SCIENTIFIC OPINION ON

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

AND RE-EDITED AT ITS MEETING OF 22-23 JULY 1999

(TEXT SUBJECT TO EDITORIAL CHANGES)

EXECUTIVE SUMMARY

1. The opinion addresses the questions whether there are risks related to non conventional transmissible agents, infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from, for example dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish). And, if so, which ones and how can they be minimised?

2. This opinion considers the risk to the public, to animals and to the environment from transmissible biological and chemical agents which may be present in fallen stock and dead animals. It covers farm animals (including fur animals), wild, exotic and zoo animals, laboratory animals, cats and condemned materials. The opinion makes recommendations on how such risks can be minimised. In the light of experience with BSE this includes consideration of unconventional and as yet unknown agents.

3. It is known that fifty per cent of greater than 1700 known microbial pathogens can be transmitted by animals (ie: they are zoonotic). Humans may also be exposed to a variety of chemical agents present in food products of animal origin. In some instances biological and/or chemical contaminants have been shown to undergo modification between farm and plate and that this may enhance[1] the risk to health.

4. Fallen stock dead animals and condemned materials involve both mammalian and non mammalian species, may arise in a variety of circumstances and can contain one or more of a very wide variety of chemical contaminants and / or biological agents. Thus the Committee has been only able to make a general risk assessment. However, on the basis of the published literature and knowledge of common procedures relating to veterinary examination and disposal methods for fallen stock and dead animals avoidable risks do exist. The Committee recommends that where the nature of the agent is identified and / or there is specific knowledge about a fallen or dead animal, a more specific risk assessment is conducted.

[1] But in certain cases also reduce

5. Risk to man from dead animals and condemned materials depends on:

   - The nature and level of the agent(s) present in the dead animal / fallen stock, which in turn relies on accurate diagnosis and measurement;
   - The prospect of intra and interspecies transmission;
   - The actual processing / disposal method used;
   - The prospects of human exposure as a consequence of the processing / disposal.

   The Committee recommends the use of HACCP[2] to identify critical and risk conditions.

6. The SSC considers that humans should not be exposed to hazardous agents via products recycled from fallen stock and condemned materials. If the reasons an animal died or was sacrificed is unknown or has been shown to involve a hazardous, chemical or biological agent, the fallen stock or suspect condemned material should be disposed of in such a way that any processing into human or animal consumption products is avoided. They may be suitable for certain industrial / technical uses provided their passage into food or feed and in medicinal products is excluded.

7. The Committee does not consider that it is currently practicable (although highly desirable) to expect a surveillance scheme in any member state which guarantees that only fallen stock and condemned material of proper quality are recycled in feed. It is also concerned about the potential for post slaughter infection or contamination of low risk material as a consequence of handling, transport and / or storage. The Committee therefore proposes that all material from dead animals of non specifiable causes should be considered as condemned.

8. Regarding the risks from TSEs and unconventional agents, according to current scientific knowledge, inter and intraspecies transmission may occur across a range of animal species. The rendering standard of at least 133°/20'/3 bars cannot, for the time being, be considered as totally effective in destroying TSE infectivity from infective materials. This applies to all animal species with potential for TSE infectivity. Thus, additional protection measures ensuring absence of TSE infectivity are required.

9. Economically feasible technologies for safely disposing of TSE risk materials are considered to be direct incineration of carcasses and incineration or burning under appropriate controlled

[2] Hazard Analysis and Critical Control Points

conditions of rendered material. A further less well evaluated but potentially suitable method is treatment of rendered material with lime followed by encapsulation followed by disposal to controlled landfill.

10. Less rigorous requirements, which may include recycling, may be acceptable for condemned material, which is TSE free but contaminated, with other chemical contaminants and/or biological agents. However, this will depend on a knowledge of the characteristics of the agent involved.

11. The Committee recognises that in emergency situations it may be necessary, as a short term measure, to seek alternative routes of disposal. It urges that the selection is based on a proper risk assessment and that unsafe practices are avoided. The appropriate authorities should carry out such assessments as part of their emergency planning work.

12. The Committee wishes to encourage research on alternative disposal methods which will minimise risks to humans, animals and the environment. It seeks further information with respect to risks from dead fish and condemned fish materials.

PRELIMINARY NOTE:

THE PRESENT OPINION AND REPORT WERE INITIALLY ADOPTED ON 18-19 MARCH 1999 BY THE SCIENTIFIC STEERING COMMITTEE AS PRELIMINARY DOCUMENTS. THESE WERE MADE PUBLICLY AVAILABLE VIA INTERNET, FOR COMMENTS AND ADDITIONAL SCIENTIFIC INPUTS.

BETWEEN 24 MARCH (DATE OF PUBLICATION ON INTERNET) AND 14 JUNE 1999, 27 COMMENTS WERE RECEIVED FROM A WIDE RANGE OF SOURCES COVERING INDIVIDUALS, GOVERNMENT INSTITUTIONS AND THE PRIVATE SECTOR (E.G., RENDERING INDUSTRY, MANUFACTURES ASSOCIATIONS, RESEARCH INSTITUTIONS, ETC.). THE COMMENTS COVERED BOTH THE SCIENTIFIC CONTENTS OF THE REPORT AND OPINION AND THE POSSIBLE POLICY (RISK MANAGEMENT) DECISIONS RESULTING FROM THE LATTER.

THEY WERE ANALYSED AND DISCUSSED BY THE WORKING GROUP (WHICH PREPARED AN UPDATED VERSION OF THE REPORT) AND BY THE TSE/BSE *AD HOC* GROUP (WHICH PROPOSED A REVISED DRAFT OPINION). THESE WERE DISCUSSED BY THE SSC AT ITS MEETINGS OF 27-28 MAY AND 24-25 JUNE 1999.

READERS SHOULD BE AWARE THAT COMMENTS AND SUGGESTIONS RELATING TO RISK MANAGEMENT WERE ONLY TAKEN INTO ACCOUNT IN SO FAR AS THEY COULD BE LINKED TO SCIENTIFIC ISSUES OR AS FAR AS THEY COULD CLARIFY FOR DECISION MAKERS THE SCIENTIFIC BASES OF POSSIBLE AVAILABLE RISK MANAGEMENT OPTIONS / SCENARIOS.

A COPY OF ALL THE CONTRIBUTIONS WAS PROVIDED TO THE COMMISSION'S SERVICES INVOLVED IN THE POSSIBLE LEGISLATIVE EXPLOITATION OF THE OPINION.

List of comments received (on 14.06.99):

1. Ashworth, C.E. (08.05.99), additional comments on landfill and burial.
2. Ashworth, C.E. (11.04.99), responding on behalf of: (1) LASSA (Licensed Animal Slaughterers and Salvage Association) and (2) RIO (Regulated Incinerator Operators Group).
3. Asso Grassi Associazione Nazionale Produttori Grassi e Proteini Animali. Letter from Mr.A.Grosso (19.04.99)
4. Asso Grassi Associazione Nazionale Produttori Grassi e Proteini Animali. Letter of 10.06.99 to Prof.G.Piva. Subject: "UNEGA Proposal" (14.06.99).
5. Danish Renderers. (11.04.99) Letter from N.C.Leth Nielsen, President.
6. Department of Agriculture and Food, Ireland. Letter from Dr.M.C. Gaynor, Chief Veterinary Officer (12.04.99).
7. Department of Trade and Industry, U.K. (Chemicals Directorate) Letter from John Shepherd (16.04.99)
8. EURA – European Renderers Association (8.04.99)
9. Facoltà di Agraria (Università Cattolica del Sacro Cuore – Piacenza, Italy). Letters from Prof.Dr.G.Piva (24.03.99, 31.03.99)
10. Foxcroft, P. D. (10.04.99)
11. GME – Gelatine Manufactures of Europe. (9.04.99) Letter from Mr.J.Thomsen, Sector Group Manager.
12. GRUNDON (Services) Ltd. (9.04.99), including the comments from WRc plc.
13. Istituto Superiore di Sanità, Rome, Italy (12.04.99): comments from Laura Achene (Laboratory of Veterinary Medicine) and Alberto Mantovani (Laboratory of Comparative Toxicology and Ecotoxicology).
14. Jordbruks Verket (Swedish Board of Agriculture) (12.04.99), comments formulated by Dr.B.Nordblom, Chief Veterinary Officer.
15. MAFF – UK Ministry of Agriculture, Fisheries and Food. Letter of 13 April 1999 of Dr.J.M.Scudamore, Chief veterinary Officer. (13.04.99)
16. Milhaud, G. (Ecole Nationale Vétérinaire d'Alfort, France, U.P. de Pharmacie et Toxicologie. 08.04.99).
17. Ministère de l'Agriculture et de la Pêche (France) – Direction Générale de l'Alimentation. Letter of 14.04.99 from B.Vallay, Chef du Service de la Qualité Alimentaire et des Actions Vétérinaires et Phytosanitaires.
18. MLC- United Kingdom Meat and Livestock Commission. Letter from M.Grantley-Smith (7.04.99).
19. NFU (UK National farmers Union). Letters of 12 and 17 May 1999 from Mrs.Betty Lee, Assistant Director BAB (Bureau de l'Agriculture Britannique). (12 and 17 .05.99).
20. Perrin, J.F. Electronic message to the SSC secretariat (dated 14.04.99).
21. SIFCO - Syndicat des Industries Françaises des Coproduits Animaux (12.04.99)
22. Surles, J., responsible for a rendering company collecting and processing dead animals in 14 Departments in the south-west of France. (2.04.99)
23. Taylor, D.W. (Centre for Tropical Veterinary Medicine, University of Edinburgh) (9.04.99).
24. The Chamberlain Partnership. Letter written by Mrs.Karen Green. (4.05.99).
25. UKRA – United Kingdom Renderers' Association (12.04.99)
26. Woodgate, S.L. (8.04.99)
27. WRc plc. (9.04.99), including the comments from S.GRUNDON (Services) Ltd.

