



Ethylene Oxide (EtO) on food products: Outcome of the meeting with Experts on technical aspects of 4 October 2021

Advisory Group

Brussels, 26/11/2021 (Webex)

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- Purpose of the meeting of 04 Oct 2021
- EtO MLs on Additives (including gums)
- EtO MRLs on Feed
- EtO MRLs for Composite products and Food supplements
- EtO MRLs for Foods for Infants and Young Children
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Purpose of the meeting of 04 Oct 2021

- Not to discuss the Conclusion of the Crisis Coordinators (CC) meeting of 13 July 2021, but to
- provide clarifications on the regulatory and technical aspects in support of the enforcement action taken by Member States.

Documents sent by stakeholders and Member States in preparation of the meeting were distributed to the participants in advance.

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EtO MLs on Additives (including gums)

- ML for additives (including gums) : 0.1*mg/kg
- Inspired by the MRL of ETO on carob beans (raw material for the production of locust bean gum) set at 0.1*mg/kg.
- Confirmed by EURL SRM to be achievable for additives.
- Current specifications for additives are limited and refer to ETO only, not 2CE → recourse to the MRL was necessary to ensure consistency.

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EtO MLs on Additives (including gums)

- Update of Regulation (EC) 231/2012 on the specifications for additives is on-going.
- Where the 0.1*mg/kg level conflicts with existing specification for additives where ETO is a purity criterion (<0.2mg/kg) the latter ML prevails.
- For additives the level of 0.1 mg/kg prevails regardless of the level established by Regulation (EC) No 396/2005.

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EtO MRLs on Feed

- The use of locust bean gum (E410) or of any other additive contaminated with ETO above the LOQ of 0.1*mg/kg for feed is prohibited. The use of a non-compliant feed material is also prohibited.
- Compound feed for which there is evidence that it was produced with a contaminated (ETO above LOQ) additive or feed material, has to be withdrawn from the market if ETO is found above 0.02*mg/kg.
- Feed for animals kept as pets with ETO levels exceeding 0.02*mg/kg shall be recalled. Feed for food-producing animals has not to be recalled.
- A specific footnote for choline chloride is foreseen.

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EtO MRLs on Feed

- The residue definition for ETO as expressed in the MRL Regulation (Sum of ethylene oxide and 2-chloro-ethanol expressed as ethylene oxide).
- When there is no evidence of the use of a non-compliant additive and/or feed material, the competent authority should calculate the composite LOQ based on the ingredients' list to verify the compliance of a compound feed.
- the processing factor to be applied is 1 (unless the feed business operator can provide robust and for the competent authority satisfactory evidence that another processing factor should be applied).

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EtO MRLs on Composite products

- In case of information on the use of a non-compliant ingredient, the conclusions as agreed at the (CC) meeting on 13 July apply (withdrawal/recall of the product from the market, or in case of imports rejection at border).

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EtO MRLs on Composite products

- Without information on the use of a non-compliant ingredient, the default MRL at the LOQ of 0.02* mg/kg should apply (considering the two components of the residue definition for ETO).
- In case there is detailed information on the composition and/or processing factors (PF), then Article 20 of the MRL Regulation is applicable to calculate the composite LOQ to assess compliance.
- In the absence of any information on PF for either ETO or 2CE, the default PF is 1.

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EtO MRLs on Food supplements

- For harmonisation and consistency purposes, the LOQ applicable is 0.1* mg/kg, including for the capsules used for production of food supplements.

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EtO MRLs on Foods for Infants and Young Children

- Recital 12 of Directive 2006/125/EC , on the careful selection of raw materials to ensure compliance of the final product with the level of 0.01* mg/kg.
- Established on the basis of the precautionary principle to protect this vulnerable consumer group.

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EtO MRLs on Foods for Infants and Young Children

- Where an additive used for the production of a food for IYC is contaminated with ETO at a level above 0.1* mg/kg, the final product should be withdrawn from the market and recalled from the consumers, regardless of the ETO level in the final product.
- If ETO was used in an additive but in compliance with the limit (< 0.1* mg/kg) but leaves measurable residues in the final product (>0.01 mg/kg) then it should be withdrawn from the market/recalled from consumers.

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Next Steps

- ✓ Request EFSA to assess BfR's assessment in the form of a statement as an urgent priority.
- ✓ Taking account of the experience gained, assess whether there is need for a refined approach to risk management in the future.
- ✓ Update the document on feed according to the discussion held in this meeting.

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Next Steps

- ✓ Include ETO controls for both food and feed at imports. Controls will be related to ETO (as sum of ETO and 2CE expressed as ETO) only and will not include analyses for other pesticides amenable to multi-residue methods.
- ✓ For foods for infants and young children, to work on the ETO analytical challenges to achieve the legal requirements.

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Thank you

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