

# Amended hygiene rules for food of animal origin

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EU proposes to amend hygiene rules for tuna frozen in brine and for certain highly refined products

Draft Commission Delegated Regulation 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

Draft Annex

## Update

The European Union (EU) has informed the World Trade Organization Sanitary and Phytosanitary Measures (WTO SPS) Committee that it intends to amend certain rules on the hygiene of foods of animal origin ([G/SPS/N/EU/844](#)). These changes concern the validation of requirements for freezing tuna in brine at  $-18^{\circ}\text{C}$  on-board freezer vessels; the declaration of food chain information for domestic ungulates that have undergone emergency slaughter outside the slaughterhouse; and the inclusion of insects as a raw material for food additives and a new process to extract vitamin D3 derived from wool grease.

## Impacted products

Domestic ungulates, highly refined products, tuna (whole Thunnus and Katsuwonus)

## What is changing?

The EU intends to amend Annex III to Regulation [853/2004](#) laying down rules on the hygiene of foods of animal origin for business operators.

### Frozen tuna in brine

Amendments are proposed to Annex III, Section VIII, Chapter I, Part I.C and Part II in Regulation 853/2004). These include:

- Vessels must be equipped with an electronic system that monitors and continuously records the temperature of the brine on board and that can be controlled by the operator onshore. The system must be certified according to relevant international standards for temperature measurements.
- Food businesses that operate freezer vessels must have in place a validation plan for the freezing capacity of such vessels. The competent authority (CA) must be able to check the validation plan before placing these freezer vessels on the list of authorised vessels published on the Commission website. They must take action against operators illegally placing tuna not frozen at -18°C on the market. The CA must also ensure that the operators carry out appropriate own checks.
- The validation plan sets strict conditions for cooling and freezing whole tuna in brine. The maximum duration for tuna to reach -18°C at core in a continuous process is 96 hours. Food business operators must continuously monitor and record temperature and salt concentration in brine in real-time.

### **Meat from emergency slaughter**

Annex III, Section I, Chapter VI point 5

- The declaration by the food business operator that should accompany meat from domestic ungulates to the slaughterhouse after emergency slaughter is replaced by a reference to the food chain information required in accordance with Section III of Annex II to Regulation 853/2004, for the sake of clarification.

### **Highly refined products**

Annex III, Section XVI

- Inclusion of insects as a raw material for food additives.
- Inclusion of a new process to extract vitamin D3 from wool grease (heat treatment of at least 135°C for at least 90 min).

## Why?

The proposed hygiene requirements regarding tuna frozen in brine will facilitate approval of only those freezing vessels that are able to freeze tuna in brine at  $-18^{\circ}\text{C}$ . Differentiating these from vessels without sufficient freezing capacity will enable the competent authorities to take action against operators illegally placing on the market tuna not frozen at  $-18^{\circ}\text{C}$  as fresh tuna for direct human consumption. Whole tuna frozen in brine at a temperature of  $-9^{\circ}\text{C}$  must be destined for canning and cannot be sold as fresh tuna, even if subsequently frozen at a temperature of  $-18^{\circ}\text{C}$ . This fraudulent practice exposes consumers to health risks from excessive exposure to histamine, which can result in scombroid syndrome.

The content of the declaration required to accompany meat from emergency slaughter to the slaughterhouse is already included in the food chain information required in accordance with point 3 of Section III of Annex II of Regulation 853/2004.

Food additives derived from insects can be considered highly refined products within the scope of Regulation 853/2004, Annex III, Section XVI, because the production of such additives eliminates any risk to animal or public health.

Information is available illustrating that vitamin D3 from fat derivatives of animal origin is acquired through a process that eliminates any risks to animal and public health.

## Timeline

The Regulation is expected to be adopted in approximately the fourth quarter of 2025.

## What are the major implications for exporting countries?

Exporters to the EU of tuna frozen in brine must equip vessels and follow the new requirements to ensure they will be met when the Regulation enters into application.

When placing freezer vessels on the list of establishments authorised to export tuna frozen in brine to the EU, competent authorities in exporting countries must check that freezer vessels flying that country's flag have the freezing capacity required to maintain fishery products in the storage holds at a core temperature of not more than  $-18^{\circ}\text{C}$ . Competent authorities must also be able to check food business operators' validation plans regarding freezing capacity.

## Recommended Actions

The WTO consultation on this proposal ([G/SPS/N/EU/844](#)) closed on 24 May 2025; the EU's [Have your say](#) consultation closed on 23 April 2025.

## Background

Regulation [853/2004](#) lays down specific rules on the hygiene of food of animal origin for food business operators.

As noted in the certificates that must accompany food exported to the EU (see [EU official health certificates for exports to the EU – explained](#)), these requirements also apply to food from non-EU countries. Recently, the Rapid Alert System for Food and Feed (RASFF) has issued increasing numbers of notifications on the presence of histamine above the maximum permitted limit (mean value  $\leq 100$  mg/kg, no values over 200 mg/kg) in vacuum-packed thawed tuna loins treated with additives and sold as fresh tuna (Regulation [2073/2005](#), Annex 1). See [Maximum levels of food additives in tuna](#).

## Sources

[Draft](#) Commission Delegated Regulation concerning specific hygiene rules for emergency slaughter of domestic ungulates, for tuna frozen in brine and for highly refined products

Draft [Annex](#)

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