SCIENTIFIC OPINION OF THE SSC
ON

"THE PROPOSAL FOR CONTROLLED USE OF RUMINANT SRMS AS FEED FOR FUR ANIMALS IN FINLAND"

27 October 2000

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OPINION

I. THE QUESTION and MANDATE

The Scientific Steering Committee was requested by the European Commission to assess whether a Finnish proposal *on the controlled use of SRMs as feed for fur animals* provides a sufficiently equivalent level of risk reduction to the provision of Decision 2000/418/EC regarding the use of material presenting risk as regards transmissible spongiform encephalopathies and amending Decision 94/474/EC.

II. THE FINNISH PROPOSAL ON THE CONTROLLED USE OF SRM AS FEED FOR FUR ANIMALS

The SRM of bovine, ovine and caprine origins would be removed at slaughter-houses in Finland according to Commission Decision 2000/418/EC, collected together with other high-risk animal wastes in *ad hoc* containers and then delivered directly to the high-risk animal waste processing plants (rendering plants) approved according to the Commission Decision 96/449/EC for later use in fur animal feed. Records of amounts of SRMs and high-risk animal wastes and their delivery to the plants would be kept. Every transport would be assisted by proper documentation. Moreover, the rendering plants would register all the incoming material.

There are two rendering plants in Finland both fulfilling the criteria laid down in the Annex 1 to Council Decision 1999/534/EC (133° C, 3 bar, 20 min). An option exists between two alternatives:

- All the high risk animal waste containing SRMs is processed in one of these plants and the other plant is to handle low risk animal waste only;
- Different production lines exist in both rendering plants and special measures are adopted to prevent contamination.

The rendered products would be labelled as “for fur animal feed only”. The rendering plants would keep record on the amount of delivered material.

The processed meat and bone meal containing SRMs as raw material would be delivered only to approved fur animal feed preparation plants and registered fur animal farms under strict transport and storage conditions. Production or handling of feed for any other animal species is not allowed at these plants or farms. On the other hand, according to the current Finnish legislation, it is forbidden to farm any other animal species in the areas for fur animal farming. The fur animal feed preparation plants have to keep record on the in-coming material and on the out-going final product. This feed would be labelled as “allowed to be used only for fur animals” and the fur animal farms would not be allowed to deliver this material further.

In connection to the autumn skinning, the carcasses of the skinned animals are heated at least at 118° C for 20 min at 2 bars in specific plants approved by the competent authority before further processing. This material will never be used elsewhere outside the fur animals.

All the critical steps of the process would take place under official veterinary control including the:

- handling of SRMs and other animal wastes at the slaughterhouse;

- the transport of SRMs and other wastes to rendering plants;
- registration upon arrival of SRMsand other wastes at the rendering plants;
- recording and supervision of delivered MBM deriving from SRMs and other animal wastes at the rendering plants;
- recording of delivery of the above-mentioned MBM to fur animal feed preparation plants; and
- recording of delivery of fur animal feeds containing the above-mentioned MBM to farms.

Fur animal feed preparation plants and fur animal farms would also be under official veterinary supervision. The farms have to notify the use of all animal waste to the competent authority that keeps record of animal waste users. A special notification system will be demanded for material containing SRMs.

On a yearly basis Finland produces about two million mink hides. There are around 420.000 adult females with an average age of 2.5 years and a maximum life span of five years. The annual mortality among the adult females is 5%. In addition to the mortality, around 25% of the females are screened out in connection to autumn skinning.

The surveillance on the fur farms for TSEs, already going on in Finland, would be strengthened. In addition to the animals with neurological symptoms as suspect animals, samples would be taken from adult female minks killed in November-December in connection to skinning. Out of nearly 100.000 adult female mink are killed each year, about 300 adult female mink would be subjected in a histological TME examination every year (this sample size is expected to allow detection of about 1% prevalence of TME (95% confidence)). The Finnish proposal also foresees the possibility of testing the sampled brains with a rapid prion test and to increase the number of samples if necessary.

