Status and perspectives regarding BSE in Member States with negligible risk

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Negligible BSE status for Austria Belgium, Denmark, Finland and Sweden
As a result of an effective monitoring and control, the risk of bovine spongiform encephalopathy (BSE) is considered negligible in Austria, Belgium, Denmark, Finland and Sweden. This is the decision of the World Organisation for Animal Health (OIE). Just over a dozen countries in the world have this status – one of them is Brazil. In the EU, the other Member States are located in the lower status of "controlled risk".

This note summarizes the monitoring and management of BSE in Denmark and the EU. The perspectives are illustrated regarding a possible change in the handling of Specified Risk Materials (SRM) in Member States, which have the status of negligible risk of BSE.

Surveillance
Surveillance for BSE includes both a passive and an active part. In the passive surveillance, animals with clinical symptoms of BSE are reported and investigated. The active surveillance involves brain tissue samples from all fallen stock or slaughtered cattle above a certain age. The relative risk of finding BSE is far greater in animals suspected of BSE at the *ante mortem* inspection. Fallen stock and emergency slaughtered cattle have higher risk compared to the normal cattle population – as noted in Table 1 - and are therefore called high-risk cattle. According to the current active surveillance program, high-risk animals must be above 48 months and normal slaughter cattle above 72 months to be tested. No carcasses can be released for human consumption before a negative test result is available.

Prevalence
Since the active surveillance was initiated in Denmark, more than two million cattle have been tested (Table 1). In February 2000, the first native case of BSE was found and since then, a total of 15 native cases of BSE have been found in Denmark as well as three cases in cattle exported. The latest case of BSE was found in November 2009 in a cow born in 1995. Of these 18 native cases, three were initially identified because of clinical symptoms, seven were found among emergency-slaughtered cattle and fallen stock, and eight were cattle that went through normal slaughter. Positive animals are removed from the food chain and thus will not pose a risk to animal or human health.

Table 1. Number of BSE-tests in Danish cattle, 2001 – 2009

Category	Number	Positive*	Risk (per 10^6)
Clinical suspicion	191	2	10.471
Fallen stock or emergency slaughtered cattle	331.476	6	18
Normal slaughter animals	1.934.190	6	3
Total	2.265.857	14*	

* This figure includes the first BSE case found in 2000 in Denmark as well as three cases found in exported animals. Source: The Danish Veterinary and Food Administration.

The incidence of BSE in the EU is on the decrease. In 2001 there were 2,167 cases found in the EU-15, and in 2008 this figure had fallen to 125. In 2009 there were only 45 cases, and it was even in the EU-27. The development in individual Member States depends on when the various control and monitoring programs were launched and how effectively they have been complied with.

Meat and bone meal feeding bans
To prevent spreading of infection, meat and bone meal of ruminant origin cannot be used as feed for ruminants. The first ban came in 1990 and involved beef-based meat and bone meal. The second ban came in 1997 and involved mammalian meat and bone meal destined for cattle feed. In 2001, the ban was extended to involve all animal protein in feed for all food-producing livestock. These bans have shown to be the only preventive measure that can be expected to lead to the eradication of the disease.

Cattle are usually infected during their first year of life. The age distribution of the positive BSE case can therefore give an impression of the spread of infection and thus the effect of the feeding bans. Figure 1 shows the age distribution of cases in the EU in 2001. It is seen that the average incubation period for BSE in cattle is 5-8 years. Most Danish cases, totaling 10, were born in 1996, which means that the first feed ban from 1990 was not fully effective. No BSE cases in Denmark have been born after 2001; hence, the total feed ban in 2001 has halted the infection.

