ANNEX VII

STANDARD FORMAT FOR APPLICATIONS FOR ALTERNATIVE METHODS

CHAPTER I

Language regime

1. Applications for authorisation of an alternative method of use or disposal of animal by-products or derived products as referred to in Article 20 of Regulation (EC) No 1069/2009 (applications) shall be submitted in one of the official languages of the European Union as referred to in Article 1 of Regulation No 1 of 1958.

2. Interested parties that submit such applications in a language other than English shall validate the official translation of their application, which EFSA shall provide, prior to the assessment.

The period referred to in Article 20(5) of Regulation (EC) No 1069/2009 shall only start once the interested party has validated the official translation of the application.

CHAPTER II

Content of applications

1. Applications shall contain all necessary information concerning the following points, in order to allow EFSA to assess the safety of their proposed alternative method:

(a) the categories of animal by-products which are intended to be submitted to the alternative method, by reference to the categories referred to in Articles 8,9, and 10 of Regulation (EC) No 1069/2009;

(b) the identification and characterisation of risk materials according to the following principles:

Significant risk materials must be identified separately. For each material, the likelihood of human and animal exposure under normal and emergency/abnormal operating conditions must be assessed. In the case of significant exposure, the potential risk must be assessed;

(c) the agent risk reduction according to the following principles:

The risk reduction for human and animal health which can be achieved by the process must be estimated on the basis of direct measurements.

Where no direct measurement is available, modelling or extrapolation from other processes may also be used. In order to demonstrate effective risk reduction, the identified hazard (such as Salmonella) must be quantified both in the input (raw) material and in the resulting output material. For the purpose of this Chapter, output material comprises any end-products resulting from and by-products derived from the process.

Estimates must be accompanied by evidence. This includes – for measurements – information on the methodology used (sensitivity and reliability of the methods used), nature of samples which have been analysed and evidence that samples are representative (relevant real samples, number of tests performed).

If surrogates for prion measurement are used, an explanation should be given of their relevance. An evaluation of the validity with the uncertainties involved must be provided;

(d) the risk containment according to the following principles:

The likely effectiveness of the technical measures used to ensure that the risks are contained must be analysed.

That analysis must reflect normal and abnormal/emergency operating conditions including a breakdown of the process.

Monitoring and surveillance procedures to demonstrate containment must be specified.

If full containment is not achievable, an assessment shall be required of any potential risk;

(e) the identification of interdependent processes according to the following principles:

Possible indirect impacts which may influence the risk reduction capacity of a particular process must be evaluated.

Indirect impacts may arise from transport, storage and safe disposal of end-products resulting from and by-products derived from a process;

(f) the intended end use of the end products and by-products according to the following principles:

The intended end use of end products and by-products of a process must be specified.

The likely risks involved must be calculated from the risk reduction estimated in accordance with point (c), which may arise to human and animal health.

2. Applications shall be submitted with documentary evidence, in particular a flow diagram showing the functioning of the process, the evidence indicated under point 1(c), as well as other evidence aiming to substantiate the explanation given under the framework set out under point 1.

3. Applications shall include a contact address for the interested party, which shall include the name and full address, telephone and/or fax numbers and/or the electronic mail address of a particular contact person that is responsible as or on behalf of the interested party.