

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 Item 16

CRD17

April 2023

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 Singapore

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

1. **Required information**

1.1 Proposal for inclusion submitted by: Singapore

1.2 Name of compound; chemical name(s): perfluoroalkyl substances (PFASs) – perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA), perfluorohexane sulfonic acid (PFHxS)

1.3 Identification of (additional) data (toxicology, metabolism, occurrence, food consumption) which could be provided to JECFA:

Toxicology / Epidemiology

- EFSA Panel on Contaminants in the Food Chain (CONTAM) 2020b Risk to human health related to the presence of perfluoroalkyl substances in food. EFSA Journal 18(9): 6223 <https://doi.org/10.2903/j.efsa.2020.6223>
- Abraham K, Mielke H, Fromm H, Völkel W, Menzel J, Peiser M, Zepp F, Willich SN and Weikert C (2020) Internal exposure to perfluoroalkyl substances (PFASs) and biological markers in 101 healthy 1-year-old children: associations between levels of perfluorooctanoic acid (PFOA) and vaccine response. Archives of Toxicology 94: 2131-2147
- Agency for Toxic Substances and Disease Registry (ATSDR) 2018 Toxicological Profile for Perfluoroalkyls Draft for Public Comment. <https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf>
- 27th Australian TDS - PFAS and Immunomodulation Review and Update (and references therein)
- J. Lin, S. Y. Chin, S. P. F Tan, H. C. Koh, E. J. Y. Cheong, E. C. Y. Chan, J. C. Y. Chan (2023) Mechanistic Middle-Out Physiologically Based Toxicokinetic Modeling of Transporter-Dependent Disposition of Perfluorooctanoic Acid in Humans. Environ. Sci. Technol. *in press*. <https://doi.org/10.1021/acs.est.2c0564>
- Ongoing epidemiological studies on PFAS and immunomodulation in China (expected publication in 2023)

Dietary exposures

- 27th Australian Total Diet Study on Per- and poly-fluoroalkyl substances <https://www.foodstandards.gov.au/publications/Pages/27th-Australian-Total-Diet-Study.aspx>
- 2nd French Total Diet Study. <https://www.anses.fr/en/system/files/PASER2006sa0361Ra1EN.pdf>
- 5th China Total Diet Study
- US FDA Total Diet Study (2022). <https://www.fda.gov/media/156351/download>; <https://www.fda.gov/food/science-research-food/fda-total-diet-study-tds>
- UK Total Diet Study (2012). <https://www.food.gov.uk/sites/default/files/media/document/research-report-total-diet-study.pdf>
- EFSA Panel on Contaminants in the Food Chain (CONTAM) 2020b Risk to human health related to the presence of perfluoroalkyl substances in food. EFSA Journal 18(9): 6223 <https://doi.org/10.2903/j.efsa.2020.6223>

- 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:
- Australia, New Zealand, France, Germany, UK, USA, China, Singapore (Er Jun Cheng, er_jun_cheng@sfa.gov.sg)

1.5 Timeline for data availability: Available immediately

2. **Optional detailed information**

- 2.1 Whether or not the occurrence of the compound in commodities will have potential to cause public health and/or trade problems;

There is increasing literature evidence suggesting that current dietary exposures to PFAS is a food safety concern to humans (see point 1.3) and contamination is widespread across the diet. Higher contaminations of PFASs were reported in commonly consumed foods such as fish and seafood, egg, and egg products.

However, there is currently a lack of consensus over the risk assessments particularly over the toxicity of PFASs in humans. This has led to misaligned policies regarding the management of PFASs (refer to point 2.4.3).

- 2.2 Whether or not commodities containing the compound are in international trade and represent a significant portion of the diet; and

Yes. Products such as fish and seafood, egg and egg products, and meat and meat products have been reported to contain higher contaminations of PFASs and contribute a significant portion of the dietary exposures.

- 2.3 Commitment that a dossier (as complete as possible) will be available for evaluation by the JECFA.

