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REPORT ON:

**THE ADDITIONAL SAFEGUARD PROVIDED BY DIFFERENT
CULLING SCHEMES UNDER THE CURRENT CONDITIONS IN
THE UNITED KINGDOM AND GERMANY**

**PREPARED BY THE TSE/BSE *AD HOC* GROUP
AS BASIS FOR ADOPTING AN OPINION BY THE SCIENTIFIC
STEERING COMMITTEE AT ITS MEETING OF**

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Report of the TSE/BSE ad-hoc group on assessing the additional safeguard provided by different culling schemes under the current conditions in the UK and DE.

1. The Mandate

- a) Does the SSC considers it necessary to up-date its opinion on "culling" in the light of the data provided in the recent opinion on this issue provided by AFSSA? If yes, the SSC is invited to do so.
- b) Does the SSC consider in the light of its (updated) position on culling that the measures described in the applications to allow for a derogation from the provisions of Article 12(1), 2nd, 3rd and 4th subparagraph, Article 13(1)(b) and (c), and Annex VII of Regulation (EC) No 999/2001 (see annex I)
 - of 24 May 2001 by the UK;
 - of 3 August 2001 by Germany;offer equivalent safeguards to the above indicated provisions, insofar as these relate to BSE in bovine animals?

1.1 Scope

The questions raised in the mandate are in fact not addressing the equivalency of culling and the measures already in place in the UK or Germany but addressing the additional safeguards provided by the culling of "at risk" animals that are epidemiological linked to BSE-index cases.

2. Background

On 25 June 2001 and 3 January 2002, AFSSA (*Agence française de sécurité sanitaire des aliments* = French Agency for Food Safety) adopted opinions addressing, *inter alia*, the issue of culling at-risk cattle that are epidemiological linked to index BSE cases.

While in France only herd-culling was applied, AFSSA discussed in its opinion of June 2001 the relative risk of total [herd] culling or selective culling with regard to its efficiency in terms of risk reduction. AFSSA suggested three options,

1. Slaughtering all herd mates except those born after the effective application of the feed ban (14/11/2000). The surviving animals would be considered "normal".
2. Slaughtering all except the youngest birth cohorts. However, the surviving cattle would not be allowed to be slaughtered for human consumption before an age allowing rapid testing. Only animals that were clearly not exposed to the same feed as the index case might be considered normal. This option foresees a differentiation for index cases born before and after the second half of 1996:
 - before: slaughter of the birth cohort and all animals born before; animals more than one year younger could survive but would have to be tested before slaughter, animals born after the effective feed ban might be considered "normal".
 - Index-case born after mid 1996: herd slaughter.
3. Slaughtering of only the index case but avoiding the surviving animals from entering the food-chain.

Finally AFSSA recommended a second stage, when culling could be limited to the age cohort. This stage could start once the following conditions were met:

- the existence of an evaluation of the actual conditions of the removal of SRM in France;¹
- the confirmation that the continuation of the current research protocol for animals from the herds, using a larger population, provides no statistically significant data on the existence of a greater risk outside the cohort;
- the verification that new diagnosis techniques (e.g. protein amplification) do not cast doubt on existing scientific and epidemiological data;
- the receipt of information on the development of the epidemiological situation in the United Kingdom;
- a better appreciation of the effect of the measures taken in 1996 in France on the dynamics of the disease.

The AFSSA opinion of June 2001 also contained information on the interim results of the French cohort study. The data showed that all BSE-infected animals that were discovered in culled herds of index cases did indeed belong to the birth cohort (born in the same herd plus/minus 12 months from the date of birth of the index case). However, the report clearly underlined certain limitations of this study.

The AFSSA opinion of January 2002 confirmed the previous findings, concluding that the prevalence in the birth cohorts was 0.11% in comparison to overall 0.16% in the population of fallen stock and emergency slaughter. In France it is 0.003% in healthy normal slaughter tested by rapid BSE-test in the period January to October 2001².

