Report and Scientific Opinion on mammalian derived meat and bone meal forming a cross-contaminant of animal feedstuffs adopted by the Scientific Steering Committee at its meeting of 24-25 September 1998

Executive summary : The Opinion of the Scientific Steering Committee

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

"Does there exist an acceptable level of cross-contamination with mammalian meat-and-bone meal of ruminant feed? If yes, which one and under which conditions is it applicable?"

A working group was created, which scientifically evaluated these issues and submitted its report to the Scientific Steering Committee. On the basis of the report of this working group, the Scientific Steering Committee elaborated and adopted the following opinion.

The Scientific Steering Committee is of the opinion that in principle, cross-contamination with mammalian meat-and-bone meal of animal feedstuffs is not acceptable and that only a zero level of cross-contamination can exclude any risk resulting from it. The risk for cross-contamination should be avoided by appropriate measures during the production, transport, storage and processing of the raw materials and of the produced feedstuffs.

*For practical reasons and taking into account the present technical limits of detection as well as a risk analyses based on present knowledge, the SSC considers that levels of cross-contamination of ruminant feeds with mammalian meat-and-bone meal - derived from raw materials sourced and processed according to the conditions laid down in the SSC's opinion on the safety of MBM - which exceeds 0.50% MBM (or 0.15% animal bone fragments or 0.25% proteins (*Considering that, on average, proteins account for at least 50% of meat and bone meals, 0.25% protein represents the equivalent of 0.50% meat and bone meal) *, whichever is the lowest) should be condemned.*

: 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.

Attachment : Report of the Working Group

1. The Question

The Working Group addressed the following question:

"Does there exist an acceptable level of cross-contamination with mammalian meat-and-bone meal of ruminant feed? If yes, which one and under which conditions is it applicable?"

2. Definitions

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

Cross-contamination with mammalian meat and bone meal (MMBM) of feed or diet for ruminants.

Cross-contamination is defined here as contamination with traces of MMBM in feed or diet for ruminants. In view of the existing MBM bans it only can occur as accidental contamination in different phases of the production process:

- during the agronomic production of the raw material, because of their possible contamination with mould which contains bone fragments;

- transport and storing of the raw materials or the produced feeds, because of the mixed use of the transport and storage

facilities for ruminant and monogastric feed;

- the industrial preparation of the ruminant feed, by using the same production systems for ruminant and non-ruminant feeds;

- the handling within a farm of the various feeds in farms with mixed breeding.

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 an 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.

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

Research carried out by Wilesmith (1996) pointed out that for the animals born after 1988 (year of the ban on the use of meat and bone meals in the feeding of ruminants), there was a positive correlation, in United Kingdom, between the new cases and their number in different areas where pigs and poultry were raised.

Wilesmith et al. (1996) suggested that this was due to the accidental cross-contamination of ruminant feeds by meals derived from specified bovine offals which were legally authorized in the feeding of non-ruminants until September

1990. One also cannot exclude the improper use of poultry and pig feedstuffs in ruminant feeding by farmers.

The adopted ban has made it possible to reduce the incidence of the disease once the initial contamination cycle was over and provided experimental evidence that, on the basis of the epidemiological findings, the aim is to avoid feed contamination. At the present time, the number of confirmed BSE cases in the UK dropped from 23,945 in 1994 to 4,297 in 1997 (and 918 cases between 1 January and 12 June 1998) while in Northern Ireland a decrease from 345 to 23 cases was observed during the same period (4 cases between 1 January and 31 May 1998). The intentional or unintentional breaching of the ban on the use of animal proteins including specific bovine offals in ruminant feeding contributed to the many cases of BSE among animals born after the ban (36,522 in the UK and 203 in Northern Ireland).

Theoretically, the Commission Decision to ban the feeding of MMBM to ruminants should be easy to implement but most European feed production systems are of a mixed type, meaning that in 90% of cases the same facilities and the same conveying systems are used for the production of feed for both ruminants and monogastrics (FEFAC, 1997). This implies possible cross-contamination of ruminants feed (produced, without animal meals of mammalian origin), by feeds for monogastrics containing meat and bone meals of mammalian origin.

Contamination often occurs at extremely low levels, e.g. less than 1/1000 in Italy. The adoption of good processing practices helps keep this phenomenon under control, even if it should be regarded as unavoidable. Its detection solely depends on good analytical procedures and on the operator's skills.

The problem of microcontamination does not simply affect the production system of the feed industry, but the whole sector of transport and production of raw materials from plant sources. One can in fact find traces of bone fragments in samples of corn seed, alpha-alpha pellets, corn gluten, soybean meal etc. This may be due to contamination induced by transport or to cropping practices (in many agricultural soils, i.e. in the mould and in the dusts which contaminate the crops, one may easily find bone fragments).

Indirect evidence for this is provided by the fact that in ruminant feeds produced in plants where feed production from plant raw materials have been introduced for a number of months, including for monogastrics, bone fragments of mammalian origin were found.

This problem affects many countries. For example, the Directorate for Plants of the Danish Ministry of Agriculture and Fishery (Lyngby, Denmark), which performed all inspections on behalf of the Swedish State Institute of Veterinary Medicine (Uppsala, Sweden), found, on the basis of analyses by microscopy, that 55% of the 60 feeds under examination were positive. In the UK, according to data reported by MAFF (1998b) on the cases of breach found in the preparation of feeds and rations for ruminants and non-ruminants in the period from August 1, 1997 to March 18, 1998, out of 3,913 samples 13 (0.33%) were positive and 8 (0.20%) were doubtful; in the rations for ruminants, out of 2,416 samples 1 was positive and 2 were doubtful. (The ELISA method was used, which does not detect the presence of mammalian proteins at levels below 0.25%). In Italy according to official data of the Ministry of Health of 1997 around 15% (out of 730 samples 109 were positive) of controlled ruminant feeds are contaminated from MBM traces (method: microscopy with a level of sensitivity of 0.01%). The data available for various countries are not always comparable because of the different methods used for the determination of the level of cross-contamination, but they indicate a situation of variability between the countries, partly resulting from the different methods but also because of differences in the type of tissue that are identified by these methods.

Decision 94/381/EC of the European Commission states that: *"The administration to ruminants of feeds containing proteins from mammalian tissues is banned."*

The lack of an accurately defined tolerance limit for mammalian meat and bone meal (MMBM) traces in feeds for ruminants, due to possible accidental cross-contamination or errors, has brought about a situation of uncertainty also caused by the lack of adequate control methods, especially in some countries.

Given the present production systems, a real zero presence level cannot be considered. The implementation of good manufacturing practice (GMP) in several plants is reducing, though not excluding, the risk of contamination of raw materials.

It therefore becomes mandatory to define whether and to what extent one may accept traces of contamination induced by mammalian tissues in general (cattle, pigs, horses, etc.) or by ruminants alone or, more precisely, by highly infectious tissues.

In the meeting of 19-20.02.1998 the SSC expressed *"the urgent need of a study and risk analysis being carried out so as to possibly define acceptable tolerance limits of the possible content of impurities and proteins from mammalian material in feed which theoretically should not contain any impurity. A zero contamination level is indeed difficult - if not impossible - to achieve, also from a scientific point of view. To determine the content of impurities and proteins, an accepted standard analysis method would also be required."*

In its accompanying report the SSC considered it to *"be useful to examine the possibility of fixing a maximum level of acceptance of proteins from mammalian material based on the sensitivity of the analytical method or on a precise definition. The risk analysis preliminary to defining tolerance limits should take into account, amongst others:*

- the fact that the "133°C / 20 minutes / 3 bar" treatment imposed by the EU has been in force since 1 April 1997;

- whether or not the meat and bone meals are produced only from low risk materials;

- the infectious potential of different extraneural tissues, which may vary according to the animal species;

- the dose needed to infect an animal."

The previous list should be completed with the assessment of the BSE status of a country, as the geographical risk of infectivity of the raw material used for the production of meat-and-bone meal is directly related to the risk that the MBM itself would be infectious.

The UK has implemented (MAFF, 1998b) a surveillance system to detect breaching or cross-contamination phenomena in the preparation of feeds for ruminants containing traces of mammalian meat meals. The investigation is carried out by means of a technique (ELISA) which has been formally in use since 1996, following a precise monitoring plan which currently requires the examination of approximately 20,000 samples per year taken from feed, premixer producers and farmers. The method is capable of detecting the presence of 1 part of animal proteins (from ruminants or pigs) in 400 parts of feed (MAFF, 1998) This value of sensitivity corresponds to the presence of 0.25% protein (from ruminants and pigs) and not of meat and bone meal in the feed. The ELISA method is also used in Ireland. The test is currently available only at the Laboratory of the Luddington MAFF Veterinary Investigation Centre (VIC). A similar procedure has been studied and proposed also by Honikel (1997). The UK veterinary services regard the ELISA method, selected with the above limit of mammalian protein detection, as capable of ensuring that a ruminant feed contains no proteins from ruminant tissues which could make it dangerous or harmful. The UK considers this measure as adequate.

In the course of 1997 and 1998, the European Commission initiated and co-ordinated a co-operative study involving 28 laboratories in the EU concerning the control by microscopic examination of meat and bone meal present in compound feedingstuffs. (EC, 1998b) The study was organised to check the current possibilities for the determination qualitatively and quantitatively by microscopic analysis, possibly in combination with other methods of analysis, of the ingredients in compound feedingstuffs, and in particular to detect the presence, the origin and the quantity of the meat-and-bone meals. From the study it was concluded that, among others:

- the presence of of constituents of animal origin can be established by microscopic examination; with reasonable experience it is possible to identify different animal constituents (bones, feathers, animal hair, meat fibres and blood); the detection limit of bone fragments by microscopy is approximately 0.1% or even smaller. But it requires more experience to differentiate bone fragment of mammalian from poultry with a reasonable accuracy;

- quantifications can only be made in case of bone fragments present in the product, and the accuracy is very dependent on the bone content in the animal ingredient to be identified ina compound feed;

- the microscopical method alone cannot be used for differentiation between terrestrial animal species. In this case it should be combined with other techniques, for example ELISA, DNA technology

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-rumimant Food Producing Farm Animals*, which was prepared for the Scientific Steering Committee and presented at its meeting of 24-25 September 1998.

The presence of meat and bone meals in ruminant feeds is a potential risk factor not so much in terms of the muscles or bone fragments (class III) but rather because of highly infectious tissue portions belonging to class I, and to a lesser extent class II and then class III according to the classification proposed by the World Health Organisation.

The assessment of the size of this phenomenon largely depends on the analytical methods used and on the operators' skills.

The detection of proteins from mammalian tissues is mostly based on a method of analysis which substantially relies on the identification of bone fragments only. This method has been developed for other purposes and has not been validated by the EU. Due to the inaccuracy which is inherent in this type of investigation, the method, which also aims at a quantitative assessment, would require that the detected percentages are expressed in integers. Broad margins of inaccuracy seem thus to be inherent to this method.

Considering that, on average, proteins account for at least 50% of meat and bone meals, 0.25% protein represents the equivalent of 0.50% meat and bone meal. (For analytical determinations based on the microscopical search for bone fragments, 0.5% of MBM corresponds with 0.15% of bone fragments)

The SSC already expressed its doubts as to the validity of the analytical methods used and applied in the different countries by stating in its opinion of 26-27 March 1998 that " *an accepted standard analysis method would also be required"*.

The difficulties in eliminating the traces of mammalian proteins from feed production are linked to the special chemical and physical properties of meat and bone meal particles which adhere to the metal walls of the silos, the storage tanks and the vehicles as well as to the mechanical and hydraulic conveying systems used in the production plants. According to data collected from some feed compounders, in order to eliminate the traces of meat and bone meal from a production line where monogastric feeds containing 3% meat and bone meal are produced, one would require four processing cycles of feeds which do not contain any meat meal. One should necessarily use raw materials which are free from MMBM traces. This procedure cannot be easily applied to the routine working diagrams.

It may also be noted that vegetable materials can be directly contaminated with mammalian protein and bone either as a result of small mammals being killed and harvested with the crop or as a result of harvesting skeletal remains that may be in pasture. Rats and mice (and birds) can die in grain stores or below owl nests (below which are pellets of bone) so there is a background level unconnected with MMBM of bone fragments in vegetable feed material. However, in view of the SSC, this presents (at present knowledge) a negligible risk in regard to TSE.

Elements of risk assessment:

For what concerns cross-contamination, where the impurities are of the order of tenths of percents, the above clearance factor of 10^{-3} (drying excluded) would result, for a cross-contamination level of 1% with MMBM derived from brain and spinal cord raw material, in 0.1 ID_{50} per ton of sterilised product and in 0.01 ID_{50} per ton of sterilised product for a cross-contamination level of 0.1%.

[For the purpose of the above assessment it is assumed that an infected animal enters a 10 ton processing batch of slaughter residues contributing with 1000g of infectious brain and spinal cord tissue. Presently, the ID_{50} is considered to be 100 mg, hence the initial infectivity is 10^4 ID_{50} in 10,000 kg, corresponding to 1 ID_{50} /kg of raw product. The pressure treatment induces a 10^3 reduction (1 ID_{50} in 1 ton of raw sterilised product). A cross contamination of 1% or 0.1% would then result in 0.1, respectively 0.01 ID_{50} per 1 ton of rendered material. In this calculation a possible additional reduction from the subsequent drying process is not taken into account. It also assumes an homogeneous distribution of the cross-contamination in the feedstuff, which may not necessarily be the case.]

The exclusion of the specified risk materials brain and spinal cord would result in an additional reduction of almost 10^{-2}. Appropriate sourcing would further reduce the risk. With a maximum contamination level of 0.5%, the risk can be considered negligible also in the case of an high ingestion of feed concentrate (for example animals used for intensive milk production).

Regarding the method used for the determination of these contamination levels, the following observations can be made:

The species specific ELISA test has been used in the UK since February 1996. It has a sensitivity of 1 part of bovine or swine protein for 800 parts of feed (0.13%). The method is exempt from pH interference and from the effect of the treatment at 133°C / 20' / 3 bars. It can give a false positive result if blood or milk proteins are present. (These mammalian proteins are not excluded from ruminant alimentation.)

Microscopic analysis is used for the identification and quantitative valuation of mammalian bone fragments, which are easily separable by gravity in an organic solvent (tetra-chloro-ethylene). The mammalian bone fragments are distinguishable by stereomicroscopy from poultry bones and from the bones and cartilaginous tissues of fish. This method is officially used in Italy. It allows the amount of bone tissue < 200 mg/kg feed to be ascertained. However, the detected value may be an index of large quantities of animal tissues present in the feed, depending upon the ratio of bones among the other constituents of the MBM.

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

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