
Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, Division Section 2. (See end of Document for details)

ANNEX XVI

OFFICIAL CONTROLS

CHAPTER I

OFFICIAL CONTROLS IN PROCESSING PLANTS

Section 2

Validation procedures

1. Prior to issuing an approval for a processing plant, as provided for in Article 44(1) of Regulation (EC) No 1069/2009, the competent authority must check that a validation of the processing plant has been carried out by the operator in accordance with the following procedures and indicators:
 - (a) a description of the process by a process flow diagram;
 - (b) an identification of critical control points (CCPs) including the material process rate for continuous systems;
 - (c) the compliance with the specific process requirements laid down by this Regulation; and
 - (d) the achievement of the following requirements:
 - (i) particle size for batch-pressure and continuous processes, defined by the mincer hole or the anvil gap size;
 - (ii) temperature, pressure, processing time and, in the case of continuous processing systems, the material processing rate, as specified in points 2 and 3.
2. In the case of a batch pressure system:
 - (a) the temperature must be monitored with a permanent thermocouple and it must be plotted against real time;
 - (b) the pressure stage must be monitored with a permanent pressure gauge; pressure must be plotted against real time;
 - (c) the processing time must be shown by time/temperature and time/pressure diagrams.At least once a year the thermocouple and the pressure gauge must be calibrated.
3. In the case of a continuous pressure system:
 - (a) the temperature and the pressure must be monitored with thermocouples, or an infrared temperature gun, and pressure gauges must be used at defined positions throughout the process system in such a way that temperature and pressure comply with the required conditions inside the whole continuous system or in a section of it; the temperature and pressure must be plotted against real time;
 - (b) measurement of the minimum transit time inside the whole relevant part of the continuous system where the temperature and pressure comply with the required

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conditions, must be provided to the competent authorities, using insoluble markers, such as manganese dioxide, or a method which offers equivalent guarantees.

Accurate measurement and control of the material process rate is essential and must be measured during the validation test in relation to a CCP that can be continuously monitored such as:

- (i) feed screw revolutions per minute (rev./min.);
- (ii) the electric power (amps at given voltage);
- (iii) the evaporation/condensation rate; or
- (iv) the number of pump strokes per unit time.

All measuring and monitoring equipment must be calibrated at least once a year.

4. The competent authority must repeat the checks on the validation procedures when it considers it necessary, and in any case each time any significant alterations are made to the process, such as modifications of the machinery or changes of raw materials.

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