OPINION OF THE SCIENTIFIC STEERING COMMITTEE

I. THE QUESTION:

"Are there risks related to 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. If so, which ones and how can they be minimised?"

II. THE OPINION

The present opinion is based on the report of a Working Group set up by the SSC's TSE/BSE ad hoc Group. The report is available as a separate document.

In the opinion hereafter,- the term "*condemned animals and materials*" covers fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish). The other explanations and definitions used in this opinion are the ones listed in the report of the Working Group. In the Sections 2 (Historical background) and 4 (Explanatory notes and Definitions) of this report, the agents and substances covered by the present opinion are listed.

The definitions used in the present opinion are given in annex 1.

1. General frame.

Taylor et al (1999), prepared a list of 1709 species of infectious agents which are pathogenic to humans. Almost half of these are zoonotic, that is, can be transmitted between humans and animals. In addition, animal materials may be contaminated by a high number of chemical compounds that may be toxic when consumed as a food or feed. Depending upon the intended end-use as a food, feed or technical product, animal materials should thus be carefully sourced and processed or disposed of if a possible residual infectivity or contamination would create an unacceptable risk for humans, animals or the environment. Recent experiences with unconventional agents (TSEs) and with persistent chemical compounds have shown that the assessment of the possible residual risks from animal-derived products should not be limited to individual "farm to plate" chains, but should take into account the possibility of adaptation of infectious agents and of gradual accumulation of compounds when the use as a feed of recycled animal materials is part of a permanent circle.

2. Preamble:

a. The term "unconventional agents" in the present opinion covers both the agent(s) causing transmissible encephalopathies and "unknown, not yet identified, possible emerging" agents. The possible existence of "as yet unknown" agents can not be ignored as the BSE crisis has clearly shown. Their appearance may eventually result

in major risks to humans, animals and the environment which must be mitigated as much as possible. The systematic combined use of "TSEs" and "unknown or other unconventional agents" in this paper requires an extrapolation of what is (already) known for TSEs, to agents which still may have to be discovered. As far as unconventional agents are concerned, the knowledge of and the experience with TSEs have served as reference. Clearly, the resulting recommendations will not guarantee full protection against possible emerging diseases for which the aetiology is not known.

b. The present opinion, deliberately, does not cover the ethical part of the issue of disposal and recycling of dead animals and condemned materials, as this was not part of the mandate given to the SSC.

c. The opinion hereafter was formulated on the basis of the report of a special Working Group[3], which considered a large amount of literature, other data and ancillary information. However, the SSC is aware that, for the formulation of a fully comprehensive opinion - including a more accurate risk characterisation of the different materials and procedures - other information and practical analyses are needed. It is recognised that in a number of areas, information is very limited or simply not available. This is, for example, the case for the fate of toxic substances during disposal or recycling processes, the possible generation of new toxic substances during such processes and the epidemiology of certain diseases (including scrapie) which is likely to affect the decision whether a given animal or material should be disposed of or could be used as recycled material, etc.

d. The opinion answers the questions posed and describes the possibilities of minimising the risk, as asked. But it does not in general discriminate the different risks in quantitative terms since these are often not known. Only a semi-quantitative description of risk has therefore been used to advise on different procedures.

   The possible risks associated with condemned animals and materials are of a complex and multidimensional nature. The present opinion addresses the risks related to non conventional transmissible agents, known infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from, for example, fallen stock and dead animals (including also exotic/zoo animals, fur animals, laboratory animals and fish) and condemned materials. Attention is also paid to the safety of various ways of recycling and disposal on the basis of the identified risks to man and animals via environmental pathways.

e. This opinion, however, does not address other risks such as the occupational risks for workers at recycling or disposal plants, the risks resulting from the storage or transport of materials prior to their recycling or disposal, nor the risk resulting from the possible generation of new toxic substances during the process of recycling or disposal. The appropriate risk reduction conditions need to be defined. There is a danger that if treatment or disposal conditions are too restrictive, increasing amounts

[3] Available on the internet site of DG XXIV.

of material would simply be stored, buried or burned and the total risk increased. These issues should be the subject of separate analyses[4]

f. When preparing its opinion, the Scientific Steering Committee was primarily concerned with human and (farmed) animal health and environmental safety aspects. However, it merits consideration whether the conclusions and recommendations related to animal feeding should also be made applicable to other animals such as zoo animals, pets, hunt kennel hounds, etc. This would imply the exclusion of dead animals and condemned materials as feed for these animals, except after appropriate sourcing and processing and only if the sourcing and processing would result in a safe product. It would be justified on animal health and animal welfare grounds and because these animals could themselves eventually be recycled into (farmed) animal feed or other consumption products.

g. The SSC considers that the limited capacity for destruction of animal wastes in certain countries or regions in the first place justifies the installation of the required facilities; it should not be used as a justification for unsafe disposal practices such as burial. However, the SSC recognises that for certain situations or places or for certain diseases (including animals killed and recycled or disposed of as a measure to control notifiable diseases), the available rendering or disposal capacity within a region or country could be a limiting factor in the control of a disease. Thus if hundreds or even millions of animals need to be rendered after killing or if the transport of a material to a rendering or disposal plant proved to be impractical, an appropriate risk assessment[5] should be carried out before deciding upon the most appropriate way of disposal or rendering. As such decisions in practice may have to be taken at very short notice, risk management scenarios according to various possible risks should be prepared in advance to allow for a rapid decision when the need arises.

3. Summary of the basic reasoning followed in the opinion.

On the basis of the report prepared by a working group, the Scientific Steering Committee is of the opinion that risks do exist from raw material from fallen stock and dead animals, exotic/zoo animals, fur animals, laboratory animals, dead fish and from condemned materials. These risks may result from non-conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains or the environment.

The basic reasoning followed in the opinion is as follows:

a. The risk resulting from dead animals and condemned materials depends on (i) the origin (source) of the material, (ii) the reason why the animal died or was killed or the reason for condemnation, (iii) whether or not this cause or reason can reliably be

[4] The analysis would also need to outline how the equipment is disinfected and sterilised. Should the equipment not be disinfected / sterilised there is an increased risk to operators, maintenance staff and the environment.

[5] See also the relevant sections and footnotes on risk assessment in the report of the Working Group, for example section 6.2 on burial and section 6.3 on controlled landfill.

determined, (iv) whether or not recycling processes exist capable of mitigating the risk and (v) on the end-uses/ final destinations of the possible recycled products. Depending upon these risks, certain uses as animal feed or for technical applications can be acceptable. However, humans should never be exposed to the risks of fallen stock and condemned materials, via products that could be recycled from them.[6].

b. If the reason why an animal died or was killed or the cause of a material to be condemned is unknown or suspect, such material should be disposed of. Ways of disposal depend upon the risk and vary from incineration to recycling into products for exclusive technical use[7].

c. If the cause of death of an animal or the reason for material to be condemned can be determined positively, and the potential resulting risk for humans, animals and the environment can be eliminated/neutralised by appropriate processing (which implies the exclusion of any TSE risk), the material can be recycled into animal feed or for technical uses.

d. Materials that present an actual or potential TSE risk, should be disposed of. Ways of disposal vary according to the level of risk, from incineration (if there is an actual TSE risk) to recycling in products for exclusive technical use (e.g., specified risk materials from healthy animals otherwise found fit for slaughter and consumption).

