[F1ANNEX VI

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

Textual Amendments

F1 Substituted by 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).

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.]