[*Association of Organic Food Processors*]

AöL Member Information

Version: 1st version of 23/11/2020

Ethylene oxide and 2-chloroethanol residues

AöL information on ethylene oxide and 2-chloroethanol residues in sesame seeds

1. Problem/Initial situation

Since 22/10/2020, alert messages on findings of ethylene oxide in sesame seeds from India have accumulated in the European Rapid Alert System for Food and Feed (RASFF). According to that, goods assuredly exceeding the maximum residue level of 0.05 mg/kg for the sum of ethylene oxide and the conversion product 2-chloroethanol, referred to as ethylene oxide, is no longer saleable. Most likely, the biocide ethylene oxide (legally classified as an active agent of plant protection products) was used for the sesame seeds as a microbiologically sensitive product, in order to exclude Salmonella findings. The use of ethylene oxide has been prohibited in the EU since 1979. Special analytics is required, which is not included in the general scope of the multi-methods. The laboratory capacities are low. So far, the Netherlands and Belgium have been primarily affected by the recalls stated. The Netherlands and Greece are the biggest direct importers of sesame seeds from India into the EU. Conventional as well as organic goods are affected. There are batches exceeding the maximum level just as uncontaminated batches. There are notifications from the Organic Farming Information System (OFIS), that ethylene oxide has not only been used for organic sesame from India, but also for cumin and thyme from Turkey, as well as black pepper from Tanzania. Processed sesame products (e.g., tahini) are affected, too. Since 26 October 2020, according to the Implementing Regulation (EU) 1540/2020 [1], at least 50 % of the sesame batches from India must be checked for ethylene oxide and 20 % for Salmonellae at the borders to the EU. In all probability, sesame batches from the new harvest have been imported into the EU at a much earlier date already, just like other microbiologically sensitive dry products.

2. Toxicology

According to the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA), the two substances have a different toxicological potential. Ethylene oxide (EO) is a volatile colourless gas and a highly reactive molecule. It is used for disinfection of medical equipment. EO has been prohibited as an active agent of plant protection products in the EU since 1979. It is flammable, is classified as toxic to humans, mutagenic and cancerogenic, and is considered as hazardous to water. Therefore, food with residues of ethylene oxide has to be classified as unsafe in terms of health.

The conversion product 2-chloroethanol, on the other hand, is "only" considered toxic. The lethal dose LD_{50} (rat, oral) is 71 mg/kg of body weight. It can be absorbed via the skin, is irritant to eyes and respiratory tract, acts on the central nervous system, and can result in liver and kidney damage [2, 3].

The maximum residue level (MRL) according to Regulation (EC) No. 396/2005 for "Ethylene oxide (sum of ethylene oxide and 2-chloroethanol, referred to as ethylene oxide)" is 0.05 mg/kg.

By contrast, in the USA and Canada, the two substances are assessed as follows: the admissible maximum residue level for ethylene oxide in the USA and in Canada for food is 7 mg/kg each [4, 5].

For the conversion product 2-chloroethanol ("ethylene chlorohydrin"), there is a separate MRL of 940 mg/kg in both countries [4, 5]. In the risk assessment document of the United States Environmental Protection Agency (EPA), an acute reference dose (ARfD) of 0.1 mg/day is derived for this substance [6].

3. Entry pathways

It is suspected that sesame seeds from India are more frequently treated with the gas ethylene oxide due to an increased risk of Salmonellae. It cannot be excluded that further products, e.g., dry products or spices, are also treated with ethylene oxide in other third countries, too, in order to exclude microbiological risks.

4. Analytical aspects

So far, ethylene oxide has not been included in routine testing. For the determination of ethylene oxide according to the specifications of the Regulation (EC) No. 396/2005, an individual method is required. In the official collection of analysis methods according to § 64 LFGB (*German Food and Feed Code*), the analysis method L 53.00-1 - 1999-11 is listed as "Gas chromatographic determination of ethylene oxide and 2-chloroethanol in spices", e.g., using GC-MS. The analysis capacities are currently scarce, in particular at official, but also private laboratories. Accordingly, longer waiting periods must be reckoned with. Not all laboratories can provide these analyses.

A selection of the following private laboratories can provide the analyses stated above and can inform you about results on findings within 2 and 10 days (please inquire in advance):

- Eurofins Dr. Specht Laboratorien GmbH, Hamburg, www.eurofins.de/lebensmittel/labore/eurofins-dr-specht-laboratorien/
- GBA Group Hamburg, www.gba-group.com
- Kwalis Qualitätsforschung Fulda GmbH, www.kwalis.de
- Labor Bilacon, Berlin, www.bilacon.de
- Labor Friedle GmbH Tegernheim, www.labor-friedle.de

Due to the scarce analysis capacities, first and foremost import companies for sesame seeds should have batches checked and then inform the subsequent chain about the results.

