytes;

(iii) they have been subjected to a PCR test, with negative results, on samples collected on the day of collection of the embryos/oocytes;

(iv) they have been kept in a seasonally BTV-free Member State or zone for a period of at least 60 days before collection of the embryos/oocytes.

3. The germinal products originate from a Member State or a zone neither BTV-free nor covered by an eradication programme for infection with BTV and comply with the requirements set out either in point 2(a)(i), 2(a)(iii), 2(a)(iv), 2(b), 2(c)(i), 2(c)(ii) or 2(c)(iii).

4. The germinal products originate from a Member State or a zone neither BTV-free nor covered by an eradication programme for infection with BTV and must comply with either point 2(a)(ii) or 2(c)(iv).

CHAPTER 3

Vector protected establishment

The status of vector protected establishment may only be granted to an establishment if:

([2]) Commission Delegated Regulation (EU) 2020/686 of 17 December 2019, supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals (see page 1 of this Official Journal).

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(a) it has appropriate physical barriers at entry and exit points;

(b) openings must be vector screened with mesh of appropriate gauge which must be impregnated regularly with an approved insecticide according to the manufacturers' instructions;

(c) vector surveillance and control must be carried out within and around the vector protected establishment;

(d) measures must be taken to limit or eliminate breeding sites for vectors in the vicinity of the vector protected establishment; and

(e) standard operating procedures must be in place, including descriptions of back-up and alarm systems, for operation of the vector protected establishment and transport of animals to the place of loading.

CHAPTER 4

Member State or zone free from infection with BTV

Section 1

Granting of the status

1. The status free from infection with BTV may only be granted to a Member State or to a zone, where BTV has never been reported, if:

   (a) surveillance in accordance with Section 1 of Chapter 1 has been conducted at least for the past 24 months; and

   (b) no case of infection with BTV has been confirmed during the past 24 months in the targeted animal population.

2. The status free from infection with BTV may only be granted to a Member State or to a zone where BTV has already been reported if:

   (a) surveillance in accordance with Section 3 of Chapter 1 has been conducted at least for the past 24 months; and

   (b) no case of infection with BTV has been confirmed during the past 24 months in the targeted animal population.

Section 2

Maintenance of the status

1. The status free from infection with BTV may only be maintained if:

   (a) the requirements laid down in point 1 of Section 1 are complied with; and

   (b) animals and germinal products from the targeted animal population are only moved into or through the Member State or zone when the requirements laid down in Articles 43 and 45 are complied with.

2. The intensity and frequency of the surveillance referred to in point 1 of Section 1 must be duly adapted to:

   (a) the health status of neighbouring Member States, zones or third countries in accordance with point 3 of Section 4 of Chapter 1;

   (b) the introduction of animals from the targeted animal population that may have jeopardised the health status of the Member State or zone, in accordance with point 6 of Section 4 of Chapter 1.

3. If no circulation of the infection has been detected for 2 consecutive years following granting of the status free from infection with BTV of a Member State or of a zone, surveillance must be based on:

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(a) random annual surveillance at least to detect, with a 95 % level of confidence, the infection with BTV at a target prevalence rate of 20 %; or

(b) risk-based annual surveillance to detect infection with BTV carried out taking into account the systems of production and the risk factors identified.

CHAPTER 5

Seasonally BTV-free Member State or zone

1. The seasonally BTV-free status may only be established in a Member State or zone thereof if:

   (a) the beginning and the end of the vector-free period and therefore of the seasonally BTV-free period has been demonstrated based on entomological surveillance in accordance with Section 5 of Chapter 1; and

   (b) the cessation of the transmission of BTV has been demonstrated by:

      (i) the implementation of surveillance in accordance with Section 2 of Chapter 1 at least for the past 12 months including one full vector activity season; and

      (ii) the absence of new cases of infection with any of the serotypes 1-24 of BTV since the end of the vector activity season.

2. By way of derogation from point 1(a), if the seasonally BTV-free period has been successfully demonstrated for a period of 3 consecutive years, additional criteria such as temperature may replace entomological surveillance to substantiate the beginning and the end of the seasonally BTV-free period on the basis of scientific evidence.

3. The seasonally BTV-free Member State or zone must immediately stop when there is evidence of the end of the vector-free period or of circulation of the virus.

PART III

INFESTATION WITH *VARROA* SPP.

Section 1

Granting of the status to a Member State or zone as free from infestation with *varroa* spp.

The status free from infestation with *Varroa* spp. may only be granted to the relevant honeybee population of a Member State or of a zone if:

(a) a risk assessment has been conducted, identifying all potential factors for *Varroa* spp. occurrence and its potential presence in the past;

(b) an ongoing awareness programme has been in place for at least one year to encourage reporting of all cases suggestive of *Varroa* spp.;

(c) there has been no confirmed case of infestation with *Varroa* spp. either in kept or in wild honeybee colonies;

(d) for at least one year, an annual surveillance has demonstrated the absence of infestations with *Varroa* spp. on a representative sample of kept honeybees of the Member State or zone thereof that allows at least for the detection, with a 95 % level of confidence, of the infestation with *Varroa* spp. at a target prevalence rate of 1 % of the apiaries and at a within-apiary target prevalence rate of 5 % of the beehives;

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(e) in the presence of a wild self-sustaining population of the species of the genus *Apis* there has been in place for at least one year an ongoing surveillance programme in the wild population which demonstrates no evidence of infestation with *Varroa* spp.; and

(f) during the whole duration of the surveillance referred to in point (d) the competent authority makes appropriate arrangements for the survey and further handling of honeybees in any stage of their lifecycle, including honeybee brood, which are moved into that Member State or into that zone to prevent the infestation of its population from introduced honeybees of lesser health status.

Section 2

Maintenance of the status of a Member State or zone free from infestation with *varroa* spp.

The status free from infestation with *Varroa* spp. granted to the relevant honeybee population of a Member State or of a zone may only be maintained if:

(a) the competent authority maintains a surveillance that:

(i) demonstrates the absence of infestations with *Varroa* spp. annually on a representative sample of kept honeybees of the free area;

(ii) enables the early detection of infestation with *Varroa* spp. in apiaries and beehives;

(iii) takes into consideration specifically target areas with higher likelihood of introduction of or infestation with *Varroa* spp., based on a risk assessment;

(b) all the suspected cases have been investigated and no case of infestation with *Varroa* spp. has been confirmed, either in kept or in wild honeybee colonies;

(c) either there is no wild self-sustaining population of the species of the genus Apis or there is an ongoing surveillance programme in the wild population which demonstrates no evidence of infestation with *Varroa* spp.; and

(d) the honeybees in any stage of their lifecycle, including honeybee brood, are only moved into the free area when:

(i) they come from a Member State or zone thereof or from a third country or territory with disease-free status regarding infestation with *Varroa* spp.; and

(ii) they are protected from infestation with *Varroa* spp. during transport.

PART IV

STATUS FREE FROM INFECTION WITH NEWCASTLE DISEASE VIRUS- WITHOUT VACCINATION

Section 1

Granting of status free from infection with Newcastle disease virus without vaccination

The status free from infection with Newcastle disease virus (NDV) status without vaccination in the population of poultry and captive birds of *Galliformes* species may only be granted to a Member State or to a zone if for at least the past 12 months:

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(a) vaccination against infection with NDV in poultry and in captive birds of *Galliformes* species has been prohibited;

(b) no poultry and no captive birds of *Galliformes* species vaccinated against infection with NDV has been kept in establishments keeping poultry or captive birds of *Galliformes* species;

(c) general surveillance requirements have been carried out in accordance with point (a) of Article 3(1) for the early detection of infection with NDV;

(d) one of the following testing regime has applied:

(i) all establishments keeping breeding poultry have been tested for the presence of antibodies against infection with NDV with negative results, on blood samples from at least 60 birds randomly chosen from each establishment and tested serologically by Haemagglutination inhibition (HI) test; or

(ii) a survey has been conducted on a representative sample of establishments which has at least the capacity at least to detect, with a 95 % level of confidence, the infection at a target prevalence rate of 1 % in the poultry establishments and at a within-establishment prevalence rate of seropositive birds of 10 %; and

(e) no case of infection with NDV has been confirmed in poultry and captive birds of *Galliformes* species.

Section 2

Maintenance of the status

1. The status free from infection with NDV without vaccination granted to a Member State or to a zone may only be maintained if the requirements in points (a) to (e) of Section 1 continue to be fulfilled.

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2. By way of derogation from paragraph 1, the status free from infection with NDV without vaccination granted to a Member State or to a zone may be maintained in the event of the confirmation of outbreaks of infection with NDV if:

(a) the competent authority has only notified a limited number of primary outbreaks during a calendar year;

(b) the competent authority has concluded that only a limited number of secondary outbreaks epidemiologically linked to each primary outbreak occurred; and

(c) the disease control measures were applied for a duration not longer than three months for each primary outbreak and related secondary outbreaks.

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3. The status free from infection with NDV without vaccination granted to a Member State or to a zone is not affected by the confirmation of the infection in another bird population, provided the competent authority has assessed, taking into account the implementation of all necessary measures to prevent transmission of infection with NDV to poultry and captive birds of *Galliformes* species, that the status was not jeopardised.

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ANNEX VI

SPECIFIC REQUIREMENTS AS REGARDS DISEASES OF AQUATIC ANIMALS

PART I

RISK-BASED SURVEILLANCE

CHAPTER 1

Minimum requirements for risk-based surveillance in certain approved aquaculture establishments

1. **General approach**

1.1. Risk-based health surveillance which includes health visits and possible sampling is applied in certain approved aquaculture establishments and in certain approved groups of aquaculture establishments in a manner that is appropriate to the nature of the production and which has the objective of detecting:

(a) increased mortality;

(b) listed diseases;

(c) emerging diseases.

1.2. The frequency of such visits will depend on the risk the approved aquaculture establishment or approved group of aquaculture establishments poses in relation to contracting and spreading disease. This risk applies to listed diseases and to potential emerging diseases and will therefore include aquaculture establishments and groups of aquaculture establishments keeping listed species and in certain cases, aquaculture establishments and groups of aquaculture establishments keeping non-listed species. The competent authority must determine the risk posed by each approved aquaculture establishment or approved group of aquaculture establishments and rank them as high, medium or low risk.

Chapter 2 provides details of the risk factors to be taken into account during the risk ranking process. Such risk ranking will be repeated and updated if any of the risk factors outlined in points (a) to (l) indicate that the risk posed by the establishment has changed.

1.3. Chapter 3 sets out the minimum frequency of health visits which must be completed, based on whether the competent authority has designated an establishment to be high, medium or low risk.

1.4. Risk-based animal health surveillance in aquaculture establishments and groups of aquaculture establishments may be combined with health visits and sampling which are carried out:

(a) as part of compulsory or optional eradication programmes for one or more listed diseases; or

(b) to demonstrate and maintain disease free status for one or more listed diseases; or

(c) as part of a surveillance programme for one or more category C diseases.

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CHAPTER 2

Risk ranking to be applied in certain approved aquaculture establishments

The risk ranking referred to in point 1.2 of Chapter 1 must as a minimum, take into account the risk factors referred to in points (a) and (b). Where relevant, points (c) to (l) will also be considered:

(a) possibility of the direct spread of pathogens via water;

(b) movements of aquaculture animals;

(c) type of production;

(d) species of aquaculture animals kept;

(e) biosecurity system, including staff competence and training;

(f) density of aquaculture establishments and processing establishments in the area around the establishment concerned;

(g) proximity of establishments with a lower health status than the establishment concerned;

(h) disease history of the establishment concerned and of other local establishments;

(i) presence of infected wild aquatic animals in the area around the establishment concerned;

(j) risk posed by human activities in the proximity of the establishment concerned for example angling, the presence of transport routes, ports at which ballast water is exchanged;

(k) access to the establishment concerned by predators which may cause disease spread;

(l) track record of the establishment as regards compliance with the requirements of the competent authority.