4. However, the Scientific Steering Committee considers that it may not be realistic to envisage a surveillance system which guarantees that only fallen stock and condemned material of a proper quality is used when the end product is allowed to be recycled into feed. It would require, on an animal-by-animal basis, a reliable systematic identification of the cause of death or a determination of the type and level of toxic or infectious substances present in the material. The implementation of such a system becomes even more difficult if one takes into account the intra-community trade and movement of animals.[8] A generally applicable system, resulting in a sorting out of the collected animals according to the identified potential danger may thus not be a realistic option, except, *for example*, in the case of systematic (prophylactic) depopulation campaigns.

The next sections of the opinion contain detailed conclusions and recommendations corresponding to various possible risks and risk levels, but their implementation may thus in practice prove to be complicated and difficult to monitor.

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6 See paragraph 10.e) for tallow derivatives.

7 The term “technical use” implies the total exclusion as a human food or animal feed (including pharmaceuticals or cosmetics) or as a fertiliser. It implies also the exclusion of any mixed use as a food, feed or fertiliser. Protection against intense exposure, for example of workers, should be ascertained.

8 The SSC also noted that several of the comments received following the public consultation *via* Internet, recommend that only animal materials fit for but not intended human consumption, for example for commercial and technological reasons, should possibly be authorised to be recycled into food or feed. This would guarantee the safety of the raw materials, facilitate control of the source and remove any ambiguity regarding the quality of the raw material. Depending upon the reasons why they were condemned, the other materials could then be used as technical and oleo-chemical products, organic fertiliser or energy source.

5. Detailed conclusions and recommendations

5.1 With respect to the risk for **TSEs and unconventional agents** in animals, the SSC summarises the present state of the scientific knowledge as follows:

- A large number of experiments, extensively reported in the scientific literature, has shown that many species are vulnerable to TSE's and that ruminants in general, fed with infectious material originating from the same species, can be infected with TSEs. Also, experimental evidence shows that BSE can be transmitted to sheep (and goats) via the oral route.
- As for the susceptibility of pigs, poultry and fish to become infected with TSEs is concerned, there is only evidence that pigs can become infected through intra-cerebral inoculation with infectious BSE material. To date no experiments have shown that pigs, poultry or fish could be infected with TSE *via* the oral route.

  The hypothesis that orally TSE-inoculated non-ruminants[9] without any signs of disease could carry the TSE-infection in their tissues has to date not been proven, but is considered unlikely.
- There is evidence that the agent of FSE in cats is identical to BSE in bovines. It has been shown that the biological properties of the agent strain in cats with FSE and cows with BSE is the same.
- Mink are susceptible to Transmissible Mink Encephalopathy (TME). Transmission of encephalopathy had been achieved to hamsters, ferrets, racoons, skunks, monkeys, sheep, goats and to cattle. In the last case, the cattle-passaged TME agent has been shown to remain pathogenic for mink by the oral or intra-cerebral routes.

  The transmission of BSE to mink has also been proven under experimental conditions, both after oral and intra-cerebral challenge. Present evidence is that the naturally occurring TME agent is a distinct entity from the other TSEs. Feeding fur animals with meat-and-bone meal obtained after processing of offals is not a generalised practice, but feeding them with non-processed slaughter products is often a routine practice.
- The risk that exotic animals are carrying an unconventional, or not as yet identified infectious agent, cannot be excluded. The specific environment of zoos also constitutes a potential hazard, because native animals live in the immediate neighbourhood of exotic animals and given the limited knowledge of exotic diseases these could easily be confused with known diseases.

The emergence and development of BSE has shown that infectious agents exist for which there is no known, effective treatment. The existing processes used for the total inactivation of commonly known infectious microbiological agents such as bacteria and viruses, can therefore not be automatically guaranteed to apply to other pathogenic agents such as the TSEs or other agents which might be identified in the future.

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9 However, experimental transmission *via* the i/c route has been shown for a number of animal species.

As the (sporadic) incidence of such agents can never be fully ruled out, their presence in fallen stock or in exotic and other dead zoo animals, in dead fish or in any animal fed with animal (derived) products, can not be fully excluded. Other dysfunctions, infectious agents or toxic substances may also be present in the in addition to the diagnosed direct cause of death of an animal.

With respect to the inactivation of TSEs, the rendering standard of at least "133°C/20'/3 bars" (or a validated equivalent method) or any other described industrially operational production process (e.g. for gelatine, tallow, …) are for the time being not considered completely safe for clearing TSE infectivity, if the initial infection of the material is high. Therefore, to obtain a safe product with respect to TSEs, additional measures are needed such as safe sourcing, elimination of risk materials and, possibly, a limitation in the applications (end-uses) of the derived products.

Given these risks, the SSC is of the opinion that the recycling or disposal of condemned animals and materials should not lead to any direct human consumption, including their use in cosmetic, pharmaceutical and medicinal products and devices. Also indirect human consumption resulting from the use of animals fed with such condemned animals or materials should be avoided but could possibly be envisaged only under the conditions described in further sections.

5.2. With respect to **conventional infectious agents**, the SSC considers that when standards are proposed for rendering condemned animals or materials, they should in principle be safe enough to clear or reduce the risks resulting from the most resistant infectious agent to a level which is acceptable according to international standards. The SSC considers that the standard of at least "133°C/20'/3bars" (or a validated equivalent method) is currently the most appropriate method for inactivating the infectivity of the most heat-resistant conventional infectious agents[10]. Other standards or processing conditions resulting in equivalent safety may exist, but should be evaluated and accepted on a case-by-case basis.

This rendering standard is applicable to all animal species, including dead poultry and fish (materials)[11]. Their cause of death is often unknown and for poultry and fish the chosen standard should in principle be safe enough to clear, or reduce to an acceptable level, the risks resulting from the most resistant infectious agent. However, because of the specificities of certain animals and materials (e.g., fish) and of the associated risks in terms of infectious agents and toxic substances, the standard could be revised for these animals and materials, should a new validated standard – prove to be of equivalent or greater safety.

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[10] One might accept the validity of different rendering conditions depending on, for example, the exact type of infectious agent present in the raw material. Accepting variable standards, however, would not be realistic, as the hazards present in the material offered to a rendering plant will change over time. Except in selected cases applicable to blood processing, it can not be guaranteed that the processed material in a given plant or chain of disposal, will never contain a greater risk than that capable of being handled by the given plant

[11] Fresh fish fit for human or animal consumption and fresh trimmings from such fresh fish from the food or feed processing sector, are not considered as condemned materials and are not included in the scope of the present opinion.

5.3 With respect to the safety of materials containing **toxic substances**, the SSC recognises that this is a complex issue because the number of substances, the reasons for their presence and the impact of treatments on the inactivation or toxicity reduction is very large. In addition, continuous recycling of materials with low initial levels of toxic compounds may eventually result in health-threatening concentrations. On this issue the present opinion therefore needs to be adapted and interpreted on a case by case basis.

6. If the clearly identified cause(s) of death or the reason for animals or materials to be condemned do not constitute any serious direct or indirect risk for human or animal health or for the environment (taking into account the dispersal and possible accumulation in the environment), then the tissue material may be considered as representing no or a lower risk. Examples include: casualties (where the cause of injury is supported by necropsy data) and fresh slaughter offals of animals fit for human consumption. Except for those animals and materials covered by sections further-on in this opinion, it is acceptable to be further processed into products for animal consumption, industrial use or use as fertiliser, provided appropriate rendering or production processes are applied.

The SSC considers that, unless post-slaughter infectivity or contamination introduced during handling, transport or storage can be excluded on reasonable grounds, the applied rendering or production process should also for these materials be safe enough to clear or reduce the risks resulting from infectious agents to a level which is acceptable according to international standards. The "133°C/20'/3 bars" standard (or equivalent) is considered the most appropriate.

For certain uses[12], materials fit for human consumption but not intended for human consumption, could be processed at conditions below the "133°C/20'/3 bars" standard, if the risk of transmission of agents can be excluded, if they handled and stored as a (future) food product, if the infectivity or (post-slaughter) contamination is excluded and provided the end product complies with internationally recognised microbiological standards. But such should be decided on a case-by-case basis.

