CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 3(a) **CX/FA 17/49/3**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-ninth Session

Macao SAR, China, 20-24 March 2017

MATTERS OF INTEREST ARISING FROM FAO/WHO AND FROM THE 82ND MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)

Matters for information from the 82nd meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

1. The results of the 82nd meeting of JECFA (Geneva, 7-16 June 2016) on certain food additives and flavouring agents will be available as follows: the meeting report (WHO Technical Report Series) and the toxicological and dietary exposure monographs (WHO Food Additive Series No 73) will be accessible through the WHO JECFA publications website: http://www.who.int/foodsafety/publications/jecfa/en/ . The specification monographs resulting from the 82nd JECFA meeting will be published as FAO JECFA Monographs 19, FAO, Rome, 2016. The publication is available on the FAO JECFA website at: http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-publications/en/

2. Some of the general considerations of the 82nd JECFA are summarized here:

Revisions of the Procedure for the Safety Evaluation of Flavouring Agents

3. At its 82nd meeting, JECFA considered that the European Food Safety Authority (EFSA) and WHO recently reviewed the general threshold for toxicological concern (TTC) approach in a joint project, building on existing and ongoing work in this area. An expert workshop was convened in December 2014, primarily to provide recommendations as to how the existing TTC framework may be improved and expanded by updating/revising the Cramer classification scheme and extending the TTC approach. An important aspect was also to develop a globally harmonized decision-tree for a tiered approach on the application of the TTC in the risk assessment of chemicals from oral exposures.

4. Based on the recommendations from this expert workshop, the 82nd JECFA discussed the consequences for the existing JECFA Procedure for the Safety Evaluation of Flavouring Agents, which is based on the TTC concept, and proposed a revised Procedure. The main change proposed is to remove question 2 of the existing Procedure ("Can the substance be predicted to be metabolized to innocuous products?") and in consequence combine the A-side and B-side of the existing Procedure, because:

(i) Metabolism is an inherent part of the Cramer, Ford & Hall scheme and the TTC values for the different classes;

(ii) Models for predicting metabolism can have significant limitations, including lack of information on interspecies extrapolation and alterations in metabolite profiles arising from saturation of metabolic pathways;

(iii) Prediction of the major pathways of metabolism may not reflect the hazard associated with a minor pathway; and

(iv) The B-side of the existing procedure requires toxicity data on the compound or a structurally related substance even if the dietary exposure was below the TTC value, which is inconsistent with the TTC concept.

5. Another change is to add an initial question regarding genotoxicity and in consequence to delete step B5 ("Do the conditions of use result in an intake greater than 1.5 µg/day?") from the Procedure. The 82nd JECFA noted that this is the original United States Food and Drug Administration threshold of regulation value of 1.5 µg/person per day, but that this value is of little practical application in the Procedure. Moreover, the Cramer class thresholds as applied would be adequately protective for a non-genotoxic cancer end-point.

6. At its 82nd meeting, JECFA recommends these points for consideration when deciding on the adequacy of a resulting margin of exposure at step 5 of the revised procedure:

(i) What is the overall strength of the database?

(ii) Is the margin of exposure based on a NOAEL for the flavouring agent or for a structurally related substance?

(iii) What is the effect on which the NOAEL is based?