CHAPTER 3

Frequency of risk-based animal health visits

The frequency of risk-based health visits which must be carried out in certain approved establishments and approved groups of establishments depends upon the risk ranking referred to in Chapter 2 and shall be carried out as follows:

(a) at least once per year in high risk establishments;

(b) at least once every two years in medium risk establishments;

(c) at least once every three years in low risk establishments.

PART II

DISEASE- SPECIFIC REQUIREMENTS FOR DISEASE-FREE STATUS OF AQUATIC ANIMALS

Part II covers the disease-specific requirements for disease-free status as regards the following listed diseases:

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Viral haemorrhagic septicaemia (VHS)	Chapter 1
Infectious haematopoietic necrosis (IHN)	Chapter 1
Infection with HPR-deleted infectious salmon anaemia virus	Chapter 2
Infection with *Marteilia refringens*	Chapter 3
Infection with *Bonamia exitiosa*	Chapter 4
Infection with *Bonamia ostreae*	Chapter 5
Infection with white spot syndrome virus (WSSV)	Chapter 6

CHAPTER 1

Eradication, disease-free status and diagnostic methods for viral haemorrhagic septicaemia (VHS) and infectious hematopoietic necrosis (IHN)

Section 1

General requirements for health visits and sampling

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Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements:

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(a) health visits and, where appropriate sampling, must be carried out during the period of the year when the water temperature is below 14 °C or when temperatures below 14 °C are not reached, samples must be taken at the lowest annual temperatures;

(b) when targeted surveillance in wild populations is required due to the small number of aquaculture establishments in an eradication programme, the number and geographical distribution of sampling points must be determined to obtain a reasonable coverage of the Member State, zone or compartment. The sampling points must be representative of the different ecosystems where wild populations of susceptible species are located;

(c) when establishments or wild populations are to be subject to health visits or sampled more than once per year, in accordance with Sections 2 to 4, the intervals between the health visits and between the collection of samples must be at least 4 months, or as long as possible, taking into account the temperature requirements provided for in point (a);

(d) all production units, such as ponds, tanks and net cages, must be examined for the presence of dead, weak or abnormally behaving fish. Particular attention must be paid to the water outlet area where weak fish tend to accumulate because of the water current;

(e) fish of listed species to be collected as samples must be selected as follows:

(i) if rainbow trout are present, only fish of that species must be selected for sampling, except where other susceptible species are present which show typical signs of VHS or IHN; if rainbow trout are not present, the sample must be representative of all other susceptible species which are present;

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(ii) if weak, abnormally behaving or freshly dead but not decomposed fish are present, such fish must be selected; if more than one water source is utilised for fish production, fish representing all water sources must be included in the sample;

(iii) the fish selected must include fish collected in such a way that all production units, such as net cages, tanks and ponds, of the establishment, as well as all year classes, are proportionally represented in the sample.

Section 2

Granting of the status free from VHS or free from IHN in Member States, zones and compartments of unknown health status

The status free from VHS or free from IHN may only be granted to a Member State, a zone or a compartment with an unknown health status with regard to VHS or IHN if:

(a) all establishments and, when required, sampling points in wild populations selected in accordance with point (b) of Section 1, have been subject to one of the following scheme:

(i) model A — 2-year scheme

The establishments or sampling points must have been subject to health visits and sampled for a minimum period of 2 consecutive years as laid down in Table 1.A.

During that 2-year period, the testing of all samples using the diagnostic methods set out in point 2 of section 5 must have produced negative results for VHS or IHN, and any suspicion of VHS or IHN must have been ruled out in accordance with the sampling and diagnostic methods set out in point 3 of Section 5;

(ii) model B — 4-year scheme with reduced sample size

The establishments or sampling points must have been subject to health visits and sampled for a minimum period of 4 consecutive years as laid down in Table 1.B. During that 4-year period, the testing of all samples using the diagnostic methods set out in point 2 of Section 5 must have produced negative results for VHS or IHN and any suspicion of VHS or IHN must have been ruled out in accordance with the sampling and diagnostic methods set out in point 3 of Section 5;

(b) if VHS or IHN have been detected during the surveillance referred to in point (a); before starting a new 2-year or 4-year scheme, relevant establishments in the Member State, zone or compartment must:

(i) be subject to the minimum disease control measures laid down in Articles 58 to 65;

(ii) be repopulated with fish from an establishment in a Member State, zone or compartment with status free from VHS or status free from IHN or from an establishment in a Member State, zone or compartment covered by an eradication programme for VHS or IHN.

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Table 1.A

Scheme for Member States, zones and compartments for the 2-year control period referred to in point (a)(i) which precedes the achievement of status free from VHS and status free from IHN

Type of establishment	Number of health visits per year to each establishment	Number of samplings per year in each establishment	Number of fish in the sample (1)	
			Number of growing fish	Number of broodstock fish (2)
(a) Establishments with broodstock	2	2	50 (first visit) 75 (second visit)	30 (first or second visit)
(b) Establishments with broodstock only	2	1	0	75 (first or second visit)
(c) Establishments without broodstock	2	2	75 (first AND second visit)	0

Maximum number of fish per pool: 10

(1) In the case of coastal zones or coastal compartments, the samples must be collected no sooner than 3 weeks after the transfer of the fish from fresh to saltwater.
(2) Ovarian or seminal fluid of broodstock shall be collected at the time of maturation, in connection with stripping.

Table 1.B

Scheme for Member States, zones or compartments using a reduced sample size for the 4-year control period referred to in point (a)(ii) which precedes the achievement of status free from VHS and status free from IHN

Type of establishment	Number of health visits per year to each establishment	Number of samplings per year in each establishment	Number of fish in the sample (1)	
			Number of growing fish	Number of broodstock fish (2)
First 2 years				
(a) Establishments with broodstock	2	1	30 (second visit)	0
(b) Establishments with broodstock only	2	1	0	30 (first or second visit)
(c) Establishments without broodstock	2	1	30 (first or second visit)	0
Last 2 years				
(a) Establishments with broodstock	2	2	30 (first visit)	30 (second visit)
(b) Establishments with broodstock only	2	2		30 (first AND second visit)
(c) Establishments without broodstock	2	2	30 (first AND second visit)	

Maximum number of fish per pool: 10

(1) In the case of coastal zones or coastal compartments, the samples must be collected no sooner than 3 weeks after the transfer of the fish from fresh to saltwater.
(2) Ovarian or seminal fluid of broodstock shall be collected at the time of maturation, in connection with stripping.

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Section 3

Granting of the status free from VHS or free from IHN in Member States, zones and compartments known to be infected with either VHS or IHN

1. The status free from VHS or free from IHN may only be granted to a Member State, a zone or a compartment known to be infected with VHS or IHN, if all establishments keeping listed species within that Member State, zone or compartment have been subject to an eradication programme that complies with the following requirements:

(a) the minimum control measures laid down in Articles 55 to 65 must have been effectively applied and a restricted zone of an appropriate size as provided for in point (c) of Article 58(1), where appropriate, divided into a protection zone and surveillance zone; must have been established in the vicinity of the establishment(s) declared infected with VHS or IHN, taking into account the requirements set out in point 2;

(b) all establishments keeping listed species within the protection zone, or where a protection zone has not been established, the restricted zone, not infected with VHS or IHN must be subject to an investigation comprising at least the following elements:

(i) the collection of samples for testing of 10 fish, when clinical signs or *post-mortem* lesions consistent with infection with VHS or IHN are observed or minimum 30 fish, when clinical signs or *post-mortem* lesions are not observed;

(ii) in those establishments where the tests referred to in (i) have produced negative results; health visits must continue once per month during the period when the water temperature is below 14 °C, except when fish ponds, tanks, raceways or net cages are covered with ice, until the protection zone is withdrawn in accordance with point (c);

(c) relevant establishments must be emptied in accordance with Article 62, cleaned and disinfected in accordance with Article 63 and fallowed in accordance with Article 64.

The duration of the fallowing period referred to in point (a) of Article 64(2) must be at least 6 weeks. When all establishments infected within the same protection zone, or where a protection zone has not been established, the restricted zone, are emptied, at least 3 weeks of synchronised fallowing must be carried out.

When fallowing of the infected establishments is carried out, the restricted zone or the protection zone, when it has been established, must be converted into a surveillance zone until the scheme set out in Section 2 is completed;

(d) repopulation may only take place when all infected establishments have been emptied, cleaned, disinfected and fallowed in accordance with point (c);

(e) all establishments other than those referred to in point (f) which keep listed species within the Member State, zone or compartment covered by the eradication programme and when surveillance in wild populations is required, all sampling points selected in accordance with point (b) of Section 1, must subsequently be subject to the scheme laid down in Section 2;

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(f) an individual establishment which keeps listed species and which has a health status which is independent of the health status of the surrounding waters is not required to comply with the scheme laid down in Section 2 following a disease outbreak, provided the establishment complies with the requirements set out in paragraph 3 of Article 80 and is repopulated with fish sourced from Member States, zones or compartments with status free from VHS or status free from IHN.

2. The restricted zone must have been defined on a case-by-case basis and:

(a) it must take into account factors influencing the risks for the spread of VHS or IHN to kept and wild fish, such as:

(i) the number, rate and distribution of the mortalities of fish on the establishment infected with VHS or IHN, or in other aquaculture establishments;

(ii) the distance to and density of neighbouring establishments;

(iii) the proximity to slaughterhouses;

(iv) contact establishments;

(v) species present at the establishments;

(vi) the farming practices applied in the infected establishments and the neighbouring establishments;

(vii) the hydrodynamic conditions; and

(viii) other factors of epidemiological significance identified;

(b) the geographical demarcation in coastal areas must comply with the following minimum requirements:

(i) the protection zone must consist of an area included in a circle with a radius of at least one tidal excursion or at least 5 km, whichever is larger, centred on the establishment infected with VHS or IHN, or an equivalent area determined according to appropriate hydrodynamic or epidemiological data; and

(ii) the surveillance zone must consist of an area surrounding the protection zone, of overlapping tidal excursion zones; or an area surrounding the protection zone and included in a circle of radius 10km from the centre of the protection zone; or an equivalent area determined according to appropriate hydrodynamic or epidemiological data;

or

(iii) where separate protection and surveillance zones are not established, the restricted zone must consist of an area comprising both the protection zone and the surveillance zone;

(c) the geographical demarcation in inland areas must comprise the entire water catchment area in which the establishment infected with VHS or IHN is located. The competent authority may limit the extent of the restricted zone to parts of the water catchment area, provided this limitation does not compromise the disease control measures with respect to VHS or IHN.

Section 4

Maintenance of status free from VHS and status free from IHN

1. When targeted surveillance is required in order to maintain the status free from VHS or free from IHN of a Member State, a zone or a compartment, in accordance with Article 81, all establishments keeping listed species within the Member State, zone or compartment concerned must be subject to health

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visits and fish must be sampled in accordance with Table 1.C, taking into account the risk level of the establishment for the contraction of VHS or IHN.

2. When determining the frequency of health visits required to maintain the status free from VHS or the status free from IHN of compartments, where the health status regarding VHS or IHN is dependent on the health status of the aquatic animal populations in surrounding natural waters, the risk for the contraction of VHS or IHN must be regarded as high.

3. Disease-free status must only be maintained as long as all samples tested, using the diagnostic methods set out in point 2 of Section 5, have produced negative results for VHS or IHN and any suspicion of VHS or IHN has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5.

Table 1.C

Scheme for Member States, zones or compartments to maintain status free from VHS or status free from IHN

Risk level ([1])	Number of health visits per year to each establishment	Number of fish in the sample ([2]), ([3])
High	1 every year	30
Medium	1 every 2 years	30
Low	1 every 3 years	30
Maximum number of fish per pool: 10		

([1]) Risk level assigned to the establishment by the competent authority as set out in Chapter 2 of Part I other than in the case of dependent compartments where all establishments are deemed to be high risk.
([2]) One sample to be taken during every health visit.
([3]) In the case of coastal zones or coastal compartments, the samples must be collected no sooner than 3 weeks after the transfer of the fish from fresh to saltwater.

