CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 16

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

16th Session

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26 April 2023 (virtual report adoption)

PRIORITY LIST OF CONTAMINANTS FOR EVALUATION BY JECFA

Comments in reply to CL 2022/84-CF

submitted by
Canada, Indonesia, Kenya, Mexico, New Zealand and Peru

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2022/84-CF[1] issued in December 2022.

Explanatory notes on the Annex

2. The comments submitted through the OCS are hereby annexed and presented in tabulated format following the template for submission of contaminants for evaluation/re-evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

[1] http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/
https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCCF

Annex

COMMENT	MEMBER
Canada would like to indicate its agreement and support of the current list of contaminants and naturally occurring toxicants recommended for evaluation by JECFA. Canada does not nominate any additional substances to be considered for the JECFA priority list at this time.	**Canada**
1.1 Proposal for inclusion submitted by: Indonesia 1.2 Name of compound; chemical name(s): Ethylene Oxide (EtO) and 2-Chloroethanol (2-CE) 1.3 Identification of (additional) data (toxicology, metabolism, occurrence, food consumption) which could be provided to JECFA: Background Due to the increasing issue of the Ethylene Oxide (EtO) contamination in food products , Indonesia would like to propose these chemicals to be included in the priority list to be evaluated by JECFA. 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%. The general public can be exposed to ethylene oxide through industrial releases from manufacturing and sterilization facilities, smoking, and residual ethylene oxide left on consumer products that have not been properly decontaminated. Ethylene oxide is typically released into the atmosphere in industrial releases and can dissolve in rain and surface waters. Exposure to ethylene oxide typically occurs through inhalation or ingestion (inhaling contaminated air, eating contaminated food, smoking, etc.). Ethylene oxide has 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. EtO is a volatile compound that reacts quickly with chloride ions in the food matrix to form 2-CE. The presence of 2-CE in processed food is considered as a marker that the product is contaminated with EtO. In addition, EtO is used in the production of a number of food additives such as polysorbate and polyethylene glycol. As a result, the EtO content in processed food may be derived from the use of food additives in processed food. 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. For instance, U.S and Canada had set the MRLs of EtO and 2-CE with different maximum limits. Some countries, on other hand, had established a uniform limit. Even though various countries regulate EtO and 2-CE as pesticides, considering that the presence of EtO and 2-CE can also come from other sources (as medical device sterilizers and food additives), we propose that these two compounds can be studied by JECFA. EtO and 2-CE Toxicity The IARC (International Agency for Research on Cancer) classified EtO as a group 1 carcinogen (carcinogenic to humans) . In 2006, Joint FAO/WHO Expert Committee on Food Additives (JECFA) withdraw the specification monograph for EtO, in view of the fact that EtO has never been used as a food additive as such and the known hazards of ethylene oxide. Since EtO is classified as a genotoxic carcinogen, deriving a health-based reference value without risk is not possible as a threshold for the effect cannot be set. Any substance residues in food are therefore considered undesirable. According to German Federal Institute for Risk Assessment (BfR) , for EtO the level of low concern was determined at 0.037 µg/kg bw/day. In their assessment, BfR stated that there is not enough data as to exclude with sufficient certainty the possibility of 2-chorethanol not having carcinogenic effects. However, there are no indications that the degradation product 2-chloroethanol might produce stronger mutagenic or carcinogenic effects than ethylene oxide. Further notice pending it is hence recommended to evaluate the genotoxicity and carcinogenicity of the metabolite 2-chloroethanol in line with that of ethylene oxide.	**Indonesia**