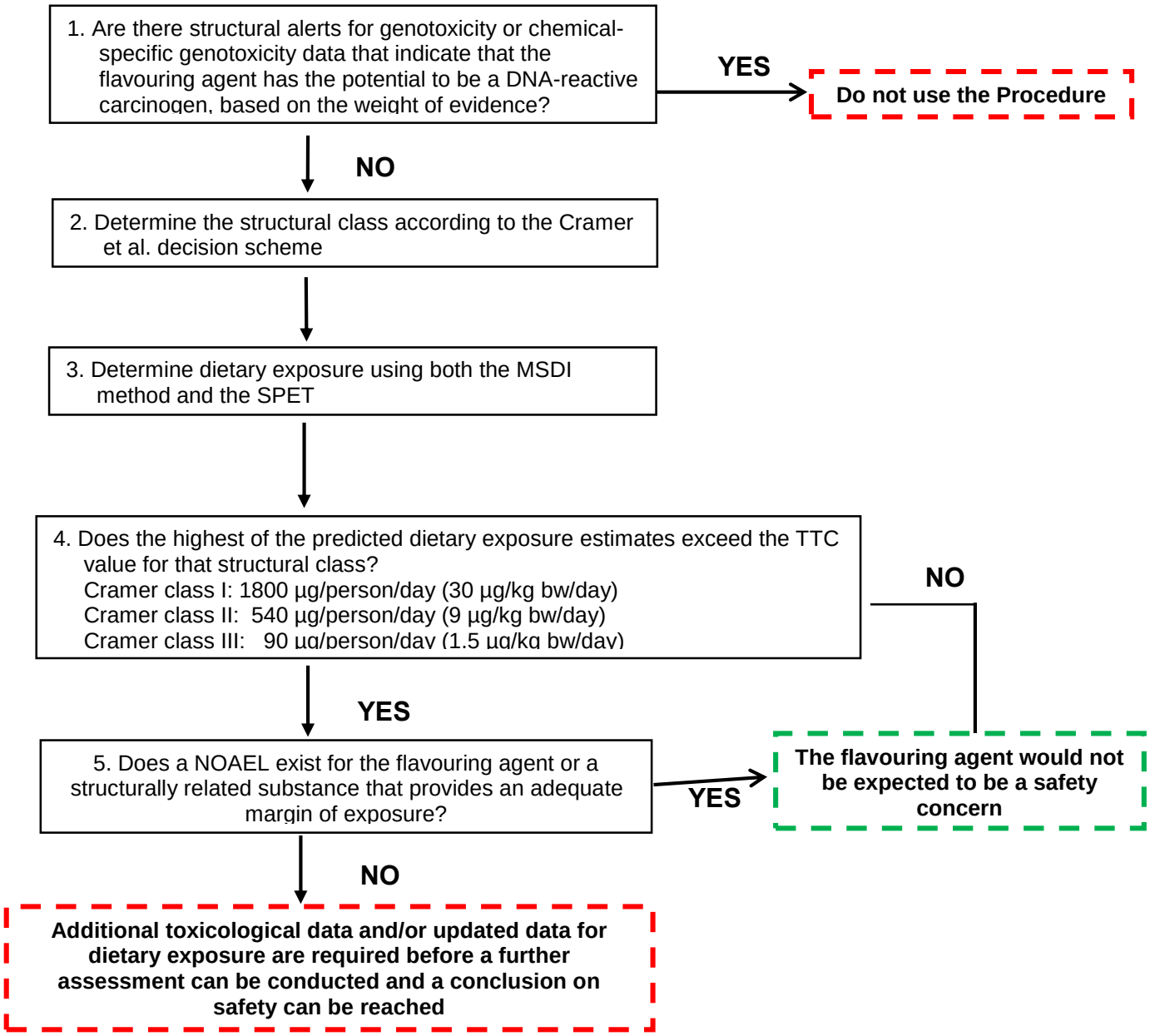
(iv) Is the NOAEL the highest dose tested or identified from a single-dose study?

(v) What is the duration of the study from which the NOAEL is identified?

7. If the overall database is considered, based on expert judgement, to be sufficiently robust, JECFA considered that a margin of exposure that accommodates at least a default safety factor as used in the assessment of food additives may be sufficient to conclude that the flavouring agent would not be expected to be a safety concern at current estimated levels of dietary exposure. JECFA further concluded that the revised Procedure for the Safety Evaluation of Flavouring Agents (see Fig. 1) should be applied in its future evaluations.

8. JECFA noted that application of the new Procedure would not have an impact on previous evaluations, because genotoxicity is considered in the current Procedure, metabolism is considered in the Cramer decision-tree and, overall, this new procedure is equally robust.

