



Brussels, **XXX**
SANTE/PLAN/364/2023 feedback
ANNEX (POOL/G5/2023/364/364-EN
ANNEX.docx)
[...] (2023) **XXX** draft

ANNEX

ANNEX

to the

Commission Delegated Regulation

**amending Annexes II et III of Regulation (EC) No 853/2004 of the European Parliament
and of the Council on specific hygiene requirements for certain fresh meat, fishery
products, dairy products and eggs**

ANNEX

Regulation (EC) No 853/2004 as amended as follows:

- (1) Annex II is amended as follows:
 - (a) in Section I, Part B is amended as follows:
 - (i) point 8 is replaced by the following:

‘8. When applied in an establishment located within the Union, the mark must be oval in shape and include the abbreviation of European Union (‘EU’) in one of the official languages of the Union as follows: EC, EU, EL, UE, EE, AE, ES, EÚ.’
 - (ii) the following point is added:

‘8a. The requirements on the form of the identification mark in this Part B may be replaced by the requirements for a special health or identification mark in accordance with Article 65(1), point (h), of Regulation (EU) 2016/429 of the European Parliament and of the Council*, and the rules adopted in accordance with Articles 67, point (a), 71(3) or (4), or 259(1) or (2) of that Regulation.
- (2) Annex III is amended as follows:
 - (a) Section I is amended as follows:
 - (i) in Chapter II, the following point is added:

‘10. Mobile slaughterhouse shall not operate in a Member State unless the competent authority of each Member State where it operates, has approved them in accordance with Article 4.2 based at least on compliance with the requirements in this Chapter.

Mobile partial slaughtering facilities operating temporarily in cooperation with complementary permanent slaughtering facilities shall not operate unless the competent authority has approved the combination as a slaughterhouse in accordance with Article 4.2 based at least on compliance with the requirements in this Chapter. Such approval shall be reviewed after a period of one year of inactivity of the combination.’;
 - (ii) in Chapter IV, point 1 is replaced by the following:

‘1. After arrival at the slaughterhouse, the slaughter of the animals must not be unduly delayed. However, where required for welfare reasons, animals must be given a resting period before slaughter. Animals that are presented at a slaughterhouse for slaughter shall be slaughtered there and direct movements to another slaughterhouse may be allowed only in exceptional cases in

* Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (‘Animal Health Law’) (OJ L 84, 31.3.2016, p. 1).’;

accordance with Article 43(6), second subparagraph, of Regulation (EU) 2019/627.’;

(b) Chapter VIa is amended as follows:

(1) the heading is replaced by the following:

‘Chapter VIa: SLAUGHTER AT THE HOLDING OF PROVENANCE OF DOMESTIC BOVINE ANIMALS, OTHERS THAN BISONS, AND OVINE, CAPRINE AND PORCINE ANIMALS AND DOMESTIC SOLIPEDS OTHER THAN EMERGENCY SLAUGHTER’;

(2) the introductory phrase is replaced by the following:

‘Up to three domestic bovine animals, other than bisons, up to three domestic solipeds, up to six domestic porcine animals or up to nine ovine or caprine animals may be slaughtered at the same occasion at the holding of provenance, when authorised by the competent authority in accordance with the following requirements:’;

(iii) point (a) is deleted;

(c) Chapter VII is amended as follows:

(i) the following point is inserted after point 2:

‘2a. For the purposes of this point, ‘dry-ageing’ means the storage of fresh meat in aerobic conditions of hanging carcasses or cuts either unpacked or packed in bags permeable to water vapour in a refrigerated room or cabinet and left to age for several weeks at controlled environmental conditions of temperature, relative humidity and airflow.

Before placing on the market or freezing, bovine meat subject to dry-ageing must be stored at a surface temperature of $-0,5$ to $3,0^{\circ}\text{C}$, with a relative humidity of 75 to 85% and an airflow of 0,2 to 0,5 m/s in a dedicated room or cabinet for a maximum of 35 days. However, food business operators may apply other combinations of surface temperature, relative humidity, airflow and time, or do dry-ageing of meat of other species, if they demonstrate to the satisfaction of the competent authority that equivalent guarantees are provided on the safety of the meat.

