



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Scientific Steering Committee

OPINION ON
SIX ALTERNATIVE METHODS FOR SAFE DISPOSAL
OF ANIMAL BY-PRODUCTS

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE

AT ITS MEETING OF

10-11 APRIL 2003

OPINION

MANDATE

The Scientific Steering Committee (SSC) was invited to evaluate 6 alternative methods for safe disposal of animal by-products submitted for approval in the framework of the Regulation (EC° N° 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption). The six submissions are:

1. High pressure high temperature hydrolysis. Applicant: Biosphere Refinery corporation.
2. High pressure hydrolysis biogas process. Applicant: ATZ - EVUS, Entwicklungszentrum für Verfahrenstechnik.
3. Biodiesel Production. Applicant: Saria Bio-Industries GmbH & CO KG.
4. “The Brookes gasification system for the safe disposal of animal tissues/carcasses that might be contaminated with BSE/TSE’s.” Applicant: Valley Industrial Supplies Ltd.
5. Combustion of Tallow in a thermal boiler. Applicant: E.F.P.R.A. (European Fat Processors and Renderers Association).
6. Bio-Reducer. Applicant: D.J. Westron / Reading Agriculture Consultants.

The SSC is grateful to the members of the Working Group and the rapporteurs that prepared the attached evaluation reports (Annexes 1-6): Prof.Dr.J.Bridges chairperson), Prof.Dr.W.Klein (co-chairperson), Prof.Dr.Em.E.Vanbelle, Prof.Dr.R.Böhm, Dr.DVM B.Urlings and Dr.R.Somerville. The SSC also gratefully acknowledges the support provided by the Joint Research Centre and the scientific contributions from Dr.C.Von Holst (Joint Research Centre). Their report was submitted to the TSE/BSE *ad hoc* Group at its meeting of 27 March 2003, discussed and amended prior to its submission to the SSC.

METHOD AND SCOPE OF THE OPINION

1. The evaluations were carried out according to the framework for the assessment of the risk from different options for the safe disposal or use of meat and bone meal, proposed on 28-29 June 2001 by the Scientific Steering Committee.
2. The evaluations hereafter only cover the assessment of risks directly resulting from the possible presence of microbiological agents (including TSEs for this purpose). The evaluations do not address other risks possibly associated with the treatment of animal waste. In addition to the contaminated materials, processes may involve substances with other risks to human health, animal health and the environment. There may for example be by-products of the treatment and toxic substances present or formed during the process resulting in, airborne emissions (for example, dioxins); toxic effluents or residues (for example, heavy metals). It is understood that the assessment of such risks is covered by other frameworks or scientific opinions and/or by European and/or national legislation for the authorisation of waste recycling or disposal plants.
3. When the opinion or attached reports refer to the “133°C/20’/3 bars” sterilisation standard, it refers to the process conditions as described in the SSC opinion of 24-25 June 1999 on animal waste disposal and recycling¹ and here attached as an **Annex 7**.
4. When the text refers to “Category 1, 2 or 3” materials, it refers to animal by-products as defined in **Annex 8**.
5. The evaluations hereafter do not address neither the hygienic framework for running the plant under practical conditions. This must be fixed by the competent authorities and the responsible for running the plant must identify critical control points.

¹ Scientific Opinion on The risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials. Adopted By the Scientific Steering Committee at its meeting of 24-25 June 1999 and re-edited at its meeting of 22-23 July 1999.

OPINION

The SSC concludes as follows with regard to the 6 submitted alternative methods for safe disposal of animal by-products. The details are provided in the attached reports, which were prepared by a special working group established for this purpose.

1. High pressure high temperature hydrolysis.

The system is considered to permit safe processing of Category 2 and 3 materials. It is of course assumed that the other organisational and construction related requirements are respected and that the competent national authorities are involved in approval and supervision.

Regarding the treatment of Category 1 (especially TSE agent) materials, the SSC considers that the current dossier does not clearly show efficient reduction of BSE infectivity. The results of the TSE infectivity clearance study, which is currently being undertaken, are needed to assess the capacity of the system to safely process TSE-contaminated materials.

To permit a correct assessment of the safety of the process with regard to TSE agent, the SSC recommends that the following additional information is provided:

- Results of TSE infectivity clearance experiments under practical conditions in a technical or semi-technical reactors (HDH and biogas reactor) carried out with the appropriate TSE – agent;
- Details on the process (preferably including a flow diagram), for example: stirring of the material (type stirrer and frequency), minimal real exposure time in the HDH – reactor, temperature at which the anaerobic reactor is run, chemical and microbial analysis of the condensed liquid phase², storage, handling and transport of the raw materials, cleaning and disinfecting of the equipment on the unclean side both routinely and at cases of technical disturbances.

2. High pressure hydrolysis biogas process.

The system is considered to permit safe processing of Category 2 and 3 materials. It is of course assumed that the other organisational and construction related requirements are respected and that the competent national authorities are involved in approval and supervision.

Regarding the treatment of Category 1 (especially TSE agent) materials, the SSC considers that the current dossier does not clearly show efficient reduction of BSE infectivity. The results of a TSE infectivity clearance study are needed to assess the capacity of the system to safely process TSE-contaminated materials.

To permit a correct assessment of the safety of the process with regard to TSE agent, the SSC recommends that the following additional information is provided:

- Results of TSE infectivity clearance experiments under practical conditions in a technical or semi - technical reactors (HDH and biogas reactor) carried out with the appropriate TSE – agent;
- Details on the process (preferably including a flow diagram), for example: stirring of the material (type stirrer and frequency), minimal real exposure time in the HDH – reactor, temperature at which the anaerobic reactor is run, chemical and microbial analysis of the liquid phase, particulate and microbial analysis of the purified gas (filtration of 1 m³), cleaning and disinfecting of the equipment on the unclean side both routinely and at cases of technical disturbances.

3. Biodiesel Production.

The SSC considers the process as a sound approach but considers that the submitted dossier do not clearly show efficient reduction of BSE infectivity by the means of the proposed technique based on transesterification. The dossier does not show evidence that the high reduction of the BSE infectivity by a factor of 10²¹ to 10²² , claimed by the submitter, can be obtained with this process.

² Micro-organisms might start growing on the substrate and this may affect its quality for certain uses, e.g., in irrigation.

