



**Food and Agriculture
Organization of the
United Nations**



**World Health
Organization**

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Agenda Item 5c

CX/FA 17/49/9
February 2017

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-ninth Session

Macao SAR, China, 20-24 March 2017

GENERAL STANDARD FOR FOOD ADDITIVES (GSFA): PROPOSALS FOR NEW AND/OR REVISION OF FOOD ADDITIVE PROVISIONS

Replies to CL 2016/8-FA A, point 4 (a), 4(b) & 4(c) of China, Japan, EFEMA, IACM, IADSA, IDF and
NATCOL

CHINA

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| THE PROPOSAL IS SUBMITTED BY: | | China | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Ascorbic acid, L- | |
| INS Number | | 300 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Antioxidant | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks(plain) | GMP | |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Evaluation year: 1981 ADI: Not specified Meeting: 25 Specs Code: R(1973) Specifications monograph: COMPENDIUM ADDENDUM 11/FNP 52 Add. 11/89 (METALS LIMITS) (2003); FAO JECFA Monographs 1 vol.1/115 | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | Ascorbic acid has been widely used as antioxidant in many FCs. Using in fluid milk, to keep quality in shelf life, and to protect product from developing a rancid off taste and/or off-flavor. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |

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| Justification that the use does not mislead consumer | The use of ascorbic acid in fluid milk as a food additive is justified according to the requirements of 3.2 of the General Principles of the GSFA. The proposed use of ascorbic acid is to enhance the keeping quality and stability of a food, not to change the nature or quality of the food so as to deceive the consumer. |
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| THE PROPOSAL IS SUBMITTED BY: | | China | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Carrageenan | |
| INS Number | | 407 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Stabilizer | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (3) |
| 01.1.2 | Other fluid milks (plain) | GMP | |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Evaluation year: 2014 ADI: Not specified Meeting: 79 Specs Code: R Specifications monograph: FAO JECFA Monographs 16/7 | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | Carrageenan is able to stabilize the fluid milk products, creating a thixotropic network together with dairy proteins, which can keep solids suspended, i.e. vitamin-mineral complexes in fortified milk products. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |
| Justification that the use does not mislead consumer | | The use of carrageenan in fluid milk as a food additive is justified according to the requirements of 3.2 of the General Principles of the GSFA. The proposed use of carrageenan is to enhance the keeping stability of a food, not to change the nature, substance or quality of the food so as to deceive the consumer. | |

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| THE PROPOSAL IS SUBMITTED BY: | | China | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Gellan gum | |
| INS Number | | 418 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Thickener, Stabilizer | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): | | The proposal for <input type="checkbox"/> a new provision; | |

| <i>The rows below may be copied as many times as needed.</i> | | or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
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| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | GMP | |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Evaluation year: 2014 ADI: Not specified Meeting: 79 Specs Code: R Specifications monograph: FAO JECFA Monographs 16/19 | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | Gellan gum could stabilize and prevent protein aggregation, fouling in UHT heat exchanger. When used in non-flavored vitamin and mineral fortified fluid milk, gellan could provide excellent suspension of insoluble particles without adding excessive mouthfeel viscosity or impacting flavor. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |
| Justification that the use does not mislead consumer | | The use of gellan gum in fluid milk as a food additive is justified according to the requirements of 3.2 of the General Principles of the GSFA. The proposed use of gellan gum is to enhance the keeping stability of a food, not to change the nature, substance or quality of the food so as to deceive the consumer. | |

| THE PROPOSAL IS SUBMITTED BY: | | China | |
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| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Lecithin | |
| INS Number | | 322(i) | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Antioxidant, Emulsifier | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | GMP | |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Evaluation year: 1973 ADI: Not limited Meeting: 17 Specs Code: R (1993) Specifications monograph: COMPENDIUM ADDENDUM 11/FNP 52 Add. 11/89 (METALS LIMITS) (2003). R; FAO JECFA Monographs 1 vol.2/259 | |
| JUSTIFICATION: | | | |

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| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | Lecithin is used for the purpose of creating a stable fat globule membrane and improve the heat stability of recombined and reconstituted milk products. |
| Safe use of additive: Dietary intake assessment <i>(as appropriate)</i> | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) |
| Justification that the use does not mislead consumer | Lecithin is used commonly as an emulsifier to form and maintain a homogenous mixture of oil and water phases. According to the requirements of 3.2 of the General Principles of the GSFA. The proposed use of lecithin is to enhance the keeping stability of a food, not to change the nature, substance or quality of the food so as to deceive the consumer. |

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| THE PROPOSAL IS SUBMITTED BY: | China | | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | Microcrystalline cellulose | | |
| INS Number | 460 | | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | Stabilizer, Thickener | | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | GMP | |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | Evaluation year: 1997 ADI: not specified Meeting: 49 Specs Code: R Specifications: <u>COMPENDIUM ADDENDUM 8/FNP 52 Add.8/65 (2000)</u> . R: <u>FAO JECFA Monographs 1 vol.2/355</u> | | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | Microcellulose is one of hydrocolloids from natural cellulose. Microcellulose can well suspend colloids or particles in milk, such as milk protein and mineral in fortified products. It could also increase viscosity of the continuous water phase and thereby reducing creaming or sediment rates. | | |
| Safe use of additive: Dietary intake assessment <i>(as appropriate)</i> | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | | |
| Justification that the use does not mislead consumer | The use of microcrystalline cellulose as a food additive in milk is justified according to the requirements of 3.2 of the General Principles of the GSFA. The proposed use of Microcrystalline cellulose is to enhance the keeping stability of a food, not to change the nature, substance or quality of the food so as to deceive the consumer. | | |

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| THE PROPOSAL IS SUBMITTED BY: | | China | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Mono- and di- glycerides of fatty acids | |
| INS Number | | 471 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Emulsifier, Stabilizer | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | GMP | |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Evaluation year: 1973 ADI: Not specified Meeting: 17 Specs Code: R Specifications monograph: COMPENDIUM ADDENDUM 8/FNP 52 Add.8/203 (METALS LIMITS) (2000). R; FAO JECFA Monographs 1 vol.2/417 | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | Mono- and Diglycerides of fatty acids are having a significant impact on the interfacial tension between water and oil phase and as such is very important for facilitating emulsification in recombined products. Mono- and diglycerides can prevent powdery mouthfeel and gritty texture. Furthermore INS 471 is used for controlling the emulsifier/protein ratio in emulsion membranes. This is important for shelf life of the products. | |
| Safe use of additive: Dietary intake assessment <i>(as appropriate)</i> | | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |
| Justification that the use does not mislead consumer | | The use of mono- and di- glycerides of fatty acids as a food additive in fluid milk is justified according to the requirements of 3.2 of the General Principles of the GSFA. The proposed use of mono- and di- glycerides of fatty acids is to enhance the keeping stability of a food, not to change the nature, substance or quality of the food so as to deceive the consumer. | |

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| THE PROPOSAL IS SUBMITTED BY: | | China | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Pentasodium triphosphate | |
| INS Number | | 451(i) | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Stabilizer, Humectant | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision | |

| | | or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
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| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | 5000 mg/kg | Note 33: As phosphorus Note 227: For use in sterilized and UHT treated milks only. |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Evaluation year: 1982 ADI: Not specified Meeting: 26 Specs Code: R,T (1976) Specifications monograph: COMPENDIUM ADDENDUM 8/FNP 52 Add.8/87 (2000). R; FAO JECFA Monographs 1 vol.3/27 | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | Pentasodium triphosphate could reduce the interfacial tension between liquid/solid, especially for using in the process of UHT milk as keep quality during the UHT process. It also could preserve the quality of milk by using as moisture conservative. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below) According to the consumption data in China, at the proposed maximum use level, the daily intake of a person with a bodyweight of 60 kg is 1.2 mg/kg bw in total population; and the daily intake of ages in 2-6 is 5.25 mg/kg (based on 20 kg bw). | |
| Justification that the use does not mislead consumer | | The use of pentasodium triphosphate in milk as a food additive is justified according to the requirements of 3.2 of the General Principles of the GSFA. The proposed use of pentasodium triphosphate is to enhance the keeping stability of a food, not to change the nature, substance or quality of the food so as to deceive the consumer. | |

| THE PROPOSAL IS SUBMITTED BY: | | China | |
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| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Polydextrose | |
| INS Number | | 1200 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Thickener | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | GMP | |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Evaluation year: 1987 ADI: not specified meeting: 31 | |

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| | Specifications: COMPENDIUM ADDENDUM 6/FNP 52 Add.6/103 (1998). R; FAO JECFA Monographs 1 vol.3/51 |
| JUSTIFICATION: | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | Polydextrose is added to low/reduced fat milks, contributing to mouthfeel and the perception of creaminess, thereby increasing organoleptic acceptability to consumers. |
| Safe use of additive: Dietary intake assessment (as appropriate) | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) |
| Justification that the use does not mislead consumer | The use of polydextrose in milk as a food additive is justified according to the requirements of 3.2 of the General Principles of the GSFA. |

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| THE PROPOSAL IS SUBMITTED BY: | | China | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Polyglycerol esters of fatty acids | |
| INS Number | | 475 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Emulsifier | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | 1000 mg/kg | |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Evaluation year: 1989 ADI: 0-25 mg/kg bw Meeting: 35 Specs Code: R Specifications: COMPENDIUM ADDENDUM 8/FNP 52 Add.8/203 (METALS LIMITS) (2000). R; FAO JECFA Monographs 1 vol.3/77 | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | Polyglycerol esters of fatty acids is an emulsifier with good interfacial activity. It can impact the surface tension between water and oil phase to help the formation of emulsion in recombined milk products. Polyglycerol esters of fatty acids can also reduce fat creaming. And keep the product stable during the shelf life, especially for recombined whole milk products. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below) According to the consumption data in China, at the proposed maximum use level, the daily intake of a person with a bodyweight of 60 kg is 0.24 mg/kg bw in total population; and the daily intake of ages in 2-6 is 1.05 mg/kg (based on 20 kg bw). | |

