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COMMISSION

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COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

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)

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(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 (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 Section I 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 freezing in brine of the whole fish intended for canning is practiced, a temperature of not more than -9°C is to be achieved. This point also states 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.

[1] 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 freezer vessels could not reach the temperature of –18ºC for freezing tuna in brine. These official controls and audits have shown that certain food business operators have illegally placed on the market as fresh tuna for direct human consumption, tuna that had been frozen in brine at -9°C, whereas 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 is a fraudulent practice that exposes consumers to health risks, as it can lead to an excessive production of histamine and result 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[2] in vacuum-packed thawed tuna loins, treated with additives to change their colour and make them appear as fresh tuna. Other notifications concern the occurrence of scombroid food poisoning associated with the consumption of such tuna products. Member States have taken measures following official controls, but more recent RASFF notifications show that these measures have not resolved the issue. Other measures should therefore be laid down.

(6) Commission consultations with the competent authorities of the Member States and stakeholders' organisations have shown that freezing technology on board of vessels has substantially improved, and it is now possible to freeze tuna in brine at -18°C, while maintaining its organoleptic characteristics, and ensuring its safety, if certain conditions are met.

(7) It is, therefore, appropriate to lay down hygiene requirements regarding the freezing of tuna in brine at -18°C. These requirements should also: (a) ensure that the operators carry out appropriate own checks and (b) facilitate the official controls by the competent authorities in particular to differentiate freezing vessels able to freeze tuna in brine at -18°C from those that cannot.

(8) The appropriate freezing capacity of freezer vessels freezing tuna in brine should be identified by means of a validation plan 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.

(9) 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. It is also necessary to set strict time and temperature parameters when freezing tuna in brine at -18°C at core. The decrease in temperature should be carried out in a continuous process, and in compliance with certain requirements. In particular, this Regulation lays down the total duration of the freezing process.

(10) In addition, to enable competent authorities to check that tuna has been frozen in brine at -18°C throughout the relevant period, freezer vessels should continuously monitor and record the temperature of the brine, using electronic means of temperature

[2] 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).

measurement. Such equipment should also allow access in real-time and onshore to the temperature of the brine by the concerned food business operators. Food business operators should make these records available, upon request, to Member States' competent authorities, during official controls.

(11) These measures should ensure the proper functioning of the internal market and a high level of consumer protection with regard to food safety, in accordance with the objectives of Regulation (EC) No 853/2004.

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

(13) 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 risk to animal or public health. Products of animal origin authorised as food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council[3] are also considered as highly refined products since the production of such additives eliminates such risks and should, therefore, be included within the scope of Section XVI of that Annex. Some of these additives are derived from insects and therefore insects should be allowed to be used as raw materials for highly refined products. Information was provided by stakeholders illustrating that another process for fat derivatives than those laid down in Section XVI of Regulation (EC) No 853/2004 results in a product of animal origin, namely vitamin D3, in which the risks to animal and public health are eliminated. Consultation of the European Food Safety Authority in accordance with Article 13 of Regulation 853/2004 is therefore not required. When fat derivatives are processed in such a way, they should fall within the scope of Section XVI of Annex III to that Regulation. Annex III, Section XVI, to Regulation (EC) No 853/2004 should, therefore, be amended accordingly.

(14) In order to allow the interested parties the necessary time to put in place procedures in order to comply with the new requirements resulting from the amendments to Annex III to Regulation (EC) No 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*.

[3] 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).

It 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,

For the Commission
The President
Ursula VON DER LEYEN