7. If the cause of death[13] or the reason for animals or materials to be condemned definitely exclude any risk of TSE[14] or possible other unconventional disease but for other reasons cannot be considered of no or low risk, then their further processing into products for animal consumption or industrial use can be considered to be of minimal risk provided the appropriate processing (inactivation) method equivalent to at least "133°C/20'/3bars" is applied and provided possible toxicity levels are reduced below recognised levels of concern.

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12 *For example* certain pet foods. This statement is without prejudice to the SSC's opinions on the safety of products such as meat-and-bone meal, tallow, gelatine, hydrolysed proteins and dicalcium phosphate and its opinion on Intra-species recycling of pigs, poultry, fish and ruminants.

13 See definition in the section "Definitions" of the attached report of the Working Group.

14 This may not be possible to achieve in many instances. However, the age of the (fallen or death) animal may be a strong help in deciding upon a possible or potential TSE risk.

8. The SSC recognises that is not always appropriate for blood[15] to be subjected to "133°C/20'/3 bars" conditions if it is to be recycled into certain consumption products (e.g., animal feed). However, blood is processed on separate and dedicated lines and therefore a different standard could be acceptable provided the identified risk *can* be inactivated and the process results in a microbiologically safe product. In this context it is mentioned that blood can become TSE contaminated during slaughtering, for example by stunning or pitting.

However, if the risk of TSE infectivity being present in the blood exists, the whole batch should be disposed of by a method which is appropriate for TSE infected materials. Burial or dispersion of such blood over (agricultural or other) land cannot be considered as safe ways of disposal.

Blood with a risk to be contaminated with infectious agents other then TSE or condemned or spoiled blood should be treated at least at "133 °C /3 bar/ 20 min", using for example a procedure as indicated in the report of the Working Group. Depending upon the residual risk, it should then be disposed of by controlled landfill or a method assuring a higher level of safety (e.g. incineration) or it could be used as an organic fertilizer or for technical purposes (if any).

In addition, the SSC has the following considerations with respect to (minimising) the possible risks resulting from recycling or disposal of condemned animals and materials.

9. If the cause of death or the reason for animals or materials to be condemned cannot be reliably identified or if appropriate systems that inactivate the infectious agent or eliminate the toxicity do not exist, then the condemned animals or materials may definitely constitute a risk for humans, animals and/or the environment. They should be disposed of in such a way that any further processing into human or animal consumption products is excluded. The risks of exposure via other routes (including by contact or via environmental pathways) would also be reduced to the maximum possible extent.

Maximum risk reduction is obtained by disposal by suitable incineration or burning of rendered material (see also annex 2 to this opinion). If for any exceptional reason (e.g., catastrophes, large epidemics, ….) landfill disposal has to be used, material should, in principle, first go through an appropriate infectivity reduction process. Any sites should be selected (a) on the basis of a specific and appropriate risk assessment, (b) at an appropriately safe distance from water courses used as drinking water or for other purposes (e.g., sport and recreation), unless their design reliably prevents the escape of any uncontrolled leachate. The site should also not be the subject of any possible future (re-)development.

The SSC considers that all material from dead animals should be considered as condemned. The option, to remove the specified risk materials (SRM) from the dead

[15] The SSC wishes to mention explicitly that human blood is not covered by this opinion and issues related to the safety of human blood should be addressed separately. Also, if there is a putative TSE infection of the slaughtered animal, the whole animal , including its blood, should be disposed of and not recycled. A comprehensive opinion on the safety of blood in general and its possible processing or disposal, will be prepared by the SSC.

animals and then to submit the remaining material to rendering at "133°C/20'/3 bars", is not an acceptable alternative. Although the removal of the SRMs could remove, depending upon the incubation stage and age, up to 90% of the infective load of *ruminant* fallen stock, it is not considered as feasible under all circumstances on all dead animals. Finally, whereas for ruminants the SRMs have been identified in the context of TSE/BSE, they are unknown for other animal species and are not necessarily the target tissues for other unconventional agents.

10. The many scientific unknowns and uncertainties relating to TSEs and their inactivation by processing, justifies to consider that *actually, suspected or potentially*[16] 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'/3 bars" (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 sub a) listed ones) also rendering at at least "133°C/20'/3 bars" (or validated equivalent) followed by controlled landfill, preferably after liming and encapsulation.

c. Rendering, composting or biogas production, are not considered as safe ways of disposal of the above animal materials (a) and (b), even if the raw material was previously rendered at "133°C/20'/3 bars"[17]. Organic fertilisers may carry the risks listed in the scientific report attached to the SSC's opinion on the safety of organic fertilisers adopted on 24-25 September 1998.

The SSC also considers that:

d. Specified risk materials[18] (SRMs) removed in slaughterhouses from ruminants over defined ages that are fit for human consumption, carry a potential risk in countries which are not free of TSE. Products obtained by recycling these SRMS may thus not be completely free of infectivity for the reasons given in the various opinions SSC on the safety of products. However, recycling these SRMs for certain industrial/technical uses would result in a negligible risk for humans, animals and/or the environment, provided any double use or destination is excluded (e.g., as a feed or food or when extensive handling of the material may be expected). Their use should also not imply a wide dispersion of the end-products in the environment[19]

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16 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.

17 The chance of biological degradation is higher in an microbiological active process as in a biogas-plant (or during composting). Organic material put into a landfill goes along with a relatively slow anaerobic decomposition. Thus, the prions possibly still present after proper rendering, will be preserved for a long time. Also when material is going into a landfill that was not treated at at least 133°C/20'/3bars this risk is higher than that from properly rendered material running through a biogas plant.

18 As defined in the SSC opinion of 9 December 1997 and updated in the opinion of 22-23 January 1998.

19 For example, as an organic fertiliser (see also the SSC opinion on the safety of organic fertilisers adopted on 24-25.09.98.)

and require the appropriate production or rendering processes as specified in the various SSC opinions.

e. Given the fact that animals and materials that carry an actual or suspected TSE risk should be disposed of (see above a and b), the SSC, in the line of its opinion of 27-28 March 1998[20], considers that purified tallow derivatives which do not contain proteins or peptides, can be considered to be safe provided (a) the raw material is fit for human or animal consumption, or (b) provided the production process uses the appropriate, validated and scientifically most up-to-date methods in terms of inactivating the TSE agent. Several amongst them have been listed in the scientific opinions of the Scientific Committee on Cosmetology[21] (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)[22] (for medicinal products). The SSC recognises that other methods may exist, but they should be evaluated and acknowledged as regards to their safety on a case-by-case basis.

f. For fur animal carcasses[23] that possibly re-enter the animal feed chain or that are recycled into fertilisers, for example because they are used as a raw material for rendering, any risk of TSE infectivity should be excluded.

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, is given in annex 2.

11. Given the absence of indications that TSEs could exist un*der natural conditions* in **pigs[24], poultry, fish,** the SSC considers that also[10] for dead animals or condemned materials[25] of these species appropriate rendering (at at least "133°C/20'/3 bars" or validated equivalent) is the most appropriate method for inactivating the infectivity of the most heat-resistant conventional infectious agents. However, as for any species, fallen or dead animals should be disposed of if the cause of death or the reason for animals or materials being condemned cannot reliably be identified or deduced from the epidemiological situation, from post-mortem examination or where there is a suspicion of an unconventional causative agent or where appropriate systems for completely inactivating the infectious agent or reduction in possible toxicity to below acceptable

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20 Updated at the SSC meeting of 10-11 December 1998

21 24 June 1997; 23 September 1998.

22 Dated 16 April 1996 and 17 December 1997; Note for the Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products (April 1999)

23 The carcass of the animal without the skin.

24 See also section 5.3 of the report of the Working Group.

25 The present opinion only addresses dead animals ("fallen stock") and condemned materials; fresh fish trimmings obtained from animals fit for human consumption are not covered by this opinion, provided of course they are properly handled, stored, transported, etc.

levels, do not exist. The appropriate ways of disposal should be inventoried by the appropriate scientific bodies.

12. Adequate diagnosis of the exact cause of death of **wild[26], zoo and exotic animals** is often difficult to achieve. Several are known to harbour TSEs and some could harbour unconventional diseases or diseases with unknown aetiology. If they are included in rendered materials they may end up in animal feed. This provides a gateway for novel agents, including TSEs, to enter the animal feed and eventually, indirectly, the human food chains. Wild, zoo and exotic animals therefore pose a risk and there is no evidence that rendering eliminates this risk. Recycling into animal feed products or fertilisers is therefore not considered a safe practice, although recycling into industrial products may be considered acceptable provided double use as a food or feed is excluded.

