COMMISSION IMPLEMENTING REGULATION (EU) 2021/934 of 9 June 2021

laying down special control measures for classical swine fever

(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') (1), and in particular Article 71(3) thereof,

Whereas:

- (1) Classical swine fever is an infectious viral disease affecting kept and wild porcine animals and can have a severe impact on the concerned animal population and the profitability of farming causing disturbance to movements of consignments of those animals and products thereof within the Union and exports to third countries. The spread of the disease can significantly affect the productivity of the farming sector due to both direct and indirect losses.
- (2) Commission Implementing Decision 2013/764/EU (²) lays down animal health control measures in relation to classical swine fever in the Member States and it has been amended several times to take account mainly of developments in the epidemiological situation in the Union as regards that disease. It applies until 21 April 2021.
- (3) Regulation (EU) 2016/429 establishes a new legislative framework for the prevention and control of diseases, which are transmissible to animals or humans. Classical swine fever is listed under Article 5(1)(a)(ii) of that Regulation, and is subject to the disease prevention and control rules laid down therein. In addition, Annex II to Commission Implementing Regulation (EU) 2018/1882 (³) lists classical swine fever as a Category A, D and E disease affecting Suidae and Tayassuidae, while Commission Delegated Regulation (EU) 2020/687 (⁴) supplements the rules for the control of Category A, B and C diseases laid down in Regulation (EU) 2016/429, including disease control measures for classical swine fever. Those three acts apply from 21 April 2021.
- (4) It is necessary to align the current Union control measures for classical swine fever laid down in Implementing Decision 2013/764/EU with the new legislative framework for animal health established by Regulation (EU) 2016/429. It is also necessary to align Union rules as much as possible with international standards, such as those set out in Chapter 15.2 'Infection with classical swine fever virus' of the Terrestrial Animal Health Code of the World Organization for Animal Health (5) (OIE Code).
- (5) The overall situation of classical swine fever in the Member States concerned by that disease, both on an epidemiological and risk management level, poses a persistent risk for its possible further spread in the Union. The general disease control measures laid down in Regulation (EU) 2016/429 and in Delegated Regulation (EU) 2020/687 do not cover all specific details and aspects in relation to the spread and the epidemiological situation of classical swine fever. It is therefore appropriate to lay down special disease control measures for a limited period of time, under conditions appropriate to the situation of classical swine fever in the Union, in order to ensure that the necessary measures are implemented in an uniform manner in the Union whenever there is a risk for the spread of that disease.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Commission Implementing Decision 2013/764/EU of 13 December 2013 concerning animal health control measures relating to classical swine fever in certain Member States (OJ L 338, 17.12.2013, p. 102).

⁽³⁾ 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).

^(*) 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).

⁽⁵⁾ OIE Terrestrial Animal Health Code, 28th Edition, 2019.

- (6) Regulation (EU) 2016/429 defines an outbreak as the officially confirmed occurrence of a listed disease or an emerging disease in one or more animals in an establishment or other place where animals or kept or located. The rules laid down in this Regulation should take account of whether or not the outbreak of classical swine fever occurred in wild or kept porcine animals.
- (7) This Regulation should provide for a regionalisation approach, which should apply in addition to the disease control measures laid down in Delegated Regulation (EU) 2020/687. This Regulation should list the restricted zones of the Member States concerned by classical swine fever in order to maintain the regionalisation approach established by Implementing Decision 2013/764/EU.
- (8) As regards risks for the spread of classical swine fever, movements of consignments of porcine animals and different porcine commodities pose different levels of risk. As a general rule, movements of consignments of kept porcine animals, germinal products and animal by-products of porcine origin from restricted zones pose a higher level of risk in terms of exposure and consequences, than movements of consignments of products of animal origin, including in particular fresh meat and meat products. Therefore, movements of consignments of kept porcine animals and various high-risk products of porcine origin from the restricted zones listed in Annex I to this Regulation should be prohibited in a manner proportionate to the risk involved, and taking into account the rules laid down in Delegated Regulation (EU) 2020/687 and in Commission Delegated Regulation (EU) 2020/2154 (6).
- (9) The rules laid down in Commission Delegated Regulation (EU) 2020/686 (7) supplement Regulation (EU) 2016/429 as regards the approval of germinal product establishments, the registers of germinal product establishments to be kept by the competent authorities, the record-keeping obligations of operators, the traceability and animal health requirements, and animal health certification and notification requirements for movements within the Union of consignments of germinal products of certain kept terrestrial animals in order to prevent the spread of transmissible animal diseases within the Union by those products. Therefore, the rules laid down in this Regulation should refer to Commission Delegated Regulation (EU) 2020/689 (8), as regards the information required to be kept by the competent authorities of approved germinal product establishments for porcine animals.
- (10) Regulation (EC) No 1069/2009 of the European Parliament and of the Council (°) lays down animal health rules for animal by-products in order to prevent and minimise risks to animal health arising from those by-products. In addition, Commission Regulation (EU) No 142/2011 (¹º) lays down certain animal health rules for animal by-products falling within the scope of Regulation (EC) No 1069/2009, including rules regarding the certification requirements for movements of consignments of animal by-products in the Union. Those legal acts do not cover all specific details and aspects in relation to the risk of the spread of classical swine fever through animal by-products obtained from kept and wild porcine animals in the restricted zones listed in Annex I to this Regulation. It is therefore appropriate to lay down in this Regulation special disease control measures for animal by-products and movements of consignments of such by-products from restricted zones listed in Annex I to this Regulation, in order to ensure that the necessary measures are implemented in an uniform manner in the Union whenever there is a risk for the spread of that disease.
- (11) In order to avoid any unnecessary disturbances to trade, it is appropriate to lay down certain conditions and derogations from the prohibitions provided for by this Regulation. The derogations should also take into account the general rules for the prevention and control of animal diseases laid down in Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/687, and the principles of the OIE Code as regards risk mitigation measures for classical swine fever.
- (6) Commission Delegated Regulation (EU) 2020/2154 of 14 October 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards animal health, certification and notification requirements for movements within the Union of products of animal origin from terrestrial animals (OJ L 431, 21.12.2020, p. 5).
- (7) Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals (OJ L 174, 3.6.2020, p. 1).
- (8) 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).
- (°) 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).
- (10) 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 by-products 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).

