



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C1 - Follow-up and dissemination of scientific opinions

UPDATED OPINION ON:

THE SAFETY OF ORGANIC FERTILISERS DERIVED FROM RUMINANT ANIMALS

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE

AT ITS MEETING OF 10-11 MAY 2001

UPDATED OPINION ON THE SAFETY OF ORGANIC FERTILISERS DERIVED FROM RUMINANT ANIMALS

I. BACKGROUND AND MANDATE

On 24 and 25 September 1998, the Scientific Steering Committee (SSC) adopted the attached opinion on the safety of organic fertilisers derived from ruminant animals.

The Commission Services invited the SSC assess the validity of this opinion, and to possibly update it, in the light of the following data and questions:

- A question submitted by an industrial consortium on the safety of a soil conditioner obtained by the hydrolysis of animal tissues (Conorzio SGS, 2000).
- A request from the Belgian Government to update, if needed, the SSC opinion on the safety of organic fertilizers in the light of recent SSC opinions (extension of the list of Specified Risk Materials), the EU-wide program of testing cattle above 30 months and new knowledge on environmental transmission routes of BSE that recently may have become available.

II. OPINION

- a. When assessing the validity of the SSC opinion of September 1998 on the safety of organic fertilizers, the TSE/BSE *ad hoc* Group took also into account the following two recent reports:
 - Report on the International Expert Discussion on Occurrence and Behavior of BSE/TSE Prions in Soil. Organized in Bonn by the German Federal Ministry for the Environment, Nature Conservation and Reactor Safety on 18 December 2000. (BMU, 2001).
 - The scientific opinion of 7 April 2001 of the French Food Safety Agency (the *Agence Française de Sécurité Sanitaire des Aliments* (AFSSA, 2001), on the safety risks linked to the different uses of meals and fats of animal origin and to the conditions of their processing and elimination.
- b. The TSE/BSE *ad hoc* Group considers that the main issue continues to be the presence of BSE-infectivity in organic fertilisers produced from BSE infected animal tissues or organs at an extent depending on the manufacturing technology and on the initial level of infectivity in the source material. Once the fertilisers so obtained are used on crops and/or on/in soils, the following risks emerge:
 1. The risk of ingestion of infectious residues of the fertiliser by humans or animals, although amounts ingested in this way are probably small. Human consumption will normally follow washing the material which could reduce the fertiliser residues on the surface, whereas animal consumption could be more substantial.
 2. The risk of soil and water contamination, including a potential accumulation of infectivity over years. This possibility is based on the resistance of TSE agents against a number of very drastic treatments (Taylor, 2000) and on the fact that high-titre scrapie agent retained infectivity after experimental, artificial burial¹

¹ The conditions of burial did, however, not necessarily represent real conditions such as for example after ploughing.

for three years, although approximately 99% of the infectivity was lost (Brown and Gadjusek, 1991). Moreover, the failure of several scrapie eradication programmes registered as yet could lead to the same conclusion (Sigurdarson, 1991). Although no information is available as to the behaviour (including accumulation) of the BSE-agent in the soil, the ground water or the surface water, it is not possible to exclude that it could be released into the environment and by that create a potential source for further infectivity recycling.

3. The risk of exposure of humans or animals during the application or handling of fertiliser, including accidental access of cattle to it.

The SSC considers that apart from the possible ingestion of infectious residues, the above risks are hardly affected by the way of application of a fertiliser or soil conditioner (on or in the soil; surface application with or without ploughing into the soil). The fact that plants do most likely not absorb TSE agent, but only the mineralised residues of the fertiliser or soil conditioner, does also not affect these risks.

- c. In order to prevent all the above mentioned risks, organic fertilisers should not be produced from animal materials suspect or confirmed to carry the TSE-agent.

Regardless of the GBR-level, cattle tissues and organs known for not hosting the BSE-agent (e.g. horn, hooves, wool, ...) can be used in the manufacturing of organic fertilisers without any special caution as long as they can be assumed to be not contaminated with potentially BSE-infected tissues or organs.

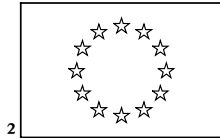
The SSC considers that, within the limits of risk indicated in the SSC opinion of 25 June 1999 on "Fallen stock" (EC, 1999), no restrictions need to be imposed on the use of organic fertilisers produced from materials originating from any cattle born and raised in a GBR level I country.

