German Federal Institute for Risk Assessment

# Health risk of ethylene oxide in food

FAQ of the BfR from 2 June 2022

Monitoring authorities of the federal states have detected residues of ethylene oxide and its conversion product 2-chloroethanol in various foods and food ingredients such as sesame seeds, spices or food additives. The use of ethylene oxide is prohibited in food production as the substance can have mutagenic and carcinogenic effects. The conversion product 2-chloroethanol was subject to a preliminary risk assessment by the German Federal Institute for Risk Assessment (BfR). Due to large data gaps the risk for 2-chloroethanol was assessed to be comparable to that of ethylene oxide. The BfR has prepared questions and answers on possible health risks of ethylene oxide and 2-chloroethanol residues in food.

**What is ethylene oxide?**
Ethylene oxide (EtO or EO for short) is a colourless, highly flammable, very reactive gas with a sweet odour that kills bacteria, viruses and fungi. It is converted in the environment and in crops to 2-chloroethanol, among other things. The conversion of ethylene oxide to 2-chloroethanol takes place relatively quickly. Thus, only 2-chloroethanol is usually detected in plants and foods derived from them. 2-Chloroethanol, in turn, is a colourless liquid with a faint sweetish odour.

**What are the sources of 2-chloroethanol? Can it also get into food from a source other than ethylene oxide?**
Trace levels of 2-chloroethanol, i.e. in the range of the limit of quantification, can also have other causes than treatment with ethylene oxide such as cross-contamination during production. The formation of 2-chloroethanol from other chlorine-containing chemicals is also possible.

**Where was and is ethylene oxide used?**
Ethylene oxide was used in plant protection and as a disinfectant. The use of ethylene oxide in plant protection products was permitted in Germany until 1981 and in the rest of the European Union (EU) until 1991. In addition, the substance could also be used in the EU until 2011 for the fumigation of food and animal feed in order to protect them from fungal and bacterial attack during transport and storage. Since 2011, all food and feed applications have been banned. The use of ethylene oxide in biocidal products is now only permitted in the area of disinfection and sterilisation outside the food sector, such as for the sterilisation of medical devices.

**Why has the use of ethylene oxide been banned in the production and storage of food in the European Union and what does it mean?**
Ethylene oxide has mutagenic and carcinogenic properties and can therefore be genotoxic or carcinogenic. As a so-called "carcinogen without threshold value", it has not been possible to determine an intake level without health risk. Residues of the substance in food are therefore generally deemed undesirable. Official analysis records ethylene oxide and its conversion product 2-chloroethanol together as a sum parameter. Accordingly foodstuffs in which ethylene oxide or 2-chloroethanol have been detected above the limit of determination are not to be put on the market. The limit of quantification, i.e. the amount above which ethylene oxide or 2-chloroethanol can be reliably detected in food, is 0.02 milligrams (mg), 0.05 mg or 0.1 mg per kilogram (kg) of food, depending on the food.

**How does the BfR assess the health risk of 2-chloroethanol?**
For 2-chloroethanol, the available data is contradictory and partly incomplete. Thus, currently no reliable statement can be made with regard to the carcinogenic properties of 2-chloroethanol. On the basis of the available data, it can be assumed that 2-chloroethanol may also potentially have mutagenic effects. However, there are currently no indications that the conversion product has a higher hazard potential (toxicity) than ethylene oxide. As long as the existing data gaps on the potential toxicity persist, 2-chloroethanol should therefore be toxicologically assessed as ethylene oxide.

**Why don't risk assessment authorities initiate studies themselves to close the data gaps on 2-chloroethanol?**
It is not up to the risk assessment authorities to initiate studies on the health risk of metabolites of an active substance banned in plant protection products in the European Union nor to finance them with taxpayers' money. Such studies are required in an application for approval of an active substance for plant protection products or in an application for import tolerance. They are to be carried out and submitted by the applicant.

**Are there maximum levels for ethylene oxide and 2-chloroethanol in food?**
Since ethylene oxide may not be used in the food sector, the maximum content for ethylene oxide and 2-chloroethanol is defined as the respective analytical limit of determination as the sum value of both substances for the corresponding food (this also includes food ingredients such as spices and additives).

