Appendix II

ACTION REQUIRED AS A RESULT OF CHANGES IN THE ACCEPTABLE DAILY INTAKE (ADI) STATUS AND OTHER RECOMMEDATIONS ARISING FROM THE 86TH JECFA

(For information and action)

INS Number	Food additive	Recommendation of CCFA51
1207	Anionic methacrylate copolymer (AMC)	Note the 86th JECFA was unable to complete the evaluation of AMC. Note the conclusion that to clarify the *in vivo* carcinogenic potential of the residual monomer methyl acrylate more data are required.
1205	Basic methacrylate copolymer (BMC)	Note the JECFA conclusion on an ADI "not specified" was established for BMC. Note the new JECFA specifications for BMC (see CX/FA 19/51/4). Include BMC (INS 1205) in Table 3 of GSFA and circulate for comments at Step 3. Request for comments/proposals on uses and use levels of BMC for the food categories listed in the Annex to Table 3 (to be provided in response to the CL requesting proposals for new and/or revision of adopted food additives provisions in the GSFA).
127	Erythrosine	Note the JECFA conclusion that the new data that have become available since the previous evaluation of erythrosine do not give reason to revise the ADI and confirmed the previous ADI of 0–0.1 mg/kg bw.
132	Indigotine	Note the JECFA conclusion that the new data that have become available since the previous evaluation of indigotine do not give reason to revise the ADI and confirmed the previous ADI of 0–5 mg/kg bw.
	Lutein and lutein esters from *Tagetes erecta* and zeaxanthin (synthetic)	Note the JECFA conclusion on an ADI "not specified" for lutein from *Tagetes* erecta, lutein esters from *Tagetes* erecta and zeaxanthin (synthetic). Note the JECFA conclusion that meso-zeaxanthin was not included in this group ADI, as specifications are not currently available. Note the JECFA conclusion that the group ADI of 0-2 mg/kg bw for lutein from *Tagetes erecta* and zeaxanthin (synthetic) was withdrawn. Note that the specifications for lutein from *Tagetes erecta* were revised and that. the specifications for lutein esters from *Tagetes erecta* and zeaxanthin (synthetic) were maintained. Include lutein from *Tagetes* erecta (INS 161b(i)) and zeaxanthin (synthetic) (INS 161h(i)) in Table 3 of GSFA and circulate for comments at Step 3. Request for comments/proposals on uses and use levels of the group food additives which includes lutein from *Tagetes* erecta (INS 161b(i)), lutein esters from *Tagetes* erecta (INS 161b(iii)) and zeaxanthin (synthetic) (INS 161h(i)) for the food categories listed in the Annex to Table 3 (to be provided in response to the CL requesting proposals for new and/or revision of adopted food additives provisions in the GSFA).

INS Number	Food additive	Recommendation of CCFA51
1206	Neutral methacrylate copolymer (NMC)	Note the 86th JECFA conclusion on an ADI "not specified" for NMC. The ADI "not specified" was made temporary because the specifications are tentative. Note the 86 the JECFA conclusion that there was no data submitted for a suitable method of assay.
420(ii))	Sorbitol syrup	Note the 86th JECFA conclusion on an ADI "not specified" for sorbitol syrup.
134	Spirulina extract	Note the 86th JECFA conclusion on an ADI "not specified" for spirulina extract. The ADI "not specified" was made temporary because the specifications are tentative. Note the JECFA request for analytical data requested by December 2019.

Table 2. Flavouring agents evaluated at the 86th JECFA meeting

The flavouring agents were evaluated by the revised Procedure for the Safety Evaluation of Flavouring Agents.

A. Alicyclic primary alcohols, aldehydes, acids and related esters

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
Mixture of 1-Vinyl-3-cyclohexenecarbaldehyde and 4-Vinyl-1-cyclohexenecarbaldehyde	2253	N	No safety concern
p-Mentha-1,8-dien-7-ol	974	N	No safety concern
p-Mentha-1,8-dien-7-yl acetate	975	N	No safety concern
Formyl-6,6-dimethylbicyclo[3.1.1]hept-2-ene	980	N	No safety concern
Myrtenol	981	N	No safety concern
Myrtenyl acetate	982	M	No safety concern
Structural class II			
(1-Methyl-2-(1,2,2-trimethylbicyclo[3.1.0]hex-3-ylmethyl)cyclopropyl)methanol	2254	N	No safety concern
Structural class III			
(±)-Bicyclo[2.2.1]hept-5-ene-2-carboxylic acid, ethyl ester	2255	N	No safety concern
Flavouring agent excluded at Step 1 of the revised Procedure			
p-Mentha-1,8-dien-7-al (Perillaldehyde)	973	T	Genotoxicity data for *p*-mentha-1,8-dien-7-al raise concerns for potential genotoxicity

N: new specifications

M: existing specifications maintained;

B. Carvone and structurally related substances

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
Pinocarvyl isobutyrate	2242	N	No safety concern
Carvyl palmitate	2243	N	No safety concern
Structural class III			
6-Hydroxycarvone	2244	N	No safety concern
Flavouring agents not evaluated according to the revised Procedure			
(+)-Carvone	380.1	M	The Committee did not re-evaluate (+)-carvone (No. 380.1) according to the revised Procedure given the lack of information on the oral exposure from all sources and the need to review the ADI. A review of the ADI is recommended based on the evaluation of all biochemical and toxicological data. Also, data are needed for an exposure assessment for oral exposure to (+)-carvone from all sources to complete the evaluation for (+)-carvone.
(-)-Carvone	380.2	M	The Committee did not re-evaluate (-)-carvone (No. 380.2) according to the revised Procedure given the lack of information on the oral exposure from all sources and the lack of toxicological data.