- (12) Article 143 of Regulation (EU) 2016/429 provides that animal health certificates should accompany the movements of consignments of animals, including kept porcine animals. Where derogations from the prohibition on movements of consignments of kept porcine animals from the restricted zones listed in Annex I to this Regulation are applied to such consignments intended for intra-Union movements, those animal health certificates should include a reference to this Regulation, to ensure that adequate and accurate animal health information is provided in those animal health certificates. It is necessary to mitigate the risks arising from movements of consignments, and movements for private use, of fresh meat, meat products and any other products of animal origin obtained from wild porcine animals, bodies of wild porcine animals, which are intended for human consumption, and wild porcine animals from restricted zones listed in Annex I to this Regulation within the same Member State concerned and to other Member States. Risks for the spread of disease should be reduced by prohibiting movements of those products and movements of wild porcine animals by operators as laid down in Article 101 of Commission Delegated Regulation 2020/688 (11) within and from Member States concerned and to other Member States.
- (13) Article 167(1)(b) of Regulation (EU) 2016/429 provides that animal health certificates issued by the competent authority of the Member State of origin are to accompany consignments of products of animal origin, including those of porcine origin, that are allowed to be moved from a restricted zone established in accordance with Article 71(3) of that Regulation subject to certain disease control measures. Where this Regulation provides for derogations from prohibitions on movements of consignments of products of animal origin from the restricted zones listed in Annex I hereto, the accompanying animal health certificates should include a reference to this Regulation, so as to ensure that adequate and accurate health information is provided in accordance with Delegated Regulation (EU) 2020/2154.
- (14) Movements of consignments of fresh or processed meat and meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I to this Regulation, or kept outside those restricted zones but slaughtered in them, should be subject to less stringent certification requirements in order to avoid any unnecessary and overly burdensome trade restrictions. It should be possible to authorise movements of those consignments within the territory of the same Member State and to other Member States based on the health or identification marks applied in establishments, provided that those establishments are designated in accordance with rules laid down in this Regulation. The competent authorities should only designate establishments if the kept porcine animals and products thereof that are eligible for movements outside such restricted zones are clearly separated from those animals and products that are not eligible for such authorised movements.
- (15) In addition, in specific situations, fresh meat from kept porcine animals should be marked in accordance with the requirements for the marking of fresh meat from protection and surveillance zones set out in Annex IX to Delegated Regulation (EU) 2020/687 or the fresh meat and meat products, including casings, from kept porcine animals should be marked with special marks. These special marks should not be confused with the health mark referred to in Article 48 of Commission Implementing Regulation (EU) 2019/627 (12) or the identification mark provided for in Article 5(1), point (b), of Regulation (EC) No 853/2004 of the European Parliament and of the Council (13).
- (16) Certain risk mitigation measures and reinforced biosecurity measures are necessary in order to prevent and control classical swine fever in establishments of kept porcine animals. Those measures should be laid down in the Annex II to this Regulation and should cover establishments subject to derogations for movements of consignments of porcine animals kept in the restricted zones listed in Annex I hereto. These measures should addresses procedures and infrastructures in place in establishments of kept porcine animals; they should also address the risk of animals (other than the kept pigs) roaming in the premises and buildings. This risk is higher when related to wild porcine animals entering the premises and buildings. When other species are involved (pets or pests), acting as fomites, the risk is still present and should be addressed as well.

⁽¹¹⁾ Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (OJ L 174, 3.6.2020, p. 140).

⁽¹²) 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).

⁽¹³⁾ 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).

- (17) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (Withdrawal Agreement), and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, Regulation (EU) 2016/429, as well as the Commission acts based on it, apply to and in the United Kingdom in respect of Northern Ireland after the end of the transition period provided for in the Withdrawal Agreement. Therefore, references to Member States in this Regulation should include the United Kingdom in respect of Northern Ireland.
- (18) As Regulation (EU) 2016/429 applies with effect from 21 April 2021, this Regulation should apply from the third day following that of its publication in the Official Journal of the European Union in order to apply the measures in a timely manner.
- (19) This Regulation should apply for a period of at least five years taking into account the Union's experience in the fight against classical swine fever and the current epidemiological situation and disease management measures in place for this disease in the Member States concerned by that disease. The duration of these measures and the restricted zones listed in Annex I to this Regulation should be monitored and reviewed when new elements appear.
- (20) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

- 1. This Regulation lays down:
- (a) special disease control measures regarding classical swine fever to be applied for a limited period of time by the Member States (14) which have restricted zones listed in Annex I to this Regulation (the Member States concerned).
 - Those special disease control measures apply to kept and wild porcine animals and to products of animal origin, germinal products and animal by-products obtained from porcine animals, and are in addition to the measures applicable for the protection and surveillance of the restricted and infected zones established by the competent authorities of the Member States concerned in accordance with Article 21(1) and Article 63 of Delegated Regulation (EU) 2020/687.
- (b) special disease control measures regarding classical swine fever to be applied for a limited period of time by all Member States.
- 2. This Regulation applies to:
- (a) the movements of consignments from the restricted zones listed in Annex I of:
 - (i) porcine animals kept in establishments located in restricted zones listed in Annex I;
 - (ii) germinal products, products of animal origin and animal by-products obtained from kept porcine animals referred to in point (a)(i);

⁽¹⁴⁾ In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Regulation references to Member States include the United Kingdom in respect of Northern Ireland.