Section 5

Diagnostic and sampling methods

1. The organs or tissue material to be sampled and examined must be the spleen, the anterior kidney, and either heart or encephalon. When sampling broodstock, ovarian or seminal fluid may also be examined.

   In case of small fry, whole fish may be sampled.

   Samples from a maximum of 10 fish may be pooled.

2. The diagnostic method for the granting or the maintenance status free from VHS or status free from IHN in accordance with Sections 2 to 4 must be:

   (a) virus isolation in cell culture with subsequent identification of the virus using ELISA, indirect fluorescent antibody test (IFAT), virus neutralisation test or virus genome detection; or

   (b) Reverse Transcription quantitative PCR (RT-qPCR) detection.

   The detailed procedures to carry out these diagnostic methods must be those approved by the EURL for fish diseases.

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3. When a suspicion of VHS or IHN is required to be confirmed or ruled out in accordance with Article 55, the following health visit, sampling and testing procedures must comply with the following requirements:

(a) the suspected establishment must be subject to at least one health visit and one sampling of 10 fish, when clinical signs or *post-mortem* lesions consistent with infection with VHS or IHN are observed or minimum 30 fish, when clinical signs or *post-mortem* lesions are not observed. Samples shall be tested using one or more of the diagnostic methods set out in points 2(a) and 2(b) in accordance with the detailed diagnostic methods and procedures approved by the EURL for fish diseases;

(b) the presence of VHS must be considered as confirmed, if one or more of those diagnostic methods are positive for VHSV. The presence of IHN must be considered as confirmed, if one or more of those diagnostic methods are positive for IHNV. The confirmation of the first case of VHS or IHN in Member States, zones or compartments previously not infected must be based on conventional virus isolation in cell culture with subsequent immunochemical or molecular identification or with genome detection including confirmation by sequencing of the amplification (RT-PCR) product;

(c) Suspicion of VHS or IHN may be ruled out, if cell cultivation or RT-qPCR tests reveal no further evidence of the presence of VHSV or IHNV.

CHAPTER 2

Eradication, disease-free status and diagnostic methods for infection with HPR-deleted infectious salmon anaemia virus (HPR-deleted ISAV)

Section 1

General requirements for health visits and sampling

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Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements:

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(a) when health visits and sampling of establishments must be carried out more than once per year in accordance with Sections 2 to 4, the intervals between the health visits or collection of samples shall be as long as possible;

(b) when targeted surveillance in wild populations is required due to the low number of aquaculture establishments in the eradication programme, the number and geographical distribution of sampling points must be determined to obtain a reasonable coverage of the Member State, zone or compartment;

(c) the sampling points must be representative of the different ecosystems where the wild populations of susceptible species are located;

(d) all production units, such as ponds, tanks and net cages, must be examined for the presence of dead, weak or abnormally behaving fish. Particular attention must be paid to the edge of cages or the water outlet area as relevant, where weak fish tend to accumulate because of the water current;

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(e) fish of listed species to be collected as samples must be selected as follows:

(i) if Atlantic salmon are present, only fish of that species must be selected for sampling, except where other susceptible species are present which show typical signs of infection with HPR- deleted ISAV. If there are no Atlantic salmon in the establishment, the sample must be representative of all other susceptible species which are present;

(ii) if moribund or freshly dead, but not decomposed fish are present, such fish must be selected, in particular fish demonstrating anaemia, haemorrhages or other clinical signs suggesting circulatory disturbances; if more than one water source is utilised for fish production, fish representing all water sources must be included in the sample;

(iii) the fish selected must include fish collected in such a way that all production units, such as net cages, tanks and ponds, of the establishment as well as all year classes are proportionally represented in the sample.

Section 2

Granting of the status free from infection with HPR-deleted ISAV in Member States, zones and compartments of unknown health status

The status free from infection with HPR-deleted ISAV may only be granted to a Member State, a zone or a compartment with an unknown health status with regard to infection with HPR-deleted ISAV if all establishments and, when required, selected sampling points in wild populations selected in accordance with (b) of Section 1, have been subject to the following scheme:

(a) the establishments or sampling points have been subject to health visits and sampled for a minimum period of 2 consecutive years as laid down in Table 2.A;

(b) during that 2-year period, the testing of all samples using the diagnostic methods set out in point 2 of Section 5 must have produced negative results for HPR-deleted ISAV and any suspicion of infection must have been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5;

(c) If infection with HPR-deleted ISAV is detected during the surveillance referred to in point (a); before re-starting the scheme, relevant establishments within the Member State, zone or compartment must:

(i) be subject to the minimum disease control measures laid down in Articles 58 to 65;

(ii) be repopulated with fish from an establishment in a Member State, zone or compartment free from infection with HPR-deleted ISAV or from an establishment in a Member State, zone or compartment covered by an eradication programme for that disease.

Table 2.A

Scheme for Member States, zones and compartments for the 2-year control period which precedes the achievement of status free from infection with HPR-deleted ISAV

Year of surveillance	Number of health visits per year to each establishment	Number of laboratory examinations per year [1]	Number of fish in the sample
Year 1	6	2	75

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Year of surveillance	Number of health visits per year to each establishment	Number of laboratory examinations per year ([1])	Number of fish in the sample
Year 2	6	2	75

([1]) Samples must be collected during spring and autumn each year.

Maximum number of fish per pool: 5.

Section 3

Granting of the status free from infection with HPR-deleted ISAV in Member States, zones and compartments known to be infected with HPR-deleted ISAV

1. The status free from infection with HPR-deleted ISAV may only be granted to a Member State, a zone or a compartment known to be infected with HPR-deleted ISAV if all establishments keeping listed species within the Member State, zone or compartment have been subject to an eradication programme that complies with the following requirements:

(a) the minimum control measures laid down in Articles 55 to Article 65 have been applied and a restricted zone of an appropriate size as provided for in point (c) of Article 58(1), where appropriate, divided into a protection zone and a surveillance zone, must have been established in the vicinity of the establishment(s) infected with HPR-deleted ISAV, taking into account the requirements set out in point 2;

(b) all establishments keeping listed species within the protection zone, or where a protection zone has not been established, the restricted zone, not infected with HPR-deleted ISAV must be subject to an investigation comprising at least the following elements:

(i) the collection of samples for testing of minimum 10 moribund fish, when clinical signs or *post-mortem* lesions consistent with infection with HPR-deleted ISAV are observed, or minimum 30 fish when clinical signs or *post mortem* lesions are not observed;

(ii) in those establishments where the tests referred to in (i) have produced negative results, the health visits must continue once per month until the protection zone is withdrawn in accordance with point (c);

(c) relevant establishments must be emptied in accordance with Article 62, cleaned and disinfected in accordance with Article 63 and fallowed in accordance with Article 64.

The duration of the fallowing period referred to in point (b) of Article 64(2) shall be at least 3 months. When all establishments infected within the same protection zone, or where a protection zone has not been established, the restricted zone, are emptied, at least 6 weeks of synchronised fallowing must be carried out.

When fallowing of the infected establishments is carried out, the restricted zone or the protection zone, when it has been established, must be converted into a surveillance zone until the scheme set out in Section 2 is completed;

(d) repopulation may only take place when all infected establishments have been emptied, cleaned, disinfected and fallowed in accordance with point (c);

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(e) all establishments other than those referred to in point (f) which keep listed species within the Member State, zone or compartment covered by the eradication programme and when surveillance in wild populations is required, all sampling points selected in accordance with point (b) of Section 1, must subsequently be subject to the scheme set out in Section 2;

(f) an individual establishment which keeps listed species and which has a health status which is independent of the health status of the surrounding waters is not required to comply with the scheme set out in Section 2 following a disease outbreak provided the establishment complies with the requirements set out in paragraph 3 of Article 80 and is re-populated with fish sourced from Member States, zones or compartments with status free from infection with HPR-deleted ISAV.

2. The restricted zone must have been defined on a case-by-case basis and:

(a) it must take into account factors influencing the risks for the spread of infection with HPR-deleted ISAV to kept and wild fish, such as:

(i) the number, rate and distribution of the mortalities on the establishment infected with HPR-deleted ISAV or in other aquaculture establishments;

(ii) the distance to and density of neighbouring establishments;

(iii) the proximity to slaughterhouses;

(iv) contact establishments;

(v) species present at the establishments;

(vi) the farming practices applied in the infected establishments and in the neighbouring establishments to the infected establishment;

(vii) the hydrodynamic conditions; and

(viii) other factors of epidemiological significance identified;

(b) the geographical demarcation in coastal areas must comply with the following minimum requirements:

(i) the protection zone must consist of an area included in a circle with a radius of at least one tidal excursion or at least 5 km, whichever is larger, centred on the establishment infected with HPR-deleted ISAV, or an equivalent area determined according to appropriate hydrodynamic or epidemiological data; and

(ii) the surveillance zone must consist of an area surrounding the protection zone, of overlapping tidal excursion zones; or an area surrounding the protection zone and included in a circle of radius 10km from the centre of the protection zone; or an equivalent area determined according to appropriate hydrodynamic or epidemiological data;

or

(iii) where separate protection and surveillance zones are not established, the restricted zone must consist of an area comprising both the protection zone and the surveillance zone;

(c) the geographical demarcation in inland areas must comprise the entire water catchment area in which the establishment infected with HPR-deleted ISAV is located. The competent authority may limit the extent of the restricted zone to parts of the water catchment area, provided this limitation does not compromise the disease control measures with respect to infection with HPR-deleted ISAV.

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Section 4

Maintenance of status free from infection with HPR-deleted ISAV

1. When targeted surveillance is required in order to maintain the status free from infection with HPR-deleted ISAV of a Member State, a zone or a compartment, in accordance with Article 81, all establishments keeping listed species within the Member State, zone or compartment concerned must be subject to health visits and fish must be sampled in accordance with Table 2.B, taking into account the risk level of the establishment for the contraction of infection with HPR-deleted ISAV.

2. When determining the frequency of health visits required to maintain the status free from infection with HPR-deleted ISAV of compartments where the health status is dependent on the health status of the aquatic animal population in surrounding natural waters, the risk for the contraction of infection with HPR-deleted ISAV must be regarded as high.

3. Disease-free status must only be maintained as long as all samples tested, using the diagnostic methods set out in point 2 of Section 5, have produced negative results for HPR-deleted ISAV and any suspicion of infection with HPR-deleted ISAV has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5.

Table 2.B

Scheme for Member States, zones or compartments to maintain status free from infection with HPR-deleted ISAV ([1])

Risk level ([2])	Number of health visits per year	Number of laboratory examinations per year ([3]), ([4])	Number of fish in the sample
High	2	2	30
Medium	1	1	30
Low	1 every 2 years	1 every 2 years	30

([1]) Shall not apply to establishments rearing only rainbow trout (*Oncorhynchus mykiss*) or brown trout (*Salmo trutta*) or both rainbow trout and brown trout, and where the water supply is exclusively based on fresh water sources which are not populated with Atlantic salmon (*Salmo salar*).
([2]) Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I other than in the case of dependent compartments where all establishments are deemed to be high risk.
([3]) Samples must be collected during spring and autumn when two samples are required each year
([4]) Samples must be collected during spring or autumn when one sample per year is required.

Maximum number of fish per pool: 5

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Section 5

Diagnostic and sampling methods

1. The organs or tissue material to be sampled and examined must be:

   (a) Histology: anterior-kidney, liver, heart, pancreas, intestine, spleen and gill;

   (b) Immunohistochemistry: mid-kidney and heart including valves and *bulbus arteriosus*;

   (c) Conventional RT-PCR and RT-qPCR analysis: mid-kidney and heart;

   (d) Virus culture: mid-kidney, heart and spleen;

   Organ pieces from a maximum of five fish may be pooled.

▼**M1**

2. The diagnostic method to be used to grant or to maintain the status free from infection with HPR-deleted ISAV in accordance with Sections 2, 3 and 4 must be RT-qPCR, followed by conventional RT-PCR and sequencing of the HE-gene of positive samples in accordance with the detailed methods and procedures which must be those approved by the EURL for fish diseases.

