

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') (Text with EEA relevance)

PART III

DISEASE AWARENESS, PREPAREDNESS AND CONTROL

TITLE I

DISEASE AWARENESS AND PREPAREDNESS

CHAPTER I

Contingency plans and simulation exercises

Article 43

Contingency plans

1 The Member States shall, after appropriate consultation of experts and relevant stakeholders, draw up, and keep up to date, contingency plans and, where necessary, detailed instruction manuals laying down the measures to be taken in the Member State concerned in the event of the occurrence of a listed disease referred to in point (a) of Article 9(1) or, as the case may be, of an emerging disease, in order to ensure a high level of disease awareness and preparedness and the ability to launch a rapid response.

2 Those contingency plans and, where applicable, detailed instruction manuals shall cover at least the following matters:

- a the establishment of a chain of command within the competent authority and with other public authorities, to ensure a rapid and effective decision-making process at Member State, regional and local level;
- b the framework for cooperation between the competent authority and the other public authorities and relevant stakeholders involved, to ensure that actions are taken in a coherent and coordinated manner;
- c access to:
 - (i) facilities;
 - (ii) laboratories;
 - (iii) equipment;
 - (iv) personnel;
 - (v) emergency funds;
 - (vi) all other appropriate materials and resources necessary for the rapid and efficient eradication of the listed diseases referred to in point (a) of Article 9(1) or of emerging diseases;

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- d the availability of the following centres and groups with the necessary expertise to assist the competent authority:
 - (i) a functional central disease control centre;
 - (ii) regional and local disease control centres, as appropriate for the administrative and geographical situation of the Member State concerned;
 - (iii) operational expert groups;
- e implementation of the disease control measures provided for in Chapter 1 of Title II for the listed diseases referred to in point (a) of Article 9(1) and for emerging diseases;
- f provisions on emergency vaccination, where appropriate;
- g principles for the geographical demarcation of the restricted zones established by the competent authority in accordance with Article 64(1);
- h coordination with neighbouring Member States and neighbouring third countries and territories, where appropriate.

Article 44

Implementing powers for contingency plans

The Commission shall, by means of implementing acts, lay down necessary measures concerning the implementation in the Member States of the contingency plans provided for in Article 43(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 45

Simulation exercises

1 The competent authority shall ensure that simulation exercises concerning the contingency plans provided for in Article 43(1) are carried out regularly or at appropriate intervals:

- a to ensure a high level of disease awareness and preparedness and the ability to launch a rapid response in the Member State concerned;
- b to verify the functionality of those contingency plans.

2 Where feasible and appropriate, simulation exercises shall be carried out in close collaboration with the competent authorities of neighbouring Member States and neighbouring third countries and territories.

3 Member States shall make available to the Commission and to the other Member States, on request, a report on the main results of the simulation exercises carried out.

4 When appropriate and necessary, the Commission shall, by means of implementing acts, lay down rules concerning the practical implementation of simulation exercises in the Member States, relating to:

- a the frequencies of simulation exercises;
- b simulation exercises covering more than one listed disease referred to in point (a) of Article 9(1).

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Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 2

The use of veterinary medicinal products for disease prevention and control

Article 46

The use of veterinary medicinal products for disease prevention and control

1 The Member States may take measures concerning the use of veterinary medicinal products for listed diseases, to ensure the most efficient prevention or control of those diseases, provided that such measures are appropriate or necessary.

Those measures may cover the following:

- a prohibitions and restrictions on the use of veterinary medicinal products;
- b the compulsory use of veterinary medicinal products.

2 Member States shall take the following criteria into consideration when determining whether or not to use, and how to use, veterinary medicinal products as prevention and control measures for a specific listed disease:

- a the disease profile;
- b the distribution of the listed disease in:
 - (i) the Member State concerned;
 - (ii) the Union;
 - (iii) where relevant, neighbouring third countries and territories;
 - (iv) third countries and territories from which animals and products are brought into the Union;
- c the availability and effectiveness of the veterinary medicinal products in question, and the risks attaching to them;
- d the availability of diagnostic tests for detecting infections in animals treated with the veterinary medicinal products concerned;
- e the economic, social, animal welfare and environmental impact of the use of the veterinary medicinal products concerned compared to other available disease prevention and control strategies.

3 Member States shall take appropriate preventive measures concerning the use of veterinary medicinal products for scientific studies or for the purposes of developing and testing them under controlled conditions to protect animal and public health.

Article 47

Delegation of powers for the use of veterinary medicinal products

1 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning what might constitute appropriate and necessary measures as set out in Article 46, in relation to:

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- a prohibitions and restrictions on the use of veterinary medicinal products;
 - b specific conditions for the use of veterinary medicinal products for a specific listed disease;
 - c risk-mitigation measures to prevent the spread of listed diseases through animals treated with the veterinary medicinal products or products from such animals;
 - d surveillance for specific listed diseases following the use of vaccines and other veterinary medicinal products.
- 2 The Commission shall take into account the criteria set out in Article 46(2) when laying down the rules provided for in paragraph 1 of this Article.
- 3 Where, in the case of emerging risks, imperative grounds of urgency so require, the procedure provided for in Article 265 shall apply to rules adopted pursuant to paragraph 1 of this Article.

