EN



Brussels, 19 December 2023 (OR. en)

16974/23 ADD 1

VETER 118 DELACT 213 FOOD 104

COVER NOTE

| From: | European Commission |
|------------------|---|
| date of receipt: | 19 December 2023 |
| To: | General Secretariat of the Council |
| No. Cion doc.: | C(2023) 8519 final |
| Subject: | 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 meat, fishery products, dairy products and eggs |

Delegations will find attached document C(2023) 8519 final.

Encl.: C(2023) 8519 final

16974/23 ADD 1 OT/mg LIFE.3



Brussels, 14.12.2023 C(2023) 8519 final

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 meat, fishery products, dairy products and eggs

ANNEX

Annexes II and III to Regulation (EC) No 853/2004 are amended as follows:

- (1) In Annex II, in Section I, Part B is amended as follows:
 - (a) 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.;

Those abbreviations must not be included in marks applied by establishments located outside the Union on products imported into the Union.'

- (b) 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 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 Article 67, point (a), Article 71(3) or (4), or Article 259(1) or (2) of that Regulation.
 - * 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).';
- (2) In Annex II, Section III is amended as follows:
 - (a) The introductory paragraph is replaced by:

'Food business operators operating slaughterhouses or game-handling establishments must, as appropriate, request, receive, check and act upon food chain information as set out in this Section in respect of all animals, other than wild game, sent or intended to be sent to the slaughterhouse or game-handling establishment.'

- (b) In points 1, 2, 4, 5, 6 and 7 the word "slaughterhouse" is replaced by the words "slaughterhouse or game-handling establishment".
- (3) Annex III is amended as follows:
 - (a) Section I is amended as follows:
 - (i) in Chapter II, the introductory phrase is replaced by the following:

'Food business operators must ensure that the construction, layout and equipment of slaughterhouses in which domestic ungulates are slaughtered meet the requirements laid down in the following points 1 to 9. Mobile partial slaughterhouses must operate in cooperation with complementary permanent slaughtering facilities in order to constitute a complete slaughterhouse complying with the requirements laid down in the following points 1 to 9. Mobile partial slaughterhouses may operate with several complementary slaughtering facilities, thus constituting several slaughterhouses.';

- (ii) in Chapter IV, point 1 is replaced by the following:
 - 11. 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 accordance with Article 43(6), second subparagraph of Implementing Regulation (EU) 2019/627.';
- (iii) 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:';

- (3) point (a) is deleted;
- (iv) Chapter VII is amended as follows:
 - (1) 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° C, with a relative humidity of a maximum of 85% and an airflow of 0.2 to 0.5 m/s in a dedicated room or cabinet for a maximum of 35 days starting at the end of the stabilisation period upon slaughter. 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 shall be applied:

(i) the dry-ageing shall start immediately after the stabilisation period upon slaughter and unduly delayed cutting and/or transport to an establishment carrying out the dry-ageing;

- (ii) 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;
- (iii) the meat shall 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;
- (iv) a higher airflow may be applied at the start of the dry-ageing process to facilitate early crust development and reduce the surface water activity;
- (v) thermometers, relative humidity probes and other equipment to accurately monitor and facilitate control of room or cabinet conditions must be used;
- (vi) air leaving the evaporator, returning to the evaporator and coming in contact with the beef must be filtered or UV treated;
- (vii) when the crust is trimmed, such trimming shall be carried out in a hygienic manner.';
- 2) in point 3(b), (iv) to (viii) are replaced by the following:
- '(iv) per transport, the vehicle transporting the carcases, half carcases, quarters, or half carcases cut into three wholesale cuts collects meat from a maximum of three slaughterhouses or from one cold store collecting directly from slaughterhouses; all the requirements laid down in this point b) shall apply to all loads of carcases, half carcases, quarters, or half carcases cut into three wholesale cuts dispatched from the slaughterhouse and cold store collecting from the above mentioned slaughterhouse;
- (v) carcases, half carcases, quarters, or half carcases cut into three wholesale cuts must have a core temperature of 15°C 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 the first loading, the time at which the first loading of the carcases, half carcases, quarters, or half carcases cut into three wholesale cuts was started, the surface temperature at that time, the maximum transportation air temperature to which the carcases, half carcases, quarters, or half carcases 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 carcases, half carcases, quarters, or half carcases cut into three wholesale cuts, not attaining the temperature referred to in point 1 before the start of transport;

- (viii) the meat must be transported in accordance with the following parameters:
 - For a maximum transport time¹ of six hours:

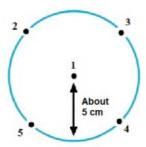
| Species | Surface temperature ² | Maximum time to chill to surface temperature ³ | Maximum transportation air temperature ⁴ | Maximum daily mean carcase aerobic colony count ⁵ |
|---------------------------|----------------------------------|---|--|---|
| Ovine and caprine animals | 7°C | 8 hours | 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 carcase 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 either:
 - (a) the shoulder; or
 - (b) 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).
- (1) Maximum time allowed from the start of loading of meat into the vehicle until the completion of the final delivery. Loading of the meat into the vehicle may be postponed beyond the maximum time allowed for chilling of the meat to its specified surface temperature. If this happens, then the maximum transport time allowed must be shortened by the same length of time by which the loading was postponed. The competent authority of the Member State of destination may limit the number of delivery points.
- (2) Maximum surface temperature allowed at loading and thereafter measures at the thickest part of the carcase, half carcases, quarters, or half carcases cut into three wholesale cuts.
- (3) Maximum time allowed from the moment of killing until the reaching of the maximum surface temperature allowed at loading.
- (4) The maximum air temperature to which the meat is allowed to be subjected from the moment loading begins, and throughout the whole duration of the transport.
- (5) Slaughterhouse maximum daily mean carcase aerobic colony count using a rolling window of 10 weeks, allowed for carcases of the relevant species, as assessed by the operator to the satisfaction of the competent authority, according to the sampling and testing procedures laid out in points 2.1.1, 2.1.2 of Chapter 2, and point 3.2 of Chapter 3, of Annex I to Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).
- (6) The maximum core temperature of the meat allowed at the time of loading, and thereafter.';
 - (b) in Section II, in Chapter II, the introductory phrase is replaced by the following:

Food business operators must ensure that the construction, layout and equipment of slaughterhouses in which poultry or lagomorphs are slaughtered meet the requirements laid down in the following points 1 to 7. Mobile partial slaughterhouses must operate in cooperation with complementary permanent slaughtering facilities in order to constitute a complete slaughterhouse complying with the requirements laid down in the following points 1 to 7. Mobile partial slaughterhouses may operate with several complementary slaughtering facilities, thus constituting several slaughterhouses.'

- (c) Section III is amended as follows:
 - (1) Point 3 is amended as follows:
 - i. Point (h) is replaced by the following:

- '(h) slaughtered and bled animals are transported to the slaughterhouse or to a game-handling establishment, as appropriate, hygienically and without undue delay. If transport takes more than two hours, the animals must be refrigerated; where climatic conditions so permit, active chilling shall not be required. Evisceration may take place on the spot, under the supervision of the official veterinarian;'
 - ii. (2) Point (i) is deleted;

and.

- iii. (3) Point (j) is replaced by the following:
- '(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, must accompany the slaughtered animal to the slaughterhouse or to a game-handling establishment, as appropriate, or must be sent in advance in any format.';

(2)Point 3a is replaced by:

- '3a By way of derogation from point 3(j), the competent authority may authorise that the attestation of the correct slaughter and bleeding and of the date and time of slaughter be included only in the food chain information in accordance with Section III to Annex II of this Regulation provided that:
 - (a) the holding is not situated in a restricted zone defined in Article 4(41) of Regulation (EU) 2016/429;
 - (b) the food business operator has demonstrated the appropriate level of competence to slaughter animals without causing the animals any avoidable pain, distress or suffering in accordance with Article 7(2) of Regulation (EC) No 1099/2009 and without prejudice to Article 12 of that Regulation.'
- (d) in Section V, in Chapter III, the following point is added:
 - '6. Meat preparations subjected to dry-ageing, shall comply with the requirements laid down in Section I, Chapter VII, point 2a of this Annex III.'
- (e) in Section VIII, in Chapter VII, the following point is added:
 - '4. Where fresh fishery products, thawed unprocessed fishery products, or processed fishery products need to be at a temperature lower than that of melting ice to permit the use of machines that slice or cut fishery products, they may be maintained at such technologically required temperature for a period of time as short as possible and in any case not exceeding 96 hours. Storage and transport at that temperature shall not be allowed.

Where frozen fishery products need to be at a temperature higher than -18°C to permit the use of machines that slice or cut fishery products, they may be maintained at such technologically required temperature for a period of time as short as possible and in any case not exceeding 96 hours. Storage and transport at that temperature shall not be allowed.'.

- (f) 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:
 - 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. 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 permitted 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 permitted 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.';

- (g) 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 odour.'.