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COVER NOTE

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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Delegations will find attached document C(2019) 4056 final.

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COMMISSION DELEGATED REGULATION (EU) …/...

of 17.12.2019

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (the 'Animal Health Law') lays down rules on transmissible animal diseases, specifically on: (i) the surveillance of listed diseases and emerging diseases; (ii) eradication programmes; and (iii) disease-free status for certain diseases of terrestrial and aquatic animals. The Animal Health Law, particularly under Chapters 2 to 4 of Part II empowers the Commission to adopt delegated acts, supplementing the aforementioned rules.

As these rules are all interrelated, in the interests of consistency and transparency and to avoid duplications, it is important that they be laid down in the same delegated act.

The rules laid down in this Delegated Regulation are largely based on rules currently laid down in existing Union acts establishing the requirements for the surveillance of certain diseases, for eradication programme and for the granting of disease-free status at establishment, compartment, zone or Member State level. As the Union rules in place before the date of application of this Regulation have proven to be effective, they form a sound basis for the rules laid down in this act. These rules have also been adapted to the new legal framework taking into account lessons learnt from the past, the updating of international standards and scientific progress and recent European Food Safety Authority (EFSA) opinions.

Accordingly, this Delegated Regulation lays down:

(a) the rules and conditions for surveillance conducted by the competent authority to ensure the detection of listed diseases and, where relevant, of emerging diseases;

(b) the criteria used to determine which disease will require a Union surveillance programme and rules setting up the requirements for these Union surveillance programmes, to be implemented by competent authorities;

(c) the rules setting out how competent authorities are to implement compulsory and optional eradication programmes for specific listed diseases focusing on their disease control strategies, their intermediate and final targets and their period of application;

(d) measures to be implemented by the competent authority and the operators under the compulsory and optional eradication programmes;

(e) the detailed rules for granting disease-free status to Member States, and zones and compartments;

(f) the detailed rules for surveillance and biosecurity measures to be implemented by competent authorities and operators for maintaining disease-free status of Member States, zones and compartments;

(g) supplementary rules for the suspension, withdrawal and restoration of disease-free status;

(h) rules necessary to ensure a smooth transition from the rules existing prior to the Animal Health Law.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission had several meetings and exchanges with the Expert Group on animal health (E00930). The draft Delegated Regulation was also made available to the European Parliament and the Council. There were no comments received from the European Parliament and the Council. A number of meetings have been held with a range of stakeholders within the framework of Animal Health Advisory Committee where the main elements of the draft act were illustrated and discussed.

In addition, stakeholders' comments on the draft Delegated Regulation were collected in the context of the Better Regulation feedback mechanism during the period between 5 June and 3 July 2019. 75 feedbacks were received in total, including opinions of the following stakeholders: Animal Health Ireland, Anses (FR), APCA (FR), Associazione Piscicoltori Italiani, Boehringer Ingelheim (DE), British Cattle Veterinary Association, British Veterinary Association, CIPA (FR), Copa-Cogeca, Danish Agriculture and Food Council, Department of Environment, Food and Rural Affairs (UK), Dibevo (NL), Dogs Trust (UK), European Association of Zoos And Aquaria, Federation of Veterinarians of Europe, Fédération Européenne pour la Santé Animale et la Sécurité Sanitaire, 25 Groupements de Defense Sanitaires (GDS) from French departements and regions, GDS FRANCE, Groupement de defense aquacole d'Aquitaine (FR), Institute of Northern Ireland Beekeepers (UK), Irish Co-operative Organisation Society, Irish Farmer's Association, LTO Dutch Organisation for Agriculture and Horticulture, MEP Matt Carthy Sinn Féin (IE), National Farmers' Union (UK), National Farmers Union Scotland (UK), NFU Cymru (UK), Ornamental Fish International (NL), RACES DE FRANCE (FR), Scottish Association of Meat Wholesalers (UK), Scottish Dairy Cattle Association (UK), Syndicat de la Vitellerie Française (FR), TED 16 (FR), Federation of Swedish Farmers, UECBV, Ulster Farmers' Union (UK), Vee&Logistiek Nederland, three from public authorities (IE, AT and NO) and 6 anonymous (FR and UK).

The main following requests were submitted and points made:

(a) the request to provide for additional derogations in the eradication programmes for infection with Mycobacterium tuberculosis complex, particularly requesting more possibilities to derogate from the systematic pre-movement testing and for a quicker restoration of the disease-free status following an outbreak. The rules in the Delegated Regulation are aligned to the standards from the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE) ('the Terrestrial Code') and the derogations already included are based on lessons taken from success or failure of eradication of this disease in the Union;

(b) the request to lay down less prescriptive approach for optional eradication programmes for category C diseases of terrestrial animals, although the flexibility provided in many of the provisions was acknowledged. The competent authority may conduct its own strategy to eradicate them before seeking the Commission's approval of the eradication programme. Nevertheless, as the approval of the eradication programme implies modifications to the requirements for the movements of animals between Member States, its approval and provisions should be subject to harmonised rules;

