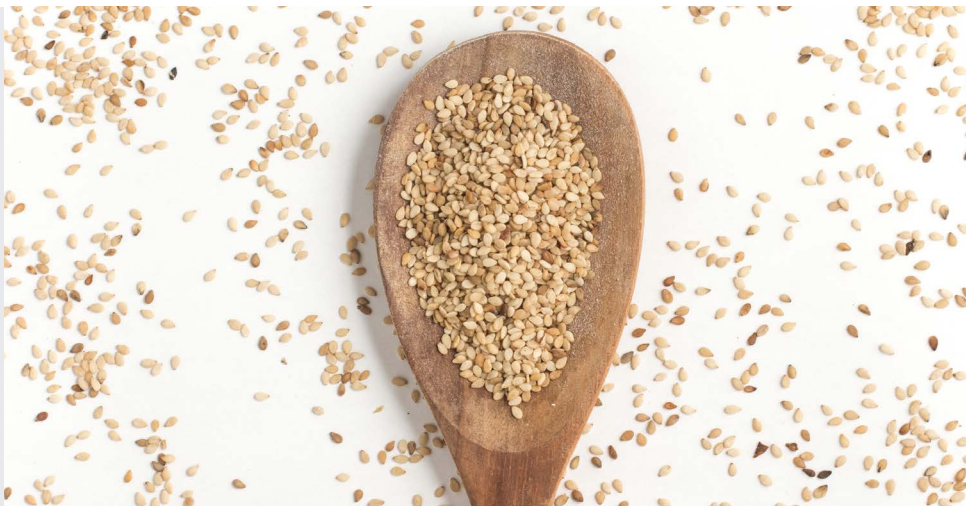




Know what's inside.



Food Analysis at the Highest Level.

**FOOD SAFETY AND RISK MANAGEMENT REGARDING
ETHYLENE OXIDE CONTAMINATION**

**ETHYLENE OXIDE AND 2-CHLOROETHANOL –
DETECTING RESIDUE**

GENERAL INFO

At room temperature, ethylene oxide is a highly volatile, colorless gas with a sweet scent. Ethylene oxide is also known by other names such as oxirane, epoxyethane, oxacyclopropane, diethylene oxide, EO, and EtO, and its chemical formula is C₂H₄O. Over the last 6 months, more than 500 food products have been recalled due to elevated levels of EtO contamination. Ethylene oxide and the metabolite 2-chloroethanol are both toxic, but ethylene oxide has furthermore been classified as carcinogenic and genotoxic ¹. The use of EtO is prohibited in the EU and the maximum residue level is 0.02 - 0.1 mg/kg, as stated in the Regulation (EC) No 396/2005 ².

APPLICATIONS

Nevertheless, ethylene oxide is still used today, both for sterilizing medicinal and pharmaceutical products (for example the test swabs for COVID-19 rapid tests) as well as for reducing microbes in food products that are sensitive to heat (e.g., sesame, herbs, and spices) and additives such as stabilizers and fillers. Ethylene oxide can kill vegetative cells and spores, such as salmonella and e. coli and is gentler on the food product than other methods of germ reduction, such as steam sterilization. Doing so can prevent a variety of potentially undesired effects, such as changes to the sensory characteristics of the product, loss of vitamins, discoloration, or increased moisture. Due to an elevated rate of salmonella contamination in the aforementioned products in the year 2017, the Regulation EC No 669/2009 ³ was lifted, thus leading to increased usage of EtO fumigation in the country of origin, India. It is generally applied prior to transport, directly in the container or in storage. After its application, the product is supposed to be ventilated well for at least 24 hours in order to allow the remaining gas to escape. If this process is not carried out properly, there is the possibility that EtO residue will remain in the product, which then could further break down into another product called 2-chloroethanol.

ANALYSIS

Until now, the analysis of ethylene oxide/2-chloroethanol has been conducted using GC-ECD technology and the standard method in accordance with §64 of German Food and Feed Law. However, this method has a few relevant limitations, for example regarding the sensitivity of the measurement or the potential to determine individual results for ethylene oxide and 2-chloroethanol content. Furthermore, executing the method involves a major time investment. For this reason, EU reference laboratory for single residue methods (EURL SRM, Stuttgart) has developed a method that does not have those limitations. It is a method based on the QUECHERS method and involving a GC-MS/MS measurement on a special chromatography column.

At the GBA Group, this new method for determining ethylene oxide and 2-chloroethanol has been validated in its entirety for all matrices and has also demonstrated its efficacy in interlaboratory proficiency tests organized by the EU reference laboratory. The method is accredited.

