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COMMISSION DELEGATED REGULATION (EU) .../...

of XXX

amending Delegated Regulation (EU) 2020/687 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)

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#### **EXPLANATORY MEMORANDUM**

#### 1. CONTEXT OF THE DELEGATED ACT

Commission Delegated Regulation (EU) 2020/687¹ lays down rules supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council ('Animal Health Law')² as regards the prevention and control of certain listed diseases, namely category A, B and C diseases. Among other things, Delegated Regulation (EU) 2020/687 provides for the establishment of restricted zones, and for restrictions and conditions for movements of animals and their products and other materials within, to and from restricted zones as part of the measures in order to prevent and control the spread of category A diseases. Such measures should be adapted to the risks involved. This Delegated Regulation, therefore, amends certain Articles of Delegated Regulation (EU) 2020/687 and certain Annexes thereto to align those measures with the risk involved in certain circumstances, and to take account of the new scientific knowledge available.

### 2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission held several meetings of the Expert Group on animal health (E00930) from September 2023 until February 2025 and had further exchanges within the same Expert Group. The draft Delegated Regulation was also made available to the European Parliament and the Council neither of which submitted any comments. A number of meetings have also 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.

### 3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Delegated Regulation is to be adopted within the framework of Regulation (EU) 2016/429, and in particular pursuant to Articles 55(2), 63(1), and 64(4), Article 67 and Article 68(3) thereof.

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 (OJ L 174, 3.6.2020, p. 64, ELI: http://data.europa.eu/eli/reg\_del/2020/687/oj).

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') (OJ L 84, 31.3.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/429/oj).

#### COMMISSION DELEGATED REGULATION (EU) .../...

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amending and correcting Delegated Regulation (EU) 2020/687 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)

#### 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')<sup>1</sup>, and in particular Articles 55(2), 63(1), and 64(4), Article 67, and Article 68(23) 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. That Regulation lays down, in particular, disease-specific rules for the prevention and control of the diseases listed in Article 5 thereof.
- Commission Delegated Regulation (EU) 2020/687² lays down rules supplementing Regulation (EU) 2016/429 as regards the prevention and control of certain listed diseases, namely category A, B and C diseases defined in Commission Implementing Regulation (EU) 2018/1882³. More particularly, Delegated Regulation (EU) 2020/687 lays down detailed rules concerning the establishment of a restricted zone in the event of an outbreak of a category A disease, and restrictions and conditions for movements of animals of listed species and their products within, to and from restricted zones, as part of the disease control measures required in order to prevent and control the spread of category A diseases.

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OJ L 84, 31.3.2016, p. 1, ELI: <a href="http://data.europa.eu/eli/reg/2016/429/oj">http://data.europa.eu/eli/reg/2016/429/oj</a>.

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 (OJ L 174, 3.6.2020, p. 64, ELI: <a href="http://data.europa.eu/eli/reg\_del/2020/687/oj">http://data.europa.eu/eli/reg\_del/2020/687/oj</a>).

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, ELI: <a href="http://data.europa.eu/eli/reg">http://data.europa.eu/eli/reg</a> impl/2018/1882/oj).

- (3) In addition, Article 7 of Delegated Regulation (EU) 2020/687 prohibits any movement of kept animals of non-listed species into and from an establishment where there is a suspicion of a category A disease. However, movements of certain animals of non-listed species into an establishment where there is a suspicion of a category A disease, or movements of such animals from such an establishment to a slaughterhouse, should be allowed, based on a risk assessment carried out, in each individual case, by the competent authority. Therefore, Article 7 of Delegated Regulation (EU) 2020/687 should be amended accordingly.
- Cleaning and disinfection of the affected establishment is one of the basic disease control measures provided for in Article 61 of Regulation (EU) 2016/429 to minimise the risk of the spread of a confirmed category A disease, and to eliminate as soon as possible the category A disease pathogen. The requirements for cleaning and disinfection consist of several procedures set out in points A (*General requirements*), B (*Preliminary cleaning and disinfection*) and C (*Final cleaning and disinfection*) of Annex IV to Delegated Regulation (EU) 2020/687. However, Articles 15 and 16 of that Delegated Regulation, which lay down the rules and derogations for cleaning and disinfection, and, when necessary, the control of insects and rodents, refer only to preliminary cleaning and disinfection, that is only a part of the complete procedure of cleaning and disinfection. Therefore, Article 15 should be amended to regulate the complete procedure of cleaning and disinfection, consisting of both the preliminary and the final cleaning and disinfection procedures.
- (5) Products from an establishment where an outbreak of category A disease has been confirmed may represent a risk for the spread of the category A disease. Therefore, those products that were moved from that establishment during a certain period are to be identified by tracing and treated or processed as required by Article 19(2) of Delegated Regulation (EU) 2020/687. However, that Article 19 does not clearly specify that the risk of the spread of the category A disease must be mitigated by the treatment or processing of those products. Therefore, Article 19 of Delegated Regulation (EU) 2020/687 should be amended accordingly.
- Based on the provisions of Article 21 of Delegated Regulation (EU) 2020/687, the possibilities of the competent authority to extend or adapt the restricted zone established in accordance with that Article are limited to certain situations. The possibilities provided for by Article 21 of Delegated Regulation (EU) 2020/687 for the establishment of a further restricted zone or for the adaptation of the restricted zone are not sufficient to effectively prevent the spread of the category A disease, in particular when the category A disease is also present in the wild animals of listed species, or if it is a vector borne disease. Therefore, Article 21 of Delegated Regulation (EU) 2020/687 should be amended to allow for the adaptation of the restricted zones, as provided for by Article 64(2) of Regulation (EU) 2016/429, without any limitation to only certain possibilities.

- (7) Regulation (EC) No. 1069/2009<sup>4</sup>, lays down rules for the safe collection, transport and disposal of animal by-products. However, in the event of a widespread outbreak of a listed disease where disposal capacities in a concerned Member State are exceeded, Article 19(1) of that Regulation provides, by way of derogation the possibility for the competent authority to dispose animal by-products in exceptional cases by burning or burial on the site, under conditions which prevent the transmission of risks to public and animal health. That possibility should also be provided for in Delegated Regulation (EU) 2020/687. Therefore, Article 22 of that Delegated Regulation should be amended accordingly.
- Article 23 of Delegated Regulation (EU) 2020/687 provides that the competent (8) authority may grant derogations from the provisions set out in Chapter II of that Delegated Regulation concerning the measures to be applied in the restricted zones under certain circumstances, to the extent necessary and after carrying out a risk assessment. However, it is not clear that the outcome of the risk assessment must indicate that the risk of spread of the disease is negligible in order for the competent authority to grant a derogation. In addition, following the amendments made to Article 21(3) of Delegated Regulation (EU) 2020/687 by Commission Delegated Regulation (EU) 2023/751<sup>5</sup> regarding establishments keeping up to 50 captive birds, point (d) of Article 23 is no longer necessary as it is covered by Article 21(3), point (g) of Delegated Regulation (EU) 2020/687. Moreover, the derogation initially provided by Article 23, point (d), of Delegated Regulation (EU) 2020/687 only covers establishments keeping up to 50 captive birds where the outbreak of the category A disease occurred. However, as a result of the amendments made by Delegated Regulation (EU) 2023/751 to Article 21(3) of Delegated Regulation (EU) 2020/687, and based on Article 23, point (d) of that Delegated Regulation derogations are currently possible in establishments keeping up to 50 captive birds, which are not the establishments where the outbreak occurred. Therefore, Article 23 of Delegated Regulation (EU) 2020/687 should be amended accordingly.
- (9) Following the confirmation of a category A disease in an establishment with kept animals of listed species, Article 26 of Delegated Regulation (EU) 2020/687 requires that official veterinarians carry out visits to the establishments located in the protection zone. The scope of these visits is to perform the necessary checks and examinations, including sampling for laboratory testing, to detect early the possible spread of the category A disease to other establishments in that zone. The procedures for the taking of samples at the establishments to be visited, and for the clinical and laboratory

