



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

**12th Session
Utrecht, The Netherlands, 12 - 16 March 2018**

**PROPOSED DRAFT GUIDELINES FOR RISK ANALYSIS OF CHEMICALS INADVERTENTLY PRESENT
IN FOOD AT LOW LEVELS
(AT STEP 4)**

Comments submitted at Step 3 by Australia, Canada, Colombia, Costa Rica, Egypt, India, Japan, Kenya, Republic of Korea, USA, FoodDrinkEurope, ICGMA, IDF, IOFI and ISDI

AUSTRALIA

- Australia confirms its previous request that cleaning agents be considered for inclusion in the scope of the proposed draft guideline. These agents are widely used in the food industry and are likely to be detected at low levels.
- Australia supports the proposal to request relevant technical information or methodological guidance from JECFA to assist with the establishment of cut-off values, particularly those derived from toxicological thresholds (e.g. TTC for genotoxic and non-genotoxic compounds). The direct application of these threshold doses ($\mu\text{g}/\text{kg}$ bw) by risk managers is not possible without a conversion to an analytical concentration (mg/kg) calibrated for variations in food consumption across population groups.

CANADA

Canada wishes to express its appreciation to the chair, New Zealand, and co-chair, the Netherlands, for leading the electronic Working Group (eWG) on the *Proposed Draft Guidelines for risk analysis of chemicals inadvertently present in food at low levels*. Canada would like to express its agreement with the recommendations put forward in paragraphs 18-19 and the proposed draft Guidelines as presented in Appendix I of this document.

COLOMBIA

Colombia is pleased to state that it is in agreement with the PROPOSED DRAFT GUIDELINES FOR RISK ANALYSIS OF CHEMICALS INADVERTENTLY PRESENT IN FOOD AT LOW LEVELS, and to declare the following:

Paragraph:

1. **3. SCOPE:** (iii) Emerging natural toxins e.g. newly characterised mycotoxins or food crop phytotoxins and (iv) Environmental contaminants e.g. corrosion inhibitors, flame retardants and musks/fragrances

Consider including, in addition: toxin-producing bacteria and marine toxins or phycotoxins. Suggestion: environmental (chemical, physical and biological) contaminants.

References: (Cusick & Saylor, 2013; Dolan, Matulka & Burdock, 2010;

Friedman & Rasooly, 2013; Rameshrad, Razavi & Hosseinzadeh, 2017).

It is important to be able to include nanomaterials or constituents used in nanotechnology.

2. **4. DEFINITIONS: Emerging contaminant:** A contaminant in the food under investigation, which is a novel or recently emerged occurrence, or has not previously reported or anticipated to be detected at the time of regulatory consideration of prior uses; and, For which there is no quantitative level or guideline for risk management established in Codex, or for an individual country, a regional or national food standard informed by toxicological assessment.

Suggested addition:

- There are no regulations on emerging contaminants.
- Emerging contaminants are chemicals or materials characterised as being a perceived or real threat to human health or the environment.
- A contaminant can also be “emerging” if a new source, a new route for transmission to humans, or a new detection method or technique is discovered.
- It does not necessarily have to be under investigation; it may be the first time that it is reported.

The term “cut-off value” needs to be defined precisely in order to make the document easier to understand.

Emergences can evolve from innocuous situations related to normal, routine foods which are not an emergence *per se*, or can arise abruptly.

References: (Murnyak et al., 2011).

We consider it important to define the period of time to which the word “recently” relates.

3. 7. REPORTING OF DETECTION(S): Information provided by the analyst to the risk manager should include:

- Type of sampling programme e.g. cross-sectional, longitudinal, targeted surveillance.
- Test method and its analytical performance.
- Number of detections and total number of samples tested.
- Summary statistics of occurrence data.
- Identification of chemical class / chemical type.

In supplying this information, the officially recognised laboratory may provide a scientific/technical opinion on the possible source(s) of the chemical substance detected.

We also consider it important to include:

- Reporting on the limit of detection and limit of quantification of the test method.
- Reporting on the sampling date and place.
- Description of the food or foods sampled, to determine consistency with the test method.
- Ensuring representativeness of the sampling plan.
- Taking account of national resources and capacity for analytical work on identifying the substance in question.

The above is the consensus reached in the Food Contaminants Subcommittee of Colombia.