III. BACKGROUND: SSC OPINIONS ON RENDERING, FUR ANIMALS AND GEOGRAPHICAL BSE RISK.

III.1. The rendering process and TSE infectivity reduction

According to the SSC Opinion on Fallen Stock of 1998[1], and within the context of the that opinion, rendering means *'the processing of fallen stock, dead animals, condemned materials, slaughter by-products (including bones, fat trimmings and other products from the further processing of slaughtered animals), animals unfit for human consumption, or meat scraps by applying a moist heat/pressure/time process. For mammalian animals or their materials, the processing is - unless otherwise stated in the text[2] - at least according to the "133°C/20'/3 bars" standard, which results in proteins intended for animal consumption, or as intermediate product for the production of organic fertiliser or other derived products. The definition used in this opinion is thus broader than "to separate fat from meat by heating" or than the one applied in Directive 90/667/EC.'*

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1 SSC- opinion on fallen stock: the risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials (Adopted by the Scientific Steering Committee at its meeting of 24-25 June 1999)

2 For example, under certain circumstances: blood and trimmings from fresh fish fit for human consumption.

The wording "133°C/20'/3 bars" refers to hyperbaric production processes of not less than 133°C over a period of not less than 20 minutes, without air entrapped in the sterilising chamber at not less than 3 bars. It may refer to an equivalent process with demonstrated efficacy in terms of inactivating TSE agents. The lag time needed to reach the core temperature is not included in the time requirement for correct rendering and will vary according to characteristics of the batch (e.g., size) and of the material (e.g. particle size and composition).

In batch processes, these conditions are expected to be realised for non-desiccated raw material with a particle size of maximum 50 mm in 2 dimensions. A pre-crushing of the raw material to thickness of 30 mm would be recommendable, as a safety margin, to diminish a possible lag phase in the development of the core temperature. This is sufficient and possible under practical conditions[3] with a lipid and water content that normally can be expected for animal tissues and where this water generates the steam during the rendering process[4]. If the starting material is dry and de-fatted, and steam was injected during the process, the lag time may have to be increased to allow heat to penetrate the particles of raw material so that equivalent infectivity reduction conditions are realised. However, any equivalent process should be evaluated and acknowledged on a case by case basis.

III.2. Geographical BSE risk (GBR) in Finland

The geographical risk of Bovine Spongiform Encephalophaty in Finland has been assessed by the Scientific Steering Committee in its opinion adopted on 6 July 2000. Two dimensions were taken into account: stability and challenge of the Finish BSE/cattle system.

III.2.1 Stability

Stability is defined as the ability of a BSE/cattle system to prevent the introduction and to reduce the spread of the BSE agent within its borders. Stability relies on the avoidance of processing of infected cattle and the avoidance of recycling of the BSE agent via the feed chain. A "stable" system would eliminate BSE over time; an "unstable" system would amplify it.

The Finnish BSE/cattle system was "very unstable" until 1988: (a) the rendering was not fully adequate to reduce BSE-infectivity, (b) feeding animal protein to cattle was frequent, (c) SRM and fallen stock was rendered for feed and (d) surveillance was not adequate for BSE. Incoming BSE-infectivity would have been quickly amplified. In 1988/90 the stability increased because of improved surveillance and of banning imported MBM from ruminant feed. However, the system remained "unstable" until 1995 when the MBM-to-ruminant-ban made the system "neutrally stable". The improvements in rendering (1996/97) made the system stable in 1997, when the systematic checking for BSE of CNS-suspects in emergency slaughter enhanced its stability. However, as long as SRM and

[3] Reducing the particle size will enhance heat penetration. A particle size of 30mm in two dimensions would constitute a safety margin. A possible inappropriate "crushing to 50mm" would indeed result in a much longer time for the temperature to reach the core of the material. Application of indirect heating with 160°C jacket steam (which causes a temperature overswing phase to nearly 140°C) would further increase the security of the sterilising process. (Other valid technical solutions may exist.)

[4] If direct steam is used, specified conditions may apply, *for example*: a water content of 50-60% with a temperature treatment for 140-150°C (at least 3.5 bars). (Other valid technical solutions may exist.)

fallen stock is still rendered for non-ruminant feed and cross-contamination is not fully mastered the system cannot be "very" or "optimally" stable.

III.2.2 External challenge

The term **"external challenge"** is referring to both the likelihood and the amount of the BSE agent entering into a defined geographical area in a given time period through infected cattle or MBM.