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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, ELI: <a href="http://data.europa.eu/eli/reg/2009/1069/oj">http://data.europa.eu/eli/reg/2009/1069/oj</a>).

Commission Delegated Regulation (EU) 2023/751 of 30 January 2023 amending Delegated Regulation (EU) 2020/687 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards rules for the prevention and control of certain listed diseases (OJ L 100, 13.4.2023, p.7 ELI: http://data.europa.eu/eli/reg\_del/2023/751/oj).

examinations in the visited establishments, are laid down in Annex I to Delegated Regulation (EU) 2020/687. The clinical and laboratory examinations of animals of listed species kept in establishments located in the protection zone is also required by Article 39(1), point (b), of that Delegated Regulation. Since the adoption of Delegated Regulation (EU) 2020/687, the European Food Safety Authority (EFSA) has issued, in 2021 and 2022, scientific opinions on the assessment of the effectiveness of control measures for each category A disease<sup>6</sup>, (the relevant scientific evidence) including recommended clinical and laboratory examinations and sampling procedures to detect those diseases. Therefore, Article 26(1), point (d), and Article 39(1), point (b), of Delegated Regulation (EU) 2020/687 should be amended to refer to the need to collect samples for laboratory examinations when the relevant scientific evidence recommends such measures. In addition, Annex I to Delegated Regulation (EU) 2020/687 should be amended to add the requirement that the sampling procedures laid down in point A of that Annex must be based on the relevant scientific evidence for the respective category A disease.

(10) Article 27 of Delegated Regulation (EU) 2020/687 provides, amongst other things, for prohibitions on movements of animals and products in the protection zone. Paragraph 3 of that Article allows for certain products to be exempted from that prohibition. An exemption is only possible for products that are safe and do not present a risk for the

Scientific Opinion on the assessment of the control measures for category A diseases of Animal Health Law: Foot and Mouth Disease, <a href="https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6632">https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6632</a>
Assessment of the control measures of category A diseases of the Animal Health Law: Infection with rinderpest virus(Rinderpest), <a href="https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7071">https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7071</a>
Assessment of the control measures of the category A diseases of Animal Health Law: Rift Valley Fever, <a href="https://www.efsa.europa.eu/en/efsajourna/pub/7070">https://www.efsa.europa.eu/en/efsajourna/pub/7070</a>

Assessment of the control measures for category A diseases of Animal Health Law: Lumpy Skin Disease, https://www.efsa.europa.eu/en/efsa.ournal/pub/7121

Assessment of the control measures for category A diseases of Animal Health Law: Contagious Bovine Pleuropneumonia, <a href="https://www.efsa.europa.eu/en/efsajournal/pub/7067">https://www.efsa.europa.eu/en/efsajournal/pub/7067</a>

Assessment of the control measures of the category A diseases of Animal Health Law: sheep and goat pox, <a href="https://www.efsa.europa.eu/en/efsajournal/pub/6933">https://www.efsa.europa.eu/en/efsajournal/pub/6933</a>

Assessment of the control measures of the category A diseases of Animal Health Law: peste des petits ruminants, <a href="https://www.efsa.europa.eu/en/efsajournal/pub/6708">https://www.efsa.europa.eu/en/efsajournal/pub/6708</a>

Assessment of the control measures for category A diseases of Animal Health Law: Contagious Caprine Pleuropneumonia, <a href="https://www.efsa.europa.eu/en/efsajournal/pub/7068">https://www.efsa.europa.eu/en/efsajournal/pub/7068</a>

Assessment of the control measures of the category A diseases of Animal Health Law: Classical Swine Fever, <a href="https://www.efsa.europa.eu/en/efsajournal/pub/6707">https://www.efsa.europa.eu/en/efsajournal/pub/6707</a>

Scientific Opinion on the assessment of the control measures of the category A diseases of Animal Health Law: African Swine Fever, <a href="https://www.efsa.europa.eu/en/efsajournal/pub/6402">https://www.efsa.europa.eu/en/efsajournal/pub/6402</a>

Assessment of the control measures of the category A diseases of Animal Health Law: Burkholderia mallei (Glanders), <a href="https://www.efsa.europa.eu/en/efsajournal/pub/7069">https://www.efsa.europa.eu/en/efsajournal/pub/7069</a>

Scientific Opinion on the assessment of the control measures of the category A diseases of Animal Health Law: African Horse Sickness, <a href="https://www.efsa.europa.eu/en/efsajournal/pub/6403">https://www.efsa.europa.eu/en/efsajournal/pub/6403</a>

Scientific Opinion on the assessment of the control measures of the category A diseases of Animal Health Law: Highly Pathogenic Avian Influenza, <a href="https://www.efsa.europa.eu/en/efsajournal/pub/6372">https://www.efsa.europa.eu/en/efsajournal/pub/6372</a>

Assessment of the control measures of the category A diseases of Animal Health Law: Newcastle disease, <a href="https://www.efsa.europa.eu/en/efsajournal/pub/6946">https://www.efsa.europa.eu/en/efsajournal/pub/6946</a>

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transmission of category A diseases to terrestrial animals. Paragraph 3 lists derived products as one such product. However, derived products may, in accordance with the rules on animal-products, and in particular Commission Regulation (EU) No 142/2011<sup>7</sup> be treated by different methods and some of those methods may not be sufficient to mitigate the risk of a category A disease in terrestrial animals. Recent experiences with the application of disease control measures in the Union have highlighted that deficiency. It is, therefore, necessary to amend Delegated Regulation (EU) 2020/687 so that only those treatments for the relevant derived products, as provided for in Regulation (EU) No. 142/2011, which are considered to mitigate the risk of pathogens of those category A diseases. In addition, gelatine and collagen as defined in Annex I, points 7.7. and 7.8. to Regulation (EC) No 853/2004 of the European Parliament and of the Council<sup>8</sup> are, due to their production process, considered to be products of animal origin which do not represent a risk as regards transmissible animal diseases falling within the scope of Regulation (EU) 2016/429. It is, therefore, necessary to exempt gelatine and collagen from the prohibitions provided for in Article 27(1) and (2) of Delegated Regulation (EU) 2020/687. Therefore, Article 27(3) of Delegated Regulation (EU) 2020/687 should be amended accordingly. Furthermore, as consequence to the amendments in Article 27(3), Articles 33(1) and 49(1) should be revised to refer to the part of Annex VII to Delegated Regulation (EU) 2020/687 where the risk mitigating treatments for those products are laid down.