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In 2022, EFSA publish the statement on BfR opinion regarding the toxicity of 2-chloroethanol. Based on the information available to EFSA, EFSA considers the genotoxicity of 2-chloroethanol as inconclusive. EFSA therefore recommends performing new in vitro gene mutation and in vitro micronucleus tests with 2-chloroethanol following the recommendations of the most recent OECD technical guidelines to clarify its genotoxic potential. From a study conducted by Allemang et al. (2022) , it has been concluded that 2-chloroethanol is not a genotoxic carcinogen. The author suggested that 2-chloroethanol must be assessed relative to non-cancer endpoints and a health protective Reference Dose should be established on that basis. Metabolism Ethylene Oxide (EtO) Ethylene oxide is readily taken up by the lungs and is absorbed relatively efficiently into the blood. A study of workers exposed to ethylene oxide revealed an alveolar retention of 75–80%, calculated from hourly measurements of ethylene oxide in ambient air, which ranged from 0.2 to 24.1 mg/m3 [0.11–13.2 ppm], and in alveolar air, which ranged from 0.05 to 6 mg/m3 [0.03–3.3 ppm] (Brugnone et al., 1985, 1986). At steady-state, therefore, 20–25% of inhaled ethylene oxide that reached the alveolar space was exhaled as the unchanged compound and 75–80% was taken up by the body and metabolized. Blood samples taken from workers at four hours after the work-shift gave venous blood/ alveolar air coefficients of 12–17 and venous blood/environmental air coefficients of 2.5–3.3. Ethylene oxide is converted (a) by enzymatic and non-enzymatic hydrolysis to ethylene glycol, which is partly excreted as such and partly metabolized further via glycolaldehyde, glycolic acid and glyoxalic acid to oxalic acid, formic acid and carbon dioxide; and (b) by conjugation with glutathione (GSH) followed by further metabolism to S-(2- hydroxyethyl)cysteine, S-(2-carboxymethyl) cysteine and N-acetylated derivatives (N-acetylS-(2-hydroxyethyl)cysteine (also known as S-(2- hydroxyethyl)mercapturic acid or HEMA) and N-acetyl-S-(2-carboxymethyl)cysteine) (Wolfs 388 Ethylene oxide et al., 1983; Popp et al., 1994), which are partly converted to thio-diacetic acid (Scheick et al., 1997).	