(c) the request to modify the requirements on diagnostic methods, case definitions and sampling patterns for certain diseases to improve clarity or to reduce constraints. The Delegated Regulation was amended to take into account requests that would not reduce the sensitivity of the surveillance;

(d) the request to reduce the requirements for the granting and maintenance of disease-free status for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis and for bovine viral diarrhoea. The provisions of this Delegated Regulation aim to achieve the disease-free status based on OIE standards, in particular as regards IBR/IPV, and take account of the best practices and difficulties identified by Member States;

(e) the risk associated of infection with bluetongue virus (serotypes 1-24) when unloading animals for a period of up to one day in certain conditions was outlined. However, this rule exists in the Union rules in place before the date of application of this Delegated Regulation and there is no evidence that it resulted in the spreading of the disease;

(f) the request to provide for less strict rules to reach disease-free status from infection with bluetongue virus (serotypes 1-24) and in particular to address each serotype independently. The requirements set out in this Delegated Regulation are based on the Terrestrial Code and certain requirements are specified considering the lessons taken from success or failure of eradication of this disease in the Union;

(g) the acknowledgements for the derogation provided for in this Delegated Regulation as regards the possibility for the competent authority to use a risk-based approach to allow certain movements of animals although more flexibility as regards the situation of the Member State of origin was requested;

(h) the request to maintain the rules for the recognition of dependent compartments as regards diseases of aquatic animals at the same level as laid down in the Union rules in place before the date of application of this Delegated Regulation. This Delegated Regulation uses the same concepts and clarifies the rules;

(i) the request to not allow the discontinuation of targeted surveillance for the maintenance of disease-free status for diseases of aquatic animals. This Delegated Regulation limits this possibility only to certain situations;

(j) the request to prohibit the possibility of granting disease-free status for infection with *Bonamia exitosia* based on historical and surveillance data because the signs of the disease are not obvious. The approach taken in this Delegated Regulation for the granting of the disease-free status based on historical and surveillance data for diseases of aquatic animals is that this pathway can be followed in the case of diseases that are not eligible for eradication programmes under the Union rules in place before the date of application of this Delegated Regulation. Eradication programmes for infection with *Bonamia exitosia* are currently not possible and thus, the granting of the disease-free status based on historical and surveillance data is possible under this Delegated Regulation;

(k) the request to clarify that the presence of vector species of diseases of aquatic animals in the absence of other listed species does not hamper the possibility to grant disease-free status on the basis of the absence of listed species;

(l) the request to maintain the status granted under the Union rules in place before the date of application of this Delegated Regulation as long as these rules are complied with. The objective of the transitional rules of the Animal Health Law is to facilitate recognition of the statuses granted under the Union rules in place before the date of application of this Delegated Regulation, not to perpetuate these rules after their repeal.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Delegated Regulation is to be adopted pursuant to Regulation (EU) 2016/429, and in particular pursuant to Article 29, Article 31(5), Article 32(2), Article 37(5), Article 39, Article 41(3), Article 42(6) and Article 280(4) thereof.

COMMISSION DELEGATED REGULATION (EU) …/...

of 17.12.2019

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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law[1]')], and in particular Article 29, Article 31(5), 32(2), 37(5), Article 39, Article 41(3), Article 42(6) and Article 280(4) thereof,

Whereas:

(1) The Animal Health Law lays down rules for the prevention and control of animal diseases transmissible to animals or to humans. The rules laid down in this Regulation are required to supplement those laid down in Chapters 2, 3 and 4 of Part II of the Animal Health Law on surveillance, eradication programmes and disease-free status, as well as those in Part IX on transitional arrangements concerning existing surveillance or eradication programmes and existing disease-free status.

(2) These rules are substantially linked with many intended to be applied together. In the interest of simplicity and transparency, as well as to facilitate their application and avoid a multiplication of rules, they should therefore be laid down in a single act rather than in a number of separate acts with many cross-references and the risk of duplication.

(3) Indeed, surveillance represents an intrinsic part of any eradication programme and disease-free status is in most cases an outcome of a successful surveillance and eradication process. Moreover, surveillance is needed, besides other measures, as a key tool for maintaining the disease-free status after its achievement. The rules on surveillance, eradication programmes and disease-free status, including transitional rules, often serve common purposes and refer to complementary activities of operators, veterinarians and competent authorities. Therefore it is appropriate to group together these rules in a single delegated regulation.

(4) Surveillance is a key element of an efficient and effective disease prevention and control policy. It should be implemented jointly by operators and the competent authority. It should also be designed to meet the objectives of early detection of outbreaks of any listed and emerging disease and to demonstrate compliance with the criteria for the granting, maintaining, suspension or withdrawal of disease-free status.

[1] OJ L 84, 31.3.2016, p. 1.

(5) The competent authority should put in place a basic general surveillance system for listed and emerging diseases of terrestrial animals based on notification and investigations of disease events in targeted animal population.

(6) These general surveillance requirements for terrestrial animals should be complemented by more specific requirements depending on the expected output of surveillance. They should be designed to serve different specific purposes such as Union surveillance programmes, compulsory and optional eradication programmes, demonstration of disease-free status, disease control measures, in the context of the approval of certain establishments and the movements of animals and animal products.

