codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 3 **CX/FA 08/40/3**

February 2008

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fortieth Session

Beijing, China, 21 – 25 April 2008

MATTERS OF INTEREST ARISING FROM FAO AND WHO AND FROM THE 68TH 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 CCFA.

2. The results of the 68th meeting of JECFA on food additives and contaminants are available in the summary report[1]. The meeting report (WHO Technical Report Series No 947, 2008) and the toxicological monographs (WHO FAS 59, 2008) 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 specifications monographs (FAO JECFA Monographs 4, 2007) are available at the FAO JECFA website: http://www.fao.org/docrep/010/a1447e/a1447e00.htm). In addition, all specifications monographs for food additives and flavouring agents are available in the updated on-line editions of the respective databases at the FAO JECFA website: http://www.fao.org/ag/agn/jecfa-additives/search.html and http://www.fao.org/ag/agn/jecfa-flav/search.html.

Exposure assessment of flavouring agents

3. JECFA employs the maximized survey-derived intake (MSDI) method as a measure of dietary exposure for use in the Procedure for the Safety Evaluation of Flavouring Agents. At its 68th meeting, the Committee discussed and evaluated an additional method of dietary exposure assessment for flavouring agents. This additional new method of dietary exposure assessment (since termed the Single Portion Exposure Technique, SPET) is based on the daily consumption of a single portion of food containing the flavouring agent, in recognition that the alternative available methods that assume daily consumption of large portions of several food categories containing the flavouring agent were overly conservative. The method is based on recommended use levels for each flavouring agent in food categories, in combination with standard portion sizes. For flavouring agents with usages in multiple food categories, only the food category resulting in highest potential dietary exposure was considered. This dietary exposure is taken to represent that of a regular consumer of a flavoured food, who is loyal to a brand containing the specific flavour of interest. Such an estimate, based on daily consumption and using a single standard portion size, is likely to provide a conservative assessment of long-term average dietary exposure. The ramification of any differences between the MSDI and the dietary exposure estimated by the additional method was examined by the Committee.

---

1 See the Summary and Conclusions of the 68th Meeting of the Joint FAO/WHO Expert Committee on Food Additives for additional details:
http://www.fao.org/ag/agn/agns/files/jecfa68_final.pdf
http://www.who.int/ipcs/food/jecfa/summaries/summary68.pdf.

4. On the basis of the analysis undertaken, the 68th JECFA meeting concluded that the MSDI and SPET dietary exposure estimates provide different and complementary information. The SPET takes account of food consumption patterns and use levels of flavouring agents, and is considered to provide an estimate of dietary exposure for a regular daily consumer of a specific food product containing the flavouring agent. The MSDI is considered to provide an estimate of the dietary exposure of the flavouring agent for an average consumer, and because it is based on the reported annual production volume it cannot take use patterns into account. The Committee noted that the addition of the SPET dietary exposure estimate to the relevant step in the Procedure would be likely to lead to a more extended evaluation in only a limited number of cases. The Committee noted that this analysis indicated that it would not be necessary to re-evaluate flavouring agents that have already been assessed using the Procedure.

5. Prior to a final decision on the addition of the SPET dietary exposure estimate to the Procedure, the Committee agreed at this meeting to repeat the assessment of a selected number of flavouring agents using both the MSDI and SPET dietary exposure estimate for evaluation at the next meeting. It was noted that the three cases where the dietary exposure estimate exceeded the TTC (derived from MSDI or SPET) were not low production volume flavouring agents, for which concern had previously been expressed by the Committee. The Committee recognized a need to consider dietary exposures for regular consumers of intermediate and high production volume flavouring agents with different use patterns. A sample representative of different levels of production volume and use patterns reported for flavouring agents will be selected for this assessment, ensuring flavouring agents from each class and group are included, the list not limited to those scheduled for evaluation at the next meeting. Another outcome of the future work will be the further development of suitable criteria for selecting flavouring agents where additional information on added use levels recommended by the industry is required for use in the SPET, prior to evaluation.

Call for experts for JECFA rosters 2007 – 2011(Chemistry and Exposure)

6. The new rosters of experts for FAO experts and exposure experts for JECFA for the period 2007 – 2011 have recently been finalized in response to the call for experts on issued by FAO and WHO in 2006. The rosters include experts for the following areas:

FAO Roster of experts for JECFA for food additives, contaminants and natural toxicants
FAO Roster of experts for JECFA for residues of veterinary drugs in food
FAO/WHO Roster of experts for JECFA for exposure assessment of chemicals in food

More information relating to JECFA expert rosters are available at the JECFA websites of FAO and WHO at: http://www.fao.org/ag/agn/agns/jecfa_experts_en.asp

and http://www.who.int/ipcs/food/jecfa/experts/en/index.html .