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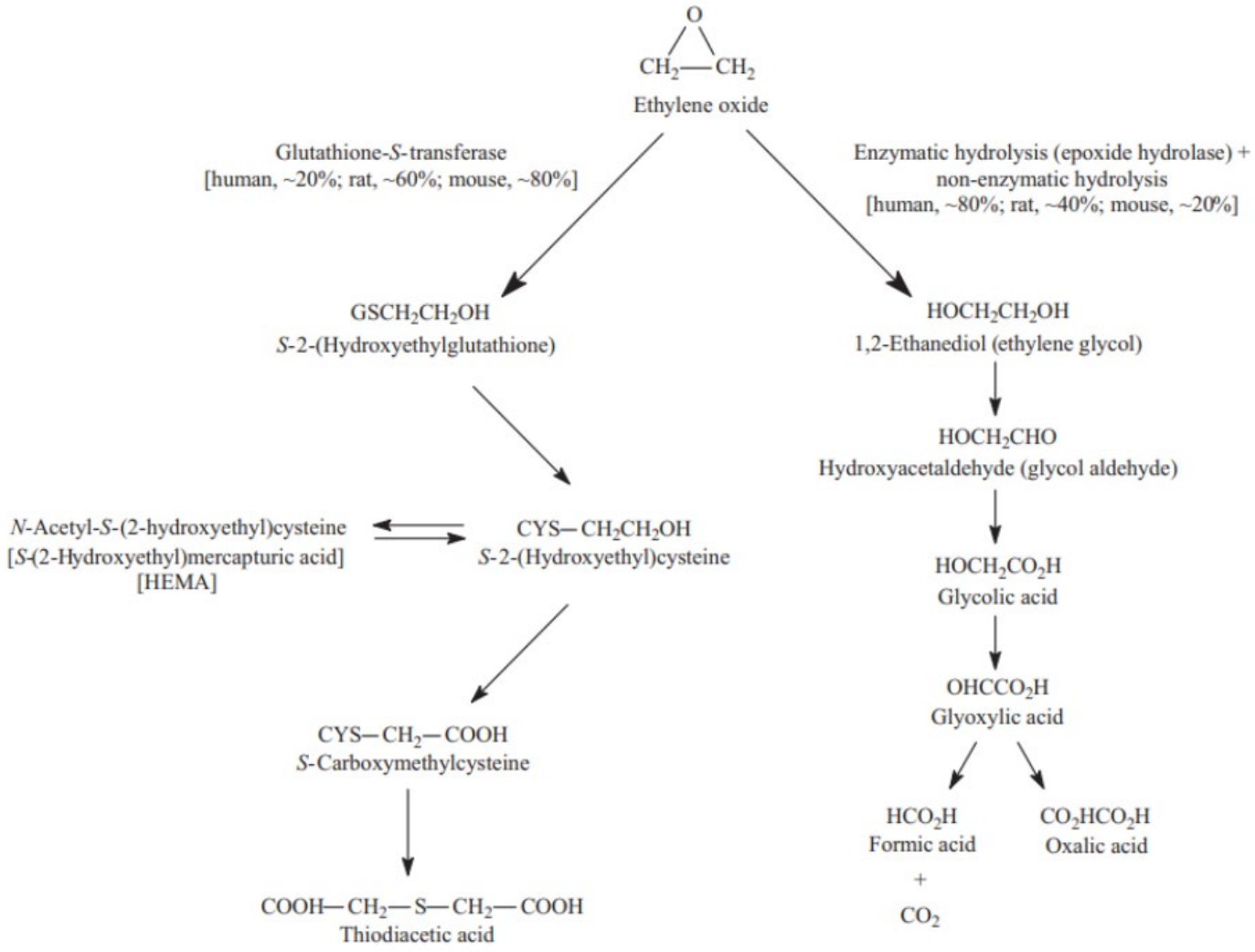
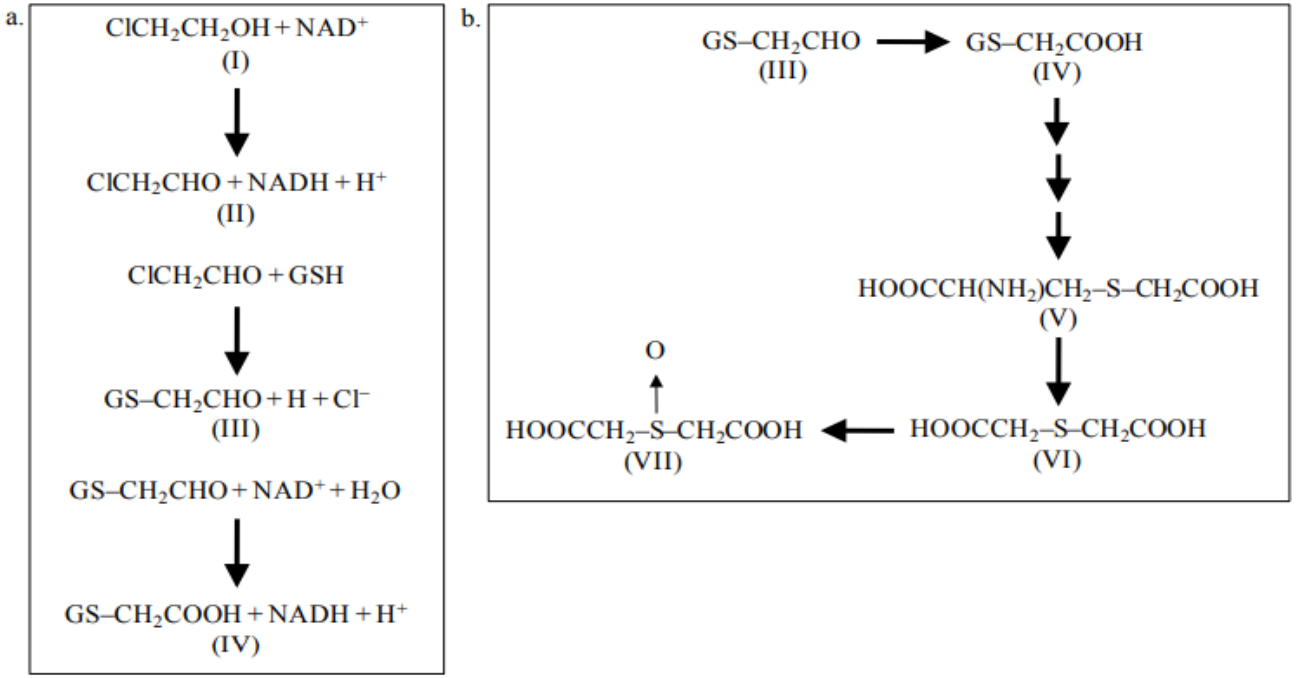


Metabolism of ethylene oxide to the GSH conjugate and ethylene glycol is generally considered to be the major pathway for the elimination of DNA-reactive ethylene oxide. However, strongly suggestive evidence in vitro was presented by Hengstler et al. (1994) that glycolaldehyde is formed by further metabolism of ethylene glycol and that this derivative leads to DNA–protein crosslinks and DNA strand-breaks (as measured with the alkaline elution assay) after in-vitro incubation with human mononuclear peripheral blood cells.

