Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the safety vis-à-vis biological risk including TSEs of the application on pastureland of organic fertilisers and soil improvers.

(Question N° EFSA-Q-2003-090)

Adopted on 3 March 2004

SUMMARY OF OPINION

The European Commission requested the European Food Safety Authority (EFSA) and its Scientific Panel on Biological Hazards (1) to reconsider, from a TSE (Transmissible Spongiform Encephalopathy) risk perspective, the opinion of the Scientific Committee on Toxicology, Eco-toxicity and the Environment (SCTEE 24 April 2001) in the light of the opinion of the Scientific Steering Committee (SSC 10-11 May 2001) and (2) to advise on the levels of biological risk clearance to allow the definition of the appropriate minimum waiting period after which grazing may be allowed following application of organic fertiliser or soil improvers from categories 2 and 3 Animal By-Products (ABP) on pastureland.

It was stressed that all conclusions depend on effective controls being in place to assure status of all 3 categories of ABP. If ABP of category 2 and 3 are to be used as a source for organic fertilisers and should there be any possibility of contamination with category 1 ABP then the whole batch should be processed according to category 1 ABP.

There are no scientific data available defining the fate of prions following application to land, pasture or directly into the soil. It remains accepted that TSE agents are cleared very slowly from the environment, however a definite period after which TSE agents can be considered to have been completely cleared, based on scientific evidence, cannot be established.

The Scientific Panel on Biological Hazards concludes that if appropriate control measures and appropriate heat treatment (as laid down by legislation) applying to category 2 and 3 ABP are in place, no waiting period in addition to the one already defined in the legislation and based on Good Agricultural Practice is necessary. In that case, the ABP of category 2 and 3 are safe to be used for spreading on pastureland.

ABP of category 3 can be processed in alternative ways, provided that product and process are microbiological safe to eliminate human, animal and environmental risk. This must be confirmed by microbiological validation.

The Scientific Panel on Biological Hazards and its Working Group concludes that in respect to TSE/BSE, the SSC opinion (10-11 May 2001) on "Safety of Organic Fertilisers derived from ruminant animals" remains entirely valid.

Key words: BSE, animal by-products, organic fertilisers, meat and bone meal, pastureland, environment.

BACKGROUND

Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 lays down health rules for the collection, transport, storage, handling, processing and uses or disposal of ABP not intended for human consumption, to prevent these products from presenting a risk to animal or public health. The Regulation sets out clear rules for what must and may be done with the 16 million tonnes of animal materials that are excluded from the food chain in the EU each year.

This regulation (EC) No 1774/2002 which applies from 1 May 2003 divides ABP into 3 categories:

a) Category 1 - animal by-products contaminated with BSE or scrapie, or with residues of prohibited substances (i.e. hormones used for growth promotion) or environmental contaminants (i.e. dioxins and PCBs)

b) Category 2 - animal by-products presenting a risk of contamination with other animal disease (i.e. animals which have died on the farm or were killed in the context of disease control measures on the farm) or at risk of residues of veterinary drugs

c) Category 3 - parts of a slaughtered animal that are not consumed by humans, can only be used in feed for farmed animals if they come from animals declared fit for human consumption following veterinary inspection.

Regulation (EC) No 1774/2002 further requires that all category 1 materials must be totally disposed of as waste by incineration or co-incineration after rendering. Category 2 materials may only be recycled for uses other than animal feed (e.g. as fertilisers or soil improvers) after appropriate heat treatment (133 °C/20 min/3 bars). Category 3 materials consisting of safe materials (i.e. derived from animals declared fit for human consumption following veterinary inspection) may be used as fertiliser or soil improver after rendering (not necessarily 133 C/20 min/3 bars) or as biogas residues or as compost. A full list of category 1, 2 and 3 materials is attached (annex 1).

The Regulation further specifies that organic fertilisers and soil improvers derived from categories 2 and 3 materials may be imported, traded, used or exported if they meet requirements to be laid down by the Commission. The regulation further bans the application of organic fertilisers or soil improvers (other than manure) to "*pastureland*". "*Pastureland*" is defined as "*land covered with grass or other herbage and grazed by farmed animals*". This is in line with the current Community feed ban. This ban is further intended to avoid possible BSE risks and other diseases transmissible by feed, which may be related to direct grazing or use of grass as silage or hay by farmed animals from pastureland, where meat and bone meal from categories 2 and 3 materials could be present since it cannot be totally excluded that these categories 2 and 3 materials may have been cross-contaminated with Category 1 materials.

