EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Scientific Steering Committee

OPINION

ON

A FRAMEWORK FOR THE ASSESSMENT OF THE RISK FROM DIFFERENT OPTIONS FOR THE SAFE DISPOSAL OR USE OF ANIMAL BY-PRODUCTS WHICH MIGHT BE CONTAMINATED WITH MICROBIOLOGICAL AGENTS, INCLUDING TSE.

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE

AT ITS MEETING OF 10-11 APRIL 2003.

BACKGROUND AND MANDATE

Regulation (EC) 1774/2002 of the European Parliament and of the Council of 3 October 2002 lays down the health rules concerning animal by-products not intended for human Consumption. This regulation devides animal by-products (ABP) into three categories (summary):

(a) ***Category 1*** material is defined in Article 4 of the Regulation. It comprises of ABP regarded as ***high risk***. This includes amongst others any animals or parts thereof suspected of being infected by a TSE or killed in the context of TSE eradication measures, specified risk material or animals containing such material. Category 1 material must be disposed of as waste by incineration, co-incineration or by burial in an approved landfill.

(b) ***Category 2*** material, defined in Article 5 of the Regulation, consists of ABP posing a risk not quite as high as category 1 material but still a high risk. This group includes for example fallen stock and animals killed to eradicate an epizootic disease (other than those under category 1) and products of animal origin containing residues or drugs. Category 2 ABP may, under certain conditions, be further processed e.g. into organic fertilizers or into technical products or may be transformed in a biogas plant.

(c) ***Category 3*** material, defined in Article 6 of the Regulation, are ABP presenting ***a low risk***. In general, Category 3 ABP are derived from animals or products thereof considered as fit for human consumption but not intended for this use. This category would for example include by-products from the slaughtering process, former foodstuffs of animal origin, fresh fish by-products or catering waste. Taking account of the specific requirements laid down in the Regulation, Category 3 material may be further used for various purposes, such as for pet-food production, for technical products, for composting or for animal feed.

Any decisions on the safety of a particular technology for the use, treatment, recycling or disposal of any of the above categories of animal by-products must be based on a sound scientific risk assessment. There is therefore a need for a framework providing 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). Such framework should be applicable to identify suitable processes to be used in a routine situation or in an acute emergency. The approach used should enable different processes to be compared in terms of potential risks for human health, animal health and the environment health.

As Regulation (EC) 1774/2002 foresees that alternative methods for the disposal of animal by-products should be subject to a scientific risk assessment, the Scientific Steering Committee developed the attached framework for the assessment of the risk from different options for the safe disposal or use of animal by-products which might be contaminated with microbiological agents, including TSE agent agents.

SCOPE OF THE PROPOSED FRAMEWORK

1. The current document is an update of an earlier version[1], which was limited to TSE risks. It enlarges the scope of the framework to include also microbiological agents. Further guidelines may need to be developed on specific elements of this framework.

   The document is intended to assist bodies preparing a dossier on the assessment of safety of specific processes and/or equipment relating to agents, including TSE. This document has, however, no legal status.

2. 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 is important to realise that the proposed framework hereafter only covers the assessment of risks directly resulting from the possible presence of pathogenic agents (including TSEs for this purpose). This framework does not directly address other risks possibly associated with the treatment of animal waste, which may result from substances involved in the actual treatment of the carcass/MBM eg hyperchlorite. The framework also does not address toxic substances present, the formation of new toxic substances during the treatment of waste, which may pose a risk to human health and the environment as airborne emissions (for example, dioxins); in effluents or as residues in the treated material (for example, heavy metals).

   It is understood that the assessment of such risks is covered by other frameworks or scientific opinions and/or by European and/or national legislation for the authorisation of waste treatment, recycling or disposal plants.

3. 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 as defined in the Framework Directive on Waste (96/350/EC) implies that processes or methods, which could harm the environment, should not be used. They should be:

   - 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.

4. 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.

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[1] 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.

There are schemes to assist evaluation of this second stage, for example, the UK's Operation and Pollution Risk Appraisal (OPRA)[2]. The SSC framework therefore addresses the generic risks only.

COMPONENTS OF THE RISK ASSESSMENT FRAMEWORK

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).

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. In addition, the availability of a flow diagram describing the process as a whole would be most helpful.

The SSC considers that the risk assessment framework and the information to be provided for all processes should comprise the following components:

1. IDENTIFICATION OF THE RISK CATEGORY/CATEGORIES.

The categories should preferably be defined according to the above listed 3 levels given in the Animal By-products Regulation which themselves are largely based on the aforementioned SSC opinion of 24-25 June 1999.

2. IDENTIFICATION AND CHARACTERISATION OF RISK MATERIALS

Each significant risk material should be identified and an assessment made of the likelihood of human/animal/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.