   In the case of a positive sequencing result for HPR-deleted ISAV, further samples must be tested before the implementation of the initial control measures provided for in Articles 55 to 65.

   Those samples must be tested as follows in accordance with the detailed methods and procedures approved by the EURL for fish diseases:

   (a) Screening of the samples by RT-qPCR, followed by conventional RT-PCR and sequencing of the HE-gene of positive samples to verify HPR-deletion; or

   (b) Detection of ISAV antigen in tissue preparations by means of specific antibodies against ISAV; or

   (c) Isolation in cell culture and subsequent identification of HPR-deleted ISAV.

3. When a suspicion of infection with HPR-deleted ISAV must be confirmed or ruled out in accordance with Article 55, the following visit, sampling and testing procedure must comply with the following requirements:

   (a) The suspected establishment must be subject to at least one health visit and one sampling of 10 moribund fish, when clinical signs or post-mortem lesions consistent with infection with HPR-deleted ISAV are observed, or a minimum of 30 fish when clinical signs or *post-mortem* lesions are not observed. Samples shall be tested using one or more of the diagnostic methods set out in point 2 in accordance with the detailed diagnostic methods and procedures approved by the EURL for fish diseases;

   (b) In the case of a positive result for infection with HPR-deleted ISAV, further samples shall be tested before the implementation of the initial control measures provided in Article 58. A suspected case of infection with HPR-deleted ISAV shall be confirmed in accordance with the following criteria using one or more of the detailed diagnostic methods and procedures approved by the EURL for fish diseases:

      (i) Detection of ISAV by RT-qPCR, followed by conventional RT-PCR and sequencing of the HE-gene to verify HPR-deletion; or

      (ii) Detection of ISAV in tissue preparations by means of specific antibodies against ISAV; or

      (iii) Isolation and identification of ISAV in cell culture from at least one sample from any fish from the establishment;

   (c) Where the presence of clinical, gross pathological or histopathological findings consistent with infection are observed, the findings must be corroborated using one or more of the diagnostic methods set out in point 3(b), in accordance with the detailed methods and procedures approved by the EURL for fish diseases.

   The suspicion of HPR-deleted ISAV may be ruled out, if tests and health visits over a period of 12 months from the date of the suspicion are found to reveal no further evidence of the presence of the virus.

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CHAPTER 3

Eradication, disease-free status and diagnostic methods for infection with *Marteilia refringens*

Section 1

General requirements for health visits and sampling

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Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements:

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(a) health visits and, where appropriate, the sampling must be carried out in the period of the year when prevalence of the parasite in the Member State, zone or compartment is known to be maximal. When such data is not available, sampling must be carried out just after the water temperature has exceeded 17 °C;

(b) when molluscs must be sampled in accordance with the requirements set out in Sections 2 to 4, the following selection criteria must apply:

(i) if *Ostrea* spp. are present, only oysters of that species must be selected for sampling. If *Ostrea* spp. are not present, the sample must be representative of all other susceptible species present;

(ii) if weak, gaping or freshly dead but not decomposed molluscs are present in the production units, such molluscs must primarily be selected. If such molluscs are not present, the molluscs selected must include the oldest healthy molluscs;

(iii) when sampling in mollusc establishments which utilise more than one water source for mollusc production, molluscs representing all water sources must be included for sampling in such a way that all parts of the establishment are proportionally represented in the sample;

(iv) when sampling in mollusc establishments or groups of establishments, molluscs from a sufficient number of sampling points, must be included in the sample in such a way that all parts of the establishment or group of establishments are proportionally represented in the sample. The main factors to be considered for the selection of these sampling points are previous sampling points where *Marteilia refringens* was detected, stocking density, water flows, presence of susceptible species, presence of vector species, bathymetry and management practices. Natural beds within or adjacent to the establishment or group of establishments must be included in the sampling.

Section 2

Granting of the status free from infection with *Marteilia Refringens* in Member States, zones and compartments of unknown health status

1. The status free from infection with *Marteilia refringens* may only be granted to a Member State, a zone or a compartment with an unknown health status with regard to infection with *Marteilia refringens* if all establishments or groups of establishments keeping listed species within the Member State, zone or compartment and where required, sampling points in wild populations, have been subject to the following 3-year scheme:

(a) the establishments or groups of establishments keeping listed species have been subject to health visits and sampled for a minimum period of 3 consecutive years as laid down in Table 3.A;

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(b) during that 3-year period, the testing of all samples using the diagnostic methods set out in point 2 of Section 5 have produced negative results for *Marteilia refringens* and any suspicion of *Marteilia refringens* has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5;

(c) when *Ostrea edulis* sourced from a Member State, zone or compartment of disease-free status are to be included in the sample, they must have been introduced into the establishment or group of establishments at least in the spring just preceding the period when the scheme is carried out.

2. If *Marteilia refringens* is detected during the 3-year scheme set out in point 1, before starting a new 3-year scheme, relevant establishments in the Member State, zone or compartment must:

(a) be subject to the minimum disease control measures laid down in Articles 58 to 65;

(b) be repopulated with molluscs from an establishment in a Member State, zone or compartment free from infection with *Marteilia refringens* or from an establishment in a Member State, zone or compartment covered by an eradication programme for that disease.

Table 3.A

Scheme for Member States, zones or compartments for the 3-year control period which precedes the achievement of status free from infection with *Marteilia refringens*

Year of surveillance	Number of health visits per year to each establishment/ group of establishments	Number of laboratory examinations per year	Number of molluscs in the sample
Year 1	1	1	150
Year 2	1	1	150
Year 3	1	1	150

Section 3

Granting of the status free from infection with *Marteilia refringens* in Member States, zones and compartments known to be infected with *Marteilia refringens*

1. The status free from infection with *Marteilia refringens* may only be granted to a Member State, a zone or a compartment known to be infected with *Marteilia refringens*, where the competent authority judges that eradication of this disease to be feasible, if all establishments or groups of establishments keeping listed species within that Member State, zone or compartment have been subject to an eradication programme that complies with the following requirements:

(a) the minimum control measures laid down in Articles 55 to 65 have effectively been applied and a restricted zone of an appropriate size as provided for in point (c) of Article 58(1), where appropriate divided into a protection zone and surveillance zone, must have been established in the vicinity of the establishment(s) or group of establishments infected with *Marteilia refringens*, taking into account the requirements set out in point 2;

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(b) all establishments and groups of establishments keeping listed species within the protection zone, or where a protection zone has not been established, the restricted zone, not infected with *Marteilia refringens* must be subject to an investigation comprising at least the collection of samples for the testing of 150 molluscs after the beginning of the transmission period of *Marteilia refringens*. When the transmission period is not known, the sampling must begin in the period after the temperature of the water exceeds 17 °C;

(c) relevant establishments and groups of establishments must be emptied in accordance with Articles 62, and if possible cleaned and disinfected in accordance with Article 63.

Fallowing must be carried out in accordance with Article 64 and the duration of the fallowing period must be at least:

(i) 2 months in case of the establishments and groups of establishments which can be fully drained and thoroughly cleaned and disinfected such as hatcheries and nurseries;

(ii) 2 months in case of the establishments and groups of establishments which cannot be drained and thoroughly cleaned and disinfected provided that the infected molluscs of the listed species and those molluscs of the listed species with epidemiological links with the infected establishment or group of establishments have been harvested or removed before the period of the year when the prevalence of *Marteilia refringens* is known to be maximal, or when that period is not known, before the period when water temperature exceeds 17 °C;

(iii) 14 months in case of the establishments and groups of establishments which cannot be drained and thoroughly cleaned and disinfected if the infected molluscs of the listed species and those molluscs of the listed species with epidemiological links with the infected establishment or group of mollusc establishments have not been harvested or removed before the period of the year when the prevalence of *Marteilia refringens* is known to be maximal or when such data is not known, when molluscs of the susceptible species have not been harvested or removed before the period when water temperature exceeds 17 °C.

When all infected establishments and infected groups of establishments are emptied, at least 4 weeks of synchronised fallowing must be carried out;

(d) repopulation may only take place when all infected establishments or infected groups of establishments have been emptied, cleaned, disinfected and fallowed in accordance with point (c);

(e) all establishments and groups of establishments other than those referred to in point (f) which keep listed species within the Member State, zone or compartment covered by the eradication programme, must subsequently be subject to the scheme set out in Section 2;

(f) an individual establishment which keeps listed species and which has a health status which is independent of the health status of the surrounding waters is not required to comply with the scheme set out in Section 2 following a disease outbreak provided the establishment complies with the requirements set out in paragraph 3 of Article 80 and is repopulated with molluscs sourced from Member States, zones or compartments with status free from infection with *Marteilia refringens*.

2. The restricted zone must have been defined on a case-by-case basis and:

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(a) it must take into account factors influencing the risks for the spread of infection with *Marteilia refringens* including other establishments and wild molluscs, such as:

(i) the number, age, rate and distribution of the mortalities of molluscs on the establishment or group of establishments infected with *Marteilia refringens;*

(ii) the distance to and density of neighbouring establishments or groups of establishments and wild molluscs;

(iii) the proximity to processing establishments, contact establishments or groups of establishments;

(iv) the species, especially susceptible species and vector species, present at the establishments or groups of establishments;

(v) the farming practices applied in the affected and neighbouring establishments and groups of establishments;

(vi) the hydrodynamic conditions; and

(vii) other factors of epidemiological significance identified;

(b) the geographical demarcation must comply with the following minimum requirements:

(i) the protection zone must consist of an area included in a circle with a radius of at least one tidal excursion or at least 5 km, whichever is larger, centred on the establishment infected with *Marteilia refringens*, or an equivalent area determined according to appropriate hydrodynamic or epidemiological data; and

(ii) the surveillance zone must consist of an area surrounding the protection zone, of overlapping tidal excursion zones; or an area surrounding the protection zone and included in a circle of radius 10km from the centre of the protection zone; or an equivalent area determined according to appropriate hydrodynamic or epidemiological data;

or

(iii) where separate protection and surveillance zones are not established, the restricted zone must consist of an area comprising both the protection zone and the surveillance zone.

Section 4

Maintenance of status free from infection with *Marteilia refringens*

1. When targeted surveillance is required in order to maintain the status free from infection with *Marteilia refringens* of a Member State, a zone or a compartment, in accordance with Article 81, all establishments keeping listed species within the Member State, zone or compartment concerned must be subject to health visits and molluscs must be sampled in accordance with Table 3.B, taking into account the risk level of the establishment for the contraction of infection with *Marteilia refringens*.

2. When determining the frequency of health visits required to maintain the status free from infection with *Marteilia refringens* of compartments, where the health-status regarding that disease is dependent on the health-status of the aquatic animal populations in surrounding natural waters, the risk for the contraction of infection with *Marteilia refringens* must be regarded as high.

3. The status free from infection with *Marteilia refringens* may only be maintained as long as all samples tested, using the diagnostic methods set out in point 2 of Section 5 have produced negative results for *Marteilia refringens* and any suspicion of infection with *Marteilia refringens* has been ruled out in accordance with the diagnostic methods set out in point 3 of section 5.

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Table 3.B

Scheme for Member States, zones or compartments to maintain disease-free status for *Marteilia refringens*

Risk level (1)	Number of health visits to each establishment/group of establishments	Number of laboratory examinations	Number of molluscs in the sample
High	1 every year	1 every 2 years	150
Medium	1 every 2 years	1 every 2 years	150
Low	1 every 3 years	1 every 3 years	150

(1) Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I other than in the case of dependent compartments where all establishments are deemed to be high risk.

Section 5

Diagnostic and sampling methods

1. The whole animal must be submitted to the laboratory for the performance of the diagnostic tests provided for in points 2 and 3.

2. The diagnostic methods to be used to grant or maintain status free from infection with *Marteilia refringens* in accordance with Sections 2 to 4 must follow the detailed diagnostic methods and procedures approved by the EURL for Mollusc Diseases and must be histopathology, tissue imprints or PCR.