Provision of Scientific Advice

7. FAO and WHO have continued their efforts in the enhancement of the FAO/WHO work to provide scientific advice. The FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition has been finalised and is available at the website of the Nutrition and Consumer Protection Division of FAO at: http://www.fao.org/ag/agn/agns/advice_en.asp . This Framework is a compilation of written procedures currently followed in relation to the provision of scientific advice on food safety and nutrition to Codex and member countries. It discusses the different types of scientific advice provided, as well as the current principles, practices and procedures that underpin this advice. The purpose is to enhance the outcomes and transparency of scientific advice generated by FAO and WHO.

Expert Consultation on the use of 'active chlorine' in the food industry

8. CCFAC and CCFH have requested FAO and WHO to address the safety of use of 'active chlorine' in the food industry. Funding has been made available for this project and FAO and WHO are in the process of executing the project. A core group of experts has been identified and met in November 2007 to clearly define the scope and outline of the project. Working papers as basis for discussion at an international expert consultation are in preparation for the consultation, which is planned for May 2008. Information on the project can be found at http://www.fao.org/ag/agn/agns/chemicals_chlorine_meeting_en.asp and http://www.who.int/ipcs/food/active_chlorine/en/index.html .

Principles and Methods for Risk Assessment of Chemicals in Food

9. FAO and WHO are in the process of updating 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 project has included several workshops on specific areas of risk assessment. The final draft document, intended to replace Environmental Health Criteria Documents 70 and 104, will be posted on the websites of FAO and WHO for public comments and joint efforts will be made to finalize the guidance in 2008/early 2009.

WHO Total Diet Study Training Courses

10 Two training course on total diet studies (TDS) were held in October 2007 in Cairo and in November 2007 in Jakarta, sponsored by the WHO Regions for Europe, Eastern Mediterranean and Southeast Asia. The training courses were also supported by the Government of New Zealand through its Institute of Environmental Science and Research and the New Zealand Food Safety Authority. As a result a number of countries are planning to undertake TDS, which is viewed as one of the most cost-effective means for assessing exposure of populations to chemicals in the food supply. Another training course for Asia is being planned for 2008 with the Centre for Food Safety in Hong Kong and the 5th International TDS Workshop is being planned for later in 2008 in Rio de Janeiro.

INFOSAN Emergency linked to International Health Regulations (IHR)

12. The International Food Safety Authorities Network (INFOSAN) was initiated in 2004 by WHO in collaboration with FAO and currently has 166 countries enrolled. INFOSAN promotes the exchange of food safety information and improves collaboration among food safety authorities at national and international levels.

13. Within INFOSAN, INFOSAN Emergency responds to food safety events of international concern under the umbrella of the International Health Regulations (2005). With regard to food safety events caused by the presence of chemicals, the absence of an Acute Reference Dose of the contaminant prevents effective risk assessment and management. WHO is interested in collaborating with Member countries that can provide support for the strengthening of INFOSAN Emergency's response to events involving chemical contamination of food.

For more information, see http://www.who.int/foodsafety/fs_management/No_04_IHR_May07_en.pdf

Action required as a result of changes in acceptable daily intake (ADI) status and other toxicological recommendations

15. This section of the document summarizes actions required by the Codex Committee on Food Additives as a result of changes in the Acceptable Daily Intake (ADI) status of food additives or other toxicological recommendations concerning additives, as proposed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at its 68th meeting in Geneva, 19 -28 June 2007.

16. At its 68th meeting, JECFA recommended changes to existing ADIs and/or established new or temporary ADIs or gave other toxicological recommendations for food additives and ingredients as contained in the attached Table 1. The CCFA should decide and agree on any action which might be required concerning these changes.

