

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda item 20

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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

17<sup>th</sup> Session

15-19 April 2024

Panama City, Panama

PRIORITY LIST OF CONTAMINANTS FOR EVALUATION BY JECFA

Comments in reply to CL 2023/95-CF

submitted by

Canada, Chile, Cuba, Indonesia, Iraq, New Zealand, Peru, Saudi Arabia, United Arab Emirates, USA and ICUMSA, PRRI

## Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2023/95-CF<sup>1</sup> issued in December 2023. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

## Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby annexed and presented in tabulated format.

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<sup>1</sup> <https://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****GENERAL COMMENTS**

<b>COMMENT</b>	<b>MEMBER / OBSERVER</b>
<p>Add the information below to the "Data availability (when, what)" column.</p> <p>Thallium Canada: Many years of Canadian Total Diet study data in numerous food composite samples. One year (2013) of human biomonitoring data.</p> <p>Perfluoroalkyl substances Canada: Occurrence data for multiple PFAS from Canadian Total Diet Study (dairy, meats, fish, fruits, vegetables, prepared foods). Targeted survey data for PFOS and PFOA (flour, cereal, popcorn, root vegetables).</p>	<b>Canada</b>
<p>Chile revisó las recomendaciones de esta carta circular y apoya el listado de prioridades expuesto, sin observaciones ni contribuciones que realizar por el momento.</p>	<b>Chile</b>
<p>Cuba en principio, apoyará la lista de prioridades que se proponga por el consenso de los miembros.</p>	<b>Cuba</b>
<p>From the 16th CCCF session, it was concluded that the proposal for addition of Ethylene Oxide (EtO) and 2-Chloroethanol (2-CE) to the priority list be deferred for consideration until CCCF17 in order to request input from the Codex Committee on Pesticide Residues (CCPR), on whether EtO and 2-CE meets the definition of a pesticide under Codex, and if not, whether some coordination with regards to a risk assessment would be required between the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) and JECFA to evaluate this compound as a contaminant. It is also recommended that CCFA be informed of CCCF decisions, as EtO and 2-CE could potentially be found as an impurity in certain food additives. Following this issue in CCPR54, CCPR agreed to advise CCCF that EtO is used in some countries as a pesticide (fumigant) and/or as a sterilant. In view of huge workload of JMPR that EtO would not be included in the priority list for evaluation by JMPR, and due to the need to establish a limit for this compound to avoid/minimize negative trade impacts, CCPR agreed that JECFA should take the lead on the evaluation of EtO, with support from JMPR. Indonesia support this approach as it would expedite the establishment of a maximum level (ML) for both of EtO and 2-CE as a contaminant by CCCF due to uses other than a pesticide. The issues pertaining to Ethylene Oxide (EtO) and 2-Chloroethanol (2-CE) have emerged as significant concerns. The absence of international standards regarding these substances has significantly impacted international trade. This is caused by the fact that while some countries, such as Canada and the United States, permit the use of EtO as a fumigant, with Maximum Residue Limits (MRLs) set at approximately 7 mg/kg for EtO and 940 mg/kg for 2-CE in certain fresh food commodities, others, like the European Union, prohibit its usage and establish MRLs at Limit of Quantification (LOQ) ranging from 0.01 to 0.1 mg/kg (as sum of EtO and 2-CE, expressed as EtO). Consequently, the wide variety of standards regarding the substances ethylene oxide (EtO) and 2-chloroethanol (2-CE) has not only created confusion in terms of their safety but has also created disruption and may led to unfair practices in the food trade.</p> <p>In the context of international trade, the lack of international standards has significantly disrupted global trade due to the detection of minute amounts of 2-chloroethanol (2-CE) in food. Consequently, these products are rejected in countries where the use of EtO is prohibited, based on the assumption that (i) the only source of 2-CE is associated with the use EtO, and (ii) the toxicity of 2-CE is deemed equivalent with that of EtO. This confusing situation has led to over nine hundred notifications by the EU Rapid Alert System for Food and Feed (RASFF) as of January 2024, Thus, this issue has affected international trade and resulted in economic and intangible losses, including damage to product reputation. Furthermore, the recalls have resulted in</p>	<b>Indonesia</b>