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| Justification that the use does not mislead consumer | The use of polyglycerol esters of fatty acids in milk as a food additive is justified according to the requirements of 3.2 of the General Principles of the GSFA. The proposed use of Polyglycerol esters of fatty acids is to enhance the keeping stability of a food, not to change the nature, substance or quality of the food so as to deceive the consumer. |
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| THE PROPOSAL IS SUBMITTED BY: | | China | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Propylene glycol alginate | |
| INS Number | | 405 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Emulsifier, Stabilizer, Thickener | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | 4000 mg/kg | |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph). | | Evaluation year: 1993 ADI: 0-70 mg/kg bw Meeting: 49 Specs Code: R (1997) Specification: COMPENDIUM ADDENDUM 5/FNP 52 Add.5/131 (1997). R; FAO JECFA Monographs 1 vol.3/189 | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | Propylene glycol alginate is able to stabilize milk protein by providing steric stabilization. Propylene glycol alginate can interact with milk proteins and adsorbed on the surface of casein micelles with a functionality of stabilization in recombined milk. As the molecule of propylene glycol alginate contains both of hydrophobic and hydrophilic groups, it also has interfacial activity and is helpful to stabilize the recombined products during shelf life. | |
| Safe use of additive: Dietary intake assessment <i>(as appropriate)</i> | | Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below) According to the consumption data in China, at the proposed maximum use level, the daily intake of a person with a bodyweight of 60 kg is 0.96 mg/kg bw in total population; and the daily intake of ages in 2-6 is 4.2 mg/kg (based on 20 kg bw). | |
| Justification that the use does not mislead consumer | | The use of Propylene glycol alginate in milk as a food additive is justified according to the requirements of 3.2 of the General Principles of the GSFA; The proposed use of Propylene glycol alginate is not linked to issues related to the freshness, quality of ingredients used or undesirable practices which would mislead the consumer. | |

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| THE PROPOSAL IS SUBMITTED BY: | | China | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive | | Sodium ascorbate | |

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| <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | | |
| INS Number | | 301 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Antioxidant | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks(plain) | GMP | |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Evaluation year: 1981 ADI: Not specified Meeting: 25 Specs Code: R(1973) Specifications monograph: COMPENDIUM ADDENDUM 11/FNP 52 Add. 11/89 (METALS LIMITS) (2003). FAO JECFA Monographs 1 vol.3/307 | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | Sodium ascorbate has been widely used as antioxidant in many FCs. Using in fluid milk, to keep quality in shelf life, and to protect product from developing a rancid off taste and/or off-flavor. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |
| Justification that the use does not mislead consumer | | The proposed use of sodium ascorbate in fluid milk as a food additive is justified according to the requirements of 3.2 of the General Principles of the GSFA. The proposed use of sodium ascorbate is to enhance the keeping quality and stability of a food, not to change the nature or quality of the food so as to deceive the consume. | |

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| THE PROPOSAL IS SUBMITTED BY: | | China | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Sodium carboxymethyl cellulose | |
| INS Number | | 466 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Stabilizer, Thickener | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | GMP | |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA | | Evaluation year: 1989 | |

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| <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | ADI: not specified Meeting: 35 Specs Code: S Specifications: COMPENDIUM ADDENDUM 12/FNP 52 Add. 12/68 (METALS LIMITS) (2004). R; FAO JECFA Monographs 1 vol.3/315 |
| JUSTIFICATION: | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | Carboxymethyl cellulose is a cellulose gum from natural cellulose with high viscosity. It is able to stabilize milk by increasing viscosity of the continuous water phase and thereby reducing creaming or sediment rates in fortified milk products, such as calcium fortified. |
| Safe use of additive: Dietary intake assessment (as appropriate) | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) |
| Justification that the use does not mislead consumer | Sodium carboxymethyl cellulose is used as a food additive in this proposed food category is justified according to the requirements of 3.2 of the General Principles of the GSFA. The proposed use of sodium carboxymethyl cellulose is to enhance the keeping stability of a food, not to change the nature, substance or quality of the food so as to deceive the consumer. |

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| THE PROPOSAL IS SUBMITTED BY: | | China | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Sodium polyphosphate | |
| INS Number | | 452(i) | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Humectant, Stabilizer | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | 5000 mg/kg | Note 33: As phosphorus Note 227: For use in sterilized and UHT treated milks only. |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Evaluation year: 1982 ADI: MTDI 70 mg/kg bw (as P) Meeting: 46 Specs Code: R (1996) Specifications: COMPENDIUM ADDENDUM 8/FNP 52 Add.8/203 (METALS LIMITS) (2000). R; FAO JECFA Monographs 1 vol.3/377 | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | Sodium polyphosphate could cause a considerable increase in the heat stability of UHT milk during the process by addition of appropriate concentration as stabilizer. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: | |

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| | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below) According to the consumption data in China, at the proposed maximum use level, the daily intake of a person with a bodyweight of 60 kg is 1.2 mg/kg bw in total population; and the daily intake of ages in 2-6 is 5.25 mg/kg (based on 20 kg bw). |
| Justification that the use does not mislead consumer | The use of sodium polyphosphate in fluid milk as a food additive is justified according to the requirements of 3.2 of the General Principles of the GSFA. The proposed use of Sodium polyphosphate is to enhance the keeping stability of a food, not to change the nature, substance or quality of the food so as to deceive the consumer. |

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| THE PROPOSAL IS SUBMITTED BY: | | China | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Sucrose esters of fatty acid | |
| INS Number | | 473 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Emulsifier | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | 1000 mg/kg | |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Evaluation year: 2010 ADI: 0-30 mg/kg bw Meeting: 73 Meeting: 49 Specs Code: R Specification: FAO JECFA Monographs 4- JECFA 68/ . R (2007) | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | Sucrose esters of fatty acid has a significant interfacial activity. It can impact the surface tension between water and oil phase to help the formation of emulsion in recombined products and calcium fortified milk products. Sucrose esters of fatty acid also can reduce fat creaming. This is very helpful for shelf life of the products. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below) According to the consumption data in China, at the proposed maximum use level, the daily intake of a person with a bodyweight of 60 kg is 0.24 mg/kg bw in total population; and the daily intake of ages in 2-6 is 1.05 mg/kg (based on 20 kg bw). | |
| Justification that the use does not mislead consumer | | The use of Sucrose esters of fatty acid fulfils the conditions listed in section 3.2 of GSFA as used as a food additive in this food category. The proposed use of Sucrose esters of fatty acid is not linked to issues related to the freshness, quality of ingredients used or undesirable practices which would mislead the consumer. | |

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| THE PROPOSAL IS SUBMITTED BY: | | China | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | TARTRATES | |
| INS Number | | 334, 335(ii), 337 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Acidity regulator, Antioxidant, Flavour enhancer, Stabilizer, Emulsifying salt, Sequestrant | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input checked="" type="checkbox"/> revising an existing provision or <input type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 05.2 | Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, 05.4 | 2,000 mg/kg 20,000 mg/kg | Note 45, &XS309R |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Evaluation year: 1977 ADI: JECFA allocated a group ADI of 0-30 mg/kg b.w./day for tartrates (L(+)-tartaric acid and its sodium, potassium, potassium sodium salts) Meeting: 21 Specs Code: R Specifications monograph: - Tartaric acid (INS 334) , http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-457.pdf ; - Sodium L(+)-tartrate (INS335(ii)), http://www.fao.org/ag/agn/jecfa-additives/specs/monograph7/additive-427-m7.pdf ; - Potassium sodium L(+)-tartrate (INS 337), http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-348.pdf | |
| JUSTIFICATION | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | Tartrates are used as acidity (i.e. pH) control agents to provide the initial impact of sourness to confectionery. It contributes to a strong tart taste and has the ability to increase and enhance the flavors of fruits where they are naturally present. The sweetness of sucrose is also increased by acid such tartaric acid, thus allowing some reduced use of sucrose. Tartrates are important ingredients for fruit flavored candy playing a role in the stability of the acidity of these candies, which in return play a synergist role in stabilizing the flavor profile of the added flavorings. Tartaric acid itself is the most water-soluble of the solids acidic substances, followed by, by decreasing order, malic acid, citric acid, adipic acid, fumaric acid and succinic acid. Tartaric acid provides the highest level of upfront tartness from the variety of commonly available food acids. In fruit flavored candies, the upfront tartness which enhances the natural flavor is of most important interest to the consumer. Thus, tartrates (INS 334, 335(ii), and 337) satisfy a consumer need that none of the other permitted acids can meet. Based on literature data, each individual consumer also differ radically in their physical and psychological ability to detect differences in acidic taste and in identifying acids. Hence, tartrates may also be found in combination with two or more acids (e.g. citric acid) to enhance the flavor of fruits. Overall, tartrates (INS 334, 335(ii), and 337) are technologically needed at 20.000 mg/kg specifically in 05.2 confectionery. | |

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| Safe use of additive: Dietary intake assessment (as appropriate) | Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below) JECFA allocated a group ADI of 0-30 mg/kg b.w./day for tartrates. Consumption of a 5 grams' piece of candy containing the future maximum permitted use level of 20,000 mg/kg of tartrates by a 60 kg adult would result in the possible ingestion of only 100 mg of tartrates, i.e. 5.6% of the ADI . |
| Justification that the use does not mislead consumer | i) the use of Tartaric acid and its Tartrate salts (INS 334, 335(ii), and 337), i.e. tartrates, should be permitted in Codex GSFA at a level 20,000 mg/kg in confectionery, expressed as tartaric acid, for use singly or in combination and ii) this level is technically justified and safe, based on the technical needs and related safety calculations mentioned above. |

