

Proposed amendment to Commission Implementing Regulation (EU) 2020/687 as regards rules for the prevention and control of certain listed diseases.

Date: April 24th 2024

The Poultry Veterinary Study Group Europe (PVSGE) welcomes the opportunity to comment on the above topic.

The PVSGE is a formally constituted group of about 90 European specialised poultry veterinarians, with practical responsibility for the health, welfare, production and food safety aspects of most European poultry production. PVSGE has existed for over 50 years and the members are mostly working as private practitioners or are sometimes working for a company (breeding companies, integrations, hatcheries, pharmaceutical companies). Full-time government veterinarians are not eligible for membership. The following 23 countries are currently represented in the PVSGE: Austria, Belgium, Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Germany, Great Britain, Greece, Hungary, Ireland, Italy, Latvia, Netherlands, Norway, Poland, Portugal, Romania, Spain, Sweden, Switzerland. This document has been prepared by the PVSGE Legislation Working Group.

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Background

From 2006 to April 2021 measures for the control of avian influenza were laid down in Council Directive 2005/94^[1]. Detailed measures were laid down for protection zones and surveillance zones. Articles 29 and 31 laid down the duration of actions in zones as respectively 21 days (protection) and 30 days (surveillance), timing of the lifting of these zones from completion of preliminary cleaning and disinfection of infected holdings. This directive was replaced on 21/04/2021 by the general Animal Health Law^[2], and a supplemental commission delegated regulation 2020/687^[3] (DR687) dealing with rules for the prevention and control of the listed animal diseases. The rules are not specific to avian diseases but lay down general principles which affect control measures. Both Avian Influenza and Newcastle disease are included as listed diseases to which this regulation applies. The existing legislation is clear, in articles 39 and 55, that the intention was that zonal restrictions around cases would be lifted at 30 days after 'preliminary cleaning and disinfection' of the final case assuming no further cases were identified in the zones as a result of the required surveillance. The purpose of preliminary C&D is to avoid the spread of the Category A disease (DR687 Annexe IV para B) and thus should be equivalent to completion of the stamping out process as required by WOAH. It is equally clear that restocking on affected sites under EU regulations requires the enhanced 'secondary cleaning and disinfection' which requires the removal of litter or manure, and 2 process of disinfection separated by 7 days. Here we focus on the specific proposal made but we must recognise that decisions made in relation to this are very likely to impact the area of trade with third countries if they constrain the ability of EU countries in the closure of disease events for WOAH purposes. Reports to WOAH and notifications of country freedom have no impact on intra-EU trade and so should continue to be governed by the principle of subsidiarity^[4]. Inconsistencies may arise between countries in relation to such reporting but this is a matter for discussion between stakeholders and their respective competent authorities and within WOAH.

Proposal

Amendment proposed by the EU Commission in December 2023

Change of Article 55(1) of DR687:

To introduce new point (d) adding the condition to complete final cleaning and disinfection before lifting disease control measures.

The justification given is "Add clarity and ensure consistency with Article 68 of $AHL^{[3]}$. This article deals with "Maintaining disease control measures in restricted zones and delegated acts" and states in sub-para 1(b)

"the **final** cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures has been carried out as appropriate for:

- (i) the listed disease referred to in point (a) of Article 9(1) for which the disease control measures havebeen applied;
- (ii) the affected species of kept animals;
- (iii) the type of production "

Our Position

The PVSG strongly opposes the proposed change in Art 55 of DR687, given the success, over many years, of lifting zonal restrictions based on **preliminary C&D**.

This proposal would, in fact, be inconsistent with article 39(1) of the same regulation. The real problem, we believe, lies with the inclusion of 'final' in relation to cleaning in Article 68 of the AHL^[2] sub-para 1(b)

We would like to emphasize that affected sites after preliminary C&D are not producing significant disease risk, since viruses do not grow in the absence of a host. In relation to the listed poultry diseases the affected sites are fully depopulated and so cannot contribute to any risk of spread (intra-EU or to 3rd country) of disease via products. It should also be noted that if EU-mandated control zones remain in place longer than necessary this sends a message to trading partners that the disease has not been effectively controlled, as well as making it difficult for member state competent authorities to properly comply with their obligations under the WOAH Terrestrial Code to ensure "the safety of international trade in animals and animal products, while avoiding unjustified sanitary barriers" [5].