COMMENT	MEMBER / OBSERVER
<p>food loss and waste, which contrasts with the Sustainable Development Goals (SDGs). Food loss and waste present a critical challenge to the sustainability of food systems. When food is lost or wasted, valuable resources like water, land, energy, labor, and capital that were invested in its production are squandered. Additionally, it affects food security and availability, contributes to rising food costs.</p> <p>Furthermore, some processes involved in the production of food additives, such as polyethylene glycol and polysorbate, also utilize EtO. Hence, the presence of EtO and 2-CE residues may be possible in processed foods as contaminants. According to information from Starch Europe Plant-Based Solutions, in February 2022, there was an EU case notification regarding wheat gluten due to EtO. The industry's information suggest that the notification was inaccurate, as only 2-CE was detected and no EtO or 2-CE are present in the starting raw materials. It is possible that the presence of 2-CE resulted from the use of monochloramine as an approved processing aids in France. Therefore, the detection of 2-CE in wheat gluten does not necessarily imply pesticide usage. Similar cases happen in calcium carbonate as reported by European Federation of Associations of Health Product Manufacturers. Consequently, the occurrence of or the detection of 2-CE in food may not be attributed to the use EtO, and may be due to process contaminants.</p> <p>Given these considerations, Indonesia is resubmitting its request for EtO and 2-CE as priority list of contaminants for evaluation or re-evaluation by JECFA</p>	
Agree	<b>Iraq</b>
<p>New Zealand supports the proposed priority list (REP23/CF16 Appendix VII), and does not nominate additional contaminants for evaluation or re-evaluation by JECFA.</p> <p>New Zealand holds data on arsenic (inorganic and organic), dioxins and dioxin-like PCBs, thallium and perfluoroalkyl substances, and will ensure all data is submitted to GEMS.</p>	<b>New Zealand</b>
<p>El Perú desea agradecer a la Secretaría de la Comisión del Codex Alimentarius, Programa Conjunto FAO/OMS sobre Normas Alimentarias, respecto a la Solicitud de observaciones sobre la Lista de prioridades de contaminantes para su evaluación o reevaluación por el JECFA, al respecto no tenemos comentarios, gracias.</p>	<b>Peru</b>
<p>Saudi Arabia would like to indicate its agreement and support of the current list of contaminants and naturally occurring toxicants recommended for evaluation by JECFA. Saudi Arabia does not nominate any additional substances to be considered for the JECFA priority list at this time.</p>	<b>Saudi Arabia</b>
<p>United Arab Emirates appreciates the work and efforts done by CCCF and JECFA regarding the priority list of contaminants, and we would like to inform you that we have no comments on the priority list of contaminants for evaluation or re-evaluation by JECFA.</p>	<b>United Arab Emirates</b>
<ul style="list-style-type: none"> <li>• The United States has no new nominations to the Priority List of Contaminants and Naturally Occurring Toxicants Proposed for Evaluation by JECFA (JECFA Priority List).</li> <li>• The United States plans to provide updates on dioxin and arsenic data availability at the virtual working group on the JECFA Priority List.</li> <li>• With regard to PFAS, the United States suggests changing the contaminant name in the JECFA Priority List to Per- and polyfluoroalkyl substances (PFAS) (e.g., PFOS, PFOA, PFNA, and PFHxS).</li> </ul>	<b>USA</b>
<p>There is a need to check the formatting of the references to ensure they are consistent in each document and between each document.</p>	<b>ICUMSA</b>
<p>Editorial comments provided</p>	<b>PRRI</b>

**SPECIFIC COMMENTS**

<b>NOMINATION OF CONTAMINANTS FOR EVALUATION OR RE-EVALUATION BY JECFA</b>		
<b>1.</b>	<b><u>Required information</u></b>	<b>Indonesia</b>
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:	<p><b>Background</b></p> <p>Due to the increasing issue of the Ethylene Oxide (EtO) contamination in food products<sup>2</sup>, 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<sup>3</sup> 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.).</p> <p>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.</p> <p>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 was 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 carried over from the use of food additives in processed food.</p> <p>Due to the lack of international standard 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, US 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.</p>

<sup>2</sup> European Commission Rapid Alert System for Food and Feed (EURASFF) (<https://webgate.ec.europa.eu/rasff-window/screen/search>)

<sup>3</sup>US EPA: Ethylene Oxide Releases Trend (<https://www.epa.gov/trinationalanalysis/ethylene-oxide-releases-trend>)

While various countries regulate EtO and 2-CE as pesticides, it is essential to consider that their presence can also originate from other sources, such as medical device sterilizers and food additives. Therefore, Indonesia propose that these two compounds be evaluated 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)<sup>4</sup>. 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<sup>5</sup>.