(7) The approach to designing general surveillance requirements for aquatic animals is similar to that for terrestrial animals, although not identical. All aquaculture establishments need to implement a basic surveillance system based on notification and investigation of disease events in a targeted animal population. In addition, surveillance for listed and emerging diseases of aquatic animal needs to incorporate certain disease control measures, when it is necessary to take such measures in aquaculture establishments.

(8) In addition to the general surveillance requirements, which apply to all aquaculture establishments, specific surveillance requirements apply to certain approved aquaculture establishments. These specific measures include implementing a risk-based surveillance scheme based on assessment of the risk that an establishment has of contracting and spreading an aquatic disease, be it listed or non-listed.

(9) The specific surveillance requirements also relate to the implementation of eradication programmes for certain listed diseases in order to obtain disease-free status from that disease and to maintain that status once achieved.

(10) In addition, Member States should be given the possibility to implement surveillance, in the form of 'surveillance programmes' for Category C diseases of aquatic animals at establishment level, without opting for a disease eradication programme. Surveillance programmes differ from eradication programmes in that they are based on a system of targeted surveillance which is comprehensive but which does not encompass all the elements of an eradication programme. Unlike eradication programmes, surveillance programmes do not offer the possibility to achieve official disease-free status.

(11) The specific eradication and surveillance programmes set out in this Regulation serve to substantiate health requirements for certain movements of animals and products of animal origin within the Union and in certain cases, of animals and products of animal origin entering the Union.

(12) The Animal Health Law requires rules for listed diseases to apply to listed species. Surveillance may not be relevant for all categories of animals of listed species, in particular as regards wild animals or certain categories of kept animals. Therefore this Regulation should provide rules to specify the relevant targeted animal population for the purpose of surveillance. It should also be possible to expand the targeted animal population to non-listed kept species to ensure early detection of emerging diseases.

(13) Derogations should also make possible to further limit targeted terrestrial animal populations to specific surveillance purposes, namely: (i) Union surveillance programmes; (ii) compulsory or optional eradication programmes; and (iii) surveillance-based animal health requirements for movements within the Union or for entry into the Union.

(14) Diagnostic methods, together with the subsequent collection of samples to perform them, techniques, validation and interpretation are of a very technical nature and are subject to frequent modifications due to developments in scientific standards. Therefore to ensure that they are up to date, the rules on diagnostic methods should indicate in a flexible manner which methods should be used and how. In the area of animal diseases, there are different possible sources of scientific standards for diagnostic methods. It is therefore important to indicate the hierarchical order in which the methods should be considered, taking into account the general principles of sampling, analyses, tests and diagnoses laid down in Regulation (EU) 2017/625[2].

(15) To ensure optimal use of all resources and to avoid unnecessary administrative burdens and costs for operators and the competent authorities, the detection of listed and emerging diseases should draw on sources of information gathered during official controls and other official activities not primarily intended for the surveillance of those diseases.

(16) The confirmation of a disease according to its case definition is the responsibility of the competent authority; it should be supported by appropriate investigations to confirm or rule out the presence of a suspected disease. Such investigations are relevant where the confirmation of the disease triggers disease control measures, as well as in certain other circumstances depending on the consequences of the confirmation of the disease. It is therefore important that this Regulation should lay down the additional circumstances where the confirmation of the disease is necessary.

(17) The definitions of a suspected case and confirmed case of a listed disease and, where relevant, an emerging disease are of key importance. These enable operators, veterinarians and other stakeholders involved in surveillance to identify circumstances where it is necessary to notify the competent authority and for the competent authority to apply disease control measures. Therefore it is necessary to provide general criteria for the definitions of a suspected case and a confirmed case and to provide, where needed, disease-specific definitions, depending on the specific characteristics of certain diseases.

(18) A Union surveillance programme is a surveillance programme relevant for the Union as a whole. This is necessary in order to achieve greater harmonisation of surveillance of a specific disease across the Union due to its specific public or animal health concerns. Therefore it is necessary to lay down the criteria that diseases eligible for Union surveillance programme should meet.

(19) Commission Decision 2010/367/EU[3] lays down minimal requirements for surveillance programmes for avian influenza in poultry and in wild birds and sets out technical

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[2] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

[3] Commission Decision 2010/367/EU of 25 June 2010 on the implementation by Member States of surveillance programmes for avian influenza in poultry and wild birds (OJ L 166, 1.7.2010, p. 22).

guidelines in its annexes. This Regulation should provide for similar technical guidelines in an annex. However, the level of detail in this Regulation is lower to ensure a good capacity to adapt to changes in the situation as regards surveillance of avian influenza. Therefore the technical requirements for the Union surveillance programme for avian influenza focus exclusively on the objectives, the scope and the methodological principles to follow.

(20) The Animal Health Law sets out rules for the application of compulsory and optional eradication programmes for category B and category C diseases in Member States. These diseases, or groups of them, have their own characteristics. Their eradication should be based on a disease control strategy specific for the disease in question. This should include at least: (i) the surveillance that needs to be performed in order to achieve disease-free status as the ultimate goal; (ii) the timeframe; (iii) a definition of the animal population that is subject to the eradication programme; (iv) the territory in which this eradication programme will apply; and (v) specific disease prevention and control measures that will apply to the disease during the eradication phase.