CHAPTER 3

Antigen, vaccine and diagnostic reagent banks

Article 48

The establishment of Union antigen, vaccine and diagnostic reagent banks

- 1 For listed diseases referred to in point (a) of Article 9(1) in respect of which vaccination is not prohibited by a delegated act adopted pursuant to Article 47, the Commission may establish and be responsible for managing Union antigen, vaccine and diagnostic reagent banks for the storage and replacement of stocks of one or more of the following biological products:
- a antigens;
 - b vaccines;
 - c vaccine master seed–stocks;
 - d diagnostic reagents.
- 2 The Commission shall ensure that the Union antigen, vaccine and diagnostic reagent banks provided for in paragraph 1:
- a store sufficient stocks of the appropriate type of antigens, vaccines, vaccine master seed–stocks and diagnostic reagents for the specific listed disease in question, taking into account the needs of Member States estimated in the context of the contingency plans provided for in Article 43(1);
 - b receive regular supplies and timely replacements of antigens, vaccines, vaccine master seed–stocks and diagnostic reagents;
 - c are maintained and moved in conformity with the appropriate biosecurity, biosafety and bio–containment requirements laid down in Article 16(1) and in accordance with delegated acts adopted pursuant to Article 16(2);
- 3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:
- a the management, storage and replacement of stocks of the Union antigen, vaccine and diagnostic reagent banks as provided for in paragraphs 1 and 2 of this Article;

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- b the biosecurity, biosafety and bio–containment requirements for the operation of those banks, respecting the requirements provided for in Article 16(1) and taking into account the delegated acts adopted pursuant to Article 16(2).

Article 49

Access to the Union antigen, vaccine and diagnostic reagent banks

- 1 The Commission shall, upon request, provide for the delivery of the biological products referred to in Article 48(1) from the Union antigen, vaccine and diagnostic reagent banks, provided that stocks are available, to:
 - a in the first place, Member States; and
 - b third countries or territories, provided that such delivery is primarily intended to prevent the spread of a disease into the Union.
- 2 The Commission shall, in the event of the limited availability of stocks, prioritise access to the stocks to be delivered pursuant to paragraph 1 based on:
 - a the disease circumstances under which the request is made;
 - b the existence of a national antigen, vaccine and diagnostic reagent bank in the requesting Member State or third country or territory;
 - c the existence of Union measures for compulsory vaccination laid down in delegated acts adopted pursuant to Article 47.

Article 50

Implementing powers concerning the Union antigen, vaccine and diagnostic reagent banks

- 1 The Commission shall, by means of implementing acts, lay down rules for Union antigen, vaccine and diagnostic reagent banks, specifying for the biological products referred to in Article 48(1):
 - a which of those biological products are to be included in the Union antigen, vaccine and diagnostic reagent banks and for which of the listed diseases referred to in point (a) of Article 9(1);
 - b the types of those biological products that are to be included in the Union antigen, vaccine and diagnostic reagent banks and in what quantities for each specific listed disease referred to in point (a) of Article 9(1) for which the bank in question exists;
 - c the requirements concerning the supply, storage and replacement of those biological products;
 - d the delivery of those biological products from the Union antigen, vaccine and diagnostic reagent banks to the Member States and to third countries and territories;
 - e procedural and technical requirements for the inclusion of those biological products in the Union antigen, vaccine and diagnostic reagent banks and for requesting access to them.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

- 2 On duly justified imperative grounds of urgency relating to a listed disease referred to in point (a) of Article 9(1) representing a risk of a highly significant impact, the Commission

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shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 266(3).

Article 51

Confidentiality of information concerning the Union antigen, vaccine and diagnostic reagent banks

Information on the quantities and subtypes of the biological products referred to in Article 48(1) stored in the Union antigen, vaccine and diagnostic reagent banks shall be treated by the Commission as classified information and shall not be published.

Article 52

National antigen, vaccine and diagnostic reagent banks

1 Member States that have established national antigen, vaccine and diagnostic reagent banks for listed diseases referred to in point (a) of Article 9(1) for which Union antigen, vaccine and diagnostic reagent banks exist, shall ensure that their national antigen, vaccine and diagnostic reagent banks comply with the biosecurity, biosafety and bio-containment requirements laid down in point (a) of Article 16(1) and in delegated acts adopted in accordance with Article 16(2) and point (b) of Article 48(3).

2 Member States shall provide the Commission with up-to-date information on:

- a the existence or the establishment of the national antigen, vaccine and diagnostic reagent banks referred to paragraph 1;
- b the types of antigens, vaccines, vaccine master-seed stocks and diagnostic reagents and the quantities thereof held in such banks;
- c any changes in the operation of such banks.

That information shall be treated as classified information by the Commission and shall not be published.

3 The Commission may, by means of implementing acts, lay down rules specifying the content, frequency and format of the submission of the information provided for in paragraph 2.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

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TITLE II

DISEASE CONTROL MEASURES

CHAPTER 1

Disease control measures for listed diseases as referred to in point (a) of Article 9(1)

Section 1

Disease control measures in the event of suspicion of a listed disease in kept animals

Article 53

Obligations on operators and other relevant natural and legal persons concerned

1 In the event of suspicion of a listed disease as referred to in point (a) of Article 9(1) in kept animals, in addition to complying with the notification obligation laid down in Article 18(1) and pending any disease control measures being taken by the competent authority in accordance with Articles 54(1) and 55(1), Member States shall take measures to ensure that operators and other relevant natural and legal persons concerned take the appropriate disease control measures provided for in points (c), (d) and (e) of Article 55(1), to prevent the spread of that listed disease from the affected animals, establishments and locations under their responsibility to other unaffected animals or to humans.

