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## ANNEX I

### ANNEX XII

#### Classical swine fever (CSF) in kept porcine animals

Formateret: Ikke Fremhævning

#### Part 1

##### **SPECIFIC CONDITIONS FOR THE IMPLEMENTATION OF EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF CSF**

1. **Size of the vaccination zone:** ~~No specific conditions at least 10 km radius around affected establishments.~~
2. **Size of the peri-vaccination zone:** No specific conditions.
3. **Type of vaccine to be used or prioritised:** Live attenuated vaccines shall be prioritised. Other vaccines may be used only for duly justified reasons.
4. **Minimum coverage:** Vaccine coverage should be at least 95% of establishments in the vaccination zone representing 80% of targeted animals in each of those establishments.
5. **Targeted animals/species:** Animals of listed species, in accordance with Implementing Regulation (EU) 2018/1882, kept in the vaccination zone.

#### Part 2

##### **SPECIFIC CONDITIONS FOR THE REINFORCED CLINICAL AND LABORATORY SURVEILLANCE TO BE IMPLEMENTED IN THE VACCINATION AND PERI-VACCINATION ZONES DURING EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF CSF**

Clinical and laboratory ~~reinforced enhanced~~ active and passive surveillance shall be implemented in the ~~peri-vaccination and~~ vaccination ~~and peri-vaccination~~ zones to identify establishments keeping animals of listed species that had contact with the CSF virus without showing clinical signs of the disease. In the vaccination zone each establishment being vaccinated should be visited and samples taken during the period starting not earlier than 30 days after the completion of emergency protective vaccination.

~~This~~ The surveillance shall include in the:

Peri-vaccination zone:

1. ~~a visit by an official veterinarian of all establishments in the peri-vaccination zone~~ clinical examination by an official veterinarian of all animals of listed species kept in all establishments in the peri-vaccination zone.
2. ~~laboratory surveillance testing~~ with pathogen identification tests ~~targeted at on at least the first two~~ dead kept porcine animals over the age of 60 days or, in the absence of such dead

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animals over the age of 60 days, on any dead kept porcine animals after weaning, in [the visited each](#) establishment.

Vaccination zone: [in each establishment where vaccination was carried out](#), laboratory [surveillance examination](#) by means of testing [\(i\)](#) for antibodies on samples taken from vaccinated animals of listed species [to assess vaccination effectiveness, and \(ii\) for pathogen identification on samples from at least the first two dead kept porcine animals every week 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 all the establishments of the vaccination zone according to a sample size that shall be calculated to detect a within establishment animal prevalence of 5 % or less, with a 95 % confidence, in both vaccinated and non-vaccinated animals.

### Part 3

## ANIMALS AND PRODUCTS SUBJECT TO PROHIBITION OF MOVEMENTS AND CONDITIONS FOR GRANTING A DEROGATION IN ACCORDANCE WITH ARTICLE 13 IN A VACCINATION ZONE WHERE EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF CSF IS CARRIED OUT

### 1. Animals and products subject to prohibition of movements

The following animals, germinal products and products of animal origin from establishments located in the vaccination zone, [within and](#) to outside [of](#) the vaccination zones:

- (a) ~~vaccinated kept~~ porcine animals;
- (b) ~~piglets of seropositive sows;~~
- (c) semen, oocytes and embryos ~~for artificial insemination~~ from donor [kept](#) porcine animals ~~kept in approved germinal product establishments;~~
- (d) fresh meat [and meat products, including casings](#), obtained from vaccinated porcine animals;

### 2. Germinal products subject to prohibition of collection

Semen, oocytes and embryos for artificial insemination from ~~seropositive-vaccinated~~ donor porcine animals kept in approved germinal product establishments located in the vaccination zone.

### 3. Conditions for granting a derogation in accordance with Article 13(2), point (b)(ii), Article 13(3), point (b), and Article 13(4), point (b)

Movements of animals and products thereof that may be authorised:

- (1) movements of vaccinated porcine animals, directly from the establishment of origin to:
  - (a) [a slaughterhouse for immediate slaughter located in the vaccination zone;](#)  
[or](#)
  - (b) a slaughterhouse located as close as possible to the vaccination zone, in the same Member State, under the same conditions as those provided for

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- in Article 24, Article 28(2), (3), (4), (5) and (7) and Article 29(1) and (2) of Delegated Regulation (EU) 2020/687; or
- (bc) ~~to~~ an animal by-product approved plant, under the same conditions as those provided for in Article 24, Article 28(2), (3), (4), (5) and (7) and Article 37 of Delegated Regulation (EU) 2020/687;
- (2) movement of fresh meat and meat products, including casing from ~~vaccinated kept porcine~~ animals in accordance with Article 33(1), point (a), of Delegated Regulation (EU) 2020/687;
- (3) all movements of animals and products thereof within the same Member State, laid down in point 1, during the waiting period provided for in part 4:
- (a) all the vaccinated porcine animals kept in the vaccination zone have been slaughtered or killed, and the fresh meat obtained from those animals has been disposed or processed in accordance with Article 33(1), point (a), of Delegated Regulation (EU) 2020/687;
- (b) all the establishments where vaccinated porcine animals had been kept have been cleaned and disinfected in accordance with Article 57(1) of Delegated Regulation (EU) 2020/687;
- (c) the repopulation of the establishments above has not taken place until at least 10 days after completion of the cleaning and disinfection operations, and after all porcine animals in the establishments where vaccination has been applied have been slaughtered or killed;
- (d) after repopulation, porcine animals in all establishments of the vaccination zone have undergone clinical and laboratory examinations in accordance with Annex I to Delegated Regulation (EU) 2020/687 in order to detect the possible presence of CSF virus and those examinations have not taken place until at least 28 days ~~[two incubation periods according to the CODE]~~ have elapsed after the repopulation, during which time porcine animals are not allowed to move from that establishment.