Our members would like, as an alternative to the Commission proposal, to call on the Commission to add a sub-paragraph to article 55, as follows: "d. Completion of preliminary cleaning and disinfection is regarded as the completion of the stamping out process, but movement restrictions must continue to be applied to the affected property, and any susceptible animals and type of production on it, until completion of final cleaning and disinfection." Furthermore we propose the deletion of 'final' from Article 68, sub-para's 1(b) and 2(a) of the AHL to remove the current inconsistency. Poultry farmers around the EU have experienced serious implications for several years due to HPAI, in part as a result of the control mechanisms implemented under EU law. Where there is a complete ban for placing of day old chicks or hatching eggs for on farm hatching within 3 km, an outbreak does indeed cause serious economic damage to the farms/farmers situated within a zone. The current 21/30 days restrictions after preliminary C&D are more than sufficient for disease control purposes. This Commission proposal could easily extend zonal restrictions for 1-3 months, and sometimes much longer (depending on the type of farm and difficulty of achieving secondary C&D to the satisfaction of the competent authority), exacerbating the economic damage of the disease, for negligible benefit.

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Appendix 1 - Relevant legislation Extracts

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')

Article 68

- 1. The competent authority shall continue to apply the disease control measures provided for in this Section until the following conditions are met:
- (b) "the **final** cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures has been carried out as appropriate for:
- (i) the listed disease referred to in point (a) of Article 9(1) forwhich the disease control measures have been applied;
- (ii) the affected species of kept animals;
- (iii) the type of production "
- 2. The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules for the disease control measures to be taken by the competent authority, as provided for in paragraph 1, in relation to:
- (a) the **final** procedures for cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures and, where appropriate, the use of biocidal products for those purposes;

COMMISSION 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^[2]

Section 2

Disease control measures in the event of the official confirmation of a category A disease in kept animals

Article 15

Preliminary cleaning and disinfection and control of insects and rodents in the affected establishment

- 1. Immediately after the completion of the measures provided for in Article 12, and when relevant in Article 14, the competent authority shall order and supervise a preliminary cleaning and disinfection and, when relevant, control of insects and rodents, in the affected establishment in order to avoid spreading of the category A disease.
- 2. The preliminary cleaning, disinfection and control referred to in paragraph 1 shall be:
- (a) performed in accordance with the procedures set out in points A and B of Annex IV using theappropriate biocidal products to ensure destruction of the relevant category A disease agent; and
- (b) adequately documented.

- 3. When the competent authority grants one of the derogations provided for in Article 13(2) and (4), itshall order the preliminary cleaning, disinfection and the control referred to in paragraph 1 adapting the procedures referred to in point 2(a) to the specific situation without detriment to the control of spreading of the category A disease from the affected animals and affected establishments and locations to other unaffected animals or to humans.
- 4. In addition to the measures referred to in paragraphs 1 and 2, the competent authority shall orderand 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

Article 16

Derogations and special rules for the preliminary cleaning and disinfection and control of vectors

The competent authority may grant derogation to the requirement regarding cleaning and disinfection and control of insects and rodents set out in Article 15 in the case of:

- (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.

Section 1

General disease control measures in the restricted zone

Section 2

Disease control measures in the protection zone

Article 39

Duration of the disease control measures in the protection zone

- 1. The competent authority may lift the measures provided for in Section 1 and 2 of this Chapter only if the minimum period set out in Annex X has elapsed and the following conditions are fulfilled:
- (a) the preliminary cleaning and disinfection and, where relevant, control of insects and rodents, hasbeen performed in accordance with Article 15 in the affected establishment; and
- (b) in all establishments keeping animals of listed species in the protection zone, animals of listedspecies have undergone,

with favourable results, clinical and when necessary laboratory examinations in accordance with Article 26.

2. Where the relevant category A disease is transmitted by a listed vector, as referred to in Regulation (EU) 2018/1882,

the competent authority may:

- (a) establish the duration of the measures in the protection zone on a case by case basis, taking into account any factor influencing the risk of the disease spreading; and
- (b) provide for the introduction of sentinel animals.
- 3. After the lifting of the measures referred to in paragraph 1, the measures provided for in Section 3 of this Chapter shall apply in the protection zone for at least the additional period set out in Annex X.

CHAPTER III

Repopulation with terrestrial animals of establishments in restricted zones Article

57

Conditions to authorise the repopulation of the affected establishment

1.

