OPINION ON

The safety of tallow derived from ruminant tissues

Adopted at the Scientific Steering Committee meeting of 26-27 March 1998

Following a public consultation on the preliminary opinion adopted on 19-20 February 1998

I. Report of the Working Group

1. Definition of tallow

According to Council Directive 92/5/EEC of 10.02.92, rendered animal fat is fat derived from rendering meat, including bones, and intended for human consumption. Tallow is rendered animal fat from bovine origin.

For the purpose of the present opinion, tallow is defined as fats obtained by pressing or any extraction system down from ruminant tissues which are derived directly from discrete adipose tissue masses, from fat extracted from skeleton muscles, from mechanically recovered meat and from rendered animal waste, including bones.

2. Background

On 8 September 1997, the MDSC/SSC adopted the following opinion on the security of tallow.

" Tallow is a raw material which is used in the food, feed, medicinal and non-food sector. In the light of actual scientific knowledge on BSE, the question is still open if Tallow could transfer the BSE agent to animals (via the feed-chain) or to man (via the food and non-food chain).

To reach a sufficient degree of security when using tallow, it is therefore necessary that either the material used for the production of Tallow is safe, i.e. not infectious, or that the production process used has shown to actual knowledge that the agent is neutralised.

Concerning the raw material it has to be accepted that, as long as no test is available which allows to diagnose non-clinical BSE cases (pre-mortem), the only way of determining that the basic raw material is safe if a procedure as described by the OIE in Chapter 3.2.13 of the OIE International Zoo-Sanitary Code on BSE, is applied.

In cases where the animal material comes from a country of low risk or from a country controlled by epidemiological surveillance, this raw material has to be

classified to be suitable for human consumption. In order to minimise a possibly remaining risk of infectivity of the raw material those parts of the animals which are supposed to carry a high level of infectivity (= the Specified Risk Material SRM, as defined in the corresponding opinion) shall be excluded from the production of tallow.

A third safeguard is a transformation process. So far it was accepted that no infectivity could be found after exposing even infected material over 20 minutes to a temperature of 133°C at 3 bar or an equivalent method with demonstrated efficacy. However, during the International Meat and Bone Meal Conference held in Brussels on 1 and 2 July 1997, it was not excluded that under worst case conditions, traces of infectivity could remain. This implies that the only safeguard at present is the certified origin of the material from which the product is derived AND an appropriate production process following acknowledged production rules.

Keeping in mind the remaining scientific uncertainties the SSC therefore recommends that in all cases the process "133°C, 3 bar, 20 minutes or an equivalent method with demonstrated efficacy" is to be applied, and that an infectivity of the raw material must be reduced to the maximum possible by sourcing (geographical origin or certification of individual animals) and by avoiding the use of specified risk material."

This opinion is line with the opinion adopted on 9 April 1996 by the Scientific veterinary Committee (E.C., 1996), which states:

" (...) Data on tallow have been obtained as part of the study on rendering processes, and show no detectable BSE infectivity in material from all tested systems on bioassay in susceptible mice. New data on inactivation of scrapie agent, however, indicates that only one system evaluated (133°C at 3 bar for 20 minutes) resulted in a product (meat and bone meal) which had no detectable infectivity. Because the initial titre of the agent in the BSE experiment was lower than in the scrapie study, only this latter process can be considered as providing adequate guarantees for the production of tallow.

(...) The following processes are recognised as giving the best possible guarantees:

1. (...)

2. Tallow produced in a process which ensures that all material is subjected to 133°C for at least 20 minutes at 3 bar, followed by filtration to eliminate protein residues."