Fig. 1 Revised Procedure for the Safety Evaluation of Flavouring Agents



Approach for prioritizing flavouring agents for re-evaluation

9. The 79th JECFA meeting held a preliminary discussion concerning the fact that the submission of additional toxicology data, including genotoxicity data, and/or exposure data for previously evaluated flavouring agents may trigger the need for re-evaluation of previously evaluated flavouring agents. The 82nd JECFA reiterated the need for the development of an approach, including a prioritization process, for the re-evaluation of flavouring agents based on all available toxicological data and updated exposure estimates. When developing such an approach, compounds that are used as comparators for structurally related compounds will require specific attention when new data on these become available. JECFA also noted that there is a need to compile data on all flavouring agents that were reported in the monographs of previous meetings and from other sources but not re-evaluated, to assist the prioritization for the re-evaluation. Moreover, for any flavouring agents for which new toxicological studies are submitted, the sponsor needs to provide updated exposure data.

Limits for lead in specifications of food additives for use in infant formula

10. At its Eighth Session, the Codex Committee on Contaminants in Foods (CCCF) set a maximum limit (ML) of 0.01 mg/kg for lead in infant formula (as consumed). The 79th JECFA noted that three of the four food additives considered for risk assessment at that meeting (pectin, CITREM and starch sodium octenyl succinate) could result in exceedance of the ML for lead in infant formula at proposed use levels if lead were present at the specification limits listed in the individual monographs (i.e. at 5 mg/kg in pectin and at 2 mg/kg in both CITREM and starch sodium octenyl succinate). The 79th JECFA also noted that the introduction of lower lead limits in the specifications (e.g. 1 mg/kg for pectin, 0.5 mg/kg for CITREM and 0.1 mg/kg for starch sodium octenyl succinate) would result in none of these additives exceeding the ML for lead in the final infant formula (i.e. 0.01 mg/kg) if these additives were included in infant formula at the maximum use level reviewed by JECFA.

11. For the 82nd JECFA meeting, data were requested on the levels of lead present in CITREM, pectin and starch sodium octenyl succinate for use in infant formula, and data was received on levels of lead in CITREM and pectin, but not for starch sodium octenyl succinate. The 82nd JECFA evaluated the data presented for levels of lead in 12 non-consecutive lots of CITREM. The levels of lead were below 0.1 mg/kg, the limit of quantification of the method (inductively coupled plasma optical emission spectrometry), demonstrating that the lead level of 0.5 mg/kg proposed by the 79th JECFA was achievable for CITREM used in infant formula. The current limit of 2 mg/kg for lead in the CITREM specifications monograph was maintained for general use, and a limit of 0.5 mg/kg was included for use in infant formula.

12. The 82nd JECFA also evaluated data presented for levels of lead in pectin for use in infant formula analyzed by two different analytical methods. Levels reported for lead in 12 non-consecutive lots of pectin analyzed by inductively coupled plasma atomic emission spectrometry were below the limit of detection of the method (0.4 mg/kg). The mean level of lead reported for five non-consecutive lots of pectin analyzed by inductively coupled plasma mass spectrometry was 0.017 mg/kg. Based on the data provided, the 82nd JECFA noted that the levels of lead in pectin intended for use in infant formula were below the level of 1 mg/kg considered by the 79th JECFA. The current limit of 5 mg/kg for pectin in the specifications monograph was reduced to 2 mg/kg for general use, and a limit of 0.5 mg/kg was included for use in infant formula.

13. At its 82nd meeting, JECFA also considered the levels of lead in the specifications monographs of two other additives on the agenda for consideration for use in infant formula – namely, carob bean gum and xanthan gum – in light of this discussion. Based on the data provided, the 82nd JECFA maintained the lead limits in the specifications monographs for these two additives for general use (2 mg/kg) and reduced them to 0.5 mg/kg for use in infant formula.