COSTA RICA

Costa Rica is grateful to the working group for the work that it has done and for the opportunity to make comments. In this connection, it expresses its support for the progress made on the document and reckons that it would be a tool which would facilitate the commercial exchange of food worldwide.

EGYPT

Egypt agrees with the proposed draft Guidelines for risk analysis of chemicals inadvertently present in food at low levels.

INDIA

General Comments: India appreciates the work done by New Zealand and supports the proposed draft guidelines for risk analysis of chemicals inadvertently present in food at low levels.

With respect to section 8.1 (Exclusionary categories), to have clarity, protein and inorganic chemicals may be defined specifically as permitted ingredients and food additives or processing aids may fall in the category. Hence, India proposes to modify it as proteins (other than mentioned in the label) and inorganic chemicals (other than permitted food additive and processing aids).

JAPAN

Japan appreciates the efforts of New Zealand and the Netherlands as the chairs of the electronic working group on the “Proposed Draft Guidelines for Risk Analysis of Chemicals Inadvertently Present in Food at Low Levels” and the opportunity to submit the following comments on in response to CL 2018/8-CF.

Definition of an emerging contaminant

Japan proposes to make the definition simpler marked as tracked change as follows:

Emerging contaminant

- A contaminant in the food ~~under investigation~~, which is a novel or recently emerged occurrence, ~~and or~~ has not previously reported or anticipated to ~~enter the food chain be detected at the time of regulatory consideration of prior uses~~; and,
- For which there is no ~~quantitative level or guideline for food safety~~ risk management established in Codex, ~~or for~~ an individual country, ~~or a regional or national food standard informed by toxicological assessment~~.

Using a cut-off value as an initial risk management step

Japan considers that application of a cut-off value according to each TTC class may not be appropriate as an initial risk management step for emerging contaminants in food because contaminants may have different toxicity levels and foods containing the contaminants may be consumed at significantly different levels in different countries / regions.

We are of the view that use of a cut-off value for risk management of emerging contaminants should be considered after scientific consideration by JECFA or FAO/WHO consultations. This process would facilitate smoother discussions of the Guidelines by the CCCF.

Using an internationally agreed rapid risk assessment methodology

If there is an internationally agreed rapid risk assessment methodology with proven benefit on risk analysis of emerging contaminants, Japan can support its use. However, if it is not available at this stage, Japan thinks that it is premature to elaborate the Guidelines pending the outcomes of JECFA or FAO/WHO consultation.

Excluding feed from the Guidelines

Japan supports exclusion of feed from the scope of the Guidelines although contaminants in feed for food producing animals are included in the Codex definition of the term contaminant. A risk management decision tree for feed safety will be more complex than food safety because contaminants in feed are related not only to animal health but also to safety of foods of animal origin.

As experiences on the use of Guidelines on food safety accumulate, CCCF may revisit the issue of inclusion of feed.

Scientific advice from JECFA

Japan supports that the CCCF seeks scientific advice from expert committees such as JECFA or FAO/WHO consultations on a use of cut-off values and rapid risk assessment methodologies.

Japan thinks that it is premature to elaborate the Guidelines pending the outcome of the expert committees.

Information sharing

Whatever the emerging contaminants may be, risk managements taken by Codex members under given situation would be provisional / preliminary. Japan is of the view that risk management experiences of such contaminants by each country are invaluable sources of information for developing these Guidelines in Codex or risk management in Member countries.

KENYA

Kenya would like to thank the EWG led by New Zealand and the Netherlands for preparing this document to be circulated to members for comment

We propose the following definition.

Definition of emerging contaminants: A chemical that is not anticipated in a food in question may be present at a detectable concentration or a chemical that is known and regulated in another food is found in a food in question at a detectable concentration.

4. DEFINITIONS

These definitions should be read in conjunction with the definitions for risk analysis in the “Codex Procedural Manual, latest edition”.

For the purposes of this document, and falling within the broader definition for contaminants within the procedural manual:

Emerging contaminant

- A contaminant in the food under investigation, which **is a novel** or recently emerged occurrence, or has not previously reported or anticipated to be detected at the time of regulatory consideration of prior uses; and,
- For which there is no quantitative level or guideline for risk management established in Codex, or for **an individual country, a regional or national food standard informed by** toxicological assessment.

Rapid evaluation method

- A risk assessment methodology for provision of scientific advice within a limited time period, that informs a food safety risk management decision on a specific lot or consignment of food.

