Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (Text with EEA relevance)

## COMMISSION DELEGATED REGULATION (EU) 2020/687

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(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 (the 'Animal Health Law')<sup>(1)</sup>, and in particular Article 47(1), Article 53(2), Article 54(3), Article 55(2), Article 58(2), the first paragraph of Article 63, Article 64(4), the first paragraph of Article 67, Article 68(3), Article 70(3), Article 72(2), Article 73(3), Article 74(4), Article 76(5), Article 77(2) and Article 272(2) thereof,

## Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases which are transmissible to animals or to humans, including rules on disease awareness, preparedness and control. In particular, Regulation (EU) 2016/429 lays down disease-specific rules for the prevention and control of diseases referred to in its Article 5. Regulation (EU) 2016/429 also provides that those disease-specific rules apply to species and groups of animal species that pose a considerable risk for the spread of specific diseases and which are listed as such in Commission Implementing Regulation (EU) 2018/1882<sup>(2)</sup>.
- (2) It is necessary to lay down rules supplementing the rules on disease control measures set out in Title II of Part III of Regulation (EU) 2016/429 for certain listed diseases. Those supplementing rules and the rules set out in Regulation (EU) 2016/429 are closely linked and should be applied in tandem. In the interest of simplicity, transparency and ease of application, the supplementing rules should be laid down in a single act rather than in a number of separate acts with many cross-references and risks of duplication.
- (3) Article 53, Article 54(3), Article 55(2), Article 58(2), and Articles 63, 64, 67, 68 and 70 in Chapter 1 of Title II of Regulation (EU) 2016/429 relate to various technical aspects of the measures to be taken if there is suspicion and confirmation of diseases referred to in Article 9(1)(a) of that Regulation. Similarly, Article 72(2), Article 73(3), Article 74(4), Article 76(5) and Article 77 in Chapter 2 of Title II of Regulation (EU)

- 2016/429 relate to technical aspects of the measures to be taken if there is suspicion and confirmation of diseases referred to in Article 9(1)(b) and (c) of that Regulation.
- (4) The rules to be laid down pursuant to Articles in Title II are interrelated as they apply to disease control measures for different categories of listed diseases in Regulation (EU) 2016/429. Therefore, for the effective application of those rules and in the interests of clarity, they should be laid down in a single delegated act providing a comprehensive set of technical measures for the control of listed diseases and contributing to the overall simplification of the legal framework on animal disease control.
- of which contained rules for one or few animal diseases. Some of those rules have been replaced by Regulation (EU) 2016/429, while others need to be replaced by this Delegated Regulation in order to simplify and remove possible inconsistencies. This will provide clear, harmonised and detailed rules to control animal diseases throughout the Union. This will also enable the application of the relevant provisions by competent authorities and operators, and will increase the transparency of the rules and therefore will ensure a better response to animal disease risks.
- (6) To eradicate an outbreak of a category A disease as soon as possible and to ensure a high level of animal health and animal welfare protection, it is necessary to provide for disease control measures at Union level.
- (7) The scope of this Regulation should therefore include disease control measures for category A diseases in terrestrial and aquatic animals, as well as certain disease control measures for category B and C diseases. In the case of category B and C diseases, those disease control measures should be applied in conjunction with the rules on surveillance and eradication set out in Commission Delegated Regulation (EU) 2020/689<sup>(3)</sup>.
- (8) The disease control measures set out in this Delegated Regulation should apply to animals and to products obtained from animals, including products of animal origin, germinal products, animal by-products and derived products. These animal by-products are subject to public and animal health rules set out in Regulation (EC) No 1069/2009 of the European Parliament and of the Council<sup>(4)</sup>. The rules for safe collection, disposal and processing of animal by-products and derived products laid down in that Regulation apply in the event of the onset of a category A disease. However, that Regulation does not include disease control measures and restrictions intended to apply in such events. Therefore, those rules should be provided for in this Delegated Regulation.
- (9) Directive 2008/68/EC of the European Parliament and of the Council<sup>(5)</sup> lays down rules for the safe transport of dangerous goods. When transporting infected animal by-products or other infected material which may be considered as dangerous goods, competent authorities should comply with the rules laid down in that Directive.
- (10) It is appropriate to follow a single approach for the measures to apply in the event of a category A disease. However, the epidemiology of diseases should be taken into account to establish the appropriate moment for the competent authority to apply control measures and to carry out investigations if there is suspicion or confirmation of those diseases. Therefore 'monitoring periods' should be provided, as reference time frames