2 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules for supplementing the disease control measures provided for in paragraph 1 of this Article.

Article 54

Investigation by the competent authority in the event of suspicion of a listed disease

1 In the event of suspicion of a listed disease as referred to in point (a) of Article 9(1) in kept animals, the competent authority shall conduct without delay an investigation to confirm or rule out the presence of that listed disease.

2 For the purpose of the investigation provided for in paragraph 1, the competent authority shall, when appropriate, ensure that:

- a official veterinarians carry out a clinical examination of a representative sample of the kept animals of listed species for the listed disease in question;
- b official veterinarians take appropriate samples from those kept animals of listed species and other samples for examination in laboratories designated for that purpose by the competent authority;
- c such designated laboratories carry out examinations to confirm or rule out the presence of the listed disease in question.

3 The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules supplementing the rules for investigations by competent authorities as provided for in paragraph 1 of this Article.

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Article 55

Preliminary disease control measures by competent authorities

1 The competent authority shall, in the event that it suspects the presence of a listed disease as referred to in point (a) of Article 9(1) in kept animals, carry out the following preliminary disease control measures, subject to national requirements for gaining access to private residences, pending the results of the investigation provided for in Article 54(1) and the carrying-out of the disease control measures provided for in Article 61(1):

- a place the establishment, food and feed business or animal by-products establishment concerned, or any other location where the disease is suspected of having occurred, including locations where the suspected disease may have originated, under official surveillance;
- b compile an inventory of:
 - (i) the kept animals in the establishment, food and feed business, or animal by-products establishment concerned, or in any other location;
 - (ii) the products in that establishment, food and feed business, or animal by-products establishment, or in any other location, where relevant for the spread of that listed disease;
- c ensure that appropriate biosecurity measures are applied to prevent the spreading of that listed disease agent to other animals or to humans;
- d when appropriate to prevent the further spread of the disease agent, ensure that the kept animals of listed species for that listed disease are isolated, and that they are prevented from coming into contact with wildlife;
- e restrict the movements of kept animals, products and, if appropriate, people, vehicles and any material or other means by which the disease agent could have spread to or from the establishment, food and feed business or animal by-products establishment, or from any other location where that listed disease is suspected, as far as necessary to prevent its spread;
- f take any other necessary disease control measures, taking into account the disease control measures provided for in Section 4 of this Chapter, concerning:
 - (i) the application of the investigation by the competent authority provided for in Article 54(1) and disease control measures provided for in points (a) to (d) of this paragraph to other establishments, food and feed businesses, or animal by-products establishments, or to any other location;
 - (ii) the establishment of any temporary restricted zones which are appropriate, taking into account the disease profile;
- g initiate the epidemiological enquiry provided for in Article 57(1).

2 The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules supplementing those laid down in paragraph 1 of this Article as regards the specific and detailed disease control measures to be taken depending on the listed disease referred to in point (a) of Article 9(1), based on the risks involved for:

- a the species or category of animals concerned;
- b the type of production concerned.

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Article 56

Review and extension of the preliminary disease control measures

The disease control measures provided for in Article 55(1) shall be:

- (a) reviewed by the competent authority, as appropriate, following the findings of:
 - (i) the investigation provided for in Article 54(1);
 - (ii) the epidemiological enquiry provided for in Article 57(1);
- (b) further extended to other locations as referred to in point (a) of Article 55(1), where necessary.

Section 2

Epidemiological enquiry

Article 57

Epidemiological enquiry

- 1 The competent authority shall carry out an epidemiological enquiry in the event of the confirmation of a listed disease as referred to in point (a) of Article 9(1) in animals.
- 2 The epidemiological enquiry provided for in paragraph 1 shall aim to:
 - a identify the likely origin of the listed disease in question and the means of its spread;
 - b calculate the likely length of time that the listed disease has been present;
 - c identify establishments and epidemiological units therein, food and feed businesses or animal by-products establishments, or other locations, where animals of listed species for the suspected listed disease may have become infected, infested or contaminated;
 - d obtain information on the movements of kept animals, persons, products, vehicles, any material or other means by which the disease agent could have been spread during the relevant period preceding the notification of the suspicion or confirmation of the listed disease;
 - e obtain information on the likely spread of the listed disease in the surrounding environment, including the presence and distribution of disease vectors.

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Section 3

Disease confirmation in kept animals

Article 58

Official confirmation by the competent authority of a listed disease as referred to in point (a) of Article 9(1)

1 The competent authority shall base an official confirmation of a listed disease as referred to in point (a) of Article 9(1) on the following information:

- a the results of the clinical and laboratory examinations provided for in Article 54(2);
- b the preliminary or final results of the epidemiological enquiry provided for in Article 57(1);
- c other available epidemiological data.

2 The Commission shall adopt delegated acts in accordance with Article 264 concerning the requirements to be fulfilled for the official confirmation referred to in paragraph 1 of this Article.

Article 59

Lifting of preliminary disease control measures where the presence of the listed disease has been ruled out

The competent authority shall continue to apply the preliminary disease control measures provided for in Article 55(1) and Article 56 until the presence of the listed disease in question, as referred to in point (a) of Article 9(1), has been ruled out on the basis of the information referred to in Article 58(1) or rules adopted pursuant to Article 58(2).