With this new process, a lower limit of quantification of 0.01 mg/kg can be achieved for all matrices. Aside from that, with this method, blank values pose lower risks and there are no limitations in terms of which products can be analyzed. The method contains individual identification and quantification for ethylene oxide and 2-chloroethanol. In addition, as was previously the case, there is also the determination of the total content of ethylene oxide, which is relevant for the assessment. The individual results for ethylene oxide (free) and 2-chloroethanol are therefore possible without any additional analytical effort, and express analysis or even same-day analysis can also be realized.

ANALYTIC RESULTS / RELEVANT PRODUCTS AND FIELDS

At the end of 2020, the European Rapid Alert System Food & Feed (RASFF) reported very high levels of ethylene oxide in certain batches containing sesame seeds and oil (e.g., snacks, bars, salad toppings, and baked goods) that were imported from India. These products were declared unmarketable. The ethylene oxide levels in certain cases exceeded the maximum residue level provided in the Regulation (EC) No 396/2005, which is 0.02 - 0.1 mg/kg, by a factor of more than a thousand.

At the beginning of 2021, the RASFF encountered the same situation with further products, primarily in the field of herbs and spices, such as turmeric, ginger, coriander, spice mixtures, pepper, chili, and more. These products were used as ingredients in sausages and convenience food. Since ethylene oxide and 2-chloroethanol are toxic, these kinds of residues are undesirable in food. Nowadays, in the food trade, sometimes sellers are required to provide evidence that the products listed are free of these residues.

TREND

After repeated testing, now ethylene oxide residue has also been found in products such as psyllium husks, amaranth, guar gum, as well as spirulina and ashwagandha, which is also commonly used in the field of dietary supplements. Furthermore, additives such as glossers (oils and waxes) and fillers (maltodextrin and cellulose) are being critically examined. Also, India is apparently no longer the only country of origin being closely monitored by the RASFF. Products from other countries such as Uganda and Nigeria, for example, are now also under scrutiny ⁴.

OUTLOOK

According to the Regulation (EC) No 396/2005, the maximum residue level is 0.02 - 0.1 mg/kg. Indian sesame seeds and the other products previously mentioned can also end up in the EU via Africa or other third countries.

This aspect can therefore change the "country of origin." If there is a high level of (total) EtO in the product, one can assume there was active usage for the purpose of reducing germs. If there are "low" levels of (total) EtO, the root cause could also be cross-contamination, e.g., during storage or if ship containers were fumigated.

That means that results of approximately 0.1 mg/kg do not always indicate a targeted application of EtO, which, on the other hand, also could lead to difficulties in the assessment, especially in the case of organic products, since the orientation value of 0.01 mg/kg applies in principle. Results in low concentrations do not necessarily have to originate from illegal applications, but potential sources of cross-contamination have to be examined.

There are some indications that cleaning products and disinfectants containing chlorine can also lead to the formation of 2-chloroethanol (though they have not been published yet).

BENEFITS

The GBA Group has long-term experience analyzing ethylene oxide and 2-chloroethanol. We carry out these analyses together with additional services upon request (such as sampling in the country of origin, audits) as a complete package for you. That way, we can help you ensure the safety of your products. At the same time, by using our services, you can minimize risk throughout the entire supply chain and increase consumer trust in your products.

In the fall of 2020, a new regulation from the EU Commission went into effect (Implementing Regulation (EU) 2020/1540 of 22 October 2020). This regulation states that 50% of the sesame seeds imported from India have to be tested for ethylene oxide residue. It replaces the previous Implementing Regulation (EU) 2019/1793 ⁵.

SOURCES:

- (1) echa.europa.eu/de/information-on-chemicals
- (2) eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32005R0396&qid=1622627048554&from=DE
- (3) <https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32009R0669&from=DE>
- (4) <https://bvlk.de/fachinformationen.html>
- (5) <https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32019R1793&qid=1622627919500&from=DE>



ABOUT US

GBA Group is an international life science service company with a broad range of analytical, logistical and specialist services in the fields of pharmaceuticals, medical products, cosmetics, chemicals, food, drinking water and the environmental sustainability.

The range of services offered by the GBA Group includes laboratory analytics, data management, special logistical services for clinical trials, as well as consulting services for private companies and public institutions in connection with their activities in the fields of research, product development, market development, and consumer protection.

Through its work, the GBA Group makes a sustainable contribution to public health, the environment and society as a whole.

The GBA Group operates sites in Austria, Belgium, Finland, France, Germany, Poland, Spain, and the United States.

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