CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 3 **CX/CF 16/10/3**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Tenth Session
Rotterdam, The Netherlands, 4 – 8 April 2016

MATTERS OF INTEREST ARISING FROM FAO AND WHO (INCLUDING JECFA)

1. This document provides information on FAO and WHO activities in the area of provision of scientific advice to Codex and Member countries, as well as other activities which are of interest to the Committee on Contaminants in Foods.

Joint FAO/WHO Expert Committee on Food Additives (JECFA)

2. Since the last session of CCCF (March 2015), two JECFA meetings (i.e. JECFA 80th and 81st) have been convened. These meeting addressed food additives, and two groups of contaminants: non-dioxin-like PCBs and pyrrolizidine alkaloids (JECFA 80th), and veterinary drug residues (JECFA 81th). The summary reports of these meetings have been published and full reports and detailed monographs from these meetings are/will be available at the relevant FAO and WHO sites:

   FAO: www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/

   WHO: www.who.int/foodsafety/publications/jecfa/en/

3. At its 80th meeting, JECFA considered non-dioxin-like polycholorinated biphenyls (NDL-PCBs) and pyrrolizidine alkaloids (PAs). For NDL-PCBs, six NDL-PCBs, often called “indicator PCBs” (i.e. PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180) were used for the evaluation as there were sufficient data available for the evaluation. Other NDL-PCBs were also considered where adequate data were available to make a risk characteri.tion, as in the case of PCB 128. None of the available studies on the six indicator PCBs and PCB 128 was suitable for derivation of health-based guidance values, or for the assessment of the relative potency of the NDL-PCBs compared with a reference compound. Therefore, a comparative approach using the minimal effect doses was developed in order to estimate Margin of Exposure (MOE) to provide guidance on human health risk.

4. National estimates of dietary exposure to the sum of the six indicator PCBs ranged, for mean exposure, from <1 to 82 ng/kg bw per day and, for high percentile exposure, from <1 to 163 ng/kg bw per day. International estimates based on Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (GEMS/Food) consumption cluster diets are in the same range. For the sum of the six indicator PCBs, the contribution of each of the individual congeners differs between countries and population groups. However, for both dietary exposure and body burden estimates (which also take into consideration kinetics and half-lives), the main contributor is PCB 153, followed by PCB 180, then PCB 101 and PCB 28, with the lowest contribution from PCB 52.

5. Owing to the long half-lives and to eliminate interspecies differences in toxicokinetics, the Committee considered it appropriate to estimate body burdens rather than using external dose (dietary exposure) for the risk characteri.tion using the MOE approach. MOEs for adults range from 4.5 to 5000. MOEs for breastfed infants, which may have a body burden up to 2-fold higher than that of adults, would be approximately half of the adult values. The MOEs for children would be expected to be intermediate between those for adults and those for breastfed infants, owing to the initial contribution from breastfeeding and the subsequent lower dietary contribution compared with human milk.

6. Because the MOEs are based on minimal effect doses, they were considered to give some assurance that dietary exposures to NDL-PCBs are unlikely to be of health concern for adults and children, based on the available data.

7. For PAs, the Committee undertook a new approach for this evaluation following the principles of a systematic review. A systematic review protocol was developed, with six defined research questions that were used for the literature search in selected databases, resulting in more than 10000 relevant references. Due to time-constraints the evaluation could not be finalized, but sufficient data were reviewed to agree on an approach and reach the following preliminary conclusions:

    - Rats are the most sensitive species, and the liver is the most sensitive target organ.
    - The genotoxic mode of action does not allow derivation of a health-based guidance value for chronic toxicity.
    - Of the two long-term carcinogenicity studies, one on lasiocarpine and one on riddelliine, the Committee considered the study on riddelliine more appropriate for dose–response modelling, and a benchmark dose for a 10% response (BMDL10) of 182 µg/kg bw per day for liver haemangiosarcoma in female rats treated with riddelliine was used as the point of departure in an MOE approach.
    - Dietary exposures were estimated based on limited data for exposure to PAs through honey and tea consumption, for adults and children.
    - The calculated MOEs for adult high consumers of tea and honey and for average tea consumption by children indicated a concern.
    - Available data are not sufficient to identify relative potency factors for different 1,2-unsaturated PAs in order to evaluate the possible effects of combined exposure.
    - Acute toxicity is of concern, and data, in particular human case reports, will be reviewed in detail for their potential use in the derivation of dose levels of concern.