14. Based on the data submitted for CITREM, pectin, carob bean gum and xanthan gum, the 82nd JECFA was reassured that the overall criterion for lead levels in the ingredients for use in infant formula is achievable. However, the 82nd JECFA further reaffirmed that it is the responsibility of the infant formula manufacturers to ensure that the lead levels in the final infant formula (as consumed) comply with the ML for lead as set by the 8th Session of CCCF, and recommended that all additives (including starch sodium octenyl succinate) for use in infant formula be reviewed for lead levels in the specifications.

Tentative specifications for food additives

15. At its 82nd meeting, JECFA could not adopt specifications for Steviol glycosides (INS 960) and could not revise the specifications of other additives (Rosemary extract (INS 392), Cassia gum (INS 427), and 13 Modified starches) as the information available was insufficient. The missing information and the suggested deadline for its submission are given in Table 1. It is recommended that such pending evaluations and the data needed are considered by the CCFA Working Group on priorities and by CCFA49 under Agenda Item 7 “Proposals for additions and changes to the Priority List of Substances proposed for evaluation by JECFA” with a view to have a clear commitment on whether and when data will be made available.

Requests for scientific advice

16. Both organizations continue to jointly prioritize the requests for scientific advice taking into consideration the criteria proposed by Codex as well as the requests for advice from Member Countries and the availability of resources. A list of all pending requests for scientific advice by JECFA will be posted on the respective FAO and WHO websites.

17. In scheduling the JECFA meetings and developing the agenda, the Joint Secretaries have to take into account the priorities requested by CCFA, CCCF, and CCRVDF. Due to the increasing requests for scientific advice to JECFA, not all requests can be addressed in the subsequent meeting. In prioritizing the work the JECFA Secretariat takes into account existing criteria, on-going Codex work and available resources.

18. To facilitate provision of extra-budgetary resources for scientific advice activities, please contact Dr Markus Lipp, FAO Food Safety and Quality Unit (jecfa@fao.org) and Dr Angelika Tritscher, Department of Food Safety and Zoonoses, WHO (jecfa@who.int).

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

19. At its 82nd meeting, JECFA evaluated the safety of 10 food additives. Toxicological recommendations or other scientific advice for these food additives are provided in the attached Table 1.

20. At its 82nd meeting JECFA also evaluate 26 flavouring agents. The results are summarized in Table 2.

21. CCFA49 **is invited** to consider the recommended actions (presented in Table 1) which might be required following the evaluations of these food additives.

Table 1. Food additives evaluated toxicologically and/or considered for specifications at the 82nd JECFA meeting

INS Number	Food additive	Acceptable daily intakes (ADIs) and other toxicological or safety recommendations and dietary exposure information	Recommended action by CCFA
129	Allura Red AC	The 82nd JECFA concluded that the new data do not give reason to revise the ADI and confirmed the ADI of 0–7 mg/kg body weight (bw). The 82nd JECFA noted that the range of estimated dietary exposures to Allura Red AC for children based on reported or industry use data were below the upper bound of the ADI and concluded that dietary exposure to Allura Red AC for children and all other age groups does not present a health concern.	Note the JECFA conclusion on an ADI of 0–7 mg/kg body weight (bw) for the Allura Red AC, which does not present a health concern for children and all other age groups.
410	Carob bean gum	The 82nd JECFA concluded that the available studies are not sufficient for the evaluation of carob bean gum for use in infant formula at the proposed use level. The 82nd JECFA requests toxicological data from studies in neonatal animals, adequate to evaluate the safety for use in infant formula, to complete the evaluation. **Data are requested by end of 2017**.	Note the JECFA request for additional toxicological data to complete the evaluation.
161b(iii)	Lutein esters from *Tagetes erecta*	The 82nd JECFA removed the temporary designation (because the tentative status of the specifications was removed) and established an ADI "not specified" for lutein esters from *Tagetes erecta.*	Note the JECFA conclusion on an ADI "not specified" for lutein esters from *Tagetes erecta*. Consider to - Include lutein esters from *Tagetes erecta* (INS 161b(iii)) in Table 3 of GSFA and circulate for comments at Step 3; - Request for comments/proposals on uses and use levels of lutein esters from *Tagetes erecta* (INS 161b(iii)) for the food categories listed in the Annex to Table 3
423	Octenyl succinic acid (OSA)–modified gum arabic	The 82nd JECFA removed the temporary designation and established an ADI "not specified" for OSA-modified gum arabic. The 82nd JECFA confirmed the validity of the dietary exposure estimate for risk assessment purposes set at a previous meeting.	Note the JECFA conclusion on an ADI "not specified" for OSA-modified gum arabic. Consider to - Include OSA–modified gum arabic (INS 423) in Table 3 of GSFA and circulate for