(21) If the territory in which an eradication programme will be implemented includes the external border of the Member State, the competent authority should make efforts to address the risk of introduction of the disease from outside its borders.

(22) The purpose of an eradication programme is to achieve disease-free status on the territory covered by the programme. Ideally, for terrestrial animals it should cover the whole territory of the Member State where the disease is present. If this is not possible, the minimum area that is acceptable should be defined. The minimum surface of the area should take into account the experience gained through previous eradication programmes and allow for flexibility depending on the specific characteristics of the disease.

(23) The programme's qualitative or quantitative targets should be set by the competent authority. Final targets should be based on the criteria for granting disease-free status, while intermediate targets may also comprise other activities or steps important for achieving the disease-free status, reflecting the evolution of the programme.

(24) The competent authority should determine the period of application of the eradication programmes. In the case of optional eradication programmes for category C diseases, a maximum period of application of the programme is laid down in order to prevent disproportionate and long lasting disruption of movements within the Union. Nevertheless, the competent authority may start the eradication programme before its approval by the Commission but should not implement restrictions to the movements within the Union at that stage. A possibility should also be provided for Member States to request that the Commission extend this period where justified circumstances exist.

(25) The eradication strategy of certain diseases might be based on granting disease-free status at establishment level. The disease-specific measures for such diseases should be grouped and spell out obligations for the operators and for the competent authorities.

(26) The targeted animal population to be included in the disease eradication programme should be set out on a disease-specific basis. The possibility for the competent authority to include in the programme certain additional animal populations should also be set out on a disease-specific basis.

(27) The primary responsibility for obtaining and maintaining the establishment's disease-free status lies with the operator as it is the primary recipient of the benefits linked to the disease-free status. Therefore the operator should comply with certain obligations in order to be granted and maintain disease-free status.

(28) Once the general and disease specific criteria for achieving disease-free status have been met by the operator, it is for the competent authority to grant that status. When these specific criteria are no longer met, it is also for the competent authority to either suspend or withdraw the status.

(29) Moreover, the obligations for operators and competent authorities in the context of eradication programmes should, where necessary, be detailed considering the specific disease profile. The disease-specific requirements are of a technical nature and are set out for each specific disease in annexes to this Regulation.

(30) Commission Implementing Regulation (EU) 2018/1882[4] lists infection with *Brucella abortus*, *B. melitensis* and *B. suis* and infection with *Mycobacterium tuberculosis* complex for compulsory eradication programmes and lists enzootic bovine leukosis, infection with Aujeszky's disease virus, infectious bovine rhinotracheitis / infectious pustular vulvovaginitis and bovine viral diarrhoea for optional eradication programmes. For these diseases, eradication programmes should be based on the granting of establishment disease-free status.

(31) Eradication programmes based on granting disease-free status at establishment level should include all establishments keeping animals from the targeted animal population. However, the competent authority should have the possibility to exclude certain specific types of establishments and slaughterhouses from the eradication programme provided appropriate risk mitigating measures are implemented.

(32) In the case of eradication programmes based on granting disease-free status at establishment level, the competent authority should have the possibility to attribute different health status to different epidemiological units.

(33) In the case of terrestrial animals, the requirements to demonstrate disease-free status at establishment level are based on the absence of infection supported by the testing and surveillance regime, by the conditions for introducing animals and germinal products into the establishments and, if necessary, by restrictions on the use of vaccination. When the conditions for maintaining the disease-free status are no longer satisfied, specific requirements apply to suspend, withdraw and restore this status. Due to their technical nature, the disease-specific detailed requirements and the list of diagnostic methods to be used for granting and maintenance of the status are laid down in annexes.

(34) Conditions for granting, maintaining, suspending and withdrawing disease-free status at establishment level were set out in the following Union rules in place before the date of application of this Regulation: Council Directive 64/432/EEC[5] for bovine

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[4] Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

[5] Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ No 121, 29. 7. 1964, p. 1977/64).

brucellosis and bovine tuberculosis and Council Directive 91/68/EEC[6] for brucellosis in sheep and goats. The Animal Health Law repealed those provisions. Also, Commission Delegated Regulation (EU) 2018/1629[7] has aligned the scope of disease agents involved in brucellosis and bovine tuberculosis with the Terrestrial Animal Health Code of the World Organisation for Animal Health[8] (OIE) ('the Terrestrial Code'). They are now infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* and infection with *Mycobacterium tuberculosis* complex. It is therefore appropriate to revise the technical requirements related to the status of these diseases, so as to seek alignment with the Terrestrial Code while taking into account the experience gained in previous eradication programmes for these diseases.

(35) In the case of disease eradication programmes for terrestrial animals based on granting disease-free status at establishment level, if a disease is suspected or confirmed, the competent authority should implement measures to prevent its spread. These measures are to be implemented primarily in the establishment where the suspected case is kept but the competent authority should have the possibility to expand the measures to other animals or establishments when there is a risk of spreading the disease.