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| THE PROPOSAL IS SUBMITTED BY: | | China | | | |
| IDENTITY OF THE FOOD ADDITIVE: | | | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Tocopherols (d-alpha-Tocopherol, Tocopherol concentrate, mixed, dl-alpha-Tocopherol) | | | |
| INS Number | | 307a d-alpha-Tocopherol 307b Tocopherol concentrate, mixed 307c dl-alpha-Tocopherol | | | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Antioxidant | | | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | | | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) | | |
| 01.1.2 | Other fluid milks(plain) | 200 mg/kg | | | |
| EVALUATION BY JECFA: | | | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | | 307a | 307b | 307c |
| | | Evaluation year | 1986 | 1973 | 1986 |
| | | ADI | 0.15-2 mg/kg bw | 0-2 mg/kg bw | 0.15-2 mg/kg bw |
| | | Meeting | - | 17 | - |
| | | Specs Code | - | R(1977) | - |
| Specifications monograph | COMPENDIUM ADDENDUM 11/FNP 52 Add. 11/89 (METALS LIMITS) (2003). R: FAO JECFA Monographs 1 vol.3/535 | NMRS 57-JECFA 21/91 (1977) | COMPENDIUM ADDENDUM 11/FNP 52 Add. 11/89 (METALS LIMITS) (2003). R: FAO JECFA Monographs 1 vol.3/531 | | |
| JUSTIFICATION: | | | | | |
| Justification for use and technological need | | Tocopherols could keep products' quality in shelf life, and to protect product from developing a rancid off taste and/or off-flavor. | | | |

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| <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | |
| Safe use of additive: Dietary intake assessment (as appropriate) | Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below) According to the consumption data in China, at the proposed maximum use level, the daily intake of a person with a bodyweight of 60 kg is 0.048 mg/kg bw in total population; and the daily intake of ages in 2-6 is 0.21 mg/kg (based on 20 kg bw). |
| Justification that the use does not mislead consumer | The use of tocopherols in fluid milk as a food additive is justified according to the requirements of 3.2 of the General Principles of the GSFA. The proposed use of tocopherols is to enhance the keeping quality and stability of a food, not to change the nature or quality of the food so as to deceive the consumer. |

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| THE PROPOSAL IS SUBMITTED BY: | | China | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Trisodium citrate | |
| INS Number | | 331 (iii) | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Stabilizer | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | GMP | |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Evaluation year: 1973 ADI: NOT LIMITED Meeting: 17 Specs Code: R(1975) Specifications: COMPENDIUM ADDENDUM 10/FNP 52 Add.10/34 (METALS LIMITS) (2002). R; FAO JECFA Monographs 1 vol.3/569 | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | Trisodium citrate could help to prevent protein denature and maintain a good stability during the manufacture processing of the products in FC 1.1.2. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |

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| Justification that the use does not mislead consumer | The use of trisodium citrate in fluid milk as a food additive is justified according to the requirements of 3.2 of the General Principles of the GSFA. The proposed use of trisodium citrate is to enhance the keeping stability of a food, not to change the nature, substance or quality of the food so as to deceive the consumer. |
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| THE PROPOSAL IS SUBMITTED BY: | | China | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Trisodium Phosphate | |
| INS Number | | 339(iii) | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Humectant, Stabilizer | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | 5000 mg/kg | Note 33: As phosphorus Note 227: For use in sterilized and UHT treated milks only. |

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| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Evaluation year: 1982 ADI: MTDI 70 mg/kg bw (as P) Meeting: 26 Specs Code: R(1975) Specifications: <u>WITHDRAWN (2005)</u> | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | Trisodium phosphate reduces ionic calcium and sediment during UHT treatment in the manufacture processing of UHT milk, therefore, to increase stability. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below) According to the consumption data in China, at the proposed maximum use level, the daily intake of a person with a bodyweight of 60 kg is 1.2 mg/kg bw in total population; and the daily intake of ages in 2-6 is 5.25 mg/kg (based on 20 kg bw). | |
| Justification that the use does not mislead consumer | | The use of trisodium phosphate in fluid milk as a food additive is justified according to the requirements of 3.2 of the General Principles of the GSFA. The proposed use of trisodium phosphate is to enhance the keeping stability of a food, not to change the nature, substance or quality of the food so as to deceive the consumer. | |

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| THE PROPOSAL IS SUBMITTED BY: | | China | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive | | Xanthan gum | |

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| <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | | |
| INS Number | | 415 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Stabilizer | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | GMP | |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Evaluation year: 1986 ADI: Not specified Meeting: 30 Specs code: R (1993) Specifications monograph: COMPENDIUM ADDENDUM 7/FNP 52 Add.7/105 (1999). R; FAO JECFA Monographs 1 vol.3/589 | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | Xanthan stabilizes fluid milk products by giving steric stabilization through interaction with proteins. It also helps to keep solids suspended, i.e. vitamin-mineral complexes in fortified products. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |
| Justification that the use does not mislead consumer | | The use of Xanthan gum fulfils the conditions listed in section 3.2 of GSFA as used as a food additive in this food category. And the use does not change the nature of the product and does not have any impact on the sensorial properties which would mislead the consumer (e.g. use of faulty raw materials). | |

JAPAN

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| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Lecithin | |
| INS Number | | 322(i) | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Antioxidant, Emulsifier | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | 100 mg/kg | For use in non-flavoured vitamin and mineral fortified fluid milks only. |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Lecithin was evaluated and an ADI "not limited" was established at the 17 th JECFA (1973). The specification was prepared at the 41 st JECFA and published in FAO Food and Nutrition Paper 52 Addendum 2 (1993), and revised at the 61 th JECFA (2003). | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | Lecithin is used to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milks. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |
| Justification that the use does not mislead consumer | | The above-mentioned use does not affect nature and quality of the food that would be expected by consumers. Lecithin is widely used in a variety of food as emulsifier. | |

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| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Citric acid | |
| INS Number | | 330 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Acidity regulator, Antioxidant, Colour retention agent, Sequestrant | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | 20 mg/kg | For use in non-flavoured mineral fortified fluid milks only. |

| EVALUATION BY JECFA: | |
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| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or “not specified”); specifications monograph).</i> | <i>Citric acid was evaluated and a group ADI “not limited” for citric acid and its calcium, potassium, sodium and ammonium salts was established at the 17th JECFA (1973). The latest specification was prepared at the 79th JECFA and published in FAO JECFA Monographs 16 (2014).</i> |
| JUSTIFICATION: | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | <i>Citric acid is used to adjust pH to prevent degradation of protein in non-flavoured iron fortified fluid milks.</i> |
| Safe use of additive: Dietary intake assessment (as appropriate) | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) |
| Justification that the use does not mislead consumer | <i>The above-mentioned use does not affect nature and quality of the food that would be expected by consumers. Citric acid is widely used in a variety of food as acidity regulator.</i> |

| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
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| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Trisodium citrate | |
| INS Number | | 331 (iii) | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Acidity regulator, Emulsifier, Emulsifying salt, Sequestrant, Stabilizer | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 “Other fluid milks (plain)” | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | 600 mg/kg | <i>For use in non-flavoured mineral fortified fluid milks only.</i> |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or “not specified”); specifications monograph).</i> | | <i>Trisodium citrate was evaluated and an ADI “not limited” was established at the 17th JECFA (1973). The specification was prepared at the 19th JECFA (1975) and published in FAO Food and Nutrition Paper 52 (1992), and revised at the 59th JECFA (2002).</i> | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | <i>Trisodium citrate is used to adjust pH to prevent sedimentation in non-flavoured mineral fortified fluid milks.</i> | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |

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| Justification that the use does not mislead consumer | <i>The above-mentioned use does not affect nature and quality of the food that would be expected by consumers. Trisodium citrate is widely used in a variety of food as acidity regulator.</i> |
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| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Carrageenan | |
| INS Number | | 407 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | <i>Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener</i> | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | 800 mg/kg | <i>For use in non-flavoured vitamin and mineral fortified fluid milks only.</i> |

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| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | <i>Carrageenan was evaluated and an ADI "not specified" for carrageenan and processed Eucheuma seaweed was established at the 57th JECFA (2001). The latest specification was prepared at the 79th JECFA (2014) and published in FAO JECFA Monographs 16 (2014).</i> | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | <i>Carageenan is used to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milks.</i> | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |
| Justification that the use does not mislead consumer | | <i>The above-mentioned use does not affect nature and quality of the food that would be expected by consumers.</i> | |

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| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Gum arabic | |
| INS Number | | 414 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | <i>Bulking agent, Carrier, Emulsifier, Glazing agent, Stabilizer, Thickener</i> | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |

| Food Category No. (²) | Food Category Name (²) | Maximum Use Level (³) | Comments (⁴) |
|--|---------------------------|--|--|
| 01.1.2 | Other fluid milks (plain) | 500 mg/kg | For use in non-flavoured vitamin and mineral fortified fluid milks only. |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph). | | Gum arabic was evaluated and an ADI "not specified" was established at the 35 th JECFA (1989). The specification was prepared at the 51 st JECFA (1998) and published in FNP 52 Add 7 (1999). | |
| JUSTIFICATION: | | | |
| Justification for use and technological need Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function). | | Gum arabic is used to prevent sedimentation in non-flavoured vitamin and mineral fortified fluid milks. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |
| Justification that the use does not mislead consumer | | The above-mentioned use does not affect nature and quality of the food that would be expected by consumers. | |

| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
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| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | Xanthan gum | |
| INS Number | | 415 | |
| Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | Emulsifier, Foaming agent, Stabilizer, Thickener | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (¹): The rows below may be copied as many times as needed. | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (²) | Food Category Name (²) | Maximum Use Level (³) | Comments (⁴) |
| 01.1.2 | Other fluid milks (plain) | 140 mg/kg | For use in non-flavoured mineral fortified fluid milks only. |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph). | | Xanthan gum was evaluated and an ADI "not specified" was established at the 30 th JECFA (1986). The latest specification was prepared at the 53 rd JECFA (1999) and published in FNP Add 7 (1999). | |
| JUSTIFICATION: | | | |
| Justification for use and technological need Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function). | | Xanthan gum is used to prevent sedimentation in non-flavoured mineral fortified fluid milks. | |