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)<sup>6</sup>, the level of low concern for EtO 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.

In 2022, EFSA<sup>7</sup> 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)<sup>8</sup>, 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.

**Again, the fact that there are different scientific views regarding the toxicity of EtO and 2-CE has not only caused confusion regarding their safety status, but also disruption to international trade. For this reason, international standard is needed, from CCCF, which can be used as a reference for consumer protection and fair international trade.**

#### **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:

		<p><b>1. Instant Noodle</b></p> <p>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: <a href="#">World Instant Noodles Association</a>.</p> <p>The average EtO content in instant noodles reported ranges between 0,06-63,73 mg/kg. However, the detected and measured compound was 2-CE according to testing methods from the EU Reference Laboratories for Residues of Pesticides (December 2020), the analysis results of 2-CE are converted to EtO. In fact, some references stating that EtO is volatile and rarely found in products. Furthermore, it has different toxicities to 2-CE (US EPA), and hence the exposure should be separately calculated for EtO and 2-CE. Based on conversion factor of 0,55, the concentration of 2-CE is 0,10-115,87 mg/kg. Therefore the estimated exposure of 2-CE in humans with a body weight of 60 kg and a <a href="#">consumption</a> of 23,7 g/day (men) and 11,1 g/day (women) with the Chronic Reference Dose (cRfD) value of 0,824 mg/kg/day, ranges from 0,004-5,55% (men) and 0,002-2,60% (women). These levels of exposure do not exceed the cRfD value and remain below 30%.</p> <p><b>2. Ice Cream</b></p> <ul style="list-style-type: none"> <li>The average American consumes approximately 23 pounds of ice cream and related frozen desserts per year. <a href="#">Ice Cream Sales &amp; Trends - IDFA</a></li> <li>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. <a href="#">Which Country Eats the Most Ice Cream? - WorldAtlas</a></li> </ul>	
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<sup>4</sup> International Agency for Research on Cancer (IARC) Monographs on The Identification of Carcinogenic Hazards to Humans (<https://monographs.iarc.who.int/list-of-classifications/>)

<sup>5</sup> Compendium of Food Additive Specification - Joint FAO/WHO Expert Committee on Food Additives (JECFA) 67<sup>th</sup> meeting 2006 (<https://www.fao.org/3/a0675e/a0675e.pdf>)

<sup>6</sup> Bundesinstitut für Risikobewertung. 2021. Health risk assessment of ethylene oxide residues in sesame seeds. BfR Opinion, 24. (<https://www.bfr.bund.de/cm/349/health-risk-assessment-of-ethylene-oxide-residues-in-sesame-seeds.pdf>)

<sup>7</sup> EFSA. 2022. Statement on the BfR opinion regarding the toxicity of 2-chloroethanol. EFSA Journal. (<https://www.efsa.europa.eu/en/efsajournal/pub/7147>)

<sup>8</sup> Allemang, A., Lester, C., Roth, T., Pfuhrer, S., Peuschel, H., Kosemund, K., Mahony, C., Bergeland, T., & O'Keefee, L. (2022). Assessing the genotoxicity and carcinogenicity of 2-chloroethanol through structure activity relationships and in vitro testing approaches. Food and Chemical Toxicology, 168. (<https://pubmed.ncbi.nlm.nih.gov/35863484/>)