- (b) the movements of:
 - (i) consignments of wild porcine animals in the Member States concerned;
 - (ii) consignments and movements for private use by hunters of products of animal origin and animal by-products obtained from wild porcine in the restricted zones listed in Annex I or processed in establishments located in those restricted zones;
- (c) food business operators handling consignments referred to in points (a) and (b).
- 3. The disease control measures referred to in paragraph 1 cover the following:
- (a) Chapter II lays down special rules for the establishment of restricted zones listed in Annex I in the event of an outbreak of classical swine fever;
- (b) Chapter III lays down special disease control measures applicable to consignments of porcine animals kept in restricted zones listed in Annex I and products obtained thereof in the Member States concerned;
- (c) Chapter IV lays down special risk-mitigating measures for food businesses in the Member States concerned;
- (d) Chapter V lays down special disease control measures applicable to wild porcine animals in the Member States concerned;
- (e) Chapter VI lays down the final provisions.

Definitions

For the purposes of this Regulation, the definitions laid down in Delegated Regulation (EU) 2020/687 shall apply.

In addition, the following definitions shall apply:

- (a) 'porcine animal' means an animal of the species of ungulates of the family *Suidae* listed in Annex III to Regulation (EU) 2016/429;
- (b) 'germinal products' means porcine semen, oocytes and embryos obtained from kept porcine animals for artificial reproduction;
- (c) 'Category 2 materials' means animal by-products referred to in Article 9 of Regulation (EC) 1069/2009 obtained from kept porcine animals;
- (d) 'Category 3 materials' means animal by-products referred to in Article 10 of Regulation (EC) 1069/2009 obtained from kept porcine animals.

CHAPTER II

SPECIAL RULES FOR THE ESTABLISHMENT OF RESTRICTED ZONES IN THE EVENT OF AN OUTBREAK OF CLASSICAL SWINE FEVER AND THE APPLICATION OF SPECIAL DISEASE CONTROL MEASURES IN ALL MEMBER STATES

Article 3

Special rules for the establishment of restricted and infected zones in the event of an outbreak of classical swine fever

In the event of an outbreak of classical swine fever in kept or wild porcine animals, the competent authorities of the Member States shall establish either:

- (a) in the case of an outbreak in kept porcine animals, a restricted zone in accordance with Article 21(1) of Delegated Regulation (EU) 2020/687; or
- (b) in the case of an outbreak in wild porcine animals, an infected zone in accordance with Article 63 of Delegated Regulation (EU) 2020/687.

Special rules for the listing of restricted zones in Annex I in the event of an outbreak of classical swine fever in wild porcine animals in a Member State

- 1. Following an outbreak of classical swine fever in wild porcine animals in an area of a Member State, that area shall be listed as a restricted zone in Annex I.
- 2. The competent authorities of the Member State concerned shall ensure that the boundaries of the infected zone established in accordance with Article 63 of Delegated Regulation (EU) 2020/687 are adjusted without delay to comprise at least the relevant restricted zone listed in Annex I to this Regulation for that Member State.

Article 5

General application of special disease control measures in restricted zones

The Member States concerned shall apply the special disease control measures laid down in Articles 3 and 4 of this Regulation in the restricted zones listed in Annex I to this Regulation in addition to the disease control measures to be applied in accordance with Delegated Regulation (EU) 2020/687 in:

- (a) the restricted zones established in accordance with Article 21(1) of Delegated Regulation (EU) 2020/687;
- (b) the infected zones established in accordance with Article 63 of Delegated Regulation (EU) 2020/687.

CHAPTER III

SPECIAL DISEASE CONTROL MEASURES APPLICABLE TO CONSIGNMENTS OF PORCINE ANIMALS KEPT IN RESTRICTED ZONES AND PRODUCTS THEREOF IN THE MEMBER STATES CONCERNED

SECTION 1

Specific prohibitions on movements of consignments of kept porcine animals and products thereof in the Member States concerned

Article 6

Specific prohibition on movements from the restricted zones of consignments of porcine animals kept in restricted zones

The competent authorities of the Member States concerned shall prohibit movements from the restricted zones listed in Annex I of consignments of porcine animals kept in those restricted zones.

Article 7

Specific prohibition on movements from the restricted zones of consignments of germinal products obtained from porcine animals kept in restricted zones

The competent authorities of the Member States concerned shall prohibit movements from the restricted zones listed in Annex I of consignments of germinal products obtained from porcine animals kept in those restricted zones.

Specific prohibition on movements from the restricted zones of consignments of animal by-products obtained from porcine animals kept in restricted zones

The competent authorities of the Member States concerned shall prohibit movements from the restricted zones listed in Annex I of consignments of animal by-products obtained from porcine animals kept in those restricted zones.

Article 9

Specific prohibition on movements from the restricted zones of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones

- 1. The competent authorities of the Member States concerned shall prohibit movements from the restricted zones listed in Annex I of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in those restricted zones.
- 2. The competent authorities of the Member States concerned may decide that the prohibition provided for in paragraph 1 of this Article shall not apply to consignments of meat products, including casings, obtained from porcine animals kept in restricted zones listed in Annex I to this Regulation, which have undergone the relevant risk-mitigating treatment as regards classical swine fever in accordance with Annex VII to Delegated Regulation (EU) 2020/687, in establishments designated in accordance with Article 23(1) of this Regulation.