8. The evaluation of PAs is currently being finalized and will be published at later time point.

9. Future meetings:

    The 82nd meeting of JECFA will be held on 7 - 16 June 2016 in Geneva, Switzerland, the meeting is dedicated to the evaluation of a number of food additives and flavouring agents. The 83rd meeting of JECFA will be held 8-17 November 2016 and will be dedicated to contaminants, the call for data is available from the respective JECFA websites:

    http://www.fao.org/3/a-bc465e.pdf

    http://www.who.int/foodsafety/JECFA83.pdf?ua=1

    Requests for scientific advice

10. Both organi.tions continue to jointly prioritise the requests for scientific advice taking into consideration the criteria proposed by Codex as well as the requests for advice from Member Countries and the availability of resources. A list of all pending requests for scientific advice by JECFA will be posted on the respective FAO and WHO websites.

11. In scheduling the JECFA meetings and developing the agenda, the Joint Secretaries have to take into account the priorities requested by the Committees on Food Additives, Contaminants in Foods and Residues of Veterinary Drugs in Foods. Due to the increasing requests for scientific advice to JECFA, not all requests can be addressed in the subsequent meeting. In prioritizing the work the JECFA Secretariat takes into account existing criteria, on-going Codex work and available resources.

12. To facilitate provision of extra-budgetary resources for scientific advice activities, please contact Dr Markus Lipp, FAO Food Safety and Quality Unit (jecfa@fao.org) and Dr Angelika Tritscher, Department of Food Safety and Zoonoses, WHO (jecfa@who.int).

    GEMS/Food programme

13. FAO and WHO encourage Member States to submit analytical data intended to be used by Codex Committees and working groups through the GEMS/Food contaminant database (https://extranet.who.int/gemsfood/).

14. GEMS/Food contaminant database is a web-based platform to allow the submission of data on food contamination from different countries and institutions. As one of the major user of occurrence data for chemicals in food, a restricted access can be provided upon request to CCCF working group leaders to extract data submitted. A guidance document is available for CCCF on how to extract and how to analyze the data in a consistent way. A distance-learning tool is under development to improve the use of the GEMS/Food system.

15. A dashboard enables other users to select a particular contaminant from the GEMS/Food contaminants database and view the average levels of detection by commodity, the total number of samples and the percentage of commodities that make up the total. User may also filter the results by food name, food origin and WHO Region. Data displayed on this dashboard are mean-lower bound for individual results.

https://extranet.who.int/sree/Reports?op=vs&path=/WHO_HQ_Reports/G7/PROD/EXT/GEMS_contaminants

16. A call for data to support the work of JECFA on contaminants and for other FAO/WHO scientific advice activities was published and is available here: http://www.who.int/foodsafety/call_for_data_2016.pdf?ua=1

Global Food Consumption Database

17. FAO and WHO have commenced new work to collate available sex and age disaggregated food consumption data collected at individual level to make this information readily accessible, and easily referenced and cross linked to other existing global databases e.g. FAOSTAT, GEMS Cluster Diets. The Database will serve three main end uses: 1) assess dietary exposure to chemicals and biological agents; 2) assess nutrient intake to inform agriculture and nutrition policies and programmes; 3) assess the environmental impact of food consumption patterns. In that context a two-year project supported by the Codex Trust Fund was launch in 2016 to harmonize the collection of food consumption data in ASEAN countries and to integrate them into the FAO/WHO database.

18. Improved exposure data at country level will be useful to a range of Codex Committees (contaminants in food, fish and fishery products, food additives among others) in setting MLs or developing other risk management recommendations, including codes of practice. This database will have additional uses in developing national nutrition and food safety policies and decisions.