- for each category A disease affecting terrestrial animals based on incubation periods and other relevant elements that may affect the spread of the disease.
- (11) Article 54 of Regulation (EU) 2016/429 requires the competent authority to carry out investigations on the occurrence of a category A disease at different stages: (i) when the disease is suspected; (ii) when the disease is confirmed; and (iii) when it is necessary to rule out its spreading to epidemiologically linked establishments and locations as well as neighbouring establishments and zones. Those investigations include clinical examination and sampling for laboratory testing. It is appropriate to lay down general rules on sampling in order to ensure the validity of sampling procedures, diagnostic methods and biosecurity measures.
- (12) Article 43 of Regulation (EU) 2016/429 requires the competent authority to draw up and update contingency plans and, where necessary, provide detailed instruction manuals on implementing of measures to be taken in case of a category A disease as provided for in Part III of that Regulation. The measures set out in this Delegated Regulation supplement those laid down in Part III of Regulation (EU) 2016/429 and it is therefore necessary that they be implemented in accordance with the contingency plans provided for in Regulation (EU) 2016/429.
- (13) Articles 53 and 55 of Regulation (EU) 2016/429 lay down obligations on operators and competent authorities in the case of a suspicion of a category A disease. The aim is to prevent the spread of the disease from affected animals and establishments under their responsibility to unaffected animals or to humans even before the disease has been confirmed. The disease control and biosecurity measures provided for in Regulation (EU) 2016/429 should be applied at this early stage in the affected establishment as regards movements of animals and products from and to that establishment and its surroundings. It is also necessary to detail those measures in order to ensure their effectiveness and proportionality.
- (14) Article 54 of Regulation (EU) 2016/429 requires the competent authority to conduct an official investigation if there is a suspicion of a category A disease, to either confirm or rule out the presence of the disease. In order to establish a standard operating procedure for such official investigations in all Member States, it is necessary to detail the circumstances which justify the conduct of an investigation, the minimum investigation tasks to be performed by official veterinarians and the way those tasks should be carried out.
- (15) Regulation (EU) 2016/429 requires that, if there is a suspicion or confirmation of a category A disease, disease control measures be applied not only in establishments keeping animals but also in food and feed businesses, in animal by-products establishments or in other locations that may pose a risk of spreading of diseases. It is necessary to specify which control measures apply in those cases, in particular in the case of border control posts and means of transport.
- (16) Regulation (EU) 2016/429 requires that the confirmation of a category A disease is the starting point for the competent authority to implement stricter disease control measures than those applied in the suspicion phase and to carry out further investigations. It is therefore necessary to specify when a category A disease should be

- considered confirmed. This confirmation should be done in accordance with Union acts adopted pursuant to Regulation (EU) 2016/429 on surveillance of diseases, eradication programmes and disease-free status.
- (17) Regulation (EU) 2016/429 lays down the basic rules on the disease control measures to apply in the affected establishments in the event of an outbreak of a category A disease. At the same time, it provides competent authorities with a certain flexibility in deciding which of those measures should apply. In order to allow competent authorities to take the most proportionate and efficient control measures and ensure a harmonised implementation of the measures taken by Member States, it is appropriate to establish detailed decision making criteria based on epidemiological circumstances, type and location of establishments, species and categories of animals and economic or social conditions of the area affected by the disease.
- (18) The competent authority should have the possibility to grant, in justified cases and under supplementary guarantees if necessary, derogations from certain disease control measures, in particular from the requirement to kill the animals in the affected establishment, taking into account epidemiological factors and after carrying out an accurate risk assessment. Such derogations could be granted for confined establishments, for animals kept for scientific purposes or for purposes related to conservation of protected or endangered species and for officially registered rare breeds or for animals with a justified high genetic, cultural or educational value. In such cases, the application of general measures could have undesirable and disproportioned consequences.
- (19) In order to adapt the disease control measures to each specific situation, the competent authority should have the possibility to apply disease control measures that are not specifically provided for in Regulation (EU) 2016/429 or in this Delegated Regulation, taking into consideration epidemiological factors and after carrying out a risk assessment.
- (20) Cleaning and disinfection in the affected establishment is one of the basic disease control measures provided for in Regulation (EU) 2016/429 to minimise the risk of spreading a confirmed category A disease. Preliminary cleaning and disinfection are the most effective measures to reduce the disease agent load in the affected establishment once the affected animals have been taken off. The competent authority should therefore have the obligation to check the performance of the immediate preliminary cleaning and disinfection and, when necessary, the control of insects and rodents. It is appropriate to detail the cleaning and disinfection procedure, specifying when it must be initiated and the criteria for selecting the biocidal products to be used.
- (21) Article 62 of Regulation (EU) 2016/429 requires the competent authority to extend the disease control measures applied in the affected establishments to other establishments, epidemiological units therein, food and feed businesses, or animal by-products establishments or any other location of relevance, including means of transport, where epidemiological evidences give reason to suspect the spread of the category A disease to, from or through them. It is necessary to specify the traceability investigation which