SECTION 2

General conditions for derogations authorising movements from restricted zones of consignments of porcine animals kept in restricted

Article 10

General conditions for derogations from the specific prohibition in relation to movements from the restricted zones of consignments of porcine animals kept in restricted zones

- 1. By way of derogation from the specific prohibition provided for in Article 6, the competent authorities of the Member States concerned may authorise movements from the restricted zones listed in Annex I of consignments of porcine animals kept in those restricted zones in the cases covered by Articles 18 to 22, subject to compliance with the specific conditions laid down in those Articles, and with the following conditions:
- (a) the general conditions laid down Article 28(2) to (7) of Delegated Regulation (EU) 2020/687; and
- (b) the additional general conditions concerning:
 - (i) movements of consignments of kept porcine from the restricted zones listed in Annex I, laid down in Article 11;
 - (ii) establishments for kept porcine animals located in restricted zones listed in Annex I, laid down in Article 12;
 - (iii) the means of transport used for the transportation of kept porcine animals from restricted zones listed in Annex I, laid down in Article 13.
- 2. Prior to granting authorisations provided for in Articles 18 to 22, the competent authorities of the Member States concerned shall assess the risks deriving from such authorisations and that assessment must demonstrate that the risk of the spread of classical swine fever is negligible.

Additional general conditions for movements from the restricted zones of consignments of porcine animals kept in restricted zones

- 1. The competent authorities of the Member States concerned shall only authorise movements from the restricted zones listed in Annex I of porcine animals kept in those restricted zones in the cases covered by Articles 18 to 22, subject to compliance with the specific conditions laid down in those Articles and provided that:
- (a) the porcine animals have been kept in and have not been moved from their establishment of dispatch for a period of at least 90 days prior to the date of movement, or since birth, if they are younger than 90 days of age, and during the 30-day period immediately prior to the date of dispatch no other kept porcine animals have been introduced into that establishment from the restricted zones listed in Annex I into either:
 - (i) that establishment of dispatch; or
 - (ii) the epidemiological unit of that establishment of dispatch where the porcine animals to be moved were kept completely separated. The competent authority shall determine, after carrying out a risk assessment, the boundaries of such epidemiological unit confirming that the structure, size and distance between the different epidemiological units and the operations being carried out ensure separate facilities for the housing, keeping and feeding of kept porcine animals so that the classical swine fever virus cannot spread from one epidemiological unit to another;
- (b) a clinical examination has been carried out on the porcine animals kept in the establishment of dispatch, including those animals to be moved, with favourable results concerning classical swine fever:
 - (i) by an official veterinarian;
 - (ii) within the 24-hour period prior to the time of movement of the consignment; and
 - (iii) in accordance with Article 3(1) and (2) of Delegated Regulation (EU) 2020/687 and point A.1 of Annex I thereto;
- (c) if necessary, following the instructions of the competent authority, pathogen identification tests or antibody detection tests have been carried out prior to the date of the movement of the consignment from the establishment of dispatch:
 - (i) following the clinical examination referred to in point (b) for porcine animals kept in the establishment, including those animals to be moved; and
 - (ii) in accordance with point A.2 of Annex I to Delegated Regulation (EU) 2020/687.
- 2. The competent authorities of the Member States concerned shall obtain, where relevant, negative results of pathogen identification tests referred to in point (1)(c) before authorising the movement of consignment.

Article 12

Additional general conditions for establishments of kept porcine animals located in restricted zones

The competent authorities of the Member States concerned shall only authorise movements from the restricted zones listed in Annex I of porcine animals kept in establishments located in those restricted zones outside those zones in the cases covered by Articles 18 to 22, subject to compliance with the specific conditions laid down in those Articles and provided that:

- (a) the establishment of dispatch has been visited by an official veterinarian at least once following the listing of the restricted zones in Annex I to this Regulation, and is subject to regular visits by official veterinarians as provided for in Article 26(2) of Delegated Regulation (EU) 2020/687 at least twice a year, with an interval of at least four months between such visits;
- (b) the establishment of dispatch implements biosecurity requirements for classical swine fever:
 - (i) in accordance with the reinforced biosecurity measures for establishments of kept porcine animals located in restricted zones listed set out in Annex II; and
 - (ii) as established by the Member State concerned;

- (c) continuous surveillance by means of testing with pathogen identification tests and antibody detection tests for classical swine fever is carried out in the establishment of dispatch:
 - (i) in accordance with Article 3(2) of Delegated Regulation (EU) 2020/687 and Annex I thereto;
 - (ii) with negative results, each week, on at least the first two dead kept porcine animals over the age of 60 days or, in the absence of such dead animals over the age of 60 days, on any dead kept porcine animals after weaning, in each epidemiological unit;
 - (iii) at least during the monitoring period for classical swine fever set out in Annex II to Delegated Regulation (EU) 2020/687 before the movement of the consignment from the establishment of dispatch.

Additional general conditions for the means of transport used for the transportation from the restricted zones of porcine animals kept in restricted zones

The competent authorities of the Member States concerned shall only authorise movements from the restricted zones listed in Annex I of consignments of porcine animals kept in those restricted zones if the means of transport used for the transportation of those consignments:

- (a) comply with the requirements laid down in Article 24(1) of Delegated Regulation (EU) 2020/687; and
- (b) are cleaned and disinfected in accordance with Article 24(2) of Delegated Regulation (EU) 2020/687 under the control or supervision of the competent authorities of the Member States.