		<p><b>3. Sesame oil</b></p> <p>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 Türkiye lagged somewhat behind, together accounting for a further 25%.</p> <p><a href="#">Global Sesame Oil Market - Key Findings And Insights   Food Dive.</a></p> <p><b>4. Dried Chilli Powder</b></p> <p>The analysis results of dried chili powder indicate a 2-CE content ranging from 0.05 to 0.1 mg/kg. Therefore, with a consumption rate of 8 grams per day and a body weight of 60 kg, the exposure levels amount to 0.0008-0.001% of the cRfD. This exposure level does not exceed the cRfD value and remains below 30%.</p>	
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:	<p>1. United States</p> <p>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. (<a href="#">Ethylene Oxide (EtO). Draft Human Health and Ecological Risk Assessment in Support of Registration Review</a>)</p> <p>2. EURASSF</p> <p>Database for ethylene oxide and 2-chloroethanol notification <a href="#">RASFF Window - Search</a></p> <p>3. CVUA Stuttgart</p> <p>Analytical result for ethylene oxide and 2-chloroethanol of instant noodle products from various country <a href="#">Chemicals Rather than Bacteria? – Neither is Permitted in the EU</a></p>	
1.5	Timeline for data availability:	-	

2.	<b><u>Optional detailed information</u></b>	
2.1	Whether or not the occurrence of the compound in commodities will have potential to cause public health and/or trade problems;	<p>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.</p> <p>Ethylene oxide has caused a major trade problem in recent years. There were more than eight hundred cases of notification by EURASFF<sup>1</sup> as per February 2023. It can be expected that the recalls will result in a huge cost for food companies.</p> <p>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.</p> <p>Indonesia believes that <b>EtO</b> and <b>2-CE</b> should be regulated independently due to their <b>distinct potential impact on health and trade</b>. Considering that these substances can originate from various sources, we suggest that <b>JECFA assess them as contaminants</b>, with <b>possible future regulation by CCCF</b>.</p>
2.2	Whether or not commodities containing the compound are in international trade and represent a significant portion of the diet; and	Yes, numerous products in international trade could be affected due to the lack of international standards for <b>EtO</b> and <b>2-CE</b> . Food recalls due to this substance began in various countries since 2020. Referring to EURASFF <sup>1</sup> , there are 885 notifications on ethylene oxide (February 2023). The products recalled include
2.3	Commitment that a dossier (as complete as possible) will be available for evaluation by the JECFA.	Given the global impact on international trade, Indonesia wishes member countries to support the dossier, particularly those with data on the differing toxicities of <b>ethylene oxide (EtO)</b> and <b>2-chloroethanol (2-CE)</b>
2.4	<b><u>Relevant justification and information on the following prioritization criteria1:</u></b>	
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 consumption mentioned above, the establishment of standard for EtO and 2-CE could enhance consumer protection and promote fairness in the food trade
2.4.2	The needs and concerns of developing countries;	This impact of this issue extends to developing countries both in trade and safety. Especially in terms of trade, EtO and 2-CE have become global trade issues. Numerous notifications and recalls have affected food products from developing nations, which play a crucial role in their economic development.

<p>2.4.3</p>	<p>The diversity of national legislations and any apparent impediments to international trade;</p>	<p>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.</p> <p>A. Food Additives</p> <ol style="list-style-type: none"> <li>1. JECFA Monographs <ol style="list-style-type: none"> <li>a. Polyethylene glycol (INS 1521) <ul style="list-style-type: none"> <li>• Definition: Addition polymers of <b>ethylene oxide</b> and water usually designated by a number roughly corresponding to the molecular weight</li> <li>• Impurity EtO in polyethylene glycol: not more than 0,02% or 200 mg/kg.</li> </ul> </li> <li>b. Polysorbates, for example Polysorbate 20 (INS 432) and Polysorbate 40 (INS 434) <ul style="list-style-type: none"> <li>• Definition Polysorbate 20: Consists of a mixture of the partial esters of sorbitol and its mono- and dianhydrides (which have an acid value below 7 and a water content below 0.2%) with edible commercial lauric acid and condensed with approximately 20 moles of <b>ethylene oxide</b> per mole of sorbitol and its anhydrides.</li> <li>• Definition Polysorbate 40: Consists of a mixture of the partial esters of sorbitol and its mono- and dianhydrides (which have an acid value below 7.5 and a water content below 0.2%) with edible commercial oleic acid and condensed with approximately 20 moles of <b>ethylene oxide</b> per mole of sorbitol and its anhydrides.</li> </ul> </li> </ol> </li> <li>2. European Union (EU) <p>Commission Regulation EU 2022/1396: 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)).</p> <p><a href="#">32022R1396 - EN - EUR-Lex</a></p> </li> <li>3. Indonesia <p>The Indonesian Food Codex Year 2018 has set a maximum limit for EtO impurities in polyethylene glycol at 0.02% or 200 mg/kg.</p> <p><a href="#">e-KMI</a></p> </li> </ol> <p>B. Pesticide Residues</p> <ol style="list-style-type: none"> <li>1. Countries that regulate ethylene oxide (EtO) and 2-chloroethanol (2-CE) separately <ol style="list-style-type: none"> <li>a. USA <p>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</p> <p><a href="#">eCFR :: 40 CFR 180.151 -- Ethylene oxide; tolerances for residues.</a></p> </li> </ol> </li> </ol>	
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**b. 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](#)

