Letterhead of Environment and Food Bureau Government Secretariat

BY HAND

OUR REF.: 9/55/03/155
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27 November 2001

Miss Becky Yu
Clerk to the Panel on Environmental Affairs
Legislative Council Building
8 Jackson Road
Hong Kong

Dear Miss Yu,

In an earlier meeting of the Joint EA and Health Services Panel, Members have asked for information on the following: -

(a) the methodologies adopted in the study "An Assessment of Dioxin Emissions in Hong Kong" when it estimated the local dietary intake of dioxin;

(b) report of the European Union relating to the treatment of clinical waste;

(c) specific clauses extracted from the service contract of the Chemical Waste Treatment Centre (CWTC) relating to dioxin exceedance; and

(d) informaton on alternative technologies for clinical waste treatment.

On (a), please find at Appendix A an extract (pages 25-28) from the report "An Assessment of Dioxin Emisions in Hong Kong". The consultancy study, commissioned by the Environmental Protection Department, was completed in March 2000, and its report was discussed at the Joint Panel in May 2000 [Paper No CB(2)1845/99-00(01)-(05)]. The extracted section describes the method that the consultant adopted in estimating the daily dietary intake of dioxin in Hong Kong. The report has pointed out that the estimated dioxin intake is in line with similar estimates in other countries and is within the range recommended by the World Health Organisation.

On (b), Professor J Bridges has advised that the Scientific Steering Committee of the European Union considers that among the economically feasible technologies for treating "condemned animals and materials", direct incineration carries the least risk. A copy of the report is at Appendix B. (Please refer to Section 7 on page 58 of the report.) Professor Bridges considered that this assessment wold also be applicable to the disposal of other materials contaminated by infectious agents, including clinical waste.

On (c), please see at Appendix C a copy of Clause F20 of the CWTC contract which sets out the basis for deduction of contract payment. Clause F20.4 specifically refers to the dedcution of operation fee arising from any failure to comply with pollution control limits. Separately, the CWTC is also bound by the licence granted under the Air Pollution Control Ordinance. Contravention of the licence conditions may lead to a fine, imprisonment or cancellation of the licence.

On (d), EPD has commissioned a study on the different available technologies for treating clinical waste. We are examining the findings of the study, and will report to the Joint Panel once we are in a position to do so.

If Members have further questions, please let me know.

(Ms Annie Choi)
for Secretary for the Environment and Food

cc DEP (Attn: Mr Conrad Lam 2591 0630
Mr Patrick Lei) 2318 1877

Appendix A

Extract of "An Assessment of Dioxin Emissions in Hong Kong" Final Report

4.3.2 Effect of the Existing Ambient Air Levels on the Intake of PCDD/Fs

Task 2 of the Terms of Reference also requires the Consultant to advise on the short and long term impacts on the local community of PCDD/F emissions from existing waste management facilities in Hong Kong.

The PCDD/F data supplied to the Consultants is limited to the ambient air data listed in *Tables 4.2a* and *4.3b*. To the extent that these data are inclusive of releases from all current waste treatment facilities in Hong Kong (and in the case of the data in *Table 4.3b*, inclusive of the local impact of the CWTC), an assessment of present ambient air quality is an appropriate surrogate for the assessment of impacts from current waste management facilities.

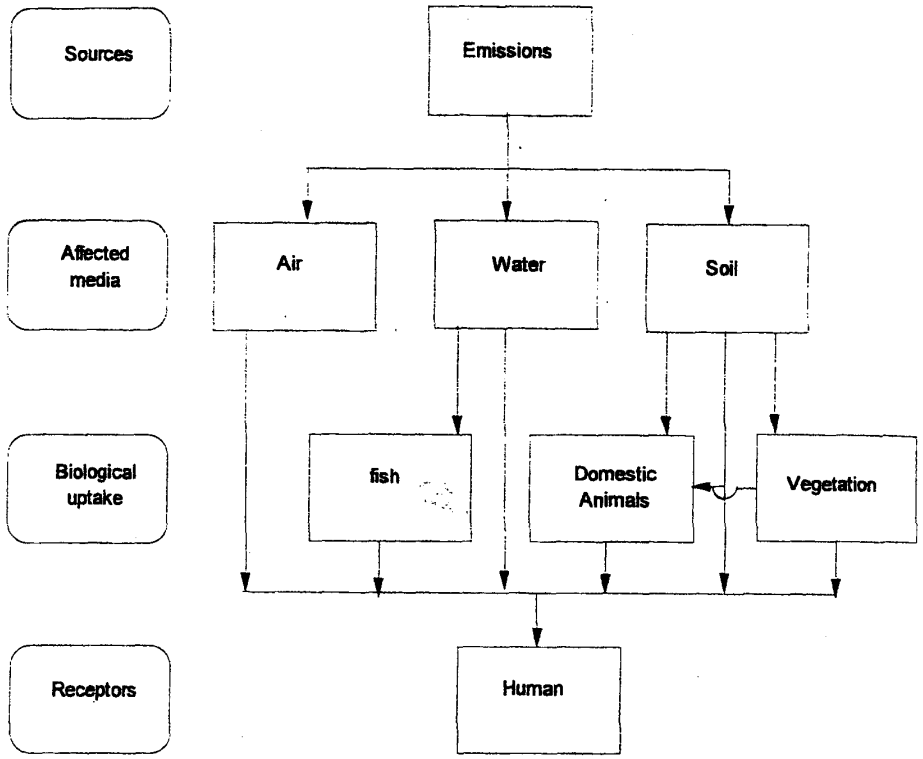
The lack of a discernible difference between the air quality local to the CWTC and the air quality measured at the Central/Western and Tsuen Wan monitoring stations suggests that the presence of the CWTC has not increased the background PCDD/F intake to any significant extent. As indicated above, this judgement is supported by the generally low PCDD/F emission concentrations measured in the CWTC stack gases.

In terms of the total dose experienced by exposed populations, it is necessary to appreciate that air quality *per se* is an insufficient indicator of public health. Following their release to atmosphere, PCDD/Fs partition into other environmental media. Humans in the vicinity of waste incinerators can be exposed via several direct and indirect pathways, via inhalation, the terrestrial and aquatic food chain, and through ingestion of soil and water impacted by the emissions (see *Figure 4.3a*).

It is now recognised that the food chain is responsible for the majority of PCDD/F uptake into humans, accounting for over 98% of the total uptake from the environment (Eduljee and Gair, 1996). Under exposure conditions typically encountered by the general population, direct contact with ambient air (i.e. via inhalation) contributes at most up to 2% of the total PCDD/F uptake. Therefore, any assessment of the appropriateness of a particular

PCDD/F emission concentration should take into account multimedia partitioning of these chemicals.

Figure 4.3a ***Multipathway Exposure to PCDD/Fs***



In the absence of measured data on other environmental media (soil, grass, food products) which would be in contact with or ingested by humans and thus contribute to the body burden of PCDD/Fs, and in the absence of ambient air data indicative of rural/agricultural environments in Hong Kong, we have estimated the typical inhalation dose experienced by an exposed individual by multiplying the 50th percentile concentration of PCDD/Fs in urban air (0.1 pg I-TEQ m^{-3}) by a nominal inhalation rate of 20 m^3 day^{-1}. The Consultants select the median PCDD/F concentration in urban air in preference to an arithmetic average of the data set in *Table 4.2a*, since environmental data tends to be log-distributed and the median provides a truer representation of mean concentrations than the arithmetic average. This calculation provides an estimate for the inhalation dose of 2 pg I-TEQ day^{-1}, or 0.03 pg I-TEQ kg^{-1} (bw) day^{-1} using a nominal body weight of 70 kg. The total intake is therefore estimated as 1.5 pg I-TEQ kg^{-1} (bw) day^{-1}, assuming the inhalation dose represents 2% of the total intake of PCDD/Fs. This estimate is almost certainly an over-estimate, since ambient air PCDD/F concentrations in rural and agricultural areas, where food production activities take place, would be at the lower end of the concentration range measured at the Central/Western and Tsuen Wan stations.

This notional total PCDD/F intake can be compared against estimated dietary intakes of PCDD/Fs in other countries (*Table 4.3c*). The conservative estimate of PCDD/F intake for Hong Kong is in line with estimates for dietary intakes in other countries. A more detailed assessment of exposure cannot be made without data on PCDD/F concentrations in environmental media other than air, and in food products.

Table 4.3c ***Estimated Dietary Intakes of PCDD/Fs per Day in Various Countries***

Country	**Dietary Intake (pg I-TEQ day^{-1})**	**Reference**
Canada	92	Birmingham *et al* (1989)
Germany	62 - 100	Malisch (1998)
Italy	260 - 480	Di Domenico (1990)(a)
Japan	63	Ono *et al* (1987)
Netherlands	70	Theelen *et al* (1993)
Norway	51 - 85	Becher *et al* (1998)
Russia	139	Maystrenko *et al* (1998)
Spain		Schuhmacher *et al* (1997)(b)
■ Catalonia	210	
■ Madrid	120	
■ Basque Country	128	
UK	70	Eduljee and Gair (1996)
United States	18 - 192	Schecter *et al* (1994)
Hong Kong	**105**	**This study (conservative estimate)**

Notes:
(a) 117 pg I-TEQ day^{-1} if vegetables were excluded from the diet.
(b) Fruits and cereals contributed 35% of the total dietary intake in Catalonia.

Given the limitations of the data available for Hong Kong, a firm conclusion as to the likely PCDD/F dose experienced by exposed populations cannot be drawn. From the screening calculations performed in this report, it appears likely that the total intake of PCDD/Fs presently experienced by the population in Hong Kong is of the same order as for other countries. This intake *includes* the presence of current waste management facilities and other PCDD/F emitters. In general, the contribution of the former facilities to the total PCDD/F intake is, as a first approximation, proportional to the contribution of these facilities to ambient air ground level concentrations. From the screening calculations presented above, this contribution is likely to be in the region of 0.1-0.4% of the general background.

The tentative PCDD/F uptake of 105 pg I-TEQ day^{-1} via the foodchain calculated in this report equates to 1.5 pg I-TEQ kg^{-1} (bw) day^{-1} for a nominal individual with a body weight of 70 kg. Assuming that conversion to WHO-TEQs is on a 1:1 basis and that coplanar PCBs contribute a further 1.5 pg WHO-TEQ from the diet (Alcock *et al*, 1998a), the total uptake of PCDD/Fs and coplanar PCBs in Hong Kong is 3 pg WHO-TEQ kg^{-1} (bw) day^{-1}. This can be compared against the Tolerable Daily Intake (TDI) recommended by WHO of 1 to 4 pg WHO-TEQ kg^{-1} (bw) day^{-1} (see *Annex B*). WHO recommend that every effort should be made to reduce intake towards the lower end of this range. While in other industrialised countries this can be achieved by lowering PCDD/F discharges to water and by further tightening PCDD/F emission limits on combustion sources, in the case of Hong Kong this course

of action has been pre-empted by the adoption of the PCDD/F emission standard of 0.1 ng I-TEQ m^{-3}, and by the fact that the preponderance of food items consumed in Hong Kong are imported and are therefore out of the direct influence of local emission sources.

Appendix B

Scientific Report by Professor J Bridges

SCIENTIFIC REPORT 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.

SUBMITTED TO THE SCIENTIFIC STEERING COMMITTEE AT ITS MEETING OF 24-25 JUNE 1999

(CONTAINING UPDATES, 13.07.99)

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. (11.04.99), responding on behalf of: (1) LASSA (Licensed Animal Slaughterers and Salvage Association) and (2) RIO (Regulated Incinerator Operators Group).
2. Ashworth, C.E. (08.05.99), additional comments on landfill and burial.
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 of the attachment: "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. EURO – 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. 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.
17. MLC - United Kingdom Meat and Livestock Commission. Letter from M.Grantley-Smith (7.04.99).
18. Milhaud, G. (Ecole Nationale Vétérinaire d'Alfort, France, U.P. de Pharmacie et Toxicologie. 08.04.99).
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 Francaises 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. UKRA – United Kingdom Renderers' Association (12.04.99)
25. Woodgate, S.L. (8.04.99)
26. WRc plc. (9.04.99), including the comments from S.GRUNDON (Services) Ltd.
27. The Chamberlain Partnership. Letter written by Mrs.Karen Green. (4.05.99).

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9. Acknowledgements

REPORT OF THE WORKING GROUP

1. The Question

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

2. Historical background[1]

a. In its opinion of 21 October 1996 (EC, 1996), the Scientific Veterinary Committee recommended that "Consideration should be given to preventing specified tissues or carcasses from species (e.g., cats, mink, zoological ruminants), other than domestic ruminants known to be naturally susceptible to TSE from entering any food or feed chain". The possibility of making an exception, for practical reasons, for fur animals since they are not for human consumption, is mentioned but not further discussed.

b. Between November 1997 and end 1998, the European Commission requested from the Scientific Steering Committee various scientific opinions on a number of issues related to (1) the recycling or disposal of animal waste, (2) the health risks related to the presence of undesirable substances in animal material destined to the production of feedingstuffs, and(3) disease transmission and environmental risks to man and animal in relation to a number of disposal options as an alternative to rendering.

c. The processing of fallen stock, dead animals and condemned materials is traditionally a task of rendering plants (or, sometimes, of knacker-yards). At the beginning of the century the importance of this business with respect to either spreading or preventing infectious animal diseases had been discovered and legal instructions had been fixed in several countries in order to use it as a tool in the field of veterinary public health.

Those countries which regarded the rendering systems a part of the legal and structural network for prevention, eradication and control of infectious diseases especially notifiable animal diseases (anthrax, rinderpest, etc.) defined legal requirements for collection, storage and processing those fallen or "stamped out" animals and put the systems under veterinary supervision. In order not to waste the protein and fat, safe recycling of those materials was the aim and this was achieved by appropriate autoclaving procedures for conventional micro-organisms. (e.g., 133℃/20'/3bars, after cooking until decomposition of the soft parts). In some countries, the carcasses were burned or buried to control infectious diseases (e.g., Foot and Mouth Disease) and no strictly controlled general rendering system was in place for the recycling of animal protein.

[1] This section is not part of the scientific argumentation in the rest of the report and does not necessarily reflect the opinion of the Working Group or of the Scientific Steering Committee.

Historically, different developments in public veterinary health policy regarding the habits, systems and infrastructure for collecting and processing carcasses of condemned, fallen or killed animals did thus exist in the European countries.

d. Currently, the EU legislation can be summarised as follows:

Council Directive 90/667/EEC[2] lays down the animal and public health requirements for the disposal and processing of animal waste in order to destroy pathogens which might be present in this material.

Animal waste is defined as carcases or parts of animals, including fish, or products of animal origin, not intended for direct human consumption. Animal waste is classified either as high-risk material, if it is suspected to present serious risks for the health of people or animals, or as low-risk[3] material, if it does not present a serious risk.

According to the Directive, the following animal waste is classified as high-risk material:

- all bovine animals, pigs, goats, sheep, solipeds, poultry and all other animals kept for agricultural production which have died on the farm but were not slaughtered for human consumption, including stillborn and unborn animals;
- dead animals not referred to above but which are designated by the competent authority of the Member State;
- animals which are killed in the context of disease control measures (see annex II for the list of diseases subjected to control measures):
- animal waste 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;
- all those parts of an animals 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;
- all meat, poultrymeat, fish, game and foodstuffs of animal origin which are spoiled and thus present a risk to human and animal health;
- animals and animal products imported from third countries which in the course of the inspections provided for in the Community legislation fail to comply with the veterinary requirements for their importation into the Community, unless they are re-exported or their import is accepted under restrictions laid down in Community provisions;
- without prejudice to instances of emergency slaughtering for reasons of welfare, farm animals which have died in transit;
- animal waste containing residues of substances which may pose a danger to human and animal health; milk, meat or products of animal origin rendered unfit for human consumption by the presence of such residues;
- fish which show clinical signs of diseases communicable to man or fish.