SECTION 3

Obligations on operators with regard to animal health certificates

Article 14

Operators' obligations with regard to animal health certificates for movements from the restricted zones of consignments of porcine animals kept in restricted zones

Operators shall only move consignments of porcine animals kept in the restricted zones listed in Annex I to this Regulation, from those restricted zones to another Member State in the cases covered by Article 18 of this Regulation, if those consignments are accompanied by an animal health certificate, as provided for in Article 143(1) of Regulation (EU) 2016/429, that contains the following attestation of compliance with the requirements laid down in this Regulation:

Porcine animals kept in restricted zone in compliance with the special control measures relating to classical swine fever laid down in Commission Implementing Regulation (EU) 2021/934.'.

Article 15

Operators' obligations with regard to animal health certificates for movements from the restricted zones of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones

- 1. Operators shall only move consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I to this Regulation, from those restricted zones to another Member State in the cases covered by Article 22 of this Regulation, if those consignments are accompanied by an animal health certificate as provided for in Article 167(1) of Regulation (EU) 2016/429 that contains:
- (a) the information required in accordance with Article 3 of Delegated Regulation (EU) 2020/2154; and

(b) the following attestation of compliance with the requirements laid down in this Regulation:

Fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zone in compliance with the special control measures relating to classical swine fever laid down in Commission Implementing Regulation (EU) 2021/934'.

- 2. Operators shall only move consignments of processed meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I, from those restricted zones to another Member State, subject to compliance with the following conditions:
- (a) the processed meat products, including casings, have undergone the relevant risk-mitigating treatment set out in Annex VII to Delegated Regulation (EU) 2020/687;
- (b) those consignments are accompanied by an animal health certificate as provided for in Article 167(1) of Regulation (EU) 2016/429 that contains:
 - (i) the information required in accordance with Article 3 of Delegated Regulation (EU) 2020/2154; and
 - (ii) the following attestation of compliance with the requirements laid down in this Regulation:

Processed meat products, including casings, obtained from porcine animals kept in restricted zones in compliance with the special control measures relating to classical swine fever laid down in Commission Implementing Regulation (EU) 2021/934.'.

- 3. Operators shall only move consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in areas outside the restricted zones listed in Annex I and slaughtered in slaughterhouses located in those restricted zones, from such restricted zones to another Member State, if those consignments are accompanied by:
- (a) an animal health certificate as provided for in Article 167(1) of Regulation (EU) 2016/429 that contains the information required in accordance with Article 3 of Delegated Regulation (EU) 2020/2154; and
- (b) the following attestation of compliance with the requirements laid down in this Regulation:

'Fresh meat and meat products, including casings, obtained from porcine animals kept in areas outside restricted zones and slaughtered in restricted zones in compliance with the special control measures relating to classical swine fever laid down in Commission Implementing Regulation (EU) 2021/934'.

- 4. Operators shall only move consignments of processed meat products, including casings, obtained from porcine animals kept in areas outside the restricted zones listed in Annex I, and processed in those restricted zones, from such restricted zones to another Member State, subject to compliance with the following conditions:
- (a) the processed meat products, including casings, have undergone the relevant risk-mitigating treatment set out in Annex VII to Delegated Regulation (EU) 2020/687;
- (b) those consignments are accompanied by an animal health certificate as provided for in Article 167(1) of Regulation (EU) 2016/429 that contains:
 - (i) the information required in accordance with Article 3 of Delegated Regulation (EU) 2020/2154; and
 - (ii) the following attestation of compliance with the requirements laid down in this Regulation:

Processed meat products, including casings, obtained from porcine animals kept in areas outside restricted zones and processed in restricted zones in compliance with the special control measures relating to classical swine fever laid down in Commission Implementing Regulation (EU) 2021/934.'.

- 5. The competent authorities of the Member States concerned may decide that a health mark or, where relevant, an identification mark provided for in Article 5(1), point (b) of Regulation (EC) No 853/2004 applied on the fresh or processed meat and meat products, including casings, in establishments designated in accordance with Article 23(1) of this Regulation may be substituted for the animal health certificate for movements from the restricted zones listed in Annex I for the following consignments of:
- (a) fresh meat and meat products, including casings, obtained from porcine animals kept in the restricted zones, listed in Annex I, to another Member State, as laid down in paragraph 1;
- (b) processed meat products, including casings, obtained from porcine animals kept in the restricted zones, listed in Annex I, to another Member State, as laid down in paragraph 2;
- (c) fresh meat and meat products, including casings, obtained from porcine animals kept in areas outside the restricted zones, listed in Annex I, and slaughtered in slaughterhouses located in those restricted zones to another Member State, as laid down in paragraph 3;
- (d) processed meat products, including casings, obtained from porcine animals kept in areas outside the restricted zones, listed in Annex I, and processed in those restricted zones to another Member State, as laid down in paragraph 4.

Operators' obligations with regard to animal health certificates for movements from the restricted zones of consignments of germinal products obtained from porcine animals kept in establishments located in restricted zones

Operators shall only move consignments of germinal products obtained from porcine animals kept in the restricted zones listed in Annex I, from those restricted zones to another Member State in the cases covered by Article 19 of this Regulation if those consignments are accompanied by an animal health certificate as referred to in Article 161(4) of Regulation (EU) 2016/429. That animal health certificate shall contain the following attestation of compliance with the requirements laid down in this Regulation:

'Germinal products obtained from porcine animals kept in restricted zone in compliance with the special control measures relating to classical swine fever laid down in Commission Implementing Regulation (EU) 2021/934.'.

Article 17

Operators' obligations with regard to animal health certificates for movements from the restricted zones of consignments of Category 2 and 3 material obtained from porcine animals kept in restricted zones

Operators shall only move consignments of Category 2 and 3 material obtained from porcine animals kept in the restricted zones listed in Annex I, from those restricted zones to another Member State in the cases covered by Articles 20 and 21, if those consignments are accompanied by:

- (a) the commercial document referred to in Chapter III of Annex VIII to Regulation (EU) No 142/2011; and
- (b) an animal health certificate referred to in Article 22(5) of Delegated Regulation (EU) 2020/687.

