A FRAMEWORK FOR THE ASSESSMENT OF THE RISK FROM DIFFERENT OPTIONS FOR THE SAFE DISPOSAL OR USE OF MEAT AND BONE MEAL (MBM) AND OTHER PRODUCTS WHICH MIGHT BE CONTAMINATED WITH TSE'S AND OTHER MATERIALS.

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE AT ITS MEETING OF 28-29 JUNE 2001.

IMPORTANT NOTE:

The present document is intended to assist bodies preparing a dossier on the assessment of safety of specific processes and/or equipment relating to TSE's. This document has no legal status. It is acknowledged that more detailed guidance will need to be developed on particular aspects of this framework.

However in order not to delay the evaluation of proposals for the safe processing and/or disposal of (TSE) waste, it was agreed by the SSC that this draft framework should be used, in the interim to evaluate the pending submissions.

PREAMBLE

The Commission has recently recommended a ban in all Member States on the practice of feeding meat and bone meal (MBM) to animals reared for human consumption. This ban will lead to a very substantial accumulation of MBM, which must be disposed of safely. Although this is, in the first instance, a temporary ban, its duration is uncertain and may be prolonged.

The SSC has recently provided an opinion on the safe disposal of MBM. The SSC identified high temperature incineration as the only route, which guarantees safe disposal of MBM. *(reference to be added*).

Currently, high temperature incineration facilities across Europe have a relatively low annual capacity and many Member States have very few facilities of this kind. To honour the ban imposed by the Commission will require:

- Identification of alternative means of safe disposal
- A very substantial increase in safe storage capacity (for guidance see SSC note of 26-27th October 2000)

The identification of safe alternatives to high temperature incineration in addition to addressing methods for treatment of MBM should cover all processes (current or proposed) for volume reduction of carcasses. It is relevant in considering safe disposal methods to identify the application of any process to pathogens other than prions.

Any decisions on the safety of a particular technology must be based on a sound scientific risk assessment. An essential requisite of utilising a risk assessment framework is to ensure that human health (both health of workers and the general public); animal health and the environment in the EU are properly protected. This assurance should be determined prior to the widespread adoption of any process for

dealing with animal carcasses and other derived materials. It may be argued that in an emergency situation there is insufficient time for a risk assessment. However, routes of disposal / forms of use for different types of animal potentially contaminated with pathogens, etc should be evaluated as part of normal emergency planning. The legal requirement is defined in Article 4 of the Framework Directive on Waste (96/350/EC):' without using processes or methods, which could harm the environment, and, in particular:

- without risk to water, air, soil, plants and animals
- without causing a nuisance through noise or odours
- without adversely affecting the countryside or places of special interest'

Typically, a risk assessment of any equipment/facility/ process has two stages:

- Identification of the *generic risk* (i.e. the one intrinsically associated with the specific equipment/ facility/process
- Identification of *situation specific risks* which may include site sensitivity, effectiveness of the local management systems, etc.

There are schemes to assist evaluation of this second stage, for example, the UK's Operation and Pollution Risk Appraisal (OPRA). The SSC framework therefore addresses the generic risks only.

For a framework to be employed for risk assessment purposes it must identify each source of human, animal and environmental risk in the risk management chain. (See Figure 1). In this context it should be recognised that, if restrictions are placed on use of one process, there will be an inevitably increase in the use of other(s).

ROLE OF THE SSC

The intention of this framework is to provide a structured approach to the assessment of the direct and indirect risks involved in the treatment of materials (potentially contaminated with TSE's. or indeed other pathogens). The framework can be applied to identify suitable processes to be used in a routine situation or in an acute emergency. It is not part of the current activities of the SSC to evaluate specific commercial equipment and products.

COMPONENTS OF THE RISK ASSESSMENT FRAMEWORK

In each case, **the proposed process as a whole and each of its steps need to be described and** the key operating parameters need to be defined. The risk assessment framework should comprise the following components:

1. Identification and characterisation of the risk materials involved the possible means for their transmission and potential 'at risk' groups.
2. The risk reduction achieved by the particular process.
3. The degree to which the risks can be contained under both normal and emergency/ abnormal operating conditions
4. Identification of interdependent processes, for example, transport, storage, loading of any TSE related risk materials.

5. The intended end-use of the product(s), for example, disposal, recycling, etc.

Note: Although each of these steps is relevant to dealing with many pathogens , the risks from processes involving TSE's are addressed in the remaining text.

1. Identification and characterisation of risk materials

In addition to the TSE contaminated materials processes may involve substances with other risks to human health (workers and the public), animal health and the environment. These materials may be involved in the actual treatment of the carcass/MBM eg hyperchlorite. They may also be by-products of the treatment, such as airborne emissions (for example, dioxins); effluent or residues (for example, heavy metals).

Each significant risk material should be identified and an assessment made of the likelihood of human/environmental exposure of 'at risk' groups under:

- normal operating conditions
- emergency/abnormal operating conditions

If significant exposures are deemed possible, an assessment will be needed of the potential risks involved.

2. TSE risk reduction

An estimate is required of the degree of the TSE risk reduction (in terms of human health, animal health and the environment) which can be achieved by the process.

This may be based on one or more of the following:

- Direct measurements
- Modelling
- Extrapolation from procedures which were previously proved to be effective in another context.

In each case the evidence to support the estimate must be cited. Where measurements have been made, information on the methodology used should be provided. This would include sensitivity and reliability of the methods used, the nature of samples which have been analysed and evidence that these samples are representative (relevant real samples and the number of tests performed).

If surrogates for prion measurement are used, for example analysis of peptide levels, an explanation should be given of their relevance.