#### Part 4

#### WAITING PERIODS FOR CSF FOLLOWING EMERGENCY PROTECTIVE VACCINATION

The competent authority shall maintain in the vaccination zone the conditions provided for in ~~paragraph 3 of part 4.3~~ of this Annex until:

- ~~1. 3 months have elapsed after all vaccinated porcine animals have been slaughtered or killed, excluding kept porcine animals referred to in Article 13(2) of Regulation (EU) 2020/687 when there are means, validated in accordance with the Terrestrial Manual of the WOA, of distinguishing between vaccinated and infected kept porcine animals.~~
- ~~2. Clinical and laboratory (genome detection and serological) surveillance have been implemented.~~

**Formateret:** Ingen punkttegn eller nummerering

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<b><i>Waiting period</i></b>	<b><i>Type of surveillance implemented during the waiting period</i></b>
<i>3 months after all vaccinated porcine animals have been slaughtered or killed, excluding kept porcine animals referred to in Article 13(2) of Regulation (EU) 2020/687 when there are means, validated in accordance with the Terrestrial Manual of the WOA, of distinguishing between vaccinated and infected kept porcine animals</i>	<i>Clinical and laboratory surveillance (pathogen identification and antibody detection)</i>

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## **ANNEX II**

### **ANNEX XIII** **Highly Pathogenic Avian Influenza (HPAI)**

#### **Part 1**

#### **SPECIFIC CONDITIONS FOR THE IMPLEMENTATION OF EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF HPAI**

1. **Size of the vaccination zone:** at least 3 km radius around the affected establishments.
2. **Size of the peri-vaccination zone:** at least 7 km width from the perimeters of the vaccination zone.
3. **Type of vaccine to be used:** Vaccines that do not contain live avian influenza virus (vaccines containing live avian influenza virus, whether attenuated or not, shall not be used).
4. **Minimum coverage:** No specific conditions.
5. **Targeted animals/species:** poultry and/or captive birds kept in the establishments included in the official vaccination plan.

#### **Part 2**

#### **SPECIFIC CONDITIONS FOR THE REINFORCED LABORATORY SURVEILLANCE TO BE IMPLEMENTED IN THE VACCINATION AND PERI-VACCINATION ZONES DURING EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF HPAI**

Laboratory surveillance to early detect occurrence of infection with HPAI field virus shall be implemented by means of pathogen identification methods, in the vaccination and peri-vaccination zones, as follows:

1. in the establishments where vaccination has been carried out:
  - (a) at least every three weeks, by sampling of all dead birds up to 15 collected from each flock within the 48 hours before the sampling. The number of sampled birds per flock and the frequency of the sampling has to enable detection of the infection with the HPAI virus in the vaccinated establishment with a probability of at least 99% and a confidence level of at least 95 %.
  - (b) by sampling all dead birds up to 15 per flock when the daily normal mortality rate for that establishment is overpassed.
2. in the poultry establishments where vaccination has not been carried out:
  - (a) by passive surveillance of gallinaceous species, and
  - (b) by weekly sampling of all dead birds up to 15 per flock of Anseriformes species, collected within a week.

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### Part 3

#### **ANIMALS AND PRODUCTS SUBJECT TO PROHIBITION OF MOVEMENTS AND CONDITIONS FOR GRANTING A DEROGATION IN ACCORDANCE WITH ARTICLE 13 IN A VACCINATION ZONE WHERE EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF HPAI IS CARRIED OUT**

- 1. Animals and products subject to prohibition of movements:** vaccinated poultry or captive birds and their products within and outside the vaccination zone.
- 2. Germinal products subject to prohibition of collection:** not applicable.
- 3. Conditions for granting a derogation in accordance with Article 13(2), point (b)(ii), Article 13(3), point (b), and Article 13(4), point (b).**

Movements of vaccinated poultry or captive birds and their products within and outside the vaccination zone may be authorised only in the cases covered by and under the same general and specific conditions as those provided for in Articles 28, 29 and 30, Article 31(1) and Articles 33, 34 and 37 of Delegated Regulation (EU) 2020/687.

After the end of the recovery period, the measures provided for in points 2 to 4 of Part 5 shall remain in place in the establishments keeping vaccinated animals, as long as they keep vaccinated animals.

