codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 3 **CX/FA 10/42/3**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-second Session

Beijing, China, 15 – 19 March 2010

MATTERS OF INTEREST ARISING FROM FAO AND WHO AND FROM THE 71ST 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.

Matters for information and action from the 71st meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

2. The results of the 71st meeting of JECFA on food additives are available in the summary report[1]. The meeting report (WHO Technical Report Series No 956 , 2009) and the toxicological monographs (WHO FAS 62, 2009) 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 7, 2009) are available at the FAO JECFA website at ftp://ftp.fao.org/docrep/fao/012/i0971e/i0971e00.pdf. 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. See also paragraphs 11-12 and Table 1 below.

Guidelines for the safety evaluation of enzymes produced by genetically modified microorganisms (GMMs)

3. At its 71st meeting, JECFA discussed the new regulation for enzymes enacted by the European Parliament and related draft guidance documents. The Committee considered that an update the General Specifications and Considerations for Enzymes Used in Food Processing to expand recommendations for microbiology and molecular biology information to be submitted in dossiers for enzymes from microorganisms (including those from GMMs) may be necessary and decided in addition to discuss toxicological and other safety studies for enzymes from all sources at a future meeting, pending the elaboration of a revised draft guidance document on enzymes.

Periodic re-evaluation of food additives

4. JECFA has repeatedly noted the importance of reviewing substances previously evaluated when new data on those substances become available and in light of further developments in science and risk assessment methodologies. This was brought to the attention of the forty-first session of CCFA, which requested the JECFA Secretariat to prepare a discussion paper on the topic for consideration at the next session of CCFA (see Agenda Item 9b). The 71st JECFA noted that many re-evaluations have already been undertaken, based on specific requests from Member States and CAC, and considered that it will be

[1] ee the Summary and Conclusions of the 71st Meeting of the Joint FAO/WHO Expert Committee on Food Additives for additional details: http://www.fao.org/ag/agn/agns/jecfa/JECFA71_Summary_report_final.pdf and http://www.who.int/ipcs/food/jecfa/summaries/summary71.pdf .

necessary to develop criteria for a periodic review of substances. Criteria that may trigger a review have already been published in EHC 70, and that revised criteria will be published in the updated principles and methods document (EHC 240, see below). These may serve as a basis for further consideration, and the revised criteria areas are as follows:

- a new manufacturing process;
- a new specification;
- new data on the biological properties of the compound;
- new data concerning the nature and/or the biological properties of the impurities present;
- advances in scientific knowledge relevant to the nature or mode of action;
- changes in consumption patterns, levels of use or dietary exposure estimates; and
- improved requirements for safety evaluation. These are made possible by new scientific knowledge and the quality and quantity of safety data considered necessary in the case of food additives and residues of pesticides and veterinary drugs.

5. JECFA further noted that it is important to take existing assessments into account in the re-evaluation of a food additive and that a process must be developed by which the information needed for the re-evaluation can be provided.

Provision of Scientific Advice from FAO and WHO

Expert meeting on the benefits and risks of the use of chlorine-containing disinfectants in food production and food processing

6. CCFAC and CCFH have requested FAO and WHO to address the safety of use of 'active chlorine' in the food industry. The Joint FAO/WHO Expert meeting on the benefits and risks of the use of chlorine-containing disinfectants in food production and food processing was held 27 - 30 May 2008 in Ann Arbor, Michigan, United States of America. The executive summary has been published on the respective websites, and the full report will be available shortly 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

7. 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 will be published shortly as Environmental Health Criteria No 240 and will be made available on the web: http://www.who.int/ipcs/food/principles/en/index.html

Expert Consultation on the application of nanotechnology in the food industry

8. In response to concerns raised by member countries on the possible food safety implications of the application of nanotechnology to food and agriculture, FAO and WHO has implemented an expert meeting to address this issue, in June 2009 at FAO HQ in Rome. The aim of the meeting was three-fold (1) summarize actual and anticipated nanotechnology applications in the food and agriculture sectors, and develop a common view of their implications for food safety, (2) to review current risk assessment procedures and evaluate their adequacy for the assessment of nano-particles in relation to foods, (3) consider issues related to communication with all stakeholders, and overall agree on priority research to fill information gaps related to potential food safety issues and to provide guidance FAO and WHO how to address food safety issues linked to nanotechnology applications. The report is available at: http://www.fao.org/ag/agn/agns/meetings_consultations_en.asp and http://www.who.int/foodsafety/fs_management/meetings/nano_june09/en/index.html .