- For animal fats from Category 1 materials: Since the document is lacking the proof that the assumed BSE infectivity reduction can be obtained and, based on the current documents, the technique for processing of fat from category 1 can thus not be considered as fully safe with respect to TSE agents. However, this recommendation should be reappraised if a bio-assay or equivalent reliable and precise laboratory analytical data demonstrated the capability of the process to reduce efficiently BSE infectivity.
- For animal fats from Category 2 materials: The processing of this material is considered to be safe provided that the animal fat has been treated at 133 °C/20 min/3bar prior to being used for the production of biodiesel. Fat produced in rendering plants where the fat is removed *prior* to the subsequent pressure sterilization should be considered to possibly pose a risk if used for the production of biodiesel.
- For animal fats from Category 3 materials: The process is considered to be safe.

4. The Brookes gasification system for the safe disposal of animal tissues/carcasses that might be contaminated with BSE/TSE's.

In principle the Brookes Gasification System may be an appropriate method for the safe destruction of animal waste that might contain BSE/TSE's. However the company to support this conclusion has provided minimal data. In the absence of such supporting data the Brookes Gasification System cannot (yet) be considered safe for the treatment of such Category 1 wastes. However, the system can be considered safe for the treatment of Category 2 and 3 wastes.

5. Combustion of tallow in a thermal boiler.

If the tallow was pre-treated by sterilisation at “133°C/20’/3 bars’ or equivalent the process is considered suitable for disposing of Category 2 and Category 3 waste materials. In the absence of such pre-treatment, the process is currently only considered suitable for disposing of Category 3 waste materials.

The process might have (and probably has) the capacity to safely dispose of Category 2 and 1 animal waste (and totally clear TSE infectivity if present in Category 1

materials), but the applicant's report does not provide enough evidence (firm data) supporting this claim. In addition, precisions are required on a number of process conditions to permit the assessment of a number critical points, for example: how the particles are generated around the nosl, the (statistical) spread of the particle size around the average of 20 μ (some particles may be not burned at all during the very short residence time of 0,2 seconds), etc. These data should be provided as the results of measurements, not only as average figures or estimates.

For the process to be possibly considered as sufficiently efficacious to clear also Category 1 and/or 2 materials, the following additional information is needed:

- An description (preferably with flow diagram) of the overall process and it's various steps, including on how the particles are generated; the pre-treatment, storage, transport, loading, etc of the raw material; the emission controls of the process; the treatment of residual wastes; etc.
- Measured data and additional information along the lines indicated in the above report should be collected and provided by accredited laboratories.

Should this information permit to conclude that the process is safe for disposing of category 1 waste material, than it will also be safe for category 2 and 3 material.

6. Bio-Reducer.

This system is not an alternative method as such for safe disposal of animal by products. It concerns a procedure to store by-products in a contained environment, awaiting further processing and/or disposal and without decontaminating the material. The SSC considers that it is not the appropriate instance to comment on the corresponding technicalities. It signals nevertheless that the submitted dossier is insufficient with regard to major information related to (1) the biological processes that can occur within the vessel after filling of the vessel with biological active materials and (2) the control measures that are possibly needed to control this part of the biological process.

ANNEX 1:

HIGH PRESSURE HIGH TEMPERATURE HYDROLYSIS

APPLICANT: BIOSPHERE REFINERY CORPORATION

Summary conclusion of the Working Group of the SSC³

PRELIMINARY REMARKS:

1. The evaluation hereafter only covers the assessment of risks directly resulting from the possible presence of microbiological agents (including TSEs for this purpose). This evaluation does not address other risks possibly associated with the treatment of animal waste. In addition to the contaminated materials, processes may involve substances with other risks to human health, animal health and the environment. There may for example be by-products of the treatment and toxic substances present or formed during the process resulting in, airborne emissions (for example, dioxins); toxic effluents or residues (for example, heavy metals). It is understood that the assessment of such risks is covered by other frameworks or scientific opinions and/or by European and/or national legislation for the authorisation of waste recycling or disposal plants.
2. When the text refers to the “133°C/20’/3 bars” sterilisation standard, it refers to the process conditions as described in the SSC opinion of 24-25 June 1999 on animal waste disposal and recycling⁴.
3. The evaluation hereafter does not address the hygienic framework for running the plant under practical conditions. This must be decided by the competent authorities and those responsible for running the plant must identify critical control points.

SUMMARY DESCRIPTION OF THE PROCESS

The process is designed in order to process whole animal carcasses, meat and bone meal, food processing wastes, other compostable materials, paper and comparable materials as well as cereal straws alone or in combination. The material shall be treated at 180 °C at 12 bar for 40 min, heated by indirect steam application to the biolytic reactor. In the dehydration cycle the steam water is condensed and may be used for other purposes or may be discarded. It is planned to build it as a modular system with two reactors run in a batch mode alternatively, each cycle for one reactor will last 4h. It is estimated that about

³ The Working Group met on 31 January and 10 March 2003.

⁴ Scientific Opinion on The risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials. Adopted By the Scientific Steering Committee at its meeting of 24-25 June 1999 and re-edited at its meeting of 22-23 July 1999.

20,000 Mg (t) of raw materials may be processed per year with an output of 6,000 to 10,000 Mg (t) per year.

GENERAL CONCLUSIONS:

The general conclusions hereafter follow the format given in the framework for the assessment of the risk from different options for the safe disposal or use of meat and bone meal adopted by the Scientific Steering Committee at its meeting of 28-29 June 2001.

1. Identification of the risk category/categories of the materials for which the proposed process is claimed to be suitable.

The process is claimed to be suitable for Category 1, 2 and 3 waste materials.

2. Identification and characterisation of the risk agents possibly present and targeted to be cleared by the proposed process; the materials involved; the possible means for their transmission and potential 'at risk' groups.

All microbiological agents, including TSE agents, as they may be present in any animal by-product and animal waste, including materials that would pose a TSE risk.

Since it is a closed vessel system only the liquid and solid products have to be regarded from the epidemiological point of view. The following risks from residual infectivity possibly present in the materials have to be regarded here:

- Transmission via process water (liquid phase) orally to man and/or animals via products after agricultural irrigation or during utilization as non potable water in technical processes via contact or introduction in the environment via wastewater.
- Transmission of an agent to people, animals or the environment would thus result by the products used as organic fertilizers or for soil amendment due transmission via food or feed as well as by contact during handling.