### Part 4

#### **WAITING PERIODS FOR HPAI FOLLOWING EMERGENCY PROTECTIVE VACCINATION**

The competent authority shall maintain in the vaccination zone the conditions provided for in part 3 of this Annex until:

<b><i>Waiting period</i></b>	<b><i>Type of surveillance to be implemented during the waiting period</i></b>
<i>28 days after completion of the emergency protective vaccination or at the time of the lifting of the restricted zones established in accordance with Article 21 of Delegated Regulation 2020/687 if this comes later.</i>	<i>Reinforced surveillance in accordance with Article 9(1), point (c) and Part 2 of this Annex.</i>

### Part 5

#### **SPECIFIC CONDITIONS FOR PREVENTIVE VACCINATION OF HPAI**

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1. **Type of vaccine to be used:** Vaccines that do not contain live avian influenza virus (vaccines containing live avian influenza virus, whether attenuated or not, shall not be used).
2. **Reinforced surveillance to be implemented in case of preventive vaccination:**
  - 2.1 Passive surveillance must be implemented in all the establishments where poultry or captive birds are kept in the area where preventive vaccination against HPAI has been implemented when any clinical signs or post-mortem lesions suggesting HPAI are observed or when there is a change in normal production and health parameters such as mortality rate and feed and water intake.
  - 2.2 After the start of vaccination, the following active surveillance must be carried out at least every 30 days by an official veterinarian or under their supervision in all establishments where vaccinated poultry or captive birds are kept, to detect occurrence of infection with HPAI field virus:
    - (a) a clinical examination that includes a check of the production records and health records of the establishment for each flock, including an evaluation of its clinical history and clinical examinations of the poultry or captive birds;
    - (b) sampling for testing by pathogen identification methods of all dead birds up to 15 per flock collected within the 48 hours before the sampling;
    - (c) out of the high risk period for infection with HPAI virus, the testing required in point (b) may be carried out only in a sufficiently representative sample of establishments where vaccinated poultry or captive birds are kept;
    - (d) the number of establishments sampled for the purpose of surveillance as required in point (b) and (c) and the frequency of sampling must comply with:
      - i) the following minimum requirements:

Species	% of vaccinated establishments to be sampled	Frequency of sampling (days)
Chicken layers	100	30
	25	7
Ducks	100	30
	50	7
Turkeys	100	30

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	50	14
	25	7

or

- ii) any scientifically valid sampling design that ensures with at least 95[99]% confidence that the population of vaccinated poultry and captive birds is free from HPAI, with at least 90% sensitivity for early detection of infection with HPAI virus.
- 2.3 Vaccinated captive birds from confined establishments and from establishments keeping up to 50 captive birds are exempted from the surveillance requested in point 2.2, subpoints (b), (c) and (d).
  - 2.4 The surveillance provided for in points 2.1 and 2.2 must remain in place in the establishments keeping vaccinated animals as long as they keep vaccinated animals. By way of derogation, in case of long living vaccinated captive birds or those from confined establishments, the surveillance provided for in points 2.1 and 2.2 must be maintained for a period of 12 months from the date when the last vaccination was applied.
- 3. Animals and products subject to prohibition of movements in accordance with Article 14(1):** vaccinated poultry or captive birds and their products [hatching eggs and products of animal origin thereof].
- 4. Conditions for granting a derogation in accordance with Article 14(2), point (b).**
- 4.1 Conditions for granting a derogation for movements of vaccinated poultry or captive birds including day-old chicks and hatching eggs derived from such poultry or captive birds:**
- (a) They are vaccinated poultry or captive birds for which the results of the passive and active surveillance, implemented in accordance with point (2) of this Part, are negative for detection of infection with HPAI field virus, or they are day-old chicks and hatching eggs derived from such poultry or captive birds, and:
    - (i) in case of poultry, these are moved to a slaughterhouse for immediate slaughter; or
    - (ii) they are moved from their establishments to other establishments:
      - where vaccination is carried out; or
      - where only vaccinated poultry or captive birds are kept; or
      - where complete separation between vaccinated and non-vaccinated poultry or captive birds can be ensured;
- and
- (iii) the moved poultry or captive birds remain in the establishment of destination, referred to in subpoint (ii), for at least 21 days, unless these are poultry moved from the establishment of destination to a slaughterhouse for immediate slaughter;



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- (iv) the poultry or captive birds, including day-old chicks and hatching eggs derived from such poultry or captive birds, referred to in subpoints (i) and (ii) are not moved to another Member State;

or

- (b) they are vaccinated captive birds from confined establishments moved to a confined establishment in another Member State provided that:
  - (i) authorisation of such type of movements has been granted by the competent authority of the Member State of destination;
  - (ii) within 72 hours before movement they have been subjected to a sampling for testing by pathogen identification methods with favourable results;

or

- (c) they are vaccinated poultry sent for immediate slaughter to another Member State, provided that:
  - (i) the surveillance applied in the establishment of origin in accordance with point (2) of this Part has favourable results;
  - (ii) poultry of the consignment to be dispatched were clinically inspected with favourable results by an official veterinarian within 72 hours before the time of loading, and favourable results were obtained from testing by pathogen identification methods on samples collected from the flock of origin within 72 hours prior to the time of departure of that consignment from all up to 15 dead birds;

or

- (d) they are hatching eggs derived from vaccinated poultry or captive birds:
  - (i) which originate from a vaccinated breeding flock for which the passive and active surveillance in accordance with point (2) of this Part has favourable results;
  - (ii) which have been disinfected before dispatch in accordance with a method approved by the competent authority;
  - (iii) which are transported directly to the hatchery of destination;
  - (iv) which are traceable within the hatchery;
  - (v) and the movement of which, in case they are moved to another Member State, has been notified by the competent authority of the Member State of origin to the competent authority of the Member State of destination;

or

- (e) they are day-old chicks derived from vaccinated poultry:
  - (i) which originate from a vaccinated breeding flock for which the reinforced passive and active surveillance in accordance with point (2) of this Part has favourable results;
  - (ii) which are placed in a poultry house or shed where there is no resident poultry;

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- (iii) which remain in the establishment of destination for at least 21 days;
- (iv) and the movement of which, in case they are moved to another Member State, has been notified by the competent authority of the Member State of origin to the competent authority of the Member State of destination.
- (f) by way of derogation from point (a)(iv), the vaccinated birds from confined establishments moved to another confined establishment for breeding purposes may be kept not separated from non-vaccinated captive birds that are part of the same breeding programme.