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2 OJ No L 363, 27.12.1990, p.51 as last amended by the Act of Accession of Austria, Finland and Sweden

3 Not to be confused with the TSE-related ruminant Specified Risk Materials

The above high-risk material must be either disposed of by burning or burial, or processed in an approved plant under official veterinary surveillance in order to be incorporated into animal feed.

From 1 April 1997, Decision 96/449/EC[4] requires that all[5] mammalian animal waste must be processed in accordance with the following minimum parameters which have been demonstrated as being effective to a certain amount for the inactivation of the agents of scrapie and BSE:

- maximum particle size 50 mm;
- temperature> 133℃;
- time 20 minutes;
- pressure (absolute) 3 bar,

in a batch or continuous system.

Some products derived from mammalian animal waste are exempt from this new rendering standard, such as petfood produced with low risk material, feed for fur animals, rendered fats, gelatine etc., and, in general, products which can be guaranteed not to enter any food or feed chain.

Meat-and-bone meal not produced in accordance with the above standard must be destroyed by burial, incineration, burning as fuel or a similar method which ensures safe disposal.

It must be noted that, at present, the vast majority of high-risk animal waste is processed by the rendering industry and therefore recycled into the production chain with minor dispersion into the environment.

Meat-and-bone meal derived from non-mammalian animal waste (for example fish and poultry) may still be produced using alternative heat treatment systems (in the case of high risk material) laid down in Decision 92/562/EEC[6] (in the case of high risk non-mammalian waste) or other processing systems provided that the final products comply with microbiological standards.

According to Decision 97/534/EC[7], from 1 January 2000 specified risk material, defined as the skull including brain and eyes, tonsils and spinal cord, from cattle, sheep and goats over one year of age and spleens from sheep and goats, must be removed from all food and feed chains. In the case of fallen cattle, sheep and goats either the specified risk materials must be removed or the whole carcass must be destroyed.

Commission Decision 98/272/EC on epidemio-surveillance for TSEs, establishes that the carcass and all parts of animals infected by TSE must be destroyed.

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4 OJ No L 184, 24.7.96, p.43

5 Decision 90/667/EC introduced this standard already for high risk material.

6 OJ No L 359, 9.12.92, p.23 as last amended by the Act of Accession of Austria, Finland and Sweden

7 OJ No L 216, 8.8.1997, p.95

Commission Decision 94/381/EC[8], as amended by Decision 95/60/EC[9] and (for hydrolysed proteins) amended by Decision 99/129/EC, lays down certain protection measures with regard to bovine spongiform encephalopathy, requiring EU Member States to prohibit the feeding of protein derived from mammalian tissues to ruminant species. Nonetheless, the following protein products derived from mammalian tissues are considered to be safe and consequently excluded from this prohibition:

- milk;
- gelatin;
- amino acids produced from hides and skins by a process which involves exposure of the material to a pH of 1 to 2 followed by a pH of> 11 followed by heat treatment at 140℃ for 30 minutes at 3.0 bars;
- dicalcium phosphate derived from defatted bones;
- dried plasma and other blood products.

e. Regarding the national legislation, it should be mentioned that Directive 90/667/EEC has been transposed into the national legislation of all the 15 Member States of the European Union. However, two Member States (Sweden and France) have prohibited the use of some high-risk material in animal feed:

- since 1986 Sweden has banned the use of fallen animals and deceased parts of slaughtered animals in the manufacture of animal feed;
- since 28 June 1996, France has banned the use of fallen animals and certain other high risk material in the manufacture of animal feed.

In United Kingdom it has been illegal to feed any farmed livestock with mammalian meat-and-bone meal since 4 April 1996.

f. In practice, and according to the various Commission's requests, the present scientific report and opinion should provide the necessary elements required to verify whether the present legislation is adequate or should be amended with respect to the following issues:

f.1. criteria for the sourcing, production and final (intended) use of condemned materials of animal origin which are the most appropriate to avoid the risk of the spread of serious transmissible diseases to man or animal, with particular reference to the diseases listed in Section 4 "Definitions".

f.2. risks related to the presence of toxic substances in animal material (list not exhaustive):

- increased levels of biogenic amines indicative of spoilage
- endotoxins
- residues of substances (veterinary drugs, feed additives, contaminants, natural toxins) and relevant transformation products in concentrations

[8] OJ No L 172, 7.7.1994, p.23
[9] OJ No L 55, 11.3.1995, p.43

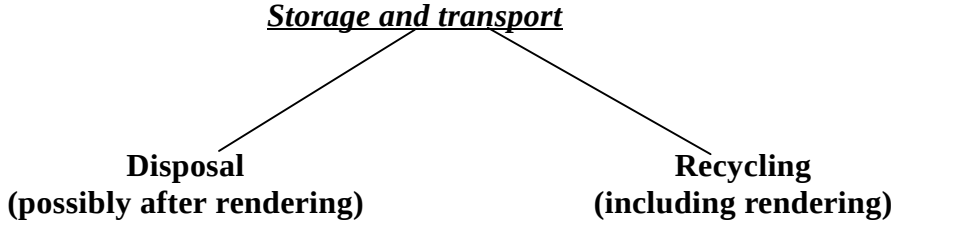
beyond maximum levels established by international standards and Community legislation (such as established maximum residue limits (MRL) for animal drug residues)[10]

f.3. disease transmission risk to man and animal in relation to the following alternative disposal options to rendering:
- Disposal of animal carcasses or raw animal material by burning;
- Disposal by incineration;
- Burning of meat-and-bone meal in power stations;
- Burial of animal carcases or raw animal material;
- Disposal by landfill;
- Disposal of meat-and-bone meal as fertiliser;
- Composting
- Disposal as biogas
- Use for feed of animals which never re-enter the food/feed chain.

3. Known ways of recycling or disposing of fallen stock, dead animals and condemned materials.

The ways for recycling or disposal of animals and animal materials that are practised or have been practised in the past are numerous. Without for the time being attributing any value in terms of safety, the most commonly used ways can be schematically listed as follows (adapted from Klein, 1997):

Disposal or recycling of fallen and dead animals and condemned materials



Disposal (possibly after rendering)	**Recycling (including rendering)**
Burying Composting Landfill Bio-gas production Burning Burning for fuel Incineration, cremation	Raw or incompletely processed material; Processed products, for example: - meat-and-bone meal, organic fertilisers, hydrolysed proteins, dicalcium phosphate, gelatine, tallow, tallow derivatives... . products for heat generation (e.g., tallow, MBM, ... ;

[10] It needs to be recognised that MRL do not exist for all toxic substances possibly present in animal material. For some substances used as growth promoters for example, no MRL has been set because of a lack of a sensitive method of analysis, precluding the establishment of a meaningful MRL.

4. Explanatory notes and definitions

The definitions, clarifications and general considerations provided hereafter are provided for the purpose of the present report and opinion; they are not necessarily identical to definitions or concepts that may be used elsewhere nor to the ones used in E.U. legislative documents.

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 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[11]; milk, meat or products of animal origin rendered unfit for human consumption by the presence of such residues;

(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* are 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.) above accepted levels/concentrations[12] and provided the laboratory or test environment is free from other tests implying the use of

[11] It needs to be verified whether further work involving risk assessment and risk reduction as regards residues of chemicals present in sites of injection veterinary drugs is needed.

[12] It is clear that certain exposures are perfectly acceptable and would not result in a risk, for example a correctly administrated drug where the recommended time between administration and slaughter was respected.

such agents and substances which may result in an unacceptable exposure. Where appropriate, a case-by-case approach needs to be followed to determine which animals, agents or substances may constitute a risk.

"133℃/20'/3 bars"

The wording "133℃/20'/3 bars" refers to hyperbaric production process of not less than 133℃ 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[13].) 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[14]. 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℃, the corresponding pressure, if all air is evacuated, will be slightly below then 3 bars[15]. 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 133℃ is given here.

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[13] 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℃ jacket steam (which causes a temperature overswing phase to nearly 140℃) would further increase the security of the sterilising process. (Other valid technical solutions may exist.)

[14] If direct steam is used, specified conditions may apply, *for example*: a water content of 50-60% with a temperature treatment for 140-150℃ (at least 3,5 bar). (Other valid technical solutions may exist.)

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

b. 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[16] 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 "133℃/20'/3 bars" standard as a post-sterilisation phase in stead of applying it during the production process itself, would result in an equivalent inactivation of a TSE agent provided the material contains enough water[17] 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[18], 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[19], it is necessary to verify whether, in order to obtain the same efficacy, the parameters "133℃/20'/3 bars" needs to be modified in the case of a post-sterilisation process.[20]

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℃ 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.[21]

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16 *For example, and depending upon the vessel size*: at least 100℃ 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℃ till nearly 140℃ through the vapour valve of the vessel. (Other valid technical solutions may exist.)

17 Approximately 60%.

18 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.)

19 If there enough steam supply during the whole operation, there may be no loss of pressure.

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

21 With certain limitations, the ELISA test may be used for monitoring the quality of the sterilisation process. Appropriate R-values need therefore to be set.

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 - unless otherwise stated in the text[22] - at least according to the "133℃/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).

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

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 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 ℃. However, incinerators designed for the disposal of animal carcasses usually operate at the "lower" temperatures of 750-850℃. 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 ℃ but may also be above 1000 ℃. 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[23]) 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[24].

> 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)

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[23] 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).

[24] 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.

Particular reference to:

- BSE, Scrapie, other TSEs

- Foot-and-Mouth Disease,
  Vesicular Stomatitis,
  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,

- (No 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.

Note: Reference is made to Taylor *et al* (1999), in which a lsit of 1709 species of infectious agents which are pathogenic to humans is presented. Almost half of these are zoonotic, that is, can be transmitted between humans and animals.

Toxic substances.

Any given chemical may produce deleterious (adverse) effects in a living organism depending on the dose applied. 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 toxic 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 toxic 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.

The following categories of potentially dangerous substances including relevant tarnsformation products can be listed (non exhaustive list):

- Veterinary drug residues, including euthanasia agents
- Feedingstuff additives (having the nature of an active substance)
- persistent organic pollutants
- heavy metals
- Plant protection product residues
- Disinfectants in rendering plants
- decomposition products of carcass parts
- Endocrine disrupters[25].
- Natural toxins
- Radionuclides

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[26]. In practice, "remote areas" should thus only be areas such as small islands or isolated farming areas (e.g., on hills) with only a

[25] Further information is available in the Opinion of 4 March 1999 of the Scientific Committee on Toxicity, Ecotoxicity and the Environment on *Human and Wildlife Health Effects of Endocrine Disrupting Chemicals, with Emphasis on Wildlife and on Ecotoxicology Test Methods.*

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

limited number of animals or herds. They have a different risk to the "classical" farming areas and it may be often 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).

5. Identification of possible hazards and elements of risk assessment

5.1 Preamble:

Condemned animals and materials may constitute a potential risk for one or several of the following reasons (non exhaustive list):

- the presence in animals or materials of infectivity due to conventional micro-organisms such as bacteria or their spores or toxins, viruses, fungi etc. or to known or unknown agents such as TSE and which may be at the origin of a risk for human or animal health.

- the presence in animals or materials of hazardous levels of toxic substances and which may be at the origin of a risk for human or animal health. This includes also the animals killed or succumbed during (or even as the result of) the treatment with substances including drugs;

- the residual infectivity or toxicity after processing of these animals or materials, which depends upon the capacity of inactivation of the process and the quality of the process applied under field (industrial) conditions;

- The animals may have been fed with feed that may have been incompletely processed or inappropriately sourced with respect to potential hazards (e.g., fur and zoo animals). They may therefore be part of an (initially silent) cycle of building-up infectivity.

- The exact causes of death may not have been diagnosed. These cases include not only the typical "fallen stock" cases, but also the cases where animals were killed by euthanasia upon showing suspect symptoms but before a final diagnosis was carried out. The carcasses or material may be carriers of (conventional or unconventional, known or unknown) infectious agents or toxic substances.

Whether there is a potential resulting risk, will depend upon, amongst other factors:

a) whether or not it was possible to identify with certainty by veterinary diagnosis, ante-mortem health inspection and/or post-mortem examination the cause of death or reason for euthanasia, or the reason for animals or materials to be condemned;

b) whether this cause or reason are possibly to be attributed to unconventional or as yet unknown transmissible agents;

c) the type of hazard (toxic substance, infectious agent,...) and its concentration or potential infectivity level;

d) the infectivity reduction capacity of certain measures (e.g., sourcing), existing recycling or disposal processes (e.g., whether or not a given agent can be completely inactivated by a production process), the quality (reliability) of these

processes when operated under field (industrial) conditions and the possible final destinations (end-uses) of recycled products.

e) It should also be noted that other dysfunctions or infectious agents may be present in the body besides the diagnosed direct cause of death of an animal.

According to the SSC opinion of 26-27.03.98 and the updated report of 24-25.09.98 on the Safety of Meat-and-Bone Meal, TSEs may not be completely inactivated by the "133℃ / 20 minutes / 3 bars" conditions if the initial infectivity level of the material was high. It may not be the case for other non conventional transmissible agents which might be identified in the future or for certain toxic chemicals such as thermostable persistent hazardous residues and heavy metals.

However, for conventional infectious micro-organisms (bacteria, viruses, fungi, ...) appropriate inactivation processes exist. It is accepted that the standard "133℃ / 20 minutes / 3 bars" or equivalent, if properly applied, result in the complete inactivation of the most resistant conventional infectious agents.

It needs thus to be addressed whether under what conditions certain of these animals or materials can be possibly recycled for further use or whether they should be disposed of. This will depend upon the initial hazard present in the dead animal or condemned material, the possible inactivation or elimination of the hazard by treatment, the possible final destinations (end-uses) of recycled products and the accepted residual risk.

5.2 Risks related to Bovine Spongiform Encephalopathy in domesticated ruminants

A large number of experiments, abundantly reported on in the scientific literature, have shown that cattle and small ruminants are vulnerable to TSE's originating from their own species and that ruminants in general fed with infectious material originating from the same species can be infected with TSE's. Also, experimental evidence (EC, 1998h) shows that BSE can be transmitted to sheep (and goats) via the oral route.

a. BSE in domesticated bovines

A key-question to be addressed is whether the BSE prevalence and infectivity in fallen cattle is likely to be higher or lower than in the animals sent for slaughter and passing the ante- and post-mortem inspections.

One could argue that in many countries bovines are normally kept under conditions which imply a daily observation of the health status of the animals. A significant part (but certainly not all) animals that show neurological symptoms are likely to be reported on and killed following an active intervention of a veterinarian, especially if an adequate epidemio-surveillance system is in place. These animals must be classified as unfit for human consumption, hence enter the category of condemned materials. Also, animals are no more likely to die suddenly because they have BSE than other stock that havent. BSE It might therefore be considered unlikely that the numbers of animals that would die suddenly as a result of terminal BSE would be high. This would imply that the prevalence of BSE in fallen stock and dead animals entering the rendering chain is not higher than in the rest of the cattle population.

However, it must be stated that, as a general principle, any disease has a higher probability to occur in fallen stock and dead animals than in apparently healthy

animals sent for slaughter. Most animals are slaughtered before signs of illnesses may develop. This relates to diseases like slow virus infections or tuberculosis. No study has permitted an assessment of the epidemiology of TSE infection in animals found dead and nothing is known about the potential associations between a given TSE pathology and the consequences of its association with an infection with unconventional transmissible agents. For what concerns BSE, nobody knows exactly its prevalence in the live cattle population. It is moreover likely that the infective load of BSE infected fallen stock and dead animals would be higher than in normally slaughtered animals because they were terminally ill and because it may be difficult t to remove the specified risk materials (although it can be done in knackeries). The infective agent may also have a more widespread tissue distribution.