Global Initiative for Food-related Scientific Advice (GIFSA)

9. 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. FAO and WHO would like to express their appreciation to the USA for their recent second contribution.

10. 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 Jorgen Schlundt, Department of Food Safety, Zoonoses and Foodborne Diseases, WHO (schlundtj@who.int; Tel: + 41 22 791 3445).

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

11. 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 71st meeting in Geneva, Switzerland, 16 -24 June 2009.

12. At its 71st 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 71st JECFA meeting

INS Number	Food additive	Acceptable daily intake (ADI) and other toxicological recommendations	Recommended action by CCFA
	Branching glycosyltransferase from *Rhodothermus obamensis* expressed in *Bacillus subtilis*	Branching glycosyltransferase is manufactured by pure culture fermentation of a genetically modified strain of *Bacillus subtilis* containing a synthetic gene coding for branching glycosyltransferase from *Rhodothermus obamensis* The branching glycosyltransferase preparation is intended for use in the production of modified starch with improved functional properties, such as higher solubility, lower viscosity and reduced retrogradation. An **ADI "not specified"** was allocated for branching glycosyltransferase from *Rhodothermus obamensis* expressed in*Bacillus subtilis* used in the specified applications and in accordance with Good Manufacturing Practice.	Consider whether to: - Add to the inventory of processing aids (IPA).
427	**Cassia gum**	Cassia gum is the purified flour from the endosperm of the seeds of *Cassia tora* and *Cassia obtusifolia*, which belong to the Leguminosae family. Cassia gum is used as a thickener, emulsifier, foam stabilizer, moisture retention agent and/or texturizing agent in processed cheese, frozen dairy desserts and mixes, meat products and poultry products. An **ADI "not specified"** was allocated for cassia gum that complies with the tentative specifications established and when used in the applications specified and in accordance with Good Manufacturing Practice. The Committee decided to make the specifications tentative pending submission of data on a suitable and validated method for determination of anthraquinones at a level of 0.5 mg/kg and below, by the end of 2010.	Consider whether to: - Encourage submission of the requested data for specifications.
952(i) 952(ii) 952(iv)	**Cyclamic acid and its salts** **Cyclamic acid** **Calcium cyclamate** **Sodium cyclamate**	The impact on dietary exposures to cyclamates of different maximum levels of use of cyclamates in the Codex GSFA Food Category 14.1.4 was assessed at the request of CCFA, This food category includes water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulated drinks, which includes all carbonated and non-carbonated varieties and concentrates, products based on fruit and vegetable juices[2] and coffee-, tea- and herbal-based drinks. The different use levels to be considered were 250, 500, 750 and 1000 mg/kg. While there are provisions for the use of cyclamates in the GSFA in a wide range of food categories, the GSFA does	Consider to: - Review the existing and draft MLs of cyclamates in the GSFA; - Propose MLs of cyclamates in the GSFA for food category 14.1.4 in accordance with the outcome of the exposure assessment.

[2] Fruit and vegetable juices per se are found in Codex GSFA Food Categories 14.1.2.1 and 14.1.2.2, respectively.