Section 4

Disease control measures in the event of confirmation of disease in kept animals

Article 60

Immediate disease control measures to be taken by the competent authority

In the event of an official confirmation in accordance with Article 58(1) of an outbreak of a listed disease as referred to in point (a) of Article 9(1) in kept animals, the competent authority shall immediately:

- (a) declare the affected establishment, food or feed business, animal by-products establishment or other location as officially infected with that listed disease;
- (b) establish a restricted zone appropriate for that listed disease;
- (c) implement the contingency plan provided for in Article 43(1) to ensure full coordination of the disease control measures.

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Article 61

Affected establishments and other locations

1 In the event of an outbreak of a listed disease as referred to in point (a) of Article 9(1) in kept animals, the competent authority shall immediately take one or more of the following disease control measures, subject to national requirements for gaining access to private residences, in an establishment, food or feed business, animal by-products establishment, or any other location referred to in point (a) of Article 60, in order to prevent the further spread of that listed disease:

- a the imposition of restrictions on movements of persons, animals, products, vehicles or any other material or substance that may be contaminated and contribute to the spread of the listed disease;
- b the killing and disposal or slaughtering of animals that may be contaminated or contribute to the spread of the listed disease;
- c the destruction, processing, transformation or treatment of products, feed, or any other substances, or the treatment of equipment, means of transport, plants or plant products, or water which may be contaminated, as appropriate to ensure that any disease agent or vector of the disease agent is destroyed;
- d the vaccination or treatment with other veterinary medicinal products of kept animals in accordance with Article 46(1) and Article 69 and any delegated acts adopted pursuant to Article 47;
- e the isolation, quarantine or treatment of animals and products that are likely to be contaminated and contribute to the spread of the listed disease;
- f the cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures to be applied to the affected establishment, food or feed business, animal by-products establishment or other locations to minimise the risk of spread of the listed disease;
- g the taking of a sufficient number of appropriate samples needed to complete the epidemiological enquiry provided for in Article 57(1);
- h the laboratory examination of samples;
- i any other appropriate measures.

2 When determining which of the disease control measures provided for in paragraph 1 are appropriate to take, the competent authority shall take the following into account:

- a the disease profile;
- b the type of production, and epidemiological units within the affected establishment, food or feed business, animal by-products establishment or other location;

3 The competent authority shall only authorise the repopulation of the establishment concerned, or of any other location, when:

- a all appropriate disease control measures and laboratory examinations provided for in paragraph 1 have been successfully completed;
- b a sufficient period of time has elapsed to prevent re-contamination of the affected establishment, food or feed business, animal by-products establishment or other location with the listed disease that caused the outbreak referred to in paragraph 1.

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Article 62

Epidemiologically linked establishments and locations

1 The competent authority shall extend the disease control measures provided for in Article 61(1) to other establishments, epidemiological units therein, food or feed businesses, or animal by-products establishments, or any other location, or means of transport where the epidemiological enquiry provided for in Article 57(1) or the results of clinical or laboratory investigations or other epidemiological data, give reason to suspect the spread to, from or through them of the listed disease referred to in point (a) of Article 9(1) in respect of which such measures were taken.

2 If the epidemiological enquiry provided for in Article 57(1) shows that the likely origin of the listed disease referred to in point (a) of Article 9(1) is another Member State, or if it is likely that that listed disease has spread to another Member State, the competent authority shall inform that Member State and the Commission without delay.

3 Should any of the events referred to in paragraph 2 occur, the competent authorities of the different Member States shall cooperate in a further epidemiological enquiry and in the application of disease control measures.

Article 63

Delegation of powers in respect of disease control measures in affected and epidemiologically linked establishments and other locations

The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules on the disease control measures to be taken by the competent authority in accordance with Articles 61 and 62 in affected and epidemiologically linked establishments, food or feed businesses, or animal by-products establishments, and other locations in respect of any listed disease referred to in point (a) of Article 9(1), including rules on which disease control measures referred to in Article 61(1) are to be applied in relation to each listed disease.

Those detailed rules shall cover the following matters:

- (a) the conditions and requirements for the disease control measures provided for in points (a) to (e) of Article 61(1);
- (b) the procedures for cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures as provided for in point (f) of Article 61(1), specifying, where appropriate, the use of biocidal products for those purposes;
- (c) the conditions and requirements for sampling and laboratory examination as provided for in points (g) and (h) of Article 61(1);
- (d) the detailed conditions and requirements in respect of repopulation as provided for in Article 61(3);
- (e) the carrying-out of the necessary disease control measures provided for in Article 62 in epidemiologically linked establishments, other locations and means of transport.

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Article 64

Establishment of restricted zones by the competent authority

1 The competent authority shall establish a restricted zone as referred to in point (b) of Article 60 around the affected establishment, food or feed business, animal by-products establishment or other location where the outbreak of a listed disease as referred to in point (a) of Article 9(1) in kept animals has occurred, where appropriate taking into account:

- a the disease profile;
- b the geographical situation of the restricted zone;
- c the ecological and hydrological factors of the restricted zone;
- d the meteorological conditions;
- e the presence, distribution and type of vectors in the restricted zone;
- f the results of the epidemiological enquiry provided for in Article 57(1) and other studies carried out and epidemiological data;
- g the results of laboratory tests;
- h the disease control measures applied;
- i other relevant epidemiological factors.

