CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7a CRD 5

Original Language

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-eighth Session

Xi'an, China, 14-18 March 2016

REPORT OF THE IN-SESSION WORKING GROUP ON PRIORITIES FOR EVALUATION BY JECFA

15 March 2016

I. Introduction

1. The in-session working group (WG) was chaired by Mr. Matthew Bauder (Canada). Mr. Steven Theriault (Canada) served as Rapporteur, and Dr. Angelika Tritscher (JECFA, WHO), and Dr. Markus Lipp (JECFA, FAO) assisted the Chair. The following members and organisations participated: Australia, Belgium, Brazil, Canada, Chad, China, Colombia, Denmark, Eritrea, EU, Finland, France, Germany, Iran, Ireland, Israel, Japan, Mexico, Netherlands, New Zealand, Nigeria, Norway, Philippines, Republic of Korea, Russian Federation, Saudi Arabia, Senegal, Singapore, South Sudan, Sudan, Switzerland, Thailand, United Kingdom, United States of America, African Union, AIDGUM, AMFEP, CCC, ELC, ETA, IACM, IADSA, ICA, ICBA, ICGA, ICGMA, IDF, IFAC, IGTC, ILSI, IOFI, ISC, ISDI, IUFoST, NATCOL, OENOPPIA, OIV, YLFA.

II. Adoption of the agenda

2. The agenda was adopted without changes.

III. Notes

3. The Chair also stated the WG's Terms of Reference. These being:

To consider and prepare recommendations for the Plenary on:

i. To consider and prepare recommendations for the Plenary on proposals for additions and changes to the Priority List of Substances Proposed for Evaluation by JECFA (replies to CL 2015/11-FA) (CX/FA 16/48/15, CX/FA 16/48/15 Add.1 and CRD 21);

4. The Chair reminded the group to use the form on which information on the compound to be evaluated by JECFA is provided when submitting requests, and noted in particular:

i. data to be submitted in response to JECFA's call for data must be submitted by December of 2016, and should the data not be provided, then the substance will be withdrawn from the Priority List of Substances Proposed for Evaluation by JECFA (the Priority List) and a new request for its inclusion on the Priority List will need to be made during the 49th CCFA; and

ii. future forms will include a field to address if an additive to be used in infant foods is considered to be technologically justified by the CCNFSDU prior to consideration for evaluation by JECFA, but that for this year, CCFA will forward requests for the inclusion of additives to be used in infant foods on the Priority List to the CCNFSDU for confirmation of technological justification prior to evaluation by JECFA.

5. Further to point 4(i), JECFA clarified during the physical working group that JECFA has no facility to store data outside of their call for data. Therefore, data should not be submitted to JECFA outside of the call for data, and if data were previously submitted, that they should be resubmitted in response to the call for data.

6. The Chair explained that the working group would first consider those substances that were added to the Priority List during the 47th CCFA. The Chair explained that entries that were struck-through on the Priority List were subject to JECFA's previous call for data, and would not be considered in this session. The remaining 19 substances, with the exception of Gum Arabic, were considered, to seek confirmation of interest in the substance remaining on the Priority List and clarification on the data availability for submission

to JECFA by December 2016. Consideration of Gum Arabic would be postponed until all other substances were considered.

7. The Chair explained that after the list of substances carried-over from last year is considered, that the new requests for additions of substances to the Priority List would be considered. The requests were considered case-by-case, although in some instances the WG addressed similar requests as a group.

8. As a matter of referral from the Plenary discussion of Agenda item 7(b), sodium sorbate (INS 221) was considered as a new request for a substance to be added on the Priority List as there are provisions for its use in the GSFA but there are no specifications for it.

IV. Working group recommendations to the 48th CCFA on proposals for additions and changes to the priority list of food additives proposed for evaluation by JECFA

9. The WG had 19 substances that were carried over from the 47th CCFA, and 22 new requests for consideration for the Priority List (not including flavouring substances that were also considered). **Chair's note to the WG report:** A separate listing for the colours to be re-evaluated is consistent with the decision of CCFA46 referred to in paragraph 144 of REP14/FA.

10. For those substances that were carried over from the 47th CCFA, confirmation was made that data would be available by December 2016, for consideration by JECFA, except for the following:

i. Carbohydrate-derived fulvic acid: the supporter did not attend the in-session working group and so the matter is referred to the Plenary to seek confirmation on the availability of data and if the substance should be retained on the Priority List; and

ii. Potassium bisulphite (INS 228): the supporter confirmed that they would no longer support the request and so the substance was removed from the Priority List.