Since the MDSC/SSC meeting of 8 September 1997, during which opinions on Tallow were adopted, a number of industry associations and third countries submitted a number of comments and technical and scientific dossiers. The main comment is that imposing a process "133°C / 3 bars / 20 minutes" is not reasonable for tallow production. The final product seems to be of inferior quality (discolouring of the material, altering of the fatty acids content, altering of the structural properties of tallow). However, in a comment on the preliminary opinion on the safety of tallow, the Irish State Veterinary Office stated that even a heat treatment of up to 300°C would have no impact on tallow quality, if carried out under vacuum conditions. Normal industrial tallow production processes - even the

ones using the lowest time/temperature combinations - and corresponding research have shown to result in a product which is free from detectable TSE infectivity (injection into the brain of mice), even if the source material was highly infective. The explanation of these results seems to lay in the fact that "*because of the proteinaceous nature of the TSE agents they would tend to remain with the cellular residues of meat and bone meal during extraction process, rather than be extracted with the lipids of tallow.*" (WHO, 1995; WHO, 1996; WHO, 1997).

In addition the final results of the 1991-1997 Rendering study became available (MAFF, 1997). This study is often used as a justification for the preceding statement that tallow can be considered safe even if it is submitted to much less harsh conditions. It is also part of the scientific basis of Commission Decisions N° 94/382/CE (repealed) and 96/449/CE.

The thesis that tallow is a safe product is also supported in the Guidelines to minimise the transmission of spongiform encephalopathies in medicinal products issued in 1994 by the German Federal Health Authority (BGA, 1994), which classified tallow in the lowest risk class which includes also milk. Also for the US-FDA, tallow and other fats are considered as non infective (see also the Report of the International scientific conference on animal meal held in Brussels on 1 and 2 July 1997) (EC, 1997).

On the basis of what precedes, the MDSC/SSC decided during its meeting of 16 October 1997, to create a working group on the safety of tallow.

3. On the production of tallow

In order to express an opinion on the safety of tallow it is important to keep into account a number of aspects of the fat production methodologies and conditions.

3.1 **Production of tallow** (See also UNEGA, 1997a and UNEGA 1997b)

Tallow and other animal fats are manufactured primarily from the animal materials arising from the meat industry (slaughterers, cutting plants and butchers shops) which are not required for direct human consumption. Raw materials such as subcutaneous, abdominal and intermuscular fats, organ fats, offal and bones are by far the main sources of tallow and other animals fats. Some sectors of the rendering industry utilise materials from animals rejected at ante or post mortem inspection and farm-dead animals (fallen stock).

Tallow is produced from animal tissues containing fat by a variety of processes called 'rendering ' or 'fat melting'. Fat melting is a term usually reserved for the processing of edible fats. However, rendering is the term used in some countries, notably Germany and the Netherlands, only for the processing of inedible and 'high risk' animal waste which will contain fallen-stock . In many other countries rendering is used to describe the whole range of animal by-products processing operations. (Collins English Dictionary: to render - to extract fat from meat by melting).

Typically the raw materials are minced and heated, mechanically agitated and the moisture evaporated or separated. The lipid fraction is separated from the protein by centrifugation and pressing. Processing conditions vary in the different fat melting and rendering systems which will be determined by the

type and quality of the raw materials being processed and the desired quality characteristics of the tallow's end use.

Specifications of tallow as a commodity are typically set for titre (solidification temperature), free fatty acid level, peroxide value, colour, moisture content, insoluble impurities, unsaponifiable matter, etc. In general, the freshness of the raw material, the origin and the nature of the tissues will determine the end quality of the tallow or animal fat. Fresh adipose tissue and bones is needed to give the high quality specification of colour, free fatty acid and peroxide levels required for edible purposes and toilet soap manufacture, for example. Less fresh material or the presence of significant quantities of offals in the raw material mix will result in fat with darker colour and higher free fatty acid levels - generally suitable for animal feeds or further processing by the oleochemical industry to produce chemical derivatives.