Pending adoption of harmonised rules, Member States (MS) may adopt or maintain national rules restricting the use of organic fertilisers or soil improvers. All MS and operators have raised concerns about a ban on the application to pastureland of organic fertilisers and soil improvers. This is a sensitive issue and the Commission currently tolerates that MS can continue the spreading on land of digestion residues and compost derived from category 2 and 3 ABP as referred to in Articles 5(2)(e) and 6(2)(f)) in accordance with national rules. This is based on the opinions delivered by CSTEE (April 2001) concerning the "Evaluation of sludge treatments for pathogen reduction", and by the SSC opinion (May 2001) on "The safety of organic fertilisers derived from ruminant animals". Such a

tolerance is on condition that farmed animals are not allowed to graze for at least 3 weeks following application to land of organic fertilisers or soil improvers and that the competent authority supervises the spreading of such materials, taking into account the risks to animal and human health and the environment.

TERMS OF REFERENCE

The Scientific Panel on Biological Hazards was asked

1. To reconsider, from a TSE risk perspective, the SCTEE opinion of 24 April 2001 on "Evaluation of sludge treatment for pathogen reduction" and this in the light of the SSC opinion of 10-11 may on "Safety of organic fertilizers derived from ruminant material"

2. More in particular to advice on the levels of biological risk clearance to allow the definition of the appropriate minimum waiting periods after which grazing may be allowed following application of organic fertiliser or soil improvers (e.g. meat and bone meal, digestion residues or compost from categories 2 and 3 animal tissues) on pastureland.

The identification of such a minimum waiting period is actually necessary to the proper interpretation of the definition of "pastureland" given in point 39, Annex I to the Regulation.

ASSESSMENT

The experts of the working group reviewed the two documents which were the basis for this request besides analysis of additional documents.

Preamble

It is assumed that, if all control measures currently in place to avoid contamination of category 2 and 3 ABP by category 1 ABP are effective, the ABP of category 2 and 3 are safe to be used for spreading on pastureland, taking into account the appropriate heat treatments as laid down by legislation applying to category 2 and category 3 ABP. Avoidance of possible cross-contamination of category 2 and 3 ABP with category 1 ABP is based on efficient implementation of control mechanisms to avoid such cross contamination. This in turn is a matter for the risk manager.

Assessment

It was argued that category 1 materials should be excluded from this mandate since opinions of the SSC (e.g. 10-11 May 2001) do indicate that when the sourcing of the material is regarded as safe (e.g. GBR I countries) and/or appropriate processing is applied, there should be no waiting time needed.

Currently the ABP of category 2 and 3 can be used as organic fertilizers and applied on pastureland taking into account the conditions as set out in the legislation, i.e. appropriate heat treatment in case of category 2 and sourcing from animals declared fit for human consumption in case of category 3. Therefore, in consideration of TSE-related risk from ABP, the differences between ABP classed as category 3 from ABP classed as category 1 and category 2 have to be taken into account. Despite the fact that the ABP classed category 3 come from animals considered fit for human consumption there is no absolute guarantee that TSE infective material would not be present in the material (e.g. animals in early stage of incubation not picked up by rapid testing).

This risk assessment therefore, refers to ABP of category 2 and category 3 however, with a risk of these being contaminated with ABP category 1. As explained in EC regulation 1774/2002, a mixture of ABP of category 1 with category 2 is automatically regarded as being category 1 ABP and similarly in case of a mixture of category 2 and 3 the resulting product is regarded as category 2. Therefore, if there is the slightest possibility of risk of contamination of category 2 and 3 ABP with TSE infected or possibly infected materials (i.e. category 1 ABP) then these should be treated as category 1 and banned from any further use, incinerated and disposed off in accordance with the ABP regulation (EC, 1774/2002).

It is recognised that a cross-contamination of ABP of category 2 and 3 with category 1 ABP can in theory never be excluded, however, such contamination is adjudged to as extremely unlikely given all the precautionary measures in place already.

There is no evidence available that defines the fate of prions following application to land either to pasture or directly into the soil. Different factors influence the fate of material spread on land and therefore impact on the determination of a necessary quarantine period following application. In relation to pastureland, these factors will include inter alia the type of pasture, rate of passage through the soil, the filtration effect of the soil, the survival characteristics and level of contaminant in the material applied. The Working Group acknowledges that research in this area is currently underway which could assist in identifying the period of quarantine required following applications of waste generated from animals.

