

Opinion on the safety of bones produced as by-product of the Date Based Export Scheme adopted by the Scientific Steering Committee at its meeting of 22-23 October 1998

The Question:

"What is the risk that bones -vertebral column, skull, and / or other bones - produced as offal under the conditions of the DBES may carry the BSE-agent?"

The background:

The OIE states in its latest draft proposal for a chapter on BSE (Art.3.2.13.14) that bones from countries with a high incidence of BSE may not be used for the preparation of food, feed, cosmetics, pharmaceuticals or medical devices. Importing gelatine or collagen produced from bones from countries with a high incidence of BSE is not permitted (Art 13.2.13.15).

In the opinion of the SSC on Specified Risk Material (9/12/97) bones are not classified as specified risk material. However, in a footnote to table 6 of the full opinion, the SSC states "In high risk countries, all tissues of cattle over 30 months of age may be considered as being at greater risk and therefore be considered as SRM. Long bones from cattle below 30 months showing no clinical signs of BSE may be considered at present acceptable for human consumption."

In its opinion covering both the "UK Date Based Export Scheme (DBES) and the UK proposal on compulsory slaughter of the offspring of BSE cases" (9/12/97), the SSC states that "the DBES should be restricted to de-boned meat only." It also states that "the Committee considers that any remaining risk can further be reduced by only allowing de-boned meat from animals between 6 and 30 months for export, ..."

In its opinion on gelatine the SSC recommends exclusion from the production of gelatine all ruminant materials, except hides, from animals from a high-risk source. However, in a footnote to the summary table it states "In certain circumstances the risk profile can be changed, e.g. on the basis of the age of the animal, the origin (source) of the animal, etc. This could result in bovine material from high risk areas to be possibly acceptable for gelatine production, provided those circumstances carry no risk and provided the conditions applicable for lower-risk countries are respected." These conditions for lower-risk countries are - animals fit for human consumption, and SRM excluded, and appropriate production process.

Recently the question arose of the status of the bones left over after the de-boning process. Given the economic importance of that issue and the unclear scientific advice currently available, the SSC is requested to provide a clear scientific advice as to the safety of that material and whether it should be disposed of or could be used as raw material for further processing.

Risk Assessment

The risk to be assessed is the likelihood that the bones, including skull and vertebral column, which remain after the de-boning of cattle complying with conditions equivalent to those specified in the proposed DBES for the UK, carry the BSE-agent.

A) The Hazard

The bones produced in the context of the DBES, or an equivalent scheme, may only carry a BSE-risk if BSE-infected animals are processed.

If that would be the case, the infective load of the bones could be in the bone material itself, in the bone marrow, or in

infective nervous tissue attached to and remaining on the bones, e.g. dorsal root ganglia remaining on a vertebral column.

Infectivity might also be attached to the bones through cross contamination from CNS or other SRM from the infected animal itself or, if the animal in question is not infected, from an infected animal processed in the same batch (It should be noted that the proposed DBES foresees slaughtering of these animals in dedicated slaughterhouses. This would exclude the risk of cross contamination from other animals).

B) The Risk

Because of the conditions of the DBES (See list of key conditions of the DBES in annex 1) the risk that animals processed under the DBES, or an equivalent scheme, do carry BSE is regarded as negligible. (In its opinion on the DBES the SSC used the wording "remote".)

However, the fact that the SSC proposed to de-bone the meat indicates that the remaining risk is still regarded as important enough to justify this measure. Accordingly the risk that bones after the de-boning could carry some BSE-infectivity is depending on the risk that a (sub-clinical) BSE case is entering the system. It has already been stated that this risk is considered to be remote.

However, if this remote possibility becomes real the assessment of the BSE-risk carried by the bones remaining after de-boning has to take account of the following:

- Bone material itself has not been found to carry any BSE-infectivity. However, it cannot be excluded that BSE infectivity may exist below the current detection level.
- Bone marrow has been found to carry BSE infectivity if the animal was clinically affected by BSE late, i.e. 38 months after experimental infection by oral challenge and not earlier in the incubation period. However, it cannot be excluded that BSE infectivity exists in bone marrow earlier on, albeit below the current detection level.
- Nervous tissue is known to carry the BSE-agent at least at the later stages of the incubation period and the agent is found in particular in the trigeminal and dorsal root ganglia. While the trigeminal ganglia will normally remain in the skull, dorsal root ganglia will at least partly remain with the vertebral column.
- Cross contamination by CNS of bones is possible because of the spilling of brain tissue and of spinal cord.

Conclusion

On the basis of the above the SSC considers that the risk borne by bones remaining after the de-boning of meat from animals fulfilling the conditions of the DBES is first of all depending on the risk that undiscovered (pre-clinical) BSE-cases are entering that scheme.

Given the conditions imposed by the DBES or an equivalent scheme, and given the risk analysis that was carried out as part of the elaboration of the DBES proposal, this risk is considered to be remote.

However, if a BSE infected (non-clinical) animal is slaughtered, the risk for bones to carry infectivity is higher for older animals because the disease becomes more advanced and hence the load with the BSE-agent rises. Also bone marrow may show infectivity.

It is noted that the DBES already includes an age limit of 30 months, which would have a substantial impact on the theoretically possible infective load of any infected animal being slaughtered under this scheme.

Given this age limit it is possible to assume that the risk that bones and bone marrow are infective is negligible. Only nervous and CNS-tissue attached to or spilt over bones could pose a non-negligible risk if an animal would be slaughtered under the scheme which has been infected very young.

In order to address the remote risk that a clinically sound but BSE-infected animal would be slaughtered in the context of the DBES, or an equivalent scheme, it is therefore recommended to exclude the skull (including the trigeminal ganglia) and the vertebral column (including the spinal cord and the dorsal root ganglia) from further use.

The other bones should be assumed to be at least as safe as bones from animals from geographical areas classified as lower-risk. When transformed into gelatine or other products, they would have to be treated as if coming from such a source. (See the relevant SSC-opinions for reference.)

Annex I - Key elements of the Date-based Export Scheme (DBES)

The DBES scheme allows the export of

deboned fresh meat from which all adherent tissues, including obvious nervous and lymphatic tissue has been removed, and which is obtained from animals:

- born after the date at which the animal feeding standards (feed ban) were effectively enforced, and

- certified to meet the following conditions:

* the animal is clearly identified, enabling it to be traced back to the dam and herd of origin; its unique eartag number, date and holding of birth and all movements after birth are recorded either in the animal's official passport or on an official computerised identification and tracing system; the identity of its dam is known;

* the animal is more than 6 months but less than 30 months of age, determined by reference to an official computer record of its date of birth, or to the animal's official passport;

* the competent authority has obtained and verified positive evidence that the dam of the animal has lived for at least 6 months after the birth of the eligible animal;

* the dam of the animal has not developed BSE and is not suspected of having contracted BSE.

If any animal presented for slaughter or any circumstance surrounding its slaughter does not meet all of the requirements, the animal must be automatically rejected

Slaughter of eligible animals must take place in slaughterhouses exclusively used for slaughter of animals under a Date-based Export Scheme or under a Certified Animal Scheme.

The following lymph nodes have to be removed:

Popliteal, ischiatic, superficial inguinal, deep inguinal, medial and lateral iliac, renal prefemoral, lumbar, costocervical, sternal, prescapular, axillary and caudal deep cervical.

Meat must be traceable back to the eligible animal, or after cutting, to the animals cut in the same batch, by means of an official tracing system until the time of slaughter. After slaughter, labels must be capable of tracing fresh meat and products back to the eligible animal to enable the consignment concerned to be recalled.