3. The risk reduction achieved by the particular process; specifications on how this risk reduction level has been measured or estimated.

The working group considers that there is enough evidence that the process would safely clear all microbiological agents, except possibly TSE for the following reasons.

- The proposed procedure ensures a thermal treatment at a higher pressure than 3 bar , at a higher temperature than 133 °C and at a longer exposure time than 30 min in a batch process.
- According to Appel et al, 2001, moist heat of 170 °C applied for 20 min will theoretically result in a 5 log reduction of 263 K prion rods in a water/fat emulsion, roughly extrapolated to an exposure time of 40 min at 180 °C or even higher at least a 10 log reduction could theoretically be supposed.

CONCLUSIONS :

The system is considered to permit safe processing of Category 2 and 3 materials. It is of course assumed that the other organisational and construction related requirements are respected and that the competent national authorities are involved in approval and supervision.

Regarding the treatment of Category 1 (especially TSE agent) materials, the working group considers that the current dossier does not clearly show efficient reduction of BSE infectivity. The results of the TSE infectivity clearance study, which is currently being undertaken, are needed to assess the capacity of the system to safely process TSE-contaminated materials.

RECOMMENDATIONS:

To permit a correct assessment of the safety of the process with regard to TSE agent, the working group recommends that the following additional information is provided:

- Results of TSE infectivity clearance experiments under practical conditions in a technical or semi - technical reactors (HDH and biogas reactor) carried out with the appropriate TSE – agent;
- Details on the process (preferably including a flow diagram), for example: stirring of the material (type stirrer and frequency), minimal real exposure time in the HDH – reactor, temperature at which the anaerobic reactor is run, chemical and microbial analysis of the condensed liquid phase⁵, storage, handling and transport of the raw materials, cleaning and disinfecting of the equipment on the unclean side both routinely and at cases of technical disturbances.

REFERENCE

Appel, Th. R., Wolff, M., von Rheinbaben, F., Heinzl, M. and Riesner, D. : Heat stability of prion rods and recombinant prion protein in water, lipid and lipid-water mixtures. *J. Gen. Virol.* 82 : 456 – 473.

⁵ Micro-organisms might start growing on the substrate and this may affect its quality for certain uses, e.g., in irrigation.

ANNEX 2:

HIGH PRESSURE HYDROLYSIS BIOGAS PROCESS

**APPLICANT: ATZ - EVUS, ENTWICKLUNGSZENTRUM FÜR VERFAHRENSTECHNIK,
FEDERAL REPUBLIC OF GERMANY**

Summary conclusion of the Working Group of the SSC⁶

PRELIMINARY REMARKS:

1. The evaluation hereafter only covers the assessment of risks directly resulting from the possible presence of microbiological agents (including TSEs for this purpose). This evaluation does not address other risks possibly associated with the treatment of animal waste. In addition to the contaminated materials, processes may involve substances with other risks to human health, animal health and the environment. There may for example be by-products of the treatment and toxic substances present or formed during the process resulting in, airborne emissions (for example, dioxins); toxic effluents or residues (for example, heavy metals). It is understood that the assessment of such risks is covered by other frameworks or scientific opinions and/or by European and/or national legislation for the authorisation of waste recycling or disposal plants.
2. When the text refers to the “133°C/20’/3 bars” sterilisation standard, it refers to the process conditions as described in the SSC opinion of 24-25 June 1999 on animal waste disposal and recycling⁷ and quoted in annex for ease of reference.
3. The evaluation hereafter does not address the hygienic framework for running the plant under practical conditions. This must be fixed by the competent authorities and the responsible for running the plant must identify critical control points.

SUMMARY DESCRIPTION OF THE PROCESS

The process is designed to process defatted material coming out of a conventional rendering plant (“133°C/20’/3bars”) processing whole animal carcasses and mixed animal by-products in a continuous process. The defatted miscella are treated at 220 °C at 25 bar for 20 min, heated in a two step procedure first by direct steam injection secondly indirect in a coaxial heat exchanger run with thermo-oil. The heated material is mixed

⁶ The Working Group met on 31 January and 10 March 2003.

⁷ Scientific Opinion on The risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials. Adopted By the Scientific Steering Committee at its meeting of 24-25 June 1999 and re-edited at its meeting of 22-23 July 1999.

with water and anaerobically fermented in a biogas reactor. The material coming out of the reactor is decanted, the liquid phase is going to the sewage treatment plant and the solid phase is dried and burned. The biogas is purified and partly used in the same plant for energy supply (heat and electricity) or given into the public gas net.

GENERAL CONCLUSIONS:

The general conclusions hereafter follow the format given in the framework for the assessment of the risk from different options for the safe disposal or use of meat and bone meal adopted by the Scientific Steering Committee at its meeting of 28-29 June 2001.

1. Identification of the risk category/categories of the materials for which the proposed process is claimed to be suitable.

The process is claimed to be suitable for Category 1, 2 and 3 waste materials.

2. Identification and characterisation of the risk agents possibly present and targeted to be cleared by the proposed process; the materials involved; the possible means for their transmission and potential 'at risk' groups.

All microbiological agents, including TSE agents, as they may be present in any animal by-product and animal waste, including materials that would pose a TSE risk.

Since it is a closed vessel system only the liquid and solid products have to be regarded from the epidemiological point of view. The following risks from residual infectivity possibly present in the materials have to be regarded here:

- Transmission via liquid phase and sewage treatment plant over surface water to man and/or animals .
- Transmission via biogas prior burning .
- Transmission via solid phase collected before and after the process.

3. The risk reduction achieved by the particular process; specifications on how this risk reduction level has been measured or estimated.

The working group considers that there is enough evidence that the process would safely clear all microbiological agents, except possibly TSE for the following reasons.

- The proposed procedure ensures a thermal treatment at a higher pressure than 3 bar , at a higher temperature than 133 °C for a real exposure time calculated as 20 min (experimental proof is missing) after a continuous rendering process (133 °C / 3bar / 20 min).
- According to Appel *et al*, 2001, moist heat of 200 °C applied for 20 min will theoretically result in a 7 log reduction of 263 K prion rods in a water/fat emulsion. At least a 2 log reduction can be attended in the conventional rendering process.
- No data are available concerning the reduction in the biogas process under the given circumstances, preliminary data from Kirchmayr *et al* (2002) show that in

the thermophilic biogas process run with slaughterhouse offal about 1 to 2 log of PrPsc could be reduced within 350h.