For other countries materials from animals found to be fit for human consumption, after removal of the Specified Risk Materials and after submission of the raw materials to an appropriate treatment should be used. The type of treatment will depend upon the raw materials:

- > raw materials such as bones, trimmings, meat rests, slaughter offals excluding SRMs, etc. should be submitted to the "133°C/20 min/3 bar" standard treatment or validated equivalent as described in the SSC opinion on "Fallen stock" (EC, 1999) or to hydrolysis as described in the SSC opinion on "Hydrolysed Proteins" (EC, 2000b).
 - > blood could be used within the limits of the risk assessments presented in the SSC-opinions on the safety of ruminant blood (EC, 1999; EC, 2000a).
 - > ruminant hides can safely be used within the limits of the risk assessments presented in the SSC-opinion on the safety of collagen (EC, 2001).
- d. Because of the risk of contamination with risk materials and lack of traceability, sewage sludge (e.g., from slaughterhouses or rendering plants) can only be used in GBR I countries as possible raw material for the production of organic fertilisers. In all other countries it should not be dispersed in the environment.

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- Belgian Ministry of Agriculture and Medium-sized Classes.** Letter of 24 January 2001 of Minister J.Gabriels to Commissioner Byrne.
- BMU (Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit), 2001.** Report on the International Expert Discussion on Occurrence and Behavior of BSE/TSE Prions in Soil. Organized in Bonn by the German Federal Ministry for the Environment, Nature Conservation and Reactor Safety on 18 December 2000. prepared by: Fraunhofer-Institute for Environmental Chemistry and Ecotoxicology D-57392 Schmallenberg, Germany.
- Brown, P., Gajdusek, D.C., 1991.** Survival of scrapie agent after 3 years internment. *Lancet* **337**: 269-270.
- Consorzio SGS, 2000.** Petition submitted by Consorzio SGS regarding the use of its soil conditioner named NATIFERT (including a technical report on the products).
- E.C. (European Commission), 1999.** The Scientific Steering Committee. 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 SSC at its meeting of 24-25/06/99 (containing updates, 13/07/99).
- E.C. (European Commission), 2000.** Opinion of 13-14 April 2000 of the Scientific Steering Committee on the *Safety of ruminant blood with respect to TSE risks*.
- E.C. (European Commission), 2000.** Updated Report and Scientific Opinion of 25-26 May 2000 of the Scientific Steering Committee on the safety of hydrolysed proteins produced from bovine hides. Initially adopted on 22-23 October 1998).
- E.C. (European Commission), 2001.** Opinion and Report of 10-11 May 2001 of the Scientific Steering Committee on the Safety with respect to TSE risks of collagen produced from ruminant hides
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**SCIENTIFIC OPINION ON THE SAFETY
OF ORGANIC FERTILISERS DERIVED FROM
MAMMALIAN ANIMALS**

Adopted by the Scientific Steering Committee
at its meeting of 24-25 September 1998

OPINION OF THE SCIENTIFIC STEERING COMMITTEE ON THE SAFETY OF ORGANIC FERTILISERS DERIVED FROM MAMMALIAN ANIMALS

EXECUTIVE SUMMARY

The question

The scientific Steering Committee was invited to address the following question:

“Can organic fertilisers derived from materials from mammalian animals, naturally or experimentally susceptible to Transmissible Spongiform Encephalopathies, be safely used? If so, under what conditions?”

The opinion

As a matter of general principle the SSC wants to state that neither organic fertiliser nor any other product should be produced from material coming from animals suspect or confirmed to carry the BSE agent.

- a) No organic fertiliser should be produced from bovine material originating from countries carrying a high BSE risk.*
- b) Organic fertilisers derived from mammals originating from BSE free (negligible BSE-risk) regions/countries carry a zero or negligible BSE-risk for man, animals or the environment. They may be used as a fertiliser.*
- c) For other countries:*
 - Organic fertilisers, derived from mammalian tissues that are known to have the potential to carry the BSE-agent, should always be produced in accordance with the criteria laid down by the SSC for the safe production of MBM² or hydrolysed proteins. They may be used as fertiliser. Ingestion by man or ruminants must be prevented.*
 - Organic fertilisers derived from mammalian tissues which have not been found to be infected by the BSE-agent (e.g. blood, horn, hoof may be used as fertiliser. Ingestion by man or ruminants must be prevented.*

Note: The SSC does not exclude the possibility that production systems may exist which can produce safe organic fertilisers also from infected material, e.g. by more severe temperature/time/pressure combinations. Such processes should be evaluated on a case by case basis.

Note: The above opinion of the SSC is based on the attached report of the working group of the TSE/BSE ad hoc Group, which was accepted by the TSE/BSE ad-hoc group and then by the SSC, following critical discussion and review.