INS Number	Food additive	Acceptable daily intakes (ADIs) and other toxicological or safety recommendations and dietary exposure information	Recommended action by CCFA
			comments at Step 3; - Request for comments/proposals on uses and use levels of OSA–modified gum arabic (INS 423) for the food categories listed in the Annex to Table 3
440	Pectin	The no-observed-adverse-effect level (NOAEL) in a previously evaluated neonatal pig study was recalculated to be 1049 mg/kg bw per day using measured concentrations of pectin in milk replacer rather than target concentrations. At the new maximum proposed use level of 0.2%, the estimated exposure of infants 0–12 weeks of age would be up to 360 and 440 mg/kg bw per day at mean and high consumption. The margins of exposure for average and high consumers are 2.9 and 2.4, respectively, when compared with the NOAEL of 1049 mg/kg bw per day. On the basis of a number of considerations, the 82nd JECFA concluded that the margins of exposure calculated for the use of pectin at 0.2% in infant formula indicate low risk for the health of infants and are not of concern.	Note the JECFA conclusion on the margins of exposure calculated for the use of pectin at 0.2% in infant formula indicate low risk for the health of infants and are not of concern. Refer the result of JECFA evaluation to CCNFSDU for consideration of the inclusion of pectin in relevant standards.
104	Quinoline Yellow	The 82nd JECFA concluded that it was reasonable to use toxicology data on D&C Yellow No. 10 to support the database for Quinoline Yellow. The 82nd JECFA established an ADI of 0–3 mg/kg bw (rounded value) for Quinoline Yellow on the basis of a NOAEL of 250 mg/kg bw per day for effects on body weight and organ weights in two long-term studies in rats on D&C Yellow No. 10. An uncertainty factor of 100 was applied to account for interspecies and intraspecies variability. The 82nd JECFA concluded that dietary exposure to Quinoline Yellow for children and all other age groups does not present a health concern.	Note the JECFA conclusion on an ADI of 0–3 mg/kg bw (rounded value) for Quinoline Yellow, which does not present a health concern for children and all other age groups. Consider to - Request for comments/ proposals on uses and use levels of quinolone yellow for inclusion in table 1 and 2 of the GSFA.
392	Rosemary extract	The 82nd JECFA established a temporary ADI of 0–0.3 mg/kg bw for rosemary extract, expressed as carnosic acid and carnosol, on the basis of a NOAEL of 64 mg carnosic acid + carnosol/kg bw per day, the highest dose tested in a short-term toxicity study in rats, with application of a 200-fold uncertainty factor. This uncertainty factor incorporates a factor of 2 to account for the temporary designation of the ADI. The 82nd JECFA made the ADI temporary pending the submission of studies to elucidate the potential developmental and	Note the JECFA request for information to complete to revise a temporary ADI of 0–0.3 mg/kg bw for rosemary extract and the tentative specifications.

