



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FATS AND OILS

Twenty-fourth Session

Melaka, Malaysia, 9 – 13 February 2015

REVIEW THE CODEX LIST OF ACCEPTABLE PREVIOUS CARGOES

(Prepared by the electronic working group led by Malaysia)

BACKGROUND

1. At the 23rd Session of the Codex Committee on Fats and Oils (CCFO), it was recalled that the Commission had adopted the List of Acceptable Previous Cargoes (List) annexed to the *Code of Practice for the Storage and Transport of Edible Fats and Oils in Bulk* (CAC/RCP 36-1987) (CoP). The Commission had directed CCFO: to review the List against the four (4) criteria (see Appendix I) stated in the CoP as a matter of priority; and to identify the most critical substances for review by JECFA taking into account the limitations of JECFA resources and the availability of data.

2. In view of the importance of the task, the Committee recognised that it was essential to have an approach in place for adding or removing substances from the List and decided that the review of the List should be a standing item on the agenda of the CCFO. The Committee agreed to establish an Electronic Working Group (eWG) chaired by Malaysia, open to all members and observers, working in English only, with the following Terms of Reference:

- (i) To review available data of each substance on the ability to be adequately cleaned between cargoes as required by criterion 1.
- (ii) To compile available information for each substance against criteria 2, 3 and 4.
- (iii) To identify substances that meets all the criteria and recommend them as acceptable.
- (iv) To identify and if necessary, prioritise substances to be submitted to JECFA for evaluation.
- (v) To consider proposals from Members on new substances to be added to the List provided such proposals are supported by adequate and relevant information provided by the proponent.
- (vi) To identify substances currently on the List not carried as previous cargoes and recommend to the Committee that they be removed from the List.
- (vii) To report to the Committee with recommendations as indicated by the findings.

3. In addition, based on comments received and discussions at the Session, the Committee agreed to forward the following items to the eWG:

- (i) Calcium Lignosulphonate Liquid, Carnauba Wax, Montan Wax, Silicon Dioxide and Mineral oils.
- (ii) To request for information on substances (e.g. candelilla wax, bees wax white /yellow, etc.) that appear not to be transported as previous cargoes.¹

4. Additionally, the Committee agreed to the proposal by Canada that the working group should review the category of white mineral oils some of which had high and some low viscosity and a range of ADI to check which were acceptable and which could be of a food safety concern.²

5. On 20 September 2013, Malaysia as Chair of the eWG to Review the List of Acceptable Previous Cargoes distributed an invitation for participation in the eWG via the Codex Secretariat. The following countries and interested organizations announced their interests: Argentina, Australia, Canada, the European Union (EU), France, India, Japan, Malaysia, the Netherlands, Republic of Korea, Russia, Thailand,

¹ REP13/FO para. 28

² REP13/FO para. 26

United Kingdom, Ukraine, United States of America, American Oil Chemists' Society (AOCS), EU Vegetable Oil and Proteinmeal Industry (FEDIOL), Federation of Oils, Seeds and Fats Associations International (FOSFA) and International Alliance of Dietary/Food Supplement Association (IADSA).

a) First Circulation

6. On 24 January 2014, two (2) excel-spreadsheet matrices were circulated namely: (i) matrix for evaluation of 112 substances currently in the List and (ii) matrix for proposal of new substances to be recommended to be accepted in the List in accordance to flowcharts decision tree developed by Malaysia as Chair of the eWG. The flowcharts decision tree were developed based on criteria 1, 2, 3 and 4 following the Term of Reference of the eWG. The matrices were designed to automatically provide three (3) recommendations for the substances, i.e. (i) recommended as acceptable in the List; (ii) recommended for evaluation by JECFA; and (iii) recommended to be removed from the List. Deadline for submission of inputs and comments was 24 March 2014. Comments were received from the EU, Japan, the Netherlands, United States of America, Ukraine, Russian Federation, FOSFA and FEDIOL.

