

## Chapter 10

# VACCINATION

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### 1. Prohibition on routine prophylactic vaccination

- 1.1 Under Article 18.1 of Council Directive 2001/89/EC, the use of vaccine against CSF is prohibited.
- 1.2 The manipulation, manufacture, storage, supply, distribution and sale of CSF vaccines must be carried out under official supervision.

### 2. Emergency vaccination

- 2.1 By way of derogation from this prohibition, emergency vaccination is permitted under Article 19 of Council Directive 2001/89/EC, where:
  - CSF has been confirmed
  - The epidemiological data available suggest that it threatens to spread
  - The procedures outlined in **Sections 4 and 5 below** are complied with

### 3. Decision to vaccinate

- 3.2 The decision to vaccinate will depend on:
  - the criteria and risk factors listed in **Table 1** below
  - access to suitable vaccine in sufficient quantities

Criteria	Decision	
	For vaccination	Against vaccination
Number/incidence slope of outbreaks in the previous 10-20 days	High/rising rapidly	Low/shallow or slow rise
Location of holdings where vaccination might be applied in an area with a high density* of pigs	Yes	No
Likelihood of further outbreaks in the area for the next 2 months or more	Highly likely	Not likely
Shortage of rendering capacity	Yes	No

*Table 1: Criteria and risk factors to be considered when deciding whether or not to introduce emergency vaccination*

- 3.2 An “area with a high density of pigs” is defined in article 2 (u) of Directive 2001/89/EC as a geographical area with a radius of 10 km around a holding containing susceptible animals suspected of or infected with CSF, where there is a pig density higher than 800 pigs per km<sup>2</sup>. The holding in question must be situated either in a region (county) where there is a density of pigs higher than 300 pigs per km<sup>2</sup> or at a distance of less than 20 km from such a county.
- 3.3 The NDCC, in consultation with the CSF Expert Group, will assess these factors and make their recommendations to the Minister.

#### **4. Vaccination Plan**

- 4.1 Under Article 19.3, 2<sup>nd</sup> paragraph, where a Member State wishes to carry out emergency vaccination, they must present a detailed vaccination plan to the Commission and the Member States for approval at the Standing Committee of the Food Chain and Animal Health (SCoFCAH).
- 4.2 The vaccination plan must include the:
- disease situation that has led to the request for emergency vaccination
  - extent of the geographical region in which vaccination is to be carried out
  - number of pig holdings in the vaccination zone
  - categories and approximate number of pigs to be vaccinated
  - vaccine to be used
  - duration of vaccination programme
  - identification and registration of the vaccinated animals
  - movement controls to be introduced on vaccinated pigs and their products
  - criteria to be considered when deciding to slaughter out or vaccinate pigs on contact holdings of infected premises
  - clinical and laboratory examinations to be carried out (especially if a marker vaccine is to be used)

- 4.3 The plan may be approved with or without amendments.
- 4.4 The plan may be subsequently amended, to take account of new developments in the disease situation.
- 4.5 Article 19.7 allows a Member State to introduce emergency vaccination without SCoFCAH approval, provided:
- the Community interests are not jeopardised
  - an outline Vaccination Plan has been drawn under the Contingency Plan, which includes the information in Section 4.2 above,
  - the vaccinated pigs are slaughtered as soon as possible after vaccination
  - The meat from the vaccinated pigs must be X-stamped and treated in accordance with **Annex 7** of Chapter 3, **Slaughter plants**.
  - the Commission has been notified before vaccination commences
- 4.6 This vaccination plan would then be reviewed at the next SCoFCAH meeting.

## **5. Measures to be taken within a vaccination zone**

- 5.1 Article 19.4 and 5 of Council Directive 2001/89/EC lay down the measures to be taken during vaccination and until **6 months** after completion of vaccination:
- a) No live pigs may leave the vaccination zone unless:
    - direct to a designated slaughter plant in the vaccination zone or close to it or
    - direct to a rendering plant for slaughter and rendering under official supervision
  - b) Fresh pig meat produced from vaccinated pigs must be:
    - rendered or
    - X-stamped and treated (in accordance with **Annex 7** of Chapter 3, **Slaughter plants**)
  - c) Semen, ova and embryos collected from pigs in the 30 days prior to vaccination must be traced and destroyed under official supervision
- 5.2 Under Article 19.6, the following must be prohibited:
- a) Sero-positive pigs may not leave a holding, except for immediate slaughter
  - b) Semen, ova and embryos may not be collected from sero-positive animals
  - c) Piglets from sero-positive sows may not leave the holding unless direct to :
    - A slaughter plant for immediate slaughter
    - A designated holding, from which they are to be sent direct to a slaughter plant
    - A holding, after testing negative for CSF antibodies
- 5.3 The measures to be taken are summarised in the diagrams in **Annex 1** below.
- 5.4 Under Article 19.8, the measures in Section 7.1 and 7.2 above may be lifted following:

- a) Slaughter of all pigs on holdings where vaccine has been used, followed by rendering or X-stamping and treating the meat (in accordance with **Annex 7** of Chapter 3, **Slaughter plants**)
  - b) Cleaning and disinfection of the holdings in accordance with **Protocol CSF P16** of Chapter 5, **Protocols**.
- 5.5 Under Article 19.8.2<sup>nd</sup> paragraph, **restocking** of holdings following lifting of the vaccination zone measures, may not take place until at least 10 days after completion of cleaning and disinfection.
- 5.6 At least 40 days after restocking, a clinical examination and sampling of the pigs must be carried out in accordance with **Protocol CSF P10** of Chapter 5, **Protocols**.

## 6. Vaccines available

### 6.1 C Strain vaccines

Attenuated C strain vaccines are available commercially. These vaccines may only be used if the pigs are slaughtered as soon as possible after vaccination.

### 6.2 Marker vaccines

- a) Marker vaccines may be used to vaccinate pigs to live, providing a suitable discriminatory test is available to differentiate vaccinated from infected animals.
- b) Two E2 sub-unit marker vaccines have been evaluated by the EU CSF Reference Laboratory, in a trial with their corresponding discriminatory test:
  - *Bayovac*® (Bayer) + E<sup>ms</sup> ELISA test *Ceditest*®
  - *Porcilis*® *Pesti* (Intervet) + E<sup>ms</sup> ELISA test *Chekit*®
- c) Both vaccines have been found to be adequate in terms of protection. However, the vaccines are not as immunogenic as the C strain vaccines.
- d) Of the discriminatory tests, only *Chekit*® has been found to be adequate. The test is less sensitive than conventional E2 Ab ELISAs, but is acceptable as a herd test, provided sufficient pigs are randomly sampled and tested. The test may be complicated by cross-reaction with BDV and/or BVDV in regions with a high prevalence of these diseases.
- e) Where marker vaccines are used, Article 19.9 of Directive 2001/89/EC allows for a derogation from the measures detailed in **Sections 5.1** and **5.2** above to be granted (in particular marking of meat from vaccinated pigs, its subsequent use and the destination of treated products). Such a derogation would be granted by SCoFACH procedure, providing:
  - The vaccination plan is approved before commencing vaccination
  - Following vaccination and subsequent discriminatory testing, a request in writing has been submitted to the Commission, accompanied by a

comprehensive report on the implementation of the vaccination campaign, its results and the overall epidemiological situation, and

- An on-the-spot check has been carried out by FVO inspectors

In granting the derogation, consideration will be given to the risk of spread of CSF virus by movements or trade in vaccinated pigs, their offspring or products.

## **7. Recovery of CSF-free status with or without vaccination**

7.1 Under Article 2.1.13.6. of the Animal Health Code of OIE the following criteria must be met to recover CSF-free status following an outbreak of disease:

Should a CSF *outbreak* occur in an *establishment* of a free country or zone (free in domestic and wild pigs, or free in domestic pigs only), the status of the country or zone may be restored at least 30 days after completion of a *stamping-out policy* which should include the following measures:

- 1) a CSF domestic pig control area (including an inner protection area of at least 3 kilometres radius and an outer surveillance area of at least 10 kilometres radius) should be delineated around the *outbreak*, taking into account the control measures applied, the presence of natural and administrative boundaries, and an assessment of the risk of disease spread;
- 2) all the pigs have been killed and their carcasses destroyed, and *disinfection* has been applied within the *establishment*;
- 3) in the protection area around a CSF *outbreak*:
  - a) a risk assessment should be carried out to determine the likelihood of CSF infection in neighbouring *establishments*; when a significant risk is indicated, a *stamping-out policy* of all domestic pigs within a radius of at least 0.5 kilometre may be applied;
  - b) an immediate clinical examination of all pigs in all pig *establishments* situated within the protection area has been carried out;
- 4) in the surveillance area around a CSF *outbreak*, all sick pigs should be subjected to laboratory tests for CSF;
- 5) an epidemiological examination including clinical examination, and/or serological and/or virological testing has been carried out in all pig *establishments* that have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within the CSF domestic pig control area. demonstrating that these *establishments*

are not infected;

- 6) measures aimed at preventing any virus spread by live pigs, pig semen and pig embryos, contaminated material, *vehicles*, etc. have been implemented.

7.2 If emergency vaccination has been practised within the CSF domestic pig control area, recovery of the free status can not occur before all the vaccinated pigs have been slaughtered, unless there are validated means of distinguishing between vaccinated and infected pigs.

## ANNEX 1

### Measures applying during of vaccination campaign and for the following 6 months