COMMENT	MEMBER
Ethylene oxide and its metabolites are rapidly excreted in urine. In a study of mice exposed to radiolabeled ethylene oxide for 60–75 minutes, an average of 78% of the absorbed radioactivity was eliminated in the urine within 48 hours (Ehrenberg et al. 1974). Filser and Bolt (1984) found that ethylene oxide administered in a closed-system inhalation chamber exhibited first-order elimination kinetics. Metabolites recovered in urine from rats exposed to airborne ethylene oxide include ethylene glycol, 2-hydroxyethylmercapturic acid, and thiodiacetic acid (Scheick et al. 1997). Metabolism of ethylene oxide (IARC, 2012) References: ATSDR. 2022. Toxicological Profile for Ethylene Oxide. p 83. Toxicological Profile for Ethylene Oxide 2-Chloroethanol (2-CE) NTP (1985) summarized the proposed metabolic pathway of 2-chloroethanol as follows:  **Figure 2a,b. Metabolic Pathway of 2-Chloroethanol** Source: NTP (1985a,b,c).	

COMMENT	MEMBER
Johnson (1967) suggested that the toxicity of 2-chloroethanol (I) was due to the formation of chloroacetaldehyde (II) by the test animal in amounts greater than could be detoxified by glutathione (GSH). Both ethanol and 2-chloroethanol are known to be substrates for the purified cytoplasmic alcohol dehydrogenase of human liver, rat liver, or yeast. Co-administration with ethanol reduces the toxicity of 2-chloroethethanol, presumably by competition for the alcohol dehydrogenase. Johnson (1967) demonstrated the in vivo and in vitro formation of S-carboxymethyl-GSH (IV) in livers of rats dosed with 2-chloroethanol; S-carboxymethyl-GSH (IV) is presumably formed from GSH and chloroacetaldehyde, the dehydrogenation product of 2-chloroethanol; S-formylmethyl-GSH is the presumed intermediate. Grunow and Altmann (1982) reported finding thiodiacetic acid (VI) and thionyldiacetic acid in the urine of rats given an oral dose of 2-chloroethanol; both these compounds are derivable from S-carboxymethylcysteine, the hydrolysis and deamination product of S-carboxymethyl-GSH. Thiodiacetic acid has been shown to be a metabolite of compounds that have the general property of being converted to chloroacetaldehyde (II); these compounds include vinyl chloride, 1,2-dichloroethanol, and vinylidene chloride. References: US EPA. 2012. Provisional Peer-Reviewed Toxicity Values for 2-Chloroethanol. Provisional Peer-Reviewed Toxicity Values for 2-Chloroethanol (CASRN 107-07-3) Food Consumption 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. Food recalls due to this substance began in various countries since 2020 (EURASFF). The following is consumption data for these products: 1. Instant Noodle Based on Word Instant Noodles Association, Instant noodles have become a global food that supports the diets of people around the world, with more than 100 billion servings consumed annually. The latest data on demand for instant noodles in each country and region could be accessed in this link: World Instant Noodles Association. 2. Ice Cream • The average American consumes approximately 23 pounds of ice cream and related frozen desserts per year. Ice Cream Sales & Trends – IDFA • New Zealand leads the world in ice cream consumption with a per capita consumption of 28.4 liters per year. Followed by US, 20.8 liters of ice cream per capita annually. Ice cream consumption in Australia stands at 18.0 liters per capita annually and in Finland is estimated at 14.2 liters per capita annually. Which Country Eats the Most Ice Cream? – WorldAtlas 3. Sesame oil The countries with the highest volumes of sesame oil consumption in 2017 were Tanzania (362K tonnes), Myanmar (333K tonnes), and China (249K tonnes), with a combined 58% share of global consumption. Mozambique, India, Sudan, Japan, South Korea, and Turkey lagged somewhat behind, together accounting for a further 25%. Global Sesame Oil Market - Key Findings And Insights | Food Dive. Considering these products are consumed a lot, thus if EtO contaminates food, it can affect food safety and health. 1.4 List of countries where surveillance data are likely to be available, and if possible, name of contact person who could provide such data, including quality assurance information on the data: 1. United States US EPA has conducted chronic dietary risk assessment was conducted for 2-CE using the Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEM-FCID, ver. 3.16). A dietary assessment was not conducted for EtO since sterilization studies show that no EtO residues will be present in spices at the time of consumption. (Ethylene Oxide (EtO). Draft Human Health and Ecological Risk Assessment in Support of Registration Review)	

