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COMMISSION DELEGATED REGULATION (EU) 2025/1449

of 18 July 2025

amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council concerning specific hygiene rules for emergency slaughter of domestic ungulates, for tuna frozen in brine and for highly refined products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin⁽¹⁾, and in particular Article 10(1), second subparagraph, points (a), (b), (c), (d) and (e) thereof,

Whereas:

- (1) Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators. Food business operators are required to comply, inter alia, with the specific requirements laid down in Annex III to that Regulation.
- (2) Annex III, Section I, Chapter VI, to Regulation (EC) No 853/2004 provides that food business operators are to ensure that meat from domestic ungulates that have undergone emergency slaughter outside the slaughterhouse may be used for human consumption only if the meat complies with the requirements laid down in that Chapter. Point 5 of that Chapter VI requires a declaration by the food business operator to accompany the slaughtered animal to the slaughterhouse. The content of that declaration is included in the food chain information required in accordance with Point 3 of Section III of Annex II of Regulation (EC) No 853/2004. For clarity and the avoidance of possible duplication, point 5 of Chapter VI of Annex III to Regulation (EC) No 853/2004 should be replaced by a reference to the food chain information required in accordance with Section III of Annex II to that Regulation.
- (3) Annex III, Section VIII, Chapter I, Part I.C, point 1, to Regulation (EC) No 853/2004 requires freezer vessels to have freezing equipment with sufficient capacity to freeze as quickly as possible in a continuous process and with a thermal arrest period as short as possible, so as to achieve a core temperature of not more than – 18 °C. Point 2 of that Part requires freezing vessels to have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than – 18 °C. In accordance with Annex III, Section VIII, Chapter I, Part II, point 7, of Regulation (EC) No 853/2004, where the whole fish intended for canning is frozen in brine, its temperature is to be not more than – 9 °C. This point also lays down that even if the whole fish initially frozen in brine at a temperature of not more than – 9 °C is subsequently frozen at a temperature of – 18 °C, it is to be destined for canning.
- (4) Official controls carried out by Member States and audits and official controls carried out by the Commission both in Member States and in third countries, have shown that, in practice, freezer vessels could not reach the temperature of – 18 °C for freezing tuna in brine. The audit reports have also shown that certain food business operators have illegally placed on the market as unprocessed tuna for direct human consumption, tuna frozen in brine at – 9 °C. In accordance with Annex III, Section VIII, Chapter I, Part II, point 7, of Regulation (EC) No 853/2004 such tuna can only be destined for canning. This practice can expose consumers to health risks, as an excessive production of histamine results in scombroid syndrome.

⁽¹⁾ OJ L 139, 30.4.2004, p. 55, ELI: <http://data.europa.eu/eli/reg/2004/853/oj>.

- (5) An increasing number of notifications have been issued on the Rapid Alert System for Food and Feed (RASFF) regarding the presence of histamine above the limit set in row 1.26 of Chapter I of Annex I to Commission Regulation (EC) No 2073/2005 ⁽⁷⁾ in vacuum-packed thawed tuna loins, treated with additives, and of scombroid food poisoning associated with the consumption of such products. Member States have taken measures following official controls but recent RASFF notifications demonstrated that these measures have not solved the issue.
- (6) Commission consultations with the competent authorities of the Member States and stakeholders' organisations showed that freezing technologies on board certain vessels have substantially improved and it is now possible to freeze tuna in brine at -18°C while maintaining their organoleptic characteristics and ensuring the safety of the tuna where subject to certain conditions. It is therefore appropriate to lay down requirements regarding the freezing of tuna in brine at -18°C intended for the production of prepared fishery products. These requirements should also ensure that the operators carry out appropriate own-checks and facilitate the official controls to be carried out by the competent authorities, necessary to differentiate those freezing vessels from those freezing tuna in brine at -9°C and only destined for canning.
- (7) Those requirements should ensure that the freezer vessels are equipped so as to be able to freeze tuna in brine at -18°C for a pre-determined period of time. In addition, the food business operators concerned should be able to monitor the temperature of the brine in real-time, using remote means of communication. Such data should be kept available to Member State competent authorities. The appropriate freezing capacity of freezer vessels freezing tuna in brine should be identified during the approval procedure of such freezer vessels to enable the competent authorities to identify tuna coming from such freezer vessels during official controls and to take action against operators illegally placing on the market tuna not frozen at -18°C . Those measures should ensure the proper functioning of the internal market while protecting consumers, in accordance with the objectives of Regulation (EC) No 853/2004.
- (8) In addition, it is necessary to set strict time/temperature parameters for freezing tuna in brine at -18°C at core in freezer vessels approved for that activity. The decrease of temperature should be carried out in a continuous process, and subject to compliance with established requirements. In particular, the total duration of the freezing process should be established.
- (9) Section VIII, Chapter I, Parts I and II of Annex III to Regulation (EC) No 853/2004 should be amended accordingly.
- (10) Annex III, Section XVI, to Regulation (EC) No 853/2004 lays down specific requirements for certain highly refined products where food business operators must ensure that the treatment of the raw materials eliminates any animal or public health risk. Products of animal origin authorised as food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁽⁸⁾ are also such highly refined products since the production of such additives eliminates these risks and should therefore be included in Section XVI of that Annex. Some of these additives are derived from insects and therefore insects should be allowed as raw materials for highly refined products. Annex III, Section XVI to Regulation (EC) No 853/2004 should therefore be amended accordingly.
- (11) In order to allow the interested parties the necessary time to put in place procedures to comply with new requirements resulting from the amendments to Section VIII to Annex III to Regulation (EC) No 853/2004, by this Regulation, it should apply from 27 January 2026,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III of Regulation (EC) No 853/2004 is amended in accordance with the Annex to this Regulation.