SECTION 4

Specific conditions for derogations authorising movements from the restricted zones of consignments of kept porcine animals and products thereof in the Member States concerned

Article 18

Specific conditions for derogations authorising movements from the restricted zones of consignments of porcine animals kept in restricted zones to other Member States and to third countries

- 1. By way of derogation from the prohibition provided for in Article 6, the competent authorities of the Member States concerned may authorise movements from the restricted zones listed in Annex I of consignments of porcine animals kept in those restricted zones to an establishment located in the territory of other Member States and to third countries provided that:
- (a) no evidence of classical swine fever has been recorded in the previous 12 months in the establishment of dispatch and that establishment is located outside a protection zone or a surveillance zone established in accordance with Article 21 of Delegated Regulation (EU) 2020/687;
- (b) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
- (c) the additional general conditions laid down in Articles 10 to 13 are met.
- 2. The competent authorities of all Member States shall ensure that consignments of porcine animals subject to an authorised movement referred to in paragraph 1 of this Article remain in the establishment of destination for at least the duration of the monitoring period required for classical swine fever set out in Annex II to Delegated Regulation (EU) 2020/687 or are sent for immediate slaughter.

Article 19

Specific conditions for derogations authorising movements from the restricted zones of consignments of germinal products obtained from germinal product establishments located in restricted zones to other Member States and to third countries

By way of derogation from the prohibition provided for in Article 7, the competent authorities of the Member States concerned may authorise movements from the restricted zones listed in Annex I of consignments of germinal products from germinal product establishments located in those restricted zones to other Member States and to third countries provided that:

- (a) the germinal products were collected or produced, processed and stored in establishments and were obtained from kept porcine animals that comply with conditions laid down in Article 11(1)(b) and (c), Article 11(2) and Article 12;
- (b) the donor males and donor females of the porcine animals were kept at germinal product establishments:
 - (i) for a period of at least 90 days prior to the date of the collection or production of the germinal products;
 - (ii) where no other kept porcine animals were introduced from the restricted zones listed in Annex I for a period of at least 90 days prior to the date of the collection or production of the germinal products.

Specific conditions for derogations authorising movements from the restricted zones of consignments of Category 2 materials obtained from porcine animals kept in restricted zones for the purpose of disposal in another Member State or third country

- 1. By way of derogation from the prohibition provided for in Article 8 of this Regulation, the competent authorities of the Member States concerned may authorise movements from the restricted zones listed in Annex I to this Regulation of consignments of animal by-products of Category 2 materials obtained from porcine animals kept in those restricted zones to a processing plant to be processed by methods 1 to 5, as set out in Chapter III of Annex IV to Regulation (EU) No 142/2011, or to an incineration or co-incineration plant, as referred to in Article 24(1)(a), (b) and (c) of Regulation (EC) No 1069/2009, located in another Member State or to a third country, provided that:
- (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
- (b) the additional general conditions laid down in Article 10(2) are met;
- (c) the means of transport is equipped with a satellite navigation system to determine, transmit and record its real time location.
- 2. The transport operator responsible for movements of consignments of Category 2 materials shall:
- (a) enable the competent authority to control, by means of a satellite navigation system, the real time movement of the means of transport; and
- (b) keep the electronic records of that movement for a period of at least two months from the date of movement.
- 3. The competent authorities of both the Member States of dispatch and of destination of the consignment of Category 2 materials shall ensure the controls of dispatch of that consignment in accordance with Article 48(1) and (3) of Regulation (EC) No 1069/2009.

Article 21

Specific conditions for derogations authorising movements from the restricted zones of consignments of Category 3 materials obtained from porcine animals kept in restricted zones to another Member State or third country for further processing or transformation

- 1. By way of derogation from the prohibition provided for in Article 8 of this Regulation, the competent authorities of the Member States concerned may authorise movements from the restricted zones listed in Annex I of consignments of Category 3 materials obtained from porcine animals kept in those restricted zones to a plant or establishment approved by the competent authority for the processing of Category 3 material into processed feed, processed pet food, derived products intended for use outside the feed chain, or the transformation of Category 3 materials into biogas or compost as referred to in Article 24(1)(a), (e) and (g) of Regulation (EC) No 1069/2009, located in another Member State or to a third country, provided that:
- (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
- (b) the additional general conditions laid down in Article 10(2) are met;
- (c) the Category 3 materials originate from kept porcine animals and establishments that comply with the general conditions laid down in Articles 11 and 12;
- (d) the means of transport is equipped with a satellite navigation system to determine, transmit and record its real time location;
- (e) the animal by-products are moved directly from the slaughterhouse designated in accordance with Article 23(1) to:
 - (i) a processing plant for the processing of derived products referred to in Annexes X and XIII to Regulation (EU) No 142/2011;

- (ii) a pet food plant approved for the production of processed pet food referred to in Chapter II, point 3(b)(i), (ii) and (iii), of Annex XIII to Regulation (EU) No 142/2011;
- (iii) a biogas or a compost plant approved for transformation of animal by-products into compost or biogas in accordance with the standard transformation parameters referred to in Chapter III, Section I, of Annex V to Regulation (EU) No 142/2011.
- 2. The transport operator responsible for the movements of consignments of Category 3 materials shall:
- (a) enable the competent authority to control, by means of a satellite navigation system, the real time movement of the means of transport; and
- (b) keep the electronic records of the movement for a period of at least two months from the date of movement.