- the competent authority must perform, under the epidemiological enquiry provided for in Regulation (EU) 2016/429, in order to properly identify those epidemiological links.
- (22) It is also appropriate to detail the control measures to apply in identified linked establishments and locations. In order to be effective, those measures should be flexible and proportionate, without imposing unnecessary burdens on operators or competent authorities. The competent authorities should consequently be allowed to derogate from general provisions in exceptional circumstances, after carrying out a risk assessment.
- Article 64 of Regulation (EU) 2016/429 requires competent authorities to establish a restricted zone around the affected establishment when an outbreak of a category A disease is confirmed, in order to prevent any further spread of the disease. The restricted zone may include a protection zone and a surveillance zone. It is appropriate to set supplementary rules on how to establish and modify, if necessary, the restricted zone, including details on the protection zone, on the surveillance zone and on the possibility to establish further restricted zones depending on the epidemiology of the disease. It is also appropriate to provide for specific derogations for those cases where the establishment of restricted zones would not contribute to control the spreading of the disease or would impose an unjustified burden on operators and competent authorities.
- Article 65 of Regulation (EU) 2016/429 lists the measures that the competent authority may take in the restricted zone to prevent the spreading of the disease. In order to allow competent authorities to take the most proportionate and efficient control measures and ensure a harmonised implementation of the measures in all Member States, it is appropriate to establish detailed decision making criteria based on epidemiological circumstances, type and location of production establishments, species and categories of animals and economic or social conditions of the area affected by the disease.
- (25) It is necessary to specify the prohibitions of movements of animals and products within, from or through the protection and surveillance zone and the prohibitions of other activities that can pose a risk of spreading a category A disease. Those prohibitions should be proportional to the risk of spreading the disease linked to each activity and commodity. Consequently, they need to be established taking into account the epidemiological disease profile. This is especially important in respect of prohibitions concerning products since there are certain products that should be exempted, in particular those considered safe commodities in relation to the risk of spreading certain diseases.
- The prohibitions of activities in the restricted zone should be limited as far as possible. For that reason, there should be the possibility for the competent authority to grant derogations from the prohibitions when certain risk-mitigating measures are taken and certain procedural conditions are met. Such derogations may be granted, in particular, when the competent authority can check the reinforcement of biosecurity measures and when general and specific conditions, related to the relevant animals, products obtained from those animals, or other substances and materials that may be contaminated, are fulfilled.
- (27) Movements of ungulates should be limited to transports to a slaughterhouse. Poultry movements should be limited to the transport to slaughterhouses and to younger animals

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such as day-old-chicks and ready-to-lay poultry. Movements of products of animal origin should be allowed if the products have been produced before the high-risk period determined for the disease. Movements of products of animal origin and by-products produced within or after the high risk period should be allowed if the products have been subjected to specific treatments that inactivate the disease agent. Those treatments should be in line with existing Union legislation, international standards and new scientific evidence.

