Summary of the Technical Meeting on Ethylene Oxide (ETO)

Webex, Thursday 20.01.2022

Participants:

Representatives from EU Member States, Norway, Switzerland, the European Food Safety Authority (EFSA), the European Commission (DG Health and Food Safety) and the EU Reference Laboratories (EURLs)

The objective of the meeting was to obtain clear insight into the actual implementation by the Competent Authorities of the EU Member States of the EU harmonised approach for the management of the incident of ETO findings as agreed during the Crisis Coordinators' meeting of 13 July 2021[1].

A.01 Exchange of experiences with the implementation of the EU approach

The EU Member States and Norway presented an overview of their experience in applying the EU approach for the incident of ethylene oxide findings on locust bean gum as agreed on 13 July 2021 and as further detailed for other gums, composite products, supplements, baby foods and feed during the technical meeting of the 4th of October 2021[2]. The EU Member States and Norway provided details on official controls and self controls from Food Business Operators (FBOs) and on further enforcement actions regarding ingredients, composite/processed food products, ready-to-eat (RTE) meals and feed both domestically (EU) manufactured and imported from Third Countries.

Overall, according to the EU Member States and Norway, the EU harmonised approach, while supported and followed by the majority of the reporting countries, is not fully applied in practice by some.

For ingredients[3] with residues of ETO above the Maximum Residue Levels (MRLs), applicable for the management of this incident, all EU Member States clarified that Competent Authorities withdraw them from the market/recall them from consumers. Incidents notified in the Rapid Alert System for Food and Feed (RASFF) are followed up in the same manner by all EU Member States.

For composite/processed food products, many of the reporting countries confirmed applying the EU approach, thus withdrawing from the market/recalling from consumers such products in case they contain a contaminated ingredient, regardless of their ETO content. Other countries reported using a risk assessment approach based on the opinion of the German Federal Institute for Risk Assessment (BfR)[4] and/or using a calculated/composite ETO MRL based on the proportion of the ingredients in the composite product and comparing it with the ETO residue in it to assess compliance.

Several EU Member States highlighted the high burden of the agreed management approach as more and more products are found contaminated from different origins to the extent that it is no longer manageable and undermines the efficiency of the RASFF system. For that reason some Member States have taken a more proportionate approach as regards compound foods that underwent several processing steps.

[1] https://ec.europa.eu/food/system/files/2021-07/rasff_ethylene-oxide-incident_e410_crisis-coord_sum.pdf

[2] https://ec.europa.eu/food/system/files/2021-12/rasff_ethylene-oxide-incident_e410_crisis-coord_20211004_sum.pdf

[3] This includes fod additives.

[4] https://www.bfr.bund.de/cm/349/health-risk-assessment-of-ethylene-oxide-residues-in-sesame-seeds.pdf

Some Member States pointed out the lack of a level playing field in the EU market for domestically (EU) manufactured products and for imported products, whereas, for domestic products, non compliant ingredients can be traced back, while this is not possible for imported products. An EU Member State expressed concerns over the specific requirements communicated to Third Countries with respect to the explicit need for compliance with ETO MRLs.

Several Member States highlighted the difficulties resulting from different approaches in Member States. Information was provided on a RASFF-notified product that was recalled from consumers in one EU Member State but not in another and reported excessive pressure from FBOs and media. Another EU Member State shared a similar experience for a RTE meal.

In this sense, some EU Member States voiced concerns on whether, in practice, there is a really EU harmonised approach applied by all, and called for a new Crisis Coordinators'(CC) Meeting.

The Commission clarified that a harmonised EU approach had been agreed at the CC meeting of 13 July 2021. Furthermore, CC meetings are convened whenever an incident arises and this has already been done twice, i.e. to deal with the findings of ETO on sesame seeds in October 2020[5] and the findings of ETO in locust bean gum (E410) in July 2021. Those meetings were followed up by technical meetings further detailing the technical aspects of applying the agreed approach on how to manage each incident. Therefore, the Commission clarified that another CC meeting could be organised, but not to review the management of those incidents, rather to build on the experience gained and to draw lessons learnt notably on the adherence to the harmonised management approaches once agreed.

For feed, only few Member States were able to provide feedback and the experience was reportedly limited to only a few voluntary recalls initiated by FBOs. Some Member States reported no ETO findings on feed, while all others reported findings in ingredients, but not in the final composite feed, thus not requiring further enforcement action, in compliance with the EU agreed approach.

A.02 Feedback on 2-chloro-ethanol from EFSA

The Commission reminded that at the meeting of 4 October 2021, it was decided to request EFSA's view on the BfR opinion, taking into account the studies assessed in the frame of this opinion and any other relevant available studies on the toxicity of 2-chloro-ethanol (2CE), not assessed by the BfR.

EFSA presented preliminary findings as follows: EFSA performed an assessment of existing *in vitro* and *in vivo* genotoxicity data and newly available *in vitro* data and its provisional conclusion, pending their formal reply to the Commission's mandate, is that genotoxicity and carcinogenicity of 2CE cannot be excluded and that, therefore, no safe level can be derived. Additionally, EFSA agrees with the BfR assumption that the genotoxic and carcinogenic potency of 2CE as a metabolite of ETO is unlikely to exceed that of ETO after oral intake. EFSA further recommends that a battery of new *in vitro* genotoxicity tests for 2CE would be conducted using standard methods. The EFSA statement is expected to be published in February 2022 .

