Amended hygiene rules for food of animal origin

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EU amends hygiene rules for tuna frozen in brine and for certain highly refined products

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.

Update

The European Union (EU) has amended certain rules on the hygiene of foods of animal origin. These changes concern the validation of requirements for freezing tuna in brine at –18°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 has amended Annex III to Regulation 853/2004 laying down rules on the hygiene of foods of animal origin for business operators. Amendments to Annex III of Regulation 853/2004 include the following.

Frozen tuna in brine

- 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 a validation plan in place 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 European Commission's list of

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authorised establishments (Fishery products). 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 checks of their own.

- 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.

These are amendments to Section VIII Fishery products; and Chapter I, Parts I.C Requirements for freezer vessels, and II Hygiene requirements.

Meat from emergency slaughter

- 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.

This is an amendment to Section I, Chapter VI: Emergency slaughter outside the slaughterhouse, point 5.

Highly refined products

- 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.).

These are amendments to Section XVI: Highly refined products.

Why?

Under the new hygiene requirements regarding tuna frozen in brine, only those freezing vessels that can freeze tuna in brine at –18°C will be approved. 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°C as fresh tuna for direct human consumption. Whole tuna frozen in brine at a temperature of –9°C must be destined for canning and cannot be sold as fresh tuna, even if subsequently frozen at a temperature of –18°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 [Regulation 853/2004,

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Annex II, Section III(3)].

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 applies from **18 November 2025**. The rule changes relating to tuna frozen in brine apply from **27 January 2026.**

What are the major implications for exporting countries?

Exporters to the EU of tuna frozen in brine must equip vessels appropriately and follow the new requirements to ensure they will be met by the time 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°C. Competent authorities must also be able to check food business operators' validation plans regarding freezing capacity.

Recommended Actions

Exporters to the EU of tuna frozen in brine must verify that vessels are equipped to meet new requirements, when the Regulation enters into application.

Competent authorities in exporting countries must take steps to ensure the effectiveness of operators' validation plans.

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

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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 ≤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.

Resources

Regulation 853/2004 laying down specific hygiene rules for food of animal origin.

Regulation 2073/2005 on microbiological criteria for foodstuffs.

European Commission: Microbiological criteria.

Sources

Commission Delegated Regulation (EU) 2025/1449 concerning specific hygiene rules for emergency slaughter of domestic ungulates, for tuna frozen in brine and for highly refined products.

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