(11) Articles 28 and 43 of Delegated Regulation (EU) 2020/687 lay down the general conditions for granting derogations from the prohibitions to be applied in the protection and surveillance zones, respectively as established following confirmation of a category A disease in kept animals of listed species. Commission Delegated Regulation (EU) 2024/26239 lays down the rules for the approval and recognition of disease-free status of compartments keeping terrestrial animals as regards certain category A diseases. Therefore, Articles 28 and 43 of Delegated Regulation (EU) 2020/687 should be amended to allow movements of animals and products from a restricted zone if they originate from compartments approved for the relevant category

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Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal byproducts and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, pp. 1, ELI: <a href="http://data.europa.eu/eli/reg/2011/142/oj">http://data.europa.eu/eli/reg/2011/142/oj</a>).

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55, ELI: http://data.europa.eu/eli/reg/2004/853/oj).

Commission Delegated Regulation (EU) 2024/2623 of 30 July 2024 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for approval and recognition of disease-free status of compartments keeping terrestrial animals (OJ L, 2024/2623, ELI: http://data.europa.eu/eli/reg\_del/2024/2623/oj).

- A disease in accordance with Delegated Regulation (EU) 2024/2623, and listed in Annex XI to Commission Implementing Regulation (EU) 2021/620<sup>10</sup>.
- Specific conditions for authorising movements of manure, including litter and used (12)bedding, from protection and surveillance zones are laid down in Articles 35 and 51 of Delegated Regulation (EU) 2020/687. In addition, Articles 37(2) and 53(2) of Delegated Regulation (EU) 2020/687 lay down the specific conditions for authorising movements of products from protection or surveillance zones to an animal by-product approved plant. Manure, including litter and used bedding, are also products, and therefore they fall within the scope of Articles 37(2) and 53(2) of that Delegated Regulation. However, that is not clear, considering that movements of those products from establishments in the protection and surveillance zone are already referred to Articles 35 and 51 of that Delegated Regulation. Therefore, for clarity of Union rules on possibilities for movements of manure, including litter and used bedding from establishments located in the protection and surveillance zones. Articles 35 and 51 of Delegated Regulation (EU) 2020/687 should be amended so that they refer to all those provisions. Moreover, Point C, paragraph 1(a)(i), of Annex IV to Delegated Regulation (EU) 2020/687 provides for a treatment deemed to inactivate the category A disease pathogens in manure, litter and used bedding from an affected establishment. The same treatment should be deemed safe also for the manure, including litter and used bedding from establishments located in the protection zone. Therefore, Articles 35 and 51 of Delegated Regulation (EU) 2020/687 should be amended accordingly.
- Moreover, it is important to ensure that the risk mitigating treatments used for animal-by products originating from protection and surveillance zones presenting an imminent risk for the transmission of the animal disease are safe to destroy the disease agent. This can only be ensured by processing those products with processing methods which are considered as safe in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council<sup>11</sup> and therefore fully harmonised under that legislation. It is, therefore, necessary to refer to these safe methods in Delegated Regulation (EU) 2020/687 and amend Articles 37 and 53 accordingly.
- (14) Article 46(1), point (b), of Delegated Regulation (EU) 2020/687 limits the possibility to authorise movements of day-old chicks originating in the surveillance zone to movements of such animals to establishments in the same Member State only. However, movements from establishments in the surveillance zone of day-old chicks

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Commission Implementing Regulation (EU) 2021/620 of 15 April 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of the disease-free and non-vaccination status of certain Member States or zones or compartments thereof as regards certain listed diseases and the approval of eradication programmes for those listed diseases (OJ L 131, 16.4.2021, p. 78, ELI: http://data.europa.eu/eli/reg\_impl/2021/620/oj).

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, ELI: http://data.europa.eu/eli/reg/2009/1069/oj).

obtained from hatching eggs originating outside the restricted zone may be deemed to be safe if those eggs and the day-old chicks have had no contact with other hatching eggs or day-old chicks from the restricted zone. Therefore, Article 46(1), point (b), of Delegated Regulation (EU) 2020/687 should be amended to permit, subject to certain conditions, movements of day-old chicks hatched from eggs originating outside the restricted zone to any establishment.

- A surveillance zone is considered to represent a lower risk for the spread of a category A disease pathogen than a protection zone. Therefore, feed materials of plant origin and straw produced in the surveillance zone represent a lower risk than those produced in the protection zone and may be used in the protection zone without increasing the risk of the spreading of the category A disease in that zone. Therefore, Article 52, point (c), of Delegated Regulation (EU) 2020/687 should be amended to permit the use of feed materials of plant origin and straw produced in the surveillance zone in both the protection and surveillance zones.
- (16)Disease control measures must be applied in the restricted zone established for a category A disease until the final cleaning and disinfection has been carried out, as required by Article 68 of Regulation (EU) 2016/429. Therefore, Article 55 of Delegated Regulation (EU) 2020/687 should be amended to clearly refer to the completion of the final cleaning and disinfection as a condition to be fulfilled before lifting the disease control measures applied in the surveillance zone. However, in certain situations, such as force majeure or because of long period of unfavourable weather conditions, the completion of the final cleaning and disinfection in accordance with the procedures set out in Annex IV to Delegated Regulation (EU) 2020/687 might be delayed. As such delays might significantly extend the duration of the restrictions more than doubling the length of the minimum duration required in accordance with Annex XI to Delegated Regulation (EU) 2020/687, this can cause serious disturbances to the activity of the non-affected establishments located in the surveillance zone and significant economic losses for those operators. Therefore, it is appropriate to permit, in such exceptional circumstances, the lifting of the disease control measures in the surveillance zone before the completion of the final cleaning and disinfection in the affected establishment if certain conditions are fulfilled to ensure that the risk of spread of the category A disease from that establishment is negligible. Therefore, Article 55 of Delegated Regulation (EU) 2020/687 should be amended accordingly.
- (17) The restricted zone may also comprise a further restricted zone as established by the competent authority in accordance with Article 21 of Delegated Regulation (EU) 2020/687 when certain epidemiological situations warrant applying such measure to effectively control the spread of the category A disease. In those circumstances, it also might be necessary to maintain certain disease control measures in the entire restricted zone after the lifting of the disease control measures applied in the protection and surveillance zones. Therefore, Articles 39 and 55 of Delegated Regulation (EU) 2020/687 should be amended accordingly.