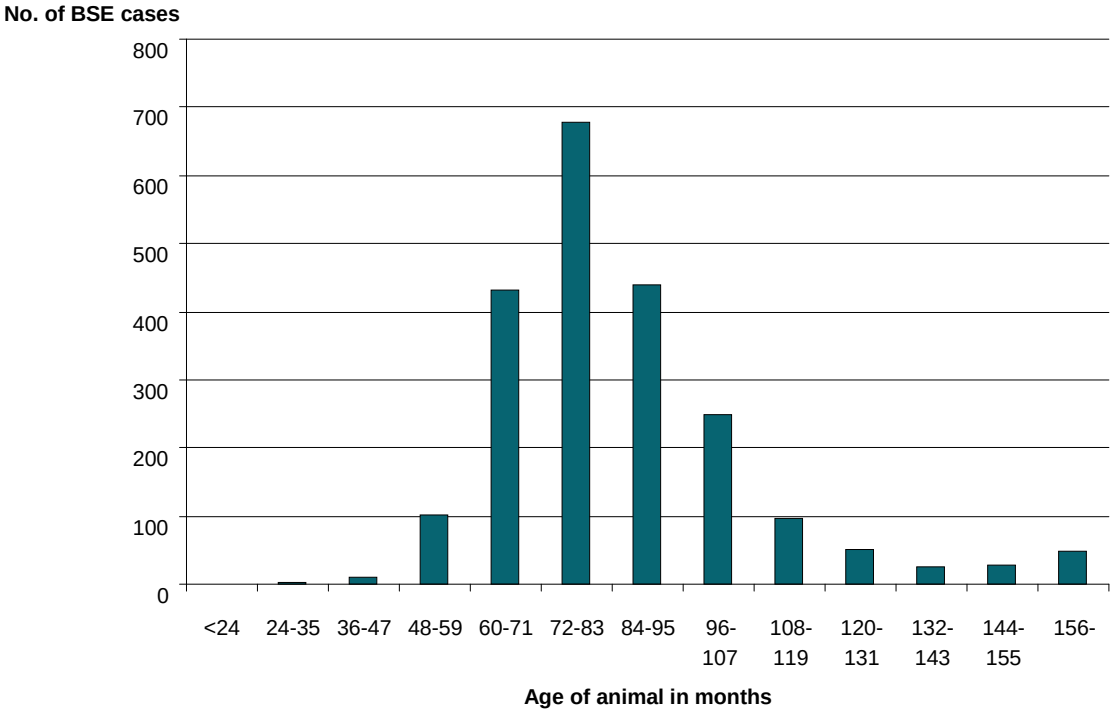

Figure 1. Age distribution of diagnosed cases of BSE in 2001 in EU (EU-15). Source: http://www.efsa.europa.eu/en/efsajournal/doc/476.pdf

The rendering process

The BSE epidemic began in Great Britain and was most likely caused by the feeding of cattle with meat and bone meal containing prions. The prions probably originated from sheep with scrapie, a sheep disease similar to BSE. These prions were not eliminated during the rendering process. If the processing of meat and bone meal is performed using pressure sterilization, the infection is eliminated. Pressure sterilization means that the temperature is high (≥ 133°C), the pressure is high (≥ 3 atmosphere), and that this takes place for a sufficient period (≥ 20 min). It is essential that rendering takes place under these conditions, when - and if – it will be allowed to use animal protein as feed in livestock production again. If this is not the case, there is a risk that a new BSE epidemic will develop.

Specified Risk Material (SRM)

The parts of a carcass, which potentially contains the largest amount of prions are removed to eliminate the risk to humans (consumer safety). This applies to the skull including the brain and eyes and the spinal cords from cattle older than 12 months. Further, the spine including the backbone from animals over 30 months are removed as well as the tonsils and intestines from the small intestine to the rectum and omentum from all animals regardless of age. This is described in the TSE Regulation 999/2001 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001R0999:20110318:EN:PDF). It is a requirement that SRM is first subjected to pressure sterilization and next incinerated at a temperature of at least 800°C.

It is stated in preamble 10 to the Regulation that the categorization of SRM is based on the pathogenesis of TSE (= disease progression) and the epidemiological status of the country or region where the animal originated.

Age limit for the discovery of prions
Experimental evidence indicates that the BSE prion in the central nervous system of cattle can be detected post mortem by use of laboratory tests in the last quarter of the incubation period in the animal. This implies before the animal exhibits clinical signs of disease. According to EFSA's work prions can be present but undetectable in cattle up to 33 months. There have been four cases of BSE in animals younger than 40 months born after 2000 (the United Kingdom: 36 and 39 months; Portugal: 32 months; Poland: 25 months - but there are doubts about the age of the latter case).

According to EFSA, there is - therefore - no reason to change neither the ages nor the list of SRM, as long as BSE is present in a country's cattle population. EFSA recommends regular evaluations of the likelihood that prions are present in SRM in individual countries or groups of countries with the same status with respect to BSE.

Source: Opinion of the Scientific Panel on biological hazards (BIOHAZ) on the assessment of the likelihood of the infectivity in SRM derived from cattle to different age groups estimated by back calculations were modeling, 2007, http://www.efsa.europa.eu/en/efsajournal/pub/476.htm.

Risk Assessment
In risk assessment the probability that the prion is present in the animal (release assessment) is weighted together with the probability that the prion is present in the meat we consume or in the feed for cattle (exposure assessment). This weighted together with the degree of seriousness of the disease, which can cause infection (consequence assessment). Consequences of human infection are very serious, because the person develops variant Creutzfeldt-Jakob disease (vCJD) which has a fatal course. In total, there have been 175 cases of vCJD in the United Kingdom and 49 cases in other countries in the period 1996-2011.

For both humans and cattle, the risk can be narrowed down to:

Risk = Probability of Release x Probability of Exposure

If either release or exposure is zero, then the risk is absent.

Release assessment
The negligible risk status means that the incidence of BSE in live cattle is assessed as negligible. In other words: The release assessment shows an extremely low probability of BSE - at least in cattle born later than in 2001.

