COMMISSION RECOMMENDATION

of 22 July 1998

concerning information necessary to support applications for the evaluation of the epidemiological status of countries with respect to transmissible spongiform encephalopathies

(notified under document number C(1998) 2268)

(Text with EEA relevance)

(98/477/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 155 thereof,

1. Whereas new information has been published in the United Kingdom further supporting the hypothesis that exposure to the bovine spongiform encephalopathy (BSE) agent is linked to the new variant of Creutzfeldt Jacob disease in humans; whereas on 16 September 1997 the Spongiform Encephalopathy Advisory Committee of the United Kingdom concluded that recent research provided compelling new evidence that the agent which causes BSE is identical to the agent which causes the new variant of CJD in humans; whereas on 18 September 1997 the Advisory Committee on Dangerous Pathogens concluded that the BSE agent should now be classified as a human pathogen; whereas on 26 November 1997 the Commission adopted Directive 97/65/EC which classified the BSE and other animal TSE agents in the same group of risk as the human pathogen causing CJD;

2. Whereas the Council on 31 March 1998 invited the Commission to submit an appropriate proposal in the field of specified risk material after the conclusions of the World Organisation for Animal Health (OIE) session in May 1998; whereas the Commission reconfirmed its intention to elaborate a wider Community proposal on the basis of Article 100A, involving both the Council and the European Parliament; whereas Chapter 3.2.13 of the OIE code on BSE recommends to take account of the epidemiological status when importing from a country or a zone;

3. Whereas a risk assessment based on accepted scientific methodology may show that there is a significantly higher risk of exposure of animals or humans to transmissible spongiform encephalopathies (TSEs) in certain countries; whereas a thorough epidemiological evaluation conducted to common standards through a Community procedure will give the necessary information about the status of each country;

4. Whereas the Scientific Steering Committee (SSC), in its opinion of 23 January 1998, has established the list of factors determining the geographical risk in a given geographical zone; whereas the SSC, in its opinion of 19 and 20 February 1998, has established the contents of a complete dossier of epidemiological status with respect to TSEs;

5. Whereas the task of countries in preparing an application for recognition of the epidemiological status of countries with respect to TSEs will be facilitated when information is presented according to the above scientific opinion; whereas the evaluation of those applications will be facilitated when such data are presented according to the above scientific opinion;

6. Whereas the Commission will base its approach concerning the epidemiological status on the opinion of the SSC; whereas, therefore, the Commission encourages countries to submit a dossier according to this recommendation,

HEREBY RECOMMENDS THAT:

1. Member States are invited to submit as soon as possible, and preferably before 1 October 1998, an application for recognition of their epidemiological status with respect to TSEs, in at least one of the official languages of the Community.

2. Member States should ensure that supporting documents accompanying the application are prepared and presented in accordance with the recommendations set out in the Annex.

3. All the applications and requests for additional information should be addressed to:

European Commission
Directorate-General for Consumer Policy and Consumer Health Protection
DG XXIV/B.1,
Rue de la Loi/Wetstraat 200,
B-1049 Brussels.
Tel. (32-2)295 39 62, fax (32-2)299 63 01,
e-mail: tse-status@dg24.cec.be

4. The possibilities foreseen by this recommendation shall also be open to non-member countries.

5. The Commission services will ensure evaluation of the dossiers and will ask the Scientific Steering Committee to give an opinion on all applications.

For the Commission
Franz FISCHLER
Member of the Commission

ANNEX

Information to be submitted in support of an application for recognition of epidemiological status

All data must be provided on an annual basis and preferably from 1980 onwards, but at least from 1988.

Applicant States must make every effort to provide comprehensive and consistent information. Data, which are not provided or are regarded as incomplete or as unsatisfactory, may have to be replaced by worst-case assumption for the purposes of a risk assessment.

Information must be provided on

1. *Structure and dynamics of the bovine, ovine and caprine animal populations*

   (a) absolute numbers of animals per species and breed, alive and at time of slaughter;

   (b) age distributions of animals per species and breed, sex and type;

   (c) age distribution of animals per species and breed, sex and type at time of slaughter;

   (d) geographical distribution of the animals by species and breeds;

   (e) geographical distribution of the animals by husbandry systems, herd sizes and production purposes;

   (f) system of identification and capacities for tracing of animals.

2. *Animal trade*

   (a) imports and exports;

   (b) trade within the geographical area;

   (c) imports of embryos and semen;

   (d) use made of imported animals, embryos or semen;

   (e) mechanisms used by slaughterhouses to identify animals and their origins, as well as data from these procedures.

3. *Animal feed*

   (a) domestic production of meat and bone meal (MBM), and its use per species and husbandry system (in particular the proportion of the domestically produced MBM fed to bovine, ovine and caprine animals);

   (b) imports of MBM, specifying country of origin, and its use per species and husbandry system (in particular the proportion of that MBM fed to bovine, ovine and caprine animals);

   (c) exported MBM, specifying country of destination.

4. *Meat and bone meal (MBM) bans*

   (a) complete description;

   (b) dates of introduction;

   (c) actual implementation, policing and compliance figures;

   (d) possibilities of cross-contamination with other feed.

5. *Specified bovine offal (SBO) and specified risk materials (SRM) bans*

   (a) complete description;

   (b) dates of introduction;

   (c) actual implementation, policing and compliance figures.

6. *Surveillance of TSE, with particular reference to BSE and scrapie*

(a) incidence of laboratory confirmed cases of BSE and scrapie;

(b) age distribution, geographical distribution, and countries of origin of cases;

(c) incidence of neurological disorders in which TSE could not be excluded on clinical grounds in any animal species;

(d) methodologies and programmes of surveillance and recording of clinical cases of BSE and scrapie, including awareness training for farmers, veterinarians, supervisory bodies and authorities;

(e) incentives for reporting cases, compensation and reward schemes;

(f) methodologies of laboratory confirmation and recording of suspect cases of BSE and scrapie;

(g) strains of BSE and scrapie agents possibly involved;

(h) existing systems or current plans for targeted active surveillance.

7. *Rendering and feed processing*

(a) all rendering and feed processing systems used;

(b) nature of the records of rendering and processing plants;

(c) quantitative and qualitative parameters of MBM and tallow production by each of the processing systems;

(d) the geographical areas from which the rendered materials originate;

(e) the type of raw material used;

(f) parameters on separate processing lines for materials from healthy and suspected animals;

(g) transport and storage systems for MBM or feed containing MBM.

8. *BSE or scrapie related culling*

(a) culling criteria;

(b) date of introduction of the culling scheme and of any subsequent modification;

(c) animals culled (details as specified in point 1);

(d) sizes of herds in which animals were culled.