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| Safe use of additive: Dietary intake assessment (as appropriate) | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) |
| Justification that the use does not mislead consumer | <i>The above-mentioned use does not affect nature and quality of the food that would be expected by consumers.</i> |

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| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Gellan gum | |
| INS Number | | 418 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Stabilizer, Thickener | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | 120 mg/kg | <i>For use in non-flavoured mineral fortified fluid milks only.</i> |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | <i>Gellan gum was evaluated and an ADI "not specified" was established at the 37th JECFA (1990). The latest specification was prepared at the 79th JECFA (2014) and published in FAO JECFA Monographs 16 (2014).</i> | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | <i>Gellan gum is used to prevent sedimentation in non-flavoured mineral fortified fluid milks.</i> | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |
| Justification that the use does not mislead consumer | | <i>The above-mentioned use does not affect nature and quality of the food that would be expected by consumers.</i> | |

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| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Microcrystalline cellulose (Cellulose gel) | |
| INS Number | | 460(i) | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Anticaking agent, Bulking agent, Carrier, Emulsifier, Foaming agent, Glazing agent, Stabilizer, Thickener | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision | |

| | | or ■ a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
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| Food Category No. (²) | Food Category Name (²) | Maximum Use Level (³) | Comments (⁴) |
| 01.1.2 | Other fluid milks (plain) | 3000 mg/kg | For use in non-flavoured mineral fortified fluid milks only. |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph). | | Microcrystalline cellulose was evaluated and an ADI "not specified" was established at the 49 th JECFA (1998). The latest specification was prepared at the 55 th JECFA (2000) and published in FNP52 Add 8 (2000). | |
| JUSTIFICATION: | | | |
| Justification for use and technological need Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function). | | Microcrystalline cellulose is used to prevent sedimentation in non-flavoured mineral fortified fluid milks. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: ■ Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |
| Justification that the use does not mislead consumer | | The above-mentioned use does not affect nature and quality of the food that would be expected by consumers. | |

| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
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| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | Sodium carboxymethyl cellulose (Cellulose gum) | |
| INS Number | | 466 | |
| Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | Bulking agent, Emulsifier, Firming agent, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (¹): The rows below may be copied as many times as needed. | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or ■ a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (²) | Food Category Name (²) | Maximum Use Level (³) | Comments (⁴) |
| 01.1.2 | Other fluid milks (plain) | 150 mg/kg | For use in non-flavoured mineral fortified fluid milks only. |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph). | | Sodium carboxymethyl cellulose (Cellulose gum) was evaluated and an ADI "not specified" for modified celluloses was established at the 35 th JECFA (1989). The latest evaluation was prepared at the 74 th JECFA (2011) and published in FAO JECFA Monographs 11 (2011). | |
| JUSTIFICATION: | | | |
| Justification for use and technological need Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function). | | Sodium carboxymethyl cellulose is used to prevent sedimentation in non-flavoured mineral fortified fluid milks. | |

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| Safe use of additive: Dietary intake assessment (as appropriate) | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) |
| Justification that the use does not mislead consumer | <i>The above-mentioned use does not affect nature and quality of the food that would be expected by consumers.</i> |

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| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Mono-and Di- glycerides of fatty acids | |
| INS Number | | 471 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Emulsifier, Stabilizer | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | 120 mg/kg | <i>For use in non-flavoured vitamin and mineral fortified fluid milks only.</i> |

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| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | <i>An ADI "not limited" was established at the 17th JECFA (1973). The latest specification was prepared at the 17th JECFA (1973) and revised at the 55th JECFA (2000).</i> | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | This food additive is used to prevent sedimentation in non-flavoured vitamin and mineral fortified milk. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |
| Justification that the use does not mislead consumer | | The above-mentioned use does not affect nature and quality of the food that would be expected by consumers. | |

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| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Acetic and fatty acid esters of glycerol | |
| INS Number | | 472a | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Emulsifier, Sequestrant, Stabilizer | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision | |

| | | or ■ a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
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| Food Category No. (²) | Food Category Name (²) | Maximum Use Level (³) | Comments (⁴) |
| 01.1.2 | Other fluid milks (plain) | 120 mg/kg | For use in non-flavoured vitamin and mineral fortified fluid milks only. |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph). | | An ADI "not limited" was established at the 17 th JECFA (1973). The latest specification was prepared at the 17 th JECFA (1973) and revised at the 55 th JECFA (2000). | |
| JUSTIFICATION: | | | |
| Justification for use and technological need Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function). | | This food additive is used to prevent sedimentation in non-flavoured vitamin and mineral fortified milk. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: ■ Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |
| Justification that the use does not mislead consumer | | The above-mentioned use does not affect nature and quality of the food that would be expected by consumers. | |

| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
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| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | Lactic and fatty acid esters of glycerol | |
| INS Number | | 472b | |
| Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | Emulsifier, Sequestrant, Stabilizer | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (¹): The rows below may be copied as many times as needed. | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or ■ a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (²) | Food Category Name (²) | Maximum Use Level (³) | Comments (⁴) |
| 01.1.2 | Other fluid milks (plain) | 120 mg/kg | For use in non-flavoured vitamin and mineral fortified fluid milks only. |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph). | | An ADI "not limited" was established at the 17 th JECFA (1973). The latest specification was prepared at the 17 th JECFA (1973) and revised at the 55 th JECFA (2000). | |
| JUSTIFICATION: | | | |
| Justification for use and technological need Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function). | | This food additive is used to prevent sedimentation in non-flavoured vitamin and mineral fortified milk. | |

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| Safe use of additive: Dietary intake assessment (as appropriate) | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) |
| Justification that the use does not mislead consumer | The above-mentioned use does not affect nature and quality of the food that would be expected by consumers. |

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| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | Citric and fatty acid esters of glycerol | |
| INS Number | | 472c | |
| Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | Antioxidant, Emulsifier, Flour treatment agent, Sequestrant, Stabilizer | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (*) : The rows below may be copied as many times as needed. | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.2 | Other fluid milks (plain) | 120 mg/kg | For use in non-flavoured vitamin and vitamin fortified fluid milks only. |

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| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph). | | An ADI "not limited" was established at the 17 th JECFA (1973). The latest specification was prepared at the 79 th JECFA (2014). | |
| JUSTIFICATION: | | | |
| Justification for use and technological need Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function). | | This food additive is used to prevent sedimentation in non-flavoured vitamin and mineral fortified milk. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |
| Justification that the use does not mislead consumer | | The above-mentioned use does not affect nature and quality of the food that would be expected by consumers. | |

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| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | Diacetyltartaric and fatty acid esters of glycerol | |
| INS Number | | 472e | |
| Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | Emulsifier, Sequestrant, Stabilizer | |

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| PROPOSED USE(S) OF THE FOOD ADDITIVE (¹): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (²) | Food Category Name (²) | Maximum Use Level (³) | Comments (⁴) |
| 01.1.2 | Other fluid milks (plain) | 120 mg/kg | <i>For use in non-flavoured vitamin and mineral fortified fluid milks only.</i> |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | <i>An ADI of 0–50 mg/kg bw was established at the 61st JECFA (2003). The total intake of tartaric acid from food additives should not exceed the ADI for tartaric acid (0–30 mg/kg bw). The latest specification was prepared at the 71st JECFA (2009).</i> | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | This food additive is used to prevent sedimentation in non-flavoured vitamin and mineral fortified milk. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below) According to a national Total Diet Study (market basket method) conducted by Ministry of Health of Japan in 2005, dietary intakes of glyceryl monostearate and glyceryl monopalmitate, main components of glycerol esters of fatty acids, are 46.58 mg/day (0.84 mg/kg bw/day) and 26.15 mg/day (0.47 mg/kg bw/day) respectively. Therefore, it is highly unlikely that dietary exposure of diacetyltartaric and fatty acid esters of glycerol would exceed the upper bound of the JECFA ADI. Also, dietary intake of L(+)-tartaric acid is 65.1 mg/day (1.18 mg/kg bw/day), which is far below the upper bound of the JECFA ADI of tartrates, according to a national Total Diet Study (market basket method) conducted by Ministry of Health of Japan in 1998 and 1999. | |
| Justification that the use does not mislead consumer | | The above-mentioned use does not affect nature and quality of the food that would be expected by consumers. | |