5. Legal aspects

Maximum residue levels of plant protection product residues in food and feed are regulated in the Regulation (EC) No. 396/2005. Ethylene oxide has been prohibited as an active agent of plant protection products in the EU since 1979. In the Regulation (EU) No. 2015/868, the maximum residue level for the sum (of ethylene oxide and the conversion product 2-chloroethanol), referred to as ethylene oxide, has been specified as 0.05 mg/kg. If this value is exceeded, the food is no longer marketable. According to the Implementing Regulation (EU) 2020/1540 of 22 October 2020 [1] with regard to sesame seeds originating from India, physical checks for pesticide residues and identity checks on 50 % with the multi-residue methods GC-MS and LC-MS and for ethylene oxide (sum of ethylene oxide and 2-chloroethanol) must now be performed at the EU borders. If the maximum level of 0.05 mg/kg for sesame seeds is exceeded, then, according to Para. 19 Regulation (EC) No. 396/2005, these must not be mixed or processed.

Furthermore, according to a notification of the Federal Ministry of Food and Agriculture (BMEL) of 13/10/2020: "[...] in case of this maximum level (note: 0.05 mg/kg) being exceeded, sesame seeds and goods produced therewith must be taken off the market or recalled, resp. ..." [7]

<u>Legal aspects on organic sesame seeds or products produced therefrom:</u>
If, according to the general food law, the maximum level of ethylene oxide or 2-chloroethanol, resp., of 0.05 mg/kg is assuredly exceeded in organic sesame seeds or products manufactured therefrom, then this food is no longer marketable.

In case of findings below the limit value (<0.05 mg/kg), a withdrawal of the organic product status will be undertaken, if the investigation of causes arrives at the conclusion, that the substance inadmissible for organic products was actively used or insufficient precautions against its spread were taken. According to information we received, the EU states handle findings in organic sesame products differently. Thus, the organic status of the goods is withdrawn from findings of 0.01 mg/kg on or from 0.02 mg/kg on in individual countries.

6. Recommendations/Conclusion

It cannot be excluded that, besides sesame from India, in particular dry products and spices from other third countries, too, were likewise inadmissibly treated with ethylene oxide. Here, increased care must be taken. Please check, whether you as a processing company must analyse products in any case. It is more reasonable, if the importers perform these analyses and then, if applicable, inform the delivery chain in case of positive findings.

In case of further processed products with a small portion of sesame, a recall may be waived. Here, a case-by-case assessment must be undertaken, since this, on the one hand, depends on the measured content of ethylene oxide in the seeds, as well as on the further processing, e.g., the portion of sesame in the product. This end product may then possibly still be assessed as a safe food. This should be coordinated with the competent food authorities. Regarding observation of the organic status of the product, please contact the competent organic control authority. If applicable, consult a specialist lawyer.

7. Literature references

[1] Implementing Regulation (EU) 2020/1540 of the European Commission of 22 October 2020

[2] European Food Safety Authority (EFSA) Conclusion on the peer review of active substance ethylene 2012 (ethylene oxide as a metabolite of ethylene) p. 7 and 9 cont.

[3] European Chemicals Agency (ECHA) Ethylene oxide, Substance description, 2-chloroethanol, Substance description

[4] USA, Electronic Code of Federal Regulations: Ethylene oxide: tolerances for residues

[5] Canada: https://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php

[6] United States Environmental Protection Agency (EPA) Archive EPA, "Toxicological information" for 2-Chloroethanol (Ethylene Chlorohydrin) pages 19/20

[7] Notification of the BMEL of 13/10/2020: Ethylene oxide in sesame seeds from India

AöL information

The Association of Organic Food Processors is an alliance of more than 120 companies of the food industry. Its European members generate an organic turnover of more than 4 billion Euros. Its work is focusing on the political representation of interests as well as promoting exchange and cooperation of the members among one another.

This information was compiled with the participation of the Scientific Committee of AöL.

Contact:

Brunhard Kehl
Assoziation ökologischer Lebensmittelhersteller e.V.
Untere Badersgasse 8 | 97769 Bad Brückenau / Germany | Tel: +49 9741 - 938 733 - 0
brunhard.kehl@aoel.org | www.aoel.org