3.2 **The separation of fat from proteins** and from all the other impurities can be realised through the following steps:

- ***centrifugation:*** highly efficient process, but it doesn't always guarantee the complete elimination of the residues;
- ***filtration***: some methodologies of microfiltration on ceramics, on filtering beds (earth filtering, clays, bentonite, montmorillonite, philipsite) (20-25µ) with appropriate filtration co-adjuvants (celite) are available. These methodologies are effective and lead to very low residues levels. Afterwards it is necessary to eliminate the filtration supports (filtering beds and co-adjuvants) which cause costs and environmental problems.
- ***treatment with phosphoric acid*** homogenate with a phosphoric acid water solution and afterwards centrifugation. Residual nitrogen levels are approximately less than 0.01%.

All these processes are usually realised at a temperature around or over 80°C.

3.3 **Maximum impurities acceptable level**. Under the assumption that it is not scientifically acceptable to make the hypothesis of zero nitrogen residues, it is necessary to give indications of the fat residual nitrogen acceptable levels.

The requirement of imposing a maximum acceptable value of nitrogen residues as the maximum molecular weight of remaining peptides and polypeptides is not straightforward. These peptides and polypeptides residues are probably not present in the lipid fraction because, due to their water solubility, they should have been pushed away in the first step of the process. It is instead credible that the residual protein fractions mainly come from cellular protein fragments of the fatty tissue.

A maximum level of total insoluble impurities below a given content (e.g. 0.15% in weight, to be confirmed) and/or a maximum level of nitrogen (determined according to the Kjeldhal method, to be confirmed) and if possible the residual peptides or polypeptides having a molecular weight below 10.000 Dalton may therefore be proposed to indicate the maximum impurities acceptable level. Regarding the nitrogen levels, the not published laboratory analyses (Piva, 1997) resulted in Nitrogen levels of 0.01 - 0.02 %.

4. Some considerations regarding the safety of tallow.

Regarding the safety of tallow, the working group has made the following considerations:

- Wilesmith et al. (1988) indicated already that the geographical variation in the incidence of BSE in the UK is not consistent with the distribution and use of tallow in cattle feed.
- Normal industrial tallow production processes - even the ones using the lowest time/temperature combinations - and corresponding research have shown to result in a product which is free from detectable TSE infectivity (injection into the brain of mice), even if the source material was highly infective. (See also Taylor et al., 1995; Taylor et al., 1997; MAFF et al., 1997).
- The explanation of the preceding result seems to lie in the fact that "*because of the proteinaceous nature of the TSE agents they would tend to remain with the cellular residues of meat and bone meal during extraction process, rather than be extracted with the lipids of tallow.*" (WHO, 1995).
- Although tissues with high titres of infectivity will be more difficult to decontaminate than those with low titres, there are no data that show any difference between the scrapie and BSE agents in terms of their susceptibility to inactivation by chemical or physical methods.. Therefore, although the degree of survival of infectivity was greater during the study of rendering processes spiked with scrapie-infected sheep-brain (Taylor et al., 1997), compared with BSE-infected bovine brain (Taylor et al., 1995), this was likely to be due to the fact that the scrapie-spiked raw materials contained $10^{1.4}$ ID_{50}/G more infectivity than the BSE -spiked raw materials. This would imply that one of the bases of the ScVC opinion of 9.04.96 to declare *133°C at 3 bar for 20 minutes as the only process that can be considered as providing adequate guarantees for the production of tallow,* is not relevant (anymore).
- Apart from the major experiment run in Edinburgh (Taylor et al., 1995; MAFF, 1997; Taylor et al., 1997), the number of other scientific experiments looking into the safety of tallow with regard to TSEs is, to the knowledge of the Scientific Steering Committee, rather limited if not nihil. Also, the experiment, because of its scope, size and duration, has not been repeated in other laboratories. Finally, the experiments were simulations carried out at a pilot scale and the extrapolation of the results (scaling up) into the real operational industrial conditions may therefore not be automatic. No test results, confirming the hypothesis that tallow is 100% safe, are available from operational rendering plants. On the other hand, the above pilot-scale experiments were not simply laboratory approximations of rendering processes, but were carried out in actual (although pilot-scale) rendering equipment. In collaboration with the industry it was determined how the pilot-scale equipment could be operated to provide a realistic representation of what occurs in full-scale rendering. Also, most validation studies done on to the safety of a wide variety of biopharmaceutical products with respect to TSE agents, are almost always carried out on scaled down versions of the manufacturing processes that are spiked with TSE agents.

