Ethylene oxide in food additives

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EU revises specifications for food additives to eliminate presence of ethylene oxide

Commission Regulation (EU) 2022/1396 of 11 August 2022 amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the presence of ethylene oxide in food additives

Update

On 11 August 2022, the EU published a Regulation stipulating that the presence of ethylene oxide (EtO), irrespective of its origin, is not authorised for any food additives, and setting the maximum limit of 0.1 mg/kg at the limit of quantification in those products.

Impacted products

food additives

What is changing?

The European Commission amends the Annex to Regulation (EU) No 231/2012 regarding the presence of ethylene oxide (EtO), irrespective of its origin, for all food additives, by reducing the maximum limit to the limit of quantification (0.1 mg/kg).

Why?

Recent concern about the presence in food products of EtO, a substance classified as carcinogenic, mutagenic and toxic for reproduction in accordance with Regulation (EC) No 1272/2008, included EtO in food additives. Current food additive specifications permit the presence of EtO in certain additives up to a limit of 0.2 mg/kg. This complicates Member State controls of EtO and potentially undermines the protection of public health.

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Timeline

Date of application: 11 August 2022

What are the major implications for exporting countries?

The new rules remove any ambiguity regarding the presence of EtO in food additives, but may complicate export of the food additives xanthan gum, guar gum and locust bean gum, and their derivatives. Exports of certain of these products from China, India, Malaysia and Turkey are already facing a temporary increase in controls introduced under Implementing Regulation 2021/2246.

Goods from third countries can be held subject to a temporary increase of official controls at border control posts in cases where the European Commission has decided (by means of Implementing Acts) that a known or emerging risk makes stricter controls necessary, or there is evidence of widespread serious non-compliance with EU agri-food chain legislation.

Recommended Actions

Exporters of food additives must urgently review practices regarding EtO. Exporters may consider substituting other treatments for EtO fumigation, ensuring that products are compliant with EU maximum residue levels.

Alternatives to EtO for microbiological decontamination of low-moisture foods include pasteurisation, or other gas treatments such as ozone. The efficacy of these treatments must first be assessed and validated for each product.

Background

The Regulation amends the Annex to Commission Regulation (EU) No 231/2012 and lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.

Ethylene oxide is a chemical substance used as a sterilising agent and raw material in the manufacture of certain products. Under Regulation (EU) No 231/2012, EtO may not be used for sterilising purposes in food additives. However, for those food additives for which EtO is used in the production process, a limit of 0.2 mg/kg EtO is specified in the Regulation. This makes it difficult to establish whether or not the presence of EtO in food additives complies with EU law. The new rules aim to clarify the situation.

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This decision comes in the context of multiple food safety incidents involving very high levels of EtO, particularly in locust bean gum, food supplements, seasonings and spices, and instant noodles. These incidents, notified through the Rapid Alert System for Food and Feed (RASFF), have required amending Annex II to Implementing Regulation (EU) 2019/1793 in view of the serious human health risk from food contaminated with EtO. The official certificate accompanying all such consignments, particularly from India, must now state that the products have been sampled and analysed for residues of pesticides. All results of sampling and analysis must show compliance with EU legislation on maximum residue levels of pesticides. The results of the sampling and analysis must be attached to that certificate.

Resources

SCF (2002) Opinion of the Scientific Committee on Food on impurities of ethylene oxide in food additives

Sources

Implementing Regulation (EU) 2019/1793

Regulation 231/2012

Regulation 2022/1396

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