2.4 **Relevant justification and information on the following prioritization criteria¹:**

- 2.4.1 Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade;

There is increasing literature evidence suggesting that current dietary exposures to PFAS is a food safety concern to humans (see point 1.3) and contamination is widespread across the diet. Higher contaminations of PFASs were reported in commonly consumed foods such as fish and seafood, egg, and egg products.

- 2.4.2 The needs and concerns of developing countries;

- 2.4.3 The diversity of national legislations and any apparent impediments to international trade;

Diversity of legislations on PFAS in food

The EU has moved ahead to establish maximum levels of certain PFAS compounds in eggs, seafood, and meat. Other countries, such as Australia, New Zealand, and the United States, adopt non-regulatory measures, in which further investigations into products may be launched if PFAS levels are found to exceed their trigger levels. The misaligned policies regarding the management of PFASs may be an apparent impediment to international trade particularly since the foods involved are commonly traded items.

European Union	Australia and New Zealand	United States
EU has established MLs for PFOS, PFOA, PFHxS and PFNA and for the sum of PFOS, PFOA, PFNA and PFHxS in eggs, seafood (fish meat, crustaceans, bivalve molluscs), meat and edible offal of terrestrial animals. (See attachment for draft amendments to the regulation). https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R2388	Food Standards Australia New Zealand (FSANZ) has non-regulatory 'trigger points' for fish and seafood, animal products (e.g., eggs, meat, and offal). The trigger points may be used by government authorities to identify whether further investigation may be required if PFAS are detected in analysed foods, e.g., whether further farm investigation may be required.	Food and Drug Administration (US FDA) evaluates the level of PFAS in food for possible human health concern. A case of voluntary recall of canned clam samples was reported in July 2022 after FDA shared with the two distributors on the health concern of two highest levels of PFOA detected in FDA's seafood survey.

¹ Section 3, paragraph 10 of the *Risk Analysis Principles Applied by the Codex Committee on Contaminants in Foods*. The Risk Analysis Principles, the *Criteria for the Establishment of Work Priorities* and the Terms of Reference of CCCF are available in the Procedural Manual of the Codex Alimentarius Commission. The latest editions of the Procedural Manual and the Codex Strategic Plan are available online at: <https://www.fao.org/fao-who-codexalimentarius/publications/en/>

2.4.4 Work already undertaken by other international organisations;

Yes. (refer to point 1.3)

2.4.5 The prospect of completing the work in a reasonable period of time;

2.4.6 The impact on international trade (i.e., magnitude of the problem in international trade);

Higher contaminations of PFASs were reported in commonly consumed and traded foods such as fish and seafood, egg, and egg products. The lack of consensus regarding the risk assessment and policies managing the contamination of PFASs in these commonly traded foods could pose a major impact on international trade.

2.4.7 Compliance with the Codex Alimentarius Commission's Strategic Plan¹ and its relevant plans of work;

The proposed work is consistent with the Commission's mandate to develop standards, guidelines, and other international recommendations to protect consumer health and to ensure fair food trade practices. The new guidelines will contribute to the achievement of Strategic Goals 1, 2, 3, and 4.

Goal 1: Address current, emerging and critical issues in a timely manner

- 1.1. To identify needs and emerging issues
- 1.2. To prioritize needs and emerging issues

PFAS contaminants are known to persist in the environment and cause widespread contamination of drinking water sources, soil and air. Recent scientific evidence suggests that some of these PFASs could accumulate in humans more than other living organisms, and that current dietary exposures to PFAS is a food safety concern (see point 1.3). In view of these recent studies, it is critical and timely to re-assess, and if necessary, further manage the risks to PFASs.

Goal 2: Develop standards based on science and Codex risk-analysis principles

- 2.1 Use scientific advice consistently in line with Codex risk-analysis principles.
- 2.2 Promote the submission and use of globally representative data in developing and reviewing Codex standards.