In addition, the following specific measures must be applied:

(i) the meat shall not be loaded into the room or the cabinet until the temperature and relative humidity referred to in the second subparagraph have been achieved;

(ii) the meat must be hanged from the bone or, if using a shelf, sufficient perforation to facilitate air flow with regular turning using hygienic methods must be ensured;

(iii) a high airflow must be applied at the start of the dry-ageing process to facilitate early crust development and reduce the surface water activity;

- (iv) the room or the cabinet and air conditioning refrigeration system components must be regularly cleaned and disinfected;
 - (v) calibrated thermometers, relative humidity probes and other equipment to accurately monitor and facilitate control of room or cabinet conditions must be used;
 - (vi) the air in contact with the beef must be filtered or UV treated;
 - (vii) the crust must be trimmed in a hygienic manner in a dedicated air controlled environment.’;
- (ii) in point 3(b), (iv) to (viii) are replaced by the following:
- ‘(iv) per transport, the vehicle transporting the carcasses, half carcasses, quarters, or half carcasses cut into three wholesale cuts collects meat from a maximum of three slaughterhouse or from one cold store collecting directly from slaughterhouses; all the requirements laid down in this point (b) shall apply from the first loading of the carcasses, half carcasses, quarters, or half carcasses cut into three wholesale cuts in a slaughterhouse;
 - (v) carcasses, half carcasses, quarters, or half carcasses cut into three wholesale cuts must have a core temperature of 15 degrees at the start of the transport if they are to be transported in the same compartment as meat which meets the temperature requirement set out in point 1 for offal and 7°C for other meat;
 - (vi) a declaration by the food business operator accompanies the consignment; that declaration must state the duration of chilling before loading, the time at which loading of the carcasses, half carcasses, quarters, or half carcasses cut into three wholesale cuts was started, the surface temperature at that time, the maximum transportation air temperature to which the carcasses, half carcasses, quarters, or half carcasses cut into three wholesale cuts may be subjected, the maximum transport time permitted, the date of authorisation and the name of the competent authority authorising the transport in accordance with point (ii);
 - (vii) the food business operator of destination must notify the competent authority before receiving for the first time carcasses, half carcasses, quarters, or half carcasses cut into three wholesale cuts, not attaining the temperature referred to in point 1 before transport;
 - (viii) the meat must be transported in accordance with the following parameters:

- For a maximum transport time¹ of six hours:

Species	Surface temperature ²	Maximum time to chill to surface temperature ³	Maximum transportation air temperature ⁴	Maximum daily mean carcass aerobic colony count ⁵
Ovine and caprine animals	7°C	8 hours	6°C	log ₁₀ 3,5 cfu/cm ²
Bovine animals		20 hours		log ₁₀ 3,5 cfu/cm ²
Porcine animals		16 hours		log ₁₀ 4 cfu/cm ²

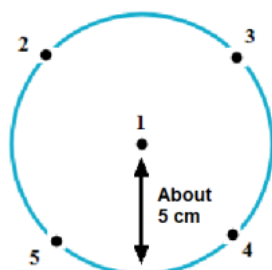
The maximum transport time may be extended to 30 hours if a core temperature below 15°C is reached before the start of the transport.

- For a maximum transport time¹ of 60 hours:

Species	Surface temperature ²	Maximum time to chill to surface temperature ³	Core temperature ⁶	Maximum transportation air temperature ⁴	Maximum daily mean carcass aerobic colony count ⁵
Ovine and caprine animals	4°C	12 hours	15°C	3°C	log ₁₀ 3 cfu/cm ²
Bovine animals		24 hours			

(ix) methods for measuring the surface temperature shall be validated and the following method shall be used as reference method:

- a thermometer calibrated in accordance with the latest version of ISO 13485 shall be used;
- the sensor shall be penetrated perpendicularly in the thickest part at a depth of 0,5 to 1 cm of the external part of:
 - the shoulder; or
 - the leg for bovine, ovine and caprine animals or of the ham, or the internal surface of the ham in the middle upper part for porcine animals;
- five temperature measurements shall be carried out as follows:



- at least one of the five measurements must be below the surface temperature requirements laid down in point (viii).’;

(d) in Section II, in Chapter II, the following point is added:

‘8. Mobile slaughterhouse shall not operate in a Member State unless the competent authority of each Member State where it operates, has approved them in accordance with Article 4.2 based at least on compliance with the requirements in this Chapter.