Before 1988 the Finnish system was exposed to a low, and during 1988/89 a moderate or high external challenge. Thereafter the external challenges were negligible. The pre-1990 challenges resulted mainly from import of large amounts of MBM/MM from countries other than the UK (116,547 tons in total between 1980-1990, of which 59,773 tons from The Netherlands) but also from imports of some (84 in total) cattle directly from the UK. Eleven of the cattle imported from the UK and processed in Finland were found being at risk to have been exposed to the BSE-agent prior to export. It is uncertain if the MBM exported in the late 80s from other European countries than the UK to Finland could have been contaminated with the BSE-agent. However, this cannot be excluded because of the export of about 50,000 tonnes of MBM from the UK to other European countries, in particular BE, FR and NL, in 1988/89.

III.2.3 The geographical BSE risk of Finland.

The current geographical BSE-risk (GBR) level is II, i.e. it is unlikely but cannot be excluded that cattle is infected (clinical or pre-clinical) with the BSE agent.

Note: This assessment is based on the assumption that the MBM imports from the Netherlands or other European Countries in 1988/89 did not pose a very high challenge. Given the uncertainty of this assumption that results from the fact that thousands of tonnes of MBM were exported at that time from the UK to other European countries, inter alia to the Netherlands, and from the practical impossibility to monitor the trade flows of that MBM, this assumption might be wrong. In that case Finland would have been exposed to a very high external challenge at a moment when the system was unstable. It therefore would have to be seen as GBR-level III (i.e., likely but not confirmed).

III.3. TSEs in mink

The SSC addressed this issue in its already mentioned opinion on "Fallen stock".

Transmissible Mink Encephalopathy (TME) is a very infrequent disease first described in 1947 in two farms located in Wisconsin and Minnesota (USA). Affected animals are usually over one year of age. Incubation time ranges between 7 and 12 months.

By mid-1998, TME had been reported in 23 mink- ranches in United States, Finland, Canada, Germany, and former Soviet Union. So far, very few outbreaks have been recorded in the EU. These outbreaks mostly occur as "explosions" which are limited in time either because of the severity of the outbreaks or because in practice the animals of a given cohort are all culled during the same part of the year and within a short period of time.

First similarity with TSE was noted by W.J. Hadlow and the first experimental transmission of TME to other species was obtained in 1965. Today, transmission has been achieved to hamsters, ferrets, racoons, skunks, monkeys, sheep, goats and cattle. In this last case, one should consider that the cattle-passaged TME agent remains pathogenic for mink by the oral or intra-cerebral routes. TME has never been directly transmitted to mice.

TME may also result from the feeding of mink with scrapie-affected sheep carcasses. Nevertheless, although intracerebral injection of scrapie led to a TME-like disease in mink within one year, none of the natural scrapie strains inoculated into mink has succeeded in producing TME when the oral route of infection was used. These facts may be interpreted as follows: TME is due to a scrapie strain that has so far not been identified, or TME results from infection of an unknown TSE agent coming from another species. One should note that animals which succumbed to the TME epidemic that occurred in Stetsonville (Wisconsin, USA) in 1985 were said never to have been fed with sheep carcasses.

Contrary to scrapie, the transmission of BSE to mink has been proven under experimental conditions, both after oral and intra-cerebral challenge. The disease produced was not identical to natural TME. Present evidence is therefore that the naturally occurring TME agent is a distinct entity from the TSEs in other animals. TME is also the only natural TSE in mink.

Feeding fur animals with meat-and-bone meal obtained after processing of offal is not a generalised practice, but feeding them with non-processed slaughter by-products is common in certain regions. Also, the animals may have been fed with feed that may have been incompletely processed or inappropriately sourced with respect to potential hazards. They might therefore become part of an (initially silent) cycle of building-up infectivity.

In general terms, risks for humans and animals could indirectly or directly result from the following:

- consumption by mink, other fur animals, other carnivorous species and rodents of TSE infected feed intended for mink or other fur animals or derived from infected mink or other fur animals (e.g. MBM);
- a potential risk for humans, if they consume products of farmed animals reared for food that have been fed with TSE infected products (e.g. MBM derived from TSE infected fur animals[5]);

Moreover, it should also be considered that contact with feed, mink or fur animals could constitute a risk if a horizontal route of transmission exists.

The risk of an outbreak would be high if inadequately processed carcasses of infected animals were fed back to the same species (this is most likely to occur on the same farm). This would result in the rapid propagation of the infection within a farm. It should however be noted that most fur animals are killed at young ages: approximately 80% of the fur animals are killed before the age of 7 months[6]. The risk would also be smaller and decrease accordingly as the appropriate measures for reducing potential TSE infectivity in the raw material were respected (processing, sourcing of the material, etc.). This applies also if the raw material contains fur animal carcasses.

