

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Items 9 and 16

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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

16th Session

18-21 April 2023 (physical plenary meeting)

26 April 2023 (virtual report adoption)

Comments submitted by Indonesia

Agenda Item 9: Maximum Levels for Total Aflatoxins and Ochratoxin A in Nutmeg, Dried Chili and Paprika, Ginger, Pepper and Turmeric and Associated Sampling Plans (At Step 4)

Indonesia wishes to thank India for leading the discussion on maximum levels for total aflatoxins and ochratoxin A in nutmeg, dried chili and paprika, ginger, pepper and turmeric and associated sampling plans.

Accordingly, Indonesia would like to reiterate the previous comment on the 15th CCCF Meeting to support the proposed ML of 20 µg/kg for total aflatoxins in nutmeg.

Agenda Item 16: Priority list of contaminants for evaluation by JECFA

1. Indonesia has submitted comments through the Codex Online Commenting System (OCS) in response to CL 2022/84-CF (Request for comments on the Priority List of contaminants for evaluation or re-evaluation by JECFA) regarding the proposal for evaluation for Ethylene oxide (EtO) and 2-Chloroethanol (2-CE).
2. EtO and 2-CE have emerged as a global trade concern. Food recalls due to this substance began in various countries since 2020. As a consequence of this issue, stakeholders may suffer significant financial losses.
3. Due to the increasing issue of the EtO contamination in food products, Indonesia would like to propose these chemicals to be included in the priority list to be evaluated by JECFA.
4. Several trade problems related to EtO and its metabolites have been identified in instant noodle products, ice cream, sesame seeds and several food additives such as locust bean gum. As of the beginning of 2023, there have been 885 notification on EtO in various product from the European Union (27 January 2023).
5. The consumption data of instant noodle products, ice cream, sesame seeds and several food additives such as locust bean gum show that these commodities have been widely consumed globally.
6. There are countries which allow the use of EtO as fumigant, therefore it may be presents in food as contaminants.
7. There is no international standard available for EtO and 2-CE residues in food products, each country has its own policy in regard to this matter. Various countries regulate EtO and 2-CE within the scope of pesticide regulations. Some countries, on other hand, had established a uniform limit. The difference in regulations of each country could be a problem in international trade.
8. The regulation on the maximum level of the EtO in food is also varied among countries but as pesticides not as contaminant.

SAFETY ASPECT

9. EtO is mutagenic and carcinogenic. For EtO the BfR has calculated this "intake of low concern" to be as low as 0.037 micrograms per kilogram of body weight/day (µg/kg body weight/day). Currently there is not enough data as to exclude with sufficient certainty the possibility of 2-CE not having carcinogenic effects. However, there are no indications that the degradation product 2-CE might produce stronger mutagenic or carcinogenic effects than EtO. Further notice pending it is hence recommended to evaluate the genotoxicity and carcinogenicity of the metabolite 2-CE in line with that of EtO. (BfR, 2021)

10. In 2022, EFSA publish the statement on BfR opinion regarding the toxicity of 2-CE. Based on the information available to EFSA, EFSA considers the genotoxicity of 2-CE as inconclusive. EFSA therefore recommends performing new in vitro gene mutation and in vitro micronucleus tests with 2-CE following the recommendations of the most recent OECD technical guidelines to clarify its genotoxic potential.
11. From a study conducted by Allemang et al. (2022), it has been concluded that 2-CE is not a genotoxic carcinogen. The author suggested that 2-CE must be assessed relative to non-cancer endpoints and a health protective Reference Dose should be established on that basis.
12. In several cases, EtO may not be detected in food. Thus, 2-CE is used as a marking for the present of EtO. However, those compounds have different toxicity value. Therefore, they need to be evaluated independently.
13. Other than their function as pesticides, the contamination of these chemicals in food products may come from other sources, for instance EtO is found in food products due to the use of the food additive polyethylene glycol (PEG, INS 1521). The JECFA monograph states that the EtO in PEG should not exceed 0.02%. EtO residues have been detected in BTP mixture of stabilizers containing locus beans in Europe with a level of 0.4 - 1.1 mg/kg.
14. EtO may be from natural content. In the Risk Assessment of EtO document published by the National Institute of Food and Drug Safety Evaluation, MFDS Korea (2016), it is stated that EtO can be contained naturally because the ethylene content as the natural plant growth regulator. This compound can be decomposed into EtO in some plants. EtO can also be produced through ethylene catabolism in certain microorganisms. However, there is no research that quantifies the number of EtO from natural sources so that at this time it is estimated that the EtO residue can be ignored (negligible). This is in accordance with the study of Health Canada (2016) that the potential for ethylene exposure from consumption of fruits and vegetables is negligible.

CONCLUSION

15. EtO has caused a major trade problem in recent years. There were more than eight hundred cases of notification by EURASFF as per February 2023. It can be expected that the recalls will result in a huge cost for food companies.
16. However, these substances are not always associated with pesticide residues. It can also come from other sources such as food additives carryover, pollutants (from its use as sterilizer, smoke, etc. that pollutes the environment), or natural occurrence. All of these sources have a potential to contaminate food.
17. In conclusion, provision of EtO and 2-CE must be established because they have the potential to cause health and trade issues. Given that these substances can originate from other sources, we propose that JECFA could assess it as contaminants and could be further considered by CCCF to facilitate international trade in the future.
18. Due to the increasing issue of the EtO contamination in food products, Indonesia would like to propose these chemicals to be included in the priority list to be evaluated by JECFA.