- (18) The rules laid down in Chapter III of Part II of Delegated Regulation (EU) 2020/687 refer to repopulation of the affected establishment and lifting of the disease control measures in that establishment. Therefore, the title of that Chapter should be corrected accordingly.
- (19) Article 58 of Delegated Regulation (EU) 2020/687 provides for derogations from the conditions required to authorise the repopulation of affected establishment as laid down in Article 57 of that Delegated Regulation. However, the title of Article 58 of Delegated Regulation (EU) 2020/687 incorrectly refers to Article 55 and therefore should be corrected.
- Repopulation of an affected establishment is to be performed in accordance with the requirements laid down in Article 59 of Delegated Regulation (EU) 2020/687, to ensure that repopulated animals are free of the relevant category A disease. Accordingly, the official veterinarian is to visit, at least once, the affected establishment and check the repopulated animals. The visits are to take place within a specific period that takes into account the date on which the animals were placed into the establishment and the last day of the monitoring period for the relevant category A disease. However, when the monitoring period, in accordance with Annex II to Delegated Regulation (EU) 2020/687, is longer than 30 days, the visit should be performed within 30 days from the date on which the animals were placed into the establishment. Therefore, Article 59(5) of Delegated Regulation (EU) 2020/687 should be amended accordingly.
- The lifting of the disease control measures applied in an establishment affected by an outbreak of a category A disease is linked with the finalisation of the repopulation of that establishment, as required by Article 61 of Delegated Regulation (EU) 2020/687. The requirements of Article 61 of Delegated Regulation (EU) 2020/687 do not cover cases where repopulation is not taking place in the affected establishment either due to the cessation of keeping of animals by the operator or in cases when the competent authority granted derogations from the killing of animals of listed species kept in certain affected establishments and of certain categories of animals as listed in Article 13(1) and (2) of Delegated Regulation (EU) 2020/687. Therefore, Article 61 of Delegated Regulation (EU) 2020/687 should be amended to lay down conditions for lifting the disease control measures in affected establishments, covering those situations as well as when repopulation is not intended in the affected establishment.
- Article 75 of Delegated Regulation (EU) 2020/687 provides for several circumstances to be taken into account by the competent authority when establishing temporary restricted zones. One of these circumstances provided for in point (b) of that Article is the movements of animals in the vicinity of the suspected establishment. As that Article of Delegated Regulation (EU) 2020/687 refers to disease control measures for category A diseases in aquaculture animals, it is appropriate to specify that the circumstance to be taken into account is the movement of aquatic animals. Article 75 Delegated Regulation (EU) 2020/687 should, therefore, be amended accordingly.

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- (23) Article 78(1), point (f) (i) and (ii), and Article 78(5) of Delegated Regulation (EU) 2020/687 lay down rules concerning animal by-products and products of animal origin, although there are already rules for those products laid down in Article 78(1), point (b), and Article 78(3) of that Delegated Regulation. Therefore, Article 78 should be amended to ensure that there is no duplication of rules for the same products in the same Article.
- When purification is required before molluscs can be processed from aquaculture establishments in the protection zone, such purification should be completed in a manner which does not create a risk for the spread of the disease. In order to simplify and harmonise certain elements of Delegated Regulation (EU) 2020/687, Article 83 thereof should be amended by deleting the reference to "a bio-secure purification centre", to ensure that molluscs from infected aquaculture establishments, are only purified in a disease control aquatic food establishment. In addition, Article 83 should be revised to align the provisions referred to Article 78 with the amendments done to that Article.
- Article 90(2), point (b), of Delegated Regulation (EU) 2020/687, provides that exchanges and discharges of water during transportation in the protection zone, must be carried out in areas, establishments or water exchange points approved by the competent authority. Such discharges and exchanges often require vehicles to stop. Such stopping is, however, prohibited by Article 90(2), point (a), of Delegated Regulation (EU) 2020/687. To ensure that those provisions are logistically feasible, the reference to stopping should be updated accordingly in Article 90(2), point (a), of Delegated Regulation (EU) 2020/687.
- Article 99(1) of Delegated Regulation (EU) 2020/687, prohibits movements of aquaculture animals from within the surveillance zone for slaughter, further keeping or release into the wild outside the surveillance zone. Article 99(4) of that Delegated Regulation, however, allows the competent authority in agreement with the competent authority of the place of destination to authorise movements of aquaculture animals, provided that appropriate biosecurity measures are applied to prevent the spread of the category A disease. While this derogation is appropriate for many types of movements, it is not appropriate for animals which are to be released into the wild, where such release may result in the infection of natural waters, which may be very difficult to eradicate. The derogation laid down in Article 99(4) should, therefore, be limited to movements other than for the purpose of release into the wild.
- The EFSA issued scientific opinions concluding and recommending on the effectiveness of the disease control measures laid down in Delegated Regulation (EU) 2020/687 for each category A disease<sup>5</sup>, in particular on the effectiveness of the monitoring period, of the radiuses of the protection and surveillance zones, and on the duration of the measures to be applied in those zones, as laid down in Annexes II, V, X and XI to Delegated Regulation (EU) 2020/687. In addition, prohibitions in restricted zones and risk-mitigating treatments for products of animal origin and other materials, as laid down in Annexes VI, VII and VIII to Delegated Regulation (EU)

2020/687 have been assessed by EFSA, and conclusions on the effectiveness of those measures and risk-mitigation treatments have been published in a scientific opinion on the 'Assessment of the control measures of the Category A diseases of the Animal Health Law: prohibitions in restricted zones and risk-mitigating treatments for products of animal origin and other materials' 12. Therefore, Annexes II, V to VIII, X and XI to Delegated Regulation (EU) 2020/687 should be amended, to take account of the effective measures, prohibitions and risk-mitigating treatments relevant for each category A disease in accordance with EFSA recommendations. In addition, following the amendment of Article 27(3) of Delegated Regulation (EU) 2020/687, Annex VII to that Delegated Regulation should be amended to also include the methods for mitigating the risk of the derived products from the restricted zone.

- (28)Annex IV to Delegated Regulation (EU) 2020/687 sets out the procedures for the cleaning, disinfection and when necessary, the control of insects and rodents, as referred in certain Articles of that Delegated Regulation. Therefore, the subtitle of that Annex IV should refer to the rules laid down in all the Articles of Delegated Regulation (EU) 2020/687 that require cleaning and disinfection in accordance with Annex IV. In addition, amendments should be made to Point B of Annex IV to that Delegated Regulation in relation to the maximum required contact time of the disinfectant with the treated surfaces, to take account of situations when unnecessarily maintaining the disinfectant on the surfaces to be disinfected longer than the maximum required contact time indicated by the manufacturer may damage the disinfected materials. Moreover, the duration of steam treatment required for manure as part of the final cleaning and disinfection as laid down in Point C, paragraph 1(a)(i), of Annex IV should be clarified for its duration to ensure the effective inactivation of category A disease agents. Furthermore, the period of 7 days required by Point C, paragraph 3, of Annex IV aims to allow the buildings, surfaces and equipment that were cleaned and disinfected as required by paragraph 2 of that Point to dry before being cleaned and disinfected again. However, in certain circumstances or weather conditions the surfaces, buildings and equipment are dry earlier than 7 days. It is therefore correct to allow the cleaning and disinfection provided for in Point C, paragraph 3, to be carried out earlier than 7 days if the surfaces have dried.
- (29) For the control of category A diseases, in the case of authorised movements of fresh meat obtained from animals of listed species kept in establishments located in the protection and surveillance zones, Annex IX to Delegated Regulation (EU) 2020/687 provides for the marking of fresh meat of poultry which is not intended to be dispatched to another Member State, as well as of fresh meat moved to a processing establishment to undergo one of the relevant risk-mitigating treatments, as required by Articles 33 and 49 of that Delegated Regulation. Different shapes of marks are described for marks to be applied to fresh meat of poultry and to fresh meat of other species. In addition, the description of the marks to be applied to fresh meat, as laid