M: existing specifications maintained; N: new specifications

C. Furan-substituted aliphatic hydrocarbons, alcohols, aldehydes, ketones, carboxylic acids and related esters, sulfides, disulfides and ethers

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class III			
2-Pentylfuran	1491	M[a]	No safety concern
2-Heptylfuran	1492	M[a]	No safety concern
2-Decylfuran	1493	M[a]	No safety concern
3-Methyl-2-(3-methylbut-2-enyl)-furan	1494	M[a]	No safety concern
2,3-Dimethylbenzofuran	1495	M[a]	No safety concern
2,4-Difurfurylfuran	1496	M[a]	No safety concern
3-(2-Furyl)acrolein	1497	M[a]	No safety concern
2-Methyl-3(2-furyl)acrolein	1498	M[a]	No safety concern
3-(5-Methyl-2-furyl)prop-2-enal	1499	M[a]	No safety concern
3-(5-Methyl-2-furyl)butanal	1500	M[a]	No safety concern
2-Furfurylidene-butyraldehyde	1501	M[a]	No safety concern

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
2-Phenyl-3-(2-furyl)prop-2-enal	1502	M[a]	No safety concern
2-Furyl methyl ketone	1503	M[a]	No safety concern
2-Acetyl-5-methylfuran	1504	M[a]	No safety concern
2-Acetyl-3,5-dimethylfuran	1505	M[a]	No safety concern
3-Acetyl-2,5-dimethylfuran	1506	M[a]	No safety concern
2-Butyrylfuran	1507	M[a]	No safety concern
(2-Furyl)-2-propanone	1508	M[a]	No safety concern
2-Pentanoylfuran	1509	M[a]	No safety concern
1-(2-Furyl)butan-3-one	1510	M[a]	No safety concern
4-(2-Furyl)-3-buten-2-one	1511	M[a]	No safety concern
Pentyl 2-furyl ketone	1512	M[a]	No safety concern
Ethyl 3-(2-furyl)propanoate	1513	M[a]	No safety concern
Isobutyl 3-(2-furan)propionate	1514	M[a]	No safety concern
Isoamyl 3-(2-furan)propionate	1515	M[a]	No safety concern
Isoamyl 3-(2-furan)butyrate	1516	M[a]	No safety concern
Phenethyl 2-furoate	1517	M[a]	No safety concern
Propyl 2-furanacrylate	1518	M[a]	No safety concern
2,5-Dimethyl-3-oxo-(2*H*)-fur-4-yl butyrate	1519	M[a]	No safety concern
Furfuryl methyl ether	1520	M[a]	No safety concern
Ethyl furfuryl ether	1521	M[a]	No safety concern
Difurfuryl ether	1522	M[a]	No safety concern
2,5-Dimethyl-3-furanthiol acetate	1523	M[a]	No safety concern
Furfuryl 2-methyl-3-furyl disulfide	1524	M[a]	No safety concern
3-[(2-Methyl-3-furyl)thio]-2-butanone	1525	M[a]	No safety concern
O-Ethyl S-(2-furylmethyl)thiocarbonate	1526	M[a]	No safety concern
(E)-Ethyl 3-(2-furyl)acrylate	2103	M[a]	No safety concern
di-2-Furylmethane	2104	M[a]	No safety concern
2-Methylbenzofuran	2105	M[a]	No safety concern

M: existing specifications maintained

[a] The text indicating that the safety evaluation for these flavouring agents had not been completed was removed from the specifications and the specifications were maintained as full

D. Linear and branched-chain aliphatic, unsaturated, unconjugated alcohols, aldehydes, acids and related esters

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
trans-6-Octenal	2240	N	No safety concern
2,6-Dimethyl-5-heptenol	2241	N	No safety concern

N: new specifications

E. Maltol and related substances

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class II			
Maltol	1480	M	No safety concern[a]
Structural class III			
Ethyl maltol isobutyrate	2252	N	No safety concern

M: existing specifications maintained

N: new specifications

[a] The previously established ADI for maltol was withdrawn by the Committee.

F. Menthol and structurally related substances

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
Menthyl formate	2246	N	No safety concern
Menthyl propionate	2247	N	No safety concern
l-Menthyl butyrate	2248	N	No safety concern
dl-Isomenthol	2249	N	No safety concern
Dimenthyl glutarate	2250	N	No safety concern
Menthol	427	M	No safety concern[a]
Structural class III			
(±)-2-[(2-*p*-Menthoxy)ethoxy]ethanol	2251	N	No safety concern

M: existing specifications maintained

N: new specifications

[a] The ADI of menthol of 0–4 mg/kg bw established at the fifty-first meeting was maintained.

G. Miscellaneous nitrogen-containing substances

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class III			
2-(((3-(2,3-Dimethoxyphenyl)-1*H*-1,2,4-triazol-5-yl)thio)methyl)pyridine	2235	N	No safety concern
S)-1-(3-(((4-Amino-2,2-dioxido-1*H*-benzo[c][1,2,6]thiadiazin-5-yl)oxy)methyl)piperidin-1-yl)-3-methylbutan-1-one	2236	N	No safety concern
2-(4-Methylphenoxy)-*N*-(1*H*-pyrazol-3-yl)-*N*-(thiophen-2-ylmethyl)acetamide	2237	N	No safety concern

N: new specifications

H. Saturated aliphatic acyclic branched-chain primary alcohols, aldehydes, and acids

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
8-Methyldecanal	2238	N	No safety concern
8-Methylnonanal	2239	N	No safety concern

N: new specifications