REGULATIONS

COMMISSION REGULATION (EU) No 955/2010

of 22 October 2010

amending Regulation (EC) No 798/2008 as regards the use of vaccines against Newcastle disease

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs [1], and in particular Article 25(1)(b) and Article 26(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements [2] lays down veterinary certification requirements for those commodities. Those requirements take into account whether or not additional guarantees or specific conditions are required due to the Newcastle disease status of those third countries, territories, zones or compartments.

(2) Regulation (EC) No 798/2008 also lays down conditions for determining whether or not a third country, territory, zone or compartment is to be considered as free from Newcastle disease. One such criterion is that no vaccination against that disease is carried out using vaccines that do not comply with the criteria for recognised Newcastle disease vaccines set out in Part I of Annex VI to that Regulation. Point 2 of Part II of that Annex sets out specific criteria for Newcastle disease vaccines including for inactivated vaccines.

(3) The Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (the OIE Manual) sets out requirements for vaccines against Newcastle disease including safety controls at different stages of the manufacturing process.

(4) In the interests of safeguarding the health status of poultry in the Union and in order to facilitate trade in poultry and poultry meat, it is appropriate that the requirements for Newcastle disease vaccines and their use in third countries from where poultry and poultry meat may be imported, take into account the requirements for such vaccines set out in the OIE Manual.

(5) For that purpose, the general criteria for recognised Newcastle disease vaccines set out in Part I of Annex VI to Regulation (EC) No 798/2008 should refer to the requirements of the OIE Manual, which should be kept as a dynamic reference to take into account the regular updates to that Manual in the light of new scientific developments.

(6) In addition, in view of technical progress that has been made in relation to the production of Newcastle disease vaccines, in particular as regards inactivation techniques, as well as the requirements laid down in the OIE Manual, the specific criteria for inactivated Newcastle disease vaccines set out in point 2 of Part II of Annex VI to Regulation (EC) No 798/2008 should be deleted.

(7) It is necessary to amend certain provisions for meat of poultry set out in Annex VII to Regulation (EC) No 798/2008 and the corresponding model veterinary certificate for meat of poultry (POU) set out in Annex I, in order to take account of the amendments to Annex VI to that Regulation.

(8) Regulation (EC) No 798/2008 should therefore be amended accordingly.

[1] OJ L 343, 22.12.2009, p. 74.
[2] OJ L 226, 23.8.2008, p. 1.

(9) It is appropriate to lay down a date of application of this Regulation, in order to align it with the date of application of Commission Decision 93/152/EEC [1], as amended by Decision 2010/633/EU [2], which introduces corresponding amendments for the criteria for inactivated vaccines against Newcastle disease.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I, VI and VII to Regulation (EC) No 798/2008 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 December 2010.

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

Done at Brussels, 22 October 2010.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 59, 12.3.1993, p. 35.
[2] See page 33 of this Official Journal.

ANNEX

Annexes I, VI and VII to Regulation (EC) No 798/2008 are amended as follows:

(a) in Part 2 of Annex I the model veterinary certificate for meat of poultry (POU) is replaced by the following:

'**Model veterinary certificate for meat of poultry (POU)**

COUNTRY: **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel.			I.2. Certificate reference No	I.2.a.	
			I.3. Central competent authority		
			I.4. Local competent authority		
I.5. Consignee Name Address Postal code Tel.			I.6.		
I.7. Country of origin	ISO code	I.8. Region of origin / Code	I.9. Country of destination	ISO code	I.10.
I.11. Place of origin Name / Approval number Address			I.12.		
I.13. Place of loading			I.14. Date of departure		
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references			I.16. Entry BIP in EU		
			I.17.		
I.18. Description of commodity			I.19. Commodity code (HS code)		
			I.20. Quantity		
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐			I.22. Number of packages		
I.23. Seal/Container No			I.24. Type of packaging		
I.25. Commodities certified for: Human consumption ☐					
I.26.			I.27. For import or admission into EU ☐		

I.28. Identification of the commodities

Species (scientific name)	Nature of commodity	Treatment type	Approval number of establishments: Abattoir	Cutting plant	Cold store	Number of packages	Net weight