It was considered that the determination of a waiting period of three weeks following application of organic fertilizers on pastureland as defined in legislation can not be supported by scientific evidence but is more based on Good Agricultural Practise (GAP). Scientific data to confirm clearance of biological hazards (especially in case of viruses and prions) from the environment are scarce or non-existing. There are no new scientific data available which may give an indication of the environmental survival of prions. It remains accepted that TSE agents are cleared very slowly from the environment, and therefore a definite period after which TSE agents are completely cleared, based on scientific evidence, cannot be established.

Considering the above, related to the present state of knowledge regarding the persistence of prions in the environment, it is not possible to define the waiting period, if any, for grazing of pasture land following the application of organic fertilizer or soil improvers derived from ABP of category 2 and 3 taking into account a possible TSE risk.

The current active surveillance of TSEs in MS is adding to the understanding of the incidence of TSEs in the animal population. However this surveillance programme, while it supports the reporting of clinical cases or gross pathological and histopathological findings, is at an early stage and has already been changed a number of times thus limiting the value of the data.

CONCLUSIONS

The Working group did not identify new scientific data giving an indication of the environmental survival of prions. It remains accepted that TSE agents are cleared very slowly from the environment, however a definite period after which TSE agents can be considered to have been completely cleared from the environment, based on scientific evidence, cannot be established. Therefore, if ABP of category 2 and 3 are suspected of being contaminated with category 1 ABP, it is impossible to advice on appropriate waiting periods.

Category 2 ABP are subject to a treatment as defined by legislation (133 degrees Celsius /20 minutes /3 bar). This treatment although responding to requirements for TSE inactivation, aims the reduction of the risk in case of contamination with other animal diseases than TSEs. This provides further level of control in cases there is an assumption of contamination of category 2 ABP with category 1 ABP. The same reasoning is valid for category 3 ABP: only if there is an assumption that these may be contaminated with category 1 ABP, an appropriate heat treatment (133/20/3) as for category 2 ABP should be applied.

The Scientific Panel on Biological Hazards and its Working Group concludes that in respect to TSE/BSE, the opinion of the SSC of 10-11 May 2001 on "Safety of Organic Fertilizers derived from ruminant animals" remains entirely valid and no new data were found since the 2001 opinion that could justify a revision of this opinion.

More in particular and under the condition that effective controls are in place to assure the status of all 3 categories of ABP, the Scientific Panel on Biological Hazards conclude:

1. If ABP of category 2 and 3 are to be used as a source for organic fertilizers and should there be any possibility of contamination with cat 1 ABP then the whole batch should be processed according to category 1 ABP.

2. ABP of category 3 can be processed in alternative ways provided that product and process are microbiological safe to eliminate human, animal and environmental risk. This must be confirmed by microbiological validation.

3. If in addition, appropriate heat treatment (as laid down by legislation) applying to category 2 (133/20/3) and category 3 (validated microbiological safe) is in place, no waiting period in addition to the one already defined in the legislation and based on Good Agricultural Practice is necessary. In that case, the ABP of category 2 and 3 are safe to be used for spreading on pastureland, ABP.

RECOMMENDATIONS

The Scientific Panel on Biological Hazards recommends:

1. The Commission should propose harmonised rules for the application to land including pastureland of certain organic fertilisers/soil improvers, derived from appropriately treated category 3 materials, or category 2 materials already subjected to appropriate heat treatment (133 °C/20 min/3 bars).

2. The process and product validation must include studies that show the decontaminating effect on bacteria and viruses. When epidemiological data suggest, also studies for other types of micro-organisms, such as parasites and spore forming bacteria should be included. The validation studies should be carried out using test organisms that have shown to be a good model for microbiological hazards potential present in the process and/or product. The test organisms used should at least be as resistant as micro-organisms potentially present. The test organisms should be applied under the same conditions as how they appear to be in the raw material. The decontamination must achieve a 5 log reduction.

3. The Scientific Panel on Biological Hazards further recommends continuation or initiation of new research in the field of:

- Study of the transmission routes of prions via the soil or pasture
- Investigation on the persistence, accumulation and mobility of prions in the soil
- Inactivation of prions by more sustainable processes.

This information is crucial for in order to answer the question on the risk of using organic fertilizers for which contamination with prions cannot be excluded. In addition this would also provide some explanation for those epidemiological findings where a direct link with feeding BSE contaminated MBM or TSE outbreaks in sheep and goat flocks, for example cannot be made.