13. The SSC considers that the exposure risk to humans or other animals resulting from the consumption of products infected with BSE originating from **infected cats** is small, especially in countries with a low BSE risk status and where appropriate measures have been taken to reduce or eliminate the propagation of BSE risk. However, if such measures have not been taken and/or if the geographical BSE risk is high, the possible TSE risks resulting from dead cats can only be eliminated by appropriate disposal which excludes a possible end-use as a fertiliser or animal feed or double use as industrial and food or feed product.

14. The SSC considers that special attention should be paid to the remainder of tissues from **laboratory and test animals** exposed to infectious agents or toxic, carcinogenic and mutagenic substances as these can result in unknown and not fully characterised hazards. Therefore, the risks from animals that are suspected to contain toxic concentrations of substances including drugs from unsuccessful treatment or previously exposed to infectious agents and where no good evidence exists that a validated process equivalent to at least "133°/20'/3 bars" would mitigate this risk, need to be eliminated.

However, animals involved in research without any use of / exposure to toxic substances or without experimental infection or contamination, could in principle be rendered (or even consumed[27]) without any additional risk.

15. There have been anecdotal reports of individuals eating processed **pet food** as a source of meat and protein. This, combined with the existing knowledge of vertical transmission of conventional and non-conventional infectious agents and with the apparent exposure of cats to BSE, dictates that the criteria applied to selection and utilisation of all foodstuffs destined for human consumption should also apply to ingredients of pet food. This is particularly important in the case of meat and applies also to the materials derived from animals fit for human consumption but not intended to be consumed by humans.

16. Regarding the risks related to **hunt kennels,** the SSC notes that little recent research is available and that more information is needed to carry out an assessment of the risk of transmission of conventional and non-conventional infectious agents by hounds and

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[26] Including game animals.

[27] If any risk can be excluded, for example animals involved zero-risk experiments such as grazing intensity trials on grassland, conventional breeding experiments, etc.

working dogs (e.g., sheep dogs). For the time being, the SSC considers that the feed provided to these animals should comply with the same safety standards as for farmed animals intended for human consumption.

17. On the basis of the risk assessment carried out by the Working Group, the Scientific Steering Committee considers that the following processes are not acceptable ways for recycling or disposing of fallen stock, dead animals, condemned materials, ~~or~~ materials infected with conventional infective agents or low risk materials that were not rendered or that did not undergo an appropriate infectivity reduction process:

- Anaerobic treatment for the production of bio-gas, without previous rendering;
- composting without previous rendering;
- controlled landfill, without previous rendering;
- burial (including sea/water burial) and burning.

Regarding burial, the SSC considers that this practice, as a way of disposal, should be limited to coping strictly with the unavoidable minimum risk, determined on the basis of a risk analysis. This should compare the risks of burial with the risk of collecting, handling, transporting and possibly storing the animals or materials before safe disposal. In any case, if burial cannot be avoided, it should be controlled by the appropriate authorities, the sites should be selected on criteria of environmental safety and public health (e.g., not in catchment areas of drinking water, risk of drainage of spoiled water to rivers, …), the animals should be reported and the sites should be authorised and registered (licensed/monitored).

For disposal

Economically feasible technologies for disposing are, in order of increasing risk and provided they are correctly applied (non exhaustive list):

- direct incineration of carcasses;
- burning of rendered products in power stations[28] or:
- direct incineration or burning after rendering of the specified risk materials; rendering at at least "133°C/20'/3 bars" of the remaining tissues, followed by their controlled landfill (preferably after liming and encapsulation).
- rendering at at least "133°C/20'/3 bars" followed by controlled landfill after liming and "encapsulation"[29] (good effluent treatment systems must be present) [30]
- rendering at at least "133°C/20'/3 bars" followed by controlled landfill, at controlled sites (good effluent treatment systems must be present);

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28 Burning rendered products is considered less safe than direct incineration, because of the additional risks associated with the rendering of the raw material, its handling, the risk of cross-contamination, etc. However, burning may be of equal - or even higher - safety value if the rendering is a pre-condition before combusting with the burning carried out within the same unit and without handling. Any handling would cause additional risks and should be avoided.

29 See the attached report of the Working Group.

30 This is an estimate. A key issue seems to be the long-term effectiveness of the encapsulation, which needs to be addressed.

Notes:

- Initial rendering of infected raw material is needed to reduce the risks if storage of the material is necessary before final incineration.
- Anaerobic treatment for the production of biogas may result in sludge containing infectious activity. The anaerobic process for the production of bio-energy is acceptable only if the risk of TSE infection or contamination is excluded. In addition, the sludge should be disposed of by burning, incineration or controlled landfill.
- The notion "good effluent treatment systems" comprises also the sterilisation of unclean waste water and; the treatment should be according to the state-of-the-technique.

For recycling (any TSE risk to be excluded, see section 9):

Economically feasible technologies for recycling are, in order of increasing risk and provided they are correctly applied (non exhaustive list):

- rendering at at least "133°C/20'/3 bars" followed by aerobic or anaerobic treatment, e.g., for the production of bio-gas (good effluent treatment systems must be present);
- rendering at at least "133°C/20'/3 bars" followed by composting (good effluent treatment systems must be present);
- either rendering at at least "133°C/20'/3 bars (good effluent treatment systems must be present), or:
- other processing of the material into derived products such as tallow, hydrolysed proteins, organic fertilisers, etc., provided strict processing and end-use conditions are respected. These conditions are defined in the present opinion and in the various opinions of the SSC on the safety of these products.

The SSC recognises that some materials with potentially hazardous concentrations of toxic substances will need to be handled or disposed of in special ways to be defined on a case by case basis.

The SSC stresses the need of industry and the research community to assess the safety of alternative disposal methods with respect to risks for humans, animals and the environment with respect to conventional and unconventional infectious agents and toxic substances. The resulting comprehensive reports could then be evaluated by the appropriate authorities or scientific committees.

18. The nature of toxicity and concentration of the chemical (including also heavy metals) under consideration and its anticipated future use, all need to be considered. However, as a general rule, animals exposed to toxic substances that cannot be inactivated or reduced by processing to levels below concern, should be disposed of.

Radioactive contamination in respective materials present no special issues other than those relating to the radioactive waste regulations. Radio-diagnosis and Radiotherapy are not common in veterinary medicine. The same rules apply to laboratory animals, which

may contain radioactive residues at elevated levels following toxico-kinetics and metabolism studies.

The SSC recommends investigating the fate of toxic substances in the rendering process as regards risk reduction.

19. However, unless explicitly stated, the above recommendations should not overrule and do not replace other principles expressed in opinions adopted by the Scientific Steering Committee on the safety of products derived from ruminant materials, on specified risk materials, on production processes, on geographical sourcing, **on intra-species recycling** and on the intended end-use of the product (e.g., feeding of ruminants with MBM).

20. The attached table summarises the above conclusions, **for ruminants**. The four classes of the geographical aspect of BSE risks used in the table are 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 classification will be updated by the Scientific Steering Committee in the light of its forthcoming opinion on the geographical aspects of TSE/BSE risks.

21. A large variety of equipment for disposal (by incineration or burning) or for rendering exists. Recommending one single technical standard as safe one is impossible and probably not justified. The Scientific Steering Committee considers that the formulation of recommendations in this field is beyond the scope of its mandate and should be addressed by the appropriate Commission Services and/or Scientific Committee(s). It therefore limits itself to list in annex 3 a number of standards which are derived from the documentation which was at the disposal of the working group and should be seen as a guidance or as a base to compare possible other suitable systems with, rather than as strict guidelines. The given standards should be seen as a guidance or as a base to compare possible other suitable systems with, rather than as strict guidelines.

22. The Scientific Steering Committee strongly recommends that HACCP[31] procedures be implemented and respected at the level of each step of the chain of collection, processing and disposal of dead animals and condemned materials.. It is essential to identify and describe the hazards and critical points for the different steps. Three of these points are certainly the traceability of the raw material (including full reporting of fallen stock to the competent authority), its treatment (including the possible removal of specified risk materials) and the intended use of the final product. The existence of a reporting system will enable a full geographical/quantity analysis to be undertaken thereby identifying at an early stage possible trends or changes in patterns.