Codex standards should be science based. Developing Codex standards based on scientific advice is in line with the Codex risk-analysis principles. Therefore, it is important for Codex standards to be developed based on scientific advice by expert committees such as JECFA.

Having scientific analysis done by international expert committees such as JECFA will enable data from around the world be taken into consideration and that standards developed are inclusive. Such standards will be relevant to countries around the world and are more likely to be recognised and adopted into local legislation.

Goal 3: Increase impact through the recognition and use of Codex standards

- 3.1 Raise the awareness of Codex standards.
- 3.2 Support initiatives to enable the understanding and implementation/application of Codex standards.
- 3.3 Recognise and promote the use and impact of Codex standards.

Having scientific analysis done by international expert committees such as JECFA will enable data from around the world be taken into consideration and that standards developed are inclusive. Such standards will be relevant to countries around the world and are more likely to be recognised and adopted into local legislation.

Goal 4: Facilitate the participation of all Codex Members through the standard setting process

- 4.1: Enable sustainable national Codex structures in all Codex Member Countries.
- 4.2: Increase sustainable and active participation of all Codex Members.
- 4.3: Reduce barriers to active participation by developing Countries.

PFASs have widespread use in consumer and industrial products and also widespread contamination in the environment and in foods. There is global interest amongst most countries in PFASs as seen by the inclusion of these substances under the Stockholm and Rotterdam conventions. Standards on PFAS will be relevant to member countries across various region. Developing standards on PFAS will enable all Member Countries and Observers to participate in the discussion.

2.4.8 The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;

Refer to point 1.3.

2.4.9 Compliance with CCCF's Terms of Reference¹;

This work is aligned with CCCF's Terms of Reference which include establishing permitted maximum levels or guidelines levels for contaminants in food.

2.4.10 Compliance with JECFA's Terms of Reference²; and

This work is aligned with JECFA's scope of work in risk assessments/safety evaluations of contaminants.

2.5 Additional data/information to complement what is provided in this template: 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.

Diversity of legislations on PFAS in drinking water

Thus far, the World Health Organisation (WHO) has not provided any guideline values for PFAS in drinking water. Nonetheless, various international organisations (including the Department of Health, Food standards Australia and New Zealand (FSANZ), National Medical Research Council in Australia, European Union (EU), Danish Environmental Protection Agency (EPA) and US EPA) have established and issued their own guideline values or regulatory limits for several common PFAS.

Australia

In 2016, the Department of Health, Food Standards Australia New Zealand (FSANZ) and the National Medical Research Council in Australia developed and adopted health-based guidance values for PFOS, PFOA and PFHxS in drinking water, at 560 ng/l for PFOA, and 70 ng/l for total sum of PFOS and PFHxS. These guidance values are intended to be used for site investigations into PFAS contamination.

EU

The European Union updated the European Drinking Water Directive to impose a limit of 500 ng/l for total PFAS and 100 ng/l for a sum of 20 PFAS compounds in drinking water under the European Drinking Water Directive. Member States would need to comply with these values by 12 Jan 2026.

USA

So far, the US EPA has not included PFAS in its National Drinking Water Regulation. In June 2022, the US EPA issued non-regulatory and non-enforceable lifetime drinking water health advisory levels of near-zero for four common PFAS (i.e., PFOA, PFOS, perfluorobutane sulfonic acid (PFBS) and hexafluoropropylene oxide dimer acid and its ammonium salts (GenX)). The interim health advisory thresholds set for PFOA, PFOS, PFBS and GenX are 0.004 ng/l, 0.02 ng/l, 2000 ng/l and 10 ng/l respectively. [Note: lifetime health advisory levels identify the concentration of chemicals in drinking water over an individual's lifetime at or below which adverse health effects are not anticipated to occur. These advisory levels are non-regulatory in nature.]

The threshold levels for PFOA and PFOS are interim lifetime health advisory levels and are subject to change following further reviews by the EPA Science Advisory Board.

² 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>