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Assessment of the control measures of the Category A diseases of the Animal Health Law: prohibitions in restricted zones and risk-mitigating treatments for products of animal origin and other materials, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7443.

down in Annex IX to Delegated Regulation (EU) 2020/687 contains elements already laid down in Annex II to Commission Implementing Regulation (EU) 2019/627<sup>13</sup> or in Section I of Annex II to Regulation (EC) No 853/2004 of the European Parliament and of the Council<sup>14</sup>. Therefore, to simplify the description of the marks as laid down in Annex IX to Delegated Regulation (EU) 2020/687, and to ensure harmonised marking of fresh meat, Annex IX to Delegated Regulation (EU) 2020/687 should provide a reference to health marks or, where relevant, identification marks, as laid down in Article 48 of, and Annex II to, Implementing Regulation (EU) 2019/627 or in Section I of Annex II to Regulation (EC) No 853/2004, respectively. In addition, when used for disease control purposes as laid down in Articles 33 and 49 of Delegated Regulation (EU) 2020/687, additional requirements should apply to the form of the health or identification marks (special health or identification marks). Therefore, Annex IX to Delegated Regulation (EU) 2020/687 should be amended accordingly.

- (30) The changes to the description of the marks as laid down in Annex IX to Delegated Regulation (EU) 2020/687, as amended by this Regulation, might create an additional administrative burden for operators. A transitional period should, therefore, be provided for in this Regulation during which time the marks as described in Annex IX in the version of Delegated Regulation (EU) 2020/687 applicable before the amendments made by this Regulation, may continue to be used, and the fresh meat with such marks applied before the end of the transitional period may remain on the market.
- (31) Annex XII to Delegated Regulation (EU) 2020/687 should be amended to ensure that three separate options exist concerning the types of samples that may be taken for clinical examination and sampling of aquatic animals, rather than those options being linked to each other. In addition, the table in point 1(b) of that Annex is missing information and certain inconsistencies concerning the samples to be collected from crustaceans and fish, under certain circumstances. The European Union Reference Laboratory (EURL) for fish and crustacean diseases has been consulted and that table should be amended according to the recommendations of that EURL.
- (32) In Annex XV to Delegated Regulation (EU) 2020/687, in the interest of clarity, it is necessary to harmonise the terminology to ensure that the term 'health visits' is used throughout, rather than using both the terms 'health visits' and 'health inspections', when they are intended for the same disease surveillance purpose.

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Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51, ELI: <a href="http://data.europa.eu/eli/reg\_impl/2019/627/oj">http://data.europa.eu/eli/reg\_impl/2019/627/oj</a>).

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30/04/2004, p. 55, ELI: <a href="http://data.europa.eu/eli/reg/2004/853/oj">http://data.europa.eu/eli/reg/2004/853/oj</a>).

- (33) After publication in the *Official Journal of the European* Union, some errors were noticed in Part III of Delegated Regulation (EU) 2020/687. Those errors should be corrected.
- (34) Delegated Regulation (EU) 2020/687 should therefore be amended and corrected accordingly,

#### HAS ADOPTED THIS REGULATION:

## Article 1 Amendments to Delegated Regulation (EU) 2020/687

Delegated Regulation (EU) 2020/687 is amended as follows:

- (1) \_\_\_\_Article 7(2), point (c) is replaced by the following is amended as follows:
  - '(c) in case of (a) in paragraph 2, the following subparagraph is added:
  - <u>'The first subparagraph, point (c), shall not apply to movements of kept</u>-animals of non-listed species, ';
  - (b) the following paragraph 2a is added:
  - '2a. By way of derogation from point 1(b), the competent authority may authorise movements of animals of non-listed species into the establishment of destination is not a slaughterhouse.'; where a category A disease is suspected, after carrying out a risk assessment and provided that:
    - (a) the animals of non-listed species were temporarily moved out of the establishment before the category A disease was suspected;
  - (b) appropriate biosecurity measures necessary to avoid the spread of the category A disease are applied.',
- (2) Article 15<del>, paragraphs 1 to 3 are is replaced by the following:</del>

#### 'Article 15

## Cleaning and disinfection and control of insects and rodents in the affected establishment

:

- '1. The competent authority shall order and supervise <u>the</u> cleaning and disinfection and, <u>whenwhere</u> relevant, <u>the</u> control of insects and rodents, in the affected establishment in order to avoid spreading of the category A disease and to eliminate as soon, as possible the pathogen of the category A disease, as follows:
  - (a) a preliminary cleaning and disinfection, and where relevant, the control of insects and rodents, immediately after the completion of the disease control measures provided for inaccordance with Article 12, and when relevant in Article 13 and 14; and

- (b) a final cleaning and disinfection, and, when where relevant, the control of insects and rodents as provided for in Article 68(1), point (b) of Regulation (EU) 2016/429, immediately after the completion of the preliminary cleaning and disinfection.
- 2. The preliminary and final cleaning, disinfection and control of insects and rodents, referred to in paragraph 1 shall be:
  - (a) performed in accordance with the general requirements as set out in point A of Annex IV and the relevant procedures set out in points B and C of that Annex, using the appropriate biocidal products to ensure the destruction of the relevant category A disease agent; and
  - (b) adequately documented.
- 3. Article 16 is replaced by the following:
  - <u>'4.</u> In addition to the measures referred to in paragraphs 1. The and 2, the competent authority may grant derogation to the requirement regarding cleaning and disinfectionshall order and supervise that the means of transport used for the transport of animals to and from the affected establishment are properly cleaned and disinfected and, where relevant, subjected to measures ensuring the control of insects and rodents.';
- (3). The title of Article 16 is replaced by the following:

# 'Derogations and special rules for the cleaning and disinfection and control of vectors';

- in Article 15 in 19, the case of following paragraph 6 is added:
  - (a) pastures epidemiologically linked to the affected establishment, under specific procedures to ensure effective inactivation of the relevant category A disease agent taking into account the disease profile, the type of establishment and the climatic conditions; and
  - (b) manure, including litter and used bedding, from the affected establishment, under specific procedures to ensure effective inactivation of the relevant category A disease agent in accordance with scientific evidence.
  - <u>'6.</u> The competent authority may grant derogation and reducing the time required in point 3 of Part C of Annex IV for establishments and locations shall order and supervise