COMMENT	MEMBER
2. EURASSF Database for ethylene oxide and 2-chloroethanol notification RASFF Window – Search 3. CVUA Stuttgart Analytical result for ethylene oxide and 2-chloroethanol of instant noodle products from various country Chemicals Rather than Bacteria? – Neither is Permitted in the EU 1.5 Timeline for data availability: - 2.1 Whether or not the occurrence of the compound in commodities will have potential to cause public health and/or trade problems Based on the data presented on point 1.3, there are differences in the toxicological effects of 2-CE and EtO. EtO is classified as a genotoxic carcinogen while 2-CE is considered less toxic. Ethylene oxide has caused a major trade problem in recent years. There were more than eight hundred cases of notification by EURASFF1 as per February 2023. It can be expected that the recalls will result in a huge cost for food companies. 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. In conclusion, EtO and 2-CE must be regulated 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 regulated by CCCF in the future. 2.2 Whether or not commodities containing the compound are in international trade and represent a significant portion of the diet Food recalls due to this substance began in various countries since 2020. Referring to EURASFF1, there are 885 notifications on ethylene oxide (February 2023). As a consequence of this issue, stakeholders may suffer significant financial losses. These recalls have been made for various food commodities such as spices, instant noodles or ice cream. Some of these commodities, i.e instant noodles, are widely consumed with high consumption. Furthermore, it has become a great concern because this food can also be consumed by children. 2.3 Commitment that a dossier (as complete as possible) will be available for evaluation by the JECFA. Indonesia wishes other member countries to support the dossier 2.4.1 Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade Referring to data of food safety and the quite a lot of consumption figures mentioned above, EtO and 2-CE have the potential to cause health and trade problems 2.4.2 The needs and concerns of developing countries This issue affects developing countries in terms of trade and health. EtO and 2-CE have become global trade issues due to a lack of international standards. High number of notifications and recalls have been issued for food products from developing countries. Furthermore, instant noodles are highly consumed.	

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2.4.3 The diversity of national legislations and any apparent impediments to international trade 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. **1. European Union (EU)** • Regulation (EC) 396/2005, Commission Regulation (EU) 2015/868, and Commission Regulation EU 2022/1396. • MRLs for ethylene oxide on food products are set at the Limit of Quantification (LOQ) of the analytical method used, depending on the matrix • Food additives: No residue above 0,1 mg/kg, irrespective of its origin, of ethylene oxide (sum of ethylene oxide and 2-chloro-ethanol expressed as ethylene oxide (ethylene oxide + 0,55* 2-chloroethanol)) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC Text with EEA relevance 32005R0396 - EN - EUR-Lex Commission Regulation (EU) 2015/868 of 26 May 2015 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2,4,5-T, barban, binapacryl, bromophos-ethyl, camphechlor (toxaphene), chlorbufam, chloroxuron, chlozolinate, DNOC, di-allate, dinoseb, dinoterb, dioxathion, ethylene oxide, fentin acetate, fentin hydroxide, flucycloxuron, flucythrinate, formothion, mecarbam, methacrifos, monolinuron, phenothrin, propham, pyrazophos, quinalphos, resmethrin, tecnazene and vinclozolin in or on certain products 32015R0868 - EN - EUR-Lex Commission Regulation (EU) 2022/1396 of 11 August 2022 amending the Annex to Regulation (EU) No 231/2012 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 as regards the presence of ethylene oxide in food additives (Text with EEA relevance) 32022R1396 - EN - EUR-Lex **2. USA** 40.CFR.180.151: MRLs for ethylene oxide and 2-CE are 7 mg/kg and 940 mg/kg respectively on various fresh products. Except MRL ethylene oxide for walnut is 50 mg/kg eCFR :: 40 CFR 180.151 -- Ethylene oxide; tolerances for residues. **3. Canada** MRLs for ethylene oxide and 2-CE are 7 mg/kg and 940 mg/kg respectively on various fresh products. If ethylene oxide and its reaction product, ethylene chlorohydrin are present in a processed food for which an MRL has not been established, residues must not exceed the 0.1 ppm general maximum residue limit (GMRL), as per Subsection B.15.002(1) of the Canadian Food and Drug Regulations. Maximum Residue Limits for Pesticides - Health Canada ARCHIVED - Food and Drug Regulations	

