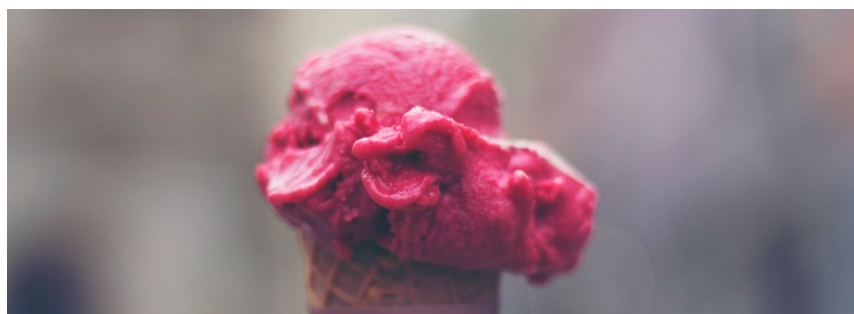


## Ethylene oxide in food and risk to human health

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Data gathered indicates that ethylene oxide is utilized as a biocide or a sterilizer for surfaces of certain crops in some non-EU countries. This includes a fumigation process for sesame and locust bean seeds. If the fumigation process is carried out incorrectly, i.e. without ventilation (and thus removal of this gas from the food), ethylene oxide may be retained in the food. In the EU, its use in food production is not allowed, regardless of the method of production (organic/conventional). This is because it's a genotoxic carcinogen, and there is not enough toxicological data available yet with regard to consumption.

Most of the data on the effects of ethylene oxide on human health have so far been obtained from people exposed to it by inhalation. The substance's bioavailability after ingestion is lower than when inhaled, but data on the proportion of ethylene oxide absorbed are not available. In a recent preparation of a toxicological profile for ethylene oxide, the U.S. Agency for Toxic Substances and Disease Registry estimated that scenarios of ingesting ethylene oxide through food that would prove to be a serious threat to health were less likely. The maximum level of ethylene oxide residue is therefore legally set at the limit of analytical determination in each food category in the EU and this represents the action limit for food safety. The use of ethylene oxide was, according to some data, banned in the food industry in certain countries of today's EU as early as 1981, but, more importantly, current legislation does not allow the use.

Analyses of foods with the possible presence of ethylene oxide have shown that ethylene oxide is converted into 2-chloroethanol in the samples, which is assessed together with the parent substance ethylene oxide in the EU. The maximum residue limit (MRL) of 0.1 mg/kg in the food additive E410 thus represents the analytical limit of determination for the sum of ethylene oxide and 2-chloroethanol, expressed as ethylene oxide. While there's limited toxicological information on 2-chloroethanol, animal research has demonstrated its mutagenic capabilities. Given the absence of sufficient data, its potential carcinogenic nature cannot be ruled out. Therefore, for the sake of consumer health safety, it is prudent to assess the substances collectively until more updated information becomes available.

## **Market surveillance in the current situation and product recall**

In the intensified control of potential raw materials that could contain traces of ethylene oxide, locust bean seeds used to make the food additive E410 (locust bean gum) were identified as contaminated. Due to the wide use of this additive, as well as the diversified distribution of products, the European Commission, with the aim of a unified approach in addressing the identified issues in all Member States, initiated activities. Consequently, products containing the additive E410 are withdrawn from the market. Although E410 is a safe and permitted food additive that is not prohibited in foods, it may nonetheless represent a source of ethylene oxide contamination in connection with the issue under consideration. The research of the [Institute of Nutrition](#) showed that in Slovenia this additive is present in 80% of pre-packaged ice creams on sale, and it is also common in various mixtures of beer and soft drinks and radlers and in vegetable substitutes of cream, yoghurts, cheese and milk.

Food recalls prevent consumers from being exposed to ethylene oxide for a long period of time, as there is too little toxicological data to be able to set a safe limit on consumption. The established concentrations of ethylene oxide in some finished products are extremely low; therefore, with short-term exposure, they pose a low concern for human health. However, it is unlikely that this substance, through the ingestion of food with the additive E410, would cause consumers to have clinical signs of intoxication.

The Administration for Food Safety, Veterinary Sector and Plant Protection (UVHVVR) has already informed distributors, food producers and retailers about the problem and called on them to tighten internal control over ethylene oxide, which is also the subject of official control. As a result of the extensive usage of the additive, numerous food items are anticipated to be withdrawn/recalled. At the same time, we recommend that consumers follow the announcements on both the websites of manufacturers and traders and the website of the Administration for Food Safety, Veterinary Sector and Plant Protection (UVHVVR), among consumer notices.

## **How did ethylene oxide end up in food?**

The resulting situation raises the question of how a substance that is prohibited in food production could have found its way into foods, especially yogurts and ice creams, which are particularly popular? The usage of ethylene oxide in food production is prohibited in the European Union. However, in some third countries, where European manufacturers obtain their raw materials, it is permitted to a certain degree. In order to prevent such risks, strict procedures and controls are in place in the European Union. Every product included in the food chain is as safe as the chain's weakest link. These weakest links can be very different. In the case of ethylene oxide, manufacturers used an additive that they did not know was contaminated with ethylene oxide. They used a permitted food additive that met the required specifications, but in this case, the problematic substance was only detected subsequently. This does not happen often, but it can happen. The European Commission reacted appropriately and took good care to minimise the risk. Food legislation in the EU is among the strictest in the world. Manufacturers are primarily responsible for food safety, and numerous procedures and controls are implemented to detect as many things as possible that could pose a health risk. Foods that are not safe are being withdrawn from the market; consumers are informed through recalls and are familiar with current events, and thus can return the products where they bought them.

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