11. **Chair's Note to the WG Report:** If CCFA 48 agrees to remove potassium bisulphite (INS 228) from the Priority List, then the Committee should consider whether provisions in the GSFA for this additive will need to be removed[1].

12. With respect to the request for Gum Arabic, it was the understanding of JECFA that the request was for the establishment of new specifications based on one of the two acceptable source materials. JECFA clarified that such an amendment to the specifications would involve establishing a new INS number, a full safety assessment, and would require sufficient technological rationale to justify the change. There was also disagreement within the working group on the suitability of this request. As there was no agreement on the appropriateness of the existing request for Gum Arabic on the Priority List, it was proposed to remove Gum Arabic from the Priority List, and a new request for evaluation could be submitted in response to the next Circular Letter, which should include a detailed technological justification for the need to revise the current specifications for Gum Arabic.

13. The availability of data by December 2016 was confirmed for a number of substances included in the new requests for substances to be added to the Priority List.

14. The supporter of Bacteroides xylanisolvens DSM 23964 withdrew the request related to this organism.

15. Two substances, ferric orthophosphate and ferric pyrophosphate, are intended for use as nutrient sources and were therefore deemed to be not under the purview of the CCFA and are thus ineligible for inclusion on the Priority List.

16. It was noted that gellan gum (INS 418) is an additive to be used in infant formulas, and as such requires confirmation by the CCNFSDU on its technological justification prior to consideration by JECFA. However, as the request was complete in reply to CL 2015/11-FA, it was proposed that gellan gum be added to the Priority List, albeit subject to confirmation of the technological justification by the CCNFSDU as a matter referred to that Committee.

17. The supporter of polyvinyl alcohol (INS 1203) could not confirm the availability of data by December 2016, and the matter was referred to the Plenary to seek confirmation on the availability of data and if the substance should be retained on the Priority List.

18. As a matter of referral from the Plenary discussion of Agenda item 7(b), sodium sorbate was recommended to be added to the Priority List as proposed by the 48th CCFA, with data availability to be confirmed by the 49th CCFA. The working group included a recommendation to add a safety assessment to the request to establish specifications.

1 As per REP13/FA, paragraphs 14-16

19. The working group agreed that the substances considered by the 47th CCFA be given higher priority over the newly requested substances, with the exception of flavouring substances.

20. The outcome of the in-session WG's deliberations is presented in the table attached to this report (Annex 1).

Recommendation 1

The in-session WG recommends that the 48th session of the CCFA consider including the substances identified in the table attached to this report (Annex 1) on the Priority List of Food Additives Proposed for Evaluation by JECFA.

ANNEX 1 - PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA
(Recommended by the in-session WG on priorities for evaluation by JECFA for consideration by the 48th CCFA

Substance(s) (High Priority (*))	***Question(s) to be answered***	***Data availability (when, what)***	***Proposed by***
Acid prolyl endopeptidase from *Aspergillus niger* expressing a gene from *Aspergillus niger*	Safety assessment and establishment of specifications	December 2016	European Union
D-Allulose 3-epimerase from *Arthrobacter globiformis* expressed in *Escherichi coli*	Safety assessment and establishment of specifications	December 2016	United States of America
Alpha-amylase from *Bacillus licheniformis* expressing a modified alpha-amylase gene from *Geobacillus stearothermophilus*	Safety assessment and establishment of specifications	December 2016	European Union
*Alpha-amylase from *Bacillus stearothermophilus* expressed in *Bacillus licheniformis*	Safety assessment and establishment of specifications	December 2016	European Union
*Alpha-amylase from *Rhizomucor pusillus* expressed in *Aspergillus niger*	Safety assessment and establishment of specifications	December 2016	European Union
Amyloglucosidase from *Talaromyces emersonii* expressed in *Aspergillus niger*	Safety assessment and establishment of specifications	December 2016	European Union
*Asparaginase from *Aspergillus niger* expressing a modified gene from *Aspergillus niger*	Safety assessment and establishment of specifications	December 2016	European Union
*Asparaginase from *Pyrococcus furiosus* expressed in *Bacillus subtilis*	Safety assessment and establishment of specifications	December 2016	European Union
Beta-amylase from *Bacillus flexus* expressed in *Bacillus licheniformis*	Safety assessment and establishment of specifications	December 2016	European Union
Beta-glucanase from *Streptomyces violaceoruber* expressed in *S. violaceoruber*	Safety assessment and establishment of specifications	December 2016	Japan
*Carbohydrate-derived fulvic acid	Safety assessment and establishment of specifications	Pending confirmation of CCFA48	South Africa
*Carotenes from *Dunaliella salina*	Safety assessment and revision of specifications	December 2016	European Union
Flavouring substances (8 new + 20 from previous Priority Lists + 55 for which JECFA requested additional info = 83 total)	Safety assessment or re-assessment, and establishment of specifications or revision of specifications, as applicable	December 2016	United States of America
Gellan gum (INS 418) (Pending confirmation of technological justification from CCNFSDU)	Safety assessment for use in infant formula, formula for special medical purposes for infants, and follow-up formula	December 2016	United States of America
*Glucose oxidase from *Penicillium chrysogenum* expressed in *Aspergillus niger*	Safety assessment and establishment of specifications	December 2016	European Union
*Gum ghatti	Safety assessment and revision of specifications	December 2016	United States of America