INS Number	Food additive	Acceptable daily intakes (ADIs) and other toxicological or safety recommendations and dietary exposure information	Recommended action by CCFA
		reproductive toxicity of the rosemary extract under consideration. An additional uncertainty factor to account for the lack of a chronic toxicity study was not considered necessary based on the absence of adverse effects in the short-term toxicity studies at doses up to and including the highest dose tested. The temporary ADI applies to rosemary extract that meets the specifications prepared at the present meeting. It will be withdrawn if the required data are not provided **by the end of 2018**. The 82nd JECFA noted that the dietary exposure estimates for rosemary extract for high consumers, 0.09–0.81 mg/kg bw per day (as carnosic acid plus carnosol), may exceed the upper bound of the temporary ADI by up to 2.7-fold (for young children at the top end of the range of estimated dietary exposures). Based on the conservative nature of the dietary exposure assessments, in which it was assumed that all foods contained rosemary extracts at the maximum use level, the 82nd JECFA concluded that this exceedance of the temporary ADI does not necessarily represent a safety concern. The 82nd JECFA prepared tentative specifications and requested validation information on the method for determination of residual solvents **by the end of 2018**. The 82nd JECFA requested that data on typical use levels in foods be provided **by the end of 2018** in order to refine the dietary exposure estimates.	
960	Steviol glycosides	The 82nd JECFA confirmed the ADI of 0–4 mg/kg bw, expressed as steviol, and also confirmed that rebaudioside A from multiple gene donors expressed in Yarrowia lipolytica is included in the ADI. The 82nd JECFA concluded that it was not necessary to make the ADI temporary because the requested information to complete the specifications refers only to an update of the method and has no safety implication. The 82nd JECFA noted that the predicted maximum dietary exposure to steviol glycosides of 4.0–4.4 mg/kg bw per day for young children who were high consumers exceeded the upper bound of the ADI (up to 110%), but the ADI was not exceeded for other age groups. Considering the conservative nature of the dietary exposure estimate, based on maximum use levels applied to all food consumed from categories with permissions for use in the countries assessed, steviol glycosides are not likely to present a health concern for any age group. The specifications were made tentative pending submission of following information **by 31 December 2017**: - Method of assay to replace the existing method and including as many steviol	Note the JECFA conclusion on an ADI of 0–4 mg/kg bw of Steviol glycosides because the requested information to complete the specifications refers only to an update of the method and has no safety implication. No action required as the new specifications is tentative. Note the JECFA request for information to complete to revise the tentative specifications.

INS Number	Food additive	Acceptable daily intakes (ADIs) and other toxicological or safety recommendations and dietary exposure information	Recommended action by CCFA
		glycosides as possible (at least those listed in Appendix 1 of the specifications) in steviol glycoside mixtures, along with supporting validation information and chromatograms; - Analysis results from a minimum of five batches for commercial samples, including supporting chromatograms.	
102	Tartrazine	The 82nd JECFA established an ADI of 0–10 mg/kg bw, on the basis of a NOAEL of 984 mg/kg bw per day for reductions in body weight in a chronic rat study, with application of a 100-fold uncertainty factor to account for interspecies and intraspecies variability. The 82nd JECFA withdrew the previous ADI of 0–7.5 mg/kg bw per day. The 82nd JECFA noted that the dietary exposure estimate for children aged 1–10 years was below the upper bound of the ADI and concluded that dietary exposure to tartrazine for the general population, including children, does not present a health concern.	Note the JECFA conclusion on an ADI of 0–10 mg/kg bw for the Tartrazine, which does not present a health concern for the general population including children.
415	Xanthan gum	A NOAEL of 750 mg/kg bw per day was established for xanthan gum in neonatal pigs, which are an appropriate animal model for the assessment of the safety of the additive for infants. The margin of exposure based on this NOAEL and the conservative estimate of xanthan gum intake of 220 mg/kg bw per day by infants (high energy requirements for fully formula-fed infants) is 3.4. On the basis of a number of considerations, the 82nd JECFA concluded that the consumption of xanthan gum in infant formula or formula for special medical purposes intended for infants is of no safety concern at the maximum proposed use level of 1000 mg/L.	Note the JECFA conclusion on the consumption of xanthan gum in infant formula or formula for special medical purposes intended for infants is of no safety concern at the maximum proposed use level of 1000 mg/L. Refer the result of JECFA evaluation to CCNFSDU for consideration of the inclusion of xantham gum in relevant standards.
427	Cassia gum	The 82nd JECFA noted that cassia gum can be obtained from a number of companies and requested information on validated methods of analysis currently in use by providers of cassia gum. The methods submitted should contain details of the use of standard (reference) materials, the extraction efficiency of the initial steps, the recovery of the analytes in question, performance data and the results of the analysis of several batches of the material in commerce. The tentative specifications will be withdrawn unless the requested information is submitted **before 31 December 2017.**	Note the JECFA request for information to revise the tentative specifications.

