Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC

CHAPTER VIII

DIAGNOSTIC PROCEDURES, DIAGNOSTIC MANUAL AND REFERENCE LABORATORIES

Article 50

Diagnostic procedures and diagnostic manual

1 The Member States shall ensure that diagnostic procedures, sampling and laboratory testing to detect the presence of avian influenza in poultry or other captive birds or avian influenza virus in mammals are carried out in accordance with the diagnostic manual in order to ensure uniform procedures for its diagnosis.

That manual shall be adopted in accordance with the procedure referred to in Article 64(2) by 3 August 2006. Any subsequent amendment to the manual shall be adopted in accordance with the same procedure.

2 The diagnostic manual provided for in paragraph 1 shall establish at least the following:

a minimum biosecurity requirements and quality standards to be observed by approved laboratories carrying out tests for the diagnosis of avian influenza;

b criteria and procedures to be followed when clinical or post-mortem examinations are carried out to confirm or exclude the presence of avian influenza;

c criteria and procedures to be followed for the collection of samples from poultry or other captive birds for laboratory tests to confirm or exclude the presence of avian influenza; including sampling methods for serological or virological screenings carried out in accordance with this Directive;

d laboratory tests to be used for the diagnosis of avian influenza, including:

(i) tests for the differential diagnosis;

(ii) tests to distinguish HPAI and LPAI viruses;

(iii) suitable tests to distinguish between birds vaccinated and those infected with the field strain of avian influenza;

(iv) criteria for the evaluation of the results of the laboratory tests;

e laboratory techniques for the typing of avian influenza virus isolates.

3 Member States shall ensure that avian influenza viruses, their genome and antigens, and vaccines for research, diagnosis or manufacture of vaccine shall be manipulated or used only in places, establishments or laboratories approved by the competent authority where the appropriate biosecurity requirements are guaranteed.

The list of approved places, establishments or laboratories shall be transmitted to the Commission by 30 September 2007 and kept up-to-date.

Article 51

Reference laboratories

1 The laboratory named in Annex VII(1) shall be the Community reference laboratory for avian influenza (hereinafter referred to as 'the Community reference laboratory').

Without prejudice to Decision 90/424/EEC, the Community reference laboratory shall carry out the functions and duties listed in Annex VII(2).

[[F1]2 Member States shall designate a national reference laboratory and shall make the details thereof, and any subsequent changes, available to the other Member State and to the public in a manner that may be specified in accordance with the procedure referred to in Article 64(2).**]**

3 Member States shall ensure that the national reference laboratories:

a carry out the functions and duties set out in Annex VIII;

b are responsible for co-ordinating standards and methods of diagnosis in each Member State in accordance with Annex VIII and liasing with the Community reference laboratory.

4 The Community reference laboratory shall maintain close cooperation and contact with the OIE and FAO reference laboratory for avian influenza and, as appropriate, with other internationally recognised laboratories within the Community in order to ensure training, excellence and support to national reference laboratories in Member States and Third Countries.

Textual Amendments

F1 Substituted by Council Directive 2008/73/EC of 15 July 2008 simplifying procedures of listing and publishing information in the veterinary and zootechnical fields and amending Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/426/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 91/496/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, Decision 2000/258/EC and Directives 2001/89/EC, 2002/60/EC and 2005/94/EC (Text with EEA relevance).