**4.2 Conditions for granting a derogation for the movement of eggs for human consumption and meat derived from vaccinated poultry:**

- (a) The eggs originate from a vaccinated flock for which the surveillance in point (2) of this Part has favourable results and are directly transported to:
  - (i) a packing centre designated by the competent authority provided that they are packed in disposable packaging or in a packaging which can be cleaned and disinfected in such way as to inactivate the HPAI virus; or
  - (ii) an establishment for the manufacture of egg products as set out in Chapter II of Section X of Annex III to Regulation (EC) No 853/2004 to be handled and treated in accordance with Chapter XI of Annex II to Regulation (EC) No 852/2004.
- (b) The movement of meat obtained from poultry in accordance with the conditions laid down in points 4.1(a)(i), 4.1(a)(iii) and 4.1(c) may be authorized without further condition.

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### ANNEX III

Formateret: Skrifttype: Fed

Formateret: Centreret

### ANNEX XV

#### Classical swine fever (CSF) in wild porcine animals

##### Part 1

#### SPECIFIC CONDITIONS FOR THE IMPLEMENTATION OF EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF CSF

1. **Size of the vaccination zone:** The vaccination area should be as large as the wild porcine animals population is spatially connected. The area to be vaccinated should be designed according to the spatial distribution of the wild porcine animals population, its size and the landscape structure. The zone shall be delimited by physical barriers to contain the population of wild porcine animals and prevent contact with wild porcine animals from the peri-vaccination zone.
2. **Size of the peri-vaccination zone:** No specific conditions.
3. **Type of vaccine to be used or prioritised:** Live attenuated vaccines shall be prioritised. Other vaccines may be used only for duly justified reasons.
4. **Minimum coverage:** A continuous oral vaccination scheme is required to maintain population immunity. Maximum immunity is reached after double vaccination three times a year: in spring, summer and autumn. Double vaccination consists of two campaigns at an interval of approximately four weeks ~~three double vaccination campaigns~~. Each campaign should aim for at least 40% of targeted animals, and the end of the vaccination scheme should aim for at least 60% of targeted animals vaccinated in the vaccination zone.
5. **Targeted animals/species:** Wild porcine ~~A~~ animals of listed species, in accordance with Implementing Regulation (EU) 2018/1882, in the vaccination zone.
6. **Hunting and other activities likely to cause displacement of wild** ~~boar~~ porcine animal populations: Should be regulated ~~restricted~~ in the vaccination zone at least until the end of the waiting period provided for in part 4. Hunted wild porcine animals should be tested with pathogen identification and antibody detection tests.

Formateret: Skrifttype: Ikke Fed

##### Part 2

#### SPECIFIC CONDITIONS FOR THE REINFORCED CLINICAL AND LABORATORY SURVEILLANCE TO BE IMPLEMENTED IN THE VACCINATION ZONE DURING EMERGENCY VACCINATION FOR PREVENTION AND CONTROL OF ASF-CSF IN WILD PORCINE ANIMALS

In the vaccination zone, after completing oral immunisation, the age class of wild porcine animals ~~boar~~ that should be examined serologically to detect a new or re-emerging infection depends on the season in which vaccination was completed and the length of time since

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completion. ~~A wild porcine animals' population is CSF free if the antibody prevalence in the age class 6-12 (or 18) months is below a certain detection level (i.e. <5%, 95% CI).~~

The following surveillance shall be implemented in wild porcine animals in the vaccination zone to verify the success of the vaccination operation. This surveillance shall include:

- Estimates of the size of the population of wild porcine animals in the vaccination and peri-vaccination zones. ~~If population size and prevalence estimates are not available, the calculation of samples size for the serological monitoring should assume 5% of prevalence and a confidence level at 95%.~~

~~Reinforced laboratory Enhanced active surveillance to assess immunity levels and detect any virus persistence in the wild porcine animals population; this includes pathogen identification and antibody detection in all hunted, culled and found dead or sick wild porcine animals; compulsory surveillance by means of the trapping and culling of wild porcine animals and testing with serological and pathogen identification tests for CSF.~~

- ~~Enhanced passive surveillance: compulsory testing of all dead wild porcine animals with pathogen identification tests for CSF.~~

### Part 3

## ANIMALS AND PRODUCTS SUBJECT TO PROHIBITION OF MOVEMENTS IN ACCORDANCE WITH ARTICLE 13 IN A VACCINATION ZONE WHERE EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF ASF/CSF IN WILD PORCINE ANIMALS IS CARRIED OUT

### 1. Animals and products subject to prohibition of movements

~~Wild porcine. The following animals and products of animal origin from wild porcine animals located in the vaccination zone to a destination within or outside the vaccination zone:~~