**How does the BfR assess the health risk of the detected levels of ethylene oxide and 2-chloroethanol in food?**
In the health risk assessment of ethylene oxide and 2-chloroethanol contents in sesame seeds, BfR applied the "large assessment factor" procedure recommended by the European Food Safety Authority (EFSA) for mutagenic and carcinogenic substances. In the case of undesirable substances, the procedure is used to estimate the severity of a possible health risk for risk management purposes. It determines the "intake level of low concern" for a potentially mutagenic and carcinogenic substance, based on one day and one kilogram of body weight. At this level (exposure) daily intake would potentially lead to one additional case of cancer for one in 100,000 people. In its risk assessment, the BfR calculated a daily intake of low concern of 0.037 µg per kilogram of body weight for ethylene oxide and the conversion product 2-chloroethanol.

**Illustrative example:** FC Barcelona's packed Camp Nou stadium holds 100,000 spectators. Of these 100,000 people, approx. 25% - i.e. 25,000 people - will develop cancer over the course of their lives. This is the expected cancer rate under today's living conditions. Assuming a lifetime intake of a carcinogenic substance (such as ethylene oxide in this case) the above approach calculates the dose at which **one person will potentially** develop cancer additionally. This means that if each of these 100,000 people ingested 0.037 µg of ethylene oxide daily throughout their lives not 25,000 but 25,001 of the 100,000 would possibly develop cancer over the course of their lifetime.

**How does the European Food Safety Authority (EFSA) assess the health risk of the detected levels of 2-chloroethanol in food?**
The European Food Safety Authority (EFSA) was asked by the European Commission to review the BfR assessment taking into account some recent studies. In its ”Statement on the BfR opinion regarding the toxicity of 2-chloroethanol” https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7147 the EFSA Panel confirms BfR's assessment of the health risks of the residues of 2-chloroethanol detected in sesame seeds. It also

agrees with the basic assessment of the BfR that 2-chloroethanol should be assessed in the same way as the parent ethylene oxide due to the existing data gaps, at least until new data are available.

**What does the intake level of low concern mean for health?**
The intake level of low concern is not a measure of food safety. It is also not a benchmark for monitoring authorities to assess the marketability of individual foods. The intake level of low concern is rather a guideline for risk management authorities on how urgent an action is required in order to reduce the health risk posed by a mutagenic and carcinogenic substance in a food. The intake level of low concern of 0.037 µg per kilogram of body weight is thus not a toxicological threshold below which adverse health effects are not to be expected.
If one follows the ALARA principle ("as low as reasonably achievable"), which applies to mutagenic and carcinogenic substances, then inputs of ethylene oxide and 2-chloroethanol into food should generally be avoided.

**Ethylene oxide has been banned for use in food and feed since 2011. Why is its presence in food only now being detected?**
Instrumental analytics for detecting ethylene oxide and 2-chloroethanol in food have been available for a long time and are continuously being improved. Food business operators are responsible for ensuring that products comply with the legal requirements. If necessary, they must also monitor and ensure this through their own analysis. This principle applies along the entire production and distribution chain up to the retail trade. The monitoring authorities of the federal states check by random sampling whether the market participants comply with their obligation. If a sample is found to exceed the legal maximum content, the specific product will be subject to management measures. If necessary, further investigations are carried out in the corresponding product groups to determine whether the exceedance is an individual case or a systematic phenomenon. Past samples also would contain ethylene oxide. The reasons for a frequent occurrence of such positive findings are manifold. Causes can be, for example, changes in production conditions or increased sampling.

## Further information on the subject from the BfR website:

Updated BfR Opinion No. 024/2021 Health assessment of ethylene oxide residues in sesame seeds

https://www.bfr.bund.de/cm/343/gesundheitliche-bewertung-von-ethylenoxid-rueckstaenden-in-sesamsamen_final.pdf

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## About the BfR

The Federal Institute for Risk Assessment (BfR) is a scientifically independent institution in the portfolio of the Federal Ministry of Food and Agriculture (BMEL). It advises the Federal Government and the Federal States on issues of food, chemical and product safety. The BfR conducts its own research on topics closely related to its assessment tasks.

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