- The mice infection tests which are in most cases carried out to detect TSE infection, may not be (fully) representative for a system of homologous detection between animals of the same species (e.g., from bovine to bovine).The sensitivity of the mouse bioassay for assaying TSE agents from cattle or sheep will be compromised by the species barrier. Cattle-to-cattle transmission of BSE by intracerebral route is known to be about 1.000-fold more effective than cattle-to-mouse transmission by the same route (unpublished data from the UK Central Veterinary Laboratory at Weybridge). Superficially, this might appear to compromise any conclusions drawn from the rendering studies with regard to the safety of tallow. However, in assessing risks related to the consumption of tallow, the much greater efficiency of establishing infection in mice by the intracerebral (compared with the oral) route of infection must be considered. For example, the difference in efficiency between these two routes for scrapie in mice is 100.000-fold (Kimberlin, 1996). Also, it has been calculated that the transmission of BSE to mice by the oral route is 200.000-fold less efficient than by intracerebral challenge (Kimberlin, 1994). These data seem to indicate that the negative results from the mouse bioassays of tallow in BSE and scrapie-spiked rendering studies can be viewed with a considerable amount of confidence with regard to any risk from infection by its consumption. On the other hand, however, certain strains of natural scrapie are transmitted as easy by the peripheral as by the central route and, for example, the infection of mink by the BSE agent is almost equally effective by the oral route as by the mixed parenteral/intracerebral route (Robinson et al., 1994). The Scientific Steering Committee notes that the scientific discussion on the absolute and relative differences in infectivity according to the way of transmission (oral or central) and depending upon the species barrier, is not yet conclusive and is still ongoing.
- Depending upon the strain and the host, it is possible to have differences in incubation times, pathogenesis, distribution of the lesions in the central nervous system, amount of infective PrP^{Res} and its location inside the central nervous system, etc. (e.g., Lasmézas et al., 1996; Kimberlin et al., 1983; Dickinson et al., 1989; Bruce et al., 1994). There are also known differences between some strains of scrapie agent in terms of their thermo-stability (Dickingson and Taylor, 1978; Kimberlin et al., 1983). To date, however, there are no compelling data to indicate that BSE agent is more thermo-stable than scrapie agent.
- The quality of the result of filtration (in terms of remaining level of impurities) depends upon the quality of the raw tallow before filtration (for example, from which type of tissues it was derived from) and depends also upon the type of production process used (for example, mechanical pressure combined with heat treatment or tallow obtained after a heat treatment).

II. Scientific Opinion

Based on the preceding report, prepared by the working group “Tallow” and approved by the TSE/BSE ad-hoc group, the SSC adopted the following scientific opinion.

5. The question.

The SSC was asked to address the following question:

"Can tallow be considered to be free of TSE infectivity, regardless of the source of the material (geographical and animal), regardless of the type of material used (e.g. incl. SRMs), regardless of the age of the animal and regardless of the production process,

but provided it is free from proteinaceous material as a result of appropriate purification?"

6. Scientific opinion

Introductory note:

In its opinion of 22-23 January 1998 defining the BSE risk for specific geographical areas, the Scientific Steering Committee has listed the factors contributing to the incident and propagation risks in a geographical area. On 20 February 1998 the SSC adopted that list, slightly amended, as final opinion. More work needs to be done on the definition of risk regions or countries. The Committee is preparing a further opinion on the geographical aspects of BSE risks.

