CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 3 **CX/FA 14/46/3**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-sixth Session

Hong Kong, China, 17-21 March 2014

MATTERS OF INTEREST ARISING FROM FAO AND WHO AND FROM THE 77TH 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 from the 77th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

2. The results of the 77th meeting of JECFA on food additives are now available. The meeting report (WHO Technical Report Series No 983, 2013) and the toxicological monographs (WHO Food Additive Series No 68, 2014) are accessible through the WHO JECFA publications website: http://www.who.int/foodsafety/chem/jecfa/publications/en/index.html. The specifications monographs (FAO JECFA Monographs 14, 2013) is available at the FAO JECFA website at http://www.fao.org/fileadmin/user_upload/agns/pdf/JECFA_Monograph_13.pdf). All specifications monographs for food additives will be available in the updated on-line edition of the database at the FAO JECFA website: http://www.fao.org/ag/agn/jecfa-additives/search.html.

Publications and Other Provision of Scientific Advice from FAO and WHO

3. FAO and WHO have developed and finalized a technical paper entitled “State of the art on the initiatives and activities relevant to risk assessment and risk management of nanotechnologies in the food and agriculture sectors" (July 2013). The FAO/WHO technical paper is available in English at http://www.fao.org/docrep/018/i3281e/i3281e.pdf

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

4. At its 77th meeting, JECFA evaluated the safety of Advantame, Glucoamylase from *Trichoderma reesei* expressed in *Trichoderma reesei*, Glycerol ester of gum rosin (GEGR), Glycerol ester of tall oil rosin (GETOR), Glycerol ester of wood rosin (GEWR), Nisin, and Octenyl succinic acid (OSA) modified gum Arabic. Toxicological recommendations or other scientific advice for these food additives are provided in the attached Table 1. The CCFA should decide and agree on any action which might be required following the evaluations of these food additives.

Table 1. Food additives evaluated toxicologically at the 77th JECFA meeting

INS Number	Food additive	Acceptable daily intake (ADI) or other toxicological recommendations	Recommended action by CCFA
969	Advantame	The Committee established an acceptable daily intake (ADI) of 0–5 mg/kg body weight (bw) for advantame on the basis of a no-observed-adverse-effect level (NOAEL) of 500 mg/kg bw per day for maternal toxicity in a developmental toxicity study in rabbits and application of a 100-fold safety factor to account for interspecies and intraspecies variability. The Committee agreed that the ADI also applies to those individuals with phenylketonuria, as the formation of phenylalanine from the normal use of advantame would not be significant in relation to this condition. Using the proposed maximum use levels and conservative assumptions, the maximum mean dietary exposure to advantame would be 1.45 mg/kg bw per day (29% of the upper bound of the ADI), and the maximum high-percentile dietary exposure would be 2.16 mg/kg bw per day (43% of the upper bound of the ADI).	In view of tentative specifications established: Wait for further evaluation by JECFA.
	Glucoamylase from *Trichoderma reesei* expressed in *Trichoderma reesei*	Based on its low toxicity and because it is reasonably anticipated that dietary exposure would be very low, the Committee established an ADI "not specified"[a] for the glucoamylase enzyme preparation from *T. reesei* expressed in *T. reesei* used in the applications specified and in accordance with good manufacturing practice.	In view of the ADI not specified: Consider whether to: Recommend inclusion in the database on processing aids.
445 (i)	Glycerol ester of gum rosin (GEGR)	As the requested two unpublished 90-day oral toxicity studies on GEGR in rats and complete information on the composition of GEGR were not submitted, the Committee withdrew the temporary group ADI of 0–12.5 mg/kg bw for GEGR and glycerol ester of wood rosin (GEWR).	In view of the temporary ADI withdrawn, specifications maintained as tentative: Wait for further evaluation by JECFA.
445 (ii)	Glycerol ester of tall oil rosin (GETOR)	No data on GETOR were submitted, and the Secretariat was informed that this compound is no longer supported by the previous data sponsor. Therefore, the Committee did not evaluate GETOR.	In view of the temporary ADI withdrawn. No action required
445 (iii)	Glycerol ester of wood rosin (GEWR)	As the requested data on GEGR were not submitted, the Committee withdrew the temporary group ADI of 0–12.5 mg/kg bw for GEGR and GEWR and re-established the ADI of 0–25 mg/kg bw for GEWR.	In view of the full ADI re-established and revised full specifications No action required (

INS Number	Food additive	Acceptable daily intake (ADI) or other toxicological recommendations	Recommended action by CCFA
234	Nisin	The Committee established an ADI for nisin of 0–2 mg/kg bw on the basis of a NOAEL of 224.7 mg of nisin per kilogram body weight per day from a 13-week study in rats and application of a safety factor of 100 to account for interspecies and intraspecies variability. The Committee did not consider it necessary to use an additional safety factor to account for the short duration of the study because the NOAEL was supported by the results of a three-generation reproductive toxicity study in rats. The Committee withdrew the previous ADI of 0–33 000 units of nisin per kilogram body weight established at the twelfth meeting.	In view of the changed ADI Consider whether: Delete Note 28 of the GSFA on ADI conversion as no longer necessary.
423	Octenyl succinic acid (OSA) modified gum arabic	The Committee decided to retain the temporary ADI "not specified"[a] pending submission of additional data on the stability of OSA modified gum arabic in food by the end of 2013, which may help to explain contradictory hydrolysis data.	In view of temporary ADI retained: Wait for further evaluation by JECFA.

[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.