<table>
<tr><th>INS Number</th><th>Food additive</th><th>Acceptable daily intakes (ADIs) and other toxicological or safety recommendations and dietary exposure information</th><th>Recommended action by CCFA</th></tr>
<tr><td></td><td>Modified starches</td><td>The 82nd JECFA prepared tentative specifications for the following 13 modified starches and require the following information for the removal of the tentative status:
<table><tr><th>Modified starch</th><th>Information required on</th></tr><tr><td>Dextrin roasted starch (INS No. 1400)</td><td>• A suitable method for the Dispersion or Reducing Sugars Distinguishing Test</td></tr><tr><td>Acid treated starch (INS No. 1401)</td><td>• A suitable method for the Dispersion or Reducing Sugars Distinguishing Test</td></tr><tr><td>Alkaline treated starch (INS No. 1402)</td><td>• A suitable method for the Dispersion or Reducing Sugars Distinguishing Test</td></tr><tr><td>Bleached starch (INS No. 1403)</td><td>• Typical levels of residual reagents or by-products</td></tr><tr><td>Enzyme-treated starch (INS No. 1405)</td><td>• A suitable method for the Dispersion or Reducing Sugars Distinguishing Test</td></tr><tr><td>Monostarch phosphate (INS No. 1410)</td><td>• A suitable test for identification of the phosphate groups</td></tr><tr><td>Distarch phosphate (INS No. 1412)</td><td>• A suitable test for identification of the phosphate groups and of crosslinking</td></tr><tr><td>Phosphated distarch phosphate (INS No. 1413)</td><td>• A suitable test for identification of the phosphate groups and of crosslinking</td></tr><tr><td>Acetylated distarch phosphate (INS No. 1414)</td><td>• A suitable test for identification of the phosphate groups and of crosslinking</td></tr><tr><td>Acetylated distarch adipate (INS No. 1422)</td><td>• A suitable test for identification of the adipate groups
• Levels of free adipic acid</td></tr><tr><td>Hydroxypropyl starch (INS No. 1440)</td><td>• A suitable method for the determination of propylene chlorohydrin</td></tr><tr><td>Hydroxypropyl distarch phosphate (INS No. 1442)</td><td>• A suitable method for the determination of propylene chlorohydrin
• A suitable test for identification of the phosphate groups</td></tr></table></td><td>Note the JECFA request for information to revise the tentative specifications</td></tr>
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INS Number	Food additive	Acceptable daily intakes (ADIs) and other toxicological or safety recommendations and dietary exposure information	Recommended action by CCFA
		Starch sodium octenyl succinate (INS No. 1450) • A suitable test for identification of octenylsuccinate groups The 82nd JECFA recommended that the call for data also include method of manufacture for each of the modified starches. The missing data are required **by 31 December 2017**.	