The four classes of the geographical aspect of BSE risks used in the opinion hereafter, are therefore indicative and, for the time being, are: "high risk countries", "lower risk countries", "countries considered free of BSE or classified as at negligible risk" and "Countries with an unknown TSE status". The corresponding wording of the opinion hereafter may thus possibly have to be revised / updated in accordance with the forthcoming Scientific Steering Committee opinion on the geographical aspects of TSE/BSE risks.

The Scientific Steering Committee is presently developing a methodology for the geographical risk assessment.

On the basis of the report of the working group, approved by the TSE/BSE ad hoc group, the Scientific Steering Committee adopted on 26-27 March 1998 the following final opinion on the safety of tallow:

6.1. Definitions:

- *For the purpose of the present opinion, tallow is defined as fats obtained by pressing or any extraction system down from ruminant tissues which are derived directly from discrete adipose tissue masses, from fat extracted from skeleton muscles, from mechanically recovered meat and from rendered animal waste, including bones.*
- *The wording "Fit for human consumption" hereafter refers to material from animals that passed both pre- and post mortem inspection by an competent veterinary authority and that are certified and identifiable as fit for human consumption on the basis of the existing national and EU legislation. The Scientific Steering Committee stresses that positive identification of material not fit for human consumption should be possible, to avoid possible entering of such material in the food or feed chains.*

– *An "appropriate purification process" can consist of adequate filtering and/or centrifugation and/or coagulation and should result in maximum levels of remaining total insoluble impurities of 0.10-0.15 % in weight or residual nitrogen below 0.02 %, and if possible the residual peptides or polypeptides should have a molecular weight below 10.000 Dalton.*

– *Unless otherwise specified, the wording "Specified risk materials" refers to all tissues listed in the opinion of the Scientific Steering Committee (SSC) adopted on 9 December 1997. However, the SSC intends to consider the possibility of making a selection of specified risk materials on the basis of the results of a risk assessment, which takes into account the geographical origin of the animals, their species and their age.*

– *The wording "133°C/20'/3 bars" refers to production process conditions of 133°C during 20 minutes at 3 bar, or an equivalent process with demonstrated efficacy in terms of inactivating TSE agents. Regarding the fact whether they should be realised under batch or continuous conditions, the Scientific Steering Committee is of the opinion that there will be no difference in the effectiveness provided the time/temperature/pressure parameters are effectively achieved in every part of the material being processed. Equivalent processes should be evaluated and acknowledged on a case by case basis.*

– *"Industrial use" means that the end product is neither for direct nor for indirect human or animal consumption or use, including as a cosmetic nor as a pharmaceutical product.*

6.2. *In principle, tallow is safe **after appropriate purification**. But due to the documented possible presence of impurities, and depending upon the intended end-use, the raw material should be obtained from appropriate sources (geographical, herd, animal and its age, ...), animal species and tissues. Where required the appropriate production processes should be used.*

6.3. *The Scientific Steering Committee strongly recommends that manufacturers implement and respect HACCP[1] procedures. It is essential to identify and describe the hazards and critical points for the different processes utilised in production. Two of these points is certainly the traceability and treatment at the origin (e.g., removal of specified risk materials) of the raw material.*

6.4. *The sections of opinion hereafter cover the approach to be followed if the risk of infectivity in the remaining impurities is to be reduced to the lowest possible level. As an alternative, a more detailed quantitative risk analysis should be carried out to assess the remaining risk for a population or individual. Such assessment would take account of:*

- *type of final product and infectivity reduction capacity of the production procedure;*
- *the geographical origin of the raw material;*
- *the type of raw material, including the age of the animals;*
- *the removal or not of specified risk materials;*

[1] Hazard Analysis and Critical Control Points

- *the incidence and propagation components of the BSE borne risk, as specified in the opinion of 22-23 January 1998 of the Scientific Steering Committee on defining the BSE risk for specified geographical areas.*

This assessment requires results of experiments on and justified estimates of, reduction factors during the various steps of the production process, from sourcing to marketing. Such data are not always available, as some experiments are still ongoing or only in a planning phase. In order to provide the Commission with two alternative choices, the Scientific Steering Committee will eventually complete the in this opinion followed approach to reduce the risk of infectivity in the final product to the lowest possible level with a quantitative risk analysis. The results of the latter analysis may eventually change or ask for an update of the recommendations hereafter.