23. The SSC invites the fish industry and research laboratories to provide it with any information and research results which could help to refine the present opinion with respect to dead fish and condemned fish materials.

24. The SSC recommends that additional research is carried out on TSE inactivation by various treatments under field conditions, including the strict application of the

[31] Hazard Analysis and Critical Control Points

"133°C/20'/3 bars" standard as defined in the section "Definitions"[32].. (The results such research would not necessarily be relevant if a new infectious agent appears.) For the present, the SSC confirms its opinion that the TSE infectivity reduction achieved during rendering carried with the "133°C/20'/3 bars" standard, is not less than 10^3 in regard to scrapie and BSE agents.

[32] And including on the heat penetration phase and the possible post-sterilisation process.

Table: Disposal or possible recycling into feed (use as human food being excluded) after appropriate rendering or processing at 133°C/20'/ 3 bars or equivalent or (="133°C/20'/3b"), of fallen ruminants and condemned ruminant materials.

BSE Status of a country or zone:	Fallen animals[33]	Condemned materials
All animals: **All countries**	• Suspicious cases of neurological diseases, unless TSE can be positively ruled out, and all animals with suspected or confirmed TSE pose a risk and should be disposed of. • Animals exposed to hazardous levels of toxic substances that can not be inactivated or reduced by processing to levels below concern, pose a risk and should be disposed of. Otherwise:	
Bovines:		•
BSE free or negligible risk	• "133ºC/20'/3b"	• "133ºC/20'/3b"
Lower and high risk	• animals > 12 months[34] pose a risk and should be disposed of.	• "133ºC/20'/3b"; SRMs pose a risk and should be disposed of; or, if from animals fit for human consumption: recycling into technical products after applying at least "133°/20'/3 bars".
	• animals < 12 months [34] : "133ºC/20'/3b"	• "133ºC/20'/3b"
BSE 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.[35]	
Sheep and goats:		•
BSE free or negligible risk	• animals > 6 months [34], in countries which are not TSE- (scrapie-) free: pose a risk and should be disposed of. • animals < 6 months [34]: "133ºC/20'/3b"	• "133ºC/20'/3b"
BSE lower and high risk:	• animals > 6 months [34] if country not TSE (scrapie) free: pose a risk and should be disposed of. • For TSE- (scrapie-) free countries and for animals < 12 months: "133ºC/20'/3b".	• "133ºC/20'/3b"; SRMs pose a risk and should be disposed of; or, if from animals fit for human consumption: recycling into technical products after applying at least "133°/20'/3 bars".
BSE 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.[35]	

Remarks: 1. For blood: see text

2. The criteria presented in the above table do not overrule the criteria given in the opinions of the Scientific Steering Committee regarding the safety of materials derived from animal materials such as meat-and bone meal used as a feed for food producing farm animals, tallow, dicalcium phosphate, organic fertilisers, hydrolysed proteins, etc., except if stated otherwise in the full text of the opinion.

[33] See also the SSC opinions on *The risk of infection of sheep and goats with BSE agent* of 25.09.98 and on *Specified risk materials* of 9.12.97.

[34] Unless passports are available, accurate ageing is impossible. A standard based on dentition would therefore be more appropriate.

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

Annex 1: Explanatory notes and definitions

For the purpose of the present report and opinion, the following definitions are used:

Fallen stock and dead animals

All (complete, thus including hides, skins, hooves, feathers, wool, horns, etc) bovine animals, pigs, goats, sheep, solipeds, fish, poultry and all other animals kept for agricultural production (including fish farming), which were killed (euthanasia with or without definite diagnosis) or have died (including stillborn and unborn animals) on a farm or any premise or during transport, but were not slaughtered for human consumption; other animals which may be designated by a competent authority (for example wild ducks affected by botulism).

Condemned material other than fallen stock and dead animals

In the frame of the present report condemned material consists of animals, parts of animals, animal products or by-products, which are suspected of presenting serious health risks to animals or man. These animals or materials are listed follows:

(a) all those parts of an animal including blood originating from animals which show, during the veterinary inspection carried out at the time of slaughtering, clinical signs of diseases communicable to man or other animals;

(b) all those parts of an animal slaughtered in the normal way which are not presented for post mortem inspection, with the exception of hides, skins, hooves, feathers, wool, horns, blood and similar products.

(c) the whole batch containing blood and other fluids or similar products of an animal whose carcass or material during pre- or post-mortem inspection points to the presence of or exposure to infectious agents communicable via blood or fluids to man or other animals or points to the presence of or exposure to toxic substances in concentrations beyond safety levels accepted by the international community, should be considered as a condemned material. In this context it is mentioned that blood can become TSE contaminated during slaughtering, for example by stunning or pitting.

(d) all meat, poultrymeat, fish, game and foodstuffs of animal origin which are spoiled and thus present a risk to human and animal health;

(e) animals, fresh meat, poultrymeat, fish, game and meat and milk products, which in the course of the inspections by a competent authority, fail to comply with the veterinary requirements to be considered as healthy (animals) or fit for human consumption (meat and meat and milk products);

(f) animal products containing residues of substances [above scientifically based and recognised threshold concentrations] which may pose a danger to human or animal health[36]; milk, meat or products of animal origin rendered unfit for human consumption by the presence of such residues;

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[36] It needs to be verified whether further work is needed involving risk assessment and risk reduction for chemical residues present at injection sites of veterinary drugs.

(g) fish and products originating from fish which show clinical signs of diseases communicable to man or to fish.

(h) Fur animal carcasses.

(i) Wild, zoo- and exotic animals (including pets); non-household pets, hunt kennel hounds and similar.

Cause of death

In this report and opinion "cause of death" is used to indicate the etiological diagnosis for the disease condition which was either directly fatal or was the reason for carrying out euthanasia of the animal in question.

The etiological condition leading to the death of the animal will be known in by far the majority of cases of fallen stock and euthanasia, at least in broad terms, eg. chronic inflammation of joints, acute inflammation of the udder with secondary complications, traumatic lesions, etc. Such conditions will be referred to as having a *definite diagnosis* to indicate that BSE is not a potential etiology behind the condition.

Fallen stock without preceding symptoms or with vague or unspecific symptoms are relatively rare in intensive animal production, as are cases with progressive neurological symptoms suspect of BSE, compared to the above mentioned group,

These latter groups of cases are the ones which should be considered to carry a potential risk of BSE infectivity, above and beyond what already may exist in apparently normal cattle of similar ages in BSE affected populations. In this respect it is assumed, that subclinical BSE infection does not increase the susceptibility of the animal to other infections or conditions, which may lead to severe disease conditions. No such situations have been reported until now.

Remark:

No reliable data have been identified to suggest what the expected incidence of *suspect conditions* is in the general cattle populations, although the OIE and also EU surveillance guidelines operate from an assumption of 100 suspect cases per 1,000,000 cattle per year, even in populations free from BSE, rabies and other epidemic conditions with progressive neurological symptoms.

Laboratory and test animals.

Excludes laboratory and test animals which can be considered as normally farmed (e.g., grazing intensity trials), without exposure to infectious agents or toxic substances (including drugs, feed additives, etc.) and provided the laboratory or test environment is free from other tests implying the use of such agents and substances.

"133°C/20'/3 bars"

The wording "133°C/20'/3 bars" refers to hyperbaric production process of not less than 133°C over a period of not less than 20 minutes, without air entrapped in the sterilising chamber conditions at not less than 3 bar or 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 50mm in 2 dimensions (According to Riedinger (1999a), a precrushing 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[37].) and 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[38]. If the starting material is dry and defatted, 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.

Regarding the fact whether these conditions should be realised under batch or continuous conditions, the Working Group is of the opinion that there may be no difference in the effectiveness *if* the time / temperature / pressure parameters are effectively achieved in every part of the material being processed under continuous conditions. The Working Group considers that the batch system is more reliable and that for continuous processes, this equivalency still needs to be validated.

Remarks:

a. The Working Group notes that at a core temperature of 133°C, the corresponding pressure, if all air is evacuated, will be lower then 3 bars[39]. Since under practical conditions temperature, pressure and overall composition of the material (e.g. salt content) can only be measured with limited accuracy, a temperature of 133ºC is given here.

a. The temperature / time / pressure combination should be realised with all air replaced by steam in the whole sterilisation chamber, which should be assured by technical means including pre-cooking[40] and continuous stirring during the sterilisation phase. Other temperature/time/pressure/particle size conditions could result in an equivalent inactivation, but should be evaluated on a case-by-case basis.

c. The working group further considers that the application of the "133ºC/20'/3 bars" standard as a post-sterilisation phase in stead of applying it during the production

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[37] 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.)