3. AGENT RISK REDUCTION

An estimate is required of the degree of the 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 (preferably), or otherwise:
- 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

[2] UK Environmental Agency (2000) Operator and Pollution Risk Appraisal, OPRA.

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 any case it is necessary to provide an evaluation of the validity with the uncertainties involved.

4. RISK CONTAINMENT

An analysis should be made of the likely effectiveness of the technical measures used to ensure that the risks are 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.

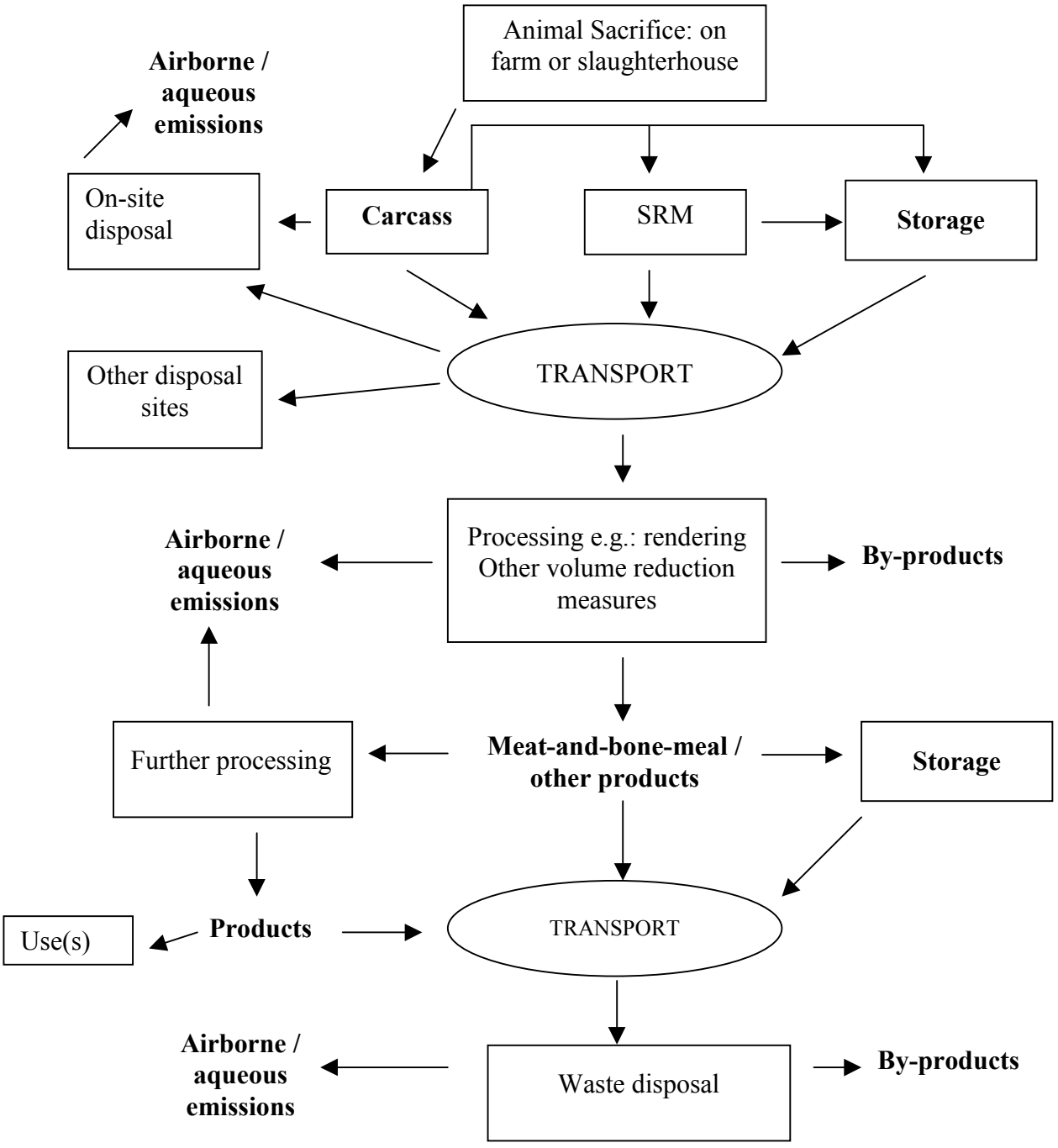
5. IDENTIFICATION OF INTERDEPENDENT PROCESSES

From a risk assessment viewpoint, any process identified to reduce the risk from the agent 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)

6. 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.

Figure 1: Risk sources in relation to possible disposal routes for animal derived material, which might be contaminated with a microbiological agent.



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