COUNTRY **POU (meat of poultry)**

II.	Health information	II.a. Certificate reference number	II.b.

Part II: Certification

II.1. **Public Health Attestation**

I, the undersigned official veterinarian, declare that I am aware of the relevant provisions of Regulations (EC) Nos 178/2002, 852/2004, 853/2004 and 854/2004 and hereby certify that the meat of poultry ([1]) described in this certificate has been obtained in accordance with those requirements, and in particular that:

(a) it comes from (an) establishments(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004;

(b) it has been produced in compliance with the conditions set out in Sections II and V of Annex III to Regulation (EC) No 853/2004;

(c) it has been found fit for human consumption following ante and post-mortem inspections carried out in accordance with Section IV, Chapter V of Annex I to Regulation (EC) No 854/2004;

(d) it has been marked with an identification mark in accordance with Section I of Annex II to Regulation (EC) No 853/2004;

(e) it satisfies the relevant criteria set out in Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;

(f) the guarantees covering live animals and products thereof provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled;

([2]) [(g) it fulfils the requirements of Regulation (EC) No 1688/2005 implementing Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards special guarantees concerning *Salmonella* for consignments to Finland and Sweden of certain meat and eggs.]

II.2. **Animal health attestation**

I, the undersigned official veterinarian, hereby certify that the meat of poultry described in this certificate:

II.2.1. comes from:

([3]) ([4]) ([6]) *either* [the territory of code .....;]

([4]) ([5]) *or* [compartment(s) .....;]

which at the date of issue of the certificate was (were) free from:

highly pathogenic avian influenza as defined in Regulation (EC) No 798/2008, and Newcastle disease as defined in Regulation (EC) No 798/2008;

II.2.2. has been obtained from poultry which:

([4]) *either* [has not been vaccinated against avian influenza;]

([4]) *or* [has been vaccinated against avian influenza in accordance with vaccination plan under Regulation (EC) No 798/2008 using:

.....

(name and type of used vaccine(s))

at the age of ..... weeks;]

II.2.3. has been obtained from poultry which has been kept in:

([3]) ([4]) ([9]) *either* [the territory(ies) of code .....;]

([4]) ([5]) ([9]) *or* [compartment(s) .....;]

since hatching or has been imported as day-old chicks or slaughter poultry from (a) third country(ies) listed for that commodity in Part 1 of Annex I to Regulation (EC) No 798/2008 under conditions at least equivalent to those in that Regulation;

II.2.4. has been obtained from poultry coming from establishments:

(a) which are not subject to any animal health restriction;

(b) within a 10 km radius of which, including, where appropriate, the territory of a neighbouring country, there has been no outbreak of highly pathogenic avian influenza or Newcastle disease for at least the previous 30 days;

II.2.5. has been obtained from poultry that:

COUNTRY **POU (meat of poultry)**

II.	Health information	II.a. Certificate reference number	II.b.

([7]) (a) has been slaughtered on ..... (dd/mm/yyyy) or between ..... (dd/mm/yyyy) and ..... (dd/mm/yyyy);

(b) has not been slaughtered under any animal-health scheme for the control or eradication of poultry diseases;

(c) during transport to the slaughterhouse, did not come into contact with poultry infected with highly pathogenic avian influenza or Newcastle disease;

II.2.6. (a) comes from approved slaughterhouses which, at the time of slaughter, were not under restrictions owing to a suspected or confirmed outbreak of highly pathogenic avian influenza or Newcastle disease and within a 10 km radius of which there has been no outbreak of highly pathogenic avian influenza or Newcastle disease for at least the previous 30 days:

(b) has not been in contact at any time during slaughter, cutting, storage or transport with poultry or meat of lower health status;

([8]) [II.2.7. comes from slaughter poultry that:

(a) has not been vaccinated with live attenuated vaccines prepared from a Newcastle disease virus master seed showing a higher pathogenicity than lentogenic strains of the virus;

(b) underwent a virus isolation test for Newcastle disease, carried out in an official laboratory at the time of slaughter on a random sample of cloacal swabs from at least 60 birds in each flock concerned and in which no avian paramyxoviruses with an Intracerebral Pathogenicity Index (ICPI) of more than 0,4 were found;

(c) has not been in contact in 30 days preceding slaughter with poultry that does not fulfil the conditions in (a) and (b).]

II.3. **Animal welfare attestation**

I, the undersigned official veterinarian, hereby certify that I have read and understood Directive 93/119/EC and that the meat described in this certificate comes from poultry that has been treated in accordance with the relevant provisions of Directive 93/119/EC in the slaughterhouse before and at the time of slaughter or killing.