- that the treatments or processing of products, as referred to in paragraph 2 of this Article 20, provided that the efficacy of the final cleaning and disinfection is not impaired, are carried out in accordance with Annex VII or VIII, as relevant.';
- 4.(5) in Article 21, point (c) of paragraph 1, and paragraph 2, are replaced as in by the following:
  - '(c) if necessary, on the basis of the criteria set out laid down in paragraph 1 of Article 64(1) of Regulation (EU) 2016/429, further restricted zones where the competent authority shall apply the same measures as those provided for in Section 3 of this Chapter for the surveillance zone.<sup>2</sup>
- 2. The competent authority shall adapt the boundaries of the restricted zone, including the boundaries of the protection, surveillance and the further restricted zones, in accordance with the provisions laid down in Article 64(2) of Regulation (EU) 2016/429:::2:
- 5.(6) in Article 22, paragraph 3 is replaced by the following:
  - '3. The competent authority shall order and supervise that all movements of entire bodies or parts of dead wild and kept animals of listed species from the restricted zone are destined for processing or disposal in accordance with Regulation (EC) No 1069/2009:
  - (a) within the territory of the Member State; or
  - (b) in a plant approved for those purposes in another Member State in accordance with Article 48(1) and (3) of Regulation (EC) No 1069/2009, where it is not feasible to process or dispose of the entire bodies or parts of dead animals in an approved plant within the territory of the Member State where the outbreak occurred. ';
- (7) Article 23 is replaced by the following:

#### 'Article 23

#### Derogations from measures to be applied in the restricted zone

- 'The competent authority may grant derogations from the provisions set outrules laid down in this Chapter concerning the measures to be applied in restricted zones, to the extent necessary and after carrying out a risk assessment that indicates that the risk of the spread of the category A disease is negligible:
  - (a) in the further restricted zones referred to in Article 21(1)(), point (c);
  - (b) in the case that where the competent authority decides to establish a restricted zone when an outbreak of a category A disease occurs in establishments and locations referred to in Article 21(3); or
  - (c) in establishments and locations referred to in Article 21(3), points (a) to (f) of Article 21(3)), located in a restricted zone. '; ';
- 6.(8) in Article 26(2), point (d) is replaced by the following:

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- '(d) the collection of samples from animals for laboratory examination in order to confirm or rule out the presence of the relevant category A disease unless, based on the relevant scientific evidence, a clinical examination is sufficient to rule out the presence of that disease.';
- 7.(9) in Article 27(3), points (a), (b) and (eb) are replaced by the following:
  - '(a) products of animal origin <u>eonsidered referred to</u> as safe commodities in <u>accordance with Part I of Annex VII</u>, as regards the relevant category A disease;
  - (b) products of animal origin which have undergone <u>one of</u> the relevant <u>treatment</u> provided in <u>Part I of</u> Annex VII for the relevant category A disease;-';
- (10) Article 27(3), is amended as follows:
  - (a) point (e) is replaced by the following:
    - '(e) derived products obtained with standard processing methods <u>and standard transformation parameters</u>, as laid down in Commission Regulation (EU) 142/2011<sup>15</sup>, <u>and provided for in Part II of Annex VII to this Regulation</u> for the relevant product.';
  - 8.(b) a new point (f) is added, as follows:
  - '(f) gelatine and collagen.';
- (11) in Article 28, paragraph 1 is replaced by the following:
  - 1. By way of derogation from prohibitions provided for in Article 27 and under the general conditions laid down in paragraphs 2 to 7 of this Article, the competent authority may authorise movements of animals and products if the risk for the spread of the category A disease deriving from such movements is negligible, and if the general conditions laid down in paragraphs 2 to 7 of this Article are fulfilled:
    - (a) in the cases covered by provided for in Articles 29 to 38, and under in accordance with the specific conditions provided for laid down in those Articles; or
    - (b) obtained(b) if animals and products originate in compartments approved in accordance with Article 5 of Commission Delegated

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Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal byproducts and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1, ELI: <a href="http://data.europa.eu/eli/reg/2011/142/oj">http://data.europa.eu/eli/reg/2011/142/oj</a>). LI: <a href="http://data.europa.eu/eli/reg/2011/142/oj">http://data.europa.eu/eli/reg/2011/142/oj</a>)

Regulation (EU) 2024/2623<sup>16</sup> for the relevant category A disease and listed in Annex XI to Commission Implementing Regulation (EU) 2021/620<sup>17</sup>, and:::

- (c) after assessing the risk deriving from that authorisation as negligible for spreading the category A disease.';
- in Article 3533(1), point (a) is replaced by the following:

'(a) they are moved to a processing establishment to undergo one of the relevant risk-mitigating treatments set out in Part I of Annex VII; or';

(13) Article 35 is replaced by the following:

#### 'Article 35

Specific conditions for authorising movements of manure, including litter and used bedding, from establishments located in the protection zone

The competent authority may authorise movements of manure, including litter and used bedding:, from:

- (a) from establishments located in the protection zone for the purpose of their disposal in a designated landfill located within the same Member State only after it has been treated in accordance with the treatment set out in <a href="Part C">Part C</a>, point (1)(a)(i) of part C), of Annex IV, or after processing in accordance with Article 13, point (c)), of Regulation (EC) No 1069/2009;
- (b) from establishments and locations in the protection zone to a plant approved for the processing or disposal of animal by-products, in which the products are disposed of or processed by one of the harmonized methods in accordance with Regulation (EC) No 1069/2009 by the methods relevant for the processing of manure provided for in Part II of Annex VII to this Regulation.';
- (14) in Article 37, paragraph 2 is replaced by the following:
  - '2. The competent authority may authorise movements of products from establishments and locations in the protection zone to a plant approved for the processing or disposal of animal by-products, in which the products are disposed of or

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Commission Delegated Regulation (EU) 2024/2623 of 30 July 2024 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for approval and recognition of disease-free status of compartments keeping terrestrial animals (OJ L, 2024/2623, 4.10.2024, ELI: <a href="http://data.europa.eu/eli/reg\_del/2024/2623/oj">http://data.europa.eu/eli/reg\_del/2024/2623/oj</a>).

Commission Implementing Regulation (EU) 2021/620 of 15 April 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of the disease-free and non-vaccination status of certain Member States or zones or compartments thereof as regards certain listed diseases and the approval of eradication programmes for those listed diseases (OJ L 131, 16.4.2021, p. 78, ELI: http://data.europa.eu/eli/reg\_impl/2021/620/oj).

processed by one of the harmonised methods in accordance with Regulation (EC) No 1069/2009 by the relevant method provided in Part II of Annex VII to this Regulation.';

