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CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 3a **CX/CF 11/5/3**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

5th Session
The Hague, The Netherlands, 21 – 25 March 2011

MATTERS OF INTEREST ARISING FROM FAO AND WHO AND FROM THE 73RD MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (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 for CCCF.

Matters for information and action from the 73rd meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

2. The results of the 73rd meeting of JECFA on food additives and contaminants in food are available in the summary report at the FAO and WHO JECFA websites: (http://www.fao.org/ag/agn/agns/jecfa/JECFA73%20Summary%20Report%20Final.pdf and http://www.who.int/foodsafety/publications/chem/summary73.pdf). The meeting report (WHO Technical Report Series 960, 2011) and the detailed toxicological monographs (WHO FAS 64, 2011) will become available in due course and will be accessible through the WHO JECFA website: http://www.who.int/ipcs/publications/jecfa/en/index.html. The CCCF is invited to consider the scientific advice and the specific recommendations of JECFA regarding the re-evaluations requested for cadmium and lead, the summaries of which are presented in Appendix 1.

Provision of Scientific Advice from FAO and WHO

Principles and Methods for Risk Assessment of Chemicals in Food

3. FAO and WHO have finalised the project to update the principles and methods for risk assessment of chemical in food, including food additives, contaminants and natural toxins, residues of veterinary drugs and pesticides. The document is published as the Environmental Health Criteria No 240 and is available on the web at this site: http://www.who.int/ipcs/food/principles/en/index1.html .

Joint FAO/WHO Expert meeting to review toxicological and health aspects of Bisphenol A

4. In the light of uncertainties about the possibility of adverse human health effects at low doses of Bisphenol A, especially on reproduction, the nervous system and on behavioural development, and considering the relatively higher exposure of very young children compared with adults, FAO and WHO have jointly organised, supported by Health Canada, the National Institute of Environmental Health Sciences, the US-FDA and by EFSA, an ad hoc expert meeting to assess all aspects related to the safety of Bisphenol A for human health. The meeting was held 2-5 November 2010 in Ottawa, Canada, and was preceded by a stakeholder meeting. A detailed summary report has been published and the final report is in preparation. The summary report is available at the FAO and WHO websites at: http://www.fao.org/ag/agn/agns/chemicals_en.asp and http://www.who.int/foodsafety/chem/chemicals/bisphenol/en/ .

Activities in the field of nanotechnology in food and agriculture sectors

5. FAO has implemented, together with CAPES and the Ministry of Agriculture of Brazil (EMBRAPA), a conference on Nanotechnology in the food and agriculture sectors in San Carlos, Brazil, 20 - 25 June 2010. New and emerging applications of nanotechnologies in food and agriculture and issues related to their use were the focus of this Conference. In addition to exploring relevant scientific and technological advances, the

Conference also highlighted areas of research with the greatest potential to benefit society. A report summarizing the discussion and recommendations from several round table discussion forums will be made available shortly. For more information, visit www.nanoagri2010.com or contact food-quality@fao.org .

6. FAO and WHO will establish an "e-Discussion Group for the Development of a Tiered Approach Diagram for Risk Assessment of Nanomaterials (NMs)". The overall objectives of the group will be to develop a decision tool to support identification of the appropriate risk assessment approach for nanomaterial categories and to review the current risk assessment approaches that are used by FAO/WHO and Codex, in order to address the specific emerging issues associated with the application of nanotechnologies in the food and agriculture sectors. For more information contact FAO (proscad@fao.org) and WHO (foodsafety@who.int).

Global Initiative for Food-related Scientific Advice (GIFSA)

7. GIFSA is a mechanism established by FAO and WHO to facilitate the provision of extrabudgetary resources for scientific advice activities. Resources provided through GIFSA are allocated to activities in an independent and transparent manner, taking into consideration the criteria for prioritization of activities already agreed by Codex, FAO and WHO and the specific needs of FAO and WHO member countries. Contributions, which are accepted from governments, organizations and foundations in accordance with WHO and FAO rules continue to be received. For additional information and advice on the procedure for making a donation/contribution please contact Ms Dominique Di Biase, Policy Assistance and Resources Mobilization Division (Dominique.DiBiase@fao.org; Tel: + 39 06 57055391) at FAO; and Angelika Tritscher, Department of Food Safety, Zoonoses and Foodborne Diseases, WHO (tritschera@who.int Tel: + 41 22 7913569).

8. In addition, FAO has developed a Strategy for the Provision of Scientific Advice for Food Safety (2010–2013) which aims to enhance the provision of scientific advice, facilitate dissemination of scientific information, strengthen national and regional scientific capacity and build scientific communities and networks. The strategy is available at http://www.fao.org/ag/agn/agns/advice_en.asp (English), http://www.fao.org/ag/agn/agns/advice_es.asp (Spanish) and http://www.fao.org/ag/agn/agns/_advice_fr.asp (French) or for more information contact: Mary.Kenny@fao.org.

Other related initiatives underway in FAO and WHO

Establishment of a new program: Emergency Prevention System for Food Safety (EMPRES Food Safety)

9. FAO's recently established Emergency Prevention System for Food Safety (EMPRES Food Safety) is now becoming operational and work will be required on assessment of emerging risks. Effective pooling of scientific excellence will contribute significantly to this effort, thus a new **FAO Food Safety Expert Roster will be established** in 2011. For more information, see Para 17 of Annex II, CX/NASWP 10/11/3 Part 2 (ftp://ftp.fao.org/codex/ccnaswp11/na11_03e_par2.pdf), contact empres-fs@fao.org or visit http://www.fao.org/ag/agn/agns/.