[38] 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 bar). (Other valid technical solutions may exist.)

[39] Due to physical laws the temperature of 133ºC under steam pressure conditions corresponds to 2.95 bars.

[40] *For example, and depending upon the vessel size*: at least 100°C for at least 10 minutes and before the valves of the cooker are closed, for material with a particle size not exceeding 30 mm in two dimensions. An alternative and surer method would be to remove possibly enclosed air in the "super sterilising phase" during the temperature overswing above 133°C till nearly 140°C through the vapour valve of the vessel. (Other valid technical solutions may exist.)

process itself, would result in an equivalent inactivation of a TSE agent provided the material contains enough water[41] to achieve the previously defined conditions. If not, steam-injection will have to be applied to achieve the required conditions. Because the average particle size of MBM is only a few millimetres[42], re-hydration of, and temperature penetration into, MBM during the autoclaving process is not considered to be a problem. Since the duration of the re-hydration phase depends upon the particle size and the fat content, and since the transition of the steam status to the water status may go along with a loss of pressure[43], it is necessary to verify whether, in order to obtain the same efficacy, the parameters "133°C/20'/3 bars" needs to be modified in the case of a post-sterilisation process.[44]

d. Regarding the equivalency of processes with the above "133°/20'/3bars" standard, the SSC considers that a validation of the process cannot be done by microbiological control of the final product. Presence or absence of one or all micro-organisms like Salmonella, Enterobacteriaceae and Clostridium (spp.) does not indicate effective heat treatment if the process itself is not validated because, not all these agents are always present in the raw material and if they are present their number and distribution will be always different. Therefore the process itself must be validated directly using a microbiological model of spiked material containing organisms of defined heat resistance. The direct process control must be accompanied by an indirect process control e.g. temperature pressure, exposure time. This had been done for 133 °C / 20min/3 bar (batch). Other treatments in a validated process for certain purposes at lower temperatures should only be allowed on a case by case basis.

Rendering

Within the context of the present 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 -

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41 Approximately 60%.

42 For example: approximately 2.2 mm as average size for UK rendering systems. It is nevertheless noted that post-sterilisation may require altered process conditions according to particle size and characteristics (e.g., water and fat levels

43 If there is sufficient steam supply to physical laws the temperature of 133ºC under steam pressure conditions corresponds to 2.95 bars.

43 *For example, and depending upon the vessel size*: at least 100°C for at least 10 minutes and before the valves of the cooker are closed, for material with a particle size not exceeding 30 mm in two dimensions. An alternative and surer method would be to remove possibly enclosed air in the "super sterilising phase" during the temperature overswing above 133°C till nearly 140°C through the vapour valve of the vessel. (Other valid technical solutions may exist.)

43 Approximately 60%.

43 For example: approximately 2.2 mm as average size for UK rendering systems. It is nevertheless noted that post-sterilisation may require altered process conditions according to particle size and characteristics (e.g., water and fat levels.)

43 If there during the whole operation, there may be no loss of pressure.

44 For example, an adjustment of the duration of the treatment according to the fat content and particle size of the dry meal.

unless otherwise stated in the text[45] - at least according to the "133°C/20'/3 bars" standard (see definition above), 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.

Disposal or recycling of animals and animal materials

Disposal of animals and animal materials excludes their recycling for further use as a raw material for the manufacture of derived products (e.g., meat-and-bone meal, organic fertilisers, tallow, hydrolysed proteins, dicalcium phosphate, pharmaceutical or medicinal products etc.). Disposal is done for example by incineration, burning as fuel, …

Burial and controlled landfill

Burial in this report refers to the practice in general of burying of animals on farm or other premises (possibly combined by covering the carcass with quicklime). Burial may or may not be a controlled/regulated process, with the site having previously been authorised on the basis of a risk assessment and with all precautions with respect to environmental and (human and animal) public health protection. Whereas landfills may be very large, burial tends to be quite small scale. Rarely is there any formal containment barrier. Moreover burial is generally fairly close to the surface. There is no particular reason to assume the microbial degradation in a burial site differs from that in a landfill unless it is very close to the surface.

Controlled landfill on the contrary is done on previously authorised sites, selected following an assessment of the characteristics of the site and a risk analysis with respect to human and animal health and the environment. Landfill has in recent years become more and more tightly regulated through various landfill directives. The nature of the landfill is consequently dictated by the type of wastes it recovers (e.g., municipal, industrial, inert, hazardous, non-hazardous, putrescible). A **contained site** is one that prevents leachate from escaping from the site. The more modern sites often use plastic liners. A contained site may or may not also have gas collection. Leachate treatment on site can vary from spraying the leachate in the air producing oxidation to a full secondary and tertiary treatment. Commonly, materials will be buried many meters under the final surface. Some estimate of microbial action can be made from the rate of gas production. (Some microbial action occurs quite rapidly but methane generation will not occur for some time).

Burning and incineration

Without attempting to exactly define these processes, "burning" and "incineration" are used in this report in the following frame:

Incineration is carefully *controlled* burning process normally using forced air to ensure good oxidation. It is carried out in an authorized and tested device. There are however several classes of incinerator, depending upon the temperature conditions, security of

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

handling, residence time, risk materials being processed, emission clean-up, etc. Some now have recovery of heat. It is a thermal destruction process of organic material in specially designed combustion chambers with filtering systems to reduce emissions, e.g. of chlorinated dioxins. The destruction process is steadily supported in an incineration chamber at temperatures between approximately 750 - 1200 °C. However, incinerators designed for the disposal of animal carcasses usually operate at the "lower" temperatures of 750-850°C. The remaining material is ash.

Burning is a simple method for the thermal destruction of organic material. Burning may be as effective as incineration for destroying many hazardous materials but typically it is *less well controlled* than incineration with respect to a number of important parameters for assuring complete oxidation, i.e., temperature, retention time, air supply or emission. Processing conditions may show high variability. The degree of destruction and the temperature reached varies in relation to moisture content available oxygen and external conditions and is often below 800 °C but may also be above 1000°C. The fire is generated by the carcass itself and additional solid or liquid fuel sometimes under open sky or in simple devices. Power stations and cement production represent the more sophisticated methods of burning. They are however less tightly regulated than incinerators.

Typically commercial incinerators and commercial burning plants will mix the animal derived material with other feedstock. Indeed animal derived material tends to have too high a carbon content to be used as the sole fuel. Both incineration and burning inevitably leave a residue which has to be disposed of. If there is a residual risk the disposal should be by controlled landfill. If there is no residual risk, the residue could be used for example as a building material etc. The residue is often about 10% of the original volume.

Fit for human consumption

The wording "Fit for human consumption" hereafter refers to material that passed post mortem inspection which was derived from animals that passed a pre-mortem inspection by a competent veterinary authority, that is certified and identifiable as fit for human consumption and without any special epidemiological risk for animal consumption after proper rendering on the basis of the existing national and EU legislation. (However, it should be noted that such material may no longer be regarded as fit for human consumption after inappropriate storage, spoilage and microbiological contamination.)

Fur animals

Fur animals are defined here as animals exclusively kept for the production of furs, e.g., mink (*Mustela vison* and *Mustela lutreola*), foxes (both *Alopex lagopus* and *Vulpes vulpes*), raccoon dogs (*Nyctereutes proconoides*), fitch (*Mustela putorius*).

Specified risk materials or SRMs

Unless otherwise specified, the wordings "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 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.

Life animals and materials at (TSE) risk, carrying an actual TSE risk or potentially-infected animals and materials.

(The text hereafter is without prejudice to the definitions which the SSC is presently developing in the framework of its Geographical BSE Risk Assessment exercise.)

Animals or materials *at (TSE) risk* are those not showing clinical signs but where the risk of being infected is definite, for example animals that, after epidemiological investigation, were found to have been exposed to a common source of infection with a confirmed TSE case (for example feed) and including the progeny of TSE cases.