7. The following recommendations were made based on inputs provided by Members:

- (a) With regards to the 112 substances currently in the List, the eWG recommended:
- i) 15 substances as acceptable in the List (comply with all of the four (4) criteria);
 - ii) 83 substances be forwarded for JECFA evaluation (do not fulfill the criteria);
 - iii) Nine (9) substances could not be categorised due to incomplete inputs received from Members, namely Calcium ammonium nitrate solution CAS No.6484-52-2; Calcium lignosulphonate liquid (lignin liquor; sulphite lye) CAS No. 8061-52-7; Calcium nitrate (CN-9) solution CAS No.35054-52-5; Unfractionated fatty acid mixture or mixtures of fatty acids from natural oils and fats; iso-Butanol (2-methyl-1-propanol) CAS No.78-83-1; Unfractionated fatty alcohol mixture or mixtures of fatty alcohols from natural oils and fats; Unfractionated fatty esters or mixtures of fatty esters from natural oils and fats; Fructose and Hydrogen peroxide;
 - iv) Three (3) substances could not be categorised due to different classification for White mineral oils by one (1) Member, namely White mineral oils-high viscosity; White mineral oils-medium and low viscosity Class I; and White mineral oils-medium and low viscosity Class II and Class III;
 - v) Two (2) substances be removed from the List (not carried as previous cargoes), namely Carnauba wax (Brazil wax) CAS No. 8015-86-9 and Silicon dioxide (microsilica) CAS No. 7631-86-9.
- (b) In addition, the eWG also recommended the following:
- i) Two (2) new substances were proposed by one (1) Member to be added to the List and recommended for JECFA evaluation, namely: Ethyl tertiary butyl ether (ETBE) CAS No. 637-92-3 and Methyl acetate CAS No. 79-20-9;
 - ii) Two (2) new reaction products were identified by one (1) Member and proposed to be recommended for JECFA evaluation, namely: 1) Fatty acid esters of glycerol mononitrate (positions 1 and 3) may be produced by Calcium ammonium nitrate solution CAS No.6484-52-2 and Calcium nitrate (CN-9) solution CAS No.35054-52-5; and 2) Wax ester may be produced by Unfractionated fatty alcohol mixture or mixtures of fatty alcohols from natural oils and fats;
 - iii) One (1) main compound i.e. Fatty acid methyl ester which was claimed to be a substance on its own right by one (1) Member was proposed to be discussed further in the Physical Working Group (pWG);
 - iv) Consideration be given to the safety evaluation done by recognised bodies other than JECFA, such as USFDA, EFSA etc. for determining the safety of substances included in the List. Supporting documents on these safety evaluations shall be provided by eWG Members and will be evaluated and concluded by the pWG.

b) Second Circulation

8. Report of the First Circulation with the above recommendations was distributed on 19 June 2014 for further comments by Members. In addition, two (2) matrices for prioritisation of the 87 substances (83 substances proposed by the eWG, two (2) new substances and two (2) new reaction products proposed by Members) for JECFA evaluation were also circulated together with the report. The first matrix focuses on the 44 substances currently not evaluated by JECFA and no ADI allocated. The second matrix focuses on

another 43 substances which have been previously evaluated by JECFA. Deadline for inputs and comments was 31 July 2014.

9. As a recommendation on the way forward for the prioritisation of substances, Malaysia as Chair of the eWG proposed that it is conducted based on criteria outlined under the *Risk Analysis Principles Applied by the Codex Committee on Food Additives* (para. 33) and *Risk Analysis Principles Applied by the Codex Committee on Contaminants in Foods* (para. 20) of the Codex Procedural Manual. In addition, substances which have been evaluated by JECFA i.e. 42 out of 83 substances in the List as outlined in CRD 8 of 21st CCFO (Review of the Codex Lists – JECFA evaluations) should not be considered to be recommended for JECFA evaluation.

