Point C.01 of AHW Agenda

COMMISSION IMPLEMENTING DECISION amending Annexes XI, XII and XV to Council Directive 2003/85/EC as regards the list of and minimum security standards applicable to laboratories authorised to handle live foot-and-mouth disease virus

SANTE/7021/2015

STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED

6 May 2015

Annex XI

Part A - lists national laboratories authorised to handle live foot-and-mouth disease virus for research and diagnostic purposes.

- **Delisting of laboratory in EL, HR and LT.**
- **Change/correction of the name of the laboratory in CZ and HU.**
- **Addition of HR, LT and PT as users of the services of The Pirbright Institute - the laboratory in UK.**
- **We are missing information from BG and EL on of which laboratory services they are using.**

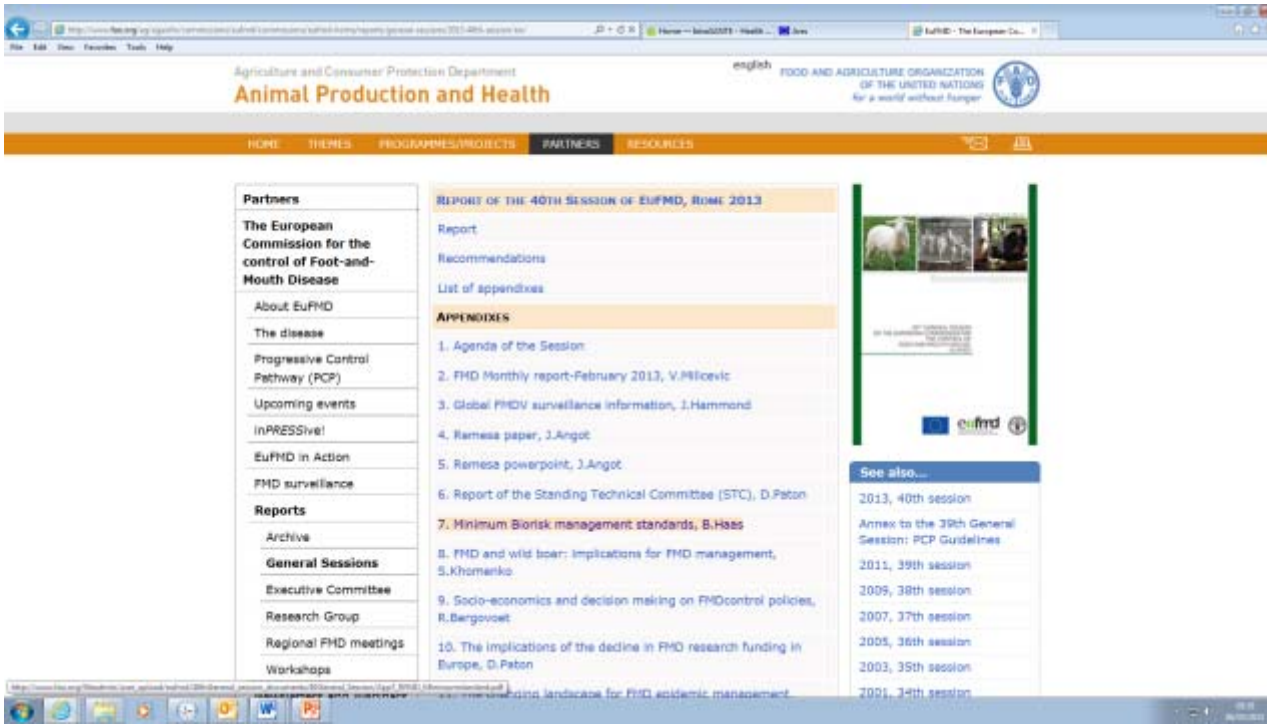
Annex XI

Part B - lists laboratories handling virus antigen during the manufacture of vaccines

Member State where laboratory is located		Laboratory
ISO code	Name	
DE	Germany	Intervet International GmbH/MSD Animal Health, Köln
NL	Netherlands	Merial S.A.S., Lelystad Laboratory, Lelystad
~~GB~~UK	United Kingdom	Merial, S.A.S., Pirbright Laboratory, Pirbright

Annex XII

Point 1 – amendment of the reference to the most recent version of the bio-security standards



http://www.fao.org/fileadmin/user_upload/eufmd/Lab_guidelines/FMD_Minimumstandards_2013_Final_version.pdf

Annex XII

Points 2 and 3

Amendments of the provisions on inspections of the laboratories and establishments handling live foot-and-mouth disease virus, their frequency, as well as inspection team composition.

1. regular and risk based inspections

2. no fixed intervals and team compositions.

Annex XV

the functions and duties of national laboratories

Point 3

A specification that the obligations detailed in that Annex apply only to those National Laboratories which are designated as National Reference Laboratories in accordance with Article 68(1)(c) of the Directive.

3. National Laboratories, designated as the National Reference Laboratories in accordance with Article 68(1)(c), must keep inactivated reference strains of all serotypes of foot-and-mouth disease virus, and immune sera against the viruses, as well as all other reagents necessary for a rapid diagnosis. Appropriate cell cultures should be in constant readiness for confirming a negative diagnosis.

Annex XV

Point 13

Obligation for MSs of listing the other than NRL designated laboratories in the contingency plans and for ensuring that the measures taken to prevent the possible escape of foot-and-mouth disease virus are based on the recommendations in Section II of the Minimum Biorisk Management Standards concerning laboratories undertaking diagnostic investigations for FMD in the framework of a national contingency plan.

13. National Laboratories shall cooperate with other laboratories designated by the competent authorities, and listed in the contingency plans for foot-and-mouth disease as referred to in Article 72, for performing tests, for example serological tests, that do not involve handling of live foot-and-mouth disease virus. These laboratories shall not carry out virus detection in samples taken from suspect cases of vesicular diseases. Such laboratories must have established procedures which ensure that the possible spread of foot-and-mouth disease virus is effectively prevented, taking into account the recommendations in Section II of the 'Minimum biorisk management standards for laboratories working with foot-and-mouth disease virus in vitro and in vivo' in Appendix 7 to the Report adopted by the 40th General Session of the European Commission for the control of foot-and-mouth disease (EuFMD) on 22-24 April 2013 in Rome (bio-security standards).

[need not comply with the bio-security standards referred to in Annex XII, point 1, but must have established procedures which ensure that the possible spread of foot- and-mouth disease virus is effectively prevented.]

DE proposition

National Laboratories shall cooperate with other laboratories designated by the competent authorities, and listed in the contingency plans for foot-and-mouth disease as referred to in Article 72, for performing tests, for example serological tests, that do not involve handling of live foot-and-mouth disease virus. These laboratories shall not carry out virus ~~detection in~~ isolation (by infection of cells or animals) from samples taken from suspect cases of vesicular diseases.