2.1 Requirements in the TSE-Regulation

The TSE-Regulation No 999/2001³ (for the text of the relevant parts see Annex I to this opinion) requires that in case of confirmation of a BSE-case, all other bovines on the holding of the animal in which the disease was confirmed are killed and destroyed. It allows Member States to decide not to kill and destroy all these animals, depending upon the epidemiological situation and traceability of the animals on that holding.

In any case

- where the disease was confirmed in a female animal, all its embryos, ova and its progeny collected or born within two years prior to, or after, clinical onset of the disease, and
- all animals of the cohort⁴ of the animal in which the disease was confirmed have to be culled.

¹ Two remarks were made by AFSSA on this point: This condition is a general measure for the prevention of BSE. However, it is logical to take it into account in a gradual process of a precautionary measure. Moreover, given the comments previously made by the Interministerial Committee, a system for carrying out a quantitative evaluation of the effectiveness of this measure is expected to be introduced in the near future.

² EU, 2001

³ Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (TSE regulation) (OJ L 147 of 31.05.2001, p. 1).

⁴ 'cohort' means a group of bovine animals which were either born in the same herd as, and within 12 months preceding or following the birth of, the affected cattle or reared together with the affected animal at any time during the first year of their life and which may have consumed the same feed as

2.2 Proposal by the UK

UK argues that other approaches are available which offer equivalent, if not better, methods for controlling BSE than those foreseen in the TSE-regulation, i.e. culling. According to the UK these are:

- (a) an effectively enforced total ban on the feeding of any mammalian meat and bone meal (MMBM) to all farmed livestock, as it exists in the UK since 1996; and
- (b) a ban on the slaughter for human consumption of animals born before the date on which a total ban on the feeding of MMBM to all farmed livestock was introduced. This is enforced in the UK by the OTMS⁵ because all animals younger than 30 months are also born after the effective feed ban (01/08/1996).

2.3 Proposal by Germany

Germany requests the right to allow competent authorities to permit exemptions from being culled for animals belonging to the same herd or which were reared together with the affected animal at any time during the first year of their life.

Germany argues that this would be justified in terms of consumer protection because

- the SSC considered culling of birth-cohorts as an effective measure in the fight against BSE;
- all cattle over 24 months are tested by means of a rapid test when they are slaughtered;
- risk material is removed during slaughter and the vertebral column during cutting.

3. Risk assessment

3.1 The need to modify the previous SSC-opinion on "culling".

The SSC shares to a large extent the reflections present in the said AFSSA opinions. It also concludes that the data from the French cohort study support its previous opinion, even if the limitations of this study are appreciated.

Concerning the different selective slaughter options presented by AFSSA, the SSC agrees that alternatives to culling (herd or cohort) do exist and might provide similar level of consumer protection as these.

3.2 Added value of culling in comparison to the measures proposed by the UK and by Germany

The measures mentioned in the proposals of UK and Germany are not, in fact, understood as equivalent alternatives to culling, as they are and remain in place independent of culling being applied or not. It is therefore understood that the

that which the affected animal consumed during the first year of its life; (TSE Regulation, Annex I, point c)

⁵ OTMS = Over-thirty-months-scheme; this scheme excludes all cattle over thirty months from animal and human consumption

proposals are rather implying that the described measures would render culling unnecessary. The following assessment therefore focuses on the additional risk reduction that could be expected from culling in accordance to the TSE-regulation.

3.21 Risk assessment

The measures foreseen in the TSE-regulation and those proposed by the UK and by Germany, respectively, that are described in the background have to be assessed taking into account both their contributions to the reduction of the risk for animals and for humans.

3.211. Contribution to the reduction of the risk for animals

3.211.1 Culling

Under an animal health perspective, culling of cohorts and other animals epidemiologically linked to an index case is aimed at saving future cases of BSE, by reducing the risk that infected animals enter the feed chain and BSE infectivity were recycled.