Total Diet Study as a tool to assess food chemical contamination

19. The regional Total Diet Study (TDS) to assess food chemical contamination in sub- Saharan Africa, supported by STDF and involving 4 countries i.e. Benin, Cameroon, Mali and Nigeria, is ongoing. Another proposal for a regional total diet study, supported by FAO and WHO, was submitted to STDF by 7 countries in Latin America and Caribbean.

WHO estimates of the Global Burden of Foodborne Diseases

20. WHO has launched the report on estimating the global burden of foodborne diseases in December 2015. Resulting from the WHO Initiative to Estimate the Global Burden of Foodborne Diseases, the report provides the first estimates of global foodborne disease incidence, mortality, and disease burden in terms of Disability Adjusted Life Years (DALYs). For the global estimates, 31 ha.rds (bacteria, viruses, parasites, toxins and chemicals), of which 3 were chemicals, were included. Some of the major findings are: almost 1 in 10 people fall ill every year from eating contaminated food and 420,000 die as a result; children under 5 years of age are at particularly high risk, with 125000 children dying from foodborne diseases every year; diarrhoeal disease are responsible for more than half of the global burden of foodborne diseases; aflatoxins are one of the major contributors to the total estimated disease burden in the African region. Disease burden estimates for heavy metals are still being finalized. The risk of foodborne diseases is most severe in low- and middle-income countries, linked to preparing food with unsafe water; poor hygiene and inadequate conditions in food production and storage

21. More information is available from the dedicated website, including all background publication and an on-line tool for detailed view of the project for all sub-regions: http://www.who.int/foodsafety/areas_work/foodborne-diseases/ferg/en/

Threshold of Toxicological Concern Approach (TTC)

22. WHO in collaboration with the European Food Safety Authority, and support by the US-FDA, have initiated a project to provide recommendations on how the existing threshold of toxicological concern (TTC) framework can be updated and extended, taking new scientific developments and ongoing work in this area into account. The overall goal of the project is to develop a globally harmonized decision tree for a tiered approach on the application of the TTC in the risk assessment of chemicals.

23. The Threshold of Toxicological Concern (TTC) is a methodology that may be used to assess potential human health concerns for a chemical based on its structural chemical characteristics and estimated exposure, when chemical-specific toxicity data are scarce or absent. It is a pragmatic, scientifically-valid approach for the safety evaluation of chemicals with relatively low oral exposure and limited chemical-specific data.

24. In light of ever improving methods in analytical chemistry, it can be expected that more unintended chemicals will be detected in food and drinking water. In order to evaluate the potential health concern, the TTC can serve as important screening tool to identify those compounds which may be of concern and require further data.

25. EFSA and WHO convened an expert consultation in December 2014, preceded by an open stakeholder meeting, to review the underlying science, update the methodology as appropriate and develop a decision tree for the application of the TTC. The conclusions and recommendations of this workshop had been made available for public comments, and the final report will be published in the first quarter of 2016, which includes a set of recommendations and a proposed decision tree.

26. Further discussions are now required between risk assessors and risk managers to agree on the application of this additional risk assessment tool and the consequences for risk management.

Toxicity Equivalency Factors (TEF) for marine toxins

27. The Committee on Fish and Fishery Products has developed the Codex standard for live and raw bivalve molluscs (CODEX STAN 292-2008), with provisions for five groups of biotoxins. Each group includes several congeners with different toxic potencies, and in order to be able to assess the total toxicity and to implement the Codex standard, toxic equivalency factor need to be derived for each of the groups. CCFFP requested advice from FAO and WHO in this matter.

28. FAO/WHO organize an expert meeting 22-24 February 2016 to discuss the issues associated with development of TEFs for marine biotoxins, and report on the state of science on the subject, including identification of areas where further research is need, and provides guidance for food safety managers to implement the Codex standard on live and raw bivalve molluscs at national level.

29. The outcome of the meeting will be published and reported to CCFFP.