- (28) The competent authority should be able to visit establishments and to examine animals. To prevent the further spread of the disease, requirements should be set and be met before the measures applying to the protection zone can be lifted. Once those measures are lifted, the measures applying to the surveillance zone should be implemented, for an additional period, in the area previously covered by the protection zone, to ensure that the disease is controlled.
- (29) The provisions on control measures applicable within the surveillance zone should include general and specific rules for animals, products obtained from those animals, or other substances and materials that may be contaminated. They should also include derogations to allow a proportional application of the control measures. The intensity of the control measures and the derogations for their proportional application should reflect the lower risk that the surveillance zone poses for the spread of the disease but should ensure that the control measures are sufficient to avoid any risk of a further spread of the disease.
- (30) The competent authority should: (i) authorise the repopulation of the affected establishments with animals; (ii) ensure that a final cleaning and disinfection of the establishment is carried out; and, if relevant, (iii) carry out a check for vectors to ensure that diseases do not reappear. The competent authority should have the flexibility needed to decide on the most appropriate repopulation measures taking into account epidemiological circumstances and specific risk mitigation conditions.
- Wild animals of listed species could also be affected by category A diseases. Control measures for those wild animals are essential in preventing the spread of the diseases and in ensuring their eradication. As for diseases occurring in kept animals, the competent authority should consider control measures for diseases in wild animals as part of the contingency plans provided for by the Regulation (EU) 2016/429. The control measures should apply to suspected and confirmed cases of a disease affecting wild animals within an infected zone. Measures restricting the movement of kept animals that are listed species from the infected zone should be applied with flexibility in mind, based on the epidemiological situation. This is to ensure robust control measures while avoiding unnecessary burdens for operators and competent authorities.
- (32) The collection and safe disposal of dead bodies of wild animals contributes to preventing the spread of category A diseases. It is appropriate to supplement Regulation (EU) 2016/429 with rules ensuring the safe collection and disposal of animal byproducts from wild terrestrial and aquatic animals affected by category A diseases or subject to restriction measures imposed in response to those diseases in line with Regulation (EC) No 1069/2009.

- (33) Article 43 of Regulation (EU) 2016/429 requires the competent authority to establish an operational expert group as part of the contingency plans. These plans are designed to ensure a high level of disease awareness and preparedness and to provide a rapid response in case of an outbreak of a category A disease. The main task of the operational expert group in the case of an outbreak of diseases in terrestrial animals is to support the competent authority assessing the relevant measures for the control or eradication of the disease. The operational expert group for diseases in wild terrestrial animals should be multidisciplinary and have representatives of relevant government departments such as environmental and forests authorities, as well as stakeholders concerned, local authorities, police or other organisations that can provide advice to the competent authority on possible actions and their implementation to control or eradicate the category A disease.
- (34) Council Directive 2006/88/EC<sup>(6)</sup> includes provisions on animal health requirements for aquaculture animals and products and on the prevention and control of certain diseases in aquatic animals. The provisions in this Delegated Regulation should be based on the provisions from previous Union legislation that have worked well and have been revised and aligned, as far as possible, with the knowledge and experience gained in the past, and updated in accordance with new evidence and international standards.
- (35) Article 61 of Regulation (EU) 2016/429 provides for the application of disease control measures in establishments and other locations upon confirmation of category A diseases. One of those measures is the killing of animals that may be contaminated or may contribute to the spread of the disease. The possibility to apply such preventive killing should be detailed in this Delegated Regulation as a disease control measure aimed at reducing the infective pressure of a category A disease and to facilitate its control.
- (36) Article 62 of Regulation (EU) 2016/429 includes criteria for extending the disease control measures applied in an affected establishment to epidemiologically linked establishments and locations. The analysis of the hydrodynamic and topographic conditions, including data from water catchments, barriers in watercourses or water flow conditions, allows predicting the possible passive spread of a category A disease to other establishments or locations and this prediction may contribute to minimise the impact of a category A disease. The result of such an analysis permits the implementation of better-informed disease control measures, which should avoid or minimise the spread of a category A disease from a high-risk to a disease free area.
- (37) The competent authority should be able to derogate from restrictions applicable upon confirmation of a category A disease in order to allow the use of aquaculture animals for human consumption, provided they do not show clinical signs of the disease and are processed in a way that reduces the risk of spreading the disease by infective material. The derogation should be aimed at reducing economic losses while minimising the risk of the disease spreading.
- (38) Article 37 of Regulation (EU) 2016/429 provides for the recognition of a diseasefree status of compartments for listed diseases. Compartments include different establishments with common and efficient biosecurity systems permitting those