Mobile partial slaughtering facilities operating temporarily in cooperation with complementary permanent slaughtering facilities shall not operate unless the competent authority has approved the combination as a slaughterhouse in accordance with Article 4.2 based at least on compliance with the requirements in this Chapter. Such approval shall be reviewed after a period of one year of inactivity of the combination.’;

(e) in Section III, point 3 (h)(i) and (j) are replaced by the following:

‘(h) slaughtered and bled animals are transported to the slaughterhouse or to a game-handling establishment hygienically and without undue delay; if transport takes more than two hours, the animals must be refrigerated; where climatic conditions so permit, active chilling is not necessary; evisceration may take place on the spot, under the supervision of the official veterinarian;

(i) a declaration by the food business operator who reared the animals, stating their identity and indicating any veterinary products or other treatments administered, dates of administration and withdrawal periods, accompanies the slaughtered animals to the slaughterhouse or the game-handling establishment;

and

(j) the health certificate set out in Chapter 3 of Annex IV to Implementing Regulation (EU) 2020/2235, issued and signed by the official veterinarian, attesting to a favourable result of the ante-mortem inspection, correct slaughter and bleeding and the date and time of slaughter, accompanies the slaughtered animal to the slaughterhouse or to a game-handling establishment, or was sent in advance in any format.’;

(f) in Section VIII, in Chapter VII, the following point is added:

‘4. In the case that the temperature of fresh or processed fishery products needs to be temporarily decreased, or in the case that the temperature of frozen fishery products needs to be temporarily increased, to a temperature higher than -18°C to permit the use of machines that slice or cut fishery products, the change of temperature to reach that required for the cutting or slicing of fishery products, and the subsequent return to the storage temperature of the fishery products, shall be as short as possible. The total time of the operation of cutting or slicing at the technologically-required temperature shall not exceed 96 hours. Storage or transportation of fishery products at that temperature shall not be allowed.’;

(g) Section IX is amended as follows:

(i) in Chapter I, in Part I, point 3 is replaced by the following:

- ‘3. However, raw milk or colostrum from animals that does not meet the requirements set out in point 2 may be used with the authorisation of the competent authority:
- (a) in the case of cows, buffaloes, sheep or goats or females from other species that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, and in the case of sheep or goats which have been vaccinated against brucellosis as part of an approved eradication programme and do not show any symptom of that disease, after having undergone a heat treatment such as to show, where applicable, a negative reaction to the alkaline phosphatase test or otherwise treated to ensure its safety. When the alkaline phosphatase test is not suitable to demonstrate the effectiveness of the heat treatment applied, such as situations where raw milk is produced from non-bovine species or separated in different fractions before being heat-treated, food business operators shall be able to provide the competent authority with the necessary assurances and keep associated records as part of their procedures based on hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004 ;
 - (b) in the case of sheep or goats that do not show a positive reaction to tests for brucellosis, or which have been vaccinated against brucellosis as part of an approved eradication programme, and which do not show any symptom of that disease, for the manufacture of cheese with a maturation period of at least two months.’;
- (ii) in Chapter II, in Part II, point 1(a) is replaced by the following:
- ‘(a) Pasteurisation is achieved by a treatment involving:
- (i) a high temperature for a short time: at least 72 °C for 15 seconds;
 - (ii) a low temperature for a long time: at least 63 °C for 30 minutes; or
 - (iii) any other combination of time-temperature conditions to obtain an equivalent effect.

The treatment referred to in (i), (ii) and (iii) shall ensure that the products show, where applicable, a negative reaction to an alkaline phosphatase test immediately after such treatment. When the alkaline phosphatase test is not suitable to demonstrate the effectiveness of the pasteurisation, such as situations where products are derived from non-bovine species or separated in different fractions before being pasteurised, food business operators shall be able to provide the competent authority with the necessary assurances and keep associated records as part of their procedures based on hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004.’;

- (h) in Section X, in Chapter I, point 1 is replaced by the following:
- ‘1. At the producer's premises, and until sale to the consumer, eggs must be kept clean, dry, free of unintended extraneous odour, effectively protected from shocks and out of direct sunshine. Any intentional application of extraneous odour to eggs must not be aimed at hiding a pre-existing extraneous odour.’.