Appendix 1

Contaminants evaluated toxicologically at the 73rd meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

Cadmium

Since cadmium was last considered by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), there have been a number of new epidemiological studies that have reported cadmium-related biomarkers in urine following environmental exposure. The Committee noted that a large meta-analysis of studies that measured the dose–response relationship between the excretion of β_2-microglobulin and cadmium in urine was available. As the apparent half-life of cadmium in human kidneys is about 15 years, steady state would be achieved after 45–60 years of exposure. Therefore, data relating β_2-microglobulin excretion in urine to cadmium excretion in urine for individuals who are 50 years of age and older provided the most reliable basis on which to determine a critical concentration of cadmium in the urine. An analysis of the group mean data from individuals who were 50 years of age and older showed that the urinary excretion of less than 5.24 (confidence interval 4.94–5.57) µg of cadmium per gram creatinine was not associated with an increased excretion of β_2-microglobulin. Higher urinary cadmium levels were associated with a steep increase in β_2-microglobulin excretion.

To determine a corresponding dietary exposure that would result in a urinary cadmium concentration at the breakpoint of 5.24 (confidence interval 4.94–5.57) µg of cadmium per gram creatinine, a one-compartment toxicokinetic model was used. The lower bound of the 5th percentile dietary cadmium exposure (on a population level) that equates to the breakpoint was estimated to be 0.8 µg/kg body weight per day or 25 µg/kg body weight per month.

The Committee noted that the existing health-based guidance value for cadmium was expressed on a weekly basis (provisional tolerable weekly intake, or PTWI), but, owing to cadmium's exceptionally long half-life, considered that a monthly value was more appropriate. **The Committee therefore withdrew the PTWI of 7 µg/kg body weight.**

In view of the long half-life of cadmium, daily ingestion in food has a small or even a negligible effect on overall exposure. In order to assess long- or short-term risks to health due to cadmium exposure, dietary intake should be assessed over months, and tolerable intake should be assessed over a period of at least 1 month. To encourage this view, the Committee decided to express the tolerable intake as a monthly value in the form of a provisional tolerable monthly intake (PTMI). **The Committee established a PTMI of 25 µg/kg body weight.**

The estimates of exposure to cadmium through the diet for all age groups, including consumers with high exposure and subgroups with special dietary habits (e.g. vegetarians), examined by the Committee at this meeting are below the PTMI.

Lead

Exposure to lead is associated with a wide range of effects, including various neurodevelopmental effects, mortality (mainly due to cardiovascular diseases), impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes. For children, the weight of evidence is greatest, and evidence across studies is most consistent, for an association of blood lead levels with impaired neurodevelopment, specifically reduction of intelligence quotient (IQ). Moreover, this effect has generally been associated with lower blood lead concentrations than those associated with the effects observed in other organ systems. For adults, the adverse effect associated with lowest blood lead concentrations for which the weight of evidence is greatest and most consistent is a lead-associated increase in systolic blood pressure. Therefore, the Committee concluded that the effects on neurodevelopment and increase in systolic blood pressure provided the appropriate bases for dose–response analyses.

Based on the dose–response analyses, the Committee estimated that the previously established PTWI of 25 µg/kg body weight is associated with a decrease of at least 3 intelligence quotient (IQ) points in children and an increase in systolic blood pressure of approximately 3 mmHg (0.4 kPa) in adults. While such effects may be insignificant at the individual level, these changes are important when viewed as a shift in the distribution

of IQ or blood pressure within a population. **The Committee therefore concluded that the PTWI could no longer be considered health protective and withdrew it.**

Furthermore, as the dose–response analyses do not provide any indication of a threshold for the key adverse effects of lead, the Committee concluded that it was not possible to establish a new PTWI that would be health protective. The dose–response analyses conducted by the Committee should be used as guidance to identify the magnitude of effect associated with identified levels of dietary lead exposure in different populations.

The mean dietary exposure estimates of children aged about 1–4 years range from 0.03 to 9 µg/kg body weight per day. The health impact at the lower end of this range (0.03 µg/kg body weight per day) is considered negligible by the Committee, because it is below the exposure level of 0.3 µg/kg body weight per day calculated to be associated with a population decrease of 0.5 IQ points. The higher end of the exposure range (9 µg/kg body weight per day) is higher than the level of 1.9 µg/kg body weight per day calculated to be associated with a population decrease of 3 IQ points, which is deemed by the Committee to be of concern. For adults, the mean dietary lead exposure estimates range from 0.02 to 3.0 µg/kg body weight per day. The lower end of this range (0.02 µg/kg body weight per day) was considerably below the exposure level of 1.2 µg/kg body weight per day, calculated by the Committee to be associated with a population increase in systolic blood pressure of 1 mmHg (0.1 kPa). The Committee considered that any health risk that would be expected to occur at this exposure level is negligible. At the higher end of the range (3.0 µg/kg body weight per day), a population increase of approximately 2 mmHg (0.3 kPa) in systolic blood pressure would be expected to occur. In a large meta-analysis, an increase of this magnitude has been associated with modest increases in the risks of ischaemic heart disease and cerebrovascular stroke. The Committee considered this to be of some concern, but less so than that for the neurodevelopmental effects observed in children.

The Committee stressed that these estimates are based on dietary exposure (mainly food) and that other sources of exposure to lead also need to be considered.

The Committee concluded that, in populations with prolonged dietary exposures to lead that are in the higher end of the ranges identified above, measures should be taken to identify major contributing sources, including foods, and to identify methods of reducing dietary exposure, if appropriate.