The restricted zone shall include, when appropriate, a protection and surveillance zone of a defined size and configuration.

2 The competent authority shall continuously assess and review the situation and, when appropriate in order to prevent the spread of the listed disease referred to in point (a) of Article 9(1), shall:

- a adapt the boundaries of the restricted zone;
- b establish additional restricted zones.

3 Where restricted zones as provided for in paragraph 1 are situated in the territory of more than one Member State, the competent authorities of those Member States shall cooperate in establishing them.

4 The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules for the establishment and modification of restricted zones, including protection or surveillance zones.

Article 65

Disease control measures in restricted zones

1 The competent authority shall ensure that, subject to national requirements for gaining access to private residences, one or more of the following disease control measures are taken in the restricted zone concerned, in order to prevent the further spread of a listed disease as referred to in point (a) of Article 9(1):

- a the identification of establishments, food or feed businesses, animal by-products establishments or other locations with kept animals of listed species for that listed disease;
- b visits to establishments, food or feed businesses, animal by-products establishments or other locations with kept animals of listed species for that listed disease, and, where necessary, examinations, sampling and laboratory examination of the samples taken;

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- c the imposition of conditions for the movement of persons, animals, products, feed, vehicles and any other material or substance that may be contaminated or contribute to the spread of that listed disease within and from the restricted zone and transport through the restricted zone;
 - d biosecurity requirements for:
 - (i) the production, processing and distribution of products of animal origin;
 - (ii) the collection and disposal of animal by-products;
 - (iii) the collection, storage and handling of germinal products;
 - e the vaccination and treatment with other veterinary medicinal products of kept animals in accordance with Article 46(1) and any delegated acts adopted pursuant to Article 47;
 - f cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures;
 - g the designation or where relevant, approval of a food business establishment for the purposes of the slaughtering of animals or the treatment of products of animal origin originating from the restricted zone;
 - h the identification and traceability requirements for the movement of animals, germinal products or products of animal origin;
 - i other necessary biosecurity and risk-mitigating measures to minimise the risk of the spread of that listed disease.
- 2 The competent authority shall:
- a take all necessary measures to fully inform persons in the restricted zone of the restrictions in force and the nature of the disease control measures;
 - b impose the necessary obligations on operators in order to prevent the further spread of the listed disease in question.
- 3 When determining which of the disease control measures provided for in paragraph 1 are to be taken, the competent authority shall take the following into account:
- a the disease profile;
 - b the types of production;
 - c the feasibility, availability and effectiveness of those disease control measures.

Article 66

Operators' obligations regarding movements in restricted zones

1 In restricted zones as provided for in Article 64(1), operators shall only move the kept animals and products with the permission of the competent authority and in accordance with any instructions given by that authority.

2 Operators keeping animals and products in a restricted zone as provided for in Article 64(1) shall notify to the competent authority intended movements of kept animals and products within or out of the restricted zone in question. In so far as the competent authority has imposed notification obligations in accordance with point (b) of Article 65(2), the operators concerned shall notify in accordance with those obligations.

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Article 67

Delegation of powers concerning disease control measures in restricted zones

The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules on the disease control measures to be taken in restricted zones as provided for in Article 65(1) for each listed disease referred to in point (a) of Article 9(1), including rules on which disease control measures referred to in Article 65(1) are to be applied in the case of each listed disease.

Those detailed rules shall cover the following matters:

- (a) the conditions and requirements for the disease control measures provided for in points (a), (c), (d), (e), (g), (h) and (i) of Article 65(1);
- (b) the procedures for cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures as provided for in point (f) of Article 65(1), specifying, where appropriate, the use of biocidal products for those purposes;
- (c) the necessary surveillance which is to be conducted following the application of the disease control measures and laboratory examinations provided for in point (b) of Article 65(1);
- (d) other specific disease control measures to limit the spread of specific listed diseases as referred to in point (a) of Article 9(1).

Article 68

Maintaining disease control measures in restricted zones and delegated acts

1 The competent authority shall continue to apply the disease control measures provided for in this Section until the following conditions are met:

- a the disease control measures appropriate to the listed disease referred to in point (a) of Article 9(1) for which they were applied have been carried out;
- b the final cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures has been carried out as appropriate for:
 - (i) the listed disease referred to in point (a) of Article 9(1) for which the disease control measures have been applied;
 - (ii) the affected species of kept animals;
 - (iii) the type of production;
- c adequate surveillance, as appropriate for the listed disease referred to in point (a) of Article 9(1) for which the disease control measures have been applied, and for the type of establishment or location concerned, has been carried out in the restricted zone substantiating the eradication of that listed disease.

2 The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules for the disease control measures to be taken by the competent authority, as provided for in paragraph 1, in relation to:

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- a the final procedures for cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures and, where appropriate, the use of biocidal products for those purposes;
 - b the design, means, methods, frequency, intensity, targeted animal population and sampling patterns of surveillance aimed at the restoration of disease-free status after the outbreak;
 - c repopulation of the restricted zone concerned after the completion of the disease control measures provided for in paragraph 1 of this Article, taking into account the conditions for repopulation provided for in Article 61(3).
- 3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules for the disease control measures to be taken by the competent authority, as provided for in paragraph 1, in relation to other disease control measures necessary for the restoration of disease-free status.