Specific conditions for derogations authorising movements from the restricted zones of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones to other Member States and to third countries

By way of derogation from the prohibition provided for in Article 9, the competent authorities of the Member States concerned may authorise movements from the restricted zones listed in Annex I of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in those restricted zones to other Member States and to third countries, provided that:

- (a) the porcine animals were kept in an establishment where there was no evidence of classical swine fever in the 12 months preceding the date of movement and that establishment is located outside a protection zone or a surveillance zone established in accordance with Article 21 of Delegated Regulation (EU) 2020/687;
- (b) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
- (c) the additional general conditions laid down in Articles 10(2) are met;
- (d) the fresh meat and meat products, including casings, are obtained from porcine animals kept in establishments that comply with the general conditions laid down in Articles 11 and 12;
- (e) the fresh meat and meat products, including casings, have been produced in establishments designated in accordance with Article 23(1).

CHAPTER IV

SPECIAL RISK-MITIGATING MEASURES CONCERNING CLASSICAL SWINE FEVER FOR FOOD BUSINESSES IN THE MEMBER STATES CONCERNED

Article 23

Special designation of slaughterhouses, cutting plants, cold stores, meat processing and game handling establishments

- 1. Subject to the authorised movement requirements laid down in Article 22, the competent authorities of the Member States concerned shall, following an application by a food business operator, designate establishments for the slaughtering, cutting, processing and storage of the fresh meat and meat products, including casings, from porcine animals kept in the restricted zones listed in Annex I and from wild porcine animals in those restricted zones.
- 2. The competent authorities of the Member States concerned may decide that the designation referred to in paragraph 1 shall not be required for establishments slaughtering, processing, cutting and storing fresh meat and meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I and from wild porcine animals in those restricted zones provided that:

- (a) the meat and meat products, including casings, of porcine origin are marked with a special health mark referred to in Article 25;
- (b) the fresh meat and meat products, including casings, of porcine origin from those establishment are only intended for within the same Member State concerned:
- (c) animal by-products of porcine origin from those establishments are only processed or disposed of within the same Member State.
- 3. The competent authorities of the Member States concerned shall:
- (a) provide the Commission and the other Member States with a link to the website of their competent authority with a list of designated establishments and their activities referred to in paragraph 1;
- (b) keep the list provided for in point (a) updated.

Special conditions for the designation of establishments for slaughtering, cutting, processing and storing of the fresh meat and meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I

The competent authorities of the Member States concerned shall only designate establishments for the slaughtering, cutting, processing and storing of the fresh meat and meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I and from wild porcine animals in those restricted zones subject to the authorised movement requirements laid down in Article 22, provided that:

- (a) the cutting, processing and storing of the fresh meat and meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I are carried out separately from fresh meat and meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I that do not comply with:
 - (i) the additional general conditions laid down in Articles 11, 12 and 13; and
 - (ii) the specific conditions laid down in Article 22;
- (b) the operator of the establishment has in place documented instructions or procedures approved by the competent authorities of the Member States concerned to ensure that the conditions laid down in point (a) are met.

Article 25

Special health marks

The competent authorities of the Member States concerned shall ensure that the following products of animal origin are marked with a special health mark or, where relevant, an identification mark that is not oval and cannot be confused with the health mark or identification mark provided for in Article 5 of Regulation (EC) No 853/2004:

- (a) the fresh meat and meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I, unless specific conditions apply for movements from those restricted zones of consignments of porcine animals kept in such restricted zones, as laid down in Article 22; and
- (b) the fresh meat and meat products from wild porcine animals obtained in the restricted zones listed in Annex I and moved from an establishment designated in accordance with Article 23(1).

CHAPTER V

SPECIAL DISEASE CONTROL MEASURES APPLICABLE TO WILD PORCINE ANIMALS IN THE MEMBER STATES CONCERNED

Article 26

Specific prohibitions in relation to the movements of wild porcine animals

The competent authorities of the Member States concerned shall prohibit movements of wild porcine animals by operators as provided for in Article 101 of Commission Delegated Regulation (EU) 2020/688:

- (a) within the whole territory of the Member State concerned;
- (b) from the whole territory of the Member State concerned to:
 - (i) other Member States; and
 - (ii) third countries.

Article 27

Specific prohibitions in relation to movements of fresh meat, meat products and any other products of animal origin obtained from wild porcine animals within and from the restricted zones listed in Annex I

- 1. The competent authorities of the Member States concerned shall prohibit movements of consignments of fresh meat, meat products and any other products of animal origin obtained from wild porcine animals within and from the restricted zones listed in Annex I.
- 2. The competent authorities of the Member States concerned shall prohibit movements of fresh meat, meat products and any other products of animal origin obtained from wild porcine animals within and from the restricted zones listed in Annex I for either:
- (a) private domestic use;
- (b) linked to the activities of hunters who supply small quantities of wild porcine game or wild game meat of porcine origin directly to the final consumer or to local retail establishments directly supplying the final consumer, as provided for in Article 1(3)(e) of Regulation (EU) 853/2004.

Article 28

Specific conditions for derogations authorising movements of consignments of fresh meat, processed meat products and any other products of animal origin obtained from wild porcine animals within the restricted zones listed in Annex I

By way of derogation from the prohibitions provided for in Article 27, the competent authorities of the Member States concerned may authorise movements of items referred to in Article 27 from an establishment located in restricted zones listed in Annex I within such restricted zones provided that:

- (a) pathogen identification tests and antibody detection tests for classical swine fever have been carried out for each wild porcine animal used for the production and processing of meat products in those restricted zones;
- (b) the competent authority obtained negative results for the tests referred to in point (a) before the treatment referred to in point (c);
- (c) the meat products from wild porcine animals were produced, processed and stored in establishments designated in accordance with Article 23(1).