The competent authority shall only authorise the repopulation of the affected establishment if the following requirements are met:

- (a) a final cleaning and disinfection and, when relevant, control of insects and rodents has been:
- (i) carried out, in accordance with the procedures set out in points A and C of Annex IV, using the appropriate biocidal products to ensure destruction of the relevant category A disease agent; and (ii) adequately documented;
- (b) the monitoring period set out in Annex II for the relevant disease, calculated forwards from the date on which the final cleaning and disinfection provided for in point (a) was carried out, has elapsed.
- 2. The competent authority shall supervise that the final cleaning and disinfection and, when relevant, control of insects and rodents in the affected establishment is carried out in compliance with the requirements in paragraph 1(a).
- 3. The competent authority shall not allow access to a pasture of kept animals of listed species during the period of time during which it is considered contaminated; this period of time shall be established after carrying out a risk assessment.
- 4. Where for duly justified reasons the final cleaning and disinfection and, when relevant, the control of insects and rodents referred to in paragraph 1, have not been entirely accomplished in the affected establishment, the competent authority may authorise the repopulation by way of derogation from paragraph 1, provided that:
- (a) a period of at least 3 months has elapsed since the preliminary cleaning and disinfection, as referred to in Article 15, was performed; and
- (b) prior to granting the authorisation, the competent authority has assessed the risks deriving from that authorisation and the assessment indicates that the risk of spreading the category A disease is negligible.

Annex IV para B

Preliminary cleaning and disinfection

For preliminary cleaning and disinfection under Article 15, to avoid spreading the category A disease:

- (a) entire bodies or parts of dead kept animals of listed species must be sprayed with disinfectant andremoved from the establishment, in closed and leak-proof vehicles or containers for processing and disposal;
- (b) any tissue or blood which may have been spilled during killing, slaughter or post-mortem examination must be carefully collected and disposed of;
- (c) as soon as the entire bodies or parts of dead kept animals of listed species have been removed forprocessing or disposal, the parts of the establishment in which these animals were kept and any parts of other buildings, surfaces or equipment contaminated during killing or post-mortem examination must be sprayed with disinfectant;
- (d) manure, including litter and used bedding, must be thoroughly soaked with disinfectant;
- (e) the disinfectant must remain on the treated surface for at least 24 hours;
- (f) equipment, containers, consumption utensils, surfaces or any material likely to becontaminated after the washing and disinfecting must be destroyed.

ANNEX IV

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

(as referred to in Articles 12, 15, 16, 39, 45 and 57 of this Regulation)

- A. General requirements
- 1. The choice of biocidal products and procedures for cleaning and disinfection operations must take into account:
- (a) the causal agent of infection;
- (b) the nature of the establishments, vehicles, objects and materials which are to be treated; and
- (c) the applicable legislation.
- 2. The conditions under which biocidal products are used must ensure that their efficacy is not impaired. In particular technical parameters provided by the manufacturer, such as pressure, temperature, required contact time or storage must be observed. The activity of the disinfectant must not be compromised by interaction with other substances.
- 3. Re-contamination of the previously cleaned parts must be avoided, in particular where washing iscarried out with liquids applied under pressure.
- 4. The water used for cleaning operations must be contained and disposed of in a way that avoids anyrisk of spreading category A disease agents.
- 5. Biocidal products must be used in a way that reduces as much as possible any adverse impact on on the environment and on public health that may arise from their use.
- B. Preliminary cleaning and disinfection

For preliminary cleaning and disinfection under Article 15, to avoid spreading the category A disease:

- (a) entire bodies or parts of dead kept animals of listed species must be sprayed with disinfectant andremoved from the establishment, in closed and leak-proof vehicles or containers for processing and disposal;
- (b) any tissue or blood which may have been spilled during killing, slaughter or post-mortem examination must be carefully collected and disposed of;
- (c) as soon as the entire bodies or parts of dead kept animals of listed species have been removed forprocessing or disposal, the parts of the establishment in which these animals were kept and any parts of other buildings, surfaces or equipment contaminated during killing or post-mortem examination must be sprayed with disinfectant;
- (d) manure, including litter and used bedding, must be thoroughly soaked with disinfectant;
- (e) the disinfectant must remain on the treated surface for at least 24 hours;
- (f) equipment, containers, consumption utensils, surfaces or any material likely to be contaminated after the washing and disinfecting must be destroyed. C. Final cleaning and disinfection:

For final cleaning and disinfection for the purpose of Article 57:

- 1. Manure, including litter and used bedding, must be removed and treated as follows:
- (a) the solid phase of manure, including litter and used bedding, must either:
- (i) undergo a steam treatment at a temperature of at least 70 °C;
- (ii) be destroyed by burning;
- (iii) be buried deep enough to prevent access by animals; or
- (iv) be stacked to heat, sprayed with disinfectant and left for at least 42 days, during which the stackmust be either covered or re-stacked to ensure thermic treatment of all layers;
- (b) the liquid phase of manure must be stored for at least 42 days, and in the case of highly pathogenic avian influenza 60 days, after the last addition of infective material.
- 2. Buildings, surfaces and equipment must be thoroughly washed and cleaned by removing the remaining grease and dirt and sprayed with disinfectants.
- 3. After 7 days the establishments must be cleaned and disinfected again.

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