⁽⁷⁾ Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/2073/oj>).

⁽⁸⁾ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16, ELI: <http://data.europa.eu/eli/reg/2008/1333/oj>).

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

However, point (2) of the Annex to this Regulation shall apply from 27 January 2026.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 July 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex III to Regulation (EC) No 853/2004 is amended as follows:

(1) in Section I, in Chapter VI, point 5 is replaced by the following:

‘5. The food chain information required in accordance with Section III of Annex II must accompany the slaughtered animal to the slaughterhouse.’;

(2) in Section VIII:

(a) Chapter I is amended as follows:

(i) Part I.C is replaced by the following:

‘C. Requirements for freezer vessels

1. Freezer vessels must:

- (a) have freezing equipment with sufficient capacity to freeze as quickly as possible in a continuous process and with a thermal arrest period as short as possible, so as to achieve a core temperature of not more than – 18 °C;
- (b) have refrigeration equipment with a sufficient capacity to maintain fishery products in the storage holds at not more than – 18 °C. Storage holds must not be used for freezing unless they fulfil the conditions laid down in (a) of this point and must be equipped with a temperature-recording device in a place where it can be easily read. The temperature sensor of the reader must be situated in the area where the temperature in the hold is the highest;
- (c) meet the requirements for vessels designed and equipped to preserve fishery products for more than 24 hours laid down in Part I.B, point 2.

2. In addition to the requirements laid down in point 1 of this Part, freezer vessels that freeze tuna in brine as referred to in Part II, point 8, must be equipped with a system that:

- (a) continuously monitors in real-time and records the temperature of the brine on board using electronic means of temperature measurement;
- (b) allows real-time onshore monitoring of the temperature of the brine by the food business operator.

3. The food business operators of freezer vessels that freeze tuna in brine as referred to in Part II, point 8, must give access, upon request, to the competent authorities to the data on the temperature of the brine collected through the system referred to in point 2(a) and (b) of this Part.

4. The food business operators of freezer vessels that freeze tuna in brine as referred to in Part II, point 8, must set up a validation plan regarding the freezing capacity of the freezer vessels freezing tuna in brine, that must include the following:

- (a) coherent kinetic studies and a correlation curve between brine and core temperature, on the one hand, and the time and cooling periods as referred to in Part II, points 8(a) and (b), on the other hand; these studies and correlation curve must be based on the tuna temperature recorded by the instruments placed in sampled tunas as well as other criteria that the competent authorities may establish;
- (b) evidence that the temperature probes or sensors are certified in accordance with the relevant international temperature measurements standards.

5. The competent authority must check the validation plan, and identify the freezing capacity, of freezer vessels that freeze tuna in brine as referred to in Part II, point 8, during the approval process of those freezer vessels in accordance with Article 4(3) of this Regulation or, in the case of freezer vessels flying the flag of a third country, when placing the freezer vessels on the list drawn up in accordance with Article 127(3), points (e)(ii) and (iii), of Regulation (EU) 2017/625.;
 - (ii) Part I.D, point 3 is replaced by the following: 'Factory vessels that freeze fishery products must have equipment meeting the requirements for freezer vessels laid down in Part I.C, points 1(a) and 1(b).';
 - (iii) Part I.E is replaced by the following: 'Reefer vessels transporting and/or storing frozen fishery products in bulk must have equipment meeting the requirements for freezer vessels laid down in point 1(b) of Part C concerning their capacity to maintain the temperature.';
 - (iv) in Part II, the following point 8 is added:
 - '8. Whole tuna (genus *Thunnus* and *Katsuwonus*) may be frozen in brine at – 18 °C at core in freezer vessels referred to in Section VIII, Chapter I, Part I.C, point 2 provided that the decrease in temperature is carried out in a continuous process, and subject to compliance with the following requirements:
 - (a) where a direct freezing process in brine is carried out, its total duration to reach – 18 °C at core must not exceed 96 hours after the first capture of tuna has been placed in brine, and the tuna must reach a core temperature below 0 °C in less than 24 hours;
 - (b) where a cooling process in cooled clean seawater is carried out before placing the tuna in brine, the temperature of the mixture of tuna and cooled clean seawater must reach 3 °C in less than 6 hours, and 0 °C in less than 16 hours; the total cooling process in cooled clean seawater must not exceed 72 hours after the first capture of tuna has been placed in the cooled clean seawater tank; once tuna is placed in brine, the total duration of the freezing process, from 0 °C to – 18 °C at core, must not exceed 72 hours;
 - (c) food business operators must monitor the salt concentration of the brine and take appropriate action to maintain the salt concentration set out in their validation plan;
 - (d) for verification purposes, the food business operators must continuously record the temperature of a sample of tuna through a temperature-measuring instrument inserted in the temperature-sensitive part of the fish that will freeze last.;
 - (b) in Chapter III, Part B, is replaced by the following: 'Establishments on land that freeze or store frozen fishery products must have equipment, adapted to the activity carried out, that satisfies the requirements for freezer vessels laid down in Section VIII, Chapter I, Part I.C, points 1(a) and 1(b).';
- (3) Section XVI is amended as follows:
- (a) in point (1), subpoint (h) is replaced by the following:
 - '(h) food additives of animal origin authorised in accordance with Article 4 of Regulation (EC) No 1333/2008 of the European Parliament and of the Council (*);

(*) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16, ELI: <http://data.europa.eu/eli/reg/2008/1333/oj>).;

- (b) point (2) is amended as following:
 - (i) the following subpoint (4) is added to subpoint (c):
‘(4) when derived from wool grease, a heat treatment at least at 135 °C for at least 90 minutes;’
 - (ii) the following subpoint (d) is added:
‘(d) insects.’
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