Under this perspective, culling animals that are epidemiological linked to an index case, i.e. the herd or the cohort, is useful if the probability of the culled animals to be incubating BSE is higher than in the overall cattle population.

The SSC addressed this question in its opinion on culling of September 2000⁶. Also AFSSA⁷ addressed this issue in its recent opinions.

These opinions conclude that the available data indicate that culling animals epidemiologically linked to index cases may exclude a number of pre-clinically incubating BSE-animals from the feed- and food chain.

The SSC in its opinion clearly stated that in this regard cohort culling is likely to be similarly effective as herd culling. This position is also supported by the study of AFFSA of the issue. This study showed that all additional cases found in the context of herd culling in France belong to the birth cohorts of the index cases. Also data from Germany, Portugal, Spain and Ireland showed that all secondary cases found when testing animals culled under the herd culling strategy were belonging to the birth cohort of the index cases.

Culling (of herds or cohorts) potentially reduces the risk of BSE-infectivity entering the feed (or food) chain. With regard to detectable BSE cases, cohort culling is apparently as effective as herd culling.

3.211.2 Other measures

A reduction of the risk that BSE-infectivity enters the feed chain is, however, only relevant for animal health if the infectivity can reach ruminants. If recycling is effectively prevented, the additional risk reduction that can be achieved through culling is negligible.

⁶ Opinion of the Scientific Steering Committee on BSE-related culling in cattle, 14/15.09.2000

⁷ Agence française de sécurité sanitaire des aliments = French Agency for Food Safety), 25.06.2001. and 03.01.2002

Such a prevention of recycling can be achieved by an effectively enforced total feed ban, as it is the case in the EU since 1st January 2001 and in UK since 1st August 1996. However, the true effectiveness of the feed ban and its control is essential and should be taken into due consideration whenever a risk management measure is based on it.

The SSC therefore considers that, with regard to **animal health**, the measures described in the application of 24 May 2001 by the UK offer safeguards that cannot be improved by the above-cited provisions of Regulation (EC) No 999/2001, assuming that the total feed ban is effectively enforced⁸. The same holds true for the German request.

In theory, a ruminant to ruminant ban could achieve a similar degree of safety. However, in view of the European experience with cross-contamination, such a ban must be combined with appropriate rendering and a well-implemented SRM-ban in order to potentially provide a similar level of protection as a total feed ban. Given the fact that a differentiation of ruminant-MBM from other mammalian-MBM is very difficult or impossible, only the combination of all three measures being effectively enforced could make the recycling of the BSE-agent as unlikely as an effectively enforced total feedban.

In general any measure that effectively interrupts recycling of ruminant MBM to ruminants ensures a degree of safety with regard to animal health that cannot be significantly improved by culling animals epidemiologically linked to an index case.

With other words, if recycling is effectively prevented, culling does not improve animal health because the infectivity carried by surviving incubating cattle that otherwise would be culled could anyway not reach cattle.

3.212. Contribution to the reduction of the risk for humans

In its opinion on the Human Exposure Risk (HER) of December 1999⁹ the SSC states that the Human Exposure Risk in any country, and at any point in time, will depend on four main factors:

1. the likelihood that an animal infected with BSE enters the human food chain;
2. the amount and distribution of infectivity in that animal;
3. the ways in which the various tissues that could contain infectivity are used in the food chain; and
4. the marketing of infected foods produced in other countries.

3.212.1 The impact of culling

Culling can influence the likelihood that an animal infected with BSE enters the human food chain because, according to the available information, the herd-mates of an index case, in particular its birth cohort, carry a somewhat higher risk of being infected with BSE than the rest of the “healthy” cattle population (see point 1.1).

⁸ The SSC expressed a view "on the importance of the BSE-cases born in the UK after the implementation of the total feed ban" on 28/29 November 2001

⁹ Opinion of the SSC on the Human Exposure Risk (HER) via food with respect to BSE.

Culling of herds or cohorts can reduce the likelihood that animals infected with BSE enter the human food chain because it potentially excludes incubating animals from the human food chain that otherwise would have been slaughtered.