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| THE PROPOSAL IS SUBMITTED BY: | <i>Japan</i> |
| IDENTITY OF THE FOOD ADDITIVE: | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | <i>Sucrose esters of fatty acids Sucrose oligoesters, type I and type II Sucroglycerides</i> |
| INS Number | <i>473, 473a, 474</i> |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | <i>INS 473 Sucrose esters of fatty acids Emulsifier, Foaming agent, Glazing agent, Stabilizer INS 473a Sucrose oligoesters, type I and type II Emulsifier, Glazing agent, Stabilizer INS 474 Sucroglycerides Emulsifier</i> |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (¹): <i>The rows below may be copied as many times as needed.</i> | The proposal for <input type="checkbox"/> a new provision; or <input checked="" type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" |

| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
|--|---|---|--|
| 01.1.2 | Other fluid milks (plain) | 300 mg/kg | For use in non-flavoured vitamin and mineral fortified fluid milks only. |
| 01.7 | Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt) | 5000 mg/kg | 348, XS 243 362 |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph). | | A group ADI of 0 – 30 mg/kg bw as the sum of sucrose esters of fatty acids, sucroglycerides, sucrose oligoesters type I and type II and sucrose monoesters or lauric, palmitic or stearic acid was established at the 73 rd JECFA (2010). The latest specification for INS 473, 473a and 474 were prepared at the 73 rd JECFA (2010), 71 st JECFA (2009) and 49 th JECFA (1997) respectively. | |
| JUSTIFICATION: | | | |
| Justification for use and technological need Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function). | | <p><u>1. Food category 01.1.2</u> These food additives are used to prevent sedimentation in non-flavoured vitamin and mineral fortified milk.</p> <p><u>2. Food category 01.7</u> Codex standard for fermented milks (CODEX STAN 243-2003) permits the use of INS 491, 492, 493, 494 and 495 as an emulsifier in flavoured products. However, the GSFA permits the use of these additives excluding products conforming to CODEX STAN 243-2003. To avoid conflicts with CODEX STAN 243-2003, Japan proposes that Note XS 243 be replaced with Note 362 "Excluding plain products conforming to the Standard for Fermented Milks (CODEX STAN 243-2003)".</p> | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | <p>Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below)</p> <p>The 73rd JECFA estimated dietary intake of sucrose oligoesters type I and type II.</p> <p>1. Dietary exposure based on poundage data USA (assuming that sucrose oligoesters type I and type II (SOE) captured 10% of the market for emulsifiers): 60 mg/day (3% of the ADI) Japan (includes SOE and sucrose esters of fatty acids) : 110 mg/day (6% of the ADI)</p> <p>2. Dietary exposure based on national nutrition survey data Japan: the mean dietary exposure to SOE type I and type II for the whole population was estimated to be 115 and 224 mg/day for typical and maximum use levels, respectively. USA: the mean dietary exposure to SOE type I and type II for the whole population was estimated to be 151 and 274 mg/day for typical and maximum use levels, respectively. Based on above estimated dietary exposures to SOE type I and type II combined for mean and high consumers, based on typical or maximum use levels, were well below the upper bound of the JECFA ADI. For more information please refer to 73rd JECFA (p.256 – 268) http://www.inchem.org/documents/jecfa/jecmono/v62je01.pdf</p> | |
| Justification that the use does not mislead consumer | | The above-mentioned use does not affect nature and quality of the food that would be expected by consumers. | |

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| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Polyglycerol esters of fatty acids | |
| INS Number | | 475 | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Emulsifier, Stabilizer | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (¹): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (²) | Food Category Name (²) | Maximum Use Level (³) | Comments (⁴) |
| 01.1.2 | Other fluid milks (plain) | 300 mg/kg | For use in non-flavoured vitamin and mineral fortified fluid milks only. |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | An ADI of 0–25 mg/kg bw was established at the 35 th JECFA (1989). The latest specification was prepared at the 35 th JECFA (1989) and revised at the 55 th JECFA (2000). | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | This food additive is used in non-flavoured vitamin and mineral fortified milk to stabilize calcium or iron which are used for fortification. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below) According to a national Total Diet Study (market basket method) conducted by Ministry of Health of Japan in 2005, daily intakes of glyceryl monostearate and glyceryl monopalmitate, main components of glycerol esters of fatty acids, are 46.58 mg/person (0.84 mg/kg bw) and 26.15 mg/person (0.47 mg/kg bw) respectively, which are far below the upper bound of the JECFA ADI. | |
| Justification that the use does not mislead consumer | | The above-mentioned use does not affect nature and quality of the food that would be expected by consumers. | |

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| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Potassium carbonate | |
| INS Number | | 501(i) | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | Acidity regulator, Anticaking agent, Raising agent, Stabilizer, Thickener | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (¹): <i>The rows below may be copied as many times as needed.</i> | | The proposal for <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input checked="" type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |

| Food Category No. (²) | Food Category Name (²) | Maximum Use Level (³) | Comments (⁴) |
|--|---------------------------|---|--|
| 01.1.2 | Other fluid milks (plain) | 800 mg/kg | For use in non-flavoured mineral fortified fluid milks only. |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph). | | An ADI not limited was established at the 9 th JECFA (1965). The latest specification was prepared at the 19 th JECFA (1975) and revised at the 59 th JECFA (2002). | |
| JUSTIFICATION: | | | |
| Justification for use and technological need Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function). | | This food additive is used in non-flavoured mineral fortified milk to prevent denaturation of protein during pasteurization. | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below) | |
| Justification that the use does not mislead consumer | | The above-mentioned use does not affect nature and quality of the food that would be expected by consumers. | |

| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
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| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | Tartrates | |
| INS Number | | 334, 335(ii), 337 | |
| Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | INS 334 L(+)- Tartaric acid Acidity regulator, Antioxidant, Flavour enhancer, Sequestrant INS 335(ii) Sodium L(+)-tartrate Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer INS 337 Potassium sodium L(+)-tartrate Acidity regulator, Emulsifying salt, Sequestrant, Stabilizer | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (¹): The rows below may be copied as many times as needed. | | The proposal for <input type="checkbox"/> a new provision; or <input checked="" type="checkbox"/> revising an existing provision or <input type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (²) | Food Category Name (²) | Maximum Use Level (³) | Comments (⁴) |
| 01.7 | Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt) | 2000 mg/kg | XS-243-362 |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph). | | An ADI of 0 – 30 mg/kg bw was established at the 17 th JECFA (1973) and reconfirmed at the 21 st JECFA (1977). The latest specification for INS 334, 335(ii) and 337 were prepared at the 53 rd JECFA (1999), the 63 rd JECFA (2004) and the 63 rd JECFA (2004) respectively. | |
| JUSTIFICATION: | | | |
| Justification for use and technological need | | Codex standard for fermented milks (CODEX STAN 243-2003) permits the use of INS 334, 335(ii) and 337 as an acidity regulator in flavoured products. | |

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| Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function). | However, the GSFA permits the use of these additives excluding products conforming to CODEX STAN 243-2003. To avoid conflicts with CODEX STAN 243-2003, Japan proposes that Note XS 243 be replaced with Note 362 "Excluding plain products conforming to the Standard for Fermented Milks (CODEX STAN 243-2003)". |
| Safe use of additive: Dietary intake assessment (as appropriate) | Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below) This proposed revision is just for consistency between the GSFA and the relevant Codex commodity standard, and would not affect the total dietary exposure of tartrates as these food additives are actually used in accordance with the CODEX STAN 243-2003. According to a national Total Diet Study (market basket method) conducted by Ministry of Health of Japan in 1998 and 1999, daily intake of L(+)-tartaric acid is 65.1 mg/person (1.18 mg/kg bw), which is far below the upper bound of the JECFA ADI. |
| Justification that the use does not mislead consumer | The above-mentioned use does not affect nature and quality of the food that would be expected by consumers. |

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| THE PROPOSAL IS SUBMITTED BY: | | Japan | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | Sorbitan esters of fatty acids | |
| INS Number | | 491 - 495 | |
| Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | INS 491 Sorbitan monostearate Emulsifier INS 492 Sorbitan tristearate Emulsifier, Stabilizer INS 493 Sorbitan monolaurate Emulsifier, Stabilizer INS 494 Sorbitan monooleate Emulsifier, Stabilizer INS 495 Sorbitan monopalmitate Emulsifier, Stabilizer | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (¹): The rows below may be copied as many times as needed. | | The proposal for <input type="checkbox"/> a new provision; or <input checked="" type="checkbox"/> revising an existing provision or <input type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (²) | Food Category Name (²) | Maximum Use Level (³) | Comments (⁴) |
| 01.7 | Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt) | 5000 mg/kg | XS-243-362 |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph). | | A group ADI of 0 – 25 mg/kg bw as the sum of sorbitan esters of lauric, oleic, palmitic and stearic acids was established at the 26 th JECFA (1982). The latest specification was prepared at the 55 th JECFA (2000). | |
| JUSTIFICATION: | | | |
| Justification for use and technological need Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function). | | Codex standard for fermented milks (CODEX STAN 243-2003) permits the use of INS 491, 492, 493, 494 and 495 as emulsifier in flavoured products. However, the GSFA permits the use of these additives excluding products conforming to CODEX STAN 243-2003. To avoid conflicts with CODEX STAN 243-2003, Japan proposes that Note XS 243 be replaced with Note 362 "Excluding plain products conforming to the Standard for Fermented Milks (CODEX STAN 243-2003)". | |

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| <p>Safe use of additive: Dietary intake assessment (as appropriate)</p> | <p>Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below)</p> <p>This proposed revision is just for consistency between the GSFA and the relevant Codex commodity standard, and would not affect the total dietary exposure of sorbitan esters of fatty acids as this food additive is actually used in accordance with the CODEX STAN 243-2003. If the CCFA needs further information on exposure of this additive from Food category 01.7, the CCFA should collect information from relevant commodity committee.</p> |
| <p>Justification that the use does not mislead consumer</p> | <p><i>The above-mentioned use does not affect nature and quality of the food that would be expected by consumers.</i></p> <p><i>The GSFA permits to use sorbitan esters of fatty acids in a variety of foods.</i></p> |

