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Subject:	ANNEX to the COMMISSION REGULATION (EU).../... amending Annex X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards further examination of positive cases of transmissible spongiform encephalopathies in ovine and caprine animals

Delegations will find attached document D067489/02 ANNEX.

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COMMISSION REGULATION (EU).../...

amending Annex X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards further examination of positive cases of transmissible spongiform encephalopathies in ovine and caprine animals

ANNEX

Point 3.2 of Chapter C of Annex X to Regulation (EC) No 999/2001 is amended as follows:

(1) in point (a) the last paragraph is replaced by the following:

'If the result of one of the confirmatory examinations referred to in points (i) to (iv) of the first subparagraph is positive, the animal shall be regarded as a positive TSE case.'

(2) in point (b) the third paragraph is replaced by the following:

'If the result of one of the confirmatory examinations is positive, the animal shall be regarded as a positive TSE case.'

(3) point (c) is amended as follows:

(a) the following paragraph is inserted after the title:

'Samples that, following the examinations referred to in points (a) or (b), are regarded as positive TSE cases, but which are not considered atypical cases, shall be examined to exclude the presence of BSE only when they come from an index case. Other cases, which display characteristics that, according to the testing laboratory, merit investigation, shall also be examined to exclude the presence of BSE.'

(b) point (i) is replaced by the following:

´(i) Primary molecular testing with a discriminatory Western blotting method

For the exclusion of the presence of BSE, samples shall be examined by a discriminatory Western blotting method, listed in the guidelines of the EU reference laboratory. The discriminatory examination shall be performed by an official laboratory, designated by the competent authority, which has participated successfully in the latest proficiency testing organised by the EU reference laboratory for the use of such a method.'

(c) point (ii) is replaced by the following:

´(ii) Secondary molecular testing with additional molecular testing methods

TSE cases in which the presence of BSE cannot be excluded according to the guidelines issued by the EU reference laboratory by the primary molecular testing referred to in point (i), shall be referred immediately to the EU reference laboratory, with all the relevant information available. The samples shall be submitted to further investigation and confirmation by at least one alternative method, differing immunochemically from the original primary molecular method. The design of the secondary molecular testing, in accordance with the latest scientific knowledge and laboratory expertise, shall be approved on a case-by-case basis by the EU reference laboratory, as described in its guidelines. The EU reference laboratory shall be assisted by a panel of experts referred to as the Strain Typing Expert Group (STEG), as well as by a representative of the relevant national reference laboratory.

The results shall be interpreted by the EU reference laboratory assisted by the STEG, as well as a representative of the relevant national

reference laboratory. The Commission shall be informed immediately about the outcome of that interpretation.'