DOCUMENTATION PROVIDED TO EFSA

Letter (ref. D(2003)MM/khk/4210000) from the European Commission, Health & Consumer Protection Directorate-General, requesting for an opinion on the safety vis-à-vis biological risk including TSEs of the application to pastureland of organic fertilisers and soil improvers including the background, terms of reference and supporting documentation.

SCIENTIFIC PANEL MEMBERS

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REFERENCES

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SSC (1999) 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: pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials. SSC meeting of 24-25 June 1999.

Annex

FULL LIST OF CATEGORIES 1, 2 AND 3 MATERIALS – EC 1774/2002

Article 4: Category 1 material

1. Category 1 material shall comprise animal by-products of the following description, or any material containing such by-products:

(a) all body parts, including hides and skins, of the following animals:

(i) animals suspected of being infected by a TSE in accordance with Regulation (EC) No 999/2001 or in which the presence of a TSE has been officially confirmed,

(ii) animals killed in the context of TSE eradication measures,

(iii) animals other than farmed animals and wild animals, including in particular pet animals, zoo animals and circus animals,

(iv) experimental animals as defined by Article 2 of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes [1], and

(v) wild animals, when suspected of being infected with diseases communicable to humans or animals;

(b) (i) specified risk material, and

(ii) where, at the time of disposal, specified risk material has not been removed, entire bodies of dead animals containing specified risk material;

(c) products derived from animals to which substances prohibited under Directive 96/22/EC have been administered and products of animal origin containing residues of environmental contaminants and other substances listed in Group B (3) of Annex I to Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC 2, if such residues exceed the permitted level laid down by Community legislation or, in the absence thereof, by national legislation;

(d) all animal material collected when treating waste water from Category 1 processing plants and other premises in which specified risk material is removed, including screenings, materials from desanding, grease and oil mixtures, sludge and materials removed from drains from those premises, unless such material contains no specified risk material or parts of such material;

(e) catering waste from means of transport operating internationally; and

[1] OJ L 358, 18.12.1986, p. 1.
[2] OJ L 125, 23.5.1996, p. 10.

(f) mixtures of Category 1 material with either Category 2 material or Category 3 material or both, including any material destined for processing in a Category 1 processing plant.

Article 5: Category 2 material

1. Category 2 material shall comprise animal by-products of the following description, or any material containing such by-products:

(a) manure and digestive tract content;

(b) all animal materials collected when treating waste water from slaughterhouses other than slaughterhouses covered by Article 4(1)(d) or from Category 2 processing plants, including screenings, materials from desanding, grease and oil mixtures, sludge and materials removed from drains from those premises;

(c) products of animal origin containing residues of veterinary drugs and contaminants listed in Group B (1) and (2) of Annex I to Directive 96/23/EC, if such residues exceed the permitted level laid down by Community legislation;

(d) products of animal origin, other than Category 1 material, that are imported from third countries and, in the course of the inspections provided for in Community legislation, fail to comply with the veterinary requirements for their importation into the Community, unless they are returned or their importation is accepted under restrictions laid down under Community legislation;

(e) animals and parts of animals, other than those referred to in Article 4, that die other than by being slaughtered for human consumption, including animals killed to eradicate an epizootic disease;

(f) mixtures of Category 2 material with Category 3 material, including any material destined for processing in a Category 2 processing plant; and

(g) animal by-products other than Category 1 material or Category 3 material.

Article 6: Category 3 material

1. Category 3 material shall comprise animal by-products of the following description, or any material containing such by-products:

(a) parts of slaughtered animals, which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons;

(b) parts of slaughtered animals, which are rejected as unfit for human consumption but are not affected by any signs of diseases communicable to humans or animals and derive from carcases that are fit for human consumption in accordance with Community legislation;

(c) hides and skins, hooves and horns, pig bristles and feathers originating from animals that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;

(d) blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;

(e) animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves;

(f) former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects which do not present any risk to humans or animals**;**

(g) raw milk originating from animals that do not show clinical signs of any disease communicable through that product to humans or animals;

(h) fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production;

(i) fresh by-products from fish from plants manufacturing fish products for human consumption;

(j) shells, hatchery by-products and cracked egg by-products originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals;

(k) blood, hides and skins, hooves, feathers, wool, horns, hair and fur originating from animals that did not show clinical signs of any disease communicable through that product to humans or animals; and

(l) catering waste other than as referred to in Article 4(1)(e).