(36) When applying the disease control measures in response to a suspected or confirmed case, the competent authority should introduce certain prohibitions on movements of animals. However, the competent authority should also have the possibility to allow the movement of certain animals from the establishment where a suspected or confirmed case is kept, to take account of animal welfare conditions and to facilitate the sustainability of the disease control measures.

(37) Following the confirmation of a case, at least all animals recognised as confirmed cases should be removed. When these animals are put to death, the competent authority should have the possibility to decide whether this is done by slaughtering, meaning that their meat is intended to enter the food chain, or by killing, meaning that the meat is not intended for that purpose.

(38) For certain diseases that can be spread by infected products of animal origin or fomites, or which may have a potential public health impact, the competent authority should introduce measures in infected establishments to prevent the spread of those diseases through these products or fomites. The measures to mitigate such risks should therefore be set out in this Regulation.

(39) In the case of terrestrial animals, once disease-free status has been achieved at establishment level, for the sake of programme efficiency, it should be possible to carry out a stepwise reduction in the level of surveillance activities after a certain period of continuous disease-free status in the establishment.

(40) Enzootic bovine leukosis (EBL) was subject to compulsory eradication under the Union rules in place before the date of application of this Regulation. This disease is now categorised for optional eradication in accordance with Implementing Regulation (EU) 2018/1882.

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6 Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19).

7 Commission Delegated Regulation (EU) 2018/1629 of 25 July 2018 amending the list of diseases set out in Annex II to Regulation (EU) 2016/429 of the European Parliament and of the Council on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')(OJ L 272, 31.10.2018, p. 11)

8 Terrestrial Animal Health Code, World Organisation for Animal Health, 2018

(41) Union rules in place before the date of application of this Regulation contained well-established and effective principles and criteria for the recognition, maintenance, suspension and restoring of officially EBL-free status. Many Member States successfully applied these rules during the implementation of past EBL eradication programmes. The rules have been reviewed against the Terrestrial Code and included in this Regulation.

(42) Member States or zones which have been free from EBL for several years and have therefore reached a steady animal health situation free of EBL, should continue to demonstrate the absence of infection. Risk-based surveillance is an appropriate means of ensuring early detection if the disease is reintroduced and of substantiating freedom from EBL. Member States should therefore establish a suitable surveillance system from the date of application of this Regulation.

(43) Additional guarantees for intra-Union trade of pigs in relation to infection with Aujeszky's disease virus (ADV) were part of Union rules in place before the date of application of this Regulation. A number of Member States have successfully applied those rules and eradicated infection with ADV in the pig population kept in their territory. The strategy for the eradication of infection with ADV in this Regulation takes account of the Terrestrial Code and of criteria that have proven successful in eradicating the infection with ADV.

(44) The rules in this Regulation on infectious bovine rhinotracheitis / Infectious pustular vulvovaginitis (IBR/IPV) are based on Commission Decision 2004/558/EC[9] with provisions on additional guarantees for intra-Community trade of bovine animals. These include requirements to obtain, maintain and restore freedom at establishment level from bovine herpesvirus 1 (BoHV-1). The rules have been developed taking into consideration the standards of the Terrestrial Code and the EFSA scientific opinion[10].

(45) Union rules in place before the date of application of this Regulation do not contain provisions for bovine viral diarrhoea (BVD) with the exception of provisions related to the trade of germinal products. In Implementing Regulation (EU) 2018/1882, BVD is now listed as a 'category C disease' for optional eradication. Therefore provisions on eradication programmes and the granting and maintenance of disease-free status with regard to BVD are laid down in this Regulation.

(46) The Terrestrial Code lacks a chapter on BVD and criteria for BVD freedom and related animal movements. However, a chapter on BVD is available in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the OIE. These diagnostic standards have been considered for the provisions related to BVD in this Regulation.

(47) Implementing Regulation (EU) 2018/1882 lists infection with the rabies virus as a category B disease. Therefore this Regulation includes provisions on compulsory eradication programmes and the granting and maintenance of disease-free status with regard to infection with the rabies virus.

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9 Commission Decision 2004/558/EC of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States (OJ L 249, 23.7.2004, p. 20)

10 The EFSA Journal (2006) 311, Opinion on the "Definition of a BoHV-1-free animal and a BoHV-1-free holding, and the procedures to verify and maintain this status".

(48) Wild foxes constitute the main reservoir of infection with the rabies virus in the EU. It is therefore appropriate that the measures in eradication programmes are primarily focused on the wild fox population. However, all other mammal species are susceptible and many other animal species are listed in Regulation (EU) 2018/1882 for this disease. The competent authorities should address other animal populations in the eradication programmes when there is a risk to human or animal health.

(49) For infection with rabies eradication programmes, the disease control strategy is primarily based on vaccination of the relevant targeted animal population, supported by other important activities such as surveillance, implementation of disease control measures, the control of pet movements and monitoring of the effectiveness of the vaccination. As the vaccination provisions are of a very technical nature, they are laid down in an annex.