10. Comments from three (3) Members were received for the Second Circulation i.e. the EU, Japan and Thailand.

DISCUSSION

Substances recommended as acceptable in the List

11. There are 57 substances recommended as acceptable in the List. These include 15 substances out of the 112 substances currently available in the List which were recommended as acceptable based on the recommendation by the eWG during the First Circulation and 42 substances out of the 87 substances reviewed during the Second Circulation which were also recommended as acceptable in the List since they have been evaluated by JECFA.

12. In addition, another five (5) substances out of the nine (9) substances, which could not be categorised during the First Circulation due to incomplete inputs by Members, were recommended as acceptable in the List based on comments received, namely (Calcium ammonium nitrate solution CAS No.6484-52-2; Calcium nitrate (CN-9) solution CAS No.35054-52-5; Unfractionated fatty acid mixture or mixtures of fatty acids from natural oils and fats; Fructose and Hydrogen peroxide).

13. This List also includes candelilla wax and bees wax white/yellow which are still transported as previous cargoes as reported by Members.

Substances recommended for evaluation by JECFA

14. 41 substances including Montan wax which have not been evaluated by JECFA were recommended to be forwarded for JECFA evaluation.

15. In addition, three (3) substances from the nine (9) substances, which could not be categorised during the First Circulation due to incomplete input by Members, were also proposed for JECFA evaluation based on comments received, namely: iso-Butanol (2-methyl-1-propanol) CAS No.78-83-1; Unfractionated fatty alcohol mixture or mixtures of fatty alcohols from natural oils and fats; and Unfractionated fatty esters or mixtures of fatty esters from natural oils and fats.

16. Unfractionated fatty alcohol mixture or mixtures of fatty alcohols from natural oils and fats and its reaction product of Wax esters, which have not been evaluated by JECFA, were recommended to be forwarded for JECFA evaluation.

17. One (1) Member provided input that two (2) substances i.e. Calcium ammonium nitrate solution CAS No.6484-52-2 and Calcium nitrate (CN-9) solution CAS No.35054-52-5 when reacts with oil may produce a reaction product: Fatty acid esters of glycerol mononitrate (positions 1 and 3). This reaction product is recommended for JECFA evaluation since it has not been evaluated by JECFA.

Criteria for prioritisation of substances for JECFA evaluation

18. Based on comments received, it was agreed that the eWG should have criteria for prioritisation of substances to be recommended for JECFA evaluation. Two (2) Members agreed with the proposal by the Chair of the eWG as in para. 9, whereas one (1) Member proposed the use of other criteria to determine the highest priority (e.g. substances that have not been previously evaluated, lack of information related to the substances themselves or their impurities or reaction products, volumes of substances transported as previous cargoes) should be explored. One (1) Member proposed to take into consideration the frequency of substances used as previous cargoes as a criteria in light of the potential exposure to consumers. One (1) Member is of the view that low priority should be given to the new substances with respect to the substances already available in the List.

Substance recommended for further discussion

19. Calcium Lignosulphonate Liquid (lignin liquor; sulphite lye) CAS No. 8061-52-7 could not be categorised due to incomplete input by Members.

New substance recommended to be accepted in the List

20. Two (2) new substances were recommended to be accepted in the List as follows:

- i) Methyl acetate CAS No.79-20-9 which has been evaluated by JECFA is recommended to be accepted in the List.
- ii) Ethyl tertiary butyl ether (ETBE) CAS No. 637-92-3 which has not been evaluated by JECFA is recommended to be forwarded for JECFA evaluation prior to being accepted in the List.

Substances recommended to be removed from the List

21. Two (2) substances namely Carnauba wax (Brazil wax) CAS No. 8015-86-9 and Silicon dioxide (microsilica) CAS No. 7631-86-9 were recommended to be removed from the List since Members provided input that these substances were not carried as previous cargoes.