- (a) ~~consignments of wild porcine animals.~~

### 2. Products subject to prohibition of movements

- (b) ~~Fresh meat, meat products and any other products of animal origin, animal by-products and derived products obtained from wild porcine animals and bodies of vaccinated wild porcine animals, which are intended for human consumption.~~

### 3. Conditions for granting a derogation in accordance with Article 13(3), point (b)

~~3.1. By way of derogation from the movement restrictions established under point 1, the competent authority may authorize the movement of products in point 2, within and outside the vaccination zone, provided that the following conditions are met:~~

~~(a) a risk assessment conducted by the competent authority demonstrates that such movement does not pose a risk of spreading CSF;~~

~~(b) wild porcine animals are tested for the presence of the CSF virus, with negative results obtained prior to any further movement of the products for processing or treatment;~~

**Formateret:** Indrykning: Venstre: 1,27 cm, Ingen punkttegn eller nummerering

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(c) the processing and storage of wild porcine animals and their derived products take place in establishments designated by the competent authority, ensuring compliance with biosecurity and CSF control measures;

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(d) (i) the products undergo the risk-mitigating treatments as set out in Annex VII to Delegated Regulation (EU) 2020/687; or

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(ii) the fresh meat, meat products and any other products of animal origin from wild porcine animals and bodies of wild porcine animals are moved within the restricted zone:

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- for private domestic use; or
- by hunters for the supply of 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), point (e), of Regulation (EC) No 853/2004;

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Formateret: Point 1, Punkttegn + Niveau: 1 + Justeret: 2,5 cm + Indrykning: 3,14 cm

3.2. The competent authority shall document and monitor all authorized movements under this derogation and ensure compliance with the conditions set out in paragraph 3.1.

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Formateret: Engelsk (Irland)

#### Part 4

### WAITING PERIODS FOR ASF/CSF FOLLOWING EMERGENCY PROTECTIVE VACCINATION

The competent authority shall maintain in the vaccination zone the conditions provided for in paragraph 1 of part 3 of this Annex until:

<u>Waiting period</u>	<u>Type of surveillance implemented demonstrating the absence of occurrence</u>
<u>12 months after the end date of the last vaccination campaign in wild porcine animals resulted negative, and supported by the favourable conclusions of the implementation of the an exit strategy that demonstrated absence of CSF virus circulation.</u>	<u>Clinical and laboratory surveillance (pathogen identification in wild porcine animals found dead or killed)</u>

Formateret: Skrifttype: Fed

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Formateret: Skrifttype: Kursiv

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## ANNEX IVH

### ANNEX XVI

#### African swine fever (ASF) in kept porcine animals

##### Part 1

#### **SPECIFIC CONDITIONS FOR THE IMPLEMENTATION OF EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF ASF IN KEPT PORCINE ANIMALS**

1. **Size of the vaccination zone:** ~~No specific conditions at least 3 km radius around affected establishments.~~
2. **Size of the peri-vaccination zone:** No specific conditions.
3. **Type of vaccine to be used:** ASF vaccines holding a centralised marketing authorization granted by the Commission in accordance with Article 44(9) of Regulation 2019/6
4. **Minimum coverage:** Vaccine coverage should be at least 95% of establishments in the vaccination zone representing 80% of targeted animals in each of those establishments..
5. **Targeted animals/species:** Animals of listed species, in accordance with Implementing Regulation (EU) 2018/1882, kept in the vaccination zone.

##### Part 2

#### **SPECIFIC CONDITIONS FOR THE REINFORCED CLINICAL AND LABORATORY SURVEILLANCE TO BE IMPLEMENTED IN THE VACCINATION AND PERI-VACCINATION ZONES DURING EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF ASF**

Clinical and laboratory ~~reinforced enhanced active and passive~~ surveillance shall be implemented in the ~~peri-vaccination and~~ vaccination ~~and peri-vaccination~~ zones to identify establishments keeping animals of listed species that had contact with the ~~CSF-ASF~~ virus (ASFV) without showing clinical signs of the disease. In the vaccination zone each establishment being vaccinated should be visited and samples taken during the period starting not earlier than 30 days after the completion of emergency protective vaccination.

~~This~~ The surveillance shall include in the:

1. ~~Peri-vaccination zone:~~

1.1. ~~a visit by an official veterinarian of all establishments in the peri-vaccination zone a clinical examination by an official veterinarian of all animals of listed species kept in all establishments in the peri-vaccination zone.~~

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1.2. ~~laboratory surveillance testing~~ with pathogen identification tests ~~targeted at or 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 the visited~~ establishment.

2. ~~\_\_\_\_\_~~ Vaccination zone:

4. ~~—In each establishment where vaccination was carried out, laboratory examination by means of: (i) testing for antibodies on samples taken from vaccinated animals of listed species to assess vaccination effectiveness, and (ii) collection of samples for pathogen identification from at least the first two dead kept porcine animals every week 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 all the establishments of the vaccination zone according to a sample size that shall be calculated to detect a within establishment animal prevalence of 5 % or less, with a 95 % confidence, in both vaccinated and non vaccinated animals.~~

### Part 3

## ANIMALS AND PRODUCTS SUBJECT TO PROHIBITION OF MOVEMENTS AND CONDITIONS FOR GRANTING A DEROGATION IN ACCORDANCE WITH ARTICLE 13 IN A VACCINATION ZONE WHERE EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF ASF IS CARRIED OUT

### 1. Animals and products subject to prohibition of movements

The following animals, germinal products and products of animal origin from establishments located in the vaccination zone ~~to a destination within or~~ ans to outside of the vaccination zone:

- (a) ~~vaccinated kept~~ porcine animals;
- ~~(b) piglets of seropositive sows;~~
- ~~(e)b~~ semen, oocytes and embryos ~~for artificial insemination~~ from donor kept porcine animals kept in approved germinal product establishments;
- ~~(e)c~~ fresh meat and meat products, including casings, obtained from vaccinated porcine animals.