(50) Implementing Regulation (EU) 2018/1882 lists infection with bluetongue virus (serotypes 1-24) (infection with BTV) as a category C disease for optional eradication programme. This implies a change in the policy against this disease as Council Directive 2000/75/EC[11], applicable prior to this Regulation, provided for its immediate eradication. New provisions are laid down in this Regulation to address the new status of the disease.

(51) For infection with BTV, the disease control strategy is primarily based on vaccination of the relevant targeted animal population supported by other activities such as surveillance, implementation of disease control measures, control of the movements of animals and germinal products, and minimising exposure to vectors.

(52) In its opinion[12] on the control, surveillance and movement of animals in the case of infection with BTV, EFSA indicates that for eradication to succeed, vaccination coverage should be at least 95% of susceptible bovine and ovine animals for a minimum period of 5 years. It is therefore expected that the eradication programmes for infection with BTV include a vaccination campaign, although flexibility should be provided for in this Regulation to take into account the specific circumstances of each case.

(53) A Member State or zone thereof free from infection with BTV or under an eradication programme for infection with BTV should be protected from the introduction of any BTV serotypes by the movement of kept animals or germinal products. Therefore requirements for the introduction of kept animals or germinal products into Member States or zones thereof free from infection with BTV or under an eradication programme for infection with BTV should be part of the provisions on eradication programmes. This should also be reflected in the criteria for the maintenance of the disease-free status. The same principles should apply to movements of animals through the Member States or zones thereof free from infection with BTV or under an eradication programme for infection with BTV.

(54) In addition, because of the diversity of the local situations that may prevail, the competent authority should have the possibility to allow the introduction of animals or germinal products based on ad hoc requirements, provided that such introduction does not jeopardise the health status at the destination. It is therefore appropriate that this

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11 Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue (OJ L 327, 22.12.2000, p. 74).

12 EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), 2017. Scientific opinion on bluetongue: control, surveillance and safe movement of animals. EFSA Journal 2017; 15(3):4698, 126

Regulation provides for the requirements and conditions under which such introduction may be authorised. Such requirements should be based on the status of animals or germinal products, independently of the Member State or zone of origin.

(55) An eradication programme for a category B or category C disease of aquatic animals should take account of the type of surveillance requirements required to obtain and maintain disease-free status, of details of the territory and the animal population to be covered by the programme; and of the programme's intermediate and final targets. The eradication programme should include the control measures to be implemented in infected establishments of aquatic animals.

(56) The eradication programme for aquatic animal diseases should include intermediate and final targets which will be used to assess progress towards achieving disease-free status. Where relevant, these targets should take account of the risk wild animals pose to the success of the eradication programme. In particular, any possibility of deviation from the proposed period of application of 6 years should be taken in to account when devising the programme's intermediate and final targets.

(57) In the case of aquatic animals, the population which is to be included in the eradication programme consists of those species which are listed in Implementing Regulation (EU) 2018/1882. However, the competent authority should have the possibility to exclude from the programme the species listed as a vector in Implementing Regulation (EU) 2018/1882 if it has carried out a risk assessment which has resulted in the risk posed by those animals being deemed negligible.

(58) The competent authority should have the possibility to include additional aquatic animal populations when such animals pose a significant risk to the health status. It also should be able to exclude certain low-risk establishments from the eradication programme if their exclusion does not jeopardise its successful completion.

(59) When a Member State has decided to participate in an eradication programme for a category C disease, operators are obliged to comply with conditions for introductions of animals of listed species, to notify suspicion of listed diseases, to comply with disease control measures when a disease is suspected or confirmed and to take any other measures that may be required by the competent authority, including vaccination.

(60) When the presence of a listed disease of aquatic animals is suspected or confirmed in a disease-free Member State, zone or compartment, or in one which is subject to a eradication programme, the competent authority should take appropriate measures to control the disease. These rules should therefore be laid down in this Regulation. These include establishing a restricted zone when the presence of a listed disease has been confirmed in an establishment participating in the eradication programme or in an establishment which has been declared disease-free. This also includes the minimum requirements applying to geographical demarcation of a restricted zone and the factors affecting it.

(61) Following the confirmation of a listed aquatic disease in a disease-free Member State, zone or compartment, or in one which is subject to a eradication programme, the competent authority carries out strict controls in infected establishments and in other establishments located in the restricted zone. The nature of the controls and the level of flexibility the competent authority applies to movements are set out in this Regulation. Where flexibility is applied, it is limited to circumstances where the health

status of aquatic animals at the establishment of destination or enroute to that destination is not jeopardised.

(62) Once an aquatic disease outbreak has occurred in an establishment and that establishment remains or commences an eradication programme, it is important to remove aquatic animals that are dead, moribund or showing clinical signs within a period set by the competent authority and in accordance with Regulation (EC) 1069/2009 of the European Parliament and of the Council[13]. In this way, the disease can be successfully controlled.

(63) The Animal Health Law requires the Commission to develop detailed rules for the granting of disease-free status to Member States, zones and compartments. These rules should include disease-specific criteria to demonstrate the absence of the disease in the targeted animal population and the general criteria that support effective control of the health status of that targeted animal population.