RECOMMENDATIONS

22. To consider the following recommendations with regards to the review of substances currently in the List:

Recommendation	Substance
Substances recommended as acceptable in the List	62 substances (Appendix II)
Recommended for JECFA evaluation	44 substances (Appendix III)
Recommended to be removed from the List	2 substances (Appendix IV)

23. To consider the following proposals for new substances and reaction products:

Recommendation	Substance
New substance recommended as acceptable to be added in the List (already evaluated by JECFA)	Methyl acetate CAS No.79-20-9
New substance recommended for JECFA evaluation	Ethyl tertiary butyl ether (ETBE) CAS No. 637-92-3
New reaction products recommended for JECFA evaluation	i. Fatty acid esters of glycerol mononitrate (positions 1 and 3)
	ii. Wax esters

24. To establish criteria for the prioritisation of substances to be recommended for JECFA evaluation based on the *Risk Analysis Principles Applied by the Codex Committee on Food Additives* (para. 33) and *Risk Analysis Principles Applied by the Codex Committee on Contaminants in Foods* (para. 20) and other requirements such as:

- i) substances that have not been previously evaluated;
- ii) lack of information related to the substances or their impurities or reaction products;
- iii) volume of substances transported as previous cargoes; and
- iv) frequency of substances used as previous cargoes.

25. Substances which have been evaluated by JECFA may be considered to be recommended for further re-evaluation by JECFA only if Members could provide data which proves that the substances pose safety concerns.

26. Safety evaluation done by internationally recognised bodies other than JECFA, such as USFDA, EFSA etc., could be considered to determine the safety of substances to be included in the List.

27. Other substances to be further deliberated:

- i) The proposal to consider main compound Fatty acid methyl esters to be a substance on its own right.
- ii) The classification of White mineral oils, taking into account the following information:
 - JECFA has classified mineral oil into two groups: mineral oil (high viscosity) and mineral oil (medium- and low-viscosity, class I, class II and class III).

- One (1) Member informed that white mineral oil are classified as 905a (Mineral oil, food grade) and 905e (Mineral oil, medium viscosity).
- iii) Whether Calcium lignosulphonate liquid (lignin liquor; sulphite lye) CAS No. 8061-52-7 be recommended as acceptable in the List; recommended for JECFA evaluation; or recommended to be removed from the List (Note: This substance could not be categorised due to incomplete input by Members).
- iv) The status for Calcium ammonium nitrate solution CAS No.6484-52-2 and Calcium nitrate (CN-9) solution CAS No.35054-52-5 since the reaction of these substances with oil produces Fatty acid esters of glycerol mononitrate (positions 1 and 3). The reaction product is recommended for JECFA evaluation. The pWG should consider whether these substances may be maintained as acceptable in the List or put on hold pending JECFA evaluation on its reaction product.

CONCLUSIONS

28. The Committee is invited to consider the recommendations above and make further specific recommendations on the way forward.

Appendix I**Four (4) criteria stated in the Recommended International Code of Practice for the Storage and Transport of Edible Fats and Oils in Bulk, CAC/RCP 36-1987 to determine whether a substance is acceptable as an immediate previous cargo**

1. The substance is transported/stored in an appropriately designed system; with adequate cleaning routines, including the verification of the efficacy of cleaning between cargoes, followed by effective inspection and recording procedures.
2. Residues of the substance in the subsequent cargo of fat or oil should not result in adverse human health effects. The ADI (or TDI) of the substance should be greater than or equal to 0.1 mg/kg bw/day. Substances for which there is no numerical ADI (or TDI) should be evaluated on a case by case basis.
3. The substance should not be or contain a known food allergen, unless the identified food allergen can be adequately removed by subsequent processing of the fat or oil for its intended use.
4. Most substances do not react with edible fats and oils under normal shipping and storage conditions. However, if the substance does react with edible fats and oils, any known reaction products must comply with criteria 2 and 3.