² *Opinion of the SSC on the safety of MBM, 26-27 March, 1998; Updated Report on the Safety of Meat-and-bone Meal derived from Mammalian Animals Fed to Non-Ruminant Food-Producing Farm Animals, prepared for the Scientific Steering Committee and presented at its meeting of 24-25 September 1998.*

REPORT OF THE WORKING GROUP

1. The question

“Can organic fertilisers derived from materials from mammalian animals, naturally or experimentally susceptible to Transmissible Spongiform Encephalopathies, be safely used? If so, under what conditions?”

2. Definitions

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

Fit for human consumption

The wording “Fit for human consumption” hereafter refers to material from animals that passed both pre- and post mortem inspection by a competent veterinary authority and that is certified and identifiable as fit for human consumption on the basis of the existing national and EU legislation. The Working Group stresses that positive identification of material from animals not fit for human consumption should be possible, to avoid such material entering the food or feed chains. This definition implies that material which was originally derived from animals fit for human consumption, may become unfit for consumption, for example because of inadequate storage or transport conditions. The latter risks should be dealt with in specific opinions or legislation.

Meat and bone meal derived from mammalian animals (MMBM).

The definition and report hereafter do not refer to blood meal.

Meat and bone meal, derived from mammalian animals (MMBM), is defined as processed animal protein intended for animal consumption, or as intermediate product for the production of organic fertiliser or other derived products.

Organic fertilisers from slaughter residues of mammalian animals

Organic fertilisers obtained from slaughter residues of animals which are not / can not be used to feed ruminants animals. For the purpose of the present report, the slaughter residues are limited to the following mammalian products: dried blood, Bones, Bone dicalcium phosphate, Bone meal, Bone waste, Bone waste meal, Bone degelatinized, Bone degelatinized meal, Hides, Hoofs and/or horns, Hoof and/or horn meal, Hair hydrolysed, Leather meal, Leather roasted, Meat, Meat and bone meal, Meat meal, Mixed animal origin, Hydrolysed proteins or amino-acids and peptides, Wool and/or hair.

Safely use

In the context of these opinions, only the safety aspects relating to the BSE agent are taken into account. Unless otherwise stated, the microbiological safety of organic fertiliser is not addressed by this opinion.

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. 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.

“133°C/20’/3 bars”

The wording “133°C/20’/3 bars” refers to hyperbaric production process of not less than 133°C during 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.

Remark: Further clarifications on the above definition are provided in the *Updated Report on the Safety of Meat-and-bone Meal derived from Mammalian Animals Fed to Non-Ruminant Food-Producing Farm Animals*, which was prepared for the Scientific Steering Committee and presented at its meeting of 24-25 September 1998.

3 Background

A tentative list of the various organic fertilisers of mammalian animal origin is:

Dried blood, Bones, Bone dicalcium phosphate, Bone meal, Bone waste, Bonewaste meal, Bone degelatinized, Bone degelatinized meal, Hides, Hoofs and/or horns, Hoof and/or horn meal, Hair hydrolysed, Leather meal, Leather roasted, Meat, Meat and bone meal, Meat meal, Mixed animal origin, Protein hydrolysed or aminoacids-peptides, Wool and/or hair

Slaughter residues are an excellent substrate for the production of fertilisers. The are produced by processes that:

- imply practically no transformation (e.g. blood meal, bone meal, etc.);
- have demonstrated a certain capacity to reduce the BSE-infectivity (e.g. MBM, hydrolysed proteins).

These fertilisers are characterised by quite high nitrogen and phosphorus contents, high and fast availability, and by the fact that they cannot be washed away. The continuous and the slow release of the nitrogen in NH_4^+ form reduces the phenomenon of potential pollution of the underground layers due to nitrate leaching. Furthermore, organic fertilisers contain compounds with growth-promoting or growth-promoting-like characteristics (free amino acids, peptides and polypeptides that are useful for qualitative crop production or are rich in specific trace minerals like Fe in blood meals).

Organic fertilisers in the form of compost improve the chemical and physical characteristics of the soil. UNEGA has estimated that no less than 350,000 tons of meals for use in fertilisers could be produced within the EU.

According to the current EU-legislation, organic fertilisers may be obtained from any slaughter residues, including the SRM (specified risk materials), as defined in the opinion of the SSC of 9/12/97, and carcasses of dead animals (fallen stock).

Since 1996, SEAC (the UK Spongiform Encephalopathy Advisory Committee) has suggested to ban the use of meat meals as fertilisers in those cases where the conditions exist for ruminants to accidentally ingest this type of material.

The recent UK Regulation - The fertilisers (Mammalian Meat and Bone Meal) 1998/954 - introduces the prohibition of mammalian meat and bone meal as or in fertiliser on agricultural land³.