(64) The general criteria comprise the territorial scope, surveillance, biosecurity, disease control measures and consistent implementation of other operational rules set out in the Animal Health Law as regards the registration and approval of establishments, traceability of animals and movement requirements.

(65) This Regulation lays down disease-specific criteria based on the absence of listed species or based on the disease agent or vector's incapacity to survive. These criteria should be drawn up in a flexible way to allow the competent authority to justify the case for obtaining disease-free status based on the specific situation. Therefore general requirements are laid down in this Regulation to indicate on what basis Member States may request the granting of disease-free status for their entire territory or a zone thereof or, in the case of aquaculture animals, for compartments.

(66) This Regulation lays down disease-specific criteria based on the outcome of eradication programme and on historical and surveillance data. These criteria are based on results of the surveillance, the implementation of measures to prevent introduction of the disease and conditions for the use of vaccines.

(67) Because of their technical nature these criteria are laid down in annexes and grouped by disease with the criteria for maintaining the disease-free statuses.

(68) It is appropriate that this Regulation lay down modernised requirements for the granting and maintenance of disease-free status taking account of the Union rules in place before the date of application of this Regulation, the Terrestrial Code, the Aquatic Animal Health Code of the OIE and, in the absence of existing provisions, the best available scientific evidence.

(69) Implementing Regulation (EU) 2018/1882 lists infestation with *Varroa* spp. as a category C disease for optional eradication. This Regulation lays down provisions for achieving and maintaining infestation with *Varroa* spp.-free status.

(70) Regulation (EU) 2018/1882 lists infection with Newcastle disease virus as a category A disease for immediate eradication measures. Therefore this Regulation does not contain provisions for an eradication programme for infection with Newcastle disease

[13] Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation (OJ L 300, 14.11.2009, p. 1).

virus. However, it should be possible for the competent authority to grant the status free from infection with Newcastle disease virus without vaccination on the basis of historical and surveillance data.

(71) Two different types of compartments are possible in the case of aquatic animals. Independent compartments operate under strictly defined conditions which ensure they operate independently of the health status of the surrounding waters. Dependent compartments on the other hand, are influenced by the health status of the surrounding waters and operate therefore, under more flexible conditions. Dependent compartments are however, only established once the competent authority has assessed a number of epidemiological factors and put in place whatever risk mitigating measures are necessary to prevent the introduction of disease into the compartment.

(72) In the case of aquatic animals, and given the lower level of risk associated with individual establishments which are independent of the surrounding waters, special provisions are laid down in this Regulation for independent compartments when they commence aquaculture activities for the first time or when they recommence aquaculture activities after a break in production. In such cases, disease-free status should be declared immediately provided certain conditions are met. Provisions are also laid down for independent compartments where a disease outbreak has occurred. To ensure that such outbreaks have been successfully dealt with by the cleaning, disinfection and fallowing which have been carried out after de-population, a sample of the animals used to repopulate the compartment should be tested before disease-free status can be declared.

(73) When conditions to maintain disease-free status are no longer fulfilled because of suspicion or confirmation of the disease, the competent authority should apply disease control measures. These measures should apply during the different steps of disease control from when an outbreak of the disease is suspected to when the event is resolved and the disease-free status restored.

(74) If the competent authority detects a breach of the conditions required to maintain disease-free status in the Member State, zone or compartment, measures should be implemented to remedy the situation. The competent authority should have the option to suspend the disease-free status when it is still possible to satisfactorily resolve the breach and therefore not to have the disease-free status withdrawn by the Commission.

(75) When a Member State wishes to obtain disease-free status for a listed aquatic disease for its entire territory or for a zone thereof accounting for more than 75% of its territory, or which is shared with another Member State or third country, it will apply to the Commission for approval. In all other cases, a system of self-declaration is followed.

(76) Self-declaration of freedom from aquatic animal diseases for zones and compartments other than those which are Commission-approved follows a system which is designed to give transparency to the process and which will make it easier and potentially quicker for Member States to declare disease-free status. The entire process will be completed electronically unless another Member State or the Commission indicate concerns which cannot be resolved satisfactorily. If there are concerns that cannot be resolved satisfactorily, the declaration is brought to the Standing Committee on Plants, Animals, Food and Feed.

(77) This Regulation contains provisions on the approval of disease-free status of Member States or zones thereof. These rules may differ from the rules in force before the date

of application of this Regulation. Appropriate transitional rules are needed to ensure a smooth transition from the existing regime on the approval of disease-free status to the new requirements.

(78) With a view to the uniform application of Union legislation on surveillance, eradication programmes and disease-free status and to ensure that it is clear and transparent, Commission Decision 2000/428/EC[14], Commission Decision 2002/106/EC[15]; Commission Decision 2003/422/EC[16], Commission Decision 2006/437/EC[17], Commission Regulation (EC) No 1266/2007,[18], Commission Decision 2008/896/EC[19] and Commission Implementing Decision (EU) 2015/1554[20] should be repealed by this Regulation.

(79) The Animal Health Law applies from 21 April 2021. Accordingly, the rules laid down in this Regulation should also apply from that date.