If an outbreak occurs or a TME case is confirmed in a farm or colony, it is likely that all farms that had a common source of possible infectivity (e.g. the same feed supplier) were exposed to the risk of TME infection and could harbour the agent in their mink population. This would be possible even if no TME is observed because the animals are killed at a young age and the disease may be pre-clinical. It may be noted that, depending upon whether a farm produces its

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5 Note: The effect of rendering on TME inactivation is not known. It is also not known whether pigs and poultry are susceptible to TME by the oral route.

6 The incubation time of TME is 7 to 12 months, hence a 7 month old animal could already approach the end of the incubation time.

own feed or not, the number of farms with a common source of infection may be highly variable, from one single farm, to all farms in a country.

As mink are also susceptible to BSE, any risk of TSE infectivity should be excluded for fur animal carcasses that possibly re-enter the animal feed chain (and hence possibly via indirect routes, the human food chain), for example because they are used as a raw material for rendering. The positive confirmation that such is the case depends upon the existence of an appropriate and targeted surveillance system for the detection of TSEs in fur animal populations. Such systems presently do not exist in most countries and have also not been fully described yet.

If a TSE outbreak in fur animals is suspected or has been confirmed, the carcasses from all fur farms that, on the basis of an epidemiological study, had common sources of possible infectivity, should be excluded for any further use except disposal and this at least until the end of the outbreak. The end of the outbreak has to be positively confirmed on the basis of criteria that still have to be established as part of a specific surveillance system surveillance system for TSEs in fur animals but should include laboratory tests and microscopic examination of the brain of statistically significant numbers of animals that do not show any symptoms of a TSE-disease.

The SSC concluded as follows on 25 June 1999:

"Because of their susceptibility to TSEs, the intra-species recycling of fur animals cannot be recommended. The SSC notes that intra-species recycling does occur and may be considered in certain regions on the basis of claims that there are sound and documented grounds to totally exclude the presence of TSE agent in the fur population of these regions.

Examples of conditions under which the (intra- or inter-species) recycling of fur animals could be considered, are:

- If the practice of intra-species recycling is nevertheless used, the TSE risk can be minimised if: (i) the recycled animals are healthy and not showing any signs pointing to the possible presence of TSE in the population, (ii) no link exists at any farm with a suspected or confirmed TSE, (iii) there exists an appropriate surveillance system for TSEs in fur animals, (iv) the material is exclusively fed to fur animals, and (v) any future rendering/processing for other purposes of the offspring (any generation) of fur animals fed with such products is totally excluded.

  Fur animals from farms with a link with a farm with a suspected or confirmed TSE, should be considered as at TSE risk.

  Although a sterilisation at “133°C/20’/3 bars” is preferred, an appropriate decontamination for non-TSE infectious agents is for the above use and under the above conditions considered to be sufficient to minimise any remaining risk from conventional infectious agents.

- The possible residual risks resulting from (inter-species) recycling (rendering) fur animal carcasses into feed products for other animals may be considered acceptable if the rendering process complies with the “133°C/20’/3bars” standard, provided the above criteria (i), (ii) and (iii) are satisfied and provided the fur animals were not part of an intra-species recycling chain as described above.

The SSC is aware that the above conditions – although scientifically justifiable - may be difficult to implement and monitor. Disposal of all fur animal carcasses may therefore be the most appropriate alternative as it would avoid both inter- and intra-species recycling in an animal species proven to be susceptible to TSEs.

IV RISK ASSESSMENT OF FEEDING SRMS TO FUR ANIMALS

Assuming that the use of MBM derived from SRMs as human food or animal feed (other than fur animals) can be excluded and the spreading of TSE via furs is unlikely, the main risks to

be taken into account when evaluating the Finnish proposal (see section II) include the risk for the fur animal health and the environmental risks, which also could have indirect repercussions for man (see table 1).