The potential BSE infectivity risk associated with fallen stock and dead animals is therefore to be assumed, to be higher than for animals sent for slaughter. The reality of this assumption was recently confirmed when it appeared from the preliminary results of a survey carried out in early 1999 on fallen cattle in Switzerland, that the incidence of BSE in cattle found dead was indeed significant relative to the number of clinical cases of BSE found in the same time period_M. Vandevelde, 1999, personal communication; OIE, 1999). This means that, depending upon the epidemiological situation of a country or region and depending upon the age of the dead animal, the potential BSE infectivity load of fallen and condemned cattle, may be higher than the overall risk resulting from sub-clinically affected animals that passed the slaughterhouse inspections.

The Working Group further expressed its concerns about a report Hart *et al* (1997), indicating that the number of reported fallen stock in the UK may have dropped by almost 50% for cattle and 80% for sheep, following the introduction of the ruminant feed ban and the reduced value of a fallen animal sold to a knacker. A not-confirmed hypothesis is that part of these animals are being buried on the farm, put in the slurry pit to rot, left to be picked clean (sheep) or, while still alive, declared as casualty. (In the United Kingdom: 2% of the cattle population is estimated to end up as fallen stock and casualty rates are also estimated at 2%. For sheep, the figures are approximately 1% and 3-5%.). This may indicate that under certain circumstances, the number of fallen stock that enter a rendering system - hence the potential infective load of a rendered batch - may drop in favour of other ways of disposal.

b. Risks related to TSEs in sheep and goats.

The Working Group considers that, complementary to the above presented risk evaluation related to bovines, the following elements should be taken into account when deciding whether fallen small ruminants should be excluded or not from rendering in all countries with a non-negligible risk of TSEs in small ruminants:

- The hypothesis that scrapie was at the origin of the UK BSE epidemic is accepted by many (but not all) scientists.

- Also the SSC in its opinion of 24-25 September 1998 concluded that it is not excluded that BSE may have been introduced in sheep and goat populations and might behave like scrapie (in terms of infectivity distribution in tissues and transmission). The transmission - if it occurred - would most probably be due to

feeding of bovine materials which were insufficiently inactivated in a low temperature rendering process. It is speculated – but not generally accepted[27] - by some scientists that with general application of the "133℃ /20'/3 bar" standard this circle of transmission may not have occurred.

- However, the fact that scrapie is a notifiable disease in all European countries, is likely to reduce significantly the number of animals fallen as a result of scrapie, that will enter a rendering process, if farmers are fully compensated and if all suspect cases are reported.

- On the other hand, not all sheep or goat herds are necessarily kept under conditions which imply a daily observation of the health status of the animals. Therefore, the prevalence of TSE infectivity in fallen small ruminants may well be higher than in the live population. Significant infection can be found in Suffolk sheep infected with natural scrapie. (Hadlow *et al*, 1982) There is also evidence of significant diagnoses of scrapie in sheep found dead in Shetland (Clarke, 1991; Clarke *et al*, 1994) In addition, it is likely that the TSE infective load of such infected animals would be higher than in normally slaughtered animals because they were terminally ill and because it is difficult to remove specified materials (although it can be done in a knackery).

5.3. Risks related to spongiform encephalopathies in pigs, poultry and fish

a. Pigs:

Several experiments have been reported to investigate the experimental transmission of TSE to pigs. Specifically they include the agents responsible for kuru, BSE and scrapie.

In regard to kuru, Gibbs, Gajdusek and Amyx, (1979) reported the unsuccessful transmission of eight strains of kuru to pigs following parenteral challenge with human brain material. The pigs were kept for from 52 - 76 months and no histological evidence of spongiform encephalopathy (SE) was found.

In regard to BSE, parenteral and oral challenge of pigs with brain material from cattle naturally affected with BSE have been described and reported (Dawson *et al*, 1990, 1991, 1994, Animal Health 1996, 1997). In the parenteral study, pigs were challenged by the combined i/c, i/p and i/v routes using a total of 1 g of brain tissue for each pig. Clinical and pathological evidence of spongiform encephalopathy was found in seven of ten pigs. Two died early in the incubation period from intercurrent disease, and in the third pig, sacrificed whilst clinically healthy two years into the incubation period, showed no evidence of SE.

In the oral challenge study, ten pigs were challenged with a total of 4 kg of brain material from cattle with confirmed natural BSE. The material was fed on three occasions at intervals of one to two weeks. No clinical or pathological evidence of TSE was found in the pigs up to seven years post-challenge. Tissues from these pigs

[27] See also the various opinions of the Scientific Steering Committee on the safety of meat-and-bone meal and the infectivity clearance capacity of the "133℃/20'/3 bars" process.

have been inoculated into mice. No detectable infectivity was found in neural and non-neural tissues from some pigs killed two years after challenge. The bioassay of tissues from pigs killed at the termination of the experiment is still in progress. None has been reported positive so far (Hawkins *et al*, 1998; and Hawkins, personal communication 1999).

Pigs have also been challenged orally with brain tissue from sheep confirmed to have scrapie in a similar manner (Animal Health 1996, 1997). The experiment is still running but no pig has shown evidence of a TSE disease to date over 63 months from the date of challenge. Bioassay of tissues from pigs killed two years following challenge is still in progress. None has been reported positive so far (Hawkins, personal communication).

In 1997, an incident that occurred in 1979 was reported in the USA in which farm pigs seemed to show neurological signs and microscopic evidence of encephalopathy (Hansen and Halloran, 1997). In one pig out of 60 examined, neuronal vacuolation and gliosis were found. The affected pig was 6 months old. Subsequent re-examination of the material showed that the lesions were not pathognomomic of those seen in TSE. Also the young age of the animal would argue against the diagnosis of a TSE. The conclusion was that no evidence was provided of the possibility of a previously unrecognized disease orTSE being present in pigs (L.Detwiler, personal communication[28]).

No reports in the world literature describing a naturally occurring TSE in pigs have been found.

b. Poultry (= domestic fowl or chickens)

Chickens have been challenged by parenteral and oral routes with brain material from cattle confirmed to have natural BSE, (Dawson et al, 1991, 1994, Animal Health, 1996, 1997).

In regard to the parenteral study 12 chicks were inoculated i/c with 50µl of a 10% saline suspension of pooled brain stem at a day old. A further 1ml was inoculated i/p when the chicks were 2 weeks old. No evidence of spongiform encephalopathy was found at the conclusion of the study. Sub-passage is in progress but no results are yet available (Hawkins, personal communication, 1999).

In regard to the oral study 11 birds were challenged with 5g of a pool of brain tissue from two cattle with confirmed BSE on three occasions when the birds were 4, 5, and 6 weeks of age. The material was deposited in the distal oesophagus/crop. No evidence of spongiform encephalopathy was found. Sub-passage is in progress but no results are yet available (Hawkins, personal communication, 1999)

c. Fish

[28] Based also on the following USA documents: (1) Dr.W.J.Hadlow's Report of 10.04.97 on the microscopic examination of pig brain Nº 2709, (2) Dr.J.Miller's comments of 31.03.97 on the incident and (3) H.W.Moon's review of 31 March of the pathology reports of the pigs.

So far, no evidence for TSE in fish was found. Alderman (1996) reports that the Fish Diseases laboratory at Weymouth (UK) has for 25 years been involved in studying the diseases of marine and freshwater fish. During that time the laboratory has not observed any scientific evidence of any condition which might in any way be described as a spongiform encephalopathy in fish, wether of species used to produce fishmeal, or directly for human food, from the UK, other EU member states or from elsewhere in the world.[29]

What precedes is confirmed by Professor Hugh Ferguson of the Institute of Aquaculture at Stirling University (SEAC, 1999, communication to the SSC secretariat). He reports that fish brains are examined quite frequently, and in young fish often as a result of investigations for gill infections[30]. As there are recognised diseases of fish that could cause vacuolation, fish experts are conscious of concerns about TSEs. Nothing suggestive of a TSE has been found however.

FIN (1999) reports that farmed marine fish feed is mainly composed of fish meal and fish oil, completed with small amounts of vegetable oil and minerals, vitamins etc. Freshwater fish such as trout, carp, etc. are unlikely to receive any fish material other than in the form of fish meal and fish oil. However, according to information obtained from rendering companies, mammalian-derived materials may be used as an ingredient for feeding farmed marine and freshwater fish.

It should further be noticed that a EC funded project FAIR5-CT97-3308 entitled "*Separation, identification and characterization of the normal and abnormal isoforms of prion protein from normal and experimentally infected fish*" has started on 1/3/1998 for three years, with the following objectives:

(i) the characterization of the normal isoforms of fish PrP and its coding nucleotide sequence;

(ii) an attempt to transmit experimentally TSE material from ovine and bovine to fish;

(iii) the setting up of a sensitive and specific diagnostic test for PrP detection in fish tissues;

(iv) the evaluation of the uptake and binding of normal fish PrP.

The final outcome should contribute to the assessment of the possibility of transmission of TSE to fish, the evaluation of the potential risk connected to fish derived foods for human and animal, the establishment of analytical protocols for PrP detection in fresh fish food and the comparison of the molecular properties of normal and abnormal isoforms of PrP.

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[29] According to Alderman (1996) there are a few recognised diseases of viral and protozoal aetiology which affect nervous tissues of farmed and wild fish which result in pathologies and which, whilst they may be described as encephalopathies, can not in any way be confused with spongiform encephalopathy group of diseases, which include BSE, CJD and scrapie either in their gross, behavioural or pathological characteristics. Such viruses and protozoans are regarded as being extremely host specific and adapted for cold blooded animals.

[30] It is easier to section the entire head, thus including the brain, than to concentrate only on gill.

d. Pigs, poultry and fish as possible silent carriers

Marsh *et al* (1969) reported the recovery of transmissible mink encephalopathy (TME) infectivity from the spleen of one chicken and from the spleen, caecal tonsil and bursa of Fabricius of a second chicken of two chickens challenged experimentally by i/v inoculation of fourth passage mink brain with TME. They noted that infectivity persisted for extended periods (30 and 50 days in the case of chickens) in lymphoid tissues of chickens, mice, cats and calves that were studied.

Race and Chesebro (1998), reported the results of i/c challenge of mice with hamster scrapie strain 263K that produces no clinical disease in mice, followed by sub-passage from brain and spleen into further mice and into scrapie susceptible hamsters. Infectivity was detected in the spleen and brain tissues by the hamsters, but not by the mice. The authors' view was that the mice had not replicated the agent. They noted that they had not tested to see if the same results were obtained after oral challenge. However, they suggested that food animal species resistant to BSE, like poultry, exposed to BSE infectivity *via* feed but might show persistent infectivity in their tissues.

Over 80% of pig meat and 80% of poultry meat produced in the EU originates from pigs less than 8 months of age and broilers less than 2 months of age respectively. Taking account of all our knowledge on prion diseases in animals, it is unlikely that clinical evidence of disease would occur at such a young age. Only adult breeding pigs would be expected to be old enough to exhibit clinical signs if ever a TSE of pigs was found. However, it can be hypothesised that infectivity of extra-neural tissues, particularly lymphoreticular tissues, could theoretically arise in these species exposed to TSE infection *via* feed whether or not replication and neuroinvasion subsequently occurred. The results of the studies using the BSE agent mentioned above do not support the hypothesis that infectivity can be sequestered in the manner described and particularly this is a unlikely event in pigs exposed to the BSE agent by the oral route two years earlier. It is noted however, that these studies used mice to detect any infectivity. Furthermore the results of bioassays done at the termination of the porcine studies are still awaited as are those from poultry.

e. Conclusions

Pigs, but not poultry are susceptible to BSE following experimental challenge by multiple parenteral routes with brain material from cattle confirmed to have BSE. Neither pigs nor poultry are susceptible to BSE following challenge by the oral route. Pigs have not succumbed to TSE following oral challenge with brain material from sheep confirmed to have scrapie over five years post-challenge. The experiment is however, incomplete. No experiments have been done to show if fish of any species are susceptible to mammalian-derived TSE agents. There is no evidence from the world literature that a natural TSE exists in pigs, poultry or fish. There is no evidence to date that pigs or poultry, challenged orally with TSE agents, could harbour these agents in their body tissues.

5.4. Risks related to Feline Spongiform Encephalopathy (FSE) in cats

There is evidence that the agent of FSE in cats is identical to BSE in bovines: Bruce et al (1994) and Bruce (1996) showed that the biological strain type of agent in cats with FSE and cows with BSE is the same.

The current estimates of total numbers of confirmed FSE cases in cats are as follows (September/October 1998): 85 in Great Britain, 1 in Northern Ireland, 1 in Norway, 1 in Liechtenstein and 1 in Italy. Like for BSE, the number of cases of FSE in Great Britain is declining and the number of cats with FSE born after September 1990 when the Specified Bovine Offals (SBO) ban was introduced is small. However the number cases may be under-detected because the disease is not considered as notifiable by cat-owners: J. Wilesmith estimates (personal communication, 1998) that only around 40% of cats with TSE in the UK were effectively detected. On the other hand, it is unlikely that non-domestic cats found dead and which were not kept by an owner, would have received pet food containing rendered bovine materials or would be collected for rendering, because cats tend to die in hidden places.

The above numbers should be evaluated against the number of cattle, small ruminants, pigs and other animals that annually enter the rendering system.. It may thus be concluded 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, one should note that the final risk can be independent of the BSE status of a country due to imports of infected raw materials or feed.)

5.5. Risks related to Transmissible Mink Encephalopathy (TME) in mink

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

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

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

TME may also result from the feeding of mink with scrapie-affected sheep carcasses. Nevertheless, although intracerebral injection of scrapie led to a TME-like disease in

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

The transmission of BSE to mink has been proven under experimental conditions, both after oral and intra-cerebral challenge (Robinson *et al*, 1994). The disease produced was not identical to natural TME. So far, scrapie has never been sucessfully transmitted orally to mink. Present evidence is that the naturally occurring TME agent is a distinct entity from the TSEs in other animals. TME is also the only natural TSE in mink.

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

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

- contact with TSE-infected feed, mink or fur animals.

- consumption by mink, fur animals, other carnivorous species and rodents of TSE infected feed intended for mink or fur animals or derived from infected mink or fur animals (e.g., MBM);

- a potential risk for humans, if they consume products of farmed animals reared for food that have been fed with TSE infected products (e.g., MBM derived from TSE infected fur animals[31]);

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

If an outbreak occurs or a TME case is confirmed in a farm or colony, it is likely that all farms that had a common source of possible infection (e.g., the feed supplier) were exposed to the risk for TME infection, even if no TME is observed. (The animals are killed at a young age and the infection may be pre-clinical). It may be noted that, depending upon whether a farm produces it own feed or not, the number of farms with a

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

common source of infection may be highly variable, from one single farm, to all farms in a country.

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

If a TSE outbreak is suspected or has been confirmed, the carcasses from all fur farms that, on the basis of an epidemiological study, had common sources of possible infection, should be excluded for any further use except disposal and this at least until the end of the outbreak. The end of the outbreak has to be positively confirmed on the basis of criteria that still have to be established as part of the specific surveillance system but should include laboratory tests and microscopic examination of the brain.

Otherwise, if the carcasses are fed back to fur animals, appropriate decontamination with respect to conventional infectious agents other then TSEs [32] may be an alternative for the "133℃/20'/3 bars" conditions (which remains nevertheless considered also in this context as the treatment to be preferred), but any rendering of future generations should be excluded. The question is whether the latter possibility/probability can reasonably be excluded and controlled.