3. When a suspicion of infection with *Marteilia refringens* is required to be confirmed or ruled out in accordance with Article 55 the following visit, sampling and testing procedure must be complied with:

   (a) the investigation must include at least one sampling of 30 molluscs of susceptible species if the suspicion is based on a mortality report or if not, 150 molluscs of susceptible species after the beginning of the transmission period of *Marteilia refringens*. When the transmission period is not known, the sampling must begin in the period after the temperature of the water exceeds 17 °C;

   (b) samples must be tested using the diagnostic methods set out in point (i) following the detailed diagnostic methods and procedures approved by the EURL for Mollusc Diseases:

      (i) the presence of *Marteilia refringens* must be considered as confirmed when a positive result by histopathology, tissue imprints or *in situ* hybridisation is combined with a positive PCR result completed by sequencing. If biological material is not available for histopathology, tissue imprints or *in situ* hybridisation, the presence of *Marteilia refringens* must be considered as confirmed when positive results are obtained using two PCR assays targeting different fragments of the parasite genome and completed by sequencing;

      (ii) the suspicion of infection with *Marteilia refringens* may be ruled out, if the tests referred to in (i) reveal no further evidence of the presence of *Marteilia refringens*.

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CHAPTER 4

Eradication, disease-free status and diagnostic methods for infection with *Bonamia exitiosa*

Section 1

General requirements for health visits and sampling

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Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements:

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(a) health visits and, where appropriate, the sampling must be carried out in the period of the year when prevalence of the parasite in the Member State, zone or compartment is known to be maximal. When such data is not available, sampling shall be carried out twice a year, in spring and autumn;

(b) when molluscs are to be sampled in accordance with the requirements set out in Sections 2 to 4, the following criteria must apply:

(i) if *Ostrea* spp. are present, only oysters of that species must be selected for sampling. If *Ostrea* spp. are not present, the sample must be representative of all other susceptible species present;

(ii) if weak, gaping or freshly dead but not decomposed molluscs are present, such molluscs must primarily be selected. If such molluscs are not present, the molluscs selected must include the oldest healthy molluscs;

(iii) when sampling in establishments or groups of establishments which utilise more than one water source for mollusc production, molluscs representing all water sources must be included for sampling in such a way that all parts of the establishment are proportionally represented in the sample;

(iv) when sampling in mollusc establishments or groups of establishments, molluscs from a sufficient number of sampling points must be included in the sample in such a way that all parts of the establishment or group of establishments are proportionally represented in the sample. The main factors to be considered for the selection of those sampling points are previous points where *Bonamia exitiosa* was detected, stocking density, water flows, the presence of susceptible species, the presence of vector species (e.g.*Crassostrea gigas*), bathymetry and management practices. Natural beds within or adjacent to the establishment or group of establishments shall be included in the sampling.

Section 2

Granting of the status free from infection with *Bonamia exitiosa* in Member States, zones and compartments of unknown health status

1. The status free from infection with *Bonamia exitiosa* may only be granted to a Member State, a zone or a compartment with an unknown health status with regard to infection with *Bonamia exitiosa* if all establishments or groups of establishments keeping listed species within the Member State, zone or compartment and where required, sampling points in wild populations, have been subject to the following 3-year scheme:

(a) the establishments and groups of establishments keeping listed species have been subject to health visits and sampled for a minimum period of 3 consecutive years as laid down in Table 4.A;

▼B

(b) during that 3-year period, the testing of all samples using the diagnostic methods set out in point 2 of Section 5 have produced negative results for *Bonamia exitiosa* and any suspicion of *Bonamia exitiosa* has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5;

(c) when *Ostrea edulis* sourced from a Member State, zone or compartment of disease-free status are to be included in the sample, they must have been introduced into the establishment or group of establishments at least one year before the scheme is carried out.

2. If infection with *Bonamia exitiosa* is detected during the 3-year scheme referred to in point 1; before starting a new 3-year scheme, relevant establishments in the Member State, zone or compartment must:

(a) be subject to the minimum disease control measures laid down in Articles 58 to 65;

(b) be repopulated with molluscs from an establishment in a Member State, zone or compartment free from infection with *Bonamia exitiosa* or from an establishment in a Member State, zone or compartment covered by an eradication programme for that disease.

Table 4.A

Scheme for Member States, zones or compartments for the 3-year control period which precedes the achievement of status free from infection with *Bonamia exitiosa*

Year of surveillance	Number of health visits per year to each establishment or group of establishments	Number of laboratory examinations per year	Number of molluscs in the sample
Year 1	2	2	150
Year 2	2	2	150
Year 3	2	2	150

Section 3

Granting of the status free from infection with *Bonamia exitiosa* in Member States, zones and compartments known to be infected with *Bonamia exitiosa*

1. The status free from infection with *Bonamia exitiosa* may only be granted to a Member State, a zone or a compartment known to be infected with *Bonamia exitiosa*, where the competent authority judges that eradication of this disease to be feasible, if all establishments or groups of establishments keeping listed species within that Member State, zone or compartment have been subject to an eradication programme that complies with the following requirements:

(a) the minimum control measures laid down in Articles 55 to 65 must have been effectively applied, and a restricted zone of an appropriate size as provided for in point (c) of Article 58(1), where appropriate, divided into a protection zone and surveillance zone; must have been established in the vicinity of the establishment or group of establishments declared infected with *Bonamia exitiosa* taking into account the requirements set out in point 2;

▼B

(b) all establishments and groups of establishments keeping listed species within the protection zone or where a protection zone has not been established, within the restricted zone, not infected with *Bonamia exitiosa* must be subject to an investigation comprising at least the collection of samples for testing of 150 molluscs of susceptible species after the beginning of the transmission period of *Bonamia exitiosa*. When the transmission period is not known, the sampling must be done on oysters which have spent at least one year within the protection zone;

(c) relevant establishments and groups of establishments must be emptied in accordance with Article 62, and if possible, cleaned and disinfected in accordance with Article 63.

Fallowing must be carried out in compliance with Article 64 and the duration of the fallowing period must be at least 6 months.

When all infected establishments or infected groups of establishments are emptied, at least 4 weeks of synchronised fallowing must be carried out;

(d) repopulation may only take place when all infected establishments or infected groups of establishments have been emptied, cleaned, disinfected and fallowed in accordance with point (c);

(e) all establishments and groups of establishments other than those referred to in point (f) which keep listed species within the Member State, zone or compartment covered by the eradication programme, must subsequently be subject to the scheme set out in Section 2;

(f) an individual establishment which keeps listed species and which has a health-status which is independent of the health-status of the surrounding waters is not required to comply with the scheme set out in Section 2 following a disease outbreak provided the establishment complies with the requirements set out in paragraph 3 of Article 80 and is repopulated with molluscs sourced from Member States, zones or compartments with status free from infection with *Bonamia exitiosa*.

2. The restricted zone must have been defined on a case-by-case basis and:

(a) it must take into account factors influencing the risks for the spread of infection with *Bonamia exitiosa* including other establishments and wild molluscs, such as:

(i) the number, age, rate and distribution of the mortalities of molluscs on the establishment or group of establishments infected with *Bonamia exitiosa*;

(ii) the distance to and density of neighbouring establishments or groups of establishments and wild molluscs;

(iii) the proximity to processing establishments, contact establishments or groups of establishments;

(iv) the species, especially susceptible species and vector species, present at the establishments or groups of establishments;

(v) the farming practices applied in the affected and neighbouring establishments and groups of establishments;

(vi) the hydrodynamic conditions; and

(vii) other factors of epidemiological significance identified;

(b) the geographical demarcation must comply with the following minimum requirements:

▼B

(i) the protection zone must consist of an area included in a circle with a radius of at least one tidal excursion or at least 5 km, whichever is larger, centred on the establishment infected with *Bonamia exitiosa*, or an equivalent area determined according to appropriate hydrodynamic or epidemiological data; and

(ii) the surveillance zone must consist of an area surrounding the protection zone, of overlapping tidal excursion zones; or an area surrounding the protection zone and included in a circle of radius 10km from the centre of the protection zone; or an equivalent area determined according to appropriate hydrodynamic or epidemiological data;

or

(iii) where separate protection and surveillance zones are not established, the restricted zone must consist of an area comprising both the protection zone and the surveillance zone.

Section 4

Maintenance of status free from infection with *Bonamia exitiosa*

1. When targeted surveillance is required in order to maintain the status free from infection with *Bonamia exitiosa* of a Member State, a zone or a compartment, in accordance with Article 81, all establishments keeping listed species within the Member State, zone or compartment concerned must be subject to health visits and molluscs must be sampled in accordance with Table 4.B, taking into account the risk level of the establishment for the contraction of infection with *Bonamia exitiosa*

2. When determining the frequency of health visits required to maintain the status free from infection with *Bonamia exitiosa* of compartments where the health status regarding that disease is dependent on the health status of the aquatic animal populations in surrounding natural waters, the risk for the contraction of infection with *Bonamia exitiosa* must be regarded as high.

3. The status free from infection with *Bonamia exitiosa* may only be maintained as long as all samples, using the diagnostic methods set out in point 2 of Section 5 have produced negative results for *Bonamia exitiosa* and any suspicion of infection with *Bonamia exitiosa* has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5.

Table 4.B

Scheme for Member States, zones or compartments to maintain status free from infection with *Bonamia exitiosa*

Risk level [1]	Number of health visits to each establishment/ group of establishments	Number of laboratory examinations	Number of molluscs in the sample
High	1 every year	1 every 2 years	150
Medium	1 every 2 years	1 every 2 years	150
Low	1 every 3 years	1 every 3 years	150

[1] Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I other than in the case of dependent compartments where all establishments are deemed to be high risk.

▼B

Section 5

Diagnostic and sampling methods

1. The whole animal must be submitted to the laboratory for the performance of the diagnostic tests provided for in points 2 and 3.

2. The diagnostic methods to be used to grant or maintain status free from infection with *Bonamia exitiosa,* in accordance with Sections 2 to 4 must follow the detailed diagnostic methods and procedures approved by the EURL for Mollusc Diseases and must be histopathology, tissue imprints or PCR.

3. When a suspicion of infection with *Bonamia exitiosa* is required to be confirmed or ruled out in accordance with Article 58, the following visit, sampling and testing procedure must be complied with:

   (a) the investigation must include at least one sampling of 30 molluscs of susceptible species if the suspicion is based on a mortality report, or if not, 150 molluscs of susceptible species after the beginning of the transmission period of *Bonamia exitiosa*. When the transmission period is not known, the sampling shall be carried out twice a year, in spring and autumn;

   (b) the samples must be tested using the diagnostic methods set out in point (i) following the detailed diagnostic methods and procedures which have been approved by the EURL for Mollusc Diseases:

      (i) the presence of *Bonamia exitiosa* must be considered as confirmed when a positive result by histopathology, tissue imprints or *in situ* hybridisation is combined with a positive result by PCR followed by sequencing. If biological material is not available for histopathology, tissue imprints or *in situ* hybridisation, the presence of *Bonamia exitiosa* must be considered as confirmed when positive results are obtained using two PCR assays targeting different fragments of the parasite genome and completed by sequencing;

      (ii) the suspicion of the presence of infection with *Bonamia exitiosa* must be ruled out, if those tests reveal no further evidence of the presence of *Bonamia exitiosa*.

CHAPTER 5

Eradication, disease-free status and diagnostic methods for infection with *Bonamia ostreae*

Section 1

General requirements for health visits and sampling

▼M1

Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements:

▼B

(a) health visits and, where appropriate, the sampling must be carried out in the period of the year when prevalence of the parasite in the Member State, zone or compartment is known to be maximal. When such data is not available, sampling must be carried out in winter or at the beginning of spring;

(b) when molluscs are to be sampled in accordance with the requirements set out in Sections 2 to 4, the following criteria must apply:

▼B

(i) if *Ostrea edulis* are present, only oysters of that species must be selected for sampling. If *Ostrea edulis* are not present, the sample must be representative of all other susceptible species present;

(ii) if weak, gaping or freshly dead but not decomposed molluscs are present, such molluscs must primarily be selected. If such molluscs are not present, the molluscs selected must include the oldest healthy molluscs;

(iii) when sampling in establishments or groups of establishments which utilise more than one water source for mollusc production, molluscs representing all water sources must be included for sampling in such a way that all parts of the establishment are proportionally represented in the sample;

(iv) when sampling in mollusc establishments or groups of establishments, molluscs from a sufficient number of sampling points must be included in the sample in such a way that all parts of the establishment or group of establishments are proportionally represented in the sample. The main factors to be considered for the selection of those sampling points are previous points where *Bonamia ostreae* was detected, stocking density, water flows, the presence of susceptible species, the presence of vector species, bathymetry and management practices. Natural beds within or adjacent to the establishment or group of establishments shall be included in the sampling.