Aspect	SRMs disposed of by rendering followed by controlled landfill	SRMs disposed of by rendering followed by feeding to fur animals
Infectivity reduction by rendering at "133°C/20'/3 bars"	10^3	10^3
Infectivity reduction by disposal	10% per year[7]	Possible building up of pool of infectivity in fur population, hidden until outbreak
Infectivity spread in the environment	In principle limited to controlled landfill site but risk of wind- rain-, drainage- and animal spread if not properly implemented.	Possibly wide, as feed may be sold throughout the country. The risk of excretions and faeces of fur animals containing TSE infectivity needs to be assessed. Escape of infected animals has to be considered possible.
Possibility of human exposure during handling and transport	Transport to rendering, handling at rendering, transport to landfill; handling at the landfill site; maintenance of site.	Transport to rendering, handling at rendering, transport to the feed manufacturing and fur farm; handling when manufacturing feed and feeding; maintenance of stores and mills.
Storage	Prolonged but localised storage with slow reduction of infectivity	Prolonged storage on feed manufacturing plants and farms is not excluded.
Cross-contamination	Excluded	Excluded, (only if properly implemented).

Table 1: Comparison of some risks associated with feeding "133°C/20'/3bars" -rendered SRMs to fur animals versus their disposal by controlled landfill, should the SRMs be contaminated with BSE agent.

IV.1. Fur animals health aspects

The risk of provoking a TSE-outbreak in the fur animal population that is fed MBM produced from Finish SRMs is regarded to be considerable. It is unlikely, but cannot be excluded, that the SRMs of bovine, ovine and caprine origins collected at the slaughterhouses in Finland carry the BSE agent. Should this be the case, the rendering treatment, even if carried out at 133°C/20 min./3 bars, is known not to be sufficient to completely inactivate the BSE infectivity. Therefore, the possibility exists that the BSE agent would enter the mink feed chain and, because of the known susceptibility of mink to BSE, affect, sooner or later, some animals. According to the Finnish proposal these animals would most likely be re-cycled to

[7] See SSC opinion of "Fallen stock" of 25 June 1999.

fur-animals. As the treatment of skinned mink carcasses at 118°C/20 min/2 bars is unable to destroy TSE infectivity. This could lead to a building up of the infectivity until TSE is finally recognised in the exposed mink population (see also Table 1).

IV.2 Environmental and other aspects

According to the SSC-opinion on Fallen Stock, "the many scientific unknowns and uncertainties relating to TSEs and their inactivation by processing, justifies to consider that *actually, suspected or potentially*[8] TSE infected animals, materials and/or products derived therefrom, carry a definite risk. Recycling for any use of such animals or products is not considered a safe practice.

a. For animals and materials that carry an ***actual or suspected*** *TSE risk*, incineration or burning after previous rendering at, at least, "133°C/20'/3bars" (or validated equivalent) are considered to be the safest ways of disposal.

b. For animals or materials that carry a ***potential*** *risk of TSE infection*, acceptable ways of disposal include (in addition to the ones listed under a.) rendering at at least "133°C/20'/3 bars" (or validated equivalent) followed by controlled landfill, preferably after liming and encapsulation.

In Finland it may be considered that the ruminant SRMs carry a ***potential*** *risk of TSE-infection*, hence the disposal-option mentioned under point (b) above would be acceptable. A key-question is thus whether the risks associated with disposal of SRMs by feeding them, after rendering at "133°C/20' 3bars", to fur animals would be sufficiently equivalent to the risks associated with rendering followed by controlled landfill (see Table 1).

From Table 1 it appears that, also from an environmental protection point of view, the feeding of rendered SRMs to fur animals is posing a higher and not fully quantifiable environmental and other risks than rendering followed by controlled landfill.

V. CONCLUSIONS

Based on present evidence, the Finnish proposal does not provide a global level of risk reduction sufficiently equivalent to the provision of Decision 2000/418/EC.

In essence, the Finnish proposal aims at establishing a completely segregated and self-contained cycle to utilise SRMs removed at Finish slaughterhouses as fur animal feed, following treatment at "133° C/20'/3 bars" to produce MBM. Even if such complete segregation and self-containment can be successfully maintained, it could not be considered sufficiently equivalent to rendering followed by controlled landfill. Reasons are the animal health risks for the exposed mink, which are likely to be higher, and additional and not yet fully quantifiable environmental and other risks, which are likely to be broader. The environmental risk may also have, probably delayed, repercussions for human health.

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8 See section "Definitions" in annex. In countries with a low or high BSE risk, the cause of death of fallen or dead bovines below 12 months of age and fallen or dead ovines and caprines below 6 months, would not be due to BSE or scrapie.