INS Number	Food additive	Acceptable daily intake (ADI) and other toxicological recommendations	Recommended action by CCFA
		not currently have a provision for the use of cyclamates in Food Category 14.1.4. Of the four maximum use levels (250, 500, 750 and 1000 mg/kg) that were considered at the request of CCFA for cyclamates in beverages covered by Codex GSFA Food Category 14.1.4, only the lowest level of 250 mg/kg was not likely to lead to dietary exposures exceeding the ADI for high consumers, including children. Moreover, it was noted that a maximum use level of 350 mg/kg also resulted in dietary exposures for high consumers, including children, that were less than the ADI.	
	Cyclotetraglucose **Cyclotetraglucose syrup**	Cyclotetraglucose and cyclotetraglucose syrup for use as a stabilizer and carrier. Cyclotetraglucose and cyclotetraglucose syrup are produced from hydrolysed food-grade starch by the action of a mixture of 6-GT and IMT derived from *Sporosarcina globispora* and cyclodextrin glycosyltransferase derived from *Bacillus stearothermophilus*. It was concluded that the bacterial strain of *S. globispora* used to produce the 6-GT/IMT enzyme preparation was identified and classified correctly and that there is no evidence of pathogenic or toxigenic potential. An **ADI "not specified"** was allocated for cyclotetraglucose and cyclotetraglucose syrup and full specifications have been prepared.	Consider whether to: - Request comments/proposals on uses and use levels of cyclotetraglucose and cyclotetraglucose syrup; - Request proposal to allocate INS number.
	Ferrous ammonium phosphate	It was concluded that ferrous ammonium phosphate is acceptable for use as a source of iron for dietary fortification, provided that the total intake of iron does not exceed the PMTDI. The available information on the toxicity of iron did not indicate a need to revise the provisional maximum tolerable daily intake (PMTDI) of 0.8 mg/kg body weight.	No action, as ferrous ammonium phosphate is added to food for other purposes than technological purposes.
	Glycerol ester of gum rosin (GEGR)	GEGR is a complex mixture of triglycerol and diglycerol esters of resin acids from gum rosin (GR), with a residual fraction of monoglycerol esters. It is obtained by the esterification of refined GR with food-grade glycerol and purified. GEGR is intended to be used as an emulsifier/density adjustment agent for flavouring substances in non-alcoholic beverages and cloudy spirit drinks. It was decided to include GEGR in the ADI for glycerol esters of wood rosin (GEWR) of 0–25 mg/kg body weight, thereby establishing a **group ADI of**	Consider whether to: - Request proposal to allocate INS number; - Encourage submission of the requested data for specifications.

INS Number	Food additive	Acceptable daily intake (ADI) and other toxicological recommendations	Recommended action by CCFA
		0–25 mg/kg body weight for GEWR and GEGR. The specifications for GEGR were made tentative pending the submission of infrared spectra that correspond to the commercially available products, data on the resin acid composition obtained with updated chromatographic techniques, and additional information on methods that enables the identification of the individual glycerol esters of rosins and their differentiation. This information should be submitted by the end of 2010.	
445	**Glycerol ester of wood rosin (GEWR)**	GEWR is used as emulsifier, glazing agent and stabilizer. A **group ADI of 0–25 mg/kg body weight for GEWR and GEGR** was established. The specifications were made tentative pending the submission of infrared spectra that correspond to the commercially available products, data on the resin acid composition obtained with updated chromatographic techniques, and additional information on methods that enables the identification of the individual rosin esters and their differentiation. This information should be submitted by the end of 2010.	Consider whether to: - Review any existing and draft provisions concerning GEWR in the GSFA; - Encourage submission of the requested data for specification.
	Glycerol ester of tall oil rosin (GETOR)	GETOR is a complex mixture of triglycerol and diglycerol esters of resin acids from tall oil rosin (TOR), with a residual fraction of monoglycerol esters. It is obtained by the esterification of TOR with food-grade glycerol and purified. TOR is obtained as a by-product of the kraft (paper) sulfate pulping process. GETOR is intended to be used as an emulsifier/density adjustment agent for flavouring substances in non-alcoholic beverages. Adequate information on the composition of GETOR was not available and as the source material and production processes are different from GEWR, this may result in different by-products of GETOR compared to GEWR. Thus, the safety of GETOR could not be evaluated without additional information on its composition in order to clarify the extent and significance of any differences relative to other glycerol esters of rosins. The specifications for GETOR were made tentative pending the submission of infrared spectra that correspond to the commercially available products, data on the resin acid composition obtained with updated chromatographic techniques, and additional information on methods that enables the	Consider whether to: - Request proposal to allocate INS number; - Encourage submission of the requested data on composition and for specifications.