The efficiency of this is related to the potential prevalence in the culled population. Clearly this is highest for those cattle exposed to the same feed as the index case. Given that feed composition changes over time and that it is assumed that most infections happen to young animals (up to 12 months), the animals that were young together with the index case carry a higher risk than other, in particular if they were exposed to the same feed. However, in general it is impossible to identify all animals that received feed from a given batch, produced several years ago. The birth cohort, i.e. the cohort of animals born 12 months before or after an index case in the same herd, is therefore a good approximation to the ideal feed-cohort.

3.212.2 The impact of other measures

An effectively enforced total ban on the feeding of any mammalian meat and bone meal (MMBM) to all farmed livestock makes it unlikely that animals born after its implementation could be infected with BSE. Again it must be underlined that the efficiency of the feed ban is of utmost importance. Already small breaches can induce significant risks.

Banning slaughter for human consumption of animals born before the date on which a total ban on the feeding of MMBM to all farmed livestock was introduced¹⁰ would therefore reduce the risk that an animal infected with BSE enters the human food chain. The degree of risk reduction that can be expected depends on the efficiency of the implementation and control of these combined two measures.

The proposal of the UK would imply that animals survive, which are born after the effective implementation of the total feed ban and are epidemiologically linked to an index case. These animals may finally enter human consumption (while being 30 months old or younger) and dairy cows would continue to produce milk until the end of their productive live.

It is therefore necessary to address these potential risks.

1. The probability that a cattle born after 01/08/1996 in UK is infected is not zero. Hitherto, 8 cases born after the total feed ban have been notified. In none of these cases firm final conclusions could be drawn as to the source of infection. However, maternal transmission seems unlikely. This raises a certain concern about the effectivity of the total feed ban but in any case the risk of cattle born after the feed ban is very much lower than for those born before.

With regard to Germany the efficiency of the total feed ban cannot be appreciated. It anyway would only be relevant for animals born after 01/01/2001.

2. In the UK the OTMS means that cattle slaughtered for human consumption could only be 30 months or younger. Today all those cattle are born after the introduction of the total feed ban in UK. This implies that the probability that a cattle entering human food is infected is low. It also means that the infective load

¹⁰ 1.8.1996 in UK; 1.1.2001 in Germany

of any cattle slaughtered could only be much lower than in a mature BSE-case¹¹ because the probability that an under-30 months cattle is close to the end of the incubation period is very small.

In Germany cattle can be older than 30 months when entering human consumption, if tested BSE-negative. These animals would also be born before the total feed ban was installed. To assess the risk that these animals could carry BSE-infectivity it has to be taken into account that a considerable number of BSE cases is over 60 months old at clinical onset and that the available test can only identify animals approaching the end of the incubation period. Therefore testing cannot exclude that incubating animals in an advanced stage of the incubation could be slaughtered for human consumption while the available test cannot detect PRP^{SC}. The older slaughtered animals are, the higher is the probability that they carry a significant infective load, even if the infectivity concentration in the brain is not detectable.

3. The SRM ban that exists in both countries (UK and DE) reduces the infectivity that could enter human consumption by excluding those tissues with the highest infectivity concentration from human (and animal) consumption. The remaining tissues could, theoretically, carry infectivity below the detection level. In its opinion of October 1999¹² the SSC reported that muscle tissue was tested in the most sensitive system of cattle-to cattle transmission via intra-cerebral injection and did not transmit BSE. Since then assays of pools of spleen and lymphnodes from clinical cases of BSE, conducted by intracerebral inoculation of cattle, were completed at 86 months post inoculation, with no evidence of infectivity detected. From a comparative titration of BSE infected brain tissue in cattle and mice, it is concluded that the assay in cattle can detect approximately 500 times less infectivity than the assay in mice. By extrapolation from this study it can be assumed that, if the spleen and lymph node pools contain any infectivity, it is less than 0.1 cattle (i.c.) LD₅₀/g, the apparent limit of detectability in this model (G.A.H.Wells and S.A.H.Hawkins, 2001, unpublished data).

