CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 3 **CX/FA 12/44/4 Add.1**

March 2012

(English only)[1]

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-fourth Session

Hangzhou, China, 12-16 March 2012

MATTERS OF INTEREST ARISING FROM FAO AND WHO AND FROM THE 74TH MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)

1. This document provides supplemental 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 CX/FA 12/44/4 did not provide specifics on actions required as a result of changes in acceptable daily intakes (ADI) status and other toxicological recommendations from the 74th JECFA. This addendum 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 74th meeting in Rome, Italy, 14-23 June 2011

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

3. At its 74th meeting, JECFA evaluated the safety of aluminium containing food additives including Aluminium lactate and Potassium aluminium lactate, not previously evaluated by the Committee as food additives, Potassium aluminium silicate and its use as a carrier substrate for pearlescent based pigments, Benzoin Tonkinensis, Glycerol Esters of Gum Rosin, Tall Oil Rosin and Wood Rosin, Octenyl succinic acid modified gum Arabic, Polydimethylsiloxane, Ponceau 4R, Pullulan, Pullulanse from *Bacillus deramificans* expressed in *Bacillus lichiformis*, Quinoline yellow and Sunset yellow FCF. Toxicological recommendations or other scientific advice for these food additives and ingredients are provided in the attached Table 1. The CCFA should decide and agree on any action which might be required concerning the results of the evaluations of these food additives.

[1] The document is available in English only that due to its late availability.

Table 1. Food additives evaluated toxicologically at the 74th JECFA meeting

INS Number	Food additive	Acceptable daily intake (ADI) or other toxicological recommendations	Recommended action by CCFA
	Aluminium-containing food additives (including new food additives potassium aluminium silicate and potassium aluminium silicate–based pearlescent pigments)	The Committee established a provisional tolerable weekly intake (PTWI) of 2 mg/kg body weight based on a no-observed-adverse-effect level (NOAEL) of 30 mg/kg body weight per day and application of a safety factor of 100. The PTWI applies to all aluminium compounds in food, including food additives. The previous PTWI of 1 mg/kg body weight was withdrawn**.** For adults, the estimates of mean dietary exposure to aluminium-containing food additives from consumption of cereals and cereal-based products are up to the PTWI. Estimates of dietary exposure of children to aluminium-containing food additives, including high dietary exposures (e.g. 90th or 95th percentile), can exceed the PTWI by up to 2-fold. For potassium aluminium silicate–based pearlescent pigments using conservative estimates, anticipated dietary exposure at the maximum proposed use levels is 200 times higher than the PTWI. The Committee emphasized that whereas substances that have long half-lives and accumulate in the body are not generally considered suitable for use as food additives, consumption of aluminium-containing food additives would not be a health concern, provided that total dietary exposure to aluminium is below the PTWI. The Committee recommended that provisions for food additives containing aluminium included in the Codex General Standard for Food Additives should be compatible with the revised PTWI for aluminium compounds of 2 mg/kg body weight as aluminium from all sources. The Committee prepared new tentative specifications for pearlescent pigments containing potassium aluminium silicate , for potassium aluminium silicate itself, as well as a combined specification for the three general types of potassium aluminium silicate–based pearlescent pigments manufactured using potassium aluminium silicate combined with titanium dioxide, iron oxide or both titanium dioxide and iron oxide.	Consider whether to- Request proposal to allocate an INS number for potassium aluminium silicate–based pearlescent pigments Encourage submission of the requested data for specifications - Review the existing and draft MLs in the GSFA
	Benzoe Tonkinensis	The Committee concluded that the available data were inadequate to establish an acceptable daily intake (ADI) because of the variability in composition of Benzoe tonkinensis and the inadequate characterization of the material tested. The margin of exposure (MOE) between the conservative dietary exposure estimate of 0.2 mg/kg body weight per day and the NOAEL of 500 mg/kg body weight per day identified in a 90-day oral toxicity study in rats is 2500. Considering the MOE as well as the nature of the hepatic effects observed at doses above the NOAEL and the negative genotoxicity results, the Committee concluded that Benzoe tonkinensis would not pose a health concern at current estimated dietary exposures, provided that it complies with the tentative specifications prepared at the current meeting, when used as a flavouring agent and in accordance with good manufacturing practice. The Committee also noted that exposure to benzoic acid and benzyl benzoate from the use of Benzoe tonkinensis is well below the upper limit of the group ADI (0–5 mg/kg body weight) for benzyl derivatives, and exposure to vanillin is also well below the upper limit of its ADI (0–10 mg/kg body	Consider whether to- Encourage submission of requested data to finalize specification to characterize the material tested Request proposal to allocate an INS number with technological purpose as a flavouring agent