Table 2 Flavouring Agents evaluated at the 82nd JECFA meeting

A. Alicyclic, alicyclic-fused and aromatic-fused ring lactones

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class III			
2-(2-Hydroxy-4-methyl-3-cyclohexenyl)propionic acid gamma-lactone	2223	N	No safety concern
2-(2-Hydroxyphenyl)-cyclopropanecarboxylic acid delta-lactone	2224	N	No safety concern

N: new specifications

B. Aliphatic and aromatic amines and amides

The Committee concluded that the concerns previously expressed by the Committee at its sixty-ninth meeting as to in vivo genotoxicity and how to address the kidney effects and identify a NOAEL have not been sufficiently addressed and that the Procedure still could not be applied to 2-isopropyl-*N*,2,3-trimethylbutyramide (No. 1595).[1]

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class III			
N1-(2,3-Dimethoxybenzyl)-*N2*-(2-(pyridin-2-yl)ethyl)oxalamide	2225	N	No safety concern
(*R*)-*N*-(1-Methoxy-4-methylpentan-2-yl)-3,4-dimethylbenzamide	2226	N	No safety concern
(*E*)-*N*-[2-(1,3-Benzodioxol-5-yl)ethyl]-3-(3,4-dimethoxyphenyl)prop-2-enamide	2227	N	No safety concern
(*E*)-3-Benzo[1,3]dioxol-5-yl-*N*,*N*-diphenyl-2-propenamide	2228	N	No safety concern
N-Ethyl-5-methyl-2-(methylethenyl)cyclohexanecarboxamide	2229	N[a]	Additional data required to complete evaluation
N-Ethyl-2,2-diisopropylbutanamide	2005	M[b]	Additional data required to complete evaluation
N-(2-Hydroxyethyl)-2,3-dimethyl-2-isopropylbutanamide	2010	M[b]	Additional data required to complete evaluation
N-(1,1-Dimethyl-2-hydroxyethyl)-2,2-diethylbutanamide	2011	M[b]	Additional data required to complete evaluation

M: existing specifications maintained; N: new specifications

[a] The specifications include a statement that the safety evaluation for the flavouring agent had not been completed.

[b] The statement currently contained in the specifications indicating that the safety evaluation had not been completed will be maintained.

[1] The statement currently contained in the specifications indicating that the safety evaluation had not been completed will be maintained.

C. Aliphatic secondary alcohols, ketones and related esters

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class II			
9-Decen-2-one	2216	N	No safety concern
Yuzunone	2217	N	No safety concern
1,5-Octadien-3-ol	2218	N	No safety concern
3,5-Undecadien-2-one	2219	N	No safety concern
3-Methyl-5-(2,2,3-trimethylcyclopent-3-en-1-yl)pent-4-en-2-ol	2220	N	No safety concern
(±)-1-Cyclohexylethanol	2221	N	No safety concern

N: new specifications

D. Cinnamyl alcohol and related substances

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
Ethyl alpha-acetylcinnamate	2211	N	No safety concern
Ethyl 2-hydroxy-3-phenylpropionate	2213	N	No safety concern
Structural class III			
3-(3,4-Methylenedioxyphenyl)-2-methylpropanal	2212	N[a]	Additional data required to complete evaluation
Cinnamaldehyde propyleneglycol acetal	2214	N	No safety concern
2-Phenylpropanal propyleneglycol acetal	2215	N	No safety concern

N: new specifications

[a] The specifications include a statement that the safety evaluation for the flavouring agent had not been completed.

E. Tetrahydrofuran and furanone derivatives

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class II			
2,5-Dimethyl-3(2*H*)-furanone	2230	N	No safety concern
Structural class III			
2,5-Dimethyl-4-ethoxy-3(2*H*)-furanone	2231	N	No safety concern
5-Methyl-3(2*H*)-furanone	2232	N	No safety concern
Ethyl 2,5-dimethyl-3-oxo-4(2*H*)-furyl carbonate	2233	N	No safety concern
4-Acetyl-2,5-dimethyl-3(2*H*)-furanone	2234	N[a]	Additional data required to complete evaluation

N: new specifications

[a] The specifications include a statement that the safety evaluation for the flavouring agent had not been completed.