Table 1. Food additives evaluated toxicologically at the 68th JECFA meeting

INS Number	Food additive	Acceptable daily intake (ADI) and other toxicological recommendations	Recommended action by CCFA
	Acidified sodium chlorite (ASC)	Acidified sodium chlorite (ASC) possesses antimicrobial properties and is intended for use primarily as a spray or dipping solution for poultry, meats, vegetables, fruits and seafoods. ASC is produced by the addition of a food-grade acid (e.g. citric acid, phosphoric acid, hydrochloric acid, malic acid or sodium hydrogen sulfate) to an aqueous solution of sodium chlorite. The available toxicological data were sufficient to assess the safety of ASC by setting ADIs for chlorite and chlorate. Chlorite: ADI of 0.03 mg/kg bw per day Chlorate: ADI of 0.01 mg/kg bw per day.	Consider whether to: - Add to the inventory of processing aids (IPA)
	Asparaginase from *Aspergillus oryzae* expressed in *Aspergillus oryzae*	Asparaginase is produced by submerged fed-batch fermentation of a genetically modified strain of *Aspergillus oryzae* which has a reduced capability for producing secondary metabolites and contains the asparaginase gene derived from A. oryzae. Asparaginase is used in food processing to reduce the formation of acrylamide from asparagine and reducing sugars during baking or frying. ADI "not specified" was established for use in the applications specified (manufacture of dough-based products and processed potato products, where asparaginase is added prior to heat treatment of these products with the intention to reduce acrylamide formation) and in accordance with good manufacturing practice.	Consider whether to: - Add to the inventory of processing aids (IPA)
407 and 407a	Carrageenan and Processed *Eucheuma* Seaweed (PES)	The group ADI "not specified" for the sum of carrageenan and processed *Eucheuma* seaweed (PES) was maintained for food additive uses in foods other than infant formula. JECFA was of the view that based on the information made available, it is inadvisable to use carrageenan or processed *Eucheuma* seaweed in infant formulas.	Consider whether to: - Discontinue work in GSFA at Step 7 on the use of carrageenan in food categories 13.1.2 (Follow-Up Formula) and 13.2 (Complementary foods for infants and young children) - Discontinue work in GSFA at Step 7 on the use of Processed *Euchema* Seaweed (PES) in food category 13.2 (Complementary foods for infants and young children) - Recommend to CCNFSDU to consider withdrawing the provision for carrageenan in CODEX STAN 156-1987 "Standard for Follow-up formula" and CODEX STAN 72-1981

INS Number	Food additive	Acceptable daily intake (ADI) and other toxicological recommendations	Recommended action by CCFA
			"Standard for Infant Formula and formulas for special medical purposes intended for infants"
	Cyclotetraglucose and cyclotetraglucose syrup (listed on draft agenda as cyclotetraose)	Cyclotetraglucose is used in food as a carrier for flavours, polyunsaturated fatty acids and vitamins and as a food ingredient. A temporary ADI "not specified" was allocated for cyclotetraglucose and cyclotetraglucose syrup pending submission of data on the identity of the bacterial strain used to produce the 6-GT/IMT enzyme preparation and evidence of its lack of pathogenicity and toxigenicity.	No action, temporary ADI
	Isoamylase from *Pseudomonas amyloderamosa*	Isoamylase is produced by submerged fed-batch pure culture fermentation of *Pseudomonas amyloderamosa*. The enzyme preparation is used in the production of food ingredients from starch. An ADI "not specified" was established for use in the applications specified (the production of food ingredients from starch (e.g. glucose syrup, maltose and maltitol, trehalose, cyclodextrins and resistant starch), typically in combination with other amylolytic enzymes) and in accordance with good manufacturing practice.	Consider whether to: - Add to the inventory of processing aids (IPA)
518	Magnesium sulfate	Magnesium sulfate is used as a nutrient, firming agent and flavour enhancer. It is also used as a fermentation aid in the processing of beer and malt beverages. No food uses have been identified for the anhydrous form of magnesium sulfate. An ADI "not specified" was established.	Consider whether to: - Include in Table 3 of GSFA and circulate for comments at Step 3. - Request comments/proposals on other uses of magnesium sulphate.
	Phospholipase A1 from *Fusarium venetatum* produced by *Aspergillus oryzae*	ADI 'not specified' when used in the applications specified (to produce modified phospholipids in milk used for the manufacture of cheese) and in accordance with good manufacturing practice.	Consider whether to: - Add to the inventory of processing aids (IPA)
	Sodium iron(III) ethylenediaminetetraacetic acid (EDTA)	Sodium iron EDTA is suitable for use as a source of iron for food fortification to fulfil nutritional iron requirements, provided that the total intake of iron from all food sources including contaminants does not exceed the PMTDI of 0.8 mg/kg bw. Total intake of EDTA should not exceed acceptable levels, also taking into account the intake of EDTA from the food additive use of other EDTA compounds. An ADI of 0-2.5 mg/kg bw was previously established for the calcium disodium and disodium salts of EDTA, equivalent to up to 1.9 mg/kg bw EDTA.	No action, food ingredient for iron supplementation

INS Number	Food additive	Acceptable daily intake (ADI) and other toxicological recommendations	Recommended action by CCFA
960	Steviol glycosides	The temporary ADI of 0–2 mg/kg bw for steviol glycosides, expressed as steviol was extended until 2008, pending submission of the results of the ongoing studies. JECFA considered that the newly available data did not raise additional concerns regarding the safety of steviol glycosides, but that the results of ongoing clinical studies, which more closely address the requirements specified at the sixty-third meeting, would be essential to its evaluation.	No action, temporary ADI