The above mentioned assays, conducted in cattle, of pools of skeletal muscles from cattle 6, 18, 26 and 32 months after experimental oral exposure to 100g BSE infected brain remain in progress, but as of 1st September, 2001, the test cattle remained healthy 35, 58, 30 and 57 months post inoculation respectively (G.A.H.Wells and S.A.H.Hawkins, 2001, unpublished data).

The available information therefore indicates that the risk carried by cattle tissue other than SRMs is significantly lower, as infectivity was below the detection level in the above mentioned experiments, than that carried by the SRM as such. The exclusion of SRM from human consumption therefore remains the most important single measure for the protection of consumers. Its impact, however, depends strongly of the degree to which the SRM ban is respected.

In both countries controls of the SRM ban are carried out and allow assuming a good but not perfect implementation.

¹¹ SSC-opinion on the Human Exposure Risk, December 1999.

¹² SSC Opinion on the scientific grounds of the advice of 30/9/99 of the French Food Safety Agency (AFSSA), to the French government on the draft decree amending the decree of 28/10/1998 establishing specific measures applicable to certain products of bovine origin exported from the UK, 28/29 October 1999.

4. With regard to cow milk, all available data indicate that the risk that BSE could be transmitted via this route is negligible¹³, even if the cow would be incubating BSE. An experiment is currently ongoing at the VLA, UK, in which whole milk and a somatic cell fraction are being collected at four different time points of sequential lactations of cattle exposed orally as calves to either 100g or 1g of BSE infected brain. Stored samples of milk will be examined by a number of methods for PrP^{Sc}.

3.22 Conclusion

3.221 Conclusion on the measures in the UK

With regard to the risk for animals and for humans, the measures in the UK (a combination of a total feed ban with excluding animals born before the ban) provide, if combined with the OTMS and the SRM-ban, a high level of safety. It is regarded unlikely that culling of at-risk animals, epidemiological linked to BSE-index cases, as required by the TSE Regulation EC 999/2001 Article 12(1), 2nd, 3rd and 4th subparagraph, Article 13(1)(b) and (c), and Annex VII (see annex I to this opinion), could significantly reduce the remaining risk. However, this fully depends on the efficiency of the implementation of each of the above mentioned measures. Already small breaches could significantly increase the risk.

3.222 Conclusion on the measures in Germany

In the case of Germany neither animals born before the total feed ban nor animals older than 30 months are excluded from the human food chain. The systematic testing of all animals over 24 months of age reduces the resulting risk to a large extent but a certain risk remains because cattle significantly older than 30 months may carry infectivity, even if the current tests cannot detect PRP^{Sc} in the brain.

In view of this risk it is concluded that under the conditions in Germany culling in accordance with the requirements of the TSE-Regulation 999/2001 could improve the level of safety with regard to the human food chain.

Under the condition that the total feed ban is appropriately implemented the risk for animal health, however, is not significantly influenced by culling animals that are epidemiological linked to a BSE-index case.

¹³ SSC Safety of milk with regard to TSE: State of affairs; 30/03/2001.

Annex I

Parts of the TSE-Regulation as cited in the question.

Article 12

Measures with respect to suspect animals

1. Any animal suspected of being infected by a TSE shall be placed under an official movement restriction until the results of a clinical and epidemiological examination carried out by the competent authority are known, or killed for laboratory examination under official control.

If BSE is suspected in a bovine animal at a holding in a Member State, all other bovine animals from that holding shall be placed under an official movement restriction until the results of the examination are available.

If BSE is suspected in an ovine or caprine animal at a holding in a Member State on the basis of objective evidence such as the results of tests capable of differentiating in a practical way between the various TSEs, all other ovine and caprine animals from that holding shall be placed under an official movement restriction until the results of the examination are available.