The above section mainly refers to mink, which are known to be highly susceptible to TME infection. However, it cannot be excluded that other fur animals, because of the specific husbandry practices (e.g., feeding with untreated or insufficiently cooked or rendered carcasses) and because some species are exotic (see section on exotic and zoo animals), may also be silent carriers of infectivity of known of unknown, conventional or unconventional diseases.

5.6. Specific risks related to laboratory and test animals

Extensive legislation governs the use of animals in experimentation. Disposal of most animals used in experiments is by incineration. The risks resulting from the possible further use of experimental animals, for example as raw materials for rendering, will depend upon the species and source of the experimental animal, the type of experiment/trial for which the animals were used, and upon the tests that were carried out on them.

Food animals can be infected with certain pathogens (eg eukaryote parasites such as *Fasciola hepatica*) for experimentation (eg vaccine development) and, following treatment and prescriptive withdrawal period, returned to the food chain.

Special attention should be paid to the residual tissues of test animals that were exposed to infectious agents, toxic, carcinogenic and mutagenic substances, as these can result in unknown and not fully characterised hazards.

[32] Cooking does not offer any additional safety with respect to risks resulting from TSE infectivity.

Laboratory and test animals could be fed animal derived products and many rodents are susceptible to TSEs. If the feed was infected, most rodents could harbour infectivity without ever showing disease. Many laboratory animals have short lives, shorter than the incubation period for a TSE. If rendered, they could be a risk.

However, animals involved in animal husbandry research that did not involve any use of toxic substances above accepted levels/concentrations31 or experimental infection, and which have not been exposed to another possible source of infection (e.g. infected feed), could in principle be rendered (or even consumed) without any additional risk resulting from the experiments.

5.7 Specific risks related to zoo- and exotic animals

For many zoo and exotic animals, a similar risk assessment as for farmed animals could in principle be carried out. This would result in rules for exclusion, or not, of these animals, depending upon whether the cause of their death is known or not, whether this cause is a conventional or non-conventional infectious agent. Definite diagnosis, however, may be less likely than in the case of domestic animals.

One could further assume that due to animal welfare restrictions and public awareness, the risk is reduced by the fact that post-mortem inspection of fallen animals is generally carried out in most zoos, and that most cases of fallen animals in zoological gardens are likely to be properly diagnosed/investigated.

However, the Working Group is of the opinion that these views are not justified. While national zoos and large private collections may routinely carry out detailed post-mortem examination of fallen animals, the cost of veterinary investigations can be high and prohibitive (particularly for small zoos and private collections) and consequently definitive diagnosis may be less likely than in the case of domestic animals. Moreover, when one is dealing with exotic species, there is an increased possibility that the aetiological agents may not be identified.

There is a risk that exotic animals could carrying undetectable and as yet unidentified (discovered) conventional pathogen or unconventional agents such as prions. The present knowledge on exotic diseases is limited and could be confused with known diseases. Also, the specific environment of zoos may constitute a potential hazard, because native animals live in the immediate neighbourhood of exotic animals. Furthermore, exotic species which, in their natural environment, would not come into contact either because of behaviour, ecology or remote geographical distance, are also placed in close proximity. Both circumstances lead to increased risk of horizontal transmission of conventional (and possibly non-conventional) pathogens. In some cases, these may give rise to sub-clinical infections with no apparent disease, which will therefore avoid detection. In addition, all animals may have been fed with feed that may have been incompletely processed or inappropriately sourced with respect to potential hazards. They may therefore be a reservoir of (initially) silent (sub-clinical) cycles of infectivity. They may therefore be part of an initially silent cycle of building-up infectivity.

Zoo and exotic animals (not only bovids and cervids, but also fish, reptiles, birds and mammals including primates) may be culled for management purposes and included in rendered materials and therefore possibly end up in animal feed or human food chains. In

theory and practice carnivore species could be fed uncooked material from exotic species or native stock from within the zoo. Wild caught native species eg lagomorphs and culled deer, can be supplied to zoos as feed for carnivores. These various routes can provide a gateway for undetected conventional pathogens and novel agents, including the causative agent of BSE, to enter the animal and human food chains. For example, in the U.K. (and probably in other EU states) most animals in zoos (from invertebrates to primates) were exposed to foods potentially contaminated with the BSE agent. Bons *et al* (1999), ~~who~~ reported on PrP histopathological changes ~~t~~ in 18 apparently healthy and 2 symptomatic lemurs in three different French primate centres, all of which had been fed diets supplemented with beef protein product manufactured by a British company. Whether it was BSE, needs to be confirmed. In the same paper, Bons *et al* report that all 5 of 5 primates that were autopsied out of 14 primates that died between 1989 and 1998 in the Montpellier zoo (F) with signs of neurological disorder32, compatible with a spongiform encephalopathy.

It cannot be excluded that some, especially long-lived, species of zoo animals, are currently incubating TSE (e.g. as FSE in cheetahs and felids and BSE in primates), but the incubation period is unknown and probably is unique to each species (Kirkwood *et al*, 1995). Whether or not subclinical infection of the BSE, or some similar, agent can be transmitted vertically (or conceivably horizontally) within one or more zoo/exotic species is, as yet, unknown, but is a possibility. In addition, it is possible that further BSE-like diseases caused by unconventional agents and as yet undiscovered, exist in exotic species.

It should also be mentioned that zoo stock may be immunologically naive with respect to pathogens which they would normally expect to be exposed to in the wild and thus develop a degree of resistance. Such naive animals, exposed to pathogens brought in by new stock (not necessarily presenting with clinical signs) from either the wild or other collections where a disease is endemic, may, at the level of the individual, develop more severe disease. More significant however at the population level, the reproductive and transmission potential of the pathogen may be effectively increased in naive animals.

Captive breeding programmes involve movement of a wide range of species from one zoo/area to another. The risk of movement of endangered and potentially susceptible species from a high risk to a low risk BSE (or other infectious agent) area should be assessed. Recently, a lion at Edinburgh zoo died of FSE. Such an animal might normally expect to participate in inter-zoo breeding programmes. Given the possibilities outlined the previous paragraphs, such animals could be considered as a possible source of infection.

Notwithstanding current quarantine regulations, zoological collections present a risk which may require further investigation and evaluation.

5.8 Specific risks relating to Hunt Kennels

Fallen stock from Knackers Yards and animal (such as deer) culled for management purposes can be purchased by Hunt kennels for feeding to hounds. Usually raw meat and offal is fed to the hounds and this posses a serious risk for transmission of infectious agents. For example, it has been known for some time that Hunt Kennels can represent a particular focus for the maintenance of the dog tapeworm *Echinococcus granulosus*, the causative agent of human hydatid disease (Smyth 1977; Thomson, 1978). The natural

cycle of *E granulosus* involves, among others, lagomorphs, boar, sheep, cattle and deer as intermediate hosts. While not all pathogens may have such a broad host range *as E granulosus* (and the related *E multiocularis* which is widespread in continental Europe), this parasite demonstrates the potential for disease spread through use of fallen animals as a food source.

This is also shown by a survey of 20 foxhound packs in mid-Wales between 1983 and 1988 revealed that 129 of 874 hounds (20 packs) were infected by tapeworms. *Taenia hydatigena* was the most common (57 infected hounds) and *Echinococcus granulosus*, the agent of hudatid disease, the second most frequently found tapeworm. Of the 129 infected hounds examined, 88 were infected with tapeworms transmitted by sheep alone (*T. hydatigena*, *T. ovis*, *T. multiceps* and *E. granulosus* [ovine strain]). The species recovered for fox hounds were the same as those of farm dogs in the same area. The prevalence of these parasites resulted from the deliberate feeding of sheep carcasses to the hounds (Jones & Walker, 1992). The prevalence of cestode infection was lower than that recorded in an earlier survey (Edwards *et al*, 1979), but there is the possibility that the imposition of fees for disposal of carcasses under the Bovine Spongiform Encephalopathy (No. 2) Amendment Order 1990 may lead to more tapeworm infected carcasses being fed to hounds and farm dogs.

Foxes surveyed in the same area during the same period were infected mainly with cestodes which utilize logomorphs (*T. pisiformis*) or rodents (*T. polyacantha*) and intermediate hosts.

An assessment of the risk of transmission of conventional and non-conventional infectious agents by hounds and working dogs (eg sheep dogs) is justified. Such an assessment should include consideration of appropriate routes of disposal of hounds and working dogs.

5.9. Risks related to toxic substances in dead animals and condemned materials[33].

The risks resulting from the presence of toxic substances (such as xenobiotics including drugs, certain categories of feed additives and their break-down products) in dead animals and condemned materials and possibly intended for rendering, is a broad issue, which should also be looked at on a case by case basis.

The risk related to toxic substances will depend upon the toxic potential and concentration level of the substance itself and upon the possible inactivation or reduction of the activity and toxicity level during processing. In this context, acutely toxic substances are of special concern as well as persistent compounds and those with a potential to accumulate in the food/feed chain. Also, some animals that die may have been treated with drugs, and their tissues may consequently contain high levels of these or their metabolites. Also euthanasia products remain in the carcasses. It should be noted that many of them are thermostable[34]. Applying the rendering standard "133℃ /20'/3 bars" will not necessarily result in a significant reduction of the activity

[33] Although residues of veterinary drugs at the injection site is an important issue in the risk assessment of veterinary drugs used for food producing animals, this aspect is not being dealt with in this report.

[34] In the context of the present opinion, "thermostable" is defined as substances which are unlikely to undergo significant destruction under 500℃.

and/or concentration of undesirable or toxic compounds. Depending on the chemical structure, the process in principle could generate more toxic substances. For most toxic substances no information is available on their fate in the normal rendering procedure.

For most substances, the levels of concern are known. If it is possible to identify the presence of toxic substances in an animal and if the concentration or activity of the substance or its metabolite is below the maximum levels established by international standards and Community legislation (such as established maximum residue limits (MRL)[35] for animal drug residues) as a result of processing and/or dilution[36], the use of these animals or condemned materials should in principle not pose a risk.

However, it should be mentioned that in the case of animals that died as the result of a disease, the amount of residues or contaminants present in the cadaver can be variable and their nature is not always systematically identified. Moreover, there are (almost no) analyses which permit the verification of the level of contamination in a cadaver.

The concentration of these substances in processed products such as meat-and-bone meal or tallow are also often not known and/or have not been legally fixed in all countries. For meat-and-bone meal, these levels should be determined. On the other hand, meat-and-bone meal in most cases does not represent more then 5%-10% of the diet. Therefore, it may be reasonable to assume, for the time being, that the presently accepted MRLs that are valid for tissues used as a human food, are also valid for the resulting final products.

Studies need to be done to evaluate the scope of the possible risks resulting from the presence of toxic substances in raw material used for rendering, to determine the dilution/destruction factors resulting from the specific use of rendered materials and to assess whether MRLs need to be established for these products. Special attention should be_given to residues of antibiotics and their non-intended dispersion, in view of the risk for the development of resistance to antibiotics.

6. Risk reduction and residual risks resulting from rendering and from various ways of disposal of TSE infected material

Preamble:

a. The Working Group noted that, except for a few bovine-derived products (e.g., meat-and-bone meal, tallow and gelatine), little or no data on the inactivation of animal TSEs and based on trials with spiked material, are available. This significantly complicates any quantitative risk assessment and the determination of the limits of trustworthiness of its results. Moreover, the scope of existing methods for disposal or recycling (and of equipments and types of material) is so large, that it becomes almost impossible to carry out comprehensive risk assessments for each of them. As a result, the little available risk assessments for which the results are

[35] It should be clear whether these MRLs refer to the dry or non-dried product.

[36] For certain substances the presence of one contaminated animal in a whole batch may not pose a risk because of dilution. However, there may also be a concentration enrichment effect in certain fractions of the rendering outputs. (For example, substances which are highly lipophilic are likely to be concentrated in the fat fraction.

published, are in most cases estimated on the basis of assumptions which can not necessarily be extrapolated.

The Working Group collected the available (but limited) data on risk reduction and residual risks resulting from rendering and from various ways of disposal of TSE infected material. Readily available sources of information were: SSC (EC, 1998b, 1998g), DNV (1996, 1997a, 1997b, 1997c, 1997d), Grundon (1998), Linköping Biogass (1998), Schreuder et al (1998), Taylor et al (1997), Riedinger (1999a, 1999b). The Working Group acknowledges the complexity of the risk assessments described in several of these reports, which took 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., wind directions), site-specific features such as underground, soil, landscape, vicinity of habitations, etc.

In order to be able to compare the safety of various ways of recycling and disposal described in the sections hereafter, the Working Group needed to harmonise some of the previously listed published data, by reducing them to comparable batch sizes, number of sites of disposal, incidence rates of BSE cases, etc. In all cases, the input number of infected animals was converted to 4000-5000 (including heads), corresponding to the 1997 BSE cases in the UK (around 4000 animals) or to all OTMS cattle slaughtered in 1996 and having BSE infectivity (estimated to be around 5000 animals). This represents a total input of infectivity[37] of around $3x10^7$ cattle ID50s.

b. Note:

Throughout the next sections of the report, cattle oral ID's have been used. However, for some of the environmental risk assessments (like the DNV studies) some of the estimated exposure levels, like risk of exposure for workers at the site, and for inhalation, were made specifically for people taking the number of people potentially working in the vicinity into consideration etc. Therefore, the given cattle oral ID's are only indicative.

The Working Group points to the Report on The Possible Vertical Transmission of BSE, adopted by the SSC on 19.03.99, in which further scientific elements are provided on the sensitivity of bioassyas, species barrier, etc.

6.1. Risk reduction and residual risks resulting from rendering

Harmonised statistics on the exact numbers and quantities of condemned carcasses, fallen stock and dead animals used in rendering or disposed of by other methods, are difficult to compile as they are not fully harmonised over the various EU Member States. The figures are highly variable from country to country, are not necessarily inter- comparable and therefore can only be indicative.

The Working Group made an incomplete survey and collected data for Denmark, Sweden, Finland, the United Kingdom, the Netherlands, Germany and the EU as a

[37] On the assumption that an ifnected bovine contains approx. 7000 cattle oral ID50s.

whole. According to Coelenbier (1997), approximately 11.4% of the total raw material going into the rendering chain[38] of the 15 EU Member States consists of dead animals from farms, fallen stock and condemned materials. These dead or fallen animals are mainly cattle, ovines, caprines, pigs, horses and poultry. The percentage of raw material from fallen *cattle* and condemned *cattle* carcasses that enter the rendering chains (as a proportion of all animal species combined) in the various EU countries seems to be comprised in the range of 0-4% (preliminary estimate). According to P.Foxcroft[39], P.De Mulder Rendering, Doncaster, UK (1999, personal communication), out of all the animal by-products to be disposed of or processed to produce economically viable products within the EU (estimated at approx. 15 million tons per annum) less than approx. 20% originates from fallen, dead or condemned animals and tissues. (This does not include animals slaughtered under specific disease control measures such as the OTMS in the UK, but would include SRMs in countries where these are removed.)

However, care should be taken when using this average range as an input for the estimation of the potential infective load. In certain countries dedicated systems for the rendering of fallen stock may exist or rendering plants may receive occasionally high amounts of condemned materials (e.g., specified risk materials, mink with TME following an outbreak, ...). In such cases, the fraction of condemned materials or animals in a batch would be much higher than the above average range.

6.1.1. Risk reduction and residual risks related to to TSEs:

In its opinion on Meat-and-bone meal of 26-27 March 1998, the Scientific Steering Committee recommended a rendering standard of at least "133℃/20'/3 bars" or equivalent. This standard, as well as hazards and risks related to meat-and-bone meal is described in detail in the *Updated Report on the Safety of Meat- and-Bone Meal Derived from Mammalian Animals fed to Non-rumimant Food Producing Farm Animals*, adopted by the Scientific Steering Committee on 24-25 September 1998. According to this report, the TSE infectivity reduction realised during the "133℃/20'/3 bars" process is at least 10^3.