CONCLUSIONS :

The system is considered to permit safe processing of Category 2 and 3 materials. It is of course assumed that the other organisational and construction related requirements are respected and that the competent national authorities are involved in approval and supervision.

Regarding the treatment of Category 1 (especially TSE agent) materials, the working group considers that the current dossier does not clearly show efficient reduction of BSE infectivity. The results of a TSE infectivity clearance study are needed to assess the capacity of the system to safely process TSE-contaminated materials.

RECOMMENDATIONS:

To permit a correct assessment of the safety of the process with regard to TSE agent, the working group recommends that the following additional information is provided:

- Results of TSE infectivity clearance experiments under practical conditions in a technical or semi - technical reactors (HDH and biogas reactor) carried out with the appropriate TSE – agent;
- Details on the process (preferably including a flow diagram), for example: stirring of the material (type stirrer and frequency), minimal real exposure time in the HDH – reactor, temperature at which the anaerobic reactor is run, chemical and microbial analysis of the liquid phase, particulate and microbial analysis of the purified gas (filtration of 1 m³), cleaning and disinfecting of the equipment on the unclean side both routinely and at cases of technical disturbances.

REFERENCES

Appel, Th. R., Wolff, M., von Rheinbaben, F., Heinzl, M. and Riesner, D. : Heat stability of prion rods and recombinant prion protein in water, lipid and lipid-water mixtures. *J. Gen. Virol.* 82 : 456 - 473

Kirchmayr, R., Baumann, F. and Braun, R. : Perspectives of anaerobic digestion in the treatment of animal by-products possibilities and limits of AD-technology. Is a TSE-post treatment monitoring possible?. *Abstr. Impacts of waste management legislation on biogas technology, IFA Tulln, September 12-14, 2002 Tulln/Austria*

ANNEX 3:

BIODIESEL PRODUCTION

APPLICANT: SARIA BIO-INDUSTRIES GMBH & CO KG

Summary conclusions of the Working Group of the SSC⁸

PRELIMINARY REMARKS:

1. The evaluation hereafter only covers the assessment of risks directly resulting from the possible presence of microbiological agents (including TSEs for this purpose). This evaluation does not address other risks possibly associated with the treatment of animal waste. In addition to the contaminated materials, processes may involve substances with other risks to human health, animal health and the environment. There may for example be by-products of the treatment, such as airborne emissions (for example, dioxins); effluent or residues (for example, heavy metals). It is understood that the assessment of such risks is covered by other frameworks or scientific opinions and/or by European and/or national legislation for the authorisation of waste recycling or disposal plants.
2. When the text refers to the “133°C/20’/3 bars” sterilisation standard, it refers to the process conditions as described in the SSC opinion of 24-25 June 1999 on animal waste disposal and recycling⁹.
3. The evaluation hereafter does not address the hygienic framework for running the plant under practical conditions. This must be fixed by the competent authorities and the responsible for running the plant must identify critical control points.

SUMMARY DESCRIPTION OF THE PROCESS

The proposed procedure processes animal fat from category 1, 2 and 3 for the production of biodiesel, which consists of methyl esters of fatty acids. This is achieved by submitting the animal fat to esterification and transesterification. The latter procedure is carried out at temperatures between 35°C-50°C. Subsequent refinement of the products including vacuum distillation at 150°C leads to “biodiesel” which is used as fuel in combustion engines.

⁸ The Working Group met on 31 January and 10 March 2003

⁹ Scientific Opinion on The risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials. Adopted By the Scientific Steering Committee at its meeting of 24-25 June 1999 and re-edited at its meeting of 22-23 July 1999.

GENERAL CONCLUSIONS:

The general conclusions hereafter follow the format given in the framework for the assessment of the risk from different options for the safe disposal or use of meat and bone meal adopted by the Scientific Steering Committee at its meeting of 28-29 June 2001.

1. Identification of the risk category/categories of the materials for which the proposed process is claimed to be suitable.

Category 1 (especially TSE agent).

2. Identification and characterisation of the risk agents possibly present and targeted to be cleared by the proposed process; the materials involved; the possible means for their transmission and potential 'at risk' groups.

All microbiological agents, including TSE agents, as they may be present in any animal by-product and animal waste, including materials that would pose a TSE risk.

The dossier clearly states that the raw fat needs to be sterilised at 133 °C/20 min/3 bars and the content of insoluble particles is below < 0.2% *prior* to being processed in the plant; the material was appropriately stored, transported and loaded to minimise exposure risk to TSE and other agents.

The risk for transmission of an agent to people, animals or the environment would thus result from residual infectivity possibly present in the products and the effluent.

3. The risk reduction achieved by the particular process; specifications on how this risk reduction level has been measured or estimated.

The working group considers that there is enough evidence that the process would safely clear all microbiological agents, except possibly TSE for the following reasons.

- a) The proposed procedure for transesterification is carried out at less stringent conditions compared to the conditions set by the regulation (EC) N° 1774/2002 requiring the process to be carried out at least 200 °C. In contrast, the proposed technique is based on transesterification conducted between 35 °C and 50 °C.
- b) The total risk reduction achieved by the total process steps can be accepted to be very substantial but not 10^{21} to 10^{22} as stated in the submitted document. A very substantial TSE agent clearance can be concluded on the following grounds:
 - Estimated reduction factor of 10^3 due to the steam pressure treatment ("133°C/3 bars/20 minutes") of the fat prior to being processed in the plant.
 - Estimated reduction factor of 10 during the esterification process (1,2-2 molar H_2SO_4 , 72 °C for 2 hours).
 - Estimated reduction factor of at least 10^1 during transesterification carried out with 15% KOH solution (1-3 molar, 15 – 30 min at 35 °C – 50 °C). This seems to be a reasonable estimate since less stringent conditions using the weaker base $Ca(OH)_2$ compared to the conditions proposed in this process yielded higher reduction than 1 log. (Taylor *et al*, 2002).