Section 2

Granting of the status free from infection with *Bonamia ostreae* in Member States, zones and compartments of unknown health status

1. The status free from infection with *Bonamia ostreae* may only be granted to a Member State, a zone or a compartment with an unknown health status with regard to infection with *Bonamia ostreae* if all establishments or groups of establishments keeping listed species within the Member State, zone or compartment and where required, sampling points in wild populations, have been subject to the following 3-year scheme:

(a) the establishments and groups of establishments keeping listed species have been subject to health visits and sampled for a minimum period of 3 consecutive years as laid down in Table 5.A;

(b) during that 3-year period, the testing of all samples using the diagnostic methods set out in point 2 of Section 5 have produced negative results for *Bonamia ostreae* and any suspicion of *Bonamia ostreae* has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5;

(c) when *Ostrea edulis* sourced from a Member State, zone or compartment of disease-free status are to be included in the sample, they must have been introduced into the establishment or group of establishments at least one year before the scheme is carried out.

2. If infection with *Bonamia ostreae* is detected during the 3-year scheme referred to in point 1; before starting a new 3-year scheme, relevant establishments in the Member State, zone or compartment must:

(a) be subject to the minimum disease control measures laid down in Articles 58 to 65;

(b) be repopulated with molluscs from an establishment in a Member State, zone or compartment free from infection with *Bonamia ostreae* or from an establishment in a Member State, zone or compartment covered by an eradication programme for that disease.

▼B

Section 3

Granting of the status free from infection with *Bonamia ostreae* in Member States, zones and compartments known to be infected with *Bonamia ostreae*

1. The status free from infection with *Bonamia ostreae* may only be granted to a Member State, a zone or a compartment known to be infected with *Bonamia ostreae*, where the competent authority judges that eradication of this disease to be feasible, if all establishments or groups of establishments keeping listed species within that Member State, zone or compartment have been subject to an eradication programme that complies with the following requirements:

   (a) the minimum control measures laid down in Articles 55 to 65 must have been effectively applied, and a restricted zone of an appropriate size as provided for in point (c) of Article 58(1), where appropriate, divided into a protection zone and surveillance zone; must have been established in the vicinity of the establishment or group of establishments declared infected with *Bonamia ostreae* taking into account the requirements set out in point 2;

   (b) all establishments and groups of establishments keeping listed species within the protection zone or where a protection zone has not been established, within the restricted zone, not infected with *Bonamia ostreae* must be subject to an investigation comprising at least the collection of samples for testing of 150 molluscs of susceptible species after the beginning of the transmission period of *Bonamia ostreae*. When the transmission period is not known, the sampling must begin in winter or at the beginning of spring;

   (c) relevant establishments and groups of establishments must be emptied in accordance with Article 62, and if possible, cleaned and disinfected in accordance with Article 63.

   Fallowing must be carried out in compliance with Article 64 and the duration of the fallowing period must be at least 6 months.

   When all infected establishments or infected groups of establishments are emptied, at least 4 weeks of synchronised fallowing must be carried out;

   (d) repopulation may only take place when all infected establishments or infected groups of establishments have been emptied, cleaned, disinfected and fallowed in accordance with point (c);

   (e) all establishments and groups of establishments other than those referred to in point (f) which keep listed species within the Member State, zone or compartment covered by the eradication programme, must subsequently be subject to the scheme set out in Section 2;

   (f) an individual establishment which keeps listed species and which has a health status which is independent of the health status of the surrounding waters is not required to comply with the surveillance scheme set out in Section 2 following a disease outbreak provided the establishment complies with the requirements set out in paragraph 3 of Article 80 and is repopulated with molluscs sourced from Member States, zones or compartments with status free from infection with *Bonamia ostreae*.

2. The restricted zone must have been defined on a case-by-case basis and:

   (a) it must take into account factors influencing the risks for the spread of infection with *Bonamia ostreae* including other establishments and wild molluscs, such as:

      (i) the number, age, rate and distribution of the mortalities of molluscs on the establishment or group of establishments infected with *Bonamia ostreae*;

▼B

(ii) the distance to and density of neighbouring establishments or groups of establishments and wild molluscs;

(iii) the proximity to processing establishments, contact establishments or groups of establishments;

(iv) the species, especially susceptible species and vector species, present at the establishments or groups of establishments;

(v) the farming practices applied in the affected and neighbouring establishments and groups of establishments;

(vi) the hydrodynamic conditions; and

(vii) other factors of epidemiological significance identified;

(b) the geographical demarcation must comply with the following minimum requirements:

(i) the protection zone must consist of an area included in a circle with a radius of at least one tidal excursion or at least 5 km, whichever is larger, centred on the establishment infected with *Bonamia ostreae*, or an equivalent area determined according to appropriate hydrodynamic or epidemiological data; and

(ii) the surveillance zone must consist of an area surrounding the protection zone, of overlapping tidal excursion zones; or an area surrounding the protection zone and included in a circle of radius 10km from the centre of the protection zone; or an equivalent area determined according to appropriate hydrodynamic or epidemiological data;

or

(iii) where separate protection and surveillance zones are not established, the restricted zone must consist of an area comprising both the protection zone and the surveillance zone.

Table 5.A

Scheme for Member States, zones or compartments for the 3-year control period which precedes the achievement of status free from infection with *Bonamia ostreae*

Year of surveillance	Number of health visits per year to each establishment or group of establishments	Number of laboratory examinations per year	Number of molluscs in the sample
Year 1	1	1	150
Year 2	1	1	150
Year 3	1	1	150

Section 4

Maintenance of status free from infection with *Bonamia ostreae*

1. When targeted surveillance is required in order to maintain the status free from infection with *Bonamia ostreae* of a Member State, a zone or a compartment, in accordance with Article 81, all establishments keeping listed species within the Member State, zone or compartment concerned must be subject to health visits and molluscs must be sampled in accordance with Table 5.B, taking into account the risk level of the establishment for the contraction of infection with *Bonamia ostreae*.

▼B

2. When determining the frequency of health visits required to maintain the status free from infection with *Bonamia ostreae* of compartments where the health status regarding that disease is dependent on the health status of the aquatic animal populations in surrounding natural waters, the risk for the contraction of infection with *Bonamia ostreae* must be regarded as high.

3. The status free from infection with *Bonamia ostreae* may only be maintained as long as all samples, using the diagnostic methods set out in point 2 of Section 5 have produced negative results for *Bonamia ostreae* and any suspicion of infection with *Bonamia ostreae* has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5.

Table 5.B

Scheme for Member States, zones or compartments to maintain status free from infection with *Bonamia ostreae*

Risk level [1]	Number of health visits to each establishment/ group of establishments	Number of laboratory examinations	Number of molluscs in the sample
High	1 every year	1 every 2 years	150
Medium	1 every 2 years	1 every 2 years	150
Low	1 every 3 years	1 every 3 years	150

[1] Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I other than in the case of dependent compartments where all establishments are deemed to be high risk.

Section 5

Diagnostic and sampling methods

1. The whole animal must be submitted to the laboratory for the performance of the diagnostic tests provided for in points 2 and 3.

2. The diagnostic methods to be used to grant or maintain status free from infection with *Bonamia ostreae,* in accordance with Sections 2 to 4 must follow the detailed diagnostic methods and procedures approved by the EURL for Mollusc Diseases and must be histopathology, tissue imprints or PCR.

3. When a suspicion of infection with *Bonamia ostreae* is required to be confirmed or ruled out in accordance with Article 58, the following visit, sampling and testing procedure must be complied with:

   (a) the investigation must include at least one sampling of 30 molluscs of susceptible species if the suspicion is based on a mortality report, or if not, 150 molluscs of susceptible species after the beginning of the transmission period of *Bonamia ostreae*. When the transmission period is not known, the sampling shall begin in the winter or at the beginning of spring;

   (b) the samples must be tested using the diagnostic methods set out in point (i) following the detailed diagnostic methods and procedures which have been approved by the EURL for Mollusc Diseases:

      (i) the presence of *Bonamia ostreae* must be considered as confirmed when a positive result by histopathology, tissue imprints or *in situ* hybridisation is combined with a positive result by PCR followed by sequencing. If biological material is not available for histopathology,

▼B

tissue imprints or *in situ* hybridisation, the presence of *Bonamia ostreae* must be considered as confirmed when positive results are obtained using two PCR assays targeting different fragments of the parasite genome and completed by sequencing;

(ii) the suspicion of the presence of infection with *Bonamia ostreae* must be ruled out, if those tests reveal no further evidence of the presence of *Bonamia ostreae.*

CHAPTER 6

Eradication, disease-free status and diagnostic methods for infection with white spot syndrome virus (WSSV)

Section 1

General requirements for health visits and sampling

▼M1

Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements:

▼B

(a) the sampling of crustaceans for laboratory examination must be carried out whenever the water temperature is likely to reach its highest annual point. That requirement concerning water temperature must also apply to health visits where these are feasible;

(b) when farmed crustaceans must be sampled in accordance with the requirements set out in Sections 2 to 4, the following criteria must apply:

(i) if weak or moribund crustaceans are present in the production units, such crustaceans must primarily be selected. If such crustaceans are not present, those selected must include crustaceans of different size cohorts namely juveniles and adults of the selected susceptible species, proportionally represented in the sample;

(ii) if more than one water source is utilised for crustacean production, susceptible crustaceans representing all water sources must be included for sampling;

(c) when targeted surveillance in wild populations is required due to the small number of establishments covered by the eradication programme, the number and geographical distribution of the sampling points must be determined to obtain a reasonable coverage of the Member State, zone or compartment. The sampling points must also be representative of the different ecosystems where the wild populations of susceptible species are located namely marine, estuary, river and lake systems. In such situations, the crustaceans to be sampled must be selected as follows:

(i) in marine and estuary systems areas, one or more of the following species must be selected: *Carcinus maenas, Cancer pagurus, Eriocheir sinensis, Liocarcinus depurator, Liocarcinus puber, Crangon crangon, Homarus gammarus, Palaemon adspersus* or penaeid shrimp species namely *Penaeus japonicus, Penaeus kerathurus, Penaeus semisulcatus*. If those species are not present, the sample must be representative of other susceptible decapod species present;

(ii) in river and lake systems, one or more of the following species must be selected: *Pacifastacus leniusculus, Astacus leptodactylus, Austropotamobius pallipes* or *Orconectes limosus*. If those species are not present, the sample must be representative of other susceptible decapod species present;

▼B

(iii) if weak or moribund crustaceans are present, such crustaceans must primarily be selected. If such crustaceans are not present, those selected must include crustaceans of different size cohorts namely juveniles and adults of the selected susceptible species, proportionally represented in the sample.

Section 2

Granting of the status free from infection with *WSSV* in Member States, zones and compartments of unknown health status

1. The status free from infection with *WSSV* may only be granted to a Member State, a zone or a compartment with an unknown health status with regard to infection with *WSSV* if all establishments or groups of establishments keeping listed species within the Member State, zone or compartment and where required, sampling points in wild populations, have been subject to the following 2-year scheme:

   (a) the establishments or groups of establishments have been subject to health visits and sampled for a minimum period of 2 consecutive years as laid down in Table 6.A;

   (b) during that 2-year period, the testing of all samples using the diagnostic methods set out in point 2 of Section 5 have produced negative results for infection with WSSV and any suspicion of infection with WSSV has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5;

2. If infection with WSSV is detected during the 2-year scheme referred to in point 1, before starting a new 2-year scheme, relevant establishments in the Member State, zone or compartment must:

   (a) be subject to the minimum disease control measures laid down in Articles 58 to 65;

   (b) be repopulated with crustaceans from an establishment in a Member State, zone or compartment free from infection with WSSV or from an establishment in a Member State, zone or compartment covered by an eradication programme for that disease.

