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Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, Division CHAPTER B. (See end of Document for details)

[F1ANNEX II

DETERMINATION OF BSE STATUS

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 722/2007 of 25 June 2007 amending Annexes II, V, VI, VIII, IX and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

CHAPTER B

Risk analysis

1. Structure of the risk analysis

The risk analyses shall comprise a release assessment and an exposure assessment.

- 2. Release assessment (external challenge)
- 2.1. The release assessment shall consist of assessing the likelihood that the BSE agent has either been introduced into the country or region via commodities potentially contaminated with a BSE agent, or is already present in the country or region.

The following risk factors shall be taken into account:

- (a) the presence or absence of the BSE agent in the country or region and, if the agent is present, its prevalence based on the outcome of surveillance activities;
- (b) the production of meat-and-bone meal or greaves from the BSE indigenous ruminant population;
- (c) imported meat-and-bone meal or greaves;
- (d) imported bovine and ovine and caprine animals;
- (e) imported animal feed and feed ingredients;
- (f) imported products of ruminant origin for human consumption, which may have contained tissues listed in point 1 of Annex V and may have been fed to bovine animals;
- (g) imported products of ruminant origin for *in vivo* use in bovine animals.
- 2.2. Special eradication schemes, surveillance and other epidemiological investigations (especially surveillance for BSE conducted on the bovine animals population) relevant to the risk factors listed in point 2.1 should be taken into account in carrying out the release assessment.
- 3. Exposure assessment

The exposure assessment shall consist of assessing the likelihood of exposure of bovine animals to the BSE agent, through a consideration of the following:

Document Generated: 2024-07-17

Status: Point in time view as at 29/09/2008.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, Division CHAPTER B. (See end of Document for details)

- (a) recycling and amplification of the BSE agent through consumption by bovine animals of meat-and-bone meal or greaves of ruminant origin, or other feed or feed ingredients contaminated with these;
- (b) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- (c) the feeding or not of ruminants with meat-and-bone meal and greaves derived from ruminants, including measures to prevent cross-contamination of animal feed;
- (d) the level of surveillance for BSE conducted on the bovine animals population to that time and the results of that surveillance.]

Status:

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Changes to legislation:

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