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Ethylene oxide and 2-Chloroethanol

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1. Introduction

Sesame seeds and other dry products such as spices and spice powders are microbiologically sensitive goods. To prevent infestation with salmonella or other harmful germs, the gas ethylene oxide is used in some countries for sterilisation.

Ethylene oxide is a highly reactive gas and kills bacteria, viruses, fungi and moulds by destroying their cells. It is routinely used in the sterilisation of medical devices.

The sterilisation of food with ethylene oxide is used in countries where it is approved, for reasons of precautionary consumer protection. In some countries (e.g., USA and Canada), sterilisation of susceptible foods with ethylene oxide is even mandatory to prevent possible microbial contamination. Ethylene oxide can also be used to prevent spoilage by moulds (f.ex. mycotoxin formation during storage)

2. Background

According to information received by the German Federal Ministry of Food and Agriculture (BMEL), an expert meeting of the "Working Group of Food and Feed Crisis Coordinators" of the EU commission, which took place on October 9, 2020, concluded about an "agreement that sesame seeds and goods produced with them in case of exceedances of this maximum level (here: Maximum residue level according to Regulation (EC) No. 396/2005: 0.05 mg/kg for the sum of ethylene oxide and 2-chloroethanol, expressed as ethylene oxide) should be withdrawn from the market or recalled." India was named as the origin of affected sesame seeds.

3. Chemistry and Analytical approach

"Ethylene oxide" is regulated as a sum parameter according to the residue definition (see above), consisting of the active ingredient ethylene oxide itself and its reaction product 2-chloroethanol. 2-Chloroethanol is formed whenever f.ex. sodium chloride is present in a product treated with ethylene oxide. With the anionic portion of the salts (usually chloride, and to a smaller extent bromide or iodide), the highly reactive ethylene oxide then forms 2-chloroethanol (resp. 2-bromoethanol or 2-iodoethanol) very rapidly. To the best of our knowledge, only 2-chloroethanol is detected in the goods tested so far, provided that individual substance-specific analysis has been carried out.
The analysis of ethylene oxide in food and feed to verify compliance with the respective maximum residue levels is carried out in Germany in accordance with the official collection of analytical methods (ASU) Method L 53.00-1.

This method detects not only the ethylene oxide itself - if present - but converts 2-chlorethanole (which is the main reaction product/metabolite in the sample) back to ethylene oxide.
In the meantime, some laboratories have also established specific methods for the determination of ethylene oxide (f.ex. by headspace gas chromatography) and 2-chloroethanol (f.ex. determination by gas chromatography after extraction and purification).
According to its own information, CVUA Stuttgart has currently developed a specific analytical method in which ethylene oxide and 2-chloroethanol can be detected and determined in one analytical run [1]. It should be possible to determine both substances simultaneously using a modification of the QuOil method [2]. According to CVUA Stuttgart, this should make it possible to test for ethylene oxide and its degradation product routinely. This specific single residue approach allows a better toxicologic evaluation of the findings.

4. Toxicology

Ethylene oxide is listed as CAS (Chemical Abstract Service database) number 75-21-8 and has been classified as relevant under the European chemicals regulation REACH and subjected to the registration and evaluation procedure formulated in this regulation (Regulation (EC) No 1907/2006).

In this process, the following basic evaluation was prepared:
Ethylene oxide is classified as a carcinogen according to category 1B and as a mutagen according to category 1B.

Due to its sterilizing effect, ethylene oxide is used in food and feed to kill bacteria, viruses, or fungi. This enables possible hygiene regulations to be complied with and ensured when importing food and feed into certain countries. Due to its properties, ethylene oxide falls within the regulatory scope of plant protection products within the EU. The placing of plant protection products on the market in the EU is regulated by Regulation (EC) No. 1107/2009. No authorization has been granted for the use of ethylene oxide under Regulation (EC) No. 1107/2009.

Since ethylene oxide is a highly reactive molecule due to its chemical structure ("epoxide"), the conversion to products such as 2-chloroethanol, which are energetically more stable, takes place very quickly. It can be assumed that already a few days after an application of ethylene oxide to food products, it is no longer detectable in the food.

2-Chloroethanol (also known as ethylene chlorohydrin) is classified as toxic (poisonous) by ingestion, inhalation, and skin contact [3]. A (moderate) mutagenic potential is also reported:
The available data indicates that ethylene chlorohydrin is significantly less mutagenic than EtO and, as such, presents a significantly reduced public health and safety risk [4].