HAS ADOPTED THIS REGULATION:

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14 Commission Decision 2000/428/EC of 4 July 2000 establishing diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation and differential diagnosis of swine vesicular disease (OJ L 167, 7.7.2000, p. 22).

15 Commission Decision 2002/106/EC of 1 February 2002 approving a Diagnostic Manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests for the confirmation of classical swine fever (OJ L 39, 9.2.2002, p. 71).

16 Commission Decision 2003/422/EC of 26 May 2003 approving an African swine fever diagnostic manual (OJ L 143, 11.6.2003, p. 35).

17 Commission Decision 2006/437/EC of 4 August 2006 approving a Diagnostic Manual for avian influenza as provided for in Council Directive 2005/94/EC (OJ L 237, 31.8.2006, p. 1).

18 Commission Regulation (EC) No 1266/2007 of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue (OJ L 238, 27.10.2007, p. 37).

19 Commission Decision 2008/896/EC of 20 November 2008 on guidelines for the purpose of the risk based animal health surveillance scheme provided for in Council Directive 2006/88/EC (OJ L 322, 2.12.2008, p. 30).

20 Commission Implementing Decision (EU) 2015/1554 of 11 September 2015 laying down rules for the application of Directive 2006/88/EC as regards requirements for surveillance and diagnostic methods (OJ L 247, 23.9.2015, p. 1).

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.

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;

(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;

(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.

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;

(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:

(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.

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'[21]) as amended or the Manual of Diagnostic Tests for Aquatic Animals of the OIE ('the Aquatic Manual'[22]) as amended;

(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.

21 http://www.oie.int/en/standard-setting/terrestrial-manual/access-online/

22 http://www.oie.int/en/standard-setting/aquatic-manual/access-online/

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;

(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.

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.

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:

(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 km² 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 km² taking into account:

(a) a minimum surface not significantly lower than 2 000 km²; 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.

2. The competent authority shall include in the eradication programme qualitative and quantitative intermediate annual or multiannual 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;

   (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;

(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:

   (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:

(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:

   (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;

(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:

(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:

   (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.

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 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.

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.

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;

  (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:

(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.

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;

(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:

(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.

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);

(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.

3. The competent authority shall include in the eradication programme qualitative and quantitative intermediate annual or multiannual 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;

(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;

   (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.

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:

(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;

(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;

   (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;

(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;

(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.

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.

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;

(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:

(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:

(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[23] 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) 1266/2007 before the date of application of this Regulation.

4. The criteria provided for in paragraph 1 to obtain disease-free status shall only apply:

(a) in a new Member State, during a maximum period of two years following its accession to the Union; or

(b) for a maximum period of two years following the date of application of the implementing acts adopted in accordance with Article 9(2) of Regulation (EU) 2016/429 that categorise for the first time the relevant disease as a category B or C disease.

5. By way of derogation from paragraph 4, the granting of disease-free status based on historical and surveillance data shall not be subject to the maximum two-year period for the following statuses:

(a) status free from infestation with *Varroa* spp.;

(b) status free from infection with Newcastle disease virus without vaccination.

6. By way of derogation from point (b) of paragraph 4, the granting of disease-free status based on historical and surveillance data shall not apply to the following diseases:

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

(b) infection with MTBC;

(c) EBL;

(d) IBR/IPV;

(e) infection with ADV;

(f) VHS;

(g) IHN;

(h) infection with HPR-deleted ISAV;

(i) infection with *Bonamia ostreae*;

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[23] 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)

(j) infection with *Marteilia refringens*.

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:

   (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;

(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;

      (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 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;

(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.

3. The criteria provided for in paragraph 1 shall only apply:

(a) in a new Member State, during a maximum period of two years following its accession to the Union; or

(b) for a maximum period of two years following the date of application of the implementing acts adopted in accordance with Article 9(2) of Regulation (EU) 2016/429 that categorise for the first time the relevant disease as a category B or C disease.

4. By way of derogation from point (b) of paragraph 3, the granting of disease-free status based on historical and surveillance data shall not apply to the following diseases:

(a) VHS;

(b) IHN;

(c) infection with HPR-deleted ISAV;

(d) infection with *Bonamia ostreae*;

(e) infection with *Marteilia refringens*.

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

(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

   (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:

   (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 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;

(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

Article 83

Derogations from approval by the Commission for certain disease-free statuses for aquatic animal diseases

1. By way of derogation from the requirements to obtain approval by the Commission for disease-free status, laid down in Articles 36(4) and 37(4) of Regulation (EU) 2016/429, for aquatic animal diseases of zones or compartments, 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 for the zone or compartment which fulfils the requirements for disease-free status 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;

(c) 60 days after publication, the provisional declaration shall take effect and the zone or compartment referred to in this paragraph shall achieve the disease-free status.

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 is 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 36(4) and 37(4) of Regulation (EU) 2016/429 shall apply.

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;

(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[24]*;*

(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[25];

(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;

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24 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).

25 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).

(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[26];

(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;

(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;

[26] 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).

(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:

(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;

– Implementing Decision 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.

Done at Brussels, 17.12.2019

For the Commission
The President
Ursula von der LEYEN