- An additional reduction of 10 can be assumed due to the reduction of the theoretical protein content of 0.2 % to less than 100 ng/kg during the distillation process.
- A reduction during the distillation process. (Note: a single distillation as described for this process is not considered to automatically result in a TSE agent-free distillate.)

The total TSE clearance resulting from the above steps is not necessarily additive and would therefore need to be quantified by an experiment (bio-assay) or precise analytical data that reliably provide evidence of the total absence in the biodiesel of proteins and peptides with a molecular weight above typical values for amino-acids/very short peptides.

4. The degree to which the risks can be contained under both normal and emergency/ abnormal operating conditions.

In general the process can be considered as safe since the applied temperatures are at maximum 150 °C and normal pressure conditions are applied with the exception of the vacuum distillation. In case of malfunction of the plant (e.g. leakage) the processing is automatically interrupted and transferred in a safe status.

5. Identification of interdependent processes, for example, transport, storage, loading of any related risk materials.

The dossier indicates that risks due to transports, storage etc. are minimised since the whole process is carried out in *one* building and contamination of the environment in case of leakages or spillages is avoided by the construction of the building.

6. The intended end-use of the product(s), for example, disposal, recycling, etc.

The product will be combusted as fuel in combustion engines and the solid waste will be subjected to incineration.

SUMMARY :

The working group considers the process as a sound approach but considers that the submitted dossier do not clearly show efficient reduction of BSE infectivity by the means of the proposed technique based on transesterification. The dossier does *not* show enough evidence that the high reduction of the BSE infectivity by a factor of 10^{21} to 10^{22} can be obtained with this process.

RECOMMENDATIONS:

- a) For animal fats from Category 1 materials: Since the document is lacking the proof that the assumed BSE infectivity reduction can be obtained and, based on the current documents, the technique for processing of fat from category 1 can thus not be considered as fully safe with respect to TSE agents. However, this recommendation should be reappraised if a bio-assay or equivalent reliable and precise laboratory

analytical data demonstrated the capability of the process to reduce efficiently BSE infectivity.

- b) For animal fats from Category 2 materials: The processing this material is considered to be safe provided that the animal fat has been treated at 133 °C/20 min/3bar prior to being used for the production of biodiesel. Fat produced in rendering plants where the fat is removed *prior* to the subsequent pressure sterilization should be considered to possibly pose a risk if used for the production of biodiesel.
- c) For animal fats from Category 3 materials: The process is considered to be safe.

REFERENCE

Taylor, D. M., Somerville, R.A., Steele, P.J., Grobber, A.H., 2002. Validation of the clearance of TSE agent by alkaline gelatine manufacturing process. IAH Edingburg (UK) 20 August 2002

ANNEX 4:

**THE BROOKES GASIFICATION SYSTEM FOR THE SAFE
DISPOSAL OF ANIMAL TISSUES/CARCASSES THAT MIGHT
BE CONTAMINATED WITH BSE/TSE'S**

APPLICANT: VALLEY INDUSTRIAL SUPPLIES LTD.

Summary conclusions of the Working Group of the SSC¹⁰

PRELIMINARY REMARKS:

1. The evaluation hereafter only covers the assessment of risks directly resulting from the possible presence of microbiological agents (including TSEs for this purpose). This evaluation does not address other risks possibly associated with the treatment of animal waste. In addition to the contaminated materials, processes may involve substances with other risks to human health, animal health and the environment. There may for example be by-products of the equipment, being residues (for example, heavy metals). It is understood that the assessment of such risks is covered by other frameworks or scientific opinions and/or by European and/or national legislation for the authorisation of waste recycling or disposal plants.
2. The evaluation hereafter does not address the hygienic framework for running the plant under practical conditions. This must be fixed by the competent authorities and the responsible for running the plant must identify critical control points.

SUMMARY DESCRIPTION OF THE PROCESS

The system is similar in a number of respects to a small animal waste incinerator. It is small (maximum capacity 6 tonnes). It employs high temperature combustion in excess oxygen to oxidise organic matter to CO₂, NO₂, and H₂O. A batch process is used with a prolonged residence time for the tissue/carcase of around 24hrs. There is no clean up of the exhaust gases.

The main differences from a convention small incinerator are:

- the source of heat is a secondary chamber fired by natural gas, which is underneath the primary chamber (in which the tissue to be processed is placed)
- gases produced as a result of the combustion process enter the secondary chamber where they are further oxidised. The gas stream has a minimum residence time of two seconds at a recommended temperature of 950 degrees centigrade. Subsequently the gases pass through a 'barometric damper' where they are mixed with ambient air.

¹⁰ The Working Group met on 31 January and 10 March 2003

IDENTIFICATION AND CHARACTERISATION OF RISK MATERIALS.

The company submission indicates that the process has been approved for the treatment of animal remains. The supporting evidence for this is an unsigned and undated certificate of authorisation under the integrated pollution control regulations from the Scottish Environmental Protection Agency (SEPA). It is unclear from the information provided whether or not the plant has been approved by SEPA for disposal of BSE/TSE's. The company claims total destruction of any pathogens in animal tissues and in whole carcasses.

1. Gaseous emissions

Likely gaseous by products of the process are:

- *Acidic gases such as NO₂ and SO₂
- *Products of incomplete combustion eg CO
- *Volatile organic compounds such as benzene
- *Polycyclic aromatic hydrocarbons and dioxins
- *Particulate matter.

The company states that continuous monitoring is conducted for oxygen, carbon monoxide and particulates. and that there is annual testing for hydrogen chloride, sulphur dioxide, total organic matter and particulates.

The company has not provided any of this monitoring data. The company describes the level of particulates as "very low". No analytical data is provided by the company for any of the other likely gaseous by-products. *The company claims that the nature of the process precludes the presence of organic chemicals in the gas stream emitted by the plant. However verification of this based on representative, reliable and sensitive analytical data is needed.*

2. Ash.

The bottom ash is described as white, and odourless and with an absence of organic chemicals. Representative analytical data is needed to support this contention.

RISK REDUCTION.

The company claim the total destruction/absolute eradication of BSE/TSE's. No tests involving BSE/TSE contaminated tissues or indeed with any other pathogens are provided to support this crucial statement. The only analytical data offered is one table summarizing some unspecified studies in which the content of amino acids was measured in the ash.