- (15) Article 39 is amended as follows:
  - (a) in paragraph 1, point +(b) is replaced by the following:
    - '(b) in all establishments keeping animals of listed species in the protection zone, animals of listed species have undergone, with favourable results, clinical and laboratory examinations as necessary, in accordance with Article 26.';
    - 13.(b) the following paragraph 4 is added:
  - '4. After the lifting of measures referred to in paragraph 3, where the competent authority has established a further restricted zone in accordance with Article 21(1), point (c), the measures applied in this further restricted zone shall also apply in the protection zone until the lifting of the measures applied in that further restricted zone.';
- in Article 43, paragraph 1 is replaced by the following:
  - '1. By way of derogation from prohibitions provided for in Article 42-and under the general conditions laid down in paragraphs 2 to 7 of this Article, the competent authority may authorise movements of animals and products: if the risk for the spread of the category A disease deriving from such movements is negligible, and if the general conditions laid down in paragraphs 2 to 7 of this Article are fulfilled:
    - (a) in the cases covered by provided for in Articles 44 to 54, and underin accordance with the specific conditions provided for laid down in those Articles; or
    - (b) obtained if the animals or products originate in compartments approved in accordance with Article 5 of Delegated Regulation (EU) 2024/2623 for the relevant category A disease and listed in Annex XI to Implementing Regulation (EU) 2021/620, and; ';
    - (e) after assessing the risk deriving from that authorisation as negligible for spreading the category A disease. ;
- (17) in Article 46 (1), point (b) is replaced by the following:
  - '(b) to any establishments, if they were hatched from eggs originating outside the restricted zone and if the hatchery of dispatch can ensure that no contact has occurred between those eggs and any other hatching eggs or day-old chicks obtained from animals kept within the restricted zone.'—;
- (18) in Article 49(1), point (a) is replaced by the following:
  - '(a) the fresh meat or the raw milk is moved to a processing establishment to undergo one of the relevant risk- mitigating treatments set out in Part I of Annex VII; or';
- (19) Article 51 is replaced by the following:

#### -Article 51

### Specific conditions for authorising movements of manure, including litter and used bedding, from establishments in the surveillance zone

- 1. The competent authority may authorise the movements of manure, including litter and used bedding, from establishments located in the surveillance zone:
  - (a) without processing, to a landfill, previously authorised for that purpose by the competent authority, located in the same surveillance zone; or
  - (b) following processing, to a landfill, previously authorised for that purpose by the competent authority, located in the territory of the same Member State.
- 2. The competent authority may authorise movements of manure, including litter and used bedding, from establishments and other locations in the surveillance zone to a plant approved for the processing or disposal of animal by-products where they are disposed of or processed by one of the harmonized methods in accordance with Regulation (EC) No 1069/2009 by the methods relevant for processing of manure provided for in Part II of Annex VII to this Regulation.';
- (20) in Article 52, point (c) is replaced by the following:
  - '(c) are intended for use within the restricted protection or surveillance zone; or '; or';
- (21) in Article 53, paragraph 2 is replaced by the following:
  - '2. The competent authority may authorise movements of products from establishments and other locations in the surveillance zone to a plant approved for the processing or disposal of animal by-products where they are disposed of or processed by one of the harmonised methods in accordance with Regulation (EC) No 1069/2009 by the relevant methods provided in Part II of Annex VII to this Regulation .';
- in Article 55, paragraph 1 is replaced and new paragraphs 3 and 4 are added as in by the following:
  - '1. The competent authority may lift the disease control measures applied in the surveillance zone pursuant to Sections 1 and 3 only if:
    - (a) the minimum period set out in Annex XI has elapsed after the date of completion of the preliminary cleaning and disinfection and, where relevant, the control of insects and rodents, is performed in accordance with Article 15 in the affected establishment;
    - (b) the requirements provided for laid down in Article 39(1), point (b), have been metcomplied with in the protection zone;
    - (c) a representative number of establishments keeping animals of listed species have undergone, with favourable results, visits carried out by official veterinarians, in accordance with Article 41, and;

- (d) the final cleaning and disinfection and, when relevant, the control of insects and rodents has been carried out in the affected establishment in accordance with at least the procedures set out in partpoints A and part C of Annex IV, using the appropriate biocidal products to ensure the destruction of the relevant category A disease agent.
- (23) in Article 55, the following paragraphs 3, 4 and 5 are added:
  - '3. After the lifting of the measures referred to in paragraph 1 of this Article, when the competent authority has established a further restricted zone in accordance with Article 21(1)), point (c), the measures implemented applied in this further restricted zone shall also apply in the surveillance zone until the lifting of the measures applied in the further restricted zone.
  - 4. In the exceptional circumstances Exceptionally, where due to delays in the completion of the final cleaning and disinfection as referred to in paragraph 1, point (1)(d) can only be completed with significant delays compared to a period of at least double the minimum period set out in Annex XI has elapsed after completion of the preliminary cleaning and disinfection, the competent authority may, after carrying out a risk assessment, lift the disease control measures applied in the surveillance zone, provided that:
    - (a) no other outbreak of the relevant category A disease has occurred in the restricted zone, since it has been established,
    - (b) the conditions set outlaid down in paragraph 1, points (a), (b) and (c) of paragraph (1) are fulfilled,
    - (c) appropriate <u>additional</u> biosecurity measures are applied in the affected establishment to prevent the risk of <u>the</u> spread of the category A disease agent,
    - (d) the risk assessment carried out by the competent authority indicates that the risk of spreadingthe spread of the category A disease is negligible. 2;
    - 5. Member States shall inform the other Member States and the Commission when the disease control measures applied in a surveillance zone established on their territory were lifted in accordance with point 4(d).';
- in Article 59(5) the introductory paragraphphrase is replaced by the following:
  - '5. Official veterinarians shall carry out at least a visit to the affected establishment on the last day of the monitoring period set out in Annex II for the relevant <u>category A</u> disease, calculated forwards from the date on which the animals were placed in the establishment, and in any case before 30 days have elapsed since that day when. Where the monitoring period <u>in accordance with Annex II</u> is longer than <u>that, performing30</u> days, the visit shall be carried out before 30 days elapsed from the date on which the animals were placed into the establishment. During the visits, the official veterinarians <u>shall perform</u> at least:';

- (25) in Article 61, paragraph 2 is replaced by the following:
  - '2. The competent authority shall lift all the disease control measures applied in the affected establishment in accordance with this Regulation when:
    - (a) the repopulation is considered finalised, as provided for in paragraph 15; or when
    - (b) the requirements set out<u>laid down</u> in Article 57 paragraphs (1 and 2) are fulfilled÷, either
      - (i) in <u>the</u> case of <u>the</u> cessation of activities related to the keeping of <u>the</u> animals by the operator or establishment concerned, or
      - (ii) in case a <u>specific</u> derogation <u>from Article 12(1)</u>, <u>point (a)</u>, in accordance with Article 13 has been granted in the affected establishment, and the animals of listed species have been subject with favourable <u>resultresults</u> to the examinations laid down in <u>Article 59(5)</u>, points (b) and (c) of <u>Article 59(5)</u>, carried out at the end of the monitoring period as <u>mentioned referred to</u> in Article 57 (21) point (b).';
- (26) in Article 75, point (b) is replaced by the following:
  - '(b) the movementmovements of aquatic animals in the vicinity of the suspected establishment;';
- (27) in Article 78(1), point (f) is replaced by the following:
  - '(f) all potentially contaminated materials or substances shall be isolated until:
    - (i) <u>the cleaning and disinfection measures</u> have been completed in accordance with the provisions in Article 80, in the case of materials and substances which are fit for cleaning and disinfection; and
    - (ii) they are removed from the establishment and disposed of under the supervision of official veterinarians, in the case of feeding stuff and other materials unfit for cleaning and disinfection.';
- (28) in Article 78, paragraph 5 is deleted;
- (29) Article 83 is replaced by the following:

