CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



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Agenda Item 5b

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fiftieth Session

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

Replies to CL 2017/47-FA of Australia, Colombia, India, Japan, New Zealand, Uganda and International Special Dietary Foods Industries (ISDI)

Australia				
THE PROPOSAL IS SUBMITTED BY:		Australia		
IDENTITY OF TH	E FOOD ADDITIVE:			
	ditive Names and the International em (INS) - CAC/GL 36-1989	Lauric arginate ethyl ester		
INS Number		243		
	s Names and the International em (INS) - CAC/GL 36-1989	Preservative		
	E(S) OF THE FOOD	The proposal for:		
ADDITIVE (1): Th as many times as	e rows below may be copied	□ a new provision; or		
as many umes as	neeueu.	revising an existing provi	sion; or	
		□ use and use levels of tocopherols (INS 307a, b, c) as antioxidant in FC 01.3.1 "Condensed milk (plain))";or		
		□ use and use levels of propylene glycol alginate (INS 405) and sucrose esters of fatty acids (INS 473) as emulsifier in FC 05.1.4 "Cocoa and chocolate products".		
Food Category No. (²)	Food Category Name (²)	Maximum Use Level (³)	Comments (⁴)	
08.2.2	Heat-treated processed meat, poultry, and game products in whole pieces or cuts	200 mg/kg	Note XS96 Note XS97 Insert new note, which reads ""For products conforming to the Standard for Cooked Cured Ham (CODEX STAN 96-1981) and the Standard for Cooked Cured Pork Shoulder (CODEX STAN 97- 1981), use is limited to ready-to-eat products which require refrigeration	

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08.3.2 Heat-treated processe comminuted meat,	d 200 mg/kg	Note XS98	
poultry, and game		Note XS88	
products		Note XS89	
•		Note 377	
Is the proposal related to a FC with corr	esponding commodity sta	ndards?	
(if yes indicate the relevant FC)			
Yes			
FC 08.2.2			
Standard for Cooked Cured Ham (CODEX	,		
Standard for Cooked Cured Pork Shoulder	(CODEX STAN 97-1981).		
FC 08.3.2			
Standard for Corned Beef (CODEX STAN	,		
Standard for Luncheon Meat (CODEX STA	,		
Standard for Cooked Cured Chopped Mea	t (CODEX STAN 98-1981)		
Is the proposal also intended to revise t	he products covered by th	e commodity standards?	
(if yes indicate the relevant commodity sta	•		
No			
EVALUATION BY JECFA:			
Evaluation by JECFA	Evaluation date: 2008	8	
Reference to the JECFA evaluation (inclu			
year and JECFA session of evaluation; ful			
(numerical or "not specified"); specifica	tions .	IECFA Monographs 7 (2009)	
monograph).		ADI 0-4 mg/kg bw for Ethyl-N ^a -Lauroyl-L-Arginate	
JUSTIFICATION:			
Justification for use and technological need Supporting information based on the crite Section 3.2 of the Preamble of the Ge Standard for Food Additives (i.e. has advantage, does not present an apprece health risk, serves a technological function	eral of these provisions was adopted with footnotes an restricted the use of the additive in products confor		

a preservative that is used in products that conform to the same corresponding commodity standards associated with FC 08.3.2. The additive is effective in controlling the growth of potentially pathogenic organisms in products falling under both food categories 08.2.2 and 08.3.2 and this is particularly the case for products that are ready-toeat and which require refrigeration. This provides an advantage in developing countries where access to stable refrigeration may be limited or in developed countries where the final consumer may not adhere to Given the use of nisin as a storage instructions. preservative in these ready-to-eat refrigerated products is now permitted under the GSFA, this proposal for new work requests that consideration is given to modification of the adopted provisions for lauric arginate ethyl ester (INS 243) to bring them in line with the provisions applied to nisin for FC 08.3.2. As such, the current notes XS88, XS 89 and XS 98 would be deleted and replaced with note 377 i.e. "For products conforming to the Standard for Luncheon Meat (CODEX STAN 89-1981), Standard for Cooked Cured Chopped Meat (CODEX STAN 98-1981), and Standard for Corned Beef (CODEX STAN 88-1981) use is limited to ready-to-eat products which require