European Food Emulsifier Manufacturers Association (EFEMA)

| <p>THE PROPOSAL IS SUBMITTED BY:</p> | | <p>EFEMA, European Food Emulsifier Manufacturers Association</p> | |
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| <p>IDENTITY OF THE FOOD ADDITIVE:</p> | | | |
| <p>Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i></p> | | <p>Polyglycerol esters of fatty acids</p> | |
| <p>INS Number</p> | | <p>475</p> | |
| <p>Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i></p> | | <p>Emulsifier, stabilizer</p> | |
| <p>PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i></p> | | <p>The proposal for <input type="checkbox"/> a new provision; or x revising an existing provision or <input type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)"</p> | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 07.2.3 | Mixes for fine bakery wares (e.g. cakes, pancakes) | 15000-16000 | Notes 11. On the flour basis |

EVALUATION BY JECFA:

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| <p>Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i></p> | <p>Prepared at the 35th JECFA (1989), published in FNP 49 (1990) and in FNP 52 (1992) superseding specifications prepared at the 27th JECFA (1983). Metals and arsenic specifications revised at the 55th JECFA (2000). An ADI of 0-25 mg/kg bw was established at the 35th JECFA (1989).</p> <p>Monograph 1 (2006) See http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/Additive-317.pdf</p> |
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JUSTIFICATION:

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| <p>Justification for use and technological need</p> | <p>At the 48th meeting of the Codex Committee on Food Additives several provisions for polyglycerol esters of fatty acids (INS 475) were adopted. Among these were the following: 07.2.1 Cakes, cookies and pies (e.g., fruit-filled or custard types) with a maximum level of 10000 mg/kg; 07.2.2 Other fine bakery products (e.g. doughnuts, sweet rolls, scones, and muffins) with a max level of 10000 mg/kg and 07.2.3 Mixes for fine bakery wares (e.g. cakes, pancakes) with a max level of 15000 mg/kg on the flour basis (Note 11).</p> |
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| <p><i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i></p> | <p>In the stated food categories polyglycerol esters of fatty acids (INS 475) is used as part of a 'whipping emulsifier' compound. This compound helps to aerates the batter during the whipping step of the batter production and stabilizes the incorporated air. Furthermore, the compound helps to ensure the stability of the batter during the baking.</p> <p>The maximum level is given on the finished product basis for food categories 07.2.1 and 07.2.2, while the maximum level is stated on the flour basis for food category 07.2.3.</p> <p>Products in the food categories 07.2.1, 07.2.2 and 07.2.3 all contain considerable amounts of ingredients besides flour. These are typically sugar, fat (butter, margarine, oil or the like), eggs, liquid and a number of minor ingredients. This means that when the amount of polyglycerol esters of fatty acids (INS 475) is calculated on the flour basis as opposed to calculated on the basis of the total product, then the permitted amount is reduced with the same fraction as the weight of the flour has to the weight of the final product. The percentage of flour in this type of baking products may be as low as 30-35% hereby reducing the permitted amount polyglycerol esters of fatty acids (INS 475) to a level where it no longer has any technological function, when it is calculated on the flour basis.</p> <p>Furthermore, some pre-mixes for fine bakery wares do not contain any flour at all, instead they are made with starch. In this type of mixes polyglycerol esters of fatty acids INS 475 is not permitted, since they contain no flour. These products included mixes for gluten-free products.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|--|------------|------------|----------------------|-------|------|-------|------------------|-------|---------------|-------|-----------------------------------|-------|---------------------|-------|------------|------------|----------------------|-------|------|-------|------------------|-------|---------------|-------|-----------------------------------|-------|
| <p>Safe use of additive: Dietary intake assessment (as appropriate)</p> | <p>Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below)</p> <p>The proposed change in the maximum permitted level of polyglycerol esters of fatty will lead to an alignment of the maximum level permitted in food categories 07.2.1, 07.2.2 and 07.2.3.</p> <p>Table 1. (below) gives the recipe for a typical 'European style' cake mix, while Table 2 (below) gives the recipe for a typical 'Asian style' cake mix. Both recipes are normalized to 1,000 kg of cake mix.</p> <p>It can be seen that 1,000 kg of cake mix will give a cake of approx. 1,620 kg or 2,030 kg. If Polyglycerol esters of fatty acids INS 475 is used at the maximum level suggested (16000 mg/kg in the mix) this will give the below level of Polyglycerol esters of fatty acids in the final cakes:</p> $\frac{16000 \frac{mg}{kg} \times 1,000 \text{ kg}}{1,620 \text{ kg}} = 9877 \text{ mg/kg}$ $\frac{16000 \frac{mg}{kg} \times 1,000 \text{ kg}}{2,030 \text{ kg}} = 7882 \text{ mg/kg}$ <p>Table 1. 'European style' cake recipe</p> <table border="1" data-bbox="507 1402 1118 1720"> <thead> <tr> <th>Ingredient</th> <th>Weight, kg</th> </tr> </thead> <tbody> <tr> <td>Typical mix for cake</td> <td>1,000</td> </tr> <tr> <td>Eggs</td> <td>0,600</td> </tr> <tr> <td>Oil and/or water</td> <td>0,200</td> </tr> <tr> <td>Weight batter</td> <td>1,800</td> </tr> <tr> <td>Weight loss (baking), approx. 10%</td> <td>0,180</td> </tr> <tr> <td>Weight after baking</td> <td>1,620</td> </tr> </tbody> </table> <p>Table 2. 'Asian style' cake recipe</p> <table border="1" data-bbox="507 1794 1118 2074"> <thead> <tr> <th>Ingredient</th> <th>Weight, kg</th> </tr> </thead> <tbody> <tr> <td>Typical mix for cake</td> <td>1,000</td> </tr> <tr> <td>Eggs</td> <td>1,000</td> </tr> <tr> <td>Oil and/or water</td> <td>0,255</td> </tr> <tr> <td>Weight batter</td> <td>2,255</td> </tr> <tr> <td>Weight loss (baking), approx. 10%</td> <td>0,226</td> </tr> </tbody> </table> | Ingredient | Weight, kg | Typical mix for cake | 1,000 | Eggs | 0,600 | Oil and/or water | 0,200 | Weight batter | 1,800 | Weight loss (baking), approx. 10% | 0,180 | Weight after baking | 1,620 | Ingredient | Weight, kg | Typical mix for cake | 1,000 | Eggs | 1,000 | Oil and/or water | 0,255 | Weight batter | 2,255 | Weight loss (baking), approx. 10% | 0,226 |
| Ingredient | Weight, kg | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Typical mix for cake | 1,000 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eggs | 0,600 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Oil and/or water | 0,200 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Weight batter | 1,800 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Weight loss (baking), approx. 10% | 0,180 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Weight after baking | 1,620 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ingredient | Weight, kg | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Typical mix for cake | 1,000 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eggs | 1,000 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Oil and/or water | 0,255 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Weight batter | 2,255 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Weight loss (baking), approx. 10% | 0,226 | | | | | | | | | | | | | | | | | | | | | | | | | | |

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| | Weight after baking | 2,030 |
| | <p>This means that the maximum level permitted in the final product is the same no matter if the product is purchased as a mix for fine bakery ware or as a finished good. As mixes for fine bakery wares are not consumed as such, but always prepared into a final product before consumption, this change would not lead to any increased level of consumption of polyglycerol esters of fatty acids (INS 475) compared to the products being purchased as baked goods.</p> | |
| Justification that the use does not mislead consumer | <p>In accordance with the General Standard for Food Additives (CODEX STAN 192-1995) Polyglycerol esters of fatty acids (INS 475) is permitted for the use as an emulsifier and stabilizer in food category 07.2.3 Mixes for fine bakery wares. The proposed change only affects the maximum permitted level in this category.</p> <p>In accordance with CODEX STAN 1-1985 on the Labelling of Prepackaged Foods, food additives like Polyglycerol esters of fatty acids (INS 475) must be declared on the label of the product in the list of ingredients by indicating either: (i) the functional class together with the specific name or (ii) the functional class together with the recognized numerical identification such as the Codex International Numbering System (CAC/GL 36-1989).</p> <p>All ingredients shall be listed in descending order of ingoing weight (m/m).</p> | |

**International Association of Color Manufacturers (IACM) and
Natural Food Colours Association (NATCOL)**

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| THE PROPOSAL IS SUBMITTED BY: | | <i>International Association of Color Manufacturers (IACM) and Natural Food Colours Association (NATCOL)</i> | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | <i>Paprika Extract</i> | |
| INS Number | | <i>INS 160c(ii)</i> | |
| Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i> | | <i>Colour</i> | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> <i>Use levels are expressed as mg/kg or mg/l of total carotenoids, with all extracts standardised to 100,000 colour units (= 7.2% total carotenoids).</i> | | <p>The proposal for <input checked="" type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)"</p> | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 1.1.2 | Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks) | 30 | Corresponding to the new 01.1.4 as a consequence of the new subcategories of Food Category 01.1 (Fluid Milk and Milk Products) as adopted by CAC in 2016. |
| 1.3.2 | Beverage whiteners | 5 | |
| 1.4.4 | Cream analogues | 5 | |
| 1.5.2 | Milk and cream powder analogues | 5 | |
| 1.6.1 | Unripened cheese | 15 | |
| 1.6.2 | Ripened cheese | | |
| 1.6.2.1 | Ripened cheese, includes rind | 30 | To standardise the colour of ripened cheeses to meet consumer expectations. Light stable "orange" colour equivalent to Annatto (as regards colour shade) without the 'pinking' associated with Annatto and by-products of ripening. |