In the case of modelling or other forms of extrapolation it is necessary to provide an evaluation of the validity of the model/extrapolation together with the uncertainties involved.

3. Risk containment

An analysis should be made of the likely effectiveness of the technical measures used to ensure that the TSE risk is fully contained. It is also necessary to evaluate how these containment measures will operate in the event of the breakdown of the process. Monitoring and surveillance procedures to demonstrate containment will need to be

specified. If full containment is not achievable, an assessment is required of any potential risk.

4. Identification of interdependent processes

From a risk assessment viewpoint, any process identified to reduce the risk from TSE cannot be considered in isolation from indirect impacts, such as transport, storage and safe disposal of the end –products and by-products. These particular aspects need to be evaluated to identify whether an increased indirect risk may occur. For example, risks due to the increased demand for storage capacity. (See Fig 1 – The Risk Management Chain)

5. The intended end-use of the product(s), e.g.disposal, recycling etc

The anticipated end uses need to be specified. From the estimated (if measured) risk reduction (in 2 above) the likely risks involved should be calculated. Based on this potential exposure of workers or the public, animal health and/or the environment should be estimated if significant levels of exposure to the product(s) may arise.

CONCLUSIONS

(a) The principal elements are set out of a framework to assess the risks from processes for dealing with carcasses and products derived from them, that may be contaminated with TSE's

(b) The approach used enables different processed to be compared in terms of potential risks for human health, animal health, animal and the environment. health.

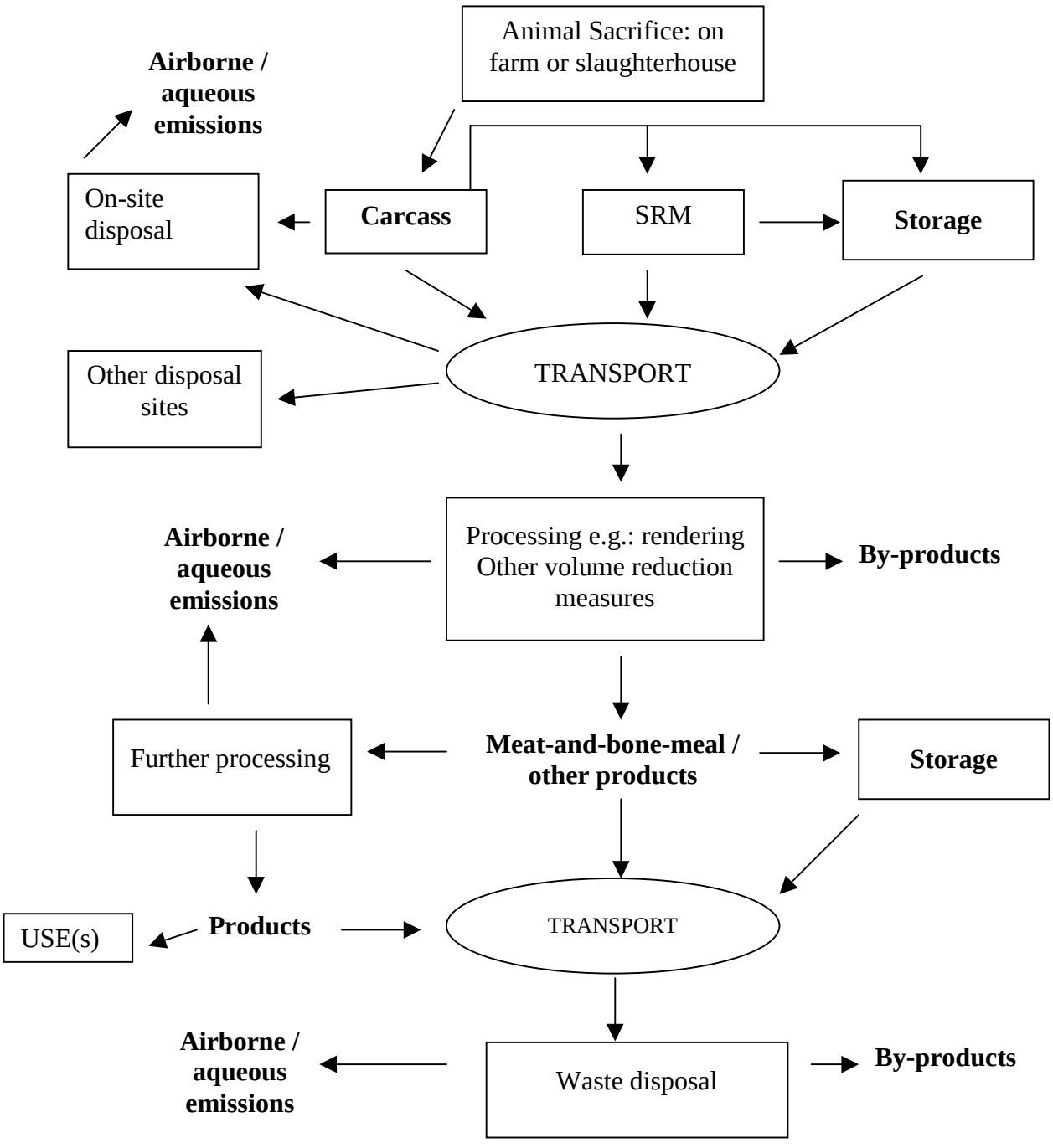
(c) Further guidelines may need to be developed on specific elements of this framework.

REFERENCE:

UK Environmental Agency (2000) **Operator and Pollution Risk Appraisal**, OPRA

Figure 1: The Risk Management Chain.

Risk sources in relation to possible disposal routes for animal derived material, which might be contaminated with BSE/TSE.



Note: The risk to workers in any of these processes and in handling materials must be assessed fully.