6.5. Four different groups of end-uses of tallow are considered hereafter.

6.5.1. The end use of the tallow is for human or animal consumption or application.

6.5.1.A. The animals from which the raw material is derived, are fit for human consumption.

a) For countries considered to be 'BSE free or classified as at negligible risk', raw material from animals fit for human consumption, can be used without conditions regarding minimal production processes or removal of specified risk materials. As a measure of additional precaution, the Scientific Steering Committee recommends that the tallow should be submitted to an appropriate and validated purification process.

b) For lower risk countries, the use of specified risk materials should be excluded. The origin of the raw material should be fit for human consumption. The tallow should be submitted to an appropriate and validated purification process.

c) For high risk countries the use of specified risk materials should be excluded. The origin of the raw material should be certified to be exclusively from animals which are fit for human consumption. The tallow should be submitted to an appropriate and validated purification process. The tallow obtained from rendering a mixture of tissues and offals should be submitted to a process respecting conditions of 133°C during 20 minutes at 3 bar, or an equivalent process with demonstrated efficacy in terms of inactivating TSE agents. (The latter conditions of 133°C/20'/3 bars may not be respected for tallow directly obtained from discrete adipose tissues alone).

d) Countries with an unknown BSE status should be evaluated individually on the basis of a detailed evaluation using appropriate criteria. If no judgement on the basis of available evidence or because of a lack of information is possible, they should be considered as high risk countries.

Remark: The previous statement does not prejudge the opinion of the SSC on the TSE/BSE status of any country. Work on geographical risk assessment is ongoing.

6.5.1.B. The animals from which the raw material is derived, are not fit for human consumption.

The Scientific Steering Committee considers that the questions relative to the risks related to the use of fallen stock, condemned carcasses, sick animals, laboratory animals, etc. should be specially addressed. This discussion should also address the possible minimal processing conditions[2] of these materials. (See also section 6.6. of this opinion.)

Until such opinion becomes available, raw material not fit for human consumption (excluding clinical TSE cases which should be excluded anyway) could be used as animal feed only, provided the specified risk materials were removed, and after appropriate purification of the tallow. In addition, the tallow should be submitted to a process respecting conditions of 133°C during 20 minutes at 3 bar, or an equivalent process.

As a precautionary measure this should also be applied in geographical areas declared BSE-free or of negligible risk, because of the theoretical possibility of sporadic cases, even if their existence has not yet been proven.

6.5.2. The possible end use of the tallow is as an injectable product.

The Scientific Steering Committee has examined the existing licensed uses in the E.U. of tallow and is not aware of any licensed use of tallow as an injectable product. If it were to be used as such, the SSC would need to issue an additional opinion.

6.5.3. The end use of the tallow is industrial (with the exception of tallow derivatives).

6.5.3.A. The animals from which the raw material is derived, are fit for human consumption.

The animals from which the material is derived, should be certified to be fit for human consumption. The tallow should be appropriately purified.

6.5.3.B. The animals from which the raw material is derived, are not fit for human consumption.

The tallow should be appropriately purified. In addition, the material should be submitted to minimal conditions of 133°C at 3 bar or equivalent process.

If the intended end use cannot be verified and controlled to exclude any human or animal consumption or use, then the conditions outlined

2 For example 133°C during 20 minutes at 3 bars

in paragraph 6.5.1.A should apply also for tallow for industrial or technical use.