Section 3

Granting of the status free from infection with WSSV in Member States, zones and compartments known to be infected with WSSV

1. The status free from infection with WSSV may only be granted to a Member State, a zone or a compartment known to be infected with WSSV if all establishments keeping listed species within that Member State, zone or compartment have been subject to an eradication programme that complies with the following requirements:

   (a) the minimum control measures laid down in Articles 55 to 65 must have been effectively applied, and a restricted zone of an appropriate size as provided for in point (c) of Article 58(1), where appropriate, divided into a protection zone and surveillance zone; must have been established in the vicinity of the establishment(s) declared infected with WSSV taking into account the requirements set out in point 2;

   (b) all establishments keeping listed species within the protection zone, or where a protection zone has not been established, the restricted zone, not infected with WSSV must be subject to an investigation comprising at least the following:

▼B

(i) the collection of samples for testing of 10 crustaceans, when clinical signs or post-mortem lesions consistent with infection WSSV are observed, or 150 crustaceans, when clinical signs or post-mortem lesions are not observed; and

(ii) health visits; in those establishments where the tests referred to in (i) have produced negative results, health visits must continue once per month during the season when the water temperature is likely to reach its highest annual points, until the protection zone has been withdrawn in accordance with point (c);

(c) relevant establishments must be emptied in accordance with Articles 62, cleaned disinfected in accordance with Article 63 and fallowed in accordance with Article 64. The duration of the fallowing period must be at least 6 weeks. When all infected establishments are emptied, at least 3 weeks of synchronous fallowing shall be carried out.

When fallowing of the officially declared infected establishments is carried out, the protection zones shall be converted into surveillance zones;

(d) repopulation may only take place when all infected establishments have been emptied, cleaned, disinfected and fallowed in accordance with point (c);

(e) all establishments other than those referred to in point (f) which keep listed species within the Member State, zone or compartment covered by the eradication programme and, when surveillance in wild populations is required, all sampling points selected to provide the greatest coverage of the geographical area included in the eradication programme must be subject at least to the scheme set out in Section 2;

(f) an individual establishment which keeps listed species and which has a health status which is independent of the health status of the surrounding waters is not required to comply with the scheme set out in Section 2 following a disease outbreak provided the establishment complies with the requirements set out in paragraph 3 of Article 80 and is repopulated with crustaceans sourced from Member States, zones or compartments with status free from infection with WSSV.

2. The restricted zone must have been defined on a case-by-case basis taking into account factors influencing the risks for the spread of WSSV to farmed and wild crustaceans, such as:

(i) the number, age, rate and distribution of the mortalities of crustaceans on the establishment or group of establishments infected with WSSV including other establishments and wild crustaceans;

(ii) the distance to and density of neighbouring establishments or groups of establishments including wild crustaceans;

(iii) the proximity to processing establishments, contact establishments or groups of establishments;

(iv) the species, especially susceptible species and vector species, present at the establishments or groups of establishments;

(v) the farming practices applied in the affected and neighbouring establishments and groups of establishments;

(vi) the hydrodynamic conditions; and

(vii) other factors of epidemiological significance identified.

▼B

Table 6. A

Scheme for Member States, zones and compartments for the 2-year control period which precedes the achievement of status free from infection with WSSV

Year of surveillance	Number of health visits per year to each establishment or group of establishments	Number of laboratory examinations per year	Number of crustaceans in the sample
Year 1	1	1	150
Year 2	1	1	150

Section 4

Maintenance of status free from infection with *WSSV*

1. When targeted surveillance is required in order to maintain the status free from infection with WSSV of a Member State, a zone or a compartment, in accordance with Article 81, all establishments keeping listed species within the Member State, zone or compartment concerned must be subject to health visits and crustaceans must be sampled in accordance with Table 6.B, taking into account the risk level of the establishment for the contraction of infection with WSSV.

2. In Member States, zones or compartments where the number of establishments is limited and targeted surveillance in those establishments does not provide sufficient epidemiological data, the surveillance to maintain disease-free status must include sampling points selected in accordance with the requirements laid down in point (b) of Section 1.

3. When determining the frequency of health visits required to maintain the status free from infection with WSSV of compartments where the health status regarding that disease is dependent on the health status of the aquatic animal populations in surrounding natural waters, the risk for the contraction of infection with WSSV must be regarded as high.

4. The status free from infection with WSSV may only be maintained as long as all samples, using the diagnostic methods set out in point 2 of Section 5 have produced negative results for WSSV and any suspicion of infection with WSSV has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5.

Table 6. B

Scheme for Member States, zones or compartments to maintain status free from infection WSSV

Risk level [1]	Number of health visits to each establishment/group of establishments	Number of laboratory examinations	Number of crustaceans in the sample
High	1 every year	1 every 2 years	150
Medium	1 every 2 years	1 every 2 years	150
Low	1 every 2 years	1 every 4 years	150

[1] Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I other than in the case of dependent compartments where all establishments are deemed to be high risk.

▼B

Section 5

Diagnostic and sampling methods

1. Samples of integumental epidermis, either dissected or contained within walking legs, pleopods, mouthparts or gills of the test animal must be fixed in 95 % ethanol prior to the preparation of samples for PCR.

   Other samples, fixed for histology and transmission electron microscopy may be collected to support diagnostic data arising from PCR.

2. The diagnostic method and procedures to be used to grant or to maintain disease-free status with regard to infection with WSSV must be PCR followed by sequencing. When applying these diagnostic methods, the corresponding detailed methods and procedures which have been approved by the EURL for Crustacean Diseases must be followed.

   In the case of a positive result from the PCR test, the result must be followed by sequencing of the amplicon before the initial control measures provided for in Article 63 of Regulation (EU) 2016/429 are implemented.

3. When a suspicion of infection with WSSV is required to be confirmed or ruled out in accordance with Article 58, the following visit, sampling and testing procedure must be complied with:

   (a) the investigation must include at least one health visit and one sampling of 10 crustaceans when clinical signs or post-mortem lesions consistent with infection with WSSV are observed or 150 crustaceans when clinical signs or post-mortem lesions are not observed. The samples must be tested using the diagnostic method set out in point 2;

   (b) the presence of WSSV must be considered as confirmed when PCR followed by sequencing, carried out in accordance with the detailed methods and procedures which have been approved by the EURL for Crustacean Diseases test positive for WSSV.

   The suspicion of infection with WSSV may be ruled out, if those tests reveal no further evidence of the presence of the virus.

PART III

REQUIREMENTS FOR DEMONSTRATING THE IMPLEMENTATION OF SURVEILLANCE PROGRAMMES FOR CATEGORY C DISEASES AND FOR RESTARTING THOSE PROGRAMMES AFTER A DISEASE OUTBREAK

Part III covers the requirements for establishments to demonstrate the implementation of a surveillance programme for a particular disease and the requirements to restart that surveillance programme following a disease outbreak.

Viral haemorrhagic septicaemia (VHS)	Chapter 1
Infectious haematopoietic necrosis (IHN)	Chapter 1
Infection with HPR-deleted infectious salmon anaemia virus	Chapter 2
Infection with *Marteilia refringens*	Chapter 3
Infection with *Bonamia exitiosa*	Chapter 4
Infection with *Bonamia ostreae*	Chapter 5
Infection with white spot syndrome virus (WSSV)	Chapter 6

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CHAPTER 1

Requirements for establishments to demonstrate the implementation of a surveillance programme for VHS or IHN and requirements to re-start that programme following a disease outbreak

Section 1

General requirements for health visits and sampling for VHS and IHN

The health visits and sampling referred to in point (b)(iv) of Article 3(2) must comply with the following requirements:

(a) health visits and sampling must be carried out during the period of the year when the water temperature is below 14 °C or when temperatures below 14 °C are not reached, samples must be taken at the lowest annual points;

(b) all production units, such as ponds, tanks and net cages, must be examined for the presence of dead, weak or abnormally behaving fish. Particular attention must be paid to the water outlet area where weak fish tend to accumulate because of the water current;

(c) fish of listed species to be collected as samples must be selected as follows:

(i) if rainbow trout are present, only fish of that species must be selected for sampling, except where other susceptible species are present which show typical signs of VHS or IHN; if rainbow trout are not present, the sample must be representative of all other susceptible species which are present;

(ii) if weak, abnormally behaving or freshly dead but not decomposed fish are present, such fish must be selected; if more than one water source is utilised for fish production, fish representing all water sources must be included in the sample;

(iii) the fish selected must include fish collected in such a way that all parts of the establishment, as well as all year classes, are proportionally represented in the sample.

Section 2

Specific requirements to demonstrate the implementation of a surveillance programme

1. Health visits must be carried out and fish must be sampled in accordance with Section 1 and Table 1.

2. Samples which are collected in accordance with Section 1 and Table 1 must be tested using the diagnostic methods set out in point 2 of Section 5 of Chapter 1 of Part II and produce negative results for VHS or IHN.

Section 3

Requirements to re-start a surveillance programme after a disease outbreak

An establishment which has been infected with VHS or IHN, may restart a surveillance programme for these diseases provided that:

(a) it has been emptied in accordance with Article 62, cleaned and disinfected in accordance with Article 63, and fallowed in accordance with Article 64; and

(b) repopulation occurs using fish that originate from establishments which are:

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(i) in a Member State, a zone or a compartment free from VHS or IHN;

(ii) in a Member State, a zone or a compartment covered by an eradication programme for VHS or IHN; or

(iii) implementing a surveillance programme for VHS or IHN.

Table 1

Surveillance programme for VHS/IHN

Risk level (1)	Number of health visits per year to each establishment	Number of fish in the sample (2)
High	1 every year	30
Medium	1 every 2 years	30
Low	1 every 3 years	30

(1) In the case of coastal zones or coastal compartments, the samples must be collected no sooner than 3 weeks after the transfer of the fish from fresh to saltwater.
(2) Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I. Maximum number of fish per pool: 10

CHAPTER 2

Requirements for establishments to demonstrate the implementation of a surveillance programme for HPR-deleted ISAV and to re-start that programme after a disease outbreak

Section 1

General requirements for health visits and sampling for infection with HPR-deleted ISAV

The health visits and sampling referred to in point (b)(iv) of Article 3(2) must comply with the following requirements:

(a) health visits and sampling must take into account all production units, such as ponds, tanks and net cages, to determine if dead, weak or abnormally behaving fish are present. Particular attention must be paid to the edge of cages or the water outlet area as relevant, where weak fish tend to accumulate because of the water current;

(b) the fish to be collected as samples must be selected as follows:

(i) only moribund or freshly dead but not decomposed fish must be selected; in particular fish demonstrating anaemia, bleeding or other clinical signs suggesting circulatory disturbances must be prioritised for collection;

(ii) if Atlantic salmon are present, only fish of that species must be selected for sampling, except where other susceptible species are present which show typical signs of ISA. If there are no Atlantic salmon in the establishment, other listed species must be sampled;

(iii) if more than one water source is utilised for fish production, fish representing all water sources must be included in the sample;

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(iv) the fish selected must include fish collected in such a way that all production units, such as net cages, tanks and ponds, as well as all year classes in the establishment are proportionally represented in the sample.

Section 2

Specific requirements to demonstrate the implementation of a surveillance programme

1. Health visits must be carried out and fish must be sampled in accordance with Section 1 and Table 2.

2. Samples which are collected in accordance with Section 1 and Table 2 must be tested using the diagnostic methods set out in point 2 of Section 5 of Chapter 2 of Part II and produce negative results for HPR-deleted ISAV.

