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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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Subject:	COMMISSION DELEGATED REGULATION (EU) .../... 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

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Delegations will find attached document C(2025) 4809 final.

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EUROPEAN  
COMMISSION

Brussels, 18.7.2025  
C(2025) 4809 final

**COMMISSION DELEGATED REGULATION (EU) .../...**

**of 18.7.2025**

**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)

## **EXPLANATORY MEMORANDUM**

### **1. CONTEXT OF THE DELEGATED ACT**

Regulation (EC) No 853/2004 of the European Parliament and of the Council<sup>1</sup> lays down specific rules on the hygiene of food of animal origin for food business operators. It empowers the Commission to adopt delegated acts amending Annexes II and III thereto.

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, to achieve a core temperature of not more than -18°C. In accordance with Section VIII, Chapter I, Part II, point 7, where the whole fish intended for canning is frozen in brine, the temperature is to be not more than -9°C. It also lays down that even if the whole fish is subsequently frozen at -18°C, it can still only be destined for canning.

Official controls carried out by national competent authorities and audits by the Commission have shown that certain food business operators illegally place on the market as fresh tuna, tuna that had been frozen in brine at -9°C and could therefore only be destined for canning. In addition, operators illegally use additives to change the colour of tuna frozen in brine at -9°C and make the fish look like fresh tuna. This does not correspond to the state of the fish, and it is therefore a fraudulent practice, which exposes consumers to health risks.

Consultations with the competent authorities of the Member States and stakeholders' organisations have shown that recent technological development has improved the freezing capacity of freezer vessels. Consequently, food business operators have invested in the freezing capacity in brine of their vessels so that their catch of tuna can be frozen in brine at -18°C in accordance with Section VIII, Chapter I, Part I.C, point 1 to Regulation (EC) No 853/2004. As tuna frozen in brine at -18°C under certain conditions does not oxidise, there is no change in colour either. Therefore, such tuna can be placed on the market not only as canned tuna.

The draft Regulation establishes conditions for freezing tuna in brine at -18°C on board freezer vessels. The freezing capacity of the freezer vessel that caught and froze tuna at -18°C in brine, should be identified during their approval. This will facilitate official controls, by making it easier to identify tuna caught and frozen by vessels that have the appropriate freezing capacity.

Section VIII, Chapter I, Parts I and II of Annex III to Regulation (EC) No 853/2004 should, therefore, be amended accordingly.

Moreover, Annex III, Section I, Chapter VI to Regulation (EC) No 853/2004 allows emergency slaughter outside the slaughterhouse if complying with certain requirements. Point 5 of that Chapter VI requires a declaration by the food business operator to accompany the slaughtered animal. The content of this declaration is included in the food chain information in accordance with Section III to Annex II of Regulation (EC) No 853/2004. For clarity and avoidance of possible duplication, point 5 of Chapter VI should be replaced by a reference to the food chain information.

Finally, Annex III, Section XVI to Regulation (EC) No 853/2004 lays down specific requirements for highly refined products where 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<sup>2</sup>

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

<sup>2</sup> 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>).

are also such highly refined products and should therefore be added to this Section XVI. In addition, an alternative treatment to produce fat derivatives (Vitamin D3) is introduced since not posing an animal or public health risk.

## **2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT**

Certain of the proposed amendments to Annex III to Regulation (EC) No 853/2004 were requested by the competent authorities of Member States and certain private stakeholders' organisations. They have been discussed during several meetings of the relevant expert group, representing the competent authorities of all Member States, and are largely supported by those experts.

In addition, private stakeholders' organisations were consulted.

Before adopting this Delegated Regulation, the Commission conducted public consultations in an open and transparent way in accordance with the procedures laid down in the Interinstitutional Agreement of 13 April 2016 between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making<sup>3</sup>.

## **3. LEGAL ELEMENTS OF THE DELEGATED ACT**

The amendments to Annex III to Regulation (EC) No 853/2004 should be made by a Delegated Regulation adopted pursuant to Article 10(1), second subparagraph, points (c), (d) and (e) thereof.

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<sup>3</sup> OJ L 123, 12.5.2016, p. 1.

**COMMISSION DELEGATED REGULATION (EU) .../...**

**of 18.7.2025**

**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<sup>1</sup>, 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.

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

- (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  $-18^{\circ}\text{C}$  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  $-9^{\circ}\text{C}$ . 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.
- (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<sup>2</sup> 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  $-18^{\circ}\text{C}$  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  $-18^{\circ}\text{C}$  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  $-9^{\circ}\text{C}$  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  $-18^{\circ}\text{C}$  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  $-18^{\circ}\text{C}$ . Those measures should ensure the proper functioning of the internal market while protecting consumers, in accordance with the objectives of Regulation (EC) 853/2004.
- (8) In addition, it is necessary to set strict time/temperature parameters for freezing tuna in brine at  $-18^{\circ}\text{C}$  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) 853/2004 should be amended accordingly.

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<sup>2</sup> Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs OJ L 338, 22.12.2005, p. 1–26 ELI: <http://data.europa.eu/eli/reg/2005/2073/oj>

- (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<sup>3</sup> 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) 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) 853/2004, by this Regulation, it should apply from [...] [*Office of publications, please, insert a date corresponding to 90 days as of the entry into force of this Regulation. This should be the same date as in Article 2 of the draft act*]

HAS ADOPTED THIS REGULATION:

*Article 1*

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

*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 [...] [*Office of publications, please, insert a date corresponding to 90 days as of the entry into force of this Regulation.*]

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

Done at Brussels, 18.7.2025

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*

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<sup>3</sup> 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. 16–33 ELI: <http://data.europa.eu/eli/reg/2008/1333/oj>