EFSA furthermore emphasized that the Margin of Exposure (MOE) approach is a tool for risk managers to prioritise risks in their decision making process and should not be used to assess the safety of non-threshold genotoxic carcinogen substances deliberately added in the food chain, as it does not provide for

[5] https://ec.europa.eu/food/system/files/2021-01/rasff_ethylene-oxide-incident_crisis-coord_sum.pdf

a safety level. The MOE approach is applicable for substances whose presence in the food chain cannot be avoided, which is not the case for intentional uses and cross-contaminations as is the present case of ETO.

The Commission noted that the above EFSA assessment confirms the discussion held at the meeting of 4 October 2021 on the approach to be followed in view of the uncertainties regarding the toxicological properties of 2CE.

A.03 Other technical aspects

Overview of RASFF notifications on ETO

The Commission provided an overview of the notifications relating to ETO received via RASFF in 2020 and 2021. In 2020, most notifications related to sesame seeds and sesame products, while in 2021, a greater variety of products was reported, including locust bean gum, food additives, food supplements and spices.

Feedback from the meeting of the working group on additives

The Commission provided an update on the status of updating Regulation (EC) 231/2012[6] on specifications for food additives with regards to clarifying the purity criteria. The approach would be to specify clearly the Limit of Quantification (LOQ) applicable to all additives. The raw materials used for the production of food additives have to comply with the MRL set by Regulation (EC) 396/2005 (when an MRL has been set for the raw material). The EURLs have been consulted and confirmed the feasibility of the proposed LOQ of 0.1 mg/kg (sum of ETO and 2CE expressed as ETO) applicable to all additives.

At its meeting on 13 December 2021, the working group on additives provided a positive feedback on the first draft of the amendment. The proposal will now proceed in line with the Commission procedures, with a view to submit a draft to the Standing Committee on Plants, Animals, Food and Feed – Section Novel Food and Toxicological Safety(SC PAFF) in February 2022.

Further to a question raised by a Member State, the Commission indicated that it intends to make a clarification in the next revision of Regulation (EC) 1793/2019 on the temporary increase of official controls for food of non-animal origin by adding a reference to Regulation (EC) 231/2012 and confirming that a LOQ of 0.1 mg/kg for ETO (sum of ETO and 2CE expressed as ETO) is applicable for the entries related to food additives.

Feedback from the meeting of the working group on import controls

Further to the update provided at the meeting of 4 October 2021, the Commission reported that the 5th revision[7] of Regulation (EU) 1793/2019[8] includes in its Annex II newly listed crop/countries combinations due to the risk of ETO contamination and that it was adopted on 15 December 2021, published on 17 December 2021, and entered in force on 6 January 2022.

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[6] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council, OJ L 83, 22.3.2012, p. 1–295

[7] Commission Implementing Regulation (EU) 2021/2246 of 15 December 2021 amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council, OJ L 453, 17.12.2021, p. 5–34

[8] Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660, OJ L 277, 29.10.2019, p. 89–129

In view of possible issues of readiness and specifically for consignments already shipped before publication of the above revision (floating consignments), at a meeting with Member States held on 11 January 2022, a temporary arrangement was agreed with Member States to provide a transitional period until 17 February 2022 for exempting imported products newly listed in Annex II from the need for a health certificate on the condition of conducting 100% sampling and laboratory analysis at border control posts.

Regarding next steps, the working group is collecting results of the official controls conducted in the second semester of 2021 and collecting proposals from Member States for a 6th revision of the Regulation.

CN codes for certain entries related to food additives in Commission Implementing Regulation (EU) 2021/2246

The Commission informed that in Annex II to Regulation (EU) 2021/2246, entries have been added for mucilages and thickeners, whether or not modified, derived from locust beans or locust bean seeds (CN code 1302 32 10), for guar gum (CN code ex 1302 32 90), and for xanthan gum (CN code ex 3913 90 00). However, mixtures of additives are often traded and are exported to the EU under the CN codes 2106 9092 or CN 3824 9993.

While it had been agreed that for the management of the incident the LOQ of 0.1 mg/kg is applicable to all feed and food additives, including mixtures of additives, the availability of different CN codes may entail that the import of these mixtures are in fact not covered by the import control measures.

Member States are invited to share their comments in writing with the Commission in order to further discuss how to solve this issue.

Findings of ETO and choline chloride in feed

The Commission reported on the conclusion agreed at the SCoPAFF, section Animal Nutrition of 14 December 2021[9] as regards ETO and choline chloride. The presence of 2CE in choline chloride is not the consequence of an illegal use of ETO as disinfectant/biocide, but an unavoidable impurity of the production process following the use of ETO and hydrochloric acid as starting materials. The 2011 EFSA opinion[10] indicates that choline chloride (75 % purity) is ETO free and that 2CE can be present in levels from 10 to 55 mg/kg. Based on this, a maximum level of ETO (sum of ETO and 2CE expressed as ETO) in choline chloride of 40 mg/kg, relative to choline chloride with 99 % purity, is to be applied for enforcement in the frame of the management of this incident.