This standard is considered safe for inactivating the infectivity of the most heat-resistant conventional infectious agents, but this standard is not considered as completely safe for clearing TSE infected material, if the initial infection of the material is high.

Conclusions:

1. For the time being, it may be concluded that rendering according to the "133℃/20'3 bars" standard is not an acceptable way of completely clearing condemned materials, fallen stock or dead animals infected with TSE.

2. The Working Group supports the SSC opinions (EC, 1998b, 1998g) that the TSE infectivity reduction during rendering materials containing naturally BSE-

[38] including most slaughter offals and waste but excluding, for example, hides for tannery and gelatine, part of the bones used for gelatine and part of the fresh offals for pet food or for fur animals

[39] Letter of 12 April 1999 to the SSC secretariat.

infected brain tissue and carried out according to the "133℃/20'/3 bars" standard, is not less than 10^3 (EC, 1998b, 1998g).

3. However the Working Group notes that_that the TSE infectivity reduction factors during rendering of materials containing naturally scrapie-infected brain tissues mentioned in the scientific literature, vary largely (see also: Riedinger, 1999b) and therefore recommends that additional research is carried out under field conditions on TSE inactivation by various treatments, including the strict application of the "133℃/20'/3 bars" standard as defined in the present report.

   The Working Group, awaiting the results of such research, and taking into account the above mentioned Updated Scientific Report, the SSC confirms its opinion that that the TSE infectivity reduction during rendering carried out according to the "133℃/20'/3 bars" standard, is not less than 10^3.

Remark: Prof.Dr.Böhm and Dr.Riedinger, members of the Working Group, expressed their disagreement with the conclusion *that rendering according to the "133℃/203 bars" standard is not an acceptable way of completely clearing condemned materials, fallen stock or dead animals infected with TSE.* They consider that *(1) this standard, if the conditions indicated in the definition are strictly respected, especially in review of the literature results, would result in a reduction of the TSE infectivity by a factor of at least 10^6 and that (2) the resulting material after a batch cooking process, contains no residual TSE infectivity. This opinion will also be supported by the lack of genuine BSE-cases in such regions, where a proper and safe rendering was applied. This point of view must not be underestimated because there exist known pathways of TSE contaminated products in nearly all European countries.*

However, the other members of the WG do not share this view, for the reasons given in the *Updated Scientific Report on the safety of meat-and-bone meal derived from mammalian animals fed to non-ruminant food-producing farm animals* submitted to the Scientific Steering Committee at its meeting of 24-25 September 1998, and because it questions the method used to estimate the reduction factor of 10^6 (Taylor *et al*, 1998a).

6.1.2 Risks related to (conventional) infectious agents in fallen stock, dead animals and condemned materials

For what concerns rendering, the residual risk of a product could also result from the release in the environment of infectious agents or their toxins or by-products that were incompletely inactivated during the process.

Numerous conventional infectious agents can be present in fallen stock, dead animals and condemned materials. They can be inactivated by appropriate specific physical or chemical conditions which may vary according to the infectious agent.

When the exact cause of death or hazard present in the dead animal or product is known, the conditions of rendering or disposal could thus theoretically be chosen or adapted according to this cause or hazard. One might then imagine variable rendering conditions according to, for example, the exact type of infectious agent present in the raw material. Such would however not be realistic, as the hazards

present in the material offered to a rendering plant will change over time. It can most likely not be guaranteed that the material that will be processed in a given plant or chain of disposal, will never contain a risk which is higher than the accepted risk reduction capacity of the conditions set for a given plant.

In addition, it is not realistic to envisage a reliable systematic identification of the cause of death of fallen stock on a case-by-case basis, resulting in a sorting out of the collected animals according to the identified potential danger. During post-mortem inspections it is also not always possible to exactly identify the infectious agent at the origin of observed lesions.

Applying at least the "133℃/20'/3 bars" standard results in an extremely high safety margin for all conventional vegetative germs in heat – resistance class I (capable of survival up to approx. 80℃[40]) and sporeformers in heat – resistance class II (capable of survival up to approx. 100℃[40] are inactivated in safety. Dependent on the parameters of the inactivation kinetics of the pathogen, the safety ranges are reached of 75 - 100 million times the necessary heating time for inactivating germ concentrations observed under practical conditions.

For pathogens (including certain spores e.g. *Cl.botulinum, Cl.perfringens and Cl.tetanus*) in heat - resistance classes III (capable of surviving to approximately 130℃[40]) and IV (moist heat), it can be deduced that, by applying the "133℃/20'/3 bars" standard, up to 20 $\log_{10}$ of such extremely heat resistant conventional agents could be inactivated. (Also in this case the exact value depends upon the parameters of a pathogen's inactivation kinetics. This calculation is based on the survival range values, that means the temperature at which in one minute one $\log_{10}$ of activity will be inactivated. The maximum heat resistance data of sporeformers range to about 130℃ in their survival range values. Higher values can only be found under dry heat conditions.)

Conclusions:

-. As far as heat/pressure/time conditions are concerned, the Working Group considers that "133℃/20'/3 bars" (or equivalent), as defined in the present report, is the most appropriate to clear the infectivity resulting from all conventional micro-organisms listed in chapter 2 – Background (TSEs excluded).

-. When standards are proposed for rendering of fallen stock, dead animals or condemned 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.

Remarks:

[40] Figures given for comparison purposes. Time, pressure and moistent content of the inactivation are also important.

- This rendering standard should be applicable to all animal species, including to poultry and dead fish and condemned poultry or fish materials[41]. The cause of death is often unknown and 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.

  Alternative heat treatment systems, operating at conditions below "133℃ /20'/3 bars" or equivalent, are not able to inactivate highly heat-resistant micro-organisms (that could cause a disease in farm or domestic animals. However, because of the specificities of certain materials (e.g., from fish) and of the associated risks in terms of infectious agents and toxic substances, the standard could be revised for certain materials, should it appear that the new (validated) standard results in an equivalent safety.

- On the processing of animal blood[42]:

  It is recognised that is not always appropriate for blood[43] to be subjected to "133 ℃ /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 lower 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.

  Blood fit for human consumption (possible TSE infection and other epidemiological risks for farm animals excluded) could therefore be processed, *for example,* as follows (or equivalent validated conditions):

  - Preheating to 60–70℃.
  - Coagulation at 100℃ to 110℃ for 1-12 min
  - Decanter (separation of liquid phase)
  - Drying for 1–2 h at 120℃

  Blood with a relatively high epidemiological risk (Infectious diseases, condemned or spoiled blood etc.) should nevertheless be treated at least at "133 ℃/3 bar/20 min". This may be achieved by, *for example:*

  - by adding 5–10% of blood to raw material processed at least at 133℃ /3b /20 min in a rendering plant.
  - by steaming and treatment of the ready product (blood meal) at least at 133 ℃/3 bar/20 min.
  - or an validated equivalent process

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41 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..

42 It should be noted that this section does not cover other provisions related to the safety of blood, for example the cooling of the blood after its collection and the use of clean containers.

43 The working Group wishes to mention explicitly that human blood is not covered by this report 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.

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 (See section "Conclusions of the Working Group"). Referring to the SSC's opinion on the Safety of organic fertilizers of 24-25 September 1998 and referring to the section on burial in the present report, burial or dispersion of such blood over (agricultural or other) land cannot be considered as a safe way of disposal.

- The Working Group is aware that the rendering or disposal of dead fish may cause technical problems, for example when large quantities of this material need to be transported from a coastal area to a rendering or disposal plant. In such cases, an appropriate risk assessment should be carried out before deciding upon possible alternatives for rendering or alternatives within the range of the available ways of disposal.

6.1.3. Risk reduction and residual risks related to toxic substances and their release in the environment:

The residual risk of a product could further result from toxic substances which were not (sufficiently) degraded, whose concentration was insufficiently reduced or diluted or which were (newly) formed during the process. The question needs also to be addressed what (additional) amounts of toxic substances are possibly introduced by rendering of fallen stock, dead animals and condemned carcasses.

Data concerning average composition of rendered raw materials and resulting products in (German) rendering plants and for a group of UK rendering and fat melting plants are summarised in **Table 1a and Table 1b** hereafter.

Reliable figures on toxic substances based on statistically representative samples and using appropriate (sensitive) methods, are not always available. Klein (1997) made a review of data and analysis results available for German rendering plants. He looked into the contamination of animal meals and into the emissions from rendering plants in waste water and air.

Table 1a: average composition of rendered raw materials and resulting products(ATV M 710, 1997)

Material/Amount		Protein		Mineral		FAT		WATER	
	1. kg	%	kg	%	kg	%	kg	%	kg
CARCASSES	**1.000**	**15**	**149**	**4**	**38**	**12**	**118**	**68**	**683**
MBM	240	62	149	16	38	12	29	5	12
FAT	90	0	0	0	0	99	89	1	1
CONDENSED VAPOR	670	0	0	0	0	0	0	100	670
SLAUGHTERING WASTES	**1000**	**9**	**90**	**2**	**20**	**14**	**137**	**74**	**739**
MBM	150	60	90	13	20	12	18	5	8
FAT	120	0	0	0	0	99	119	1	1

CONDENSED VAPOR	730	0	0	0	0	0	0	100	730

Table 1b: average composition of rendered raw materials and resulting products for a UK rendering and fat melting plants[44]

Raw material	% MBM	% Fat	% Water
Carcasses	25	30	62
Slaughter offals	15	10	73
Bones	45	12	45
mixed butchery waste	25	13	45

Regarding the contamination of *animal meal*, his findings can be summarised as follows:

- The levels of heavy metal in the products of carcass rendering is not a risk. All recorded levels of Pb, As, Cd and Hg are (far) below the accepted maximum levels as specified in scientific opinions, legislation and recommendations by international bodies. The results indicate that the animal meal industry's products do not increase the heavy metal burden on humans, animals or the environment.

- This seems also to be the case for many conventional contaminants such as coplanar PCBs, Dieldrin and DDT and for the total of HCH isomers both in the meal and in the fat fractions and of total Toxaphen in the fat fraction. (However it must be mentioned here that the available results are fractionally and often based on a small number of samples and therefore may not be representative).

- In 1993, contamination of animal meal with antimicrobial compounds was not detectable in 38 out of 39 samples from 15 plants, using an inhibition test with little sensitivity. However, despite today's availability of high sensitivity analysis methods, there is still no or little data available on antimicrobial compounds in animal meal. Presently, only speculations are possible on (the risks resulting from) recycling of antibiotics, some of which are persistent in animal carcasses. Therefore analyses with highly sensitive tests, are necessary, taking into account the relative bio-availability of the compounds. The development of antibiotic resistance is an undisputed fact where therapeutic or slightly sub-therapeutic concentrations are present; there is, however, controversy over selection and the development of resistance at low concentrations. As a precaution, therefore, antibiotic residues in rendering products should be regarded as a "risk".

- Even assuming that the pharmacologically active substances of products for euthanasia will not endanger animals receiving animal meal at the recommended daily quantity, they are present in virtually their full quantities in

[44] Prosper De Mulder Company data (Doncaster, UK). Derived from around 1 million whole cattle carcasses under the UK's Over Thirty Months Scheme (Source: Foxcroft, P., letter of 12.04.99 to the SSC secretariat).

rendering plants. It is not known to what extent these substances are broken down during processing.

R. Böhm (1996, in: Klein, 1997) published data on *wastewater* from carcass rendering plants in Germany, including feedwater concentrations. Apart from a number of technical problems caused by nutrient compositions and the low degradability of many natural components, absorbable organic halogen compounds (AOX) were also found. According to Böhm Several state-of-the-technique methods of wastewater treatment proved to be effective. Biological treatment of waste water in rendering plants results generally in AOX below the threshold value (0,1 µg/1) and in no fish-toxicity upon 1:1 dilution and is therefore not of ecotoxicological concern.

Klein (1997) further considers that emissions into the *air* do not present a risk to humans, animals or the environment if appropriate emission-reduction measures are taken. Concerning the emission into air several methods may be used in order to reduce them below acceptable levels (VDI/DIN, 1995). State-of-the-technique biofilters proved to be effective (Fetzner and Roht, 1995, Sabo *et al*, 1994). Emissions of pathogens via steam into the air can then be excluded, because the water vapour generally passes a cyclone or a particle separator and have to be condensed prior air treatment.

However, is not yet clear what potential risk to the environment there is from veterinary drug residues, in particular of antimicrobial compounds. Generally, the only significant route for antimicrobial compounds into rendering plants is by animals killed after unsuccessful treatment. But there is a high degree of dilution via untreated raw material and this would significantly reduce the concentration. An alternative means of disposal (incineration) should in any event be provided in case of an epidemic resulting in many unsuccessfully treated animals. Incineration of individual animals treated with antimicrobial compounds and which succumbed or were killed before the pharmacologically active substances were eliminated from the body, should also be recommended as a precautionary measure because the issue of selection and the development of resistance at low concentrations is still not clarified.

The contribution that animal rendering plants make to the redispersion of pollutants and pharmacologically active substances, as part of recycling seems thus to be extremely small for most substances hitherto studied, provided effective effluent treatment and emission-reduction equipment is installed. However, this conclusion is applicable only assuming a high dilution in the MBM production. Unsuccessful mass treatment with veterinary drugs may lead to substantial risks.

<u>Remarks:</u>

- The importance of the above issues has recently been highlighted by the recent discovery of dioxines (early 1999), first in eggs, then in young poultry. These dead animals were considered as "fallen stock". If improperly diagnosed, their possible recycling as an animal feed could have resulted in further building up

of increasing concentrations of the toxic substance in animals fed with products derived from them.

- The Working Group stresses the need for the availability of data on the presence of toxic substances in rendered materials, waste water and air emissions, that are based on statistically representative samples and sensitive detection methods. While a biological analysis of the introduced substances is to be preferred to a very extensive chemical monitoring process, a suitable set of parameters should further be developed based on recent research results in ecotoxicology.

- The Working Group considers that it would be appropriate to know the stability of the different drugs (including their breakdown products) and feed or food additives (including for example antibiotics, antioxidants, coccidiostatics, growth promotors, conserving agents, etc.) to rendering treatment ("133℃/20'/3 bars"). The expected noxiousness of these (breakdown) products needs also to be known. It is recommended that this information is taken into account in the application dossiers for the registration of these compounds. Drugs resistant to heat treatment would indeed be concentrated several times during rendering, because of the elimination of the water. Incineration would then be the most appropriate way of disposal, but would not be necessary if a drug is sensible to the rendering treatment.

  However, the Working Group points at the fact that it may not be realistic to envisage a reliable systematic identification on a case-by-case basis of the type and level of toxic substances in dead animals or condemned materials, resulting in a sorting out of the collected animals according to the identified potential danger.

Conclusions:

1. With respect to residual risks related to toxic substances, from the few data available it seems that for general environmental contaminants (like heavy metals or persistent organic compounds) the levels in the products after rendering are below acceptable levels. Furthermore, for most pharmacologically active substances applied to single animals, a high degree of dilution via untreated raw material can be expected and this would significantly reduce the concentration. The contribution that animal rendering plants make to the redispersion of pollutants and pharmacologically active substances, as part of recycling is extremely small for most substances hitherto studied and rendering may, therefore, be considered as an adequate process except for the situation mentioned below.

2 For the time being, rendering according to the "133℃/20'/3bars" standard can not be considered as an acceptable way of clearing fallen stock, dead animals and condemned materials containing therapeutic concentrations of

thermoresistant antimicrobial substances or pharmacological products used for euthanasia, especially in situations where an epidemic results in many unsuccessfully treated animals and no dilution must be assumed. In such situations, incineration of these animals is recommended as a precautionary measure.