COMMENT	MEMBER
4. South Korea *Uniform limit* 0,01 mg/kg https://www.foodsafetykorea.go.kr/foodcode/index.jsp https://www.foodsafetykorea.go.kr/foodcode/02_01_02.jsp?s_option=EN&s_type=4 **5. Japan** *Uniform limit* 0,01 mg/kg The Japanese Positive List System for Agricultural Chemical Residues in Foods (Enforcement on May 29, 2006) **6. Hongkong** In Hong Kong, the Pesticide Residues in Food Regulation ("the Regulation") specifies a list of maximum residue limits (MRLs) / extraneous maximum residue limits (EMRLs) for certain pesticide-food pairs. The presence of any of these pesticide residues in food at levels exceeding the MRLs/EMRLs is not permitted. For pesticide residues with no specified MRLs/EMRLs in Schedule 1, the Regulation stipulates that except for exempted pesticides, import or sale of food containing such pesticide residues is allowed if the consumption of the food concerned is not dangerous or prejudicial to health based on risk assessment conducted by CFS. Hong Kong does not have a MRL for EO nor is it an exempted pesticide under the Regulation. CFS considers that it cannot be shown by risk assessment that the consumption of food contaminated by EO is not dangerous or prejudicial to health. Hong Kong Pesticide MRL Database Cap. 132CM Pesticide Residues in Food Regulation **7. Taiwan** Standards for Pesticide Residue Limits in Foods : ethylene oxide and its metabolite 2-chloroethanol, which are not listed on Table 1 and Table 2, shall not be detected in foods. Standards for Pesticide Residue Limits in Foods - Article Content - Laws & Regulations Database of The Republic of China (Taiwan) **8. Singapore** Under the Ninth Schedule of the Food Regulations, residues of ethylene oxide are permitted only in whole spices, at levels up to 50 mg/kg. The import, sale and manufacture of any other food containing residues of ethylene oxide is not permitted under Regulation 30(2) of the Food Regulations Food Regulations - Singapore Statutes Online **9. Thailand** Ministry of Public Health Notification No. 387 B.E 2560 (2017), Food Containing Pesticide Residues shall be complied with standard that shall not contain any pesticide prescribed in Annex 1 of this Notification. Where no MRLs specified, detected pesticide residues in plant or animal shall not exceed 0.01 mg/kg of the food. Ethylene oxide is included in Annex 1. Thai FDA Revises Pesticide Residue Standards and MRLs in Food Thailand	