COMMENT ON DEFINITION

The first bullet is more clear than the second bullet so we prefer bullet.

It is a chemical that is not anticipated in food but may not be detected in the food and that chemical might be known in another food and detected. It can also be a chemical that is known but not known to occur in food.

REPUBLIC OF KOREA

The Republic of Korea agrees with the following recommendations proposed by the EWG.

- Use of an internationally agreed rapid risk assessment methodology
- Excluding feed from the proposed draft guidelines
- Seeking scientific advice from JECFA for establishing appropriate cut-off values and identifying an internationally agreed rapid risk assessment methodology

We also suggest to add a definition of “cut-off value” in the guidance to help governments to clearly understand the meaning of the term.

UNITED STATES OF AMERICA (USA)

The U.S. appreciates the work that New Zealand and The Netherlands have done in preparing the draft guidelines for risk analysis of chemical inadvertently present in food at low levels and submits the following comments.

The U.S. supports the development of the proposed draft Guidelines in principle and provided technical edits and comments on the first EWG draft. We also support requesting JECFA for further advice on the cutoff values and a potential role in identifying and reviewing harmonized approaches, as discussed in the document.

We further support continued work on the document for the next session of CCCF to allow time for JECFA to provide its advice, and to further develop the Decision Tree (Annex 1 of Appendix I) and internationally-recognized rapid evaluation methodologies and their suitability in the context of these guidelines (Annex 3 of Appendix I).

FOODDRINKEUROPE

FoodDrinkEurope would like to thank you for the opportunity to offer comment on the draft guidelines as proposed (Annex 1).

Please find below a short summary of our feedback, and we remain at your disposal should anything further be required.

- In case of chapter 7 (reporting of detection(s)) it is said that “the officially recognized laboratory may provide a scientific/technical opinion on possible source(s) of the chemical substance detected”. However, it may be that several groups, and not just an official laboratory (e.g. EU reference laboratory), would know about the possible sources/entries of a new substance in food, for e.g. the food business operators, the authorities and research institutions, etc.

- With regard to possible sources, FoodDrinkEurope believes that a “scientific/technical opinion” is always needed. Perhaps the proposed wording could change from “scientific/technical opinion” to “report”. This report then might be delivered e.g. by food business operators, research institutions, authorities etc.
- In case of chapter 10 it is said that risk communication should address to “consumers and other stakeholders”. Risk communication should also address food business operators as it is essential that FBOs know about the risks and how to communicate them. Thus, the proposed wording could change from “consumers and other stakeholders” into “food business operators, consumers and other stakeholders”.
- In the case of chapter 3, FoodDrinkEurope believes that the scope of the document should cover low levels of detergents and sanitisers in food within its guidelines. Therefore, the “Scope” should read: “(ii) *Emerging contaminants **from materials and/or compounds used during processing of food or food hygiene**: e.g. **process-formed contaminants**, non-regulated packaging materials and printing inks, **traces of chemicals (sanitizers, surfactants) that are used for food hygiene, oils/lubricants/resins used as manufacturing maintenance compounds**”*

INTERNATIONAL COUNCY OF GROCERY MANUFACTURERS ASSOCIATIONS (ICGMA)

General comments

ICGMA supports the objectives of the electronic Working Group on the development of guidelines for risk analysis of chemicals inadvertently present in food. This work has a significant potential for developing a scientific process that ensures consumer safety at the same time that it reduces impact to trade of the detection of low levels of substances that are unlikely to have adverse effects on human health.

In order to maximize the value of the guideline that is being developed, the scope of substances that would be subject to the guideline cannot be overly restrictive. This would result in a guideline that would be scientifically sound, but because of a restrictive scope, there would never be a practical application of the guideline. The examples provided in the scope of the draft guideline (Section 3) include chemicals that are both readily avoidable (chemicals that are intentionally added at some point in the supply chain, such as agricultural contaminants, printing inks, and lubricants) and not readily avoidable (chemicals that are not intentionally added such as natural toxins, environmental contaminants, and process-generated contaminants). We agree with the chairs that to maximize the value of this guideline it will be important to include both readily avoidable and not readily avoidable compounds, as we believe the scientific principles used to evaluate risk are universally applicable.

ICGMA would like to thank the eWG for taking the above comments into consideration and welcomes the opportunity to provide further clarification on specific issues flagged within the draft document. ICGMA would also like to thank the chairs of the eWG for their extensive work on preparing the draft discussion paper and looks forward to discussing the issue further.