### 2. Germinal products subject to prohibition of collection

Semen, oocytes and embryos for artificial insemination from ~~seropositive vaccinated~~ donor porcine animals kept in approved germinal product establishments located in the vaccination zone.

### 3. Conditions for granting a derogation in accordance with Article 13(2), point (b)(ii), Article 13(3), point (b), and Article 13(4), point (b).

Movements of animals and products thereof that may be authorised:

~~(3.1)~~ movements of vaccinated porcine animals, directly from the establishment of origin in the vaccination zone:

- (a) to a slaughterhouse for immediate slaughter located in the vaccination zone; or

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- (b) to a slaughterhouse for immediate slaughter located as close as possible to the vaccination zone, in the same Member State, under the same conditions as those provided for in Article 24, Article 28(2), (3), (4), (5) and (7) and Article 29(1) and (2) of Delegated Regulation (EU) 2020/687;
- (bc) to an animal by-products approved plant for killing and disposal, under the same conditions as those provided for in Article 24, Article 28(2), (3), (4), (5) and (7) and Article 37 of Delegated Regulation (EU) 2020/687;
- ~~(3.2)~~ movement of fresh meat and meat products, including casings from ~~vaccinated kept porcine~~ animals in accordance with the provisions of Article 33(1), point (a), of Delegated Regulation (EU) 2020/687;
- ~~(3.3)~~ all movements of porcine animals and products thereof within the same Member State, laid down in point 1, ~~d~~during the waiting period provided for in paragraph 4, from an establishment in a vaccination zone provided that:
  - (a) the vaccinated porcine animals kept in the vaccination zone have been slaughtered or killed, and the fresh meat obtained from those animals has been disposed of or processed in accordance with the provisions of Article 33(1), point (a), of Delegated Regulation (EU) 2020/687;
  - (b) the establishments where vaccinated porcine animals have previously been kept have been cleaned and disinfected in accordance with Article 57(1) of Delegated Regulation (EU) 2020/687;
  - (c) the repopulation of the establishments above has not taken place until at least 10 days after completion of the final cleaning and disinfection operations, ~~and after all porcine animals in the establishments where vaccination has been applied have been slaughtered or killed;~~
  - (d) after repopulation, porcine animals in all repopulated establishments of the vaccination zone have undergone clinical and laboratory examinations in accordance with Annex I to Delegated Regulation (EU) 2020/687 in order to detect the possible presence of ~~ASF virus~~ASFV and those examinations have not taken place until at least 30 days ~~(2 incubation periods)~~ have elapsed after the repopulation, during which time porcine animals are not allowed to move from that establishment.

#### Part 4

#### WAITING PERIODS FOR ~~CSE~~ASF FOLLOWING EMERGENCY PROTECTIVE VACCINATION

The competent authority shall maintain in the vaccination zone the conditions provided for in ~~paragraph 3 of part 4.3~~ of this Annex until:

- ~~— 3 months have elapsed after all vaccinated porcine animals have been slaughtered or killed, excluding kept porcine animals referred to in Article 13(2) of Regulation (EU) 2020/687 when there are means, validated in accordance with the Terrestrial Manual of the WOAAH, of distinguishing between vaccinated and infected kept porcine animals;~~



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~~1. Clinical and laboratory (genome detection and serological) surveillance have been implemented.~~

<u><i>Waiting period</i></u>	<u><i>Type of surveillance implemented demonstrating the absence of occurrence</i></u>
<u><i>3 months after all vaccinated porcine animals have been slaughtered or killed, excluding kept porcine animals referred to in Article 13(2) of Regulation (EU) 2020/687 when there are means, validated in accordance with the Terrestrial Manual of the WOA, of distinguishing between vaccinated and infected kept porcine animals</i></u>	<u><i>Clinical and laboratory surveillance (pathogen identification and antibody detection)</i></u>

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## ANNEX IV

### ANNEX XVII

#### African swine fever (ASF) in wild porcine animals

##### Part 1

#### **SPECIFIC CONDITIONS FOR THE IMPLEMENTATION OF EMERGENCY VACCINATION FOR PREVENTION AND CONTROL OF ASF IN WILD PORCINE ANIMALS**