Appendix II

SUBSTANCES RECOMMENDED AS ACCEPTABLE IN THE LIST

No.	Substance	CAS No
1	Acetic acid (ethanoic acid; vinegar acid; methane carboxylic acid)	64-19-7
2	Acetone (dimethylketone; 2-propanone)	67-64-1
3	Ammonium hydroxide (ammonium hydrate; ammonia solution; aqua ammonia)	1336-21-6
4	Ammonium polyphosphate	68333-79-9
5	Beeswax – white	8006-40-4
6	Beeswax – yellow	8012-89-3
7	Benzyl alcohol (pharmaceutical and reagent grades)	100-51-6
8	1,3-Butanediol (1,3-butylene glycol)	107-88-0
9	Calcium ammonium nitrate solution	6484-52-2
10	Calcium chloride solution	10043-52-4
11	Calcium nitrate (CN-9) solution	35054-52-5
12	Candelilla wax	8006-44-8
13	Ethanol (ethyl alcohol; spirits)	64-17-5
14	Ethyl acetate (acetic ether; acetic ester; vinegar naphtha)	141-78-6
15	2-Ethylhexanol (2-ethylhexy alcohol)	104-76-7
16	Butyric acid (n-butyric acid; butanoic acid; ethyl acetic acid; propyl forinic acid)	107-92-6
17	Caprylic acid (n-octanoic acid)	124-07-2
18	Heptoic acid (n-heptanoic acid)	111-14-8
19	Lauric acid (n-dodecanoic acid)	143-07-7
20	Myristic acid (n-tetradecanoic acid)	544-63-8
21	Oleic acid (n-octadecenoic acid)	112-80-1
22	Palmitic acid (n-hexadecanoic acid)	57-10-3
23	Pelargonic acid (n-nonanoic acid)	112-05-0
24	Ricinoleic acid (cis-12-hydroxy octadec-9-enoic acid; castor oil acid)	141-22-0
25	Stearic acid (n-octadecanoic acid)	57-11-4
26	Unfractionated fatty acid mixture or mixtures of fatty acids from natural oils and fats	
27	Caproyl alcohol (1-hexanol; hexyl alcohol)	111-27-3
28	Capryl alcohol (1-n-octanol; heptyl carbinol)	111-87-5
29	Cetyl alcohol (alcohol C-16; 1-hexadecanol; cetylic alcohol; palmityl alcohol; n-primary hexadecyl alcohol)	36653-82-4
30	Nonyl alcohol (1-nonanol; pelargonic alcohol; octyl carbinol)	143-08-8
31	Oleyl alcohol (octadecenol)	143-28-2
32	Stearyl alcohol (1-octadecanol)	112-92-5
33	Cetyl stearyl alcohol (C16-C18)	67762-27-0
34	Lauryl myristyl alcohol (C12-C14)	
35	Butyl myristate	110-36-1
36	Cetyl stearate	110-63-2
37	Oleyl palmitate	2906-55-0
38	Methyl oleate (methyl octadecenoate)	112-62-9
39	Methyl palmitate (methyl hexadecanoate)	112-39-0
40	Methyl stearate (methyl octadecanoate)	112-61-8
41	Formic acid (methanoic acid; hydrogen carboxylic acid)	64-18-6
42	Fructose	

No.	Substance	CAS No
43	Glycerine (glycerol, glycerin)	56-81-5
44	Heptane	142-82-5
45	n-Hexane	110-54-3
46	Hydrogen peroxide	
47	Kaolin slurry	1332-58-7
48	d-Limonene (dipentene)	5989-27-5
49	Magnesium chloride solution	7786-30-3
50	Methanol (methyl alcohol)	67-56-1
51	Molasses obtained from citrus, sorghum, sugar beet and sugar cane	57-50-1
52	Petroleum wax (parafin wax)	8002-74-2
53	Phosphoric acid (ortho phosphoric acid)	7664-38-2
54	Potable water	7732-18-5
55	Polypropylene glycol	25322-69-4
56	Potassium hydroxide solution (caustic potash)	1310-58-3
57	Propylene glycol, 1,2- (1,2-propylene glycol; propan-1,2-diol; 1,2- dihydroxypropane; monopropylene glycol (MPG); methyl glycol)	57-55-6
58	Sodium hydroxide solution (caustic soda, lye; sodium hydrate; white caustic)	1310-73-2
59	Sodium silicate (water glass)	1344-09-8
60	Sorbitol (D-sorbitol; hexahydric alcohol; D-sorbite)	50-70-4
61	Sulphuric acid	7664-93-9
62	Urea ammonia nitrate solution (UAN)	

