CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7 **CRD23**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-ninth Session

Macao SAR, China, 20-24 March 2017

PROPOSALS FOR ADDITIONS AND CHANGES TO THE PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA

Comments of Malaysia, Russian Federation and ISDI

Malaysia

Malaysia supports the proposals received from Calorie Control Council (CCC) and The International Council of Beverages Associations.

Russian Federation

1. Nisin (INS234) and Natamycin (Pimaricin) (INS 235)

The Russian Federation is requesting safety re-assessment of nisin and natamycin due to emerging data on the bioactivity including the role of nisin and natamycin played in: (i) promoting the antimicrobial resistance as well as speeding up virulence and pathogenic potential of microorganisms which cause food-borne illnesses; (ii) misbalance of immunity status and guts' microflora and other functions in human body. The JECFA re-evaluation is requested to allow CCFA to consider if antibiotics Nisin (INS234) and Natamycin (Pimaricin) (INS 235) should be retained in the GSFA.

The position regarding the proposals for the use of re-assessment of nisin (INS 234) and natamycin (INS 235) is set out in the comments on Agenda 7(Additional Replies CX/FA 17/49/13 Add.1)

2. The European Union and its Member States are proposing to add the following substances to the priority list of substances proposed for evaluation by JECFA:

1) Protease Aqualysin 1 from Thermus aquaticus produced by B. subtilis, strain LMGS 25520 – safety assessment and establishment of specifications

2) Inulinase from Aspergillus ficuum produced by Aspergillus oryzae, strain MUCL 44346 - safety assessment and establishment of specifications

3) Endo-1,4-β-xylanase from Bacillus subtilis produced by B. subtilis LMG S-28356 - safety assessment and establishment of specifications

4) Endo-1,4-β-xylanase from Pseudoalteromonas haloplanktis produced by B. subtilis, strain LMG S-24584 - safety assessment and establishment of specifications

5) Endo-1,4-β-xylanase from Thermotoga maritima produced by B. subtilis, strain LMG S-27588 – safety assessment and establishment of specifications.

In opinion of Ru, for all estimated strains «List of data available (please check, if available)» (point 9 Agenda 7) should be added by data:

1. On the availability of data on the nucleotide sequence of the DNA insert;
2. Characteristics of the vector used in the design of the GMO strains.

International Special Dietary Foods Industries (ISDI)

GELLAN GUM (INS 418)

In preparation for the 48th Session of CCFA, ISDI responded to CL 2015/11-FA with a proposal for the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to evaluate gellan gum (INS 418) for use as a thickener up to 0.005 g/100 mL in hydrolyzed protein and/or amino acid based formula only (formula for special

medical purposes (FSMP) for infants, food category 13.1.3). **ISDI requests that CCFA retain gellan gum on the JECFA priority list** (REP16/FA Appendix XIV; see Appendix A) for safety evaluation pending the conclusions of the electronic Working Group (eWG) established by CCNFSDU during their 38th Session in December 2016 (REP17/NFSDU para 178; see Appendix B). As CCNFSDU is still considering the technological justification for gellan gum, the listing for gellan gum should be retained on the JECFA priority list pending conclusions from CCNFSDU, which should be available for the 50th CCFA Session.

Appendix A

Appendix XIV

PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA

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
*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

Appendix B

Technological justification

Xanthan gum (INS 415) and Pectin (INS 440)

174. The observer from ISDI informed the Committee that CCNFSDU36 had recommended the evaluation of Xanthan gum (INS 415) and Pectin (INS 440), by JECFA, for use as a thickener in the *Standard for Infant Formula and Formulas for Special Medical Purposes intended for Infants* (CODEX STAN 72-1981), Section B. The Committee's attention was also drawn to the recent evaluation by JECFA82 (June 2016) that had recommended the two additives were safe for use in this product at the specified levels. ISDI, supported by several observers, requested CCNFSDU to consider including these two additives in CODEX STAN 72-1981.

175. The Chairperson noted that members had not had sufficient time to study the information on technological justification provided on the two additives (CRD11), and proposed to refer the substances to the eWG for consideration and to discuss the outcome at the next session.

Gellan gum (INS 418)

176. Regarding the technological justification on the use of gellan gum (INS 418) in infant formula, formulas for special medical purposes intended for infants, and follow-up formula, the Committee noted that in the European Union, these products were being produced without the use of gellan gum and in the EU's view, gellan gum was not necessary and not technologically justified for use in these foods. This view was supported by other delegations.

177. Noting that confirmation of the technological need was required to support JECFA evaluation of gellan gum (INS 418), the Committee agreed to refer the matter to the eWG for consideration and agreed to inform CCFA that reply would be provided at a future date.

Conclusion

178. In light of the above discussion the Committee agreed to:

i. Defer the alignment of food additives, until the guidance document on alignment of additives is finalized by CCFA;

ii. Establish an eWG, hosted by the European Union, and co-hosted by the Russian Federation working in English with the following terms of reference:

a) Propose a mechanism or framework for considering the technological justification for substances intended for inclusion on the priority list of substances for JECFA evaluation;

b) To consider and confirm the technological justification of gellan gum; and

c) To propose how to handle new substances that have already been evaluated by JECFA, but for which technological justification has not yet been confirmed by CCNFSDU (i.e. xanthan gum, pectin).

OTHER BUSINESS AND FUTURE WORK (Agenda item 11)[20]

Methods of analysis for provisions in the *Standard for infant formula and formulas for special medical purposes intended for infants* (CODEX STAN 72-1981)

179. The Committee considered the report of the in-session working group and took the following decisions:

Chromium, selenium and molybdenum: *review of criteria*

180. The Committee agreed:

i. to inform CCMAS that it did not support using the criteria approach because:

a) a general or single conversion factor to convert µg/100kCAL to µg/g should not be used, as the energy density of infant formula varies across products; and

b) none of the current methods in CODEX STAN 234-1999, nor the newer methods AOAC 2011.19 | ISO 20649 | IDF 235 meet the criteria (REP16/MAS, para. 31).

ii. to request that CCMAS reconsider the method for chromium, selenium and molybdenum, AOAC 2011.19 | ISO 20649 | IDF 235 as Type II in light of published validation data measuring the minimum level for chromium, selenium and molybdenum in CODEX STAN 72-1981, and

iii. to inform CCMAS that the other methods for chromium, selenium and molybdenum other than the AOAC method were still fit for purpose and to reconsider their classification, if necessary.

[20] CX/NFSDU 16/38/2; CX/NFSDU 16/38/12; CRD 12 (comments of Mexico, Nigeria, Thailand, African Union and ISDI); CRD 14 (comments from Benin); CRD 18 (Report of the in-session working group on methods of analysis).