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| 1.6.2.2 | Rind of ripened cheese | 30 | To standardise the colour of the rind of ripened cheeses to meet consumer expectations. Light stable colour equivalent to Annatto (as regards colour shade) |
| 1.6.2.3 | Cheese powder (for reconstitution; e.g., for cheese sauces) | 600 | Cheese powder is diluted in the final Ready-to-eat product, this value is before reconstitution; 14 would be ML as reconstituted (in cheese sauce, etc. as consumed; subject to dilution factor). To standardise the colour of cheese powders for which cheddar cheese may be used as an ingredient. |
| 1.6.4.1 | Plain processed cheese | 50 | To standardise the colour of plain processed cheese for which cheddar cheese is used as ingredient, without the 'pinking issues' associated with Annatto in processed cheese manufacture |
| 1.6.4.2 | Flavoured processed cheese, including containing fruit, vegetables, meat, etc. | 70 | To standardise the colour of processed cheese for which cheddar cheese is used as ingredient, without the 'pinking issues' associated with Annatto in processed cheese manufacture |
| 1.6.5 | Cheese analogues | 50 | To standardise the colour of cheese analogues for which cheddar cheese may be used as an ingredient |
| 1.7 | Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt) | 50 | To impart colour to ice cream, sherbet containing dairy ingredients and fruit yoghurt |
| 2.2.2 | Fat spreads, dairy fat spreads and blended spreads | 5 | |
| 2.3 | Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions | 15 | |
| 2.4 | Fat-based desserts excluding dairy-based dessert products of food category 01.7 | 50 | |
| 3.0 | Edible ices, including sherbet and sorbet | 50 | |
| 4.1.2.11 | Fruit fillings for pastries | 50 | |
| 4.1.2.5 | Jams, jellies, marmelades | 50 | For orange spreads only; To add the appearance typically expected by the consumer |
| 4.1.2.7 | Candied fruit | 50 | |
| 4.1.2.8 | Fruit preparations, including pulp, purees, fruit toppings and coconut milk | 50 | |
| 4.1.2.9 | Fruit-based desserts, including fruit-flavoured water-based desserts | 50 | |
| 4.2.2.2 | Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds | 50 | To adjust the colour of dried tomatoes (throughout a year) |

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| 4.2.2.3 | Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soybean sauce | 50 | To adjust the colour of soysauce-pickled vegetables to meet consumer expectations |
| 4.2.2.4 | Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds | 50 | |
| 4.2.2.5 | Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter) | 50 | |
| 4.2.2.6 | Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5 | 50 | |
| 4.2.2.7 | Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed products, excluding fermented soybean products of food categories 06.8.6, 06.8.7, 12.9.1, 12.9.2.1 and 12.9.2.3 | 15 | |
| 4.2.2.8 | Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds | 50 | To add the appearance typically expected by the consumer |
| 5.1.3 | Cocoa-based spreads, including fillings | 95 | Colour to be used in blended/layered products |
| 5.1.4 | Cocoa and chocolate products | 95 | Colour to be used in blended/layered products |
| 5.1.5 | Imitation chocolate, chocolate substitute products | 95 | |
| 5.2.1 | Hard candy | 95 | To designate expected flavour profile. To replace colour that is lost during cooking. To provide a visual cue to the flavour as the bulk of the ingredients are inherently off-white or beige. |
| 5.2.2 | Soft candy | 95 | To provide a visual cue to the flavour as the bulk of the ingredients are inherently off-white or beige. |
| 5.2.3 | Nougats and marzipans | 95 | To add the appearance typically expected by the consumer |

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| 5.3 | Chewing gum | 60 | To provide appropriate colour suggestive of the flavour of the product, as the bulk of the ingredients are inherently off-white or beige. The majority of the colour remains with the gum matrix and is not ingested. |
| 5.4 | Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces | 300 | |
| 6.3 | Breakfast cereals, including rolled oats | 120 | To add the appearance typically expected by the consumer |
| 6.4.3 | Pre-cooked pastas and noodles and like products | 120 | To augment colour that may be lost during cooking. Grain may vary in hue depending upon the growing region, weather etc. Colour addition allows standardization. |
| 6.5 | Cereal and starch based desserts (e.g., rice pudding, tapioca pudding) | 70 | |
| 6.6 | Batters (e.g., for breading or batters for fish or poultry) | 120 | To augment colour that may be lost during cooking. |
| 6.7 | Pre-cooked or processed rice products, including rice cakes (Oriental type only) | 30 | |
| 6.8.1 | Soybean-based beverages | 15 | |
| 6.8.4.2 | Deep fried semi-hydrated soybean curd | | |
| 6.8.8 | Other soybean protein products | 5 | |
| 7.1.2 | Crackers, excluding sweet crackers | 100 | |
| 7.1.4 | Bread-type products, including bread stuffing and bread crumbs | 100 | |
| 7.2.1 | Cakes, cookies and pies (e.g., fruit-filled or custard types) | 90 | |
| 7.2.2 | Other fine bakery products (e.g., doughnuts, sweet rolls, scones, and muffins) | 90 | |
| 7.2.3 | Mixes for fine bakery wares (e.g., cakes, pancakes) | 200 | Mixes and powders are diluted to approximately 90 mg/kg in the final Ready-to-Eat product |
| 8.4 | Edible casings (e.g., sausage casings) | 9000 | Final value in a sausage, as consumed would be 90 based on the casing being 1%w/w of the final sausage |
| 9.2 | Processed fish and fish products, including mollusks, crustaceans, and echinoderms | 150 | Note 95: For use in surimi and fish roe products only. |
| 9.2.2 | Frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms | 100 | Use rate is for the breading; To add the appearance typically expected by the consume |
| 9.2.5 | Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms | 30 | |

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| 9.3 | Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms | 150 | Note 95: For use in surimi and fish roe products only |
| 9.3.3 | Salmon substitutes, caviar, and other fish roe products | 150 | |
| 9.4 | Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms | 150 | Note 95: For use in surimi and fish roe products only |
| 10.4 | Egg-based desserts (e.g., custard) | 50 | |
| 12.2.2 | Seasonings and condiments | 350 | |
| 12.4 | Mustards | 70 | |
| 12.5.2 | Mixes for soups and broths | 500 | Mixes for soups and broths are diluted to approximately 85 mg/kg in the final Ready-to-Eat product |
| 12.6 | Sauces and like products | 150 | To provide a visual cue to the flavor of a meat based sweet and sour sauce |
| 12.6.1 | Emulsified sauces and dips (e.g., mayonnaise, salad dressing, onion dip) | 85 | |
| 12.6.2 | Non-emulsified sauces (e.g., ketchup, cheese sauce, cream sauce, brown gravy) | 85 | |
| 12.6.3 | Mixes for sauces and gravies | 500 | Mixes for sauces and gravies are diluted to approximately 85 mg/kg in the final Ready-to-Eat product |
| 12.7 | Salads (e.g., macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.5 and 05.1.3 | 70 | |
| 14.1.4.1 | Carbonated water-based flavoured drinks | 30 | |
| 14.1.4.2 | Non-carbonated water-based flavoured drinks, including punches and ades | 30 | |
| 14.1.4.3 | Concentrates (liquid or solid) for water-based flavoured drinks | 300 | Concentrates for water-based drinks are diluted to approximately 30 mg/l in the final Ready-to-Eat product |
| 14.2.2 | Cider and perry | 10 | Light stable, vegetarian naturally derived colour to standardise the colour of cider (throughout the year) |
| 14.2.4 | Wines (other than grape) | 10 | |
| 14.2.7 | Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers) | 10 | |
| 15.1 | Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes) | 100 | |
| 15.2 | Processed nuts, including coated nuts and nut mixtures (with e.g., dried fruit) | 100 | |
| 15.3 | Snacks - fish based | 100 | |

| EVALUATION BY JECFA: | |
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| Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or “not specified”); specifications monograph). | Evaluation year: 2014, 79 th Meeting ADI: 0–1.5 mg/kg bw, Expressed as total carotenoids Specification: FAO JECFA Monographs 16/49 |
| JUSTIFICATION: | |
| Justification for use and technological need Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function). | Serves a technological function as colour. The proposed MLs were determined in product development tests to cover the range of levels suitable for foods in this category to restore colour that may be lost during food processing, to provide a colour consistent with the traditional appearance and customer expectation of the food and/or to provide a natural colour alternative to artificial colours where they are already permitted. In the majority of foods, use levels will be significantly below the ML, when present. |
| Safe use of additive: Dietary intake assessment (as appropriate) | Table 3 additive: <input type="checkbox"/> Yes x No (Please provide information on dietary intake assessment below) See summary (“Potential Dietary Intakes of Carotenoids from Use of Paprika Extract as a Food Colour”) |
| Justification that the use does not mislead consumer | It is common practice that colour such as paprika extract is used in food. Any use of paprika extract in food would need to be labelled, thus informing the consumer. Other colours are already allowed in the food categories proposed so it would not be misleading to the consumer. |

International Alliance of Dietary/Food Supplements Associations (IADSA)

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| THE PROPOSAL IS SUBMITTED BY: | | IADSA (International Alliance of Dietary/Food Supplements Associations) | |
| IDENTITY OF THE FOOD ADDITIVE: | | | |
| Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) graft copolymer | |
| INS Number | | 1209 | |
| Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | Function Class: • Glazing agent • Stabilizer | Technological Purpose: • Glazing agent • Stabilizer • Binder |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): The rows below may be copied as many times as needed. | | The proposal for <input type="checkbox"/> a new provision ; Or <input type="checkbox"/> revising an existing provision or <input type="checkbox"/> a food additive provision in the new food category 01.1.2 “Other fluid milks (plain)” | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 13.6 | Food supplements | 100,000 mg/kg | Stabilizer |
| Remark: A provision for the Function Class “Glazing Agent” (50000 mg/kg) was included at step 2 (CCFA48) for the Food Category 13.6 | | | |
| EVALUATION BY JECFA | | | |
| Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or “not specified”); specifications monograph). | | Year: 2015 Meeting: 80 th (Rome, 16–25 June 2015) Specs Code: N Monograph: 17 (2015) http://www.fao.org/3/a-i5080e.pdf Page 47 ADI: The Committee decided not to establish an ADI “not specified” | |