The sensitivity limit of the testing procedure is stated to be 100mg/kg of ash. No aminoacids were detected. It is unclear whether this sensitivity refers only to the analytical test or to the extraction from the ash and analysis. *Bearing in mind the rather poor sensitivity limit and the concern that amino-acid content may be a poor indicator of prion destruction these data are insufficient to indicate effective destruction of BSE/TSE's*

RISK CONTAINMENT.

The combustion process is conducted in a well contained facility. Ash is extracted by vacuum. Both are appropriate. The only doubt is about the nature and levels of the gaseous emissions (see above). No use is proposed for the ash rather it is intended to be landfilled.

CONCLUSION.

In principle the Brookes Gasification System may be an appropriate method for the safe destruction of animal waste that might contain BSE/TSE's. However the company to support this conclusion has provided minimal data. In the absence of such supporting data the Brookes Gasification System cannot (yet) be considered safe for the treatment of such Category 1 wastes.

However, the system can be considered safe for the treatment of Category 2 and 3 wastes.

ANNEX 5:

COMBUSTION OF TALLOW IN A THERMAL BOILER

APPLICANT: EFPRA (EUROPEAN FAT PROCESSORS AND RENDERERS ASSOCIATION).

Summary conclusions of the Working Group of the SSC¹¹

PRELIMINARY REMARKS:

1. The evaluation hereafter only covers the assessment of risks directly resulting from the possible presence of microbiological agents (including TSEs for this purpose). This evaluation does not address other risks possibly associated with the treatment of animal waste. In addition to the contaminated materials, processes may involve substances with other risks to human health, animal health and the environment. There may for example be by-products of the treatment and toxic substances present or formed during the process resulting in, airborne emissions (for example, dioxins); toxic effluents or residues (for example, heavy metals). It is understood that the assessment of such risks is covered by other frameworks or scientific opinions and/or by European and/or national legislation for the authorisation of waste recycling or disposal plants.
2. When the text refers to the “133°C/20’/3 bars” sterilisation standard, it refers to the process conditions as described in the SSC opinion of 24-25 June 1999 on animal waste disposal and recycling¹² and quoted in annex for ease of reference.
3. The evaluation hereafter does not address the hygienic framework for running the plant under practical conditions. This must be fixed by the competent authorities and the responsible for running the plant must identify critical control points.

SUMMARY DESCRIPTION OF THE PROCESS

The tallow are generated by the rendering of Category 1 waste products (including high risk ruminant Specified Risk Materials) or from category 2 and 3 products. The rendering produces 2 main products: meat and bone meal (MBM) and tallow and additionally a liquid effluent. After heating of the raw materials the lipid fraction is separated from the protein by centrifugation and pressing.

¹¹ The Working Group met on 31 January and 10 March 2003

¹² Scientific Opinion on The risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials. Adopted By the Scientific Steering Committee at its meeting of 24-25 June 1999 and re-edited at its meeting of 22-23 July 1999.

In the proposed incineration process, the tallow, in a liquid form (70°C) is vaporised to form particles with an average size of 20 microns and burned at a temperature of 1,305°C (residence time at conditions of at least 850°C for 0,2 seconds)

ASSESSMENT

The general assessment hereafter follow the format given in the framework for the assessment of the risk from different options for the safe disposal or use of meat and bone meal adopted by the Scientific Steering Committee at its meeting of 28-29 June 2001.

4. Identification of the risk category/categories of the materials for which the proposed process is claimed to be suitable.

The process is claimed to be suitable for treating wastes of all three categories. The working group considers that, as far as biological risks are concerned, a temperature/pressure/time process that has the capacity to clear the TSE agent has also the capacity to clear other biological agents in all Categories (1, 2 and 3). (Note: this is not necessarily the case for other process types, e.g., enzymatic processes).

5. Identification and characterisation of the risk agents possibly present and targeted to be cleared by the proposed process; the materials involved; the possible means for their transmission and potential ‘at risk’ groups.

All microbiological agents, including TSE agents, as they may be present in any animal by-product and animal waste, including materials that would pose a TSE risk. The possible means of transmission and potential at risk groups relate to handling of the raw materials, exposure via environmental pathways of non-combusted particulates containing infectivity, etc..

6. The risk reduction achieved by the particular process; specifications on how this risk reduction level has been measured or estimated.

The raw tallow, prior to being used as an energy source for combustion, undergoes a pre-treatment (rendering), is filtered to remove insoluble particles to a level below 0,15% and is appropriately stored, transported and loaded to minimise exposure risk to TSE and other agents.

The dossier, however, does not clearly specify whether this rendering pre-treatment consists of a sterilisation at “133°/20’/3bars” or equivalent.

The risk for transmission of an agent to people, animals or the environment would thus result from residual infectivity possibly present in the emissions, the effluent (if any), solid residues, residues left behind in the equipment, etc.

Proteins are present in the output particulates at the incinerator exit, but the information provided does not permit to conclude with certainty that they would not represent a risk:

- The particle size for incineration is given as an average, not as a distribution;
- Complete combustion is assumed, whereas it can not be excluded that under the described conditions (size and residence time, turbulence in the incineration chamber), a fraction of the particles may not be combusted at all.

- The protein content of the output is given as an estimate, not as measurements;
- The protein in the dirt fraction at the input is given as a model assumption, also not as a measurement;

The current dossier does thus not permit to conclude on the total clearance of an agent, should it be present:

- Certain resistant microbiological agents such as anthrax, clostridium, etc., may remain present if the raw material was not sterilised at conditions that inactivate these agents (e.g., “133°/20’/3bars” or equivalent) and if the combustion was incomplete. (Note: if the combustion was complete, the harsh combustion conditions [1.305°C, residence time above 850°C of 0,2 seconds], can safely be considered to result in emissions, effluents, etc., that are cleared from these agents.)
- The dossier does thus not provide evidence that the combination “20µ droplets / ≥ 850°C / 0,2 seconds” would, in terms of TSE clearance, be equivalent to the “≥ 850°C / 2 seconds” incineration reference in the SSC opinion of 24-25 June 1999¹³. Even if the pre-treatment was at “133°/20’/3bars” or equivalent, there is no satisfactory evidence that TSE agent would be cleared because it can not be excluded that under the described conditions (size and residence time, turbulence in the incineration chamber), a fraction of the particles may not be combusted at all.