However, the working group recognises that in certain cases the available disposal capacity within a region or country could be a limiting factor (for example if hundreds of thousands or millions of animals need to be incinerated or if the transport of unfeasible large quantities of a material to the disposal plant proved to be impractical or would result in an even higher risk). Controlled landfill (following an appropriate risk assessment - see also sections 6.3 and 6.4) could then be considered as an alternative.

3. For many toxic substances actual data on their fate in rendering are lacking. Due to the diversity of the compounds under consideration, no general conclusion on risk reduction during the rendering process can be drawn. However, for heat labile substances, a substantial degradation may be expected. The working group therefore recommends that research should be done on the presence of toxic substances in rendered materials and on their stability to rendering ("133℃/20'/3bars").

6.1.4 Other possible risks

The Working Group considers that materials from, for example, casualties (where the cause of injury is supported by necropsy data) and fresh slaughter offal fit for human consumption[45] but not intended for human consumption, represent an increasing risk if not handled and stored like a (future) food product. Such material may quickly become spoiled and turn into high risk material, for example as a result of inappropriate storage, insufficient protection against contamination during handling and transport, etc. The (presence of an) infectious agent can then also not be easily/rapidly identified.

6.2. Risk reduction and residual risks through environmental pathways resulting from burial

a. Buried organic material is normally decomposed by microbial activity. It has the potential to pollute groundwater depending on the hydrogeological conditions at the burial site (soil permeability, groundwater table). When infected carcasses or materials are buried there is an *additional* risk of dispersion into the ground or the groundwater of pathogens that resist to decomposition. It has for example been shown that Anthrax spores may survive for years, sometimes even for more than 100 years.

[45] It may be noted that materials fit for human consumption does not automatically imply that these materials do not contain any pathogens which could harm certain animal species.

b. Regarding TSE infected material, little or no information is available on the behaviour (including potential accumulation over years) of the TSE-agent in the soil, the ground water or the surface water nor on the inactivation of TSE infectivity by external conditions such as atmospheric conditions, microbiological activity, ploughing, washing of by rain or irrigation, etc. Based on Brown & Gajdusek, (1991), landfill and burial may be assumed to have a reduction factor of 98% (i.e. a factor of 50) over 3 years. CJD-infected brain-tissue remained infectious after storing at room-temperature for 22 months (Tateishi et al, 1988). Scrapie agent is known to remain viable after at least 30 months of desiccation (Wilson et al, 1950), and pastures that had been grazed by scrapie-infected sheep still appeared to be contaminated with scapie agent three years after they were last occupied by sheep (Palsson, 1979). Results from experiments by Rubinstein *et al* (1998) suggest that mites may serve as a vector and/or reservoir for the infectious scrapie agent. A (remote?) risk may thus exist that TSE infectivity would enter TSE-resistant species (e.g. mites) and by that create a potential source for future outbreaks.

c. In relation to undesirable or toxic substances:

Although experimental data are not available it may be assumed that significant parts of contaminants present upon burial persist over longer periods of time in the decaying carcasses. Also here there is thus an additional risk of dispersion into the ground or the groundwater of toxic substances that resist decomposition.

d. Conclusion:

Land burial of all animals and materials must normally be excluded[46]. It is indeed not possible to assess if, and after which period, the environment in which infected or contaminated material was buried, could be safe. Sea/water burial is also unacceptable; because of the risks of dispersion of the infected material and the unknowns related to this way of disposal of TSE infectivity.

In certain epidemic situations, a careful risk analysis may indicate, that burial may be an acceptable alternative regarding prevention of transmission of certain diseases. However, the practice should only be accepted in extreme situations and only after other and safer ways of disposal have been considered and excluded on the basis of a risk assessment.

6.3. Risk reduction and residual risks through environmental pathways resulting from controlled landfill

a. Regarding conventional infectious agents and toxic substances, the same principles apply to any organic material put into landfill: it is normally decomposed by microbial activity and it has the potential to pollute groundwater depending on the hydrogeological conditions at the landfill site (soil permeability, groundwater

[46] In some very special cases, burial may be the only option for disposal, for example: a few individual animals on an island where weather conditions prevent other ways of disposal and/or where the risks related to temporary storage and transport of a infected carcass would largely exceed the risks of careful burying.

table). For both landfill and burial sites the principal risks of dispersal of risk materials are leachate (Gas (for volatiles) wind blown dust and vermin) as well as the dispersion into the environment (ground, groundwater, air) of toxic substances or of micro-organisms that resist to decomposition. Setting hazardous materials in a solid matrix, e.g. cement will reduce all of these processes in the short-term but will also reduce the degradation rate of the hazardous materials.[47]

However, it should be noted that progressively much organic material appears to be fixed in landfills and that there exist parallels with coal formation from decaying plant matter. Most likely, the risks can be kept under control if the landfills are well contained and if adequate measures are taken to avoid access to birds, rats, rabbits, etc., and to minimise potential wind dispersal.

b. With respect to BSE, the risks of using *uncontrolled* landfill to dispose of "high-risk" materials are in theory very much comparable to the risks that go along with burial (e.g., long-term survival of the agent, leachate, dispersion in the environment, etc.).

Controlled landfill (where the leachate is controlled and there is no exposure to drinking water supplies) has been the subject of an assessment carried out by DNV Technica on behalf of the UK Environment Agency (DNV, 1997d). This risk-assessment was based upon examination of the circumstances prevailing at a number of land-fill sites within the UK where carcasses of BSE-infected cattle had been buried responsibly and under supervision. Especially the influence of different landfill sites was evaluated in order to analyse the risk for the environment as well as humans and animals. The "highest individual risk" (as *estimated* in cattle ID_{50} per year) was estimated to be around $3x10^{-6}$ to $1x10^{-7}$ depending on the specific site[48]. The total infectivity potentially escaping from the site is around 50 cattle ID_{50} per year. The infected material itself is thus likely to last for many years at the site.

According to the DNV assumptions and calculations (DNV, 1997d) and with respect to *actual and short-term BSE* risk to human health by environmental routes, controlled landfill, especially using contained sites, seems to have a safety level comparable to rendering and the controlled landfill process in itself seems to be acceptable. However, *the long term and indirect risks* (e.g., long-term survival of BSE-like agents in the environment, the possibility of them escaping from land-fill sites in leachates) have so far not been fully evaluated.

c. Conclusions

Because of the possible and not yet fully evaluated long term and indirect risks, it is advisable to prohibit the use of landfilling/burial of untreated actually or potentially TSE infected ruminant material. In these situations, it is advisable to use of either high temperature incineration or a process involving rendering followed by burning

[47] A process not covered by the report is entombment a dry deep "burial" process widely used for radioactive substances.

[48] This assumes cumulative risk from regular exposure.

of the MBM or alternatively, alkaline treatment of the MBM followed by "encapsulation" and controlled landfill (see below).

More generally, and given also the risks associated with pollution by the materials in decomposition and with conventional infectious agents, the following material should not be disposed of by landfill: fallen stock, dead animals or other materials that were condemned or carry the risk of TSEs, unconventional diseases, long-term surviving or resistant (conventional) infectious agents (e.g., forming spores) or exposure to / contamination with unacceptable levels of persistent toxic substances.

On the other hand, for certain conventional infectious agents (with a limited longevity in time) and certain toxic waste there is appropriate controlled landfill technology available and animals or materials which can be safely rendered (see corresponding section) could then subsequently be safely disposed of in controlled landfills.

For exceptional reasons (e.g., catastrophies, large epidemics, ...) landfill of the condemned cadavers or materials may be imposed. Whether or not the leachate is contained and the exposure of any drinking water supplies are key risk factors. Sites selected for controlled landfill should therefore (a) be selected on the basis of an appropriate and specific risk assessment, (b) be at an appropriately safe distance from water courses used as drinking water, unless their design reliably prevents the escape of any leachate, and (c) presently[49] not be the subject of consideration for any future (re-) development. In addition, the material should if possible and indicated (e.g., infectious agents) first go through an appropriate risk reduction process.

6.4. An alternative landfill method for disposing of potentially TSE-infected material: alkaline treatment of the MBM followed by "encapsulation" and controlled landfill

A company has recently released plans for potentially establishing an alternative way of disposal of MBM from the OTMS and a preliminary analysis of the potential risks involved have been performed by WRc (Grundon, 1998). The planned method involves rendering of the OTMS cattle into MBM and then, instead of burning, mixing the MBM with lime, with Air Pollution Control Residues (APC, i.e. highly alkaline residues from the scrubbing units of municipal waste incinerators), with water and with cement (to encapsulate the material). The pH of the mixed materials is above 12. The end product is a damp mix of small particles[50] which are put into monofill cells with a capacity of up to 250.000m3. The material solidifies ("encapsulates" or becomes concrete) within a few days. Each cell can be referred to as an "encapsulated monofill cell".

The initial water content of the mixture (MBM + water + lime + cement) is approximately 25%. The pH of this mixture is approx.12, corresponding to a 0.01 N

[49] It is recognised that most landfills will eventually be developed for various purposes though the timing and nature of the development may vary according to the corresponding risks.

[50] In the Grundon experiments, the particle sizes of the MBM were smaller then 0.1 mm. In an operational stage, also MBM with a particle size of 50mm may be used. It is expected that such would result in a more stable solidified product.

NaOH solution. Following Brown *et al* (1986), the effect of the equivalent pH with NaOH on scrapie infectivity reduction would be 1 $\log_{10}$ after a 60 minutes of exposure.

According to the Grundon report, the combined reduction factor of the rendering and alkaline treatment should be regarded to be at least 3.8 logs and potentially more. (Grundon uses 2.8 $\log_{10}$. reduction for rendering and 1 $\log_{10}$ for the alkaline treatment). Based on the data in the Grundon report, the highest individual risk (at site) was estimated to be $3x10^{-6}$ cattle oral ID_{50} per year and the highest risk for the public to less than 10^{-7} ID_{50} per year. The total amount of infectivity released in the air from the site was estimated to be 3 ID_{50} per year. Based on a comparison with the DNV (1997b) report on burning rendered products in power stations, the total amount of infectivity potentially released during the process of handling the rendered MBM could be anticipated to be around 300 ID_{50}s per year[51] (mainly effluents from the process area). Primary workers at the site could inhale a total annual amount around $3x10^{-1}$ (cattle oral) ID_{50}.

Comments from the Working Group:

a. The working group has had to assume that the above described alkaline treatment provides reasonable penetration of tissue and animal derived material such as MBM.

b. For this particular treatment, results from trials with spiked material are missing. One could nevertheless expect that the lime treatment (pH=12) would probably contribute to a reduction of TSE infectivity due to the alkaline denaturation of proteins (including prions) in the materials (which is not the case under normal landfill conditions). In addition, the solidification of the material would prevent the material to a large extent from dispersion in the environment via the air or via leachate.

According to Brown *et al* (1986), the alkaline effect with NaOH and a pH=12 on the reduction of scrapie infectivity, would be 1 $\log_{10}$ after a 60 minutes of exposure. A weak base as ammonia was as effective as 0.01 M NaOH at destroying TSE infectivity.

In the SSC's opinion of 26-27 March 1998 (EC, 1998a) on the Safety of gelatine the infectivity reduction resulting from the alkaline treatment (45 days) was estimated at $10^{2,3.}$ (INVERESK, 1998,a,b). However, in the present process the lime conditions apply to a drying mixture with an initial water content of approx. 25%, where the water is linked as hydrated silicates and alluminates (see further), followed by solidification and may therefore be less effective than processes which

[51] The value of 30 is not taken from the GRUNDON report, but is based on an estimate derived from the DNV power station study, which estimates the release from the handling of MBM to be in that order of magnitude. It is anticipated, that handling of the same amount of MBM containing the same amount of infectivity would release approximately the same amount of infectivity whether the handling was for burning (in power stations) or for alkali treatment and "encapsulation".

apply to an alkaline (water) liquid phase[52]. The infectivity reduction by the alkaline treatment may therefore be less than 1 $\log_{10}$.

In its opinion on the Safety of gelatine, the SSC further stated that the infectivity reductions of two successive production processes were not necessarily additive. But in this specific procedure, there is a combination of a physical (rendering) and a chemical (lime) treatment, which are processes of a different nature and are therefore more likely to be additive.

For the above reasons, the WG therefore agrees that that the infectivity reduction of both processes combined is likely to be higher than with rendering alone, but probably less than the sum of rendering plus 1 $\log_{10}$ from the alkaline treatment (higher than 3 $\log_{10}$ but less than 4 $\log_{10}$).

c. An additional safety results from the "encapsulation". The technology of "encapsulation" has been extensively used in the USA, be it for other purposes. A key issue seems to be the long-term effectiveness of the "encapsulation", which needs to be addressed.

Regarding the use of cement-based materials for disposing of hazardeous materials, the following comments can further be made:

Cement based materials have been used to solidify/stabilise (S/S) inorganic wastes for many years (Freeman 1988). Perhaps the best known use is for dealing with radioactive waste. In ascertaining the appropriateness of S/S, three stages need to be evaluated:

i) The chemical and physical nature of the stablilisation process.

This occurs at high PH (typically PH 12) during which water in the waste, or which is added, reacts with the cement to form hydrated silicates and aluminates which bear a net negative charge. Sometimes a preadsorbent is introduced, eg activated carbon to enhance the adsorption of the waste components (Caldwell et al 1991).

ii) The extent of the solidification achieved and the porosity of the matrix.

A major influence on this is the amount of liquid to solid and the nature of the waste being entrapped. Some wastes appear to inhibit the S/S process. (Pollard et al 1991)

iii) The effect of the storage environment on the leachability of the entrapped waste material.

In principle, any sustained factor such as physical pressure, acidity and/or microbial friction (eg by Thiobacilli) can result in slow but progressive leaching of waste components.

[52] The Working Group suggests the testing of a procedure whereby "fresh" slaughter residues or waste would undergo an alkaline treatment under pressure, such as for example the one described in the SSC opinion of 22-23 October 1998 on the Safety of Hydrolysed Proteins.

Cement based stabilisation and solidification has gained fairly widespread acceptance as a means of disposing of those toxic metals which form water insoluble oxides or hydroxides. This is because the alkali environment of the cement matrix favours the formation and maintenance of the oxide (hydroxide) form. S/S is also used for stabilising toxic residues in drilling muds, incinerator fly ash and bottom ash and contaminated soil. (Razzell 1990).

It is estimated that even prior to 1990 and over the past few years in the USA over 1000 major S/S projects are claimed to have been completed satisfactorily (Conner et al 1992). Such projects have since become more common and there is no reliable estimate of their number. In Europe use of S/S is less common and also less controlled.

Although rather less research has been carried out in the area, it also appears to be suitable for a range of non polar low volatility organic materials, eg oily substances. Often an adsorbent is added during the cementation process, eg active carbon to enhance the bonding of the organic residues (Caldwell et al 1991). The USEPA has set an upper limit of 1% on the hazardous organic content of wastes for solidification. It has also introduced a number of leachability and other tests to ensure the integrity of the S/S process (see Koe 1993). Subject to these criteria, toxic organic wastes may be disposed of using S/S.

Although S/S potentially has application to biological wastes, eg microbial pathogens, there is very little published literature on the subject. The high PH of the cementation process is likely to be damaging to many micro-organisms and other biological materials (NB the UK Anthrax Acts from the 1800's recommended carcasses which could not be incinerated should be burried in pits of lime). More research is needed before S/S could be recommended for the safe disposal of wastes containing micro-organisms or prions.