**c. 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-diisopropyl-naphthalene, and 9,10-anthraquinone. In this guideline, the recommended maximum limits for ethylene oxide (EtO) are 0.01 mg/kg and for 2-chloroethanol (2-CE) it is 85 mg/kg in processed foods.

[KEPUTUSAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN NOMOR 229 TAHUN 2022 TENTANG PEDOMAN MITIGASI RISIKO KESEHATAN SENYAWA ETILEN O](#)

2. Countries that regulate ethylene oxide (EtO) and 2-chloroethanol (2-CE) strictly

**a. European Union (EU)**

- Regulation (EC) 396/2005, Commission Regulation (EU) 2015/868

[32005R0396 - EN - EUR-Lex](#)

[32015R0868 - EN - EUR-Lex](#)

- MRLs for ethylene oxide on food products are set at the Limit of Quantification (LOQ) of the analytical method used, depending on the matrix

**b. 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](https://www.foodsafetykorea.go.kr/foodcode/02_01_02.jsp?s_option=EN&s_type=4)

**c. Japan**

*Uniform limit 0,01 mg/kg*

[The Japanese Positive List System for Agricultural Chemical Residues in Foods \(Enforcement on May 29, 2006\)](#)

**d. 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](#)

**e. 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 \(Taiwan\)](#)

**f. 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](#)

		<p><b>g. Thailand</b></p> <p>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.</p> <p><a href="#">Thai FDA Revises Pesticide Residue Standards and MRLs in Food Thailand</a></p>	
2.4.4	Work already undertaken by other international organizations;	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);	<p>Ethylene oxide has caused a major trade problem in recent years. There were more than eight hundred cases of notification by EURASFF<sup>1</sup> as per February 2023. It can be expected that the recalls will result in a huge cost for food companies.</p> <p>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.</p> <p>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.</p>	
2.4.7	Compliance with the Codex Alimentarius Commission's Strategic Plan <sup>9</sup> and its relevant plans of work;	<p>The proposed work directly relates to the following Codex Strategic Goals from the 2020-2025 Strategic Plan.</p> <p><b>Goal 1 Address current, emerging and critical issues in a timely manner.</b></p> <p>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.</p>	

		<p><b>Goal 2 Develop standards based on science and Codex risk-analysis principles</b>  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).</p> <p><b>Goal 3 Increase impact through the recognition and use of Codex standards</b>  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.</p> <p><b>Goal 4 Facilitate the participation of all Codex Members throughout the standard setting process</b>  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.</p> <p><b>Goal 5 Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals</b>  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.</p> <p>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 works related to food contaminants of EtO.</p>	
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 Reference <sup>9</sup> ;	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 highly appreciate 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 <sup>9</sup> ; and	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 strongly propose that these two compounds can be studied by JECFA.	
2.5	<u>Additional data/information to complement what is provided in this template:</u> Note that this point does not replace the submission of the template through the OCS. This point is complementary to the data/information provided in points 1 – 2.4.	-	
2.5.1	Provide relevant links through the OCS (most preferable option): and/or	-	
2.5.2	If the information is only available as single files, please send the files separately to the Chair of the Working Group on Priorities, United States of America ( <a href="mailto:lauren.robin@fda.hhs.gov">lauren.robin@fda.hhs.gov</a> ) with a copy to the US Codex Office ( <a href="mailto:codex@fao.org">codex@fao.org</a> ) and the Codex Secretariat, as the files cannot be submitted through the OCS (less preferable option).	-	

<sup>9</sup> Information on JECFA is available from the FAO and WHO websites as follows:

FAO: <https://www.fao.org/food/food-safety-quality/scientific-advice/en/>

WHO: <https://www.who.int/teams/nutrition-and-food-safety>