*Jagua (*Genipa americana*) extract	Safety assessment and establishment of specifications	December 2016	Colombia
INS 1205 Basic methacrylate copolymer	Safety assessment and establishment of specifications	December 2016	European Union
INS 1206 Neutral methacrylate copolymer	Safety assessment and establishment of specifications	December 2016	European Union
INS 1207 Anionic Methacrylate copolymer	Safety assessment and establishment of specifications	December 2016	European Union
Lactase from *Bifidobacterium bifidum* expressed in *Bacillus licheniformis*	Safety assessment and establishment of specifications	December 2016	European Union
Lipase from *Aspergillus oryzae* expressing a modified gene from *Thermomyces lanuginosus*	Safety assessment and establishment of specifications	December 2016	European Union
*Metatartaric acid (INS 353)	Safety assessment and establishment of specifications	December 2016	Australia
*Microcrystalline cellulose (INS 460 (i))	Revision of specifications	December 2016	Japan
Phosphatidyl inositol-specific phospholipase C from a genetically modified strain of *Pseudomonas fluorescens*	Safety assessment and establishment of specifications	December 2016	European Union
*Phospholipase A2 from pig pancreas expressed in *Aspergillus niger*	Safety assessment and establishment of specifications	December 2016	European Union
Phospholipase A2 from *Streptomyces violaceoruber* expressed in *S. violaceoruber*	Safety assessment and establishment of specifications	December 2016	Japan
Polyvinyl alcohol (INS 1203)	Revision of specifications	December 2016	European Union
Sodium sorbate (INS 221)	Safety assessment and establishment of specifications	To be confirmed by CCFA 49	CCFA 48
Spirulina extract	Safety assessment and establishment of specifications	December 2016	United States of America
Sucrose esters of fatty acids (INS 473)	Revision of specifications	December 2016	Japan
*Tamarind seed polysaccharide	Safety assessment and establishment of specifications	December 2016	Japan
*Tannins	Safety assessment and establishment of specifications	December 2016	Australia
Transglucosidase/alpha-glucosidase from *Trichoderma reesei* expressing an Alpha-glucosidase gene from *Aspergillus niger*	Safety assessment and establishment of specifications	December 2016	European Union
*Xylanase from *Bacillus licheniformis* expressed in *Bacillus licheniformis*	Safety assessment and establishment of specifications	December 2016	European Union
*Xylanase from *Talaromyces emersonii* expressed in *Aspergillus niger*	Safety assessment and establishment of specifications	December 2016	European Union
*Yeast mannoproteins (INS 455)	Safety assessment and establishment of specifications	December 2016	Australia
Substances for re-evaluation			
Brilliant Blue FCF (INS 133)	Re-evaluation of safety and specifications	December 2016	CCFA46 (data from Japan; IACM; EU)
Erythrosine (INS 127)	Re-evaluation of safety and specifications	December 2016	CCFA46 (data from Japan; IACM; EU)

Fast green FCF (INS 143)	Re-evaluation of safety and specifications	December 2016	CCFA46 (data from Japan; IACM)
Indigotine (INS 132)	Re-evaluation of safety and specifications	December 2016	CCFA46 (data from Japan; IACM; EU)