Specific conditions for derogations authorising movements of consignments of processed meat products and any other products of animal origin obtained from wild porcine animals from the restricted zones listed in Annex I

By way of derogation from the prohibitions provided for in Article 27, the competent authorities of the Member States concerned may authorise movements of consignments of items referred to in Article 27 from an establishment located in restricted zones listed in Annex I to other Member States and to third countries provided that:

- (a) pathogen identification tests and antibody detection tests for classical swine fever have been carried out for each wild porcine animal used for the production and processing of meat products in those restricted zones;
- (b) the competent authority obtained negative results for the tests referred to in point (a) before the treatment referred to in points (c) and (d);
- (c) the meat products from wild porcine animals were produced, processed and stored in establishments designated in accordance with Article 23(1);
- (d) the meat products from wild porcine animals have undergone the relevant risk-mitigating treatment for products of animal origin from restricted zones in accordance with Annex VII to Delegated Regulation (EU) 2020/687, as regards classical swine fever.

Article 30

Operators' obligations with regard to animal health certificates for movements from the restricted zones of consignments of processed meat products and any other products of animal origin obtained from wild porcine animals from those restricted zones

Operators shall only move consignments of processed meat products and any other products of animal origin obtained from wild porcine animals from the restricted zones listed in Annex I to this Regulation to another Member State and to third countries in the cases covered by Article 29 of this Regulation, if those consignments are accompanied by an animal health certificate as provided for in Article 167(1) of Regulation (EU) 2016/429 that contains:

- (a) the information required in accordance with Article 3 of Delegated Regulation (EU) 2020/2154; and
- (b) the following attestation of compliance with the requirements laid down in this Regulation:

Processed meat products, obtained from wild porcine animals in compliance with the special control measures relating to classical swine fever laid down in Commission Implementing Regulation (EU) 2021/934.'.

CHAPTER VI

FINAL PROVISIONS

Article 31

Entry into force and application

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

It shall apply from third day following that of its publication to 13 June 2026.

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

Done at Brussels, 9 June 2021.

For the Commission The President Ursula VON DER LEYEN

ANNEX I

RESTRICTED ZONES

1. Bulgaria

The whole territory of Bulgaria.

2. Romania

The whole territory of Romania.

ANNEX II

REINFORCED BIOSECURITY MEASURES FOR ESTABLISHMENTS OF KEPT PORCINE ANIMALS LOCATED IN RESTRICTED ZONES LISTED IN ANNEX I

(as referred to in Article 12, point (b)(i))

- 1. The following reinforced biosecurity measures, as referred to in Article 12, point (b)(i), shall apply to establishments of kept porcine animals located in restricted zones listed in Annex I, in the case of authorised movements of consignments of:
 - (a) porcine animals kept in restricted zones listed in Annex I, as provided for in Article 18;
 - (b) germinal products obtained from porcine animals kept in restricted zones listed in Annex I, as provided for in Article 19;
 - (c) animal by-products obtained from porcine animals kept in restricted zones listed in Annex I, as provided for in Article 21;
 - (d) fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones listed in Annex I, as provided for in Article 22.
- 2. The operators of establishments of porcine animals kept in restricted zones listed in Annex I situated in the Member States concerned, in the case of authorised movements outside those restricted zones shall ensure that the following reinforced biosecurity measures are applied in those establishments of kept porcine animals:
 - (a) there must be no direct or indirect contact between the kept porcine animals and at least:
 - (i) other kept porcine animals from other establishments;
 - (ii) wild porcine animals;
 - (b) appropriate hygienic measures must be taken by persons entering and leaving the premises where porcine animals are kept, such as a change of clothes and footwear;
 - (c) persons entering the premises where porcine animals are kept must wash and disinfect their hands at the entrance;
 - (d) persons entering into contact with kept porcine animals on the establishment must not have engaged in any hunting activity related to wild porcine animals or have had any other contact with wild porcine animals for a period of at least 48 hours before entering into the establishment;
 - (e) a prohibition on unauthorised persons or means of transport entering the establishment, including the premises where porcine animals are kept;
 - adequate record-keeping of persons and means of transport accessing the establishment where the porcine animals are kept;
 - (g) the premises and buildings of the establishment where porcine animals are kept must:
 - (i) be built in such a way that no other animals can enter the premises and buildings or have contact with the kept porcine animals or their feed and bedding material;
 - (ii) allow for the washing and disinfection of hands;
 - (iii) allow for the cleaning and disinfection of the premises;
 - (iv) have appropriate changing facilities for footwear and clothes at the entrance to the premises where porcine animals are kept;
 - (h) have stock-proof fencing of at least the premises where the porcine animals are kept and buildings where their feed and bedding are kept;
 - (i) a biosecurity plan approved by the competent authority of the Member State concerned, taking account of the profile of the establishment and national legislation, must be in place; that biosecurity plan shall at least include:
 - (i) the establishment of the 'clean' and 'dirty' areas for personnel appropriate to the farm typology, such as changing rooms, a shower, a dining room;

- (ii) the setting up and the review, when applicable, of the logistical arrangements for the entry of new kept porcine animals into the establishment;
- (iii) the procedures for the cleaning and disinfection of the facilities, transport, equipment and personnel hygiene;
- (iv) rules on food for personnel on-site and a prohibition on the keeping of porcine animals by the personnel, where relevant and if applicable;
- (v) a dedicated recurrent awareness programme for personnel on the establishment;
- (vi) the setting up and the review, when applicable, of logistical arrangements in order to ensure a proper separation between different epidemiological units and to avoid porcine animals being in contact, directly or indirectly, with animal by-products and other units;
- (vii) the procedures and instructions for the enforcement of biosecurity requirements during the construction or repair of the premises or buildings;
- (viii) internal audit or self-evaluation for enforcing the biosecurity measures.