With regards to premixtures, which are primarily a mixture of feed addtives with a carrier, the applicable maximum level for ETO (sum of ETO and 2CE expressed as ETO) is:

- premixtures without choline chloride: 0.1 mg/kg
- premixtures with choline chloride: a premixture exceeding the level of 0.1 mg/kg does not have to be withdrawn from the market on the condition that the fraction of ETO above 0.1 mg/kg can be attributed to the presence in the premixture of choline chloride with a maximum level of 40 mg/kg (relative to choline chloride with 99 % purity)
- compound feed with premixture without choline chloride: 0.02 mg/kg

[9] Summary report will be published here: Animal Nutrition (europa.eu)

[10] https://www.efsa.europa.eu/en/efsajournal/pub/2353

- compound feed with premixture with choline chloride: a compound feed exceeding the level of 0.02 mg/kg does not have to be withdrawn from the market on the condition that the fraction of ETO above 0.02 mg/kg can be attributed to the use of choline chloride with a maximum level of 40 mg/kg (relative to choline chloride with 99 % purity)

Following questions received, it was clarified

- that the level of 0.1 mg/kg is applicable to premixtures for which there is no evidence available that a non-compliant ingredient in the premixture has been used. In case there is evidence that a non-compliant ingredient was used for the production of the premixture, then if the level of 0.02 mg/kg is exceeded, the premixture has to be withdrawn and cannot be used for the production compound feed.
- that in case the exact level of ETO in choline chloride used for the production of premixtures/compound feed is known, it is the measured level (insofar compliant with the maximum level of 40 mg/kg) that has to be used to determine the fraction of ETO above 0.1 mg/kg that can be attributed to choline chloride.
- that the maximum level of 0.02 mg/kg for compound feed is applicable in case there is evidence of use of a non-compliant ingredient. In case there is no such evidence then the composite LOQ is tobe applied to compound feed.

Measurement Uncertainty (MU)

Further to questions raised by some Member States, the Commission clarified that, as discussed during the meeting of 4 October 2021 and as discussed several times in the SC PAFF, most recently under the agenda item A.16.06 of the SC PAFF – Section Phytopharmaceuticals, Pesticide Residues of 14-15 June 2021[11], MU should always be taken into account for the purpose of official controls on food and feed. For self-controls performed by FBOs, the Commission recalled that in the absence of any EU legal basis as regards pesticide resdues, such policy for pesticide residues falls within the remit of the national authorities.

Analytical issues

Some Member States reported discrepancies in the analytical results for ETO from the various laboratories both in the EU and in Third Countries. The EURLs will further investigate the matter.

A.04 Conclusion

Several Member States shared their views on the implementation of the approach and the current situation. In concluding the meeting, the Commission thanked the EU Member States and Norway for their contributions and summarized the following points evoked during the meeting:

- ✓ The majority of Member States confirmed application of the harmonised risk management approach agreed at the CC meeting on 13 July 2021. They stressed the importance of implementing an EU wide approach in all EU Member States. Several of them expressed their strong disagreement with the non-uniform implementation by some Member States which leads to market distortions.

[11] Pt. A 16.06 sc_phyto_20210614_ppr_sum.pdf (europa.eu) (14/15 June 2021);
Pt. A 20.05 sc_phyto_20200928_ppr_sum.pdf (europa.eu) (28/29 Sep 2020)

- ✓ Several Member States highlighted the high burden of the agreed management approach as more and more products are found contaminated from different origins, which led to the approach not being followed for processed composite food. It was substituted by a risk-based approach and approaches based on detectability in the final product instead of ingredient traceability.
- ✓ Some Member States, while reporting full implementation of the agreed approach informed that they are mainly following up on RASFF notifications but that there is no or a limited amount of samples taken under their own monitoring programmes. Others reported little experience also due to the lack of laboratories and/or resources.
- ✓ In some Member States, the approach taken was adapted over time to take into account the evolution of the situation. Concerns raised on the current approach included:
    - Risk of disproportionality of the measures as the situation changed over time with more products concerned than in 2020 but also more dilution due to multiple processing steps;
    - Absence of a level playing field between domestic and imported products;
    - Need for more focus on imported products overall, and less sampling on the market;
    - Precedent setting for future similar situations/products.
- ✓ A number of Member States called for the organisation of another Crisis Coordinators meeting in view of the large amount of new products in which ETO is found, and with a view to learn lessons for the future.
- ✓ The EFSA preliminary conclusions confirmed the views expressed at the 4 October 2021 meeting, i.e., it cannot be excluded that 2CE is carcinogenic and genotoxic and, in view of these uncertainties, no safe level can be established. Additionally, the MOE approach should not be used for genotoxic carcinogens deliberately added to food and feed or present in food and feed due to avoidable cross contaminations, and should not be used to overrule legal requirements.

Following this meeting, the Commission will consider all the elements brought forward and consider them further in reflections about possible next steps, on which Member States will be kept informed.