Exposure assessment - Animal Health
Exposure of cattle relates to feeding with meat and bone meal. If meat and bone meal is not fed to cattle, then there is no exposure. As stated above, if and when it will be allowed to use meat and bone meal as feed to cattle, then it must processed under conditions that ensure the removal of all prions. In that future scenario it will be a precondition that all meat and bone meal of bovine origin is pressure sterilized.

Exposure assessment - Consumer Safety
Exposure relates to SRM. It is estimated that by removing SRM, 99.74% of infectivity is removed, should the animal be infected. If we remove all SRM, the likely exposure is close to zero. However, from an academic standpoint it is not necessary to remove SRM, when there is no BSE in the national cattle population - at least not in animals born after 2001, since when the feed ban has been effective; that is, animals younger than 11 years, which constitutes the vast majority of the cattle population. For animals aged 11 years or older, it makes sense to continue to remove SRM because it cannot be ruled out that one of these animals can be infected with BSE.

The position that it is unnecessary to remove SRM from cattle in areas or Member States with negligible BSE risk was prevalent at the time the original version of the TSE Regulation 999/2001 was adopted (http://ec.europa.eu / food/fs/bse/bse36_en.pdf - see Annex V, paragraph 1). This, however, was

changed later (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001R0999:20110318:EN:PDF - Consolidated version of Regulation 999/2001). So today, even if a member state has been considered as an area with negligible risk of BSE SRM must still be removed.

This does not make sense from a scientific view point, but should be viewed in light of the lack of knowledge about ways of transmission in the early years of the BSE epidemic. Therefore, the precautionary principle was used. This implies a temporary measure that can be implemented until sufficient knowledge is made available. More than two decades after the beginning of the epidemic, there is sufficient knowledge of BSE for the OIE to estimate that Austria, Belgium, Denmark, Finland, and Sweden have a negligible risk of BSE. It therefore makes sense, to work politically for an opening up for the definition of SRM for Member States with a negligible risk.

EU Commission's position

EU Commission has launched a Roadmap 2 for TSE. According to this, as well as Regulation 999/2001 the following applies:

1. The TSE Regulation does not allow for national regulations - the definition of SRM cannot be modified in Member States with a negligible risk.
2. The EU Commission has by use of TSE Roadmap 2 initiated a process to relax the risk management
3. The first relaxation concerns the feed ban (ongoing negotiations)
4. Other relaxations concerns small ruminants, where e.g. Denmark will apply for recognition of status as being free from scrapie
5. The third relaxation concerns the intestines and omentum. In March 2012, EFSA was asked to look at the risk in connection with a modified definition and handling of SRM. It is expected that it will take two years before a response to this question will be made available.
6. As the very last of the priority list, a relaxation regarding SRM will be looked at for Member States with a negligible risk of BSE, when more Member States have obtained this status. At the time the Roadmap 2 was written (July 2010), only Finland and Sweden had this status. Hence, the EU Commission is awaiting that more countries will have the status of negligible, and until then they will prioritize the other tasks on the list.

The spine (and hence the backbones which are of commercial interest) is not specifically mentioned among these initiatives, but will be included in item 6Source: http://ec.europa.eu/food/food/biosafety/tse_bse/docs/roadmap_2_en.pdf

EFSA and SRM

EFSA has recently asked interested parties to submit a bid for a research project to assess the infectivity of SRM. This project is expected to be finalized and reported in 2015. The result of the project may result in a changed way of dealing with SRM (such as amending the list of the parts of an animal that should be considered SRM, or suggest new age groups). The starting point for this work is that there is a low risk of BSE in the EU - and thus a lower need for operating with SRM (http://www.efsa.europa.eu/en/tenders/tender/cftefsabiohaz201202.htm).

Discussion

Scientific speaking, there is no reason to operate with SRM in countries with the status of negligible BSE risk, because there is no BSE in their herds (at least not among cattle under 11 years of age). The EU Commission has put an evaluation of the definition and handling of SRM for countries with a negligible risk on the agenda but is awaiting more countries achieving this status before any action will be taken.

The question is whether this waiting period can be shortened by raising the issue concerning the definition of SRM for countries with negligible BSE risk to the Commission. Only Austria, Belgium, Denmark, Finland and Sweden have the status of negligible risk. These Member States might not be significant enough and therefore unable to persuade the EU Commission to change their priorities in Roadmap 2. It will therefore be important to seek allies among the Member States that are expected to get the status of negligible risk within a year or two, because it will be in these Member States' interest to support the case.