7. The degree to which the risks can be contained under both normal and emergency/ abnormal operating conditions.

Incomplete combustion or equipment failure can never be excluded a priori. The dossier does not provide sufficient information on process control and a possible contingency plan for such conditions. The application also does not provide enough information on the workers exposure risk related to the possible inhalation of the small particulates.

8. Identification of interdependent processes, for example, transport, storage, loading of any related risk materials.

The dossier provides little explicit information on these items. From the dossier and the assumptions made therein, the Working Group assumes that pre-treatment, storage, transport, loading, etc. would be according to legislation, i.e., a pre-treatment according to the heat-pressure and filtration standards set in the legislation (e.g., “133°C/20’3bars” and < 0,15% solid particles for possibly TSE contaminated materials). A confirmation that this is indeed the case is required.

¹³ Scientific Opinion on The risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials. Adopted By the Scientific Steering Committee at its meeting of 24-25 June 1999

9. The intended end-use of the product(s), for example, disposal, recycling, etc.

No direct effluent is associated with the combustion process, but is generated due to the process spillage and maintenance activities. Process spillage is assumed, before disposal to landfill, to be treated in an air dissolved flotation unit, with an assumed removal of 90% of the solid material. Maintenance sludge is assumed to pass directly to sewer, via an interceptor pit with an assumed removal of 50% of particulates. These assumptions is not substantiated and [given the presence of proteins at the output] does not allow to conclude on total absence of TSE risk in the effluent .

No information is also provided on the cleaning of the gaseous emissions (quenching, filtration on charcoal or other devices.) Only some data are given, but no data on the presence of dioxins and other volatile toxic compounds.

CONCLUSIONS:

1. If the tallow was pre-treated by sterilisation at “133°C/20’/3 bars’ or equivalent the process is considered suitable for disposing of Category 2 and Category 3 waste materials.

In the absence of such pre-treatment, the process is currently only considered suitable for disposing of Category 3 waste materials.

2. The process might have (and probably has) the capacity to safely dispose of Category 2 and 1 animal waste (and totally clear TSE infectivity if present in Category 1 materials), but the applicant’s report does not provide enough evidence (firm data) supporting this claim. In addition, precisions are required on a number of process conditions to permit the assessment of a number critical points, for example: how the particles are generated around the nosl, the (statistical) spread of the particle size around the average of 20µ (some particles may be not burned at all during the very short residence time of 0,2 seconds), etc. These data should be provided as the results of measurements, not only as average figures or estimates.

RECOMMENDATIONS:

For the process to be possibly considered as sufficiently efficacious to clear also Category 1 and/or 2 materials, the following additional information is needed:

- An description (preferably with flow diagram) of the overall process and it’s various steps, including on how the particles are generated; the pre-treatment, storage, transport, loading, etc of the raw material; the emission controls of the process; the treatment of residual wastes; etc.
- Measured data and additional information along the lines indicated in the above report should be collected and provided by accredited laboratories.

Should this information permit to conclude that the process is safe for disposing of category 1 waste material, than it will also be safe for category 2 and 3 material.

ANNEX 6:

BIO-REDUCER

APPLICANT: D.J. WESTRON / READING AGRICULTURE CONSULTANTS

Summary conclusions of the Working Group of the SSC¹⁴

PRELIMINARY REMARKS:

1. The evaluation hereafter only covers the assessment of risks directly resulting from the possible presence of microbiological agents (including TSEs for this purpose). This evaluation does not address other risks possibly associated with the treatment of animal waste. In addition to the contaminated materials, processes may involve substances with other risks to human health, animal health and the environment. There may for example be by-products of the equipment, being residues (for example, heavy metals). It is understood that the assessment of such risks is covered by other frameworks or scientific opinions and/or by European and/or national legislation for the authorisation of waste recycling or disposal plants.
2. The evaluation hereafter does not address the hygienic framework for running the plant under practical conditions. This must be fixed by the competent authorities and the responsible for running the plant must identify critical control points.

SUMMARY DESCRIPTION OF THE PROCESS

The Bio-reducer system is not an alternative method as such for safe disposal of animal by-products. It provides the possibility to store animal by-products in a contained environment, awaiting further processing and/or disposal. The system aims only to store the by-product in a closed vessel equipped with a ventilation valve. The vessel is only opened in order to add additional by-products to the system. In order to control the biological processes within the vessel, a biological / chemical substance can be added with preservative action. The vessel is removed at least once per two years as a whole and transported to the processing plant. Opening, emptying of the vessel will occur at the processing plant. After cleansing the vessel can be re-used.

ASSESSMENT

The general assessment hereafter follows the format given in the framework for the assessment of the risk from different options for the safe disposal or use of meat and bone meal adopted by the Scientific Steering Committee at its meeting of 28-29 June 2001.

1. Identification of the risk category/categories of the materials for which the proposed process is claimed to be suitable.

The process is claimed to be suitable for storage of wastes of all three categories, although within the dossier it is sometimes mentioned that animal wastes of animals

¹⁴ The Working Group met on 31 January and 10 March 2003

that suffered notifiable diseases are not suitable for storage in the vessel. The working group considers that, as far as biological risks are concerned, no dates are provided in order to substantiate why or why not certain waste categories can be contained in the equipment.

2. Identification and characterisation of the risk agents possibly present and targeted to be cleared by the proposed process; the materials involved; the possible means for their transmission and potential ‘at risk’ groups.

All microbiological agents, including TSE agents, as they may be present in any animal by-product and animal waste, including materials that would pose a TSE risk.

From the dossier the Working Group assumes that the materials are stored in a contained environment. The dossier is not providing any data that suggest any decontamination of the material during storage and further transport within the vessel. The storage of the material is intended to contain the material;

Risk for transmission of an agent to people, animals or the environment would thus result from loading and unloading procedures. Another risk can occur when the construction of the vessel, and / or sleeve disintegrates and material can leak into the environment;

Risk occurs also as a result of biological processes within the vessel. Dead carcasses will decompose and the dominating process will be based largely on the presence of e.g. certain micro-organisms, insects and parasites. This includes that the formation of biological toxins (such as botulism toxin and mycotoxins) and the formation of spores (such as anthrax) can occur within the vessel under certain condition. As these biological processes can produce large volumes of gaseous substances, the leakage of biological active components (such as toxins, or spores) through the ventilation valve can occur.