If there is evidence that the holding where the animal was present when BSE was suspected is not likely to be the holding where the animal could have been exposed to BSE, the competent authority may decide that only the animal suspected of being infected shall be placed under an official movement restriction. If considered necessary, the competent authority may also decide that other holdings or only the holding of exposure shall be placed under official control depending on the epidemiological information available.

Under the procedure referred to in Article 24(2) and by way of derogation from the requirements of the second, third and fourth subparagraphs of this paragraph, a Member State may be exempted from the application of official restrictions on the movement of animals if it applies measures offering equivalent safeguards.

2. Where the competent authority decides that the possibility of infection with a TSE cannot be ruled out, the animal shall be killed, if it is still alive; its brain and all other tissues as the competent authority may determine shall be removed and sent to an officially approved laboratory, the national reference laboratory provided for in Article 19(1) or the Community reference laboratory provided for in Article 19(2), for examination in accordance with the testing methods laid down in Article 20.
3. All parts of the body of the suspect animal including the hide shall be retained under official control until a negative diagnosis has been made or shall be destroyed in accordance with Annex V, point 3 or 4.

4. Rules for the implementation of this Article shall be adopted in accordance with the procedure referred to in Article 24(2).

Article 13

Measures following confirmation of the presence of a TSE

1. When the presence of a TSE has been officially confirmed, the following measures shall be applied as soon as possible:
 - (a) all parts of the body of the animal shall be completely destroyed in accordance with Annex V apart from material retained for records in accordance with Annex III, Chapter B, III, 2;
 - (b) an inquiry shall be carried out to identify all animals at risk in accordance with Annex VII, point 1;
 - (c) all animals and products of animal origin referred to in Annex VII, point 2, that have been identified as being at risk by the inquiry referred to in (b), shall be killed and completely destroyed in accordance with Annex V, points 3 & 4.

ANNEX VII (to the TSE-Regulation 999/2001)

ERADICATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY

1. The inquiry referred to in Article 13(1)(b) must identify:
 - (a) in the case of bovine animals:
 - all other ruminants on the holding of the animal in which the disease was confirmed,
 - where the disease was confirmed in a female animal, all its embryos, ova and its progeny collected or born within two years prior to, or after, clinical onset of the disease,
 - all animals of the cohort of the animal in which the disease was confirmed,
 - the possible origin of the disease,
 - other animals, embryos or ova, on the holding of the animal in which the disease was confirmed or on other holdings, which may have become infected by the TSE agent or been exposed to the same feed or contamination source,
 - the movement of potentially contaminated feedingstuffs, of other material or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question;
 - (b) in the case of ovine and caprine animals:
 - all ruminants other than ovine and caprine animals on the holding of the animal in which the disease was confirmed,
 - in so far as they are identifiable, the parents, all embryos, ova and the last progeny of the animal in which the disease was confirmed,
 - all animals of the cohort, to be defined in accordance with the procedure laid down in Article 24(2), of the animal in which the disease was confirmed,
 - all other ovine and caprine animals on the holding of the animal in which the disease was confirmed in addition to those mentioned in the second and third indents,

- the possible origin of the disease and the identification of other holdings on which there are animals, embryos or ova which may have become infected by the TSE agent or been exposed to the same feed or contamination source,
 - the movement of potentially contaminated feedingstuffs, other material or any other means of transmission, which may have transmitted the BSE agent to or from the holding in question.
2. The measures laid down in Article 13(1)(c) shall comprise at least:
- (a) in case of confirmation of BSE in a bovine animal, the killing and complete destruction of bovine animals and the destruction of embryos and ova identified by the inquiry referred to in point 1(a), first, second and third indent. The Member State may decide not to kill and destroy all bovine animals on the holding of the animal in which the disease was confirmed as referred to in the first indent of point 1(a), depending upon the epidemiological situation and traceability of the animals on that holding;
 - (b) in case of confirmation of BSE in an ovine or caprine animal, killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in point 1(b), second to sixth indents.

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