Article 69

Emergency vaccination

- 1 Where relevant for the effective control of a listed disease as referred to in point (a) of Article 9(1) for which disease control measures apply, the competent authority may:
- a develop a vaccination plan;
 - b establish vaccination zones.
- 2 When deciding on the vaccination plan and the establishment of vaccination zones as provided for in paragraph 1, the competent authority shall take the following into account:
- a the requirements for emergency vaccination set out in the contingency plans provided for in Article 43;
 - b the requirements for the use of vaccines as provided for in Article 46(1) and any delegated acts adopted pursuant to Article 47.
- 3 Vaccination zones as provided for in point (b) of paragraph 1 of this Article shall meet the requirements in respect of risk-mitigating measures to prevent the spread of listed diseases and surveillance as laid down in any delegated acts adopted in accordance with points (c) and (d) of Article 47(1).

Section 5

Wild animals

Article 70

Wild animals

- 1 Where the competent authority of an affected Member State suspects or officially confirms the presence of a listed disease as referred to in point (a) of Article 9(1) in wild animals, it shall:
- a conduct, where relevant for that particular listed disease, surveillance in the wild animal population;
 - b take the necessary disease prevention and control measures.

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2 The disease prevention and control measures provided for in point (b) of paragraph 1 of this Article may include one or more of the measures laid down in Article 53 to 69 and shall take into account the disease profile and the affected wild animals and the risk of transmission of diseases to animals and humans.

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

- a criteria and procedures for surveillance pursuant to point (a) of paragraph 1 of this Article in the case of official confirmation of a listed disease as referred to in point (a) of Article 9(1), in accordance with Article 27;
- b detailed rules supplementing the disease prevention and control measures to be taken pursuant to point (b) of paragraph 1 of this Article in the case of official confirmation of a listed disease as referred to in point (a) of Article 9(1).

When adopting those delegated acts, the Commission shall take into account the disease profile and the listed species for the listed disease referred to paragraph 1 of this Article.

Section 6

Additional disease control measures by the Member States, coordination by the Commission and temporary special disease control rules

Article 71

Additional disease control measures, coordination of measures and temporary special disease control rules concerning Sections 1 to 5 (Articles 53 to 70)

1 Member States may take disease control measures additional to those provided for in Article 55, Article 61(1), Article 62, Article 65(1) and (2) and Article 68(1) and in any delegated acts adopted pursuant to Article 63, Article 67 and Article 68(2), provided that such measures respect the rules laid down in this Regulation and are necessary and proportionate to control the spread of a listed disease as referred to in point (a) of Article 9(1), taking into account:

- a the particular epidemiological circumstances;
- b the type of establishments, other locations and production concerned;
- c the species and categories of animals involved;
- d economic or social conditions.

2 Member States shall inform the Commission without delay of:

- a the disease control measures taken by their competent authority as provided for in Articles 58, 59, 61, 62, 64 and 65, Article 68(1), Article 69 and Article 70(1) and (2) and in any delegated acts adopted pursuant to Articles 63 and 67 and Articles 68(2) and 70(3);
- b any additional disease control measures taken by them as provided for in paragraph 1.

3 The Commission shall review the disease situation and the disease control measures taken by the competent authority and any additional disease control measures taken by the Member State concerned, in accordance with this Chapter, and may, by means of implementing acts, lay down special disease control measures for a limited period of time, under conditions appropriate to the epidemiological situation, where:

- a those disease control measures are found not to be suited to the epidemiological situation;

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- b the listed disease referred to in point (a) of Article 9(1) appears to be spreading despite the disease control measures taken in accordance with this Chapter.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

- 4 On duly justified imperative grounds of urgency relating to a disease representing an emerging risk of a highly significant impact, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

CHAPTER 2

Disease control measures for listed diseases as referred to in points (b) and (c) of Article 9(1)

Section 1

Disease control measures in the event of suspicion of disease in kept animals

Article 72

Obligations on operators and other relevant natural and legal persons concerned in relation to listed diseases as referred to in point (b) of Article 9(1)

1 In the event of suspicion of a listed disease as referred to in point (b) of Article 9(1) in kept animals, in addition to complying with the notification obligation laid down in Article 18(1) and pending any disease control measures being taken by the competent authority in accordance with Article 74(1), Member States shall take measures to ensure that operators and other relevant natural and legal persons concerned take disease control measures as referred to in point (a) of Article 74(1) and in any delegated acts adopted pursuant to Article 74(4), to prevent the spread of that listed disease from the affected animals, establishments and other locations under their responsibility to other unaffected animals or to humans.

2 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules for supplementing the disease control measures as provided for in paragraph 1 of this Article.

Article 73

Investigation by the competent authority in the event of suspicion of a listed disease as referred to in point (b) of Article 9(1)

1 In the event of suspicion of a listed disease as referred to in point (b) of Article 9(1) in kept animals, the competent authority shall conduct without delay an investigation to confirm or rule out the presence of that listed disease.

2 For the purpose of the investigation provided for in paragraph 1, the competent authority shall ensure that:

- a official veterinarians carry out a clinical examination of a representative sample of the kept animals of listed species for the listed disease in question;

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- b official veterinarians take appropriate samples from those kept animals of listed species and other samples for examination in laboratories designated for that purpose by the competent authority;
- c such designated laboratories carry out examinations to confirm or rule out the presence of the listed disease in question.