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| | <p>The summary report is available at the following link: http://www.fao.org/fileadmin/user_upload/agns/pdf/jecfa/Summary_report_of_the_80th_JECFA_meeting.pdf The Chemical Technical Assessment is also available here http://www.fao.org/3/a-az649e.pdf</p> |
| <p>JECFA Summary The use of PVA-PEG graft co-polymer that complies with the specifications established at the meeting in 2015 is not of safety concern when the food additive is used as stabilizer / binder for tablets in the preparation and formulation of food supplements and in accordance with good manufacturing practice.</p> | |
| JUSTIFICATION: | |
| <p>Justification for use and technological need Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</p> <p>Safe use of additive: Dietary intake assessment (as appropriate)</p> | <p>Binder, Stabilizer</p> <p>PVA-PEG graft co-polymer can be used as a binder in rapidly dispersible/soluble granules or tablets, and as a suspension and emulsion stabilizer and protective colloid.</p> <p>A use level up to 10% (100,000 mg/kg) of the weight of the food supplement would typically be needed for use of the PVA-PEG graft co-polymer as a Stabilizer/binder</p> <p>The substance is considered by JECFA to be of no safety concern when the food additive is used as a glazing agent (aqueous film coating), stabilizer and binder for tablets in the preparation and formulation of food supplements and in accordance with good manufacturing practice. This conclusion takes into consideration the dietary exposure to ethylene glycol and diethylene glycol and to vinyl acetate from both food supplements and pharmaceutical products.</p> <p>The dietary exposure estimate to ethylene glycol and diethylene glycol - from both food supplements and pharmaceutical products - does not exceed 0.016 mg/kg bw per day for children (high consumers). This is 3% of the tolerable daily intake (TDI) of 0.5 mg/kg bw per day derived by the Scientific Committee on Food of the European Union.*</p> <p>The dietary exposure estimate to vinyl acetate - from both food supplements and pharmaceutical products - is at least 62 500 times lower than the dose levels at which increases in tumor incidence are observed in oral studies of long-term toxicity and carcinogenicity in rats and mice.</p> <p>*EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food). Scientific Opinion on the safety of polyvinyl alcohol-polyethylene glycol-graft-co-polymer as a food additive. EFSA Journal 2013;11(8):3303. 30 pp doi:10.2903/j.efsa.2013.3303)</p> |
| <p>Justification that the use does not mislead consumer</p> | <p>The use of PVA-PEG graft co-polymer fulfills the conditions listed in section 3.2 by preserving the nutritional quality and stability of products and by providing aids in the manufacture of the products.</p> <p>Its use is not typically linked with issues related to the nature, freshness, quality of ingredients used or undesirable practices which would mislead the consumer.</p> |

International Dairy Federation (IDF)

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| THE PROPOSAL IS SUBMITTED BY: | International Dairy Federation (IDF) |
| IDENTITY OF THE FOOD ADDITIVE: | |
| <p>Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</p> | Paprika Extract |
| INS Number | 160c(ii) |
| <p>Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</p> | Colour |
| <p>PROPOSED USE(S) OF THE FOOD ADDITIVE (1): The rows below may be copied as many times as needed.</p> | <p>The proposal for <input checked="" type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision</p> |

| | | or <input type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
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| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| 01.1.4 | Flavoured fluid milk drinks | 120 mg/kg expressed as Paprika Extract 9 mg/kg expressed as total carotenoids | |
| 01.6.4 | Processed cheese | 1870 mg/kg expressed as Paprika Extract 140 mg/kg expressed as total carotenoids | |
| 01.6.5 | Cheese analogues | 670 mg/kg expressed as Paprika Extract 50 mg/kg expressed as total carotenoids | |
| 01.7 | Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt) | 670 mg/kg expressed as Paprika Extract 50 mg/kg expressed as total carotenoids | |
| 02.2.2 | Fat spreads, dairy fat spreads and blended spreads | 550 mg/kg expressed as Paprika Extract 40 mg/kg expressed as total carotenoids | |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i> | | Evaluation year: 2014 ADI: 0–1.5 mg/kg bw Expressed as total carotenoids Intake: The assessment of dietary exposure to paprika extract used as a colour was based on exposure to total carotenoids in paprika extract. Based on survey data, the highest exposure at the 95th percentile was estimated to be 6.3–13.2 mg/day (equivalent to 0.1–0.2 mg/kg bw per day, based on a body weight of 60 kg), which is below the ADI. The Committee concluded that dietary exposure to paprika extract used as a food colour does not present a health concern. Meeting: 79. Report: TRS 990-JECFA 79/45 Specification: FAO JECFA Monographs 16/49 | |
| JUSTIFICATION: | | | |
| Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i> | | Cat 01.1.4 Proposed levels appropriate to result in color suggestive of designated flavor profile of the product. Cat 01.6.4 To standardise the colour of processed cheese for which cheddar cheese is used as ingredient, without the 'pinking issues' associated with Annatto in processed cheese manufacture Cat 01.6.5 To standardise the colour of cheese analogues for which cheddar cheese may be used as an ingredient Cat 01.7 To standardise the colour of products of which the natural color of milk can vary due to season, feeding and breed of dairy cow. To impart color to ice cream, sherbet containing dairy ingredients and fruit yoghurt suggestive of designated flavor profile. Cat 02.2.2 To standardise the colour of products of which the natural color of milk can vary due to season, feeding and breed of dairy cow. To impart colour to fat spreads and dairy fat spreads that meets consumer expectations | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below) No information | |
| Justification that the use does not mislead consumer | | By properly displayed on the label in accordance with the law in each regions, consumers easily understand that Paprika Extract is contained in foods. | |

Natural Food Colours Association (NATCOL)

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| THE PROPOSAL IS SUBMITTED BY: | NATCOL (Natural Food Colours Association) |
| IDENTITY OF THE FOOD ADDITIVE: | |
| Name of the Additive | Lutein esters from <i>Tagetes erecta</i> |

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| As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | | |
| INS Number | | 161b(iii) | |
| Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989 | | Colour | |
| PROPOSED USE(S) OF THE FOOD ADDITIVE (1): The rows below may be copied as many times as needed. | | The proposal for <input checked="" type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision or <input type="checkbox"/> a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" | |
| Food Category No. (2) | Food Category Name (2) | Maximum Use Level (3) | Comments (4) |
| Foods as listed in Table 3 GSFA | See Table 3 GSFA | GMP | ADI "not specified" |
| EVALUATION BY JECFA: | | | |
| Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph). | | <p>79th JECFA session 2014 (WHO TRS 990): JECFA assessed toxicological data, including newly submitted toxicological data and a dietary exposure assessment. A temporary ADI "not specified" for lutein esters from <i>Tagetes erecta</i> was established. The ADI was made temporary because the specifications for lutein esters from <i>Tagetes erecta</i> were tentative.</p> <p>82nd JECFA session 2016 (WHO TRS 1000): "The tentative specifications were revised, and the tentative status was removed. A revised Chemical and Technical Assessment was prepared. The Committee removed the temporary designation from the ADI "not specified" because the tentative status of the specifications was removed and established an ADI "not specified" for lutein esters from <i>tagetes erecta</i>."</p> <p>Specification/Monograph: FAO JECFA Monographs 19 – Compendium of Food Additive Specifications, 82nd JECFA session (2016)</p> <p>CCFA document CX/FA 17/49/3: Table 1 in this document lists lutein esters with a "Recommended action by CCFA: Note the JECFA conclusion on an ADI "not specified" for lutein esters from <i>Tagetes erecta</i>. Consider to:</p> <ul style="list-style-type: none"> - Include lutein esters from <i>Tagetes erecta</i> (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 <i>Tagetes erecta</i> (INS 161b(iii) for the food categories listed in the Annex to Table 3 | |
| JUSTIFICATION: | | | |
| Justification for use and technological need Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function). | | <p>As a colour lutein esters from <i>Tagetes erecta</i> serve a technological function by adding or restoring colour to a food. There is a global need for natural food colours. Lutein esters are produced from a natural source. Its yellowish colour hue is unique and suitable to supplement the colour spectrum achievable with other carotenoids. The light stability of Lutein esters is also noteworthy and seems to be better than the light stability of curcumin for example.</p> <p>Lutein esters from <i>Tagetes erecta</i> do not present any appreciable health risk to consumers. The 2016 JECFA safety assessment of the substance at the Committees 82nd session, which included dietary exposure, concluded on an ADI "not specified" for this colour.</p> <p>It shall be used under conditions of good manufacturing practice (GMP) stated in Section 3.3 of the Preamble of the General Standard for Food Additives.</p> | |
| Safe use of additive: Dietary intake assessment (as appropriate) | | <p>Table 3 additive: X Yes -> ADI "not specified" Food categories as regulated in table 3 of the General Standard for Food Additives</p> | |

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| | <input type="checkbox"/> No (Please provide information on dietary intake assessment below) |
| Justification that the use does not mislead consumer | <p>Lutein esters from <i>Tagetes erecta</i> are intended to be used in line with the food colour definition in CAC/GL 36-1989. Food categories where colour use could be misleading to consumers, for example fluid buttermilk (plain), fats and oils essentially free from water, fresh fruit, fresh/dried pastas and noodles and like products to name a few, are excluded from lutein ester colour use through the Annex to Table 3 GSFA.</p> <p>In addition, lutein esters shall be used under conditions of good manufacturing practice (GMP) as defined in Section 3.3 of the Preamble of the GSFA.</p> |