The UK Regulation 1998 - The fertilisers (Mammalian Meat and Bone Meal) 1998/955 - further introduce the prohibition in respect of the manufacture of mammalian meat and bone meal for use as or fertilisers³:

“No person shall manufacture mammalian meat and bone meal for use as or in any fertiliser except by a rendering process in which-

(a) the particle size of the raw material prior to processing is reduced so that the maximum dimension of no particle exceeds 50 mm; and

(b) the material is heated to core temperature of more than 133°C for at least 20 minutes at a pressure of at least 3 bar.”

4. Identification of possible hazards and elements of risk assessment

Preliminary remark:

a complete section on hazards and risks related to meat-and-bone meal figures in the *Updated Report and Scientific Opinion on the Safety of Meat-and-Bone Meal Derived from Mammalian Animals fed to Non-ruminant Food Producing Farm Animals* which was prepared for the Scientific Steering Committee and presented at its meeting of 24-25 September 1998.

The first possible hazard is that the organic fertiliser would carry a residual BSE-infectivity.

If this would be the case the following additional hazards exists:

- ingestion by humans or animals of residues of the fertiliser, if this was applied to pasture, lawn or food crops (in particular leaf-vegetables);
- contact of humans or animals with the fertiliser during its application;
- potential involuntary persistence in the environment of and contamination of soil and water with the BSE-agent, including a potential accumulation of infectivity over years.

³ In these UK Regulations, the following definitions are used:

agricultural land means land used or capable of use the purpose of a trade or business in connection with agriculture; *agriculture* includes fruit growing, seed growing, dairy farming and livestock breeding and keeping, the use of land as grazing land, meadow land, osier land, the use of land for woodlands, and horticulture (except the propagation of plants and the growing of plants within greenhouses and glass or plastic structures); *mammalian meat and bone meal* means mammalian protein derived from the whole or part of any dead mammal by the process of rendering;

Elements of the risk assessment:

1. The risk that organic fertiliser would carry a residual BSE-infectivity

- Organic fertilisers which are produced without being exposed to any process known to reduce BSE infectivity (e.g. dried blood, bone meal) would carry the same BSE risk as the raw material from which they are derived.
- The risk of organic fertilisers, which are produced with being exposed to processes known to reduce BSE-infectivity (e.g. the 133/20/3 MBM-process or the hydrolisation process, see opinions of the SSC on these) will carry a considerably lower risk than the raw material from which they are produced.
- Exposing organic fertilisers, produced via MBM, to harsher conditions than the 133/20/3 would enhance the safety further.

2. The risk of ingestion of residues of the fertiliser by humans or animals

- The amounts ingested by this way are probably rather small. Human consumption will normally follow washing the material which would reduce the fertiliser residues on the surface. Animal consumption could be more substantial.
- No information is available as to the inactivation of an eventual residual infectivity of organic fertiliser by external conditions such as atmospheric conditions, microbiological activity, ploughing, washing of by rain or irrigation, etc. It is therefore not possible to assess if, and after which period, consumption of crops treated with organic fertiliser could be safe, if it could not be excluded that these carry the BSE-agent.

3. Contact of humans or animals with the fertiliser during its application

- Solid organic fertilisers could enter the human (or animal) body via the skin or through inhalation. No information is available as to the transferability of the BSE-agent by these routes. Accordingly no maximum exposure value can be defined

4. Contamination of soil and water with the BSE-agent, including a potential accumulation of infectivity over years.

- No information is available as to the behaviour (including accumulation) of the BSE-agent in the soil, the ground water or the surface water. There is, however, concern that a remote risk could exist that it would enter BSE-resistant species (e.g. mites) and by that create a potential source for future outbreaks.

Conclusion:

It is currently not possible to assess the potential risk that could be posed by BSE-contaminated organic fertilisers for human, animals or the environment.

The following considerations are therefore essential for ensuring that organic fertilisers are safe in use with respect to BSE:

- Organic fertilisers which are produced without being exposed to any process known to reduce BSE infectivity can only be regarded as BSE-“free” if the raw material can be regarded to be BSE-free. This would require that it originated

- from countries or regions classified as BSE-free (or having a negligible risk of BSE) and/or that it was only prepared from those tissues or body fluids which are not likely to carry the BSE-agent⁴.
- Organic fertilisers which are produced with being exposed to processes known to reduce BSE-infectivity may be regarded as BSE free (or carry a negligible BSE-risk) if the conditions for the safe production of MBM or hydrolysed proteins (see SSC opinions on these subjects) are respected.
 - Organic fertilisers regarded as BSE-free or as carrying a negligible BSE-risk might be used for any application as fertiliser. Except for the case where the raw material is coming from a BSE-free source, ingestion by man or animals (in particular ruminants) must be prevented.

5. Not exhaustive list of scientific and technical documents used by the working group.

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6. Acknowledgements

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