Animals *carrying an actual TSE risk* are animals that most likely are TSE infected or which are placed under suspicion because the likelihood that they are infected is high. These are *for example* the confirmed TSE cases or animals showing suspicious clinical symptoms pointing at possible TSE infection. Appropriate pre- or post-mortem tests are presently not available which could confirm the suspicion at a sufficiently early stage in the incubation period. However, on the basis of the SSC opinion on specified risk materials of 9 December 1997 (updated, 22-23 January 1998), of the available annual statistics on the ages of the youngest BSE cases (with 20 months as the lowest value since 1986[46]) and on the age of the (youngest) cases of scrapie reported in the literature which is below 12 months (e.g., Elsen *et al.*, 1999), it is considered that 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[47].

For example: fallen ruminants in high or low BSE risk countries; culled animals, herds or offspring after diagnosis of a BSE case; suspicious cases of neurological diseases unless TSE can be positively ruled out; fallen or dead animals other than ruminants if TSE in the species is endemic or epidemic; all suspicious cases deduced from the epidemiological situation.

Potentially infected animals and materials are those where the potential risk of being infected cannot be completely excluded, although the animals may have been found healthy following veterinary inspection.

For example: the animals culled in the framework of eradication schemes (e.g., the Over Thirty Months Scheme in the UK) or the ruminant specified risk materials in countries which are not BSE-free.

Serious transmissible diseases to man or animal (non exhaustive list)

Particular reference to:

- BSE, Scrapie, other TSEs
- Foot-and-Mouth Disease,
  Vesicular Stomatitis,

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46 Ages (months) of youngest case in the UK since 1986 are as respectively: 30 (in 1986), 30, 24, 21, 24, 24, 20, 29, 30, 25, 29, 37 and 37 (in 1998).

47 Knowing the age of dead animals is not obvious. Unless passports are available, accurate ageing is impossible. A standard based on dentition would therefore be more appropriate.

Swine Vesicular Disease,
Rinderpest (cattle plague),
Peste des Petits Ruminants
Contagious Bovine Pleuropneumonia,
Lumpy Skin Disease,
Rift Valley Fever,
Bluetongue,
Sheep and Goat Pox (capripox),
African Horse Sickness, Viral
African Swine Fever,
Hog Cholera (Classical Swine Fever)
Fowl Plague,
Newcastle Disease,

- (Non-exhaustive list; extract from the OIE B-List diseases, including zoonoses):
  Aleutian Disease, Anthrax, Aujesky's Disease, Brucellosis (Brucella ssp), Campylobacteriosis, Caprine Viral Arthritis/Encephalitis, Caseous Lymphadenitis, Contagious Agalactia, Crimean Congo Haemorrhagic Fever, Echinococcosis, Listeriosis, Enzootic Bovine Leukosis, Equine Encephalomyelitis, Infectious Bovine Rhinotracheitis, Infectious Haemapoietic Necrosis, Infectious Salmon Anaemia, Maedi Visna, Myxomatosis, Paratubercolosis, Psittacosis, Pulmonary Adenomatosis, Rabies, Salmonellosis and the agents thereof, Teschen Disease (Contagious Swine Paralysis), Toxoplasmosis, Transmissible Gastroenteritis, Trichinosis, Tuberculosis due to Mycobacterium Bovis, Tularemia, Viral Enteritis, Viral Haemorrhagic Disease, Viral Haemorrhagic Septicaemia, Yersiniosis, Other zoonoses,

Toxic substances.

Any given chemical may produce deleterious (adverse) effects in a living organism depending on the dose applied and on the route of exposure. Among chemicals, there is a wide range of doses needed to produce adverse effects and many substances are essential or beneficial to human health at lower dose levels. Other chemicals may represent a threat to human health by eliciting non-intended pharmacological effects (e.g. sedation, induction of antimicrobial resistance in pathogenic microbials etc.).

In the present report, "toxic substances" refer to a whole range of products (including toxic chemical substances, radio-nuclides, drugs, xenobiotics and their hazardous break-down products as well as potentially hazardeous pharmacological effects) that may be present in dead or condemned animals and materials as a result of intended or non-intended exposure or as the result of deterioration (spoilage) and at concentrations above internationally accepted safety levels. These levels may depend upon factors such as intended end-use, destination of a material, or dilution during processing, etc.

Possible cumulative effects are considered when MRLs are set. While synergisms or interactions of chemical mixtures occur in cases when the individual compounds are

present in biologically active concentrations, such effects are very unlikely when the levels are kept below MRL.

The number of substances, reasons for their presence and treatments (including dilution) resulting in possible inactivation or toxicity reduction is very large. Each individual substance therefore may also need to be addressed on a case by case basis.

Remote areas (in the context of disposal of dead animals and condemned materials)

When evaluating whether an area can be considered as "remote", one should not only take into account the availability within the area or distance to certain facilities such as rendering or incineration plants or cadaver collection services, but also the absolute (reared/farmed) animal population in that area. The fact that an area is void of certain facilities or that such facilities are far away is thus not a sufficient reason to declare it as "remote", but should in the first place rather trigger the question whether certain facilities should be installed/introduced. The cost of the latter should be weighted against the (short AND long term) environmental cost of not collecting/rendering/disposing dead animals and condemned materials but burying or burning them. The term "remote areas" should thus be used in its most strict sense, namely for areas or sites where the animal population is so small and where facilities are so far away that the risks associated with collecting and transporting them would be unacceptably high as compared to local burial[48]. In practice, "remote areas" should thus only be areas such as small islands or isolated farming areas (e.g., on hills) with only a limited number of animals or herds. They have a different risk to the "classical" farming areas and it may be often very far and difficult to get the fallen animals to a centre for disposal. In any case, if burial cannot be avoided, it should be controlled by the appropriate authorities, the sites should be selected on criteria of environmental safety and public health (e.g.,no catchment areas of drinking water, risk of drainage of spoiled water to rivers, …), the animals should be reported and the sites should be authorised and registered (licensed/monitored).

[48] In certain cases burning may have to be considered,for example in the case of anthrax and othersporeformers.

Annex 2: *Examples* of conditions under which the intra- OR inter-species recycling of fur animals could be considered.

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.

Annex 3: Listing of a number of possible standards for recycling or disposal of animal waste.

for rendering:

At least "133°C/20'/3 bars" or validated equivalent. This standard, as well as TSE hazards and risks related to meat-and-bone meal is described in detail in the Updated Report of 24-25 September 1998 on the Safety of Meat-and-Bone Meal Derived from Mammalian Animals fed to Non-rumimant Food Producing Farm Animals. The rendering plants should have effective effluent treatment and emission-reduction equipment installed or other measures taken, so that the residual infectivity or infective materials present no threat to humans, animals or the environment.

For burning of rendered products in power stations:

Safe handling procedures need to be established if use of power stations is contemplated. Conditions equivalent to: temperatures above 1000°C; the emissions should comply with appropriate and up-to-date standards (e.g., by including electrostatic scrubbing units which are highly efficient in removing particles from the flue gas). Retained particles, sludge from effluent treatments as well as ashes from potentially TSE infected animals should be disposed of in a controlled way (e.g., controlled landfill). The residue should be regularly monitored to demonstrate the effectiveness of the destruction process.

For direct incineration of carcasses:

Carcass burning under conditions equivalent to: a primary and a secondary combustion chamber should assure that all material is submitted to combustion at a temperature equal to or above 850°C for at least 2 seconds; the emissions should comply with appropriate and up-to-date standards and the equipment must include an up-to-date air purification unit. If efficient water-spray gas scrubbing unit removing particles from the flue gas are used, the water from the scrubbing unit should be re-circulated, and this water as well as sludge from it, should eventually be incinerated on site. Rain water and process water from the incinerator area should be incinerated and ash from BSE or potentially BSE infected bovines should be disposed of in a controlled way (e.g., controlled landfill). The residue should be regularly monitored for amino-acid content to demonstrate the effectiveness of the destruction process.

For landfill:

Site selection for rendered material and incineration residues should be based on a careful and documented risk analysis taking into account, amongst others, the estimated infective load of the raw material (which itself depends upon the epidemiological situation of a country or zone), geographical and climatic features (e.g., dominant wind directions), site-specific features such as underground, soil, landscape, vicinity of habitations, etc. Any sites selected for this purpose should a) be at an appropriately safe distance from water courses used as drinking water, unless their design reliably prevents the escape of any leachate, and b) presently not be the subject of consideration for any future redevelopment.

The SSC considers that the further utilisation of residues of burning and incineration may pose a risk because of the presence of toxic substances such as heavy metals and electrostatic filter waste. Also, due to possible malfunctions of the systems, the residues may still contain some low level of TSE infectivity, if TSE infected material was burned or incinerated. For these reasons, the residues should not be further used as, for example a fertiliser