6.5.4. The end use of the product is as raw material for the production of tallow derivatives. *The working group confirms the opinion of the MDSC/SSC of 8 September 1997, namely that tallow derivatives can be considered to be safe provided:*

a) the raw material is fit for human or animal consumption (see section 6.5.1.A), or:

b) provided, regardless of the source of the material and regardless of the type of material, the production process uses the appropriate, validated and scientifically most up-to-date methods in terms of inactivating the BSE agent. Several amongst them have been listed in the scientific opinion of the Scientific Committee on Cosmetology[3] *(for cosmetic products) and in the opinions of Committee for Proprietary Medicinal Products (CPMP) of the European Agency for the Evaluation of Medicinal Products (EMEA)* [4] *(for medicinal products). The working group recognises that other methods may exist, but they should be evaluated and acknowledged as regards to their safety on a case by case basis.*

6.6. The Scientific Steering Committee, in its capacity of co-ordinator of multidisciplinary questions, further recommends that additional opinions are prepared by the appropriate Scientific Committees, on the following subjects:

– *The protection against the risk of infectious agents or non conventional transmissible agents entering the human food or animal feed chains via raw material (for example as exotic/zoo animals, dead animals, condemned carcasses, sick animals, laboratory animals). This discussion should also address the possible minimal processing conditions*[5] *of these materials and the importance of the age of dead animals (of fallen stock).*

– *Whether and under which conditions can tallow be used as a source of fat in milk-replacers for calves (and possibly lambs and kids). It may indeed appear to be prudent to consider excluding tallow from the high-fat milks fed to young calves whenever it is not produced according to the conditions required for the production of tallow for human consumption.*

3 Of 24 June 1997

4 Of 16 April 1996 and of 17 December 1997.

5 For example 133°C during 20 minutes at 3 bars

Summary table: the safety of tallow derived from ruminant tissues

Intended end-use: Þ		Human or animal use	Animal use	Industrial use[6]	
Animal class: Þ		Fit for human consumption	Non fit for human consumption	Fit for human consumption	Non fit for human consumption
Conditions common to all sources: Þ		- certified as fit for human human consumption - purification	- SRMs[7] excluded - Purification - 133°C/20'/3bar or equivalent	- certified as fit for human human consumption - purification	- purification - 133°C/20'/3 bars or equivalent
ORIGIN	BSE free or negligible risk				
	LOWER RISK	- SRMs excluded[7]			
	HIGH RISK	- SRMs [7] excluded - if rendering a mixture of tissues[8]: 133°C/20'/3 bar or equivalent (except if only discrete adipose tissues).			
	STATUS UNKNOWN	To be evaluated; if no judgement on the basis of available evidence or because of a lack of information is possible: consider as high risk.[9]			
Notes			See text on risk animals and on feeding of calves.	*If human or animal consumption or use cannot be excluded, then the conditions outlined for human and animal use apply.*	

Note: Tallow derivatives are considered safe, if they were obtained from raw tallow produced according to the condition listed in the column "Human or animal use" or if appropriate and validated production processes were used, for example the ones listed in the SSC opinion of 24.06.97 or in the EMEA opinions of 16.04.96 and 17.12.97.

6 Industrial use means here that the end product is not for direct nor indirect human or animal consumption or use, including not as a cosmetic nor pharmaceutical product.

7 The wording "SRMs or Specified risk materials" refers to all tissues listed in the opinion of the Scientific Steering Committee (SSC) adopted on 9 December 1997 and amended on 19-20 February 1998. However, the SSC considers the possibility of making a selection of specified risk materials on the basis of the results of a risk assessment, which takes into account the geographical origin of the animals, their species and their age.

8 Excluding for tallow directly obtained from discrete adipose tissues.

9 This statement does not prejudge the opinion of the SSC on the TSE/BSE status of any country.

7. Non exhaustive list of the scientific and technical material used by the working group.

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