2000/428/EC: Commission Decision of 4 July 2000 establishing diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation and differential diagnosis of swine vesicular disease (notified under document number C(2000) 1805) (Text with EEA relevance)

Article 1 (1) Member States shall ensure that the confirmation of swine...

Article 2 This Decision shall apply from 1 October 2000.

Article 3 This Decision is addressed to the Member States.

Signature

## **ANNEX**

MANUAL OF DIAGNOSTIC PROCEDURES, SAMPLING METHODS AND CRITERIA FOR THE EVALUATION OF THE RESULTS OF LABORATORY TESTS FOR THE CONFIRMATION AND DIFFERENTIAL DIAGNOSIS OF SWINE VESICULAR DISEASE

#### **CHAPTER I**

# Introduction, objectives and definitions

- 1. This Manual: provides for guidelines and minimum requirements on diagnostic...
- 2. For the purpose of this Manual the following definitions shall...

# **CHAPTER II**

Guidelines for checks on pigs showing clinical signs of swine vesicular disease

- 1. Member States shall ensure that when the presence of swine...
- 2. Member States shall ensure that when pigs show clinical signs...

### **CHAPTER III**

General procedures for sampling and transport of samples

- 1. Any person entering or leaving pig holdings where there is...
- 2. All pigs sampled must be uniquely marked in such a...
- 3. The samples must be sent to the laboratory accompanied by...
- 4. Since any vesicular condition in pigs may be foot and...
- 5. Samples suspected to contain swine vesicular disease virus must only...

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- 6. All samples can be transported at 4 °C if the...
- 7. For samples destined for the Community reference laboratory from Member...
- 8. Transportation of samples to the national laboratories must be in...

#### **CHAPTER IV**

Sampling procedures in a holding with clinical suspect pigs

- 1. When the presence of swine vesicular disease virus in a...
- 2. In these holdings the preferred samples for diagnosis are epithelium...
- 3. Even if fresh epithelial tissue and vesicular fluid in sufficient...
- 4. The samples must be collected and transported in accordance with...

#### CHAPTER V

Sampling procedures for swine vesicular disease serosurveillance

- 1. When sero-surveillance is carried out with the following purposes: for...
- 2. When sero-surveillance is carried out with the following purposes: for...

# CHAPTER VI

Further actions and re-sampling procedures in case of finding of seropositive pigs

- 1. In case a single seropositive pig is detected on a...
- 2. However, the competent authority may decide to lift the measures...
- 3. If the checks and the serological tests carried out in...
- 4. In case more than one seropositive pig is detected on...
- 5. Without prejudice to the measures referred to in Article 9...
- 6. However, the competent authority may decide to lift the measures...

# **CHAPTER VII**

Principles and applications of virological tests and evaluation of their results

- A. Detection of virus antigen
  - 1. An indirect sandwich ELISA has replaced the complement fixation test...
  - 2. Alternative monoclonal antibody-based ELISA systems, using selected monoclonal antibodies as...
  - 3. A monoclonal antibody-based ELISA can be used to study antigenic...
- B. Isolation and growth of virus

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- 1. As a routine, clarified suspensions of samples of epithelium, vesicular...
- 2. To isolate and grow virus, clarified epithelial suspension is inoculated...
- 3. If a cytopathic effect develops, the supernatant fluid must be...
- 4. Suspensions of faecal samples can be processed as described in...
- 5. The simultaneous inoculation of a porcine cell line and one...
- C. The polymerase chain reaction (PCR) for genome detection
  - 1. Nucleic acid recognition methods can be used to detect swine...
  - 2. The PCR technique is rapid (the results are usually available...
  - 3. Where sub-clinical infection is suspected, or when samples are collected...
  - 4. By sequencing approximately 200 nucleotides within the 1D gene which...
- D. Evaluation of the results of virological tests

#### CHAPTER VIII

Principles and applications of serological tests and evaluation of their results

- A. Virus neutralization (VN) test
  - 1. The quantitative VN micro-test for swine vesicular disease virus antibody...
  - 2. Virus is grown in IB-RS-2 cell monolayers and stored either...
- B. ELISAs
  - 1. The ELISA for detection of antibodies is a monoclonal antibody-based...
  - 2. An indirect trapping ELISA using isotype-specific monocolonal antibodies to detect...
- C. Application of serological tests and evaluation of results
  - 1. The VN test and the ELISA are the recommended serological...
  - 2. The presence of a singleton reactor may be suspected where...
  - 3. A pig is confirmed singleton reactor when: follow-up testing does...
  - 4. However, the following additional criteria and principles must also be...

#### CHAPTER IX

Clinical signs and features of swine vesicular disease

# CHAPTER X

Swine vesicular disease reference sera

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(1) OJ L 62, 15.3.1993, p. 69.

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#### **Changes to legislation:**

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# Changes and effects yet to be applied to:

- Annex Ch. 2 words substituted by S.I. 2018/1410 reg. 6(4)(a)
- Art. 1(1) words substituted by S.I. 2018/1410 reg. 6(2)(a)
- Art. 1(1) words substituted in earlier amending provision S.I. 2018/1410, reg. 6(2)(a) by S.I. 2020/1388 reg. 25(3)(a)
- Art. 1(2) substituted by S.I. 2018/1410 reg. 6(2)(b)
- Art. 3 omitted by S.I. 2018/1410 reg. 6(3)

# Changes and effects yet to be applied to the whole legislation item and associated provisions

- Annex Ch. 3 para. 8 omitted by S.I. 2018/1410 reg. 6(4)(c)
- Annex Ch. 3 para. 7 substituted by S.I. 2018/1410 reg. 6(4)(b)(ii)
- Annex Ch. 5 para. 1(c) word omitted by S.I. 2018/1410 reg. 6(4)(d)(i)
- Annex Ch. 6 para.002(c) word substituted by S.I. 2018/1410 reg. 6(4)(e)(i)
- Annex Ch. 8 s. C words omitted by S.I. 2018/1410 reg. 6(4)(f)(ii)
- Annex Ch. 3 para. 5 words substituted by S.I. 2018/1410 reg. 6(4)(b)(i)
- Annex Ch. 5 para. 1 words substituted by S.I. 2018/1410 reg. 6(4)(d)(ii)
- Annex Ch. 6 para. 6(c) words substituted by S.I. 2018/1410 reg. 6(4)(e)(ii)
- Annex Ch. 8 s. C words substituted by S.I. 2018/1410 reg. 6(4)(f)(i)
- Art. 1(3) inserted by S.I. 2018/1410 reg. 6(2)(c)
- Art. 1(3)(a)(ii)(iii) Art. 1(3)(a)(iii)(iv) renumbered as Art. 1(3)(a)(ii)(iii) in earlier amending provision S.I. 2018/1410, reg. 6(2)(c) by S.I. 2020/1388 reg. 25(3)(b)(i)
- Art. 1(3)(a)(ii) omitted in earlier amending provision S.I. 2018/1410, reg. 6(2)(c) by
  S.I. 2020/1388 reg. 25(3)(b)(i)
- Art. 1(3)(b) words substituted in earlier amending provision S.I. 2018/1410, reg. 6(2)
  (c) by S.I. 2020/1388 reg. 25(3)(b)(ii)