#### 'Article 83

### <u>Placing on the market of products of animal origin from aquaculture</u> animals of listed species produced in infected establishments

- 1. When granting a derogation pursuant to in accordance with Article 78(3), the competent authority may allow the placing on the market of products of animal origin from aquatic animals only if the following conditions are fulfilled:
  - (a) fish must be slaughtered and eviscerated before dispatch;

- (b) molluscs and crustaceans must be fully traceable and processed to non-viable products unable to survive if returned to the water, before dispatch.When purification is required before processing and placing on the market, it shall be conducted at a disease control aquatic food establishment.
- 2. The products of animal origin referred to in paragraph 1 shall be intended for:
  - (a) direct supply to the final consumer; or
  - (b) for further processing in a disease control aquatic food establishment.';
- (30) in Article 90(2), point (a) is replaced by the following:
  - '(a) all movements must be carried out exclusively via designated routes, agreed with the competent authority, without unloading;'; or stopping for reasons other than the exchange or discharges of water as provided for in point (b);';
- in Article 99, paragraph 1 is replaced by the following:
  - '1. The competent authority shall prohibit any movements of aquaculture animals from establishments within the surveillance zone for slaughter, further keeping or release into the wild outside the surveillance zone.';
- in Article 99, paragraph 4 is replaced by the following:
  - '4. By way of derogation from paragraph 1, and in agreement with the competent authority at the place of destination, the competent authority may authorise movements of aquaculture animals, other than for release into the wild, provided that appropriate biosecurity measures to prevent the spread of the category A disease, are applied.';
- (33) Annexes I, II, IV to XII and XV are amended in accordance with the Annex to this Regulation.
  - "Classical swine fever (CSF)" is replaced by '25 days';
- 30. Annex IV is amended as follows:
  - (a) the title is replaced by the following:

### 'PROCEDURES FOR CLEANING, DISINFECTION AND WHEN NECESSARY CONTROL OF INSECTS AND RODENTS

(as referred to in Articles 12, 15, 16, 39, 45, 55 and 57 of (b) point (e) of part B is replaced by the following:

- '(e) the disinfectant must remain on the treated surface for at least 24 hours, except otherwise indicated by the manufacturer as maximum required contact time;';
- (c) point (i) of paragraph 1(a) of part C is replaced by the following:

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- '(i) undergo a steam treatment at a temperature of at least 70 °C for a minimum period of 60 minutes; ';
- 31. ANNEX V is replaced by Annex II to this Regulation;
- 32. ANNEX VI is replaced by Annex III to this Regulation;
- 33. ANNEX VII is replaced by Annex IV to this Regulation;
- 34. in ANNEX VIII, the treatment in the last row of the table is replaced by the following:
  - 'Storage in package or bales under shelter at premises situated not closer than 2 km to the nearest outbreak and releasing from the premises do not take place before at least four months have elapsed following the completion of cleaning and disinfection according to Article 15';
- 35. ANNEX IX is replaced by Annex V to this Regulation;
- 36. ANNEX X is replaced by Annex VI to this Regulation;
- 37. ANNEX XI is replaced by Annex VII to this Regulation;
- 36. in ANNEX XII, points (a) and (b) of paragraph (1) are replaced by the following:
  - '(a) the clinical examination and the sampling for laboratory examinations must include, as relevant:
    - (i) aquaculture animals of listed species showing clinical signs of the relevant category A disease;
    - (ii) aquaculture animals likely to have recently died from the suspected or confirmed category A disease; or
    - (iii) aquaculture animals suspected of being infected due to an epidemiological link to a suspected or confirmed case of a category A disease, or based on other circumstances;
  - (b) the minimum number of samples to be collected is:

-	Scenario		
Type of animals	Report of increased mortality	Post-mortem or clinical signs observed	Suspicion based on epidemiological link or other circumstances
Molluses (the whole animal)	<del>30</del>		150
Crustaceans	30	10	150
Fish	30	10	150

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in ANNEX XV, Table 2 is replaced by the table set out in Annex VIII to this Regulation.

#### Article 2

Corrections to Delegated Regulation (EU) 2020/687

Delegated Regulation (EU) 2020/687 is corrected as follows:

1. Title of Article 15 is replaced by the following:

'Cleaning and disinfection and control of insects and rodents in the affected establishment';

- Title of Article 16 is replaced by the following:
  - 'Derogations and special rules for the cleaning and disinfection and control of vectors';
- the title of Chapter III of Part II is replaced by the following: (1)
  - 'Repopulation with terrestrial animals of the affected establishment and lifting of disease control measures in the affected establishment';
- the title of Article 58 is replaced by the following: (2)
  - 'Derogation from the requirements provided for in Article 57(1)(), point (b)';
- the title of Section 2, Chapter I of Part III is replaced by the following: (3)
  - 'Disease control measures in the event of official confirmation of a category A disease in aquaculture animals';
- in Article 85(2), the introductory sentence is replaced by the following:
  - The extent of the zones shall be set on a case-by-case basis, taking into account factors influencing the risk of spreading the disease. To that end, the competent authority shall consider the following data and criteria: ';
- in Article 85(4), point (b) is replaced by the following: **(4)** 
  - '(b) establish a restricted zone consisting of a protection zone without any adjacent surveillance zone; or';
- (5) in Article 90, paragraph 1 is replaced by the following:
  - By way of derogation from the prohibitions provided for in Article 89(1), the competent authority may authorise the movement and transport of aquatic animals and products [thereof?] in the cases covered by referred to in Articles 91-to, 92 and 93 under the specific conditions provided for in those Articles and the general conditions laid down in paragraph 2 of this Article.';
- (6) in Article 99, paragraph (2) is replaced by the following:

- '(2) The competent authority shall ensure that any transport of aquaculture animals of listed species within or into the surveillance zone shall be conducted under carried out in accordance with the conditions as set outlaid down in Article 90, paragraph (2), points (a) to (e), and in Article 91.';
- (7) the title of the Article 103 is replaced by the following:

## 'Measures in the event of official confirmation of a category A disease in wild aquatic animals of listed species';

- (8) in Article 104-(1), point (e) is replaced by the following:
  - '(e) prohibit bringing into establishments keeping aquaculture animals of listed species, within the infected zone, any parts of aquatic animals of listed species whether fished, caught, collected or found dead in the infected zone, as well as any product, material or substance, which is likely to be contaminated with a category A disease.'.

## Article 3 Transitional provisions

The marks to be applied to fresh meat as described referred to in Annex IX to Delegated Regulation (EU) 2020/687, as laid down in the version of that Delegated Regulation, before the amendments made by this Delegated Regulation, may continue to be used until 31 December 2028, and the products of animal origin fresh meat with such marks applied before that date may remain on the market.

# Article 4 Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

\_This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission The President Ursula VON DER LEYEN

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