1. **Size of the vaccination zone:** The vaccination area should be as large as the wild porcine animals population is spatially connected. The area to be vaccinated should be designed according to the spatial distribution of the wild porcine animals population, its size and the landscape structure. The zone shall be delimited by physical barriers to contain the population of wild porcine animals and prevent contact with wild porcine animals from the peri-vaccination zone.
2. **Size of the peri-vaccination zone:** No specific conditions.
3. **Type of vaccine to be used or prioritised:** ASF vaccines holding a centralised marketing authorization granted by the Commission in accordance with Article 44(9) of Regulation 2019/6.
4. **Minimum coverage:** A continuous vaccination scheme is required to maintain population immunity. Maximum immunity is reached after double vaccination three times a year: in spring, summer and autumn. Double vaccination consists of two campaigns at an interval of approximately four weeks. ~~three double vaccination campaigns.~~ Each campaign should aim for at least 40% of targeted animals, and the end of the vaccination scheme should aim for at least 60% of targeted animals vaccinated in the vaccination zone.
5. **Targeted animals/species:** Wild porcine animals of listed species, in accordance with Implementing Regulation (EU) 2018/1882, in the vaccination zone.
6. **Hunting and other activities likely to cause displacement of wild ~~bear~~ porcine animal populations:** Should be restricted-regulated in the vaccination zone at least until the end of the waiting period provided for in part 4. Hunted wild porcine animals should be tested with antibody detection and pathogen identification tests.

##### Part 2

#### **SPECIFIC CONDITIONS FOR THE REINFORCED CLINICAL AND LABORATORY SURVEILLANCE TO BE IMPLEMENTED IN THE VACCINATION ZONE DURING EMERGENCY VACCINATION FOR PREVENTION AND CONTROL OF ASF IN WILD PORCINE ANIMALS**

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In the vaccination zone, after completing oral immunisation, the age class of wild porcine animals that should be examined serologically to detect a new or re-emerging infection depends on the season in which vaccination was completed and the length of time since completion. The following surveillance shall be implemented in wild porcine animals in the vaccination zone to verify the success of the vaccination operation. This surveillance shall include:

- Estimates of the size of the population of wild porcine animals in the vaccination and peri-vaccination zones.
- ~~Enhanced active~~Reinforced laboratory surveillance should be conducted to assess immunity levels and detect any virus persistence in the wild porcine animals population. This should include pathogen identification and antibody detection in all hunted, culled and of found dead/sick wild porcine animals; compulsory surveillance by means of the trapping and culling of wild porcine animals and testing with serological and pathogen identification tests for ASF.
- ~~Enhanced passive surveillance: compulsory testing of all dead wild porcine animals with pathogen identification tests for ASF.~~

### Part 3

## ANIMALS AND PRODUCTS SUBJECT TO PROHIBITION OF MOVEMENTS IN ACCORDANCE WITH ARTICLE 13 IN A VACCINATION ZONE WHERE EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF ASF IN WILD PORCINE ANIMALS IS CARRIED OUT

### 1. ~~Animals and products~~ subject to prohibition of movements

~~The following animals and products of animal origin from wild porcine animals located in the vaccination zone to a destination within or outside the vaccination zone:~~

- (a) ~~consignments of w~~Wild porcine animals.

### 2. Products subject to prohibition of movements

- (b) ~~fresh meat, meat products and any other products of animal origin, animal by-products and derived products obtained from wild porcine animals and bodies of vaccinated wild porcine animals, which are intended for human consumption.~~

### 3. Conditions for granting a derogation in accordance with Article 13(3), point (b)

3.1. By way of derogation from the movement restrictions established under point 2, the competent authority may authorize the movement of products within and outside the vaccination zone, provided that the following conditions are met:

- (a) a risk assessment conducted by the competent authority demonstrates that such movement does not pose a risk of spreading ASF;
- (b) wild porcine animals are tested for the presence of the ASF virus, with negative results obtained prior to any further movement of the products for processing or treatment;
- (c) the processing and storage of wild porcine animals and their derived products take place in establishments designated by the competent authority, ensuring compliance with biosecurity and ASF control measures;

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Formateret: Skrifttype: Fed

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(d) (i) the products undergo the risk-mitigating treatments as set out in Annex VII to Delegated Regulation (EU) 2020/687; or

(ii) the fresh meat, meat products and any other products of animal origin from wild porcine animals and bodies of wild porcine animals are moved within the restricted within zone:

- for private domestic use; or
- by hunters for the supply of 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), point (e), of Regulation (EC) No 853/2004.

3.2. The competent authority shall document and monitor all authorized movements under this derogation and ensure compliance with the conditions set out in point 3.1.

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#### Part 4

### WAITING PERIODS FOR ASF FOLLOWING EMERGENCY PROTECTIVE VACCINATION

The competent authority shall maintain in the vaccination zone the conditions provided for in ~~paragraph 1~~ of part 3 of this Annex until:

- ~~0. 12 months after the date of the last vaccination campaign in wild porcine animals found dead/culled with a positive result to a pathogen identification test and in case of demonstration of absence of ASFV circulation in a determined geographical context supported by the favorable conclusions of the implementation of the EFSA Exit Strategy.~~
- ~~0. Laboratory (genome detection and serological) surveillance have been implemented.~~

<u><i>Waiting period</i></u>	<u><i>Type of surveillance implemented demonstrating the absence of occurrence</i></u>
<u><i>12 months after the end date of the last vaccination campaign in wild porcine animals resulted negative, and supported by the favourable conclusions of the implementation of the an exit strategy that demonstrated absence of ASF virus circulation.</i></u>	<u><i>Clinical and laboratory surveillance (pathogen identification in wild porcine animals found dead or killed)</i></u>

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## ANNEX VI

### ANNEX XVIII Sheep pox and goat pox (SPGP)

#### Part 1

#### **SPECIFIC CONDITIONS FOR THE IMPLEMENTATION OF EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF SHEEP POX AND GOAT POX**

1. **Size of the vaccination zone:** No specific rules.
2. **Size of the peri-vaccination zone:** No specific conditions.
3. **Type of vaccine to be used:** No specific rules.
4. **Minimum coverage:** Vaccine coverage should be at least 95% of the establishments in the vaccination zone representing at least 80% of the targeted animals in the vaccination zone.
5. **Targeted animals/species:** Animals of listed species in accordance with Implementing Regulation (EU) 2018/1882 kept in the vaccination zone, including at least ovine and caprine animals.