Conclusions:

1. The Working Group considers that this treatment may be an acceptable alternative for disposal of *potentially* TSE infected materials from high or low risk areas, provided *actually infected material or material suspected of being so, are excluded and* provided any sites selected for this purpose are (a) selected on the basis of a comprehensive and appropriate risk assessment, (b) at an appropriately safe distance from water courses used as drinking water, unless their design reliably prevents the escape of any leachate, and (c) presently[49] not be the subject of consideration for any future (re-)development. Given these required precautions, alkaline treatment of the MBM followed by "encapsulation" and controlled landfill should not become a standard procedure. In addition, the long-term stability of the encapsulated material needs to be ascertained.

2. Industry and research institutes are encouraged to start experiments with infected material, to quantify the infectivity reduction of the above described alkaline treatment of the MBM followed by "encapsulation".

6.5. Risk reduction and residual risks through environmental pathways resulting from (licensed) direct incineration of carcasses

a. It is generally accepted that high temperature oxidative technologies are the most effective methods for destroying all organic material including all the conventional infectious agents listed in the background to this report as well as the toxic organic compounds. There are high temperature incineration technologies available and in use to destroy toxic waste, e.g. at 1200℃ with highly efficient filtering systems to reduce emissions, e.g. of chlorinated dioxins. The most effective process is oxidation in a plasma at temperatures up to 1600℃ which results in melted ashes (plasmox-technology).

However, for economical reasons these are not feasible for disposal of the material discussed in this report.

b. With respect to TSEs, it is generally assumed that incineration is a completely effective method for destroying TSE-like agents. However, there is no direct evidence for this. The dry heat experiments described in the literature[53] may not be completely relevant to incineration because exposure to dry heat does not involve oxidative combustion, as occurs during incineration. As a preliminary to considering the possibility of using the oxidative combustion that would occur in power-stations (at temperatures>1,000℃) as a means of disposing of potentially BSE-infected meat and bone meal and tallow, studies on protein destruction at high temperatures were carried out, and a risk assessment was prepared. This concluded that people were subjected to a negligible risk via the resulting environmental pathways. However, incinerators designed for the disposal of animal carcasses operate at lower temperatures (750-850℃). A further risk-assessment carried out by DNV (DNV, 1997c) has shown that even this process appears to carry a negligible risk as far as the human population is concerned. Especially the influence of flue gas scrubbing units were evaluated in order to analyse the risk for the environment as well as humans and animals. It is mentioned, that for the safety of this process, it is important to have a primary and a secondary combustion chamber assuring that all material is submitted to combustion at a temperature of equal to or more than 850℃ for at least 2 seconds. Also, it is important to have a water-spray gas scrubbing unit removing particles from the flue gas, that the water from the scrubbing unit is re-circulated, and that this water as well as sludge from it,

[53] It has been suggested that the effectiveness of incineration for TSE agents should perhaps be questioned because a residual amount of scrapie infectivity was shown to survive exposure to dry heat at 360℃ for 60 minutes (Brown et al, 1990). However, the suspension of infected brain-tissue used in this study had been lyophilised, and it is known that it becomes more difficult to inactivate scrapie-infected brain-tissue by heat after it has been dried (Asher et al, 1986; 1987). SRM awaiting incineration could not possibly dry to anything like the extent that occurred in the lyophilised tissue used in the heating experiment. Therefore, dry-heat data generated from other experiments, using 5mg samples of scrapie-infected brain-tissue, are probably more useful in predicting the effectiveness of incineration. In these experiments, there was no detectable infectivity after an exposure at 200℃ for 60 minutes, but residual infectivity was detectable after a 20 minute exposure. The rate of destruction of scrapie agent by dry heat increases progressively as the temperature is increased up to 200℃ (Taylor et al, 1996). However, Steele *et al* (1999) have shown some survival of hamster-passaged scrapie agent and mouse-passaged BSE agent after exposure to dry heat at 200℃ for an hour. It is assumed that when one uses temperatures above 750℃, the destruction time will be exceedingly short. However, the possibility that incineration might not be completely effective is clearly being considered. For example, after incinerating materials that could be TSE-infected, the USDA soaks the resulting ash in sodium hydroxide for two weeks before disposal.

eventually is incinerated on site. Rain water and process water from the incinerator area should be incinerated and ash from BSE or potentially BSE infected bovines are removed to a controlled landfill.

The reduction factor used in the study is $5x10^4$ (DNV Technica, 1997)[54]. The "highest individual risk" (as measured in cattle ID50s per year) was estimated to be around $6x10^{-9}$ (most risk from spillage and through effluents) and the risk from inhalation of flue gas estimated to around $2x10^{-9}$. The total calculated infectivity (cattle IDs) released from incineration of such 5000 (see preamble) infected cattle is 3000 (mainly in effluents). The infectivity left in the ashes can be calculated to be 3000 IDs.

It should be mentioned that the amount of infectivity released can be minimised by appropriate effluent treatment and that the amount of infectivity in ashes is not due to combustion products, but due to estimated failure of operation (estimated to be 0.2% of the running time) in these incinerators where there is not a system in place to re-incinerate ashes/residues which retain a high organic content. The effluents and can thus be retained in efficient systems and be removed (incinerated) and the residues can be deposited into a controlled landfill.

c. <u>In relation to toxic substances:</u>

With respects to toxic substances, the elimination of toxic substances and the reduction of risks in the residues depends on combustion temperature, duration, secondary combustion chamber and emission control technology. Also with respect to toxic substances, it is generally assumed that incineration is a completely effective method for destroying most organic compounds. However, it has to be recognized that there may be exceptions and (heavy) metals can not be destroyed. It further needs to be mentioned that (potentially toxic) organic substances can be created as the effluent gas cools.

d. <u>Conclusions</u>

According to the DNV study (DNV, 1997c), and with respect to TSE agents, incineration may be considered as a safe way of disposal, if conditions equivalent to the following ones are respected: a primary and a secondary combustion chamber assure that all material is submitted to combustion at a temperature equal to or above 850C for at least 2 seconds; the equipment includes an efficient water-spray gas scrubbing unit removing particles from the flue gas; the water from the scrubbing unit is re-circulated; this water as well as sludge from it, is eventually incinerated on site. (Rain water and process water from the incinerator area should

[54] It should be noted that the reduction factor of 5×10^4 resulted from considering both normal and abnormal operations. The reduction factor in normal operation was taken to be 10^6 as proposed by SEAC, but it was assumed to be only 10^2 for 0.2% of the time due to plant upset conditions. (Note: The tests on protein content showed about an 8000 reduction, based on total amino acid. However, some amino acids present in prion protein could not be detected. This suggested that the prion would no longer be intact. For this reason, SEAC proposed that the overall reduction factor for infectivity would be 10^6 or more.).

also be incinerated and ash from BSE or potentially BSE infected bovines should be disposed of in a controlled way e.g., controlled landfill).

The above described incineration is considered to be also safe for the disposal of materials infected with conventional infectious agents.

With respect to toxic substances, incineration is considered an effective method for destroying most organic compounds. However, because there may be exceptions and because (heavy) metals can not be destroyed (a relative concentration in the ashes may occur), an effective effluent treatment is necessary to avoid dispersion of these remaining substances into the environment.

Delays before incineration should be minimized as much as possible, because they may create additional risks (rotting of the material, dispersion in the environement, ...).

6.6. Risk reduction and residual risks through environmental pathways resulting from disposal by (licensed) burning as fuel of rendered materials

a. Regarding the risks related to TSEs, an evaluation study of "Risks from burning rendered products from the over the thirty month scheme in power stations" is available from DNV (1997b). For the power stations, as compared to the animal carcass incinerators, two factors are different, first, the temperature is higher in the power station burners (approximately 1000℃) and also, the scrubbing units (electrostatic units) in power stations are highly efficient in removing particles from the flue gas (retain around 99.7%). Retained particles, sludge from effluent treatments as well as ashes from potentially TSE infected animals are deposited in controlled landfill.

The reduction factor used in the DNV study (1997b) is 106 for the burning process[55] and 50 for the rendering[56]. The "highest individual risk" (as measured in cattle ID50s per year) was estimated to be around $3x10^{-10}$.

The total calculated infectivity (cattle IDs) released from the power stations from burning MBM from the 5000 infected cattle is only 300 (mainly in effluents, and can thus be retained in efficient systems and thus removed), and the infectivity left in the ashes can be calculated to be 400 IDs (deposited into a controlled landfill). It should be mentioned that the amount of infectivity released can be minimised by appropriate effluent treatment and that the amount of infectivity in ashes is not due to combustion products, but due to estimated failure of operation.

Remark: It should be noted that the estimated safety given above is for the power station part, that means, that the reduction in infectivity by initial rendering

[55] The risk reduction of 10^6 for burning in power stations can not be directly compared with the value $5x10^4$ for incineration given in the previous chapter, because in the power station study experiments were performed and in the incineration study the risk reduction was estimated, including assumptions of potential failures etc.

[56] The reduction factor proposed by the SSC in its opinion of 26-27 March 1998 on the safety of meat-and-bone meal is 10^3.

is included, but the environmental and human exposure impacts of the rendering itself is not included.

b. It can be accepted that burning under conditions equivalent to the above described ones, is a completely effective method for destroying all the conventional infectious agents listed in the Background to this report.

c. In relation to toxic substances:

With respects to toxic substances, the elimination of toxic substances and the reduction of risks in the residues depends on the temperature, duration, and emission control technology. Also with respect to toxic substances, it is generally assumed that burning is a completely effective method for destroying most organic compounds. However, it has to be recognized that there may be exceptions and (heavy) metals can not be destroyed.

e. Conclusions:

The burning *process* as such may be considered as a completely effective method for destroying all the conventional infectious agents listed in the Background to this report, as well as most undersirable or toxic substances except metals.

Based on the DNV study (DNV, 1997b) the *process* of burning MBM in power stations, respecting features equivalent to the ones described above, is considered to be a safe method also for disposal of material potentially containing TSE agent.

However, it should be mentioned, that a major part of the residual risk is due to the handling of the material. This goes along with a potential worker risk because of the additional risks associated with the handling and rendering of the raw material and with the fuel loading systems which are [mostly] unsophisticated compared with many specialised incinerators. Burning should therefore be considered as less safe than incineration.

Delays before burning should be minimized as much as possible, because they may create additional risks (rotting of the material, dispersion in the environement, ...).

e. Remarks:

- It may be argued that direct incineration may not be safer than rendering followed by burning (incineration) of the rendered product provided the rendering and the burning facility is located in the same physical plant. However, in the direct incineration process the material is only handled once while in the rendering/burning process, the material is handled more than once and furthermore, an intermediate product (MBM) is produced and may leak or be removed from the site. But burning may indeed be of equal - or even higher - safety if the rendering is a pre-condition process for combustion with the burning being carried out within the same unit and without handling which would cause additonal risks.

- The Working Group did not assess the safety of burning non-rendered products in power stations. It should be noted, that usually the loading system to a power station is less sophisticated than in animal carcass incinerators, and thus, the risk

of handling non-rendered material may be higher. Also, burning of non rendered raw material may result in relatively high contents of infectivity in the residues, if there is a malfunction.

- The Working Group also did not assess the safety of burning rendered materials as (an additional) fuel for the production of cement and the resulting ash (possibly) being used in the production of cement. The ashes, potentially containing significant amounts of TSE infectious material (estimated to be around 400 ID_{50}s) could get into direct contact with humans and animals. In the current report deposition of such ashes into controlled landfill is recommend. Additional data are needed if a specific risk assessment should be done. The industry is invited to provide the SSC with the necessary elements to carry out such risk assessment.

6.7. Risk reduction and residual risks resulting from composting

a. Background: Composting is an aerobic-thermophilic biotechnological process in which organic material is metabolised. The process runs in three phases. First phase is a mesophilic (20℃ – 40℃) metabolization of organic nutrients followed by a thermophilic (50℃ – 80℃) phase and a final cooling down phase leading to a stabile (ripe) product. The process may be carried out in windrows or in specially designed technical equipment like ventilated containers, rotating drums or fermentation chambers. Combinations of first a technical intensive composting step followed by final composting in windrows are common. Since the surface of windrows generally has a lower temperature than the center of the pile, regular turning of material is necessary for hygenization and metabolisation of the total material and to keep the process aerobic and thereby (a) reduce odour and (b) destroy aromatic compounds. Different organic materials are metabolised by the involved microorganisms with different velocity **Table 2** gives a survey.

The successive steps in the composting process are not highly defined but on the contrary highly variable. It is therefore difficult to predict what will happen in any given batch of raw material submitted to composting. The temperature ranges also imply that inactivation of micro-organisms is only possible up to a certain extend.

With regard to Entercocci which may be representative for relatively heat resistant vegetative bacteria generally not more than 5 log steps are inactivated by this process. Further it must be taken into account that windrows have to be turned at least one time in order to assure that the whole material had been exposed to the thermophilic process because the surface of the piles show a lower temperature than the center. In technical composting equipment (drums, containers etc.) an even distribution of the temperature is not always given too.

Table 2: Approximate ranking of the relative speed of microbial degradation of different materials in the composting process (in decreasing order)

No	Material	Speed of degradation

1.	Lignin	(+)
2.	Cellulose, hemicellulose and chitin	++
3.	Nucleic acids, purins and pyrimidins	++
4.	Fats and lipids	++
5.	Aromatic and aliphatic carbohydrates	++
6.	Polymeric carbohydrates: Starch and pectin	AAA
7.	Proteins and peptids	AAA
8.	Urea	AAA

(+)=very slow +=slow ++=rapid AAA=very rapid
(The speed of microbiological degradation depends upon, amongst others, the temperature and moisture conditions, the specific enzymatic activity, the exact type of material, the type of composting process, etc., and can take from less than a week so several months)

Not all viruses are inactivated by composting. For example, Urlings *et al* (1993) concluded that that fermentation of the Chicken Anaemia Virus (CAV) viraemic tissue did not affect the inactivation of CAV.

The thermal inactivation of TSE-agents during composting is not to be expected. No information is available concerning microbial or enzymatic degradation of the PrP^{Sc} during composting.

Finally, a major issue which needs to be addressed is the potential for airborne dispersal of material. However, this may appear to be a difficult exercise as (Böhm, 1999) approximately 10^3-10^4 CFU in 1 gram of material are needed to find 1 CFU in 1 m^3 of air.

b. No data could be found concerning the inactivation of TSE-agents in the composting process. The available data concerning tenacity in soil are indicating that no or slow inactivation rates have to be taken into account. Since the microbial metabolic activity in the normal soil is low compared to composting, further investigations are necessary.

c. <u>In relation to toxic substances</u>:

Non persistent organic substances are degraded to a large extent upon composting. Micro-organisms are able to adapt to practically any toxic substance and to metabolise it, in many cases, to less toxic compounds. However, the rate of metabolism may be very low. Moreover, few chemical substances are metabolized to even more toxic compounds. For a controlled degradation of substances, a selection of specialized microorganism has to take place. Such processes have been used to clean up soils contaminated with specific toxic substances (bioremediation). With respect to composting, no data is available concerning the inactivation of the vast majority of toxic organic substances. Also little or no data are available for the residues of any medicinal products in fallen stock. Composting may be rather slow for the degradation of toxic organic substances and it may not be suitable to handle large volumes in a short time. Therefore, a case by case evaluation is necessary to decide if a specific organic toxic compound may be detoxified by composting.

Antimicrobial compounds are of special concern in this respect and metals are not degradable.

d. Conclusions

Composting cannot be recommended as method for discarding animal wastes and related material. Moreover it must be taken into account that the biotechnological process itself may be strongly influenced by external factors[57] and generally gives a limited safety concerning the inactivation of pathogens. Generally it must be noted that processing of dead animals or parts of them is forbidden in most EU member states.

