

ANNEX VII

STANDARD FORMAT FOR APPLICATIONS FOR ALTERNATIVE METHODS

CHAPTER II

Content of applications

- [^{F1}1. Applications shall contain all the necessary information to allow [^{F2}the appropriate authority] to assess the safety of the proposed alternative method, and in particular describe:
- the categories of animal by-products intended to be submitted to the method,
 - the entire process,
 - the biological hazards for human and animal health involved, and
 - the degree of risk reduction to be achieved by the process.

Textual Amendments

- F1** Substituted by [Commission Regulation \(EU\) No 749/2011 of 29 July 2011 amending Regulation \(EU\) No 142/2011 implementing Regulation \(EC\) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive \(Text with EEA relevance\).](#)
- F2** Words in Annex 7 Ch. 2 para. 1 substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\), regs. 1\(2\)\(c\), 13\(45\)\(b\)](#)

2. The application referred to in paragraph 1 shall moreover:
- (a) indicate the applicable points in Articles 8, 9 and 10 of Regulation (EC) No 1069/2009 including the physical status of those materials and, if applicable, any pre-treatment to which those materials have been submitted and indicating any materials other than animal by-products which are to be used in the process.
 - (b) include a HACCP protocol and a flow diagram which clearly indicates the individual steps of the process, identifies the parameters critical for the inactivation of relevant pathogens such as temperature, pressure, exposure time, adjustment of the pH value and particle size and is complemented by technical data sheets of the equipment used during the process;
 - (c) identify and characterize biological hazards for human and animal health represented by the categories of animal by-products intended to be submitted to the method;
 - (d) show that the most resistant biological hazards associated with the category of materials to be processed are reduced in any products generated during the process, including the waste water, at least to the degree achieved by the processing standards laid down in this Regulation for the same category of animal by-products. The degree of risk reduction must be determined with validated direct measurements, unless modelling or comparisons with other processes are acceptable.
3. Validated direct measurements as referred to in paragraph 2(d) above shall mean:

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, Division CHAPTER II. (See end of Document for details)

- (a) measuring the reduction of viability/infectivity of: endogenous indicator organisms during the process, where the indicator is:
 - consistently present in the raw material in high numbers;
 - not less resistant to the lethal aspects of the treatment process, but also not significantly more resistant than the pathogens for which it is being used to monitor;
 - relatively easy to quantify, to identify and to confirm; or

- (b) using a well-characterised test organism or virus introduced in a suitable test body into the starting material.

If several treatment steps are involved, an assessment must be performed on the degree to which individual titre reduction steps are additive, or whether early steps in the process may compromise the efficacy of subsequent steps;

- (c) reporting complete results by
 - (i) describing in detail the used methodology;
 - (ii) describing the nature of samples which have been analysed;
 - (iii) showing that the number of samples analysed is representative;
 - (iv) justifying the number of tests performed and the selection of measuring points;
 - (v) indicating the sensitivity and the specificity of the detection methods used;
 - (vi) providing data on the repeatability and statistical variability of the measurements obtained during the experiments;
 - (vii) justifying, if used the significance of prion surrogates;
 - (viii) showing, where in absence of direct measurements, models or comparisons with other processes are used, that the factors leading to risk reduction are well known and the model of risk reduction is well established;
 - (ix) providing data for the entire process on direct measurements of all factors leading to the risk reduction which demonstrate that these factors are homogeneously applied throughout the treated batch.

- 4. The HACCP plan referred to in paragraph 2(b) must be based on the critical parameters which are used to obtain the risk reduction, in particular:

- temperature,
- pressure,
- time, and
- microbiological criteria.

The critical limits retained in the HACCP plan must be defined, based on the results of the experimental validation and/ or of the model provided.

If the successful functioning of the process can only be demonstrated with reference to technical parameters which are specifically related to the equipment used in the process, the HACCP plan must also include the technical limits which must be met, in particular energy uptake, number of pump strokes or dosage of chemicals.

Information must be given on the critical and technical parameters that are to be monitored and recorded in a continuous manner or after defined intervals and on the methods used for measuring and monitoring.

The variability of parameters under typical production conditions must be taken into account.

The HACCP plan must reflect normal and abnormal/ emergency operating conditions including a breakdown of the process and it must specify possible corrective actions which are to be applied in the case of abnormal/emergency operating conditions.

5. The applications shall also contain sufficient information on:
 - (a) the risks associated with interdependent processes, and in particular on the outcome of an evaluation of possible indirect impacts, which may:
 - (i) influence the level of risk reduction of a particular process;
 - (ii) arise from transport or storage of any products generated during the process and from the safe disposal of such products, including waste water.
 - (b) the risks associated with the intended end use of the products, in particular:
 - (i) the intended end use of any products generated during the process must be specified;
 - (ii) the likely risks for human health and animal health and possible impacts on the environment must be assessed on the basis of the risk reduction estimated in accordance with point 2(d).
6. Applications shall be submitted with documentary evidence, in particular:
 - (a) a flow diagram showing the functioning of the process;
 - (b) the evidence referred to in point 2(d), as well as other evidence aiming to substantiate the information provided in the framework of the application as set out in point 2.
7. Applications shall include a contact address for the interested party, which shall include the name and full address, telephone and/or fax number and/or the electronic mail address of a particular person that is responsible as or on behalf of the interested party.]

Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, Division CHAPTER II.