APPENDIX III

SUBSTANCES RECOMMENDED FOR JECFA EVALUATION

No.	Substance	CAS No.
1	Acetic anhydride (ethanoic anhydride)	108-24-7
2	Acid oils and fatty acid distillates - from animal, marine and vegetable fats and oils	
3	Animal, marine and vegetable oils and fats (including hydrogenated oils and fats) - other than cashew shell nut oil and tall oil	
4	1,4-Butanediol (1,4-butylene glycol)	110-63-4
5	Butyl acetate, n-	123-86-4
6	Butyl acetate, iso-	110-19-0
7	Butyl acetate, sec-	105-46-4
8	Butyl acetate, tert-	540-88-5
9	Cyclohexane (hexamethylene; hexanaphthene; hexahydrobenzene)	110-82-7
10	Arachidic acid (eicosanoic acid)	506-30-9
11	Behenic acid (docosanoic acid)	112-85-6
12	Capric acid (n-decanoic acid)	334-48-5
13	Caproic acid (n-hexanoic acid)	142-62-1
14	Erucic acid (cis-13-docosenoic acid)	112-86-7
15	Lauroleic acid (dodecenoic acid)	4998-71-4
16	Linoleic acid (9,12-octadecadienoic acid)	60-33-3
17	Linolenic acid (9,12,15-octadecatrienoic acid)	463-40-1
18	Myristoleic acid (n-tetradecenoic acid)	544-64-9
19	Palmitoleic acid (cis-9-hexadecenoic acid)	373-49-9
20	Valeric acid (n-pentanoic acid; valerianic acid)	109-52-4
21	Butyl alcohol (1-butanol; butyric alcohol)	71-36-3
22	iso-Butanol (2-methyl-1-propanol)	78-83-1
23	Decyl alcohol (1-decanol)	112-30-1
24	Iso decyl alcohol (isodecanol)	25339-17-7
25	Enanthyl alcohol (1-heptanol; heptyl alcohol)	111-70-6
26	Lauryl alcohol (n-dodecanol; dodecyl alcohol)	112-53-8
27	Myristyl alcohol (1-tetradecanol; tetradecanol)	112-72-1
28	Iso nonyl alcohol (isononanol)	27458-94-2
29	Tridecyl alcohol (1-tridecanol)	27458-92-0
30	Unfractionated fatty alcohol mixture or mixtures of fatty alcohols from natural oils and fats	
31	Unfractionated fatty esters or mixtures of fatty esters from natural oils and fats	
32	Methyl laurate (methyl dodecanoate)	111-82-0
33	Methyl ethyl ketone (2-butanone; MEK)	78-93-3
34	Methyl isobutyl ketone (4-methyl-2-pentanone; iso propylacetone; MIBK)	108-10-1
35	Methyl tertiary butyl ether (MBTE)	1634-04-4
36	Montan wax	8002-53-7
37	iso-Octyl alcohol (isooctanol)	26952-21-6
38	Pentane	109-66-0
39	Propyl acetate	109-60-4
40	Propyl alcohol (propane-1-ol; 1-propanol)	71-23-8
41	iso-Propyl alcohol (isopropanol; dimethyl carbinol; 2-propanol)	67-63-0

No.	Substance	CAS No.
42	1,3 -Propylene glycol	504-63-2
43	Propylene tetramer ((tetrapropylene; dodecene)	6842-15-5
44	Soybean oil epoxidized	8013-07-8

APPENDIX IV

SUBSTANCES RECOMMENDED TO BE REMOVED FROM THE LIST

No.	Substance	CAS No
1	Carnauba wax (Brazil wax)	8015-86-9
2	Silicon dioxide (microsilica)	7631-86-9