For the evaluation of 2-chloroethanol in food, a toxicological consideration after oral intake is decisive. 2-chloroethanol is neither carcinogenic, genotoxic nor toxic for reproduction [5]. The decisive factor for the toxicity of 2-chloroethanol is the medium to high acute systemic toxicity.

The toxicity of 2-chlorethanol is also questioned in the document *“Risk assessment of ethylene oxide in sesame seeds*“ of the National Institute for Public Health and the Environment, Ministry of Health, Welfare and Sport in cooperation with the Wageningen University [6]. This risk assessment refers to a statement of the EU-scientific committee of 2002 considering 2-chlorethanol not being genotoxic in vivo. Furthermore, a reference is made to Australia New Zealand Food Authority (ANZFA) stating that it is not completely clear if 2-chlorethanol is genotoxic.

5. Legal situation USA and Canada

The maximum residue level (MRL) for ethylene oxide in sesame seeds in Canada is 7 mg/kg (ethylene oxide as a single substance, without 2-chloroethanol) [7]. For the degradation product 2-chloroethanol in sesame seeds, there is a separate maximum content of 940 mg/kg [8], which also applies in the USA at the same level [9].
In the EU, on the other hand, the maximum residue level (MRL) of 0.05 mg/kg for the sum parameter ethylene oxide and 2-chloroethanol, expressed as ethylene oxide, is based on the fact, that ethylene oxide is a pesticide active ingredient that is not approved in the EU. Consequently, the specific MRLs were set at the level of the respective analytical limits of determination in relation to the residue definition (here: sum parameters ethylene oxide and 2-chloroethanol). The establishment of separate maximum levels for ethylene oxide and 2-chloro-ethanol in USA and Canada, and the also widely differing values for the active substance and its degradation product, indicate on the one hand that "ethylene oxide" is predominantly present in the products in the form of its degradation product 2-chloroethanol, and on the other hand that the toxicity of 2-chloroethanol is clearly different from that of ethylene oxide.

6. Possible entry paths / Contamination sources

Basically, a distinction must be made between deliberate sterilisation (e.g., to meet the requirements for export to certain countries) and contamination with ethylene oxide.
Deliberate disinfection with ethylene oxide generally leads to levels in spices greater than 1 mg/kg (according to the current residue definition: ethylene oxide = sum of ethylene oxide and 2-chloroethanol, expressed as ethylene oxide), while levels in the range between 0.01 mg/kg and 0.1 mg/kg are very likely to be caused by contaminations. Levels between 0.1 mg/kg and 1 mg/kg often cannot be clearly assigned. The levels discussed here apply only to single ingredient food, not to compound and/or processed foods.

A particular risk exists when companies process, store, or transport goods for export to a country for which sterilization is mandatory (see next section).

Avoidance of contamination of products by ethylene oxide (and subsequently with 2-chloroethanol) can only be successful through absolute physical separation. This separation relates in particular to storage and processing. In buildings where disinfection (fumigation) with ethylene oxide is carried out and/or where goods freshly disinfected with ethylene oxide are stored, cross-contamination can hardly be prevented, as ethylene oxide is extremely volatile and highly reactive.

It is imperative that organic products shall physically be separated from commodities destined for export to countries that specifically require sterilization (fumigation) with ethylene oxide. The organic foods should not be processed or stored in the same building.
No containers or other receptacles should be used to store or transport organic products that have been fumigated with ethylene oxide or in which goods fumigated s a preload have been stored or transported.

6. Conclusion

Detection of ethylene oxide (according to the residue definition as the sum of ethylene oxide and 2 -chloroethanol, expressed as ethylene oxide) in sesame seeds or other food products such as spices is not a specific issue regarding organically produced goods. The sterilization of foods with ethylene oxide is applied in countries where it is approved, for reasons of precautionary consumer protection. Nevertheless, it should be noted that goods are not marketable in the EU if they contain levels of ethylene oxide (according to the residue definition) above the respective maximum residue levels according to Regulation (EC) 396/2005 (as amended).

Should goods with such levels nevertheless have been placed on the market, it is necessary to assess a possible risk for the consumer through a risk assessment. In contrast to the assessment of compliance with maximum levels in accordance with a residue definition specified for this purpose, a toxicological assessment must always relate to the individual substances in question.

If the levels found in the samples tested are caused exclusively by 2-chloroethanol, the toxicological parameters relevant to 2-chloroethanol must be used for a toxicological evaluation. These differ substantially from those for ethylene oxide, which is classified as "probably carcinogenic to humans".

References

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