#### Part 2

#### **SPECIFIC CONDITIONS FOR THE REINFORCED CLINICAL AND LABORATORY SURVEILLANCE TO BE IMPLEMENTED IN THE VACCINATION AND PERI-VACCINATION ZONES DURING EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF SHEEP POX AND GOAT POX**

Passive surveillance: in the vaccination and peri-vaccination zones, enhanced passive surveillance for sheep pox and goat pox signs and symptoms as well as for increased mortality in small ruminants.

#### Part 3

#### **ANIMALS AND PRODUCTS SUBJECT TO PROHIBITION OF MOVEMENTS AND CONDITIONS FOR GRANTING A DEROGATION IN ACCORDANCE WITH ARTICLE 13 IN A VACCINATION ZONE WHERE EMERGENCY PROTECTIVE VACCINATION FOR PREVENTION AND CONTROL OF SHEEP POX AND GOAT POX IS CARRIED OUT**

1. Animals and products subject to prohibition of movements until the end of the waiting

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period laid down in Part 4:

The same animals and products, located in the vaccination zones, as those subject to restrictions in establishments located in protection and surveillance zones established in the event of an outbreak of sheep pox and goat pox provided for in Article 27 of Delegated Regulation (EU) 2020/687 and with the same restrictions.

2. Germinal products subject to prohibition of collection: semen, oocytes and embryos from animals of listed species, until the end of the waiting period.
3. Conditions for granting a derogation in accordance with Article 13(2), point (b)(ii), Article 13(3), point (b), and Article 13(4), point (b). Movements that may be authorised.
  - 3.1. Movements of vaccinated animals and products thereof from establishments located in the vaccination zone, under the same general conditions as those provided for in Article 43 of Delegated Regulation (EU) 2020/687, and only in the cases covered by and under the same specific conditions as those provided for in Articles 44, 45, 48, 49, 51 and 53 of that Regulation in relation to the surveillance zone.
  - 3.2. Movements of vaccinated animals and products thereof from establishments located in the vaccination zone, provided that those establishments do not keep vaccinated animals any more.
  - 3.3. Movements of vaccinated animals and products thereof from establishments located in the vaccination zone after 2 years have elapsed from cessation of vaccination.

#### Part 4

#### WAITING PERIODS FOR SHEEP POX AND GOAT POX FOLLOWING EMERGENCY PROTECTIVE VACCINATION

<i>Waiting period</i>	<i>Type of surveillance to demonstrate the absence of occurrence of sheep pox and goat pox</i>
<i>6 months after the slaughter or killing of the last case and of all vaccinated animals if emergency protective vaccination has been used, and during which period clinical and laboratory surveillance has demonstrated no occurrence of sheep pox and goat pox</i>	<i>Clinical and laboratory (virological and serological)</i>
<i>24 months after the slaughter or killing of the last case, or after the last vaccination if emergency protective vaccination has been used, whichever occurred last, and during which period clinical and laboratory surveillance has demonstrated no occurrence of sheep pox and goat pox</i>	<i>Clinical and laboratory (virological and serological)</i>

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## **ANNEX VI**

### **LIST OF ANNEXES**

1. Annex I on category A and B diseases for which the use of vaccines shall be prohibited by Member States and on the use of certain veterinary medicinal products, other than vaccines, for prevention and control of category A and B diseases.
2. Annex II on the criteria for the use of a vaccine to prevent and control a category A disease in animals.
3. Annex III on the information to be included in the official vaccination plan.
4. Annex IV on the preliminary information to be provided to other Member States and the Commission prior to vaccination.
5. Annex V on the minimum records on vaccination.
6. Annex VI on the minimum information to be provided by the competent authority to other Member States and the Commission on the implementation of vaccination.
7. Annex VII on vaccination against foot and mouth disease (FMD).
8. Annex VIII on vaccination against infection with Rift Valley Fever virus (RVF).
9. Annex IX on vaccination against infection with lumpy skin disease virus (LSD).
10. Annex X on vaccination against infection with peste des petits ruminants virus (PPR).
11. Annex XI on vaccination against African horse sickness (AHS).
12. Annex XII on vaccination against classical swine fever (CSF) in kept porcine animals.
13. Annex XIII on vaccination against highly pathogenic avian influenza (HPAI).
14. Annex XIV on vaccination against infection with Newcastle disease virus (NCD).
15. Annex XV on vaccination against classical swine fever (CSF) in wild porcine animals.
16. Annex XVI on vaccination against African swine fever (ASF) in kept porcine animals.
17. Annex XVII on vaccination against African swine fever (ASF) in wild porcine animals.
18. Annex XVIII on vaccination against sheep pox and goat pox (SPGP).

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