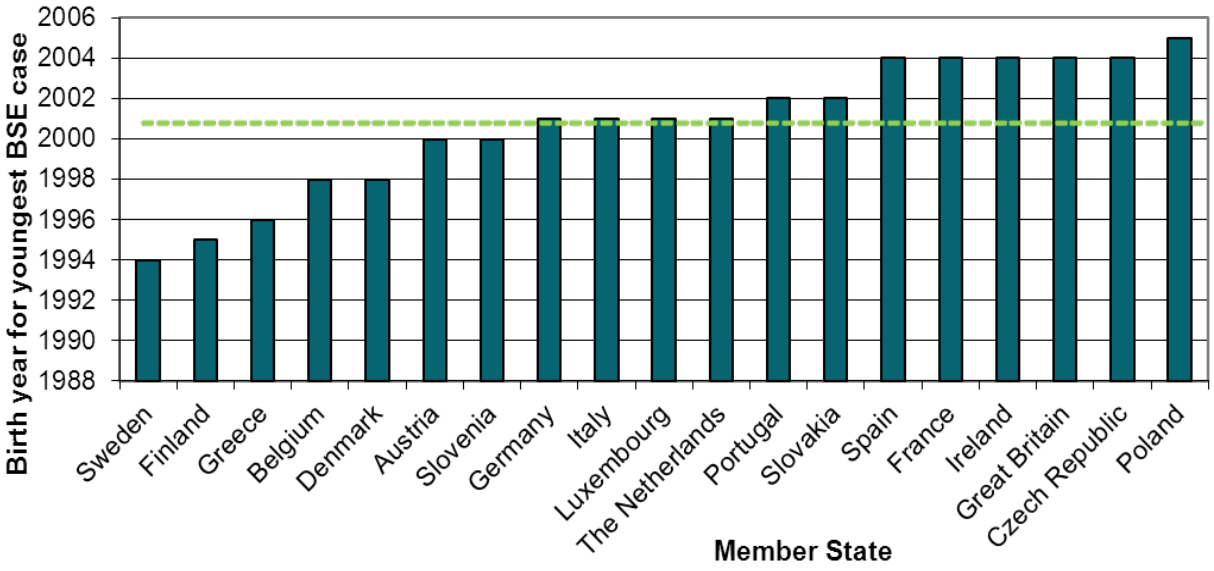

Figure 2. Year of birth of the youngest BSE case detected in selected EU Member States in 2001-2010 with an indication of year 2001

It will therefore make sense to clarify when the various Member States are expected to enter the group of countries with a negligible risk of BSE. One of the OIE requirements for obtaining the status of negligible risk is that no BSE case has been born during the preceding 11 years. For 2012, this is 2001. Figure 2 shows the year of birth of the youngest BSE case detected in selected EU Member States in 2001-2010 with an indication of year 2001 (Source: http://ec.europa.eu/food/food/biosafety/tse_bse/docs/annual_report_tse2010_en.pdf).

Member States above the green line do not meet this requirement - yet. The figure does not include information about the level of reporting. There is, according to Hanne Christensen from the Danish Veterinary and Food Administration several Member States that have problems with incomplete reporting. Based on birth year criterion alone - and assuming complete reporting, Slovenia, Germany, Italy, Luxembourg and the Netherlands constitute the Member States that seem closest to being able to obtain the status of negligible risk for BSE.

In May 2012, Brazil received OIE status of negligible BSE risk. According to a report from the OIE meeting in May 2012 prepared by the UECBV, Brazil will be granted the right to export bovine intestines into the EU provided compliance with other requirements for export (such as the intestines comes from an EU approved establishment). This seems odd, because the current EU regulation - as described above - defines the majority of bovine intestines as SRM also for EU Member States with a negligible risk of BSE. This is due to in Annex V to the Regulation where it is mentioned that SRM tissues which originate from a member state with a negligible BSE risk remains specified risk material (see paragraph in italics from Annex V from Regulation 999/2001 below). In a time of economic crisis it is even more important that the European Commission ensures that EU producers have at least equal footing with external competitors in the EU

ANNEX V

SPECIFIED RISK MATERIAL

1. **Definition of specified risk material**

The following tissues shall be designated as specified risk material if they come from animals whose origin is in a Member State or third country or of one of their region with a controlled or undetermined BSE risk:

(a) as regards bovine animals:

(i) the skull excluding the mandible and including the brain and eyes, and the spinal cord of animals aged over 12 months; ▼**M37**

(ii) the vertebral column excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia, of animals aged over 30 months; and ▼**M31**

(iii) the tonsils, the intestines from the duodenum to the rectum and the mesentery of animals of all ages.

(b) as regards ovine and caprine animals

(i) the skull including the brain and eyes, the tonsils and the spinal cord of animals aged over 12 months or which have a permanent incisor erupted through the gum, and

(ii) the spleen and ileum of animals of all ages.

2. **Derogation for Member States**

By way of derogation from point 1, tissues listed in that point whose origin is in Member States with a negligible BSE risk shall continue to be considered as specified risk material.