Specific Comments

Below are ICGMA’s comments on the recommendations to CCCF called out in paragraph 18 in the latest draft COP:

Definition of emerging contaminant

We believe that excluding from scope any substance that has a “guideline for risk management” could be interpreted very narrowly, unnecessarily excluding chemicals that are covered by general guidelines (such as Good Manufacturing Practices) that do not have quantitative levels defined. These cases would still greatly benefit from this guideline, as a lack of a quantitative value for the detection of these chemicals still results in the same challenges.

Additionally, we agree with the recommendation that the implementation of the guideline at the local level should take into consideration National food standards. Establishing standards and guidelines that can be used as a basis for developing National regulations is a key principle of the Codex process. Therefore, we do not feel that it is necessary to specifically call out that the guideline would apply at both the Codex and National level. Inclusion of this language could result in confusion about whether this would be interpreted as a need for the risk assessment/management process to survey all National regulations before determining whether a substance is in scope, rather than referring only to their own National regulations.

Use of a cut-off value as an initial risk management step

The inclusion of a “cut-off level” is a scientifically-supported and pragmatic risk assessment approach. This approach is consistent with the aspects of the scientific concept of the Threshold of Toxicological Concern (Kroes et al. 2000, Koster et al. 2011, EFSA 2012) and a regulatory concept known as the Threshold of Regulation (TOR). TOR is utilized in the United States to provide for health protective risk management concept to address the migration of constituents from food contact materials (US Code of Federal Regulations 21 CFR 170.39 and Shanklin and Cahill, 2009).

Internationally agreed rapid risk assessment methodology is used

The use of Structure Activity Relationships and TTC for rapid evaluation for non-regulated chemicals that lack a robust safety data set is appropriate.

Feed is excluded from the proposed risk guidelines

While ICGMA is supportive of the inclusion of feed in the development of these guidelines, we believe that the inclusion of feed may delay the development of these guidelines because its inclusion would mean that there would be a need to consider potential animal health impacts for all relevant species and age groups that might consume feed. If feed is included, a separate process to prioritize select animal species (e.g. those most frequently consumed) may have to be developed to make the development of the guidelines manageable.

Below are ICGMA's comments on the recommendations to CCCF in paragraph 19 that the Committee should seek advice from JECFA on the following:

The role of JECFA in identifying and reviewing an internationally agreed rapid risk assessment methodology

As mentioned above, the use of Structure Activity Relationships and TTC for rapid evaluation for non-regulated chemicals that lack robust safety data is appropriate. JECFA already employs these sound scientific concepts, and they form the basis for the JECFA Procedure for the Safety Evaluation of Flavoring Agents.

ICGMA Comments on Section 3: Scope

In addition to the proposed changes listed below, we also believe that it would be important to align with other Codex committees to ensure that all opportunities are considered. This would include providing a reference to the Codex Committee on Pesticide Residues (CCPR), Codes Committee on Food Hygiene (CCFH), and Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).

Therefore, we recommend that CCCF provide a reference to CCPR, CCFH, and CCRVDF to ask provide an opportunity for these committees to comment as to whether there are additional chemicals or classes of chemicals that this guidance could be applied to, further enhancing the value of creating the guidance.

Proposed Changes

We propose the following changes to Section 3 to provide additional clarity to *natural toxins* (which could entail proteins) as well as the types of chemicals that would be in scope for this guideline.

The following groups of chemicals provide examples:

- (i) agricultural contaminants e.g. chemicals used in agriculture to address specific environmental and climate change-related issues such as nitrification and urease inhibitors, which have not been anticipated to inadvertently be detected in food**
- (ii) Emerging process contaminants e.g. process-formed contaminants (Acrylamide, Furan), non-regulated packaging materials and printing inks, sanitizers/cleansers that remain at trace amounts on manufacturing equipment, oils/lubricants/resins used as manufacturing maintenance compounds which have not been anticipated to inadvertently be detected in food**
- (iii) Emerging natural toxins (**non-proteins**) with an initial and/or occasional detection e.g. newly characterised mycotoxins or food crop phytotoxins**
- (iv) Environmental contaminants e.g. corrosion inhibitors, perchlorate, metals, flame retardants and musks/fragrances which have not been anticipated to inadvertently be detected in food**

Chemicals identified to have a role in economic adulteration of food, and present at a level reflective of adulteration, are not covered by these guidelines.

