



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

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PROPOSED DRAFT GUIDELINES FOR RISK ANALYSIS OF CHEMICALS
INADVERTENTLY PRESENT IN FOOD AT LOW LEVELS

Comments for the JECFA Secretariat on the report of the Electronic Working Group (EWG) on the development of the proposed draft Guidelines for risk analysis of emerging contaminants in food

General remarks:

There appears to be a general confusion between the concepts of cut-off values and TTC thresholds.

A generic cut-off value as discussed in the text and proposed in the decision tree under step 2 is based on occurrence and typically expressed as mg of contaminant/kg of food.

The TTC values are human dietary exposure thresholds, and they are expressed typically as mg/kg body weight (or mg/person). TTC exposure thresholds have been derived for different classes of chemical structures. Exclusion categories have been identified for the TTC concept based on either toxicological criteria (e.g. substances that bioaccumulate are excluded from consideration by the TTC approach) or based on the fact that certain types of compounds (e.g. proteins) are simply not covered in the databases underlying the TTC thresholds. For some further explanation, please see the Annex of this document.

Q3: *If a cut-off level is an agreed decision step how do we derive it? (possible request for advice from FAO/WHO).*

Conclusion *The setting of cut off values from the TTC classes is widely supported, however in support of this it is also proposed to request advice from JECFA on establishment criteria for a cut off value, noting that further work on the TTC databases is being undertaken in 2018. It is proposed that the specific request for advice can be agreed upon at the pre-plenary informal consultation immediately prior to CCCF12.*

Remarks from the FAO/WHO JECFA Secretariats:

We recognize the utility of a cut-off values in this context as a measure that can aid risk managers in their decision making processes. However, the very nature of the proposed threshold as a guidance instrument to discern whether further risk assessments are desirable constitutes a risk management decision. We believe that the level of such a threshold is therefore first and foremost a risk management decision rather than a question for risk assessors. It may be very difficult if not impossible to justify a generic concentration threshold based on scientific and human health criteria.

Q4: *Should these guidelines provide for a harmonized methodology(s) (TTC or other; or combination) to perform a rapid evaluation (e.g. by provision of appendices)? If a harmonized approach is desirable, should JECFA (or other risk assessment bodies) play a role in identifying and reviewing harmonized approaches?*

Conclusion *A harmonized methodology is supported. It is proposed that JECFA be asked for advice as to their potential role in identifying and reviewing harmonized approaches. It is proposed that the specific request for advice can be agreed upon at the pre-plenary workshop for CCCF12.*

Remarks from the FAO/WHO JECFA Secretariats:

This question is unclear in scope and goal. The EWG did not identify any harmonized approaches that would lend itself for a consideration by JECFA with the exception of the TTC approach. The latter already being applied by JECFA (and JMPR). A rapid or abbreviated risk assessment requires the a-priori definition of boundaries (such as inclusion and exclusion criteria) and assumptions for example with regard to the risk levels that are presumed to be acceptable by risk managers. In the case of Codex, such a framework of boundaries and assumptions would need to be developed and accepted by the international community to lend the necessary credibility and acceptability of the outcome of any rapid assessment. Once such a risk management framework is set, suitable risk assessments schemes that match the desired boundaries might be developed.

We would suggest to consider adding a suitable definition of desired level of protection or acceptable risk levels and associated boundaries to such a request.

Q6: Should feed be included within the scope of the guidelines?

Conclusion As the identified risk assessment methodologies are essentially designed for human risk assessment, at this stage feed should not be included. At the point where risk assessment methodologies are demonstrated as appropriate to be extrapolated to livestock the guidelines could be expanded to allow application to feed. There may however be value in considering extrapolation of any cut-off values to feed and this can be included within the request for advice from JECFA.

Remarks from the FAO/WHO JECFA Secretariats:

Given our remarks above, and considering that this eWG itself proposed to NOT include feed at this time, we would consider that any request for scientific advice from JECFA is premature related to this topics until all other questions are resolved.

Proposed scope and definition

Remarks from the FAO/WHO JECFA Secretariats

In our understanding, this guideline aims at aiding risk managers in their decision-making processes during situations where a substance is detected at low levels in food that is not covered by any suitable regulatory framework (e.g., guidance or legislation at the international or national level).

In this context it appears unnecessary to add the concept of a new or unknown contaminant. We believe that at its core, this paper simply attempts to provide guidance in situation where no other regulatory framework is applicable, irrespective of whether this substance has been known or not. If the above matches the intentions of the authors we would suggest to limit the scope and the definition to:

Substances that may be found at low-levels in food for which no regulatory framework applies

Doing so may simplify the text further and avoid the potential need to define the term “new” or ‘emerging’.

Additional language might be helpful that specifies that in the case the substance is more frequently detected, more specific risk management measures may need to be invoked.

Some additional specific comments from the FAO/WHO JECFA secretariat on the current draft text:

5. PRINCIPLES

f. we suggest to include here that any rapid risk assessment needs to be documented in detail.

h. We suggest to specify that in the case of continuing detections of an emerging contaminant in food, targeted surveillance activities should take place to determine the extent of potential human exposure and to identify the potential source of contamination (in the text the word exposure in this context should be replaced by the word contamination).

8.7. Rapid evaluation:

There are several inaccuracies in this text, e.g. the TTC method cannot be used to obtain a hazard characterization value. This text needs to be corrected and clarified once a final decision tree has been agreed upon.

ANNEX: Short explanation on Threshold of Toxicological Concern (TTC) Concept

In light of ever improving methods in analytic chemistry, more and more chemicals will be detected at low levels in our environment, food and drinking water leading to new questions about the consequence of human exposure to these substances. To allow for a health risk assessment of these newly determined exposures in light of insufficient chemical-specific data, methods need to be developed to estimate the potential human health impact and to make informed risk management decisions.

The Threshold of Toxicological Concern (TTC) is a science-based pragmatic tool for prioritizing those chemicals with low-level exposures that require more data over those that can be presumed to present no appreciable human health risk. Overall the TTC approach integrates data on exposure, chemical structure, metabolism, and toxicity consistent with chemical risk assessment principles.

A successful application of the TTC approach requires the knowledge of two distinct pieces of information:

- It is necessary to know the chemical structure of the substance concerned
- Information on human exposure is required to an extent that the data available result in sufficient confidence that the exposure is not underestimated.

The TTC approach then utilises generic human exposure threshold values (also called TTC values) that have been established for substances grouped according to their chemical structure and likelihood of toxicity. The following human exposure threshold values have been proposed, that have been developed based on data from extensive toxicological testing in animals, covering both cancer and non-cancer endpoints:

Type of TTC value	TTC value in µg/person per day	TTC value in µg/kg bw per day
With structural alert for genotoxicity	0.15	0.0025
OPs and carbamates	18	0.3
Cramer Class III	90	1.5
Cramer Class II	540	9.0
Cramer Class I	1800	30

If the newly determined exposure of a chemical does not exceed the corresponding TTC value, the exposure is presumed to not cause any appreciable health risk. Otherwise, a full risk assessment is necessary to determine the extent of any possible public health concern.