INS Number	Food additive	Acceptable daily intake (ADI) or other toxicological recommendations	Recommended action by CCFA
		weight). The Committee noted that benzoic acid, one of the major components of Benzoe tonkinensis, is used as a preservative, but that Benzoe tonkinensis has not been assessed for this use.	
445(i)	Glycerol ester of gum rosin (GEGR)	The Committee withdrew the group ADI for GEGR and GEWR and established a temporary group ADI for GEGR and GEWR of 0–12.5 mg/kg body weight, pending the submission of the full reports of the 90-day toxicity studies on GEGR as well as additional compositional information on the GEWR from *Pinus elliottii*. The Committee noted that the temporary group ADI will be withdrawn if the requested information is not submitted by the end of 2012.	Temporary group-ADI. Consider whether to- Encourage submission of requested data to establish an ADI and information to characterize the material tested
445(ii)	Glycerol ester of tall oil rosin (GETOR)	The Committee was unable to complete the evaluation of GETOR because additional data are required to characterize the GETOR in commerce. Validated methods for the determination of the substances considered in the specifications are also required. The above information should be submitted by the end of 2012 .	Consider whether to- Encourage submission of requested information to establish an ADI (or include in the group-ADI for GEGR and GEWR) and to characterize the material tested and data for specifications
445(iii)	Glycerol ester of wood rosin (GEWR)	The Committee withdrew the group ADI for GEGR and GEWR and established a temporary group ADI for GEGR and GEWR of 0–12.5 mg/kg body weight, applying an additional safety factor of 2, because new information raises questions about the identity and composition of the product in commerce. Additional compositional information on the GEWR from *Pinus elliottii* to assess similarity with the GEWR from *Pinus palustris* is required. The Committee noted that the temporary group ADI will be withdrawn if the requested information is not submitted by the end of 2012.	Temporary group-ADI. Consider whether to- Encourage submission of requested data to establish an ADI and information to characterize the identity of the material tested
423	Octenyl succinic acid (OSA) modified gum arabic	The Committee deferred further evaluation of OSA modified gum arabic pending the submission of data on its stability in food and the extent to which it is hydrolysed in the gastrointestinal tract. The information is to be provided by the end of 2013. The existing temporary ADI "not specified"[a] was retained.	Temporary ADI. Consider whether to- Encourage submission of requested information to complete evaluation and characterize the identity of the material tested
900a	Polydimethylsiloxane	The Committee withdrew the temporary ADI of 0–0.8 mg/kg body weight per day and re-established the ADI of 0–1.5 mg/kg body weight, originally established at the eighteenth meeting.	Consider whether to- Add to technological purposes of anti-foaming and anti-caking agent in CAC/GL 36-1989

INS Number	Food additive	Acceptable daily intake (ADI) or other toxicological recommendations	Recommended action by CCFA
124	Ponceau 4R	The Committee concluded that new data do not indicate a need to revise the existing ADI of 0–4 mg/kg body weight and that dietary exposure to Ponceau 4R does not present a health concern.	No action
1204	Pullulan	Dietary exposure to pullulan as a dietary fibre could reach 1g/kg body weight per day for children (2–5 years old) and 0.4 g/kg body weight per day for the general population (2 years of age and older). These estimates are 8 and 20 times lower, respectively, than the no-observed-effect level (NOEL) observed in the 90-day rat study evaluated previously. Gastrointestinal effects observed in humans should be taken into account when considering appropriate use levels. The Committee stressed that it assessed the safety of use and not the efficacy of pullulan used as a dietary fibre. The Committee maintained the previously established ADI "not specified"[a] for the previously evaluated food additive uses.	No action
	Pullulanase from *Bacillus deramificans* expressed in *Bacillus lichiformis*	The Committee established an ADI "not specified"[a] for pullulanase from *B. deramificans* expressed in *B. licheniformis* when used in the applications specified and in accordance with good manufacturing practice.	ADI not specified. Consider whether to- Add to the inventory of processing aids
104	Quinoline yellow	The Committee established a temporary ADI of 0–5 mg/kg body weight, incorporating an additional 2-fold safety factor, pending submission of requested toxicological studies by the end of 2013. The previously established ADI of 0–10 mg/kg body weight was withdrawn. The conservative exposure estimates were within the range of the temporary ADI. Additional information on the composition of the product in commerce is required, in particular relating to the identity and purity of the unmethylated form of Quinoline Yellow.	Temporary ADI. Consider whether to- Encourage submission of requested information and information to characterize the product in commerce
110	Sunset yellow FCF	The Committee established an ADI of 0–4 mg/kg body weight and withdrew the previous ADI of 0–2.5 mg/kg body weight. The Committee concluded that dietary exposure to Sunset Yellow FCF does not present a health concern.	No action

[a] ADI "not specified" is used to refer to a food substance of very low toxicity that, on the basis of the available data (chemical, biochemical, toxicological and other) and the total dietary exposure to the substance arising from its use at the levels necessary to achieve the desired effects and from its acceptable background levels in food, does not, in the opinion of the Committee, represent a hazard to health. For that reason, and for the reasons stated in the individual evaluations, the establishment of an ADI expressed in numerical form is not deemed necessary. An additive meeting this criterion must be used within the bounds of good manufacturing practice—i.e. it should be technologically efficacious and should be used at the lowest level necessary to achieve this effect, it should not conceal food of inferior quality or adulterated food, and it should not create a nutritional imbalance.