Notes

Part I:

— Box I.8: Provide the code for the zone or the compartment of origin, if necessary, as defined under the code in column 2 of Part 1 of Annex I to Regulation (EC) No 798/2008.

— Box I.11: Name, address and approval number of the establishment of dispatch.

— Box I.15: Indicate the registration number(s) of railway wagons and lorries, the names of ships and, if known, the flight numbers of aircraft. In the case of transport in containers or boxes, the total number of these and their registration and where there is a serial number of the seal it has to be indicated in box I.23.

— Box I.19: Use the appropriate Harmonised System (HS) code of the World Customs Organisation: 02.07 or 02.08.90.

Part II:

([1]) "Poultry meat" means the edible parts of farmed birds, including birds that are not considered as domestic but which are farmed as domestic animals, with the exception of ratites, which have not undergone any treatment other than cold treatment to ensure preservation; vacuum-wrapped meat or meat wrapped in a controlled atmosphere must also be accompanied by a certificate in accordance with this model.

([2]) Delete if the consignment is not intended for import to Sweden or Finland.

([3]) Code of the territory as it appears in column 2 of Part 1 of Annex I to Regulation (EC) No 798/2008.

([4]) Keep as appropriate.

([5]) Insert the name of compartment(s).

([6]) For countries or territories with the entry "N" in column 6 of Part 1 of Annex I to Regulation (EC) No 798/2008, for meat of poultry (POU) only, this means that in the case of an outbreak of Newcastle disease as defined in Regulation (EC) No 798/2008 then the country code or territory code shall continue to be used but this will exclude any area under official restrictions, by the third country concerned in relation to Newcastle disease, at the date of issue of this certificate.

COUNTRY **POU (meat of poultry)**

II. Health information	II.a. Certificate reference number	II.b.

([7]) Indicate date or dates of slaughter. Imports of this meat shall not be allowed when obtained from poultry slaughtered in the territory or the compartment(s) mentioned under II.2.1 during a period where restrictive measures have been adopted by the European Union against imports of this meat from this territory or that (these) compartment(s).

([8]) Applicable only to the countries with the entry "VI" in column 5 of Part 1 of Annex I to Regulation (EC) No 798/2008.

([9]) If the meat comes from slaughter poultry originating from (an) other third country(ies) listed in Part 1 of Annex I to Regulation (EC) No 798/2008 for imports of that commodity into the European Union, then the code(s) of third country(ies) or of territory(ies) of those third country(ies) and of the third country slaughtering the poultry shall be indicated.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:'

Stamp:

(b) Annex VI is replaced by the following:

'*ANNEX VI*

(as referred to in Article 12(1)(b), Article 12(2)(c)(ii) and Article 13(1)(a))

CRITERIA FOR RECOGNISED NEWCASTLE DISEASE VACCINES

I. **General criteria**

1. Vaccines must comply with the standards set out in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE) in the Chapter on Newcastle disease.

2. Vaccines must be registered by the competent authorities of the third country concerned before being allowed to be distributed and used. For such registration, the competent authorities of the third country concerned must rely on a complete file containing data on the efficacy and innocuity of the vaccine; for imported vaccines the competent authorities may rely on data checked by the competent authorities of the country where the vaccine is produced, as far as these checks have been carried out in conformity with OIE standards.

3. In addition, imports or production and distribution of the vaccines must be controlled by the competent authorities of the third country concerned.

4. Before distribution is allowed, each batch of vaccines must be tested on innocuity, in particular regarding attenuation or inactivation and absence of undesired contaminating agents, and on efficacy on behalf of the competent authorities.

II. **Specific criteria**

Live attenuated Newcastle disease vaccines must be prepared from a Newcastle disease virus strain for which the master seed has been tested and shown to have an intracerebral pathogenicity index (ICPI) of:

(a) less than 0,4, if not less than 10^7 EID_{50} are administered to each bird in the ICPI test; or

(b) less than 0,5, if not less than 10^8 EID_{50} are administered to each bird in the ICPI test.';

(c) in Annex VII, in Part II, point (a) is replaced by the following:

'(a) has not been vaccinated with live attenuated vaccines prepared from a Newcastle disease virus master seed showing a higher pathogenicity than lentogenic strains of the virus within the period of 30 days preceding slaughter;'