- establishments to have a distinct animal health status. Therefore, if a category A disease is suspected or confirmed in an aquaculture establishment within a compartment, the disease control measures should be extended to other establishments within that compartment resulting in a more efficient control of the disease.
- (39) Fallowing for aquatic animals is a disease control measure already included in previous Union legislation on prevention and control of diseases in aquaculture animals and should continue to be applied. The main objective of fallowing is to prevent or minimise the risk of re-infection of establishments with the category A disease, after cleaning and disinfection has been completed, and before introducing a new population of aquatic animals. Synchronous fallowing in areas with multiple infected establishments strengthens the disease control measures and contributes to a higher success rate. Different fallowing periods should be established for different category A diseases to reduce the fallowing time to a minimum while ensuring the effectiveness of this disease control measure.
- (40) When an aquaculture establishment has been affected by a category A disease which does not pose a risk to human health, the placing on the marked of products from that establishment should be allowed after risk-mitigating measures have been taken. For fish, those measures should include slaughtering and evisceration. Crustaceans should be processed to non-viable products before they are dispatched. The products should be used for direct human consumption or undergo further processing in an establishment approved under Article 179 of Regulation (EU) 2016/429. Those measures are effective in controlling and avoiding the further spread of the disease while allowing those products to be used for human consumption rather than unnecessarily wasted.
- (41) Article 64 of Regulation (EU) 2016/429 provides that, when a category A disease breaks out in aquatic animals, restricted zones be established as an effective measure to control the disease. Restricted zones may include a protection zone around establishments that have an increased risk of being affected by a category A disease. To ensure an effective disease control and to prevent the further spread of the disease, the introduction of aquaculture animals for farming in establishments located in the protection zone should be prohibited. To avoid re-infection, the protection zone should to be maintained until the infected aquaculture establishments are emptied of animals, cleaned and disinfected and the fallowing period has been completed.
- (42) Control measures applied in a protection zone established for disease in aquatic animals should be lifted only if a series of conditions are met. Those conditions should include depopulation, cleaning, disinfection and fallowing of the affected establishments. Furthermore, the results of regular visits carried out in all establishments located in the protection zone must be satisfactory. When all those conditions are met, the protection zone should become a surveillance zone. That surveillance zone should be maintained until the surveillance period for the relevant category A disease has elapsed and there are no elements to suspect the presence of the disease.
- (43) Article 43 of Regulation (EU) 2016/429 requires the competent authority to establish an operational expert group as part of the contingency plans designed to ensure a high level of disease awareness and preparedness and to provide a rapid response in

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case of an outbreak of a category A disease. The main task of the operational expert group in the case of an outbreak of diseases in aquatic animals is to support the competent authority in assessing the relevant measures for the control or eradication of the disease. The operational expert group for diseases in wild aquatic animals should be multidisciplinary and include representatives of government departments such as environmental and fisheries authorities, as well as stakeholders concerned, local authorities, police or other organisations that can provide advice to the competent authority on possible actions to control or eradicate the category A disease.

- (44) Article 6 of Regulation (EC) No 1069/2009 provides for the implementation of general health restrictions in the case of a serious transmissible disease. When a category A disease is present in aquaculture animals, the competent authority may impose stricter rules for animal by-products originating from certain establishments. Those rules are intended to deal with situations where public health restrictions may not address the animal health risk. It is necessary, in particular, that animal by-products from such establishments must be processed or disposed of as category 2 material in compliance with Article 13 of Regulation (EC) No 1069/2009.
- (45) Article 270 of Regulation (EU) 2016/429 repealed Council Directives 92/66/EEC<sup>(7)</sup>, 2001/89/EC<sup>(8)</sup>, 2002/60/EC<sup>(9)</sup>, 2003/85/EC<sup>(10)</sup> and 2005/94/EC<sup>(11)</sup>, which contained rules for the control of animal diseases. Article 272 of Regulation (EU) 2016/429 provides that the repealed Directives continue to apply for three years after the date of application of that Regulation or an earlier date to be determined by the Commission in a delegated act. In order to ensure a harmonised and simplified approach across species and diseases, this Regulation should apply from the date of application of Regulation (EU) 2016/429 and the repealed Directives should cease to apply from the same date,

HAS ADOPTED THIS REGULATION:

- (1) OJ L 84, 31.3.2016, p. 1.
- (2) 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).
- (3) Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (see page 211 of this Official Journal).
- (4) 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).
- (5) Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).
- (6) Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14).
- (7) Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease (OJ L 260, 5.9.1992, p. 1).
- (8) Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever (OJ L 316, 1.12.2001, p. 5).
- (9) Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever (OJ L 192, 20.7.2002, p. 27).
- (10) Council Directive 2003/85/EC of 29 of September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (OJ L 306, 22.11.2003, p. 1).
- (11) Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC (OJ L 10, 14.1.2006, p. 16).

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