INS Number	Food additive	Acceptable daily intake (ADI) and other toxicological recommendations	Recommended action by CCFA
		identification of the individual glycerol esters of rosins and their differentiation. The Committee also requested information on the identity of the sulfur compounds in the commercial product. This information should be submitted by the end of 2010.	
160d(i) 160d(iii) 160d(ii)	**Lycopene from all sources** **Lycopene (synthetic)** **Lycopene from *Blakeslea trispora*** **Lycopene extract from tomato**	At the request of CCFA lycopene extract from tomato was evaluated for safety and specifications for its intended use as a food colour. It was decided to revise the group ADI earlier and replace it with a **group ADI "not specified"** for lycopene from all sources when used as food colour. Hence, the previous group ADI of 0–0.5 mg/kg for lycopene was withdrawn. The group **ADI "not specified"** applies to synthetic lycopene, lycopene derived from the fungus *Blakeslea trispora* and lycopene extract from tomato that comply with the specifications, when used in accordance with Good Manufacturing Practice.	Consider whether to: - Include lycopenes (INS 160d) in Table 3 of GSFA and circulate for comments at Step 3 and review any existing and draft provisions concerning lycopene in the GSFA; - Request for comments/proposals on uses and use levels of lycopenes (INS 160d) for the food categories listed in the Annex to Table 3.
905a	**Mineral oil (low and medium viscosity) class II and class III**	Following receipt of information that finalization of the requested toxicity studies has been delayed, it was decided to further **extend the temporary group ADI**, but noted that the temporary group ADI will be withdrawn at the end of 2011 if the data are not submitted by that time.	Consider whether to: - Encourage submission of the requested studies.
	Octenyl succinic acid (OSA) modified gum arabic	OSA modified gum arabic is produced by esterifying gum arabic *Acacia seyal* or gum arabic *Acacia senegal* with not more than 3% of octenyl succinic acid anhydride. The degree of esterification of OSA modified gum arabic is not more than 0.6%, and residual octenyl succinic acid is not more than 0.3%. OSA modified gum arabic is a cold water–soluble hydrocolloid used as an emulsifier. A **temporary ADI "not specified"** was allocated for OSA modified gum arabic used in the applications specified and in accordance with Good Manufacturing Practice. The ADI is temporary pending submission of data by the end of 2011 showing hydrolysis of OSA modified gum arabic to confirm the validity of using gum arabic data in the evaluation of OSA modified gum arabic.	Consider whether to: - Request proposal to allocate INS number; - Encourage submission of the requested data.

INS Number	Food additive	Acceptable daily intake (ADI) and other toxicological recommendations	Recommended action by CCFA
514	**Sodium hydrogen sulfate**	Sodium hydrogen sulfate is manufactured by mixing sodium chloride with sulfuric acid at elevated temperatures to form molten sodium hydrogen sulfate that is sprayed and cooled to form a solid product with uniform particle size. Sodium hydrogen sulfate is intended for use as an acidifier and has previously been considered by JECFA for use in the preparation of acidified sodium chlorite, an antimicrobial washing solution. An **ADI "not specified"** was allocated for sodium hydrogen sulfate, in line with the principles established for ionizable salts adopted by JECFA, when used in the applications specified and in accordance with Good Manufacturing Practice.	Consider whether to: - Include in Table 3 of GSFA and circulate for comments at Step 3; - Request for comments/proposals on uses and use levels for the food categories listed in the Annex to Table 3.
473a	**Sucrose oligoesters (SOE) type I and type II**	SOE type I and type II are produced by interesterification of sucrose with methyl esters of fatty acids derived from edible fats and oils, including hydrogenated fats and oils such as stearic acid and palmitic acid. A sucrose molecule has eight hydroxyl groups, and so it can produce mono- to octa-esters. *Sucrose esters of fatty acids* consist mainly of sucrose mono- to tri-esters, whereas SOE type I consists mainly of sucrose tetra- to octa-esters and SOE type II consists of sucrose mono- to octa-esters. SOE type I and type II are lipophilic emulsifiers as well as stabilizers and tableting aids for foods presented in tablet form. A **group ADI of 0–30 mg/kg bw** was allocated for sucrose esters of fatty acids, sucroglycerides and SOE type I and type II. Estimated dietary exposures to SOE type I and type II combined for mean and high consumers, based on typical or maximum use levels, were well below the ADI, with estimates ranging from 3% to 15% of the ADI.	Consider whether to: - Request comments/proposals on uses and use levels of sucrose oligoesters type I and type II.