3. The risk reduction achieved by the particular process; specifications on how this risk reduction level has been measured or estimated.

The working group considers that there is enough evidence that the construction requirements and the procedures minimises the risk concerning the damage of the vessel, and the concrete sleeve in order to protect the surrounding environment.

A detailed description of the procedures provides information concerning the protection of man and surrounding environment from substantial amounts of material that can be derived from fresh wastes. However the protection of the operators and the surrounding environment against the possible formed biological components within the vessel after storage of the waste material in the vessel is not shown in the dossier. The Working Group considers at least a detailed description of the risk reduction concerning possible contamination with toxic components and spores necessarily.

In the risk identification the risks connected to the formation of large volumes of gaseous substances within the vessel are not mentioned in detail.

No information is provided in the dossier concerning the construction, safety aspects and additional requirements for the ventilation valve.

4. **The degree to which the risks can be contained under both normal and emergency/ abnormal operating conditions.** The dossier doesn't provide data concerning loading of the vessel with material under abnormal circumstances, i.e. when products are combined that provoke together a new biological process, such as intensified fermentation processes.
5. **Identification of interdependent processes, for example, transport, storage, loading of any related risk materials.** The dossier provides explicit information concerning these items, as far as loading and transport is concerned. However, the data concerning the cleansing of the recipients after unloading doesn't provide information concerning the decontaminating properties of the procedures.
6. **The intended end-use of the product(s), for example, disposal, recycling, etc.** The intended end-use of the product is processing in a cat I processing facility. Whilst the process described in the dossier is only intended as a storage procedure for animal wastes the Working Group considers it not necessarily to provide additional information within the dossier concerning the end-use of the product.

SUMMARY :

1. While the process described in the dossier is only intended to store the animal waste for a certain period, the Working Group doesn't consider the decontamination of the original agents in the storage vessel.
2. The dossier doesn't provide sufficient information concerning the biological processes that can occur in the vessel after filling. Risk identification and control with regard to this item is insufficiently described within the dossier.
3. The dossier lacks detailed information concerning the construction and operation requirements of the ventilation valve (including possible filtration of emissions). Also the security of the ventilation valve is not shown in the dossier.

CONCLUSION:

For the procedure described in the dossier that is intended to store animal wastes without decontaminating the material, the provided information gives details and background knowledge concerning the construction and operating procedures. However technical information on certain aspects such as the ventilation system, the pressures that can be built-up in the vessels, etc. is missing. But the Working Group considers that it is not the appropriate instance to judge the corresponding technicalities.

The Dossier is insufficient with regard to major information related to (1) the biological processes that can occur within the vessel after filling of the vessel with biological active materials and (2) the control measures that are possibly needed to control this part of the biological process.

The Working Group therefore concludes that it is impossible to define a conclusion on this dossier at this stage.

ANNEX 7:

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

“133°C/20’/3 bars”

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

In batch processes, these conditions are expected to be realised for non-desiccated raw material with a particle size of maximum 50mm in 2 dimensions (According to Riedinger (1999a), a precrushing of the raw material to thickness of 30 mm would be recommendable, as a safety margin to diminish a possible lag phase in the development of the core temperature; this is sufficient and possible under practical conditions¹⁵.) 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 process¹⁶. 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.

¹⁵ Reducing the particle size will enhance heat penetration. A particle size of 30mm in two dimensions would constitute a safety margin. A possible inappropriate “crushing to 50mm” would indeed result in a much longer time for the temperature to reach the core of the material. Application of indirect heating with 160°C jacket steam (which causes a temperature overswing phase to nearly 140°C) would further increase the security of the sterilising process. (Other valid technical solutions may exist.)

¹⁶ If direct steam is used, specified conditions may apply, *for example*: a water content of 50-60% with a temperature treatment for 140-150°C (at least 3,5 bar). (Other valid technical solutions may exist.)

Remarks:

- a. (...)
- 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-cooking¹⁷ 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°C/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 water¹⁸ 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 millimetres¹⁹, 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, it is necessary to verify whether, in order to obtain the same efficacy, the parameters “133°C/20’/3 bars” needs to be modified in the case of a post-sterilisation process.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 °C / 20min/3 bar (batch). Other treatments in a validated process for certain purposes at lower temperatures should only be allowed on a case by case basis.’

¹⁷ *For example, and depending upon the vessel size:* at least 100°C for at least 10 minutes and before the valves of the cooker are closed, for material with a particle size not exceeding 30 mm in two dimensions. An alternative and surer method would be to remove possibly enclosed air in the "super sterilising phase" during the temperature overswing above 133°C till nearly 140°C through the vapour valve of the vessel. (Other valid technical solutions may exist.)

¹⁸ Approximately 60%.

¹⁹ 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)

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

ANNEX 8: DEFINITION OF ANIMAL BY-PRODUCT CATEGORIES

"Regulation (EC) 1774/2002 divides animal by-products (ABP) into three categories:

Category 1 material is defined in Article 4 of Regulation 1774/2002. It comprises of ABP regarded as high risk. This includes amongst others any animals or parts thereof suspected of being infected by a TSE or killed in the context of TSE eradication measures, specified risk material or animals containing such material. Category 1 material must be disposed of as waste by incineration, co-incineration or by burial in an approved landfill.

Category 2 material, defined in Article 5 of the ABP Regulation, consists of ABP posing a risk not quite as high as category 1 material but still a high risk. This group includes for example fallen stock and animals killed to eradicate an epizootic disease (other than those under category 1) and products of animal origin containing residues or drugs. Category 2 ABP may, under certain conditions, be further processed e.g. into organic fertilizers or into technical products or may be transformed in a biogas plant.

Category 3 material, defined in Article 6 of the ABP Regulation, are ABP presenting a low risk. In general, Category 3 ABP are derived from animals or products thereof considered as fit for human consumption but not intended for this use (any more). This category would for example include by-products from the slaughtering process, former foodstuffs of animal origin, fresh fish by-products or catering waste. Taking account of the specific requirements laid down in the Regulation, Category 3 material may be further used for various purposes, such as for petfood production, for technical products, for composting or for animal feed."