INTERNATIONAL DAIRY FEDERATION (IDF)

IDF supports conclusions made by the eWG and agrees with the proposed recommendations as a way forward.

P6, 3. SCOPE

In its comments to the eWG, IDF had requested to include **process contaminants** (acrylamide, furans) and **residues of detergents and sanitisers** within the scope of these guidelines. So, that the point (ii) of the Chapter 3 “Scope” reads:

(ii) *Emerging contaminants **from materials and/or compounds used during processing of food**, e.g. **process-formed contaminants**, non-regulated packaging materials and printing inks, **traces of chemicals (sanitizers, surfactants) that are used for food hygiene purposes**, oils/lubricants/resins used as manufacturing maintenance compounds*

P6, 5. PRINCIPLES

As indicated in IDF submission to the EWG, point d should read:

*d. Where there is a ~~detection~~ **verified presence** of an emerging contaminant in a traded consignment the competent authority in the exporting country should be notified and any relevant food safety information **and analytical data** shared.*

Besides, we suggest for inclusion in the Annex 2 “Case Studies” of the Guidelines the following publications which we believe may enhance the focus on the traces of chemicals used for food hygiene purposes:

- **The proposal to add a nonylphenol ethoxylates (NPEs) category to the list of toxic chemicals subject to reporting under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) and section 6607 of the Pollution Prevention Act (PPA).**

https://members.wto.org/crnattachments/2016/TBT/USA/16_4763_00_e.pdf

- **American Dairy Products Institute (ADPI)** – recommendation to phase this class of detergents out https://www.adpi.org/Portals/0/Academy/Intel%20and%20Commentaries/NP%E2%80%99s%20and%20NPE%E2%80%99s_Another%20Concern%20for%20the%20Industry%20TECHNICAL%20BRIEF.pdf
- **Health assessment of didecyldimethylammonium chloride (DDAC) residues in food**
<http://www.bfr.bund.de/cm/349/health-assessment-of-didecyldimethylammonium-chloride-ddac-residues-in-food.pdf>

INTERNATIONAL ORGANIZATION OF THE FLAVOR INDUSTRY (IOFI)

1. The International Organization of the Flavor Industry (IOFI) appreciates the opportunity to provide comments in response to CL 2018/8-CF, regarding the ‘Proposed Draft Guidelines for Rapid Risk Analysis of Emerging Contaminants in Food’ (Appendix I of CX/CF 18/12/12).
2. IOFI wishes to make a remark on point (iv) in 3. SCOPE of the “Draft Guidelines” which provides examples of environmental contaminants, one of the entries relating to ‘musks/fragrances’.
3. The term musks actually covers a broad range of up to 40 synthetic chemicals having a ‘musky’ odour profile. Some of these chemicals have been widely used as perfume fixative in a variety of consumer products, including laundry and home care detergents. Musk xylene, which was widely used in cosmetic and detergent applications, was found a very persistent and bio-accumulative pollutant in the aquatic environment (a so-called vPvB substance) and is now considered a substance of very high concern under the European Union REACH regulation.
4. Other musks typically do NOT feature a comparable environmental issue. Hence, referring in general to ‘musks/fragrances’ in 3. SCOPE (iv) is inappropriate.
5. IOFI recommends replacing ‘musks/fragrances’ by ‘musk xylene’ as follows:

3. SCOPE [...] The following examples are groups of chemicals that would be considered emerging contaminants if present in food:

[..]

(iv) Environmental contaminants e.g. corrosion inhibitors, flame retardants and **musk xylene**

INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

ISDI welcomes the opportunity to comment on the Proposed draft Guidelines for risk analysis of chemicals inadvertently present in food at low levels as prepared by the CCCF electronic working group led by New Zealand and The Netherlands.

ISDI comment on SCOPE of the draft Guidelines (section 3)

ISDI supports the development of guidelines for risk analysis of chemicals inadvertently present in food. This work has a significant potential for developing a scientific process that ensures consumer safety while reducing the impact to trade of the detection of low levels of substances that are unlikely to have adverse effects on human health. Codex already has numerous standards and guidelines governing risk management for many substance. However, in order to maximize the value of this new guideline, the scope should not be overly restrictive.

Thus, ISDI supports continued discussion of the scope of this guidance, including examples such as sanitizers and cleansers, in order for this effort to return value to Codex members