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules supplementing the rules for investigations as provided for in paragraph 1 of this Article.

Article 74

Preliminary disease control measures by the competent authority for listed diseases as referred to in point (b) of Article 9(1)

1 The competent authority shall, in the event that it suspects a listed disease as referred to in point (b) of Article 9(1) in kept animals, carry out the following preliminary disease control measures, subject to national requirements for gaining access to private residences, pending the results of the investigation provided for in Article 73(1) and the carrying-out of the disease control measures provided for in Article 79:

- a apply disease control measures to limit the spread of that listed disease from the affected territory, establishment, food or feed business, animal by-products establishment or other location;
- b initiate, where necessary, an epidemiological enquiry, taking into account the rules for such enquiry laid down in Article 57(1).

2 In addition to the measures referred to in paragraph 1, the competent authority may, in the cases referred to in that paragraph, take additional preliminary disease control measures, provided that those measures respect the provisions of this Regulation and are in accordance with Union law.

3 The preliminary disease control measures provided for in paragraphs 1 and 2 shall be appropriate and proportionate to the risk posed by the listed disease in question, taking into account the following:

- a the disease profile;
- b the kept animals affected;
- c the health status of the Member State, zone, compartment or establishment in which the listed disease is suspected;
- d the preliminary disease control measures provided for in Article 55(1) and Article 56 and in any delegated act adopted pursuant to Article 55(2).

4 The Commission shall adopt delegated acts in accordance with Article 264 concerning rules for listed diseases as referred to in point (b) of Article 9(1) supplementing those laid down in paragraph 1 of this Article, while taking into account the matters referred to in paragraph 3, as regards:

- a the preliminary disease control measures to be taken to prevent the spread of the listed disease, as provided for in point (a) of paragraph 1;
- b the application of the preliminary disease control measures provided for in point (a) of paragraph 1 to other establishments, epidemiological units therein, food or feed businesses and animal by-products establishments or other locations;
- c the establishment of temporary restricted zones which are appropriate in light of the disease profile.

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Article 75

Review and extension of the preliminary disease control measures for listed diseases as referred to in point (b) of Article 9(1)

The disease control measures provided for in Article 74(1) shall be:

- (a) reviewed by the competent authority, as appropriate, following the findings of the investigation provided for in Article 73(1) and, where relevant, the epidemiological enquiry provided for in point (b) of Article 74(1);
- (b) further extended to other locations, as referred to in point (b) of Article 74(4), where necessary.

Article 76

Obligations of operators and other relevant natural and legal persons and measures to be taken by the competent authority in the event of suspicion of listed diseases as referred to in point (c) of Article 9(1)

1 In the event of suspicion of a listed disease as referred to in point (c) of Article 9(1) in a Member State that has opted for the eradication programme covering the relevant parts of its territory or zones or compartments thereof, as provided for in Article 31(2), that Member State shall take measures to ensure that operators and other relevant natural and legal persons concerned take appropriate measures as provided for in Article 72(1), pending any disease control measures being taken by the competent authority in accordance with paragraph 2 of this Article.

2 The competent authority of a Member State that has opted for the eradication of a listed disease as referred to in paragraph 1 shall, in the event that it suspects the disease in question in kept animals:

- a conduct without delay an investigation to confirm or rule out the presence of that listed disease in accordance with Article 73(1) and (2);
- b pending the results of the investigation provided for in point (a) and the carrying-out of disease control measures in accordance with Article 80(1), carry out the preliminary disease control measures provided for in Article 74(1) and (2).

3 The competent authority shall review and extend the preliminary disease control measures referred to in point (b) of paragraph 2, in accordance with Article 75.

4 Paragraphs 1, 2 and 3 of this Article shall also apply to Member States or zones which have obtained disease-free status, in order to maintain that status, in accordance with Article 36, or to compartments in accordance with Article 37(2).

5 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules supplementing rules in respect of:

- a the disease control measures provided for in paragraph 1;
- b the investigation provided for in point (a) of paragraph 2;
- c the preliminary disease control measures to be taken to prevent the spread of the listed disease, as provided for in point (b) of paragraph 2.

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Section 2

Disease confirmation in kept animals

Article 77

Official confirmation of disease by the competent authority

1 The competent authority shall base an official confirmation of a listed disease as referred to in point (b) or (c) of Article 9(1) on the following information:

- a the results of the clinical and laboratory examinations provided for in Article 73(2);
- b the epidemiological enquiry provided for in point (b) of Article 74(1), where relevant;
- c other available epidemiological data.

2 The Commission shall adopt delegated acts in accordance with Article 264 concerning the requirements to be fulfilled for the official confirmation referred to in paragraph 1.

Article 78

Lifting preliminary disease control measures when the occurrence of a disease is ruled out

The competent authority shall continue to apply the preliminary disease control measures provided for in Article 74(1), Article 75 and point (b) of Article 76(2) until the presence of the listed disease in question has been ruled out in accordance with Article 77(1) and any rules adopted pursuant to Article 77(2).