Table 2

Surveillance programme for HPR-deleted ISAV

Risk level ([1])	Number of health visits per year to each establishment	Number of laboratory examinations per year	Number of fish in the sample
High	2	2 ([2])	30
Medium	1	1 ([3])	30
Low	1 every 2 years	1 every two years	30
Maximum number of fish per pool: 5			

([1]) Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I
([2]) Samples must be collected during spring and autumn when two samples are required each year
([3]) Samples must be collected during spring or autumn when only one sample is required per year

Section 3

Requirements to re-start a surveillance programme after a disease outbreak

An establishment which has been infected with HPR-deleted ISAV may restart a surveillance programme for that diseases provided that:

(a) it has been emptied in accordance with Article 62, cleaned and disinfected in accordance with Article 63, and fallowed in accordance with Article 64; and

(b) repopulation occurs using fish that originate from establishments which are:

(i) in a Member State, a zone or a compartment free from infection with HPR-deleted ISAV;

(ii) in a Member State, a zone or a compartment covered by an eradication programme for infection with HPR-deleted ISAV; or

(iii) implementing a surveillance programme for infection with HPR-deleted ISAV.

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CHAPTER 3

Requirements for establishments to demonstrate the implementation of a surveillance programme for infection with *Marteilia refringens* and requirements to re-start that programme following a disease outbreak

Section 1

General requirements for health visits and sampling for infection with *Marteilia refringens*

The health visits and sampling referred to in point (b)(iv) of Article 3(2) must comply with the following requirements:

(a) health visits and sampling for laboratory examination must be carried out in the period of the year when prevalence of the parasite in the Member State, zone or compartment is known to be maximal. When such data is not available, sampling shall be carried out just after the water temperature has exceeded 17 °C;

(b) when molluscs are to be sampled in accordance with the requirements set out in Table 3, the following criteria must apply:

(i) *Ostrea spp.* must be sampled. If *Ostrea* spp. are not present, the sample must be representative of all other listed species present;

(ii) if weak, gaping or freshly dead but not decomposed molluscs are present in the production units, such molluscs must primarily be selected. If such molluscs are not present, the molluscs selected must include the oldest healthy molluscs;

(iii) when sampling in mollusc establishments which utilise more than one water source for mollusc production, molluscs representing all water sources must be included for sampling in such a way that all parts of the establishment are proportionally represented in the sample;

(iv) when sampling in mollusc establishments or groups of establishments, molluscs from a sufficient number of sampling points must be included in the sample in such a way that all parts of the establishment or group of establishments are proportionally represented in the sample. The main factors to be considered for the selection of those sampling points are stocking density, water flows, the presence of susceptible species, the presence of vector species, bathymetry and management practices. Natural beds within or adjacent to the establishment or group of establishments must be included in the sampling.

Section 2

Specific requirements to demonstrate the implementation of a surveillance programme

1. Health visits must be carried out and molluscs must be sampled in accordance with Section 1 and Table 3.

2. Samples which are collected in accordance with Section 1 and Table 3 must be tested using the diagnostic methods set out in point 2 of Section 5 of Chapter 3 of Part II and produce negative results for *Marteilia refringens*.

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Table 3

Surveillance programme for *Marteilia refringens*

Risk level ([1])	Number of health visits to each establishment/ group of establishments	Number of laboratory examinations	Number of molluscs in the sample
High	1 every year	1 every 2 years	150
Medium	1 every 2 years	1 every 2 years	150
Low	1 every 2 years	1 every 4 years	150

([1]) Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I

Section 3

Requirements to re-start a surveillance programme after a disease outbreak

An establishment which has been infected with *Marteilia refringens* may re-start a surveillance programme for that disease provided that:

(a) it has been emptied in accordance with Article 62, cleaned and disinfected in accordance with Article 63, and fallowed in accordance with Article 64; and

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(b) repopulation occurs using molluscs that originate from establishments which are:

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(i) in a Member State, a zone or a compartment free from infection with *Marteilia refringens*;

(ii) in a Member State, a zone or a compartment covered by an eradication programme for infection with *Marteilia refringens*; or

(iii) implementing a surveillance programme for infection with *Marteilia refringens.*

CHAPTER 4

Requirements for establishments to demonstrate the implementation of a surveillance programme for infection with *Bonamia exitiosa* and to re-start that programme following a disease outbreak

Section 1

General requirements for health visits and sampling for infection with *Bonamia exitiosa*

The health visits and sampling referred to in point (b)(iv) of Article 3(2) must comply with the following requirements:

(a) health visits and sampling of production units must be carried out in the period of the year when prevalence of *Bonamia exitiosa* in the Member State, zone or compartment is known to be maximal. When such data is not available, sampling shall be carried out twice a year, in spring and autumn;

(b) when molluscs are sampled in accordance with the requirements set out in Table 4, the following criteria must apply:

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(i) if *Ostrea* spp. are present, only oysters of that species must be selected for sampling. If *Ostrea spp.* are not present, the sample must be representative of all other susceptible species present;

(ii) if weak, gaping or freshly dead but not decomposed molluscs are present, such molluscs must primarily be selected. If such molluscs are not present, the molluscs selected must include the oldest healthy molluscs;

(iii) when sampling in establishments which utilise more than one water source for mollusc production, molluscs representing all water sources must be included for sampling in such a way that all parts of the establishment are proportionally represented in the sample;

(iv) when sampling in establishments or groups of establishments, molluscs from a sufficient number of sampling points must be included in the sample in such a way that all parts of the establishment or group of establishments are proportionally represented in the sample. The main factors to be considered for the selection of those sampling points are stocking density, water flows, the presence of susceptible species, the presence of vector species (e.g.*Crassostrea gigas*), bathymetry and management practices. Natural beds within or adjacent to the establishment or group of establishments must be included in the sampling.

Section 2

Specific requirements to demonstrate the implementation of a surveillance programme

1. Health visits must be carried out and molluscs must be sampled in accordance with Section 1 and Table 4.

2. Samples which are collected in accordance with Section 1 and Table 4 must be tested using the diagnostic methods referred to in point 2 of Section 5 of Chapter 4 of Part II and produce negative results for *Bonamia exitiosa*.

Table 4

Surveillance programme for infection with *Bonamia exitiosa*

Risk level ([1])	Number of health visits to each establishment/ group of establishments	Number of laboratory examinations	Number of molluscs in the sample
High	1 every year	1 every 2 years	150
Medium	1 every 2 years	1 every 2 years	150
Low	1 every 2 years	1 every 4 years	150

([1]) Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I.

Section 3

Requirements to re-start a surveillance programme after a disease outbreak

An establishment which has been infected with *Bonamia exitiosa* may re-start a surveillance programme provided that:

(a) it has been emptied in accordance with Article 62, cleaned and disinfected in accordance with Article 63, and fallowed in accordance with Article 64; and

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(b) repopulation occurs using molluscs that originate from establishments which are:

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(i) in a Member State, a zone or a compartment free from infection with *Bonamia exitiosa*;

(ii) in a Member State, a zone or a compartment covered by an eradication programme for infection with *Bonamia exitiosa*; or

(iii) implementing a surveillance programme for infection with *Bonamia exitiosa.*

CHAPTER 5

Requirements for establishments to demonstrate the implementation of a surveillance programme for infection with *Bonamia ostreae* and to re-start that programme following a disease outbreak

Section 1

General requirements for health visits and sampling for infection with *Bonamia ostreae*

The health visits and sampling referred to in point (b)(iv) of Article 3(2) must comply with the following requirements:

(a) health visits and sampling of production units shall be carried out in the period of the year when prevalence of *Bonamia ostreae* in the Member State, zone or compartment is known to be maximal. When such data is not available, sampling shall be carried out in winter or at the beginning of spring;

(b) when molluscs are to be sampled in accordance with the requirements set out in Table 5, the following criteria must apply:

(i) if *Ostrea edulis* are present, only oysters of that species must be selected for sampling. If *Ostrea edulis* are not present, the sample must be representative of all other susceptible species present;

(ii) if weak, gaping or freshly dead but not decomposed molluscs are present, such molluscs must primarily be selected. If such molluscs are not present, the molluscs selected must include the oldest healthy molluscs;

(iii) when sampling in establishments which utilise more than one water source for mollusc production, molluscs representing all water sources must be included for sampling in such a way that all parts of the establishment are proportionally represented in the sample;

(iv) when sampling in mollusc establishments or groups of establishments, molluscs from a sufficient number of sampling points must be included in the sample. The main factors to be considered for the selection of those sampling points are stocking density, water flows, the presence of susceptible species, the presence of vector species, bathymetry and management practices. Natural beds within or adjacent to the establishment or group of establishments must be included in the sampling.

Section 2

Specific requirements to demonstrate the implementation of a surveillance programme

1. Health visits must be carried out and molluscs must be sampled in accordance with Section 1 and Table 5.

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2. Samples which are collected in accordance with Section 1 and Table 5 must be tested using the diagnostic methods referred to in point 2 of Section 5 of Chapter 5 of Part II and produce negative results for *Bonamia ostreae*.

Table 5

Surveillance programme for infection with *Bonamia ostreae*

Risk level (1)	Number of health visits to each establishment/ group of establishments	Number of laboratory examinations	Number of molluscs in the sample
High	1 every year	1 every 2 years	150
Medium	1 every 2 years	1 every 2 years	150
Low	1 every 2 years	1 every 4 years	150

(1) Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I

Section 3

Requirements to re-start a surveillance programme after a disease outbreak

An establishment which has been infected with *Bonamia ostreae* may re-start the surveillance programme for that disease provided that:

(a) it has been emptied in accordance with Article 62, cleaned and disinfected in accordance with Article 63, and fallowed in accordance with Article 64; and

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(b) repopulation occurs using molluscs that originate from establishments which are:

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(i) in a Member State, a zone or a compartment free from infection with *Bonamia ostreae*;

(ii) in a Member State, a zone or a compartment covered by an eradication programme for infection with *Bonamia ostreae*; or

(iii) implementing a surveillance programme for infection with *Bonamia ostreae.*

CHAPTER 6

Requirements for establishments to demonstrate the implementation of a surveillance programme for infection with WSSV and to re-start that programme following a disease outbreak

Section 1

General requirements for health visits and sampling for infection with infection with WSSV

The health visits and sampling referred to in point (b)(iv) of Article 3(2) must comply with the following requirements:

(a) the sampling of crustaceans for laboratory examination must be carried out whenever the water temperature is likely to reach its highest annual point. That requirement concerning water temperature must also apply to health visits where these are feasible and appropriate;

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(b) when farmed crustaceans are to be sampled in accordance with the requirements set out in Table 6, the following criteria must apply:

(i) if weak or moribund crustaceans are present in the production units, such crustaceans must primarily be selected. If such crustaceans are not present, those selected must include crustaceans of different size cohorts namely juveniles and adults, of the selected susceptible species, proportionally represented in the sample;

(ii) if more than one water source is utilised for crustacean production, susceptible crustaceans representing all water sources must be included for sampling.

Section 2

Specific requirements to demonstrate the implementation of a surveillance programme

1. Health visits shall be carried out and crustaceans shall be sampled in accordance with Section 1 and Table 6.

2. Samples which are collected in accordance with Section 1 and Table 6 must be tested using the diagnostic methods referred to in point 2 of Section 5 of Chapter 6 of Part II and produce negative results for infection with WSSV.

Table 6

Surveillance programme for infection with WSSV

Risk level [1]	Number of health visits to each establishment/ group of establishments	Number of laboratory examinations	Number of crustaceans in the sample
High	1 every year	1 every 2 years	150
Medium	1 every 2 years	1 every 2 years	150
Low	1 every 2 years	1 every 4 years	150

[1] Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I

Section 3

Requirements to re-start a surveillance programme after a disease outbreak

An establishment which has been infected with WSSV may re-start a surveillance programme for that disease provided that:

(a) it has been emptied in accordance with Article 62, cleaned and disinfected in accordance with Article 63, and fallowed in accordance with Article 64; and

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(b) repopulation occurs using crustaceans that originate from establishments which are:

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(i) in a Member State, a zone or a compartment free from infection with WSSV;

(ii) in a Member State, a zone or a compartment covered by an eradication programme for infection with WSSV; or

(iii) implementing a surveillance programme for infection with WSSV.