6.8. Risk reduction and residual risks through environmental pathways resulting from disposal by anaerobic treatment (for the production of bio-gas).

a. Background: Anaerobic microbial metabolization of organic material[58] results in a formation of mainly methane and carbon dioxide. Low amounts at hydrogen, ammonia and H2S are produced too. The process in principle runs over four steps namely hydrolysis, acidification, acetogenesis and methanogenesis. The fermenter is kept at a certain temperature, generally it has to be differentiated between a mesophilic anaerobic fermentation in a temperature range between 35℃ and 40℃ and the thermophilic anaerobic process running at temperature between 50℃ and 55℃. Biogas reactors may be operated in a continuos, semi-continuous or batch process. In the batch operation the exposure time is limited to 20-24 h. In a two-step biogas plant mesophilic and thermophilic reactors may be combined as well as continuos and batch operation. In order to achieve sufficient hygienization (pasteurization) of the material anaerobic reactors are often combined with a thermal pasteurisation device or the solids are composted after separation of the liquid phase.

b. Inactivation of pathogens in a mesophilic anaerobic process is very slow and generally limited according to the metabolic properties (aerobic/anaerobic) of the involved microorganisms and their heat resistant class. The D-value (T_{90}) for most vegetative bacteria is between one day and one week, thus the exposure time in the batch modus which is limited due to technological reasons to 24 h is too short for an sufficient inactivation of 5 log steps. A continuous or semi-continuous mode of operation must be totally excluded from this point of view.

In a thermophilic process this period of time (22-24 h) in a batch is sufficient to inactivate several vegetative pathogens such as Salmonella. The D-value (T_{90}) for most of those organisms is between 0,5 h and 4 h at 55℃. The microbiological content of ready material from bio-gas plants is listed in **Table 3.**

[57] It may be noted that biofilters are generally accepted to be a much more effective approach than simple composting because the conditions can be much better controlled.

[58] It may be noted that this process is not fundamentally different from the processes taking place in a landfill.

Table 3: Bacterial counts in the final products (effluents) from bio-gas reactors. (Sample result, Böhm, 1999, personal communication)

Type of fermenter	Total bacterial count	Enterococci	Enterobacteriaceae
mesophilic	10^6 - 10^7 cfu/g	10^4 - 10^5 cfu/g	10^2 - 10^4 cfu/g
thermophilic	10^5 - 10^6 cfu/g	10^2 - 10^4 cfu/g	10^1 - 10^3 cfu/g
mesophilic + thermophilic	10^5 - 10^6 cfu/g	10^1 - 10^3 cfu/g	0 - 10 cfu/g

cfu = colony forming units

Heat inactivation of TSE-agents is not possible neither in mesophilic nor in thermophilic biogas reactors. No information is available concerning microbial or enzymatic degradation of PrP as well as concerning undesirable or toxic substances.

c. No data are available concerning inactivation of TSE agents during anaerobic treatment of organic wastes, neither in a mesophilic nor in the thermophilic process.

d. In relation to toxic substances:

Microorganisms are able to adapt to practically any toxic substance and to metabolize it, in many cases, to less toxic compounds. However, few chemical substances are metabolized to even more toxic compounds. For a controlled degradation of substances, a selection of specialized microorganism has to take place. Such processes have been used to clean up soils contaminated with specific toxic substances (bioremediation). Degradation of toxic substances is usually less efficient under anaerobic than under oxide oxidative conditions. With respect to anaerobic treatment, no data is available concerning the inactivation of the vast majority of toxic organic substances. Anaerobic treatment may be rather slow for the degradation of toxic organic substances and it may not be suitable to handle large volumes in a short time. Also there are no data on those toxic substances which may pose an elevated risk in the materials to be disposed of. Therefore the risk of the residual sludge is not known. Finally, it should be noted that chemicals may also cause damage to the microorganisms on which the biogas production depends thereby terminating their degradation of organics. Therefore, a case by case evaluation is necessary to decide if a specific organic toxic compound may be detoxified by composting. Antimicrobial compounds are of special concern in this respect and metals are not degradable.

e. Conclusions:

This process as such is not recommended for disposal of animal waste (dead animals and related materials of animal origin). However, after heat treatment of such materials at "133℃/20 min/3 bars", it may be used in the anaerobic process for the production of bioenergy in a relatively economical way if the risk of TSE infection or contamination is excluded.

With respect to toxic substances, including heavy metals, a case by case evaluation is necessary to decide if a specific organic toxic compound may be detoxified by anaerobic treatment.

7. General conclusions from the working group

In addition to the conclusions alerady formulated in the previous sections, the WG presents the following more general conclusions:

a. From its risk assessment, the working group concludes that the sequence in terms of risk reduction or minimised residual risk resulting from the rendering or disposal of fallen stock, dead animals or condemned materials possibly contaminated with non conventional transmissible agents, infectious agents or other hazards such as toxic substances, is as follows (in decreasing order of safety):

For disposal:

- direct incineration of carcasses
- Burning of rendered products in power stations[59]
- rendering at "133℃/20'/3 bars" followed by liming and "encapsulation" and controlled landfill (good effluent treatment systems should be present)
- rendering at "133℃/20'/3 bars" followed by controlled landfill, especially at controlled sites (good effluent treatment systems should be present);

For recycling:

- rendering at "133℃/20'/3 bars" followed by anaerobic treatment for the production of bio-gas (good effluent treatment systems should be present);
- rendering at "133℃/20'/3 bars" followed by composting after previous rendering (good effluent treatment systems should be present);
- either rendering at "133℃/20'/3 bars (good effluent treatment systems should be present), or:
- other processing of the material into derived products such as gelatine, tallow, dicalcium phosphate, hydrolysed proteins, organic fertilisers, etc., provided strict sourcing, processing and end-use conditions are respected, as defined in the various opinions of the SSC on the safety of these products.

The Working Group recognises that for certain diseases (including animals killed and recycled or disposed of as a measure to control notifiable diseases, but excluding TSEs), the available rendering or disposal capacity within a region or country could be a limiting factor in the control of a disease. Thus if thousands or millions of animals need to be rendered after killing or if the transport of unfeasible large quantities of a material to a rendering or disposal plant proved to be

[59] 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, etc. However, they may be of equal - or even more - safety if the rendering is a pre-condition process for combustion with the burning being carried out within the same unit and without handling which would cause additional risks

impractical, then an appropriate risk assessment should be carried out before deciding upon the most appropriate way of disposal or rendering[60].

b. Regarding rendering, the Working Group supports the SSC opinions (EC, 1998b, 1998g) that the TSE infectivity reduction during rendering materials containing naturally BSE-infected brain tissue and carried out according to the "133℃/20'/3 bars" standard, is not less than 10^3.

The SSC stated in its opinion of 27-28 March 1998 on the safety of meat-and-bone meal, that the TSE infectivity reduction during rendering carried out according to the "133℃/20'/3 bars" standard, is not less than 10^3. Taking into account (i) the Opinion on the Safety of Meat-and-Bone Meal adopted by the SSC at its meeting of 27-28 March 1998 (ii) the additional information collected during the course of the preparation of the present report and opinion and (iii) an inventory prepared for the Working Group by Riedinger (1999b), the working group notes that the range of BSE infectivity reduction factors mentioned in the literature and in various BSE risk assessment studies, varies from $10^{1.7}$ to more than $10^{8.8}$.

The working group therefore recommends that additional research is carried out on TSE inactivation by various treatments under field conditions, including the strict application of the "133℃/20'/3 bars" standard as defined in the section "Definitions"[61]. Awaiting the results of such research, and taking into account the above mentioned Updated Scientific Report, the Working Group confirms the SSC opinion that that the TSE infectivity reduction during rendering carried out according to the "133℃/20'/3 bars" standard, is not less than 10^3 in regard to scrapie and BSE agents.

Such research would also need to address questions like: What level of infectivity titre reduction 10^x would be deemed to be (absolutely) safe? How could a 10^x ID_{50} infective spike (natural BSE, nautral scrapie) be obtained? Which one? If the strain were nota field (natural) strain, how would the results be interpreted? How and where should such validation work be done?

b. With respect to conventional infectious agents, the Working Group 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 "133℃/20'/3 bars" standard (or validated equivalent) is the most appropriate for inactivating the infectivity of the most heat-resistant conventional infectious agents.

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60 In the risk assessment the following should also be taken into account: 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 very slow anaerobic decomposition due to the lack of microbial activity and water thus, if ever still present after proper rendering, the remaining prions will be preserved for a long time. This means that when material is going into a landfill that was not treated at at least 133℃/20'/3 bars this risk is higher than that from properly rendered material running through a biogas plant. In addition, even on a controlled landfill living vectors (rats, mice, birds) may be present.

61 And including on the heat penetration phase and the possible post-sterilisation process.

This rendering standard is applicable to all animal species, including dead poultry and fish (materials)[62]. Their cause of death is often unknown and also 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 it appear that the new standard - after validation - result in an equivalent safety.

c. The working group considers that the following processes are not acceptable ways for the recycling or disposal of fallen stock, dead animals or condemned materials:

- 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)
- Burning under open air conditions, because of the risks associated with the burning process itself (incomplete burning) and with the incapacity to control the emissions (see the relevant section on burning).

d. Actually TSE infected or suspected animals or materials should be disposed of only by either incineration or burning after previous rendering.

Animals or materials that carry a high risk of TSE infection, for example animals killed in the framework of eradication schemes should be disposed of by burning after previous rendering, incineration or rendering followed by liming and "encapsulation".

- Actually TSE infected or suspected animals or materials include, for example (non exhaustive list): 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. Residues from TSE infected rendered materials.

  Potentially infected animals include, for example (non exhaustive list): healthy looking animals killed in the framework of disease control schemes (e.g., the Over-Thirty-Months-Scheme in the UK), zoo and exotic animals, test and laboratory animals (unless otherwise stated in the report); specified risk materials from animals fit for human consumption; felines in high BSE risk countries.

However, if for any exceptional reason (e.g., catastrophies, large epidemics, ...) landfill is nevertheless applied the material should if possible first go through an appropriate infectivity reduction process. Any sites selected for this purpose should a) be at an appropriately safe distance from water courses used as drinking water,

[62] 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..

unless their design reliably prevents the escape of any leachate, and b) not be the subject of consideration for any future (re-) development.

Initial rendering of infected raw material is indicated to reduce the risks if storage of the material is necessary before final incineration.

e. Regarding ruminants, pigs, poultry, wild, zoo- and exotic animals, laboratory and test animals, cats, hunt kennel hounds, blood, etc. the Working Group refers to the relevant sections of the report, where its concerns regarding conventional and unconventional diseases and toxic substances are explained.

f. Regarding fur animals, the Working Group recognises that 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.

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 (which presently seems to be the case in certain countries), (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 potentially being TSE infected.

Although a complete sterilisation at "133℃/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 risks resulting from recycling fur animal carcasses into feed products for other animals is minimised if the rendering process complies with the "133℃/20'/3 bars" 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.

g. For materials possibly contaminated with toxic substances:

Most organic chemicals can be destroyed by adequate heat treatment. Therefore, one might expect that in principle, the same ways of recycling or disposing as outlined above can be used if the material is possibly contaminated with toxic substances.

For materials possibly contaminated with hazardous concentrations of toxic substances, a risk reduction by rendering is only exceptionally known and risk reduction upon composting occurs only for non-persistent substances, so that the above sequence is not necessarily applicable. Also, (further) information needs to be developed on the fate of toxic substances[63] in the rendering process and upon

[63] Including also veterinary drugs and feed additives

composting. Therefore, the decision whether recycling or disposal will be applied and on the way it has to be done, needs to be decided on a case by case basis, depending on the nature of the chemical under consideration. With respect to heavy metals, the Working Group recommends that analytical data be collected permitting to compare their concentration in rendered or incinerated (burned) animal waste with concentrations in organic and anorganic fertilisers.

For disposal of material likely to contain hazardous concentrations of toxic substances, the following processes can be recommended (in decreasing order of safety):

– direct incineration of carcasses (see definition below)
– burning in power stations
– controlled landfill.

h. A large variety of equipment for disposal (incineration, burning) or rendering exists. Recommending one single technical standard considered being the safe one is impossible and probably not justifiable and also beyond the scope of the mandate of the Working Group. It therefore limits itself to list in annex 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[64].

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Annex: Listing of a number of possible standards for recycling or disposal of animal waste, derived from the documentation which was available to the working group.

for rendering:

at least "133℃/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 and Scientific Opinion on the Safety of Meat-and-Bone Meal Derived from Mammalian Animals fed to Non-rumimant Food Producing Farm Animals, adopted by the Scientific Steering Committee on 24-25 September 1998.

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℃; 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℃ 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 Working Group 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

Appendix C

Extract of the CWTC contact

F20 RETENTION OF AND DEDOCTION FROM OPERATION FEE

F20.1 If the Contractor shall be in breach of any of the provisions of the Contract with regard to the operation (including collection and transport services) and maintenance of the Facilities, the Employer's Representative shall have the power at any time to order the Contractor to rectify the said breach within a reasonable time. All such orders shall be in writing and shall state the time within which the breach shall be remedied.

F20.2 If the Contractor shall fail to rectify the breach within the time notified by the Employer's Representative pursuant to sub-clause 1 of this Clause, the Employer may retain the whole or any part of any one or more instalments of the Operation Fee. The Employer shall be entitled to deduct from any sums retained in accordance with the provisions of this sub-clause any loss, expense, costs or damages whether incurred by the Employer in rectifying or attempting to rectify or otherwise arising from the breach notified by the Employer's Representative in accordance with sub-clause 1 of this Clause.

F20.3 The balance, if any, of the sums recained after any deduction made in accordance with the provisions of sub-clause 2 of this Clause shall be paid to the Contractor after the breach has been rectified satisfactorily but the Contractor shall have no entitlement to interest on such balance.

F20.4 In the particular case of compliance with pollution control limits, although no direct expenditure may be incurred bythe Employer in the event of failure by the Contractor to meet any of the specified pollution control limits, the Employer will nevertheless be entitled to deduct and retain amounts from the Operation Fee which shall be deemed to be alloted to compliance with the said limits. 25% of the Operation Fee shall be deemed to be alloted to compliance with pollution control limits. It is agreed that deductions pursuant to this sub-clause will not constitute penalties but will reflect amounts agreed in respect of compliance with environmental requirements, to which the Contractor shall not be entitled, and which may therefore be retained, if those requirements are not met.

Deductions may be made by the Employer from the monthly Operation Fee (for each month concerned) in respect of exceedences as defined in the Specification in accordance with the following table:

Exceedences	Deductions
More than 10 and not exceeding 15 per month	5% of the monthly Operation Fee
More than 15 and not exceeding 25 per month	10% of the monthly Operation Fee
More than 25 and not exceeding 40 per month	15% of the monthly Operation Fee
More than 40 per month	25% of the monthly Operation Fee

Exceedence of the same limit for 2 consecutive months would count as 2 exceedences in the 2nd month, and for 3 months, 3 exceedences in the 3rd month and so on.

Notwithstanding the provisions of sub-clause 1 of this Clause, the Employer may make deductions pursuant to this sub-clause without the Employer's Representative giving notice to rectify the breach but the Employer's Representative shall notify the Contractor in writing specifying the number of exceedences for which deduction is made within 14 days of deduction being made.

F20.5 The provisions of this Clause shall be without prejudice to any other rights or remedies of the Employer and to any powers of the Employer's Representative.

F21 CONTINGENCY PROVISIONS

Without limiting the Contractor's obligations and responsibilities under the other provisions of the Contract, the Contractor shall provide from time to time all practicable temporary arrangements and contingency provisions necessary to maintain the services specified in or to be inferred from the Contract during the overhaul, renewal or breakdown and subsequent repair of any Plant.