ESA FACTSHEET

on ETO/ ECH RESIDUES IN CULINARY HERBS AND SPICES

Technical Annex – Potential ETO/ECH sources

(September 2021)

Background

In November 2020, the European Spice Association (ESA) asked all member companies to share data on ETO in herbs and spices with the Secretariat to get an overview of possible exceedances. The data collection has been continuously updated and evaluated; it shows that only about 7% of all analyses revealed an exceedance of the Maximum Residue Level (MRL) for ethylene oxide (ETO).

These analyses include all the data collected by companies, including pre-shipment test samples and analyses of rejected goods, and therefore do not reflect the situation at retail level.

In January 2021, all ESA member companies and associations were reminded about the EU legal requirements regarding residues of ETO in herbs and spices.

ESA members are committed to ensuring due diligence in all matters related to their business and to ensure compliance with all relevant EU and national legislation.[a] As part of their due diligence program, Members of ESA regularly undertake testing for ethylene oxide (ETO) and 2-chloroethanol (ECH) residues in herbs and spices.

The current EU legislation regulating residues of ethylene oxide (sum of ethylene oxide and 2-chloroethanol expressed as ethylene oxide) is Reg. (EU) 2015/868, which sets the "permitted" level (Maximum Residue Level MRL) for the sum of ETO and ECH in herbs and spices. The following MRLs apply to the products of the spice industry:

Commodity	EU Maximum residue level
spices	0.10 ppm
herbs	0.05 ppm
dehydrated vegetables (garlic, ginger, onions, paprika, tomatoes)	0.02 ppm

The use of ETO for the sterilisation of foodstuffs within the EU as well as the import of foodstuffs containing residues of ETO and ECH above the MRLs into the EU is illegal.

Applications of biocidal products containing ethylene oxide are allowed for disinfection in the EU, but without food contact.

Possible contamination sources

Ethylene Oxide (ETO) treatment

In comparison, the treatment of herbs and spices with ETO is still permitted in many producing countries outside the EU, including in the United States of America, where toxicological experts allow up to 940 mg/kg ECH residues and 7 mg/kg residues of ETO.

This data showed the typical ECH residues present in spices when the multiple washing ETO system was used. In this treatment the product is exposed to a 20% ETO and 80% CO_2 mixture for 6 hours at a temperature of 52 – 62 ^{o}C and this equates to an ETO concentration of around 300 mg/l.

Following treatment 21 low vacuum cycles are conducted to remove the ETO residue and this is followed by 4 fresh air washes. At the end of the process ETO levels seem to be in the range of zero to 25 mg/kg, then when retested after 72 hours of storage the ETO residue levels are around 1 mg/kg. The majority of results for ECH residue levels, in a product after ETO treatment, were between 25 and 335 mg/kg. Interestingly, several samples (organic material), which had not been treated revealed positive control. It is useful to mention that some organic spices are treated with ETO.

While the above-mentioned treatment applies to the USA, there is no international process standard for ETO treatment.

Cross contamination

The EU Reference Laboratories for Residues on Pesticides (EURLs) states in its report from December 2020, that findings of E'TO/ECH in lower range (<0.1 ppm) are not likely to be a result of proper fumigation. They conclude that further investigations are required to study the origins of background levels including mixing of lots, cross-contaminations during processing, transport or storage as well as the possibility that low levels end up in plants or food products through alternative pathways that go beyond fumigation.[b]

ESA members have evaluated the risk of ECH residues due to cross contamination within a manufacturing or storage environment.

The outcomes of internal risk assessments show that–there is a recognised risk of cross contamination from ethylene oxide, if non-treated material is stored or shipped together with ETO treated material. For example, if shipping containers or wooden pallets are used, which were previously exposed to Ethylene Oxide.

Within the EU, Ethylene Oxide is still permitted for the sterilisation of medical devices; this fact, as well as the frequent use of ETO-Sterilisation for other international markets like the USA or Canada, potentially add a risk factor within the supply chain.

Other sources of possible contamination

Ethylene

Large quantities of ethylene are industrially produced globally every year, 141 million tonnes in 2011, mainly used for detergent, thickener, solvent, plastic, antifreeze production.

Ethylene is a hormone and is produced by plants as part of the natural ripening process and extra ethylene is produced if the plant becomes damaged as this helps the healing process.

Ethylene is considered as a Pesticide and is listed in Annex IV of Reg. (EC) No 396/2005, for which no maximum residue levels are required. It is used on a commercial basis to induce the ripening of fruit that have been shipped from origin unripe. In this type of operation ethylene is produced from ethanol. Research indicates that burning ethanol in vehicle engines generate ethylene gas. (13.5 metric tonnes in USA in 2014).

Ethylene is produced naturally in the sea from photochemical reactions of dissolved organic carbon, it is also produced from fires and when volcanoes erupt. In fact, as humans we emit ethylene from our skin and as we breathe out.[c]

In a peer review, published on 11. January 2012, EFSA refers to ETO formation from Ethylene, mentioning a study that estimated the atmospheric half-life in air of ethylene oxide is approximately 38 days.

Ethylene Oxide production

A study from the USA, as far back as 1982, has shown that vegetables such as peas convert ethylene to ethylene oxide. The report goes on to say that over a dozen plants have been shown to have the same effect.[d]

A World Health Organisation study in 1995 reported that in addition to plants converting Ethylene to Ethylene Oxide, ETO is also generated in water logged soil, manure and sewage.[e]

This suggests that ethylene oxide could be produced naturally in the growing environment. A Spanish study published in 1999 by Félix Romojara Almela et al. of the Consejo Superior de Investigationes Cientificas, a Spanish government institution, shows that ECH can also be produced "naturally" at temperatures of 20 - 45° C, during the ripening of a plant.[f]

Approved plant protection products such as ethephon are another possible source of ethylene, which can be subsequently further converted to ETO/ECH.

Ethephon is a plant growth regulator which is used with foliar sprays to regulate growth. By Regulation (EU) No 2017/1777 of 20 October 2017, the authorised maximum residue levels were set at 0.05 mg/kg for herbs and 0.1 mg/kg for spices.

In its peer review of 7 June 2006, EFSA described that the degradation products of ethephon are ethylene gas and the non-volatile 2-hydroxyethylphosphonic acid. The major routes of dissipation appear to be chemical hydrolysis and microbial degradation. A 2005 study cited by EFSA shows that ethylene is the main degradation product of ethephon under aerobic conditions.

References

[a] ESA Self-regulating mechanism, adopted in December 2011.

[b] EURL-SRM – Analytical Observations Report concerning the compounds ethylene oxide (ETO) and 2-chloroethanol (ECH) in sesame seeds, Version 1.1, December 2020.

[c] http://www.drjoonyun.com/uncategorized/ethylene-important-molecule-youve-never-heard/

[d] Ethylene and Plant Protection by J. A. Roberts and G. A. Tucker, University of Nottingham, published by Butterworths.

[e] WHO document – Concise International Chemical Assessment Document 54.

[f] Study of the Formation of Chlorohydrins, Félix Romojaro Almela, Consejo Superior de Investigationes Cientificas, Murcia, 20.7.1999.