COMMENT	MEMBER
10. Indonesia ● Indonesia has prohibited the usage of ethylene oxide as a pesticide under Ministry of Agriculture Regulation No. 43 Year 2019 on Pesticides Registration Permentan No. 43 Tahun 2019 tentang Pendaftaran Pestisida [JDIH BPK RI] ● Indonesia has risk mitigation guidelines for EtO and 2-CE on Processed Food under Decree of the Head of Indonesia FDA No. 229 Year 2022 on risk mitigation guidelines for Ethylene Oxide, 2,6-diisopropylnaphthalene, and 9,10-anthraquinone KEPUTUSAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN NOMOR 229 TAHUN 2022 TENTANG PEDOMAN MITIGASI RISIKO KESEHATAN SENYAWA ETILEN O ● The Indonesian Food Codex Year 2018 has set a maximum limit for EtO impurities in polyethylene glycol at 0.02% or 200 mg/kg.e-KMI 2.4.4 Work already undertaken by other international organisations The work hasn't been undertaken yet by any organization 2.4.5 The prospect of completing the work in a reasonable period of time No information 2.4.6 The impact on international trade (i.e. magnitude of the problem in international trade) Ethylene oxide has caused a major trade problem in recent years. There were more than eight hundred cases of notification by EURASFF1 as per February 2023. It can be expected that the recalls will result in a huge cost for food companies. 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. In conclusion, EtO and 2-CE must be regulated 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 regulated by CCCF in the future. 2.4.7 Compliance with the Codex Alimentarius Commission's Strategic Plan1 and its relevant plans of work The proposed work directly relates to the following Codex Strategic Goals from the 2020-2025 Strategic Plan. Goal 1 Address current, emerging and critical issues in a timely manner. Codex, through its regional Committees, has never directly addressed food safety issues on pesticide residues on food products. Other than their function as pesticides, the contamination of EtO in food products may come from other sources. EtO is used in the production of a number of food additives such as polysorbate and polyethylene glycol. As a result, the EtO content in processed food may be derived from the use of food additives in processed food. EtO has 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. EtO and 2-CE have the potential to cause health and trade problems. Goal 2 Develop standards based on science and Codex risk-analysis principles Risk analysis as it applies to food safety across the food chain is an internationally accepted discipline and forms an integral part of any well-designed food safety control system. Through an active involvement of scientific and technical experts from many Codex members and observers we aim for a harmonized global standard addressing developments in the field of food safety risk management as they apply to (food products).	

COMMENT	MEMBER
Goal 3 Increase impact through the recognition and use of Codex standards By creating standards for many countries in managing domestic or imported food trade, Codex will increase its relevance to reduce the risk of exposure to EtO and 2 -CE in food. Goal 4 Facilitate the participation of all Codex Members throughout the standard setting process Development of harmonized standards for EtO and 2-CE in foods need to involve Codex Members considering that several countries already set the MRLs of EtO and 2-CE. The new work should generate great interest and broad participation from all members, with the objective to produce a user-friendly document that could be adopted and enforced as widely as possible. It provides specific attention to the food safety activities of small enterprises and to developing countries. Goal 5 Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals More expeditious and efficient work by Codex is necessary to provide members and international organizations with the standards and recommendations that they need. During the development of this harmonized standard, all working documents and electronic discussions will be distributed in a timely and transparent manner, using web-based technologies available freely to all. This strategic goal is one of the core objectives of the Committee for Food Contaminants, as it will provide a solid ground for all Codex work related to food contaminants of EtO. 2.4.8 The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries There are already available data security and studies from several countries as mentioned above. 2.4.9 Compliance with CCCF's Terms of Reference1 Even though EtO is used as a pesticide, the contamination of these chemicals in food products may come from other sources (such as medical device sterilizers and food additives). We hope this proposal is considered by CCCF, since this issue is not only related to food safety but also a trade barrier. 2.4.10 Compliance with JECFA's Terms of Reference[2] Even though various countries regulate EtO and 2-CE as pesticides, considering that the presence of EtO and 2-CE can also come from other sources (as medical device sterilizers and food additives), we propose that these two compounds can be studied by JECFA.	
Kenya supports the conclusions of REP 22/CF15 where CCCF agreed to endorse the priority list (appendix ix) of the report.	**Kenya**
México no cuenta con comentarios particulares, no obstante, apoyamos se continúe con las evaluaciones, a razón de que la información que se genere pueda ser considerada para el manejo de riesgos, como es el caso del arsénico en arroz, en donde México no tiene establecida alguna disposición legal para su limitación.	**Mexico**
New Zealand would like to indicate its support of the priority list of contaminants for evaluation or re-evaluation by JECFA. New Zealand does not nominate any additional contaminants to be included on the JECFA priority list.	**New Zealand**
De acuerdo a las listas de prioridades de contaminantes, el Perú no tiene observaciones.	**Peru**