

ANNEX VII

STANDARD FORMAT FOR APPLICATIONS FOR ALTERNATIVE METHODS

CHAPTER II

Content of applications

[^{F1} 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.]

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 \(Text with EEA relevance\).](#)

Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, Division 4. .