



Council of the
European Union

**Brussels, 14 July 2023
(OR. en)**

11834/23

**AGRILEG 140
VETER 77
DELECT 98**

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	10 July 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

No. Cion doc.:	C(2023) 4572 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 10.7.2023 amending Delegated Regulation (EU) 2020/689 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

Delegations will find attached document C(2023) 4572 final.

Encl.: C(2023) 4572 final



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

of 10.7.2023

amending Delegated Regulation (EU) 2020/689 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')¹ lays down rules for the prevention and control of diseases that are transmissible to animals or humans, including rules for surveillance, for Union surveillance programmes, for the approval by the Commission of disease-free status and for the maintenance of disease-free status. It also empowers the Commission to adopt rules to supplement certain non-essential elements of that Regulation by means of delegated acts.

The Commission laid down such rules in 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 diseases².

Delegated Regulation (EU) 2020/689 applies from 21 April 2021. Since that date, the experience gained in its application and the evolution of the epidemiological situation as regards certain animal diseases in the Union has shown the need to refine a number of its provisions. Therefore, this draft Commission Delegated Regulation amends or clarifies certain provisions as regards the following:

- supplementing the surveillance rules to allow competent authorities to implement surveillance in animal species that are currently not included in the design of the surveillance programmes; this amendment will further enable and support competent authorities to conduct structured surveillance for highly pathogenic avian influenza (HPAI) in mammals as appropriate and it is intended to better address the objective of contributing to increased knowledge on HPAI posing a potential zoonotic risk provided for in the Union surveillance programme laid down in Section 2 of Part I of Annex II to Regulation (EU) 2020/689;
- making it possible to obtain disease-free status based on historical and surveillance data without time limitation for all relevant listed diseases;
- fine tune the rules to maintain non-vaccination status for infection with Newcastle disease virus.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission consulted with members of the Expert Group on Animal Health (E00930) concerning the contents of this draft Delegated Regulation at a meeting that took place on 30 March 2023.

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 Article 29, points (a) and (d), Article 37(5), Article 39 and Article 41(3) thereof.

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¹ OJ L 84, 31.3.2016, p. 1.

² OJ L 174, 3.6.2020, p. 211.

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

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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')³, and in particular Article 29, points (a) and (d), Article 37(5), Article 39 and Article 41(3) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases which are transmissible to animals or humans, including rules for surveillance, for Union surveillance programmes, for approval by the Commission of disease free-status and for the maintenance of disease-free status.
- (2) Commission Delegated Regulation (EU) 2020/689⁴ supplements the rules on surveillance, eradication programmes and disease-free status for certain listed diseases and emerging diseases of terrestrial, aquatic and other animals laid down in Regulation (EU) 2016/429.
- (3) In accordance with Delegated Regulation (EU) 2020/689, the competent authorities are required to specify the targeted animal populations relevant for different types of surveillance. In addition, Delegated Regulation (EU) 2020/689 specifies the categories of animals that should be subject to surveillance. In the context of the current highly pathogenic avian influenza (HPAI) epizootics, the scientific report of the European Food Safety Authority on Avian influenza overview December 2022 – March 2023, published on 20 March 2023⁵, recommended to extend and enhance surveillance in both wild mammals, particularly in carnivores, and farmed animals, particularly in American mink, in higher risk areas where HPAI is present in wild birds and poultry. Mammal species are not included in the categories subject to surveillance provided for in Delegated Regulation (EU) 2020/689. Therefore, the existing provisions related to targeted species and avian influenza surveillance should be amended to address this recommendation as regards the risk posed by the current HPAI H5N1 and further enable and support competent authorities to conduct structured surveillance for HPAI in certain mammal species as appropriate.

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³ OJ L 84, 31.3.2016, p. 1.

⁴ 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 (OJ L 174, 3.6.2020, p. 211).

⁵ EFSA Journal 2023;21(3): 7917

- (4) Delegated Regulation (EU) 2020/689 provides for different pathways to obtain disease-free status. For several diseases, it is not possible to obtain that status without having previously implemented an approved eradication programme, as Member States cannot follow the pathway based on historical and surveillance data, due to certain limitations which apply concerning the diseases which may be subject to that pathway, as well as the limited timeframe within which such applications to obtain the status should be made. The experience gained since the date of application of Delegated Regulation (EU) 2020/689 has shown that this approach is not adequate as it does not necessarily provide additional reassurances for the granting of the disease-free status. Therefore, Delegated Regulation (EU) 2020/689 should be amended to provide the possibility for a Member State to obtain the disease-free status for all relevant diseases based on historical and surveillance data and without a time limitation.
- (5) Delegated Regulation (EU) 2020/689 provides for several requirements to maintain the status free from infection with Newcastle disease virus without vaccination. The experience gained since the date of application of Delegated Regulation (EU) 2020/689 has shown that the relevant provisions require further clarification as regards the applicable criteria.
- (6) Therefore, for the sake of legal certainty and clarity, Delegated Regulation (EU) 2020/689 should be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1
Amendments to Delegated Regulation (EU) 2020/689

Delegated Regulation (EU) 2020/689 is amended as follows:

1. in Article 4, the following paragraph 3 is added:
 - ‘3. The competent authority shall include in the targeted animal population kept or wild animals of species that are not listed for the purpose of the relevant listed disease when the competent authority considers that they constitute a risk for animal and human health.’;
2. in Article 70 paragraphs 4, 5 and 6 are deleted.
3. in Article 76, paragraphs 3 and 4 are deleted.
4. Annexes II and V to Delegated Regulation (EU) 2020/689 are amended in accordance with the Annex to this Regulation.

Article 2
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, 10.7.2023

For the Commission
The President
Ursula VON DER LEYEN