



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Scientific Steering Committee

OPINION ON
QUANTITATIVE RISK ASSESSMENT ON THE USE OF THE
VERTEBRAL COLUMN FOR THE PRODUCTION OF GELATINE AND
TALLOW.

ADOPTED BY
THE SCIENTIFIC STEERING COMMITTEE
AT ITS MEETING OF 13-14 APRIL 2000

OPINION

Questions and scope of the present opinion:

The Commission requested the Scientific Steering Committee to address the following general questions:

1. Is there new evidence or are there reasons to reconsider the validity of the various SSC opinions directly or indirectly related to the safety of bones opinions or to amend/update the listed conditions¹? In particular, if and under what conditions may vertebral column and dorsal root ganglia in view of their relative risk be considered as safe for human and animal consumption? Do factors like the incidence (prevalence) of the disease and effective enforcement of general risk reduction measures such as (other) specified risk material removal rules, feed bans and age reduction at slaughter (Over Thirty Month Schemes) effect the level of risk associated with vertebral column and dorsal root ganglia?
2. Are the answers to the previous questions also valid for sheep and goats; if not, how should they be amended?

The Scientific Steering Committee established various Working Groups to prepare scientific reports on the above questions. The present opinion deals only with the *Quantitative Risk Assessment on the Use of the Vertebral Column for the production of Gelatine and Tallow*. It more precisely addresses the question if and under what conditions vertebral column may, in view of its relative risk be considered as safe for human and animal consumption when used as a raw material for the production of tallow or gelatine.

Two other opinions and reports deal with the *UK decision to lift the ban on the consumption of bone-in meat* and with the *Re-assessment of the safety with respect to TSEs, of certain types of specified risk materials of small ruminants*.

¹ For example, geographical source, herd source, individual animal source (e.g., age, progeny line, ...), processing, intended end-use, risk of cross- contamination.

A quantitative approach for the assessment of bovine-derived products.

In several of its opinions the SSC recommended that quantitative risk assessments should eventually replace the qualitative method applied so far for the evaluation with respect to TSEs of the safety of ruminant-derived products such as tallow and gelatine. Such approach was applied for the first time for the preparation of the present opinion. The details are provided in the report of the Working Group, which is separately available on Internet. *Interested parties are invited to comment on this report until 10 June 2000. These comments will then be discussed by the SSC at its meeting of 6-7 July 2000.*

The opinion is based on a spreadsheet model recently developed on behalf of the SSC by the University of Utrecht (The Netherlands). It makes possible the input of several parameters influencing the infectivity level of animal products such as gelatine and tallow manufactured with or without brain, spinal cord, skull and vertebral column (SRMs).

The model was used for a quantitative risk assessment of the safety of tallow and gelatine derived from bovine bones according to three levels of SRM removal and 2 scenarios of tissue infectivity titres and species barrier. The following table provides a summary of the scenarios tested:

	Level A ₁	Level A ₂	Level B ₁	Level B ₂	Level C ₁	Level C ₂
Brain	OUT	OUT	OUT	OUT	IN	IN
Spinal cord	OUT	OUT	OUT	OUT	IN	IN
Skull	OUT	OUT	OUT	OUT	IN	IN
Vertebral column	OUT	OUT	IN	IN	IN	IN
Bone marrow	Infectious	Not infectious	Infectious	Not infectious	Infectious	Not infectious
<u>Titre and barrier:</u> Scenario 1	The infectivity titre in brain and skull is approx. 10 Cattle oral ID ₅₀ (CoID ₅₀) per gram as geometric mean (median) value; 1 and 1000 CoID ₅₀ as extreme values. The species barrier varies within the range of 10 ⁰ and 10 ⁴ , with 10 ³ as average value.					
<u>Titre and barrier:</u> Scenario 2	The infectivity titre in brain and skull is approx. 100 Cattle oral ID ₅₀ (CoID ₅₀) per gram as geometric mean (median) value; 1 and 1000 CoID ₅₀ as extreme values. The species barrier varies within the range of within the range of 10 ⁰ and 10 ⁴ , with 10 ¹ as average value.					