Section 3

Disease control measures in the event of confirmation of disease in kept animals

Article 79

Disease control measures by the competent authority for listed diseases as referred to in point (b) of Article 9(1)

In the event of an official confirmation in accordance with Article 77(1) of an outbreak of a listed disease as referred to in point (b) of Article 9(1) in kept animals, the competent authority shall, in a Member State, zone or compartment, as relevant for that outbreak:

- (a) apply the disease control measures laid down in the compulsory eradication programme provided for in Article 31(1) for that listed disease; or
- (b) where the Member State or zone, or compartment, has obtained disease-free status in accordance with Article 36 or Article 37 respectively:
 - (i) take one or more of the measures laid down in Articles 53 to 69 proportionate to the risk posed by the listed disease in question, and
 - (ii) where necessary, initiate the compulsory eradication programme for that listed disease.

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Article 80

Disease control measures to be taken by the competent authority for listed diseases referred to in Article 9(1)(c)

1 In the event of an official confirmation in accordance with Article 77(1) of an outbreak of a listed disease as referred to in point (c) of Article 9(1) in kept animals in a Member State that has opted for an eradication programme covering the relevant parts of its territory or zones or compartments thereof, as provided for in Article 31(2), as relevant for that listed disease and that outbreak, the competent authority shall apply the disease control measures laid down in the optional eradication programme.

2 The competent authority may take disease control measures additional to those provided for in paragraph 1 which may include one or more of the measures laid down in Articles 53 to 69 and shall be proportionate to the risk posed by the listed disease in question and shall take into account:

- a the disease profile;
- b the kept animals affected;
- c economic and social impacts.

3 In the event of an official confirmation in accordance with Article 77(1) of an outbreak of a listed disease as referred to in point (c) of Article 9(1) in kept animals in a Member State, zone or compartment that has obtained disease-free status in accordance with Article 36 or Article 37, and in order to maintain that status, the competent authority shall take one or more of the measures laid down in Articles 53 to 69. Those measures shall be proportionate to the risk posed by the listed disease in question and shall take into account:

- a the disease profile;
- b the kept animals affected;
- c economic and social impacts.

Section 4

Wild animals

Article 81

Disease control measures for listed diseases as referred to in point (b) of Article 9(1) in wild animals

In the event that the competent authority of an affected Member State suspects or officially confirms the outbreak of a listed disease as referred to in point (b) of Article 9(1) in wild animals, it shall throughout its territory, or in the area or zone concerned, as relevant for that outbreak:

- (a) apply the disease control measures laid down in the compulsory eradication programme provided for in Article 30(1) for that listed disease; or
- (b) initiate a compulsory eradication programme, where the eradication programme provided for in Article 31(1) for that listed disease has not yet been applied due to the

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previous absence of that disease or freedom from it, and if measures for wild animals are necessary in order to control and prevent the spread of that disease.

Article 82

Disease control measures for listed diseases as referred to in point (c) of Article 9(1) in wild animals

1 In the event that a competent authority suspects or officially confirms a listed disease as referred to in point (c) of Article 9(1) in wild animals and the affected Member State has opted for the eradication of the disease in question, and provided that measures for wild animals are envisaged in the optional eradication programme provided for in Article 31(2) for that listed disease, the competent authority shall apply the disease control measures laid down in that optional eradication programme throughout the territory of the Member State, area or zone concerned, as relevant for that suspicion or official confirmation.

2 The competent authority may take disease control measures additional to those provided for in paragraph 1, which may include one or more of the measures laid down in Articles 53 to 69 and shall be proportionate to the risk posed by the listed disease in question and shall take into account:

- a the disease profile;
- b the affected wild animals and the risk of transmission of diseases to animals and humans; and
- c economic, social and environmental impacts.

3 In the event of an official confirmation of an outbreak of a listed disease as referred to in point (c) of Article 9(1) in wild animals in a Member State, zone or compartment that has obtained disease-free status in accordance with Article 36 or Article 37, and in order to maintain that status, the competent authority shall take one or more of the measures laid down in Articles 53 to 69. Those measures shall be proportionate to the risk posed by the listed disease in question and shall take into account:

- a the disease profile;
- b the affected wild animals and the risk of transmission of diseases to animals and humans;
- c the relevance of the presence of the disease in wild animals in relation to the health status of kept animals; and
- d economic, social and environmental impacts.

Section 5

Coordination by the Commission and temporary special disease control rules

Article 83

Coordination of measures by the Commission and temporary special rules concerning Sections 1 to 4

1 Member States shall inform the Commission of:

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- a disease control measures taken by their competent authorities in accordance with Articles 77(1), 78, 79 and 81 and with any delegated acts adopted pursuant to Article 77(2) in respect of a listed disease as referred to in point (b) of Article 9(1);
- b disease control measures taken by their competent authorities in accordance with Articles 77(1), 78, 80(1) and 82 and with any delegated acts adopted pursuant to Article 77(2) in respect of a listed disease as referred to in point (c) of Article 9(1).

2 The Commission shall review the disease situation and the disease control measures taken by the competent authority in accordance with this Chapter and may, by means of implementing acts, lay down special rules for disease control measures for a limited period of time in respect of a listed disease as referred to in point (b) or point (c) of Article 9(1), under conditions appropriate to the epidemiological situation, where:

- a those disease control measures taken by the competent authority in question are found not to be suited to the epidemiological situation;
- b that listed disease appears to be spreading despite the disease control measures taken in accordance with this Chapter, where relevant.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

3 On duly justified imperative grounds of urgency relating to a listed disease as referred to in point (b) or point (c) of Article 9(1) representing an emerging risk of a highly significant impact, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

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