Within each scenario, the main input parameters were identified as follows:

- incidence of clinically and subclinically infected animals which are slaughtered for food;
- yearly number of adult animals slaughtered;

- estimated number of animals that make up a batch of fresh material to be processed, that depends, amongst others, on the total amount of fresh bone material per animal;
- number of batches of fresh material processed per year;
- BSE infectivity titres in tissues which depend on species barrier and infective dose;
- Reduction of BSE infectivity titres in tissues by processing;
- Size of an average edible portion of the end product.
- Average batch size of the end product.

The values adopted for the different parameters in different scenarios are outlined in detail in the report of the Working Group.

Both a deterministic and a probabilistic (stochastic) approach were applied. In the deterministic approach, calculations for the best, average or worst case scenarios would assume that all input parameters would simultaneously either be best, average or worst.

In the probabilistic approach, during each calculation of the model, a value is selected from each of the probability distributions attributed to any input parameter. Therefore, all possible combinations have been explored so far during about 100.000 repetitions selected for the modelling process. This model provides not only possible extreme values but also most likely outcome for the chosen combination of input distributions.

Quantitative risk assessments always go along with a level of uncertainty that increases as the scientific unknowns increase. Their results should thus be exploited keeping in mind not only the uncertainties as such but also the range of values that may be attributed to a given parameter. In the report attached to the present opinion, two approaches are explored. In a deterministic approach a chosen "worst case" "best case" and "average" value are attributed to each parameter that intervenes in the assessment. In a probabilistic approach, the values for each parameter are selected at random from a given probability distribution that is assumed to be valid for that parameter; the number of model runs should be taken sufficiently high (until the results stabilize) to guarantee that all possible combinations of parameters have eventually been selected a sufficient number of times to allow an evaluation of the probability of occurring of the corresponding risks.

The SSC considers that the rigidity of the deterministic approach may result in unrealistic scenarios as, for example, the likelihood is almost zero that all values, assumptions and scenarios combined will at once be "average", "best" or "worst", although it can formally not be excluded.

The probabilistic approach on the contrary is likely to result in more realistic scenarios and allow decision makers to take a decision in the light of the risk level they find acceptable. However, when evaluating/exploiting the results of the probabilistic approach it should be clear that the residual risks defined are not to be considered as exact values, but should be seen as indicative of the order of probability of a risk level occurring.

The opinion.

As appears from the summary tables in the report of the Working Group, the most important risk reduction results from the removal of the tissues that carry the highest infectivity at the end of the incubation period. The additional safety level resulting from the removal of the vertebral column is much lower. Whether or not it should be removed has to be decided upon in the light of the residual risk levels that are considered to be acceptable. **The** preliminary report offers a frame for such decision. The possible decision whether or not and/or under what conditions tallow should be submitted to an additional treatment of "133°C/20'/3Bars" (or validated equivalent), should be discussed in the same context. However, for the time being, and in the light of the preliminary results presented in the report of the Working Group, the SSC considers that the additional safety gained from the removal of vertebral column for the production of tallow and gelatine is limited in countries with a lower BSE risk, but should be considered as sufficiently important to exclude it in higher risk countries.

Apart from the apparent factors such as the incidence or prevalence of the disease, processing conditions, etc., it is clear that other conditions such as the effective enforcement of a feed ban and the age at slaughter will affect the level of risk associated with vertebral column. In this respect, the SSC refers to its various opinions on the UK Date Based Export Scheme, from which it can be derived that bones from a high risk country, but sourced from animals that comply with a number of conditions such date of birth after a feed ban, age,

avoidance of cross-contamination, etc., can be considered as representing a safety [or risk] level which is similar as for a lower risk country.

Remark:

In its opinion of March 1998 on the safety of gelatine, the SSC mentioned that the issue of the safety of tallow in calf feed needed to be addressed. The SSC considers that the method explained in the attached report, could be applied for such assessment. For the time being, it may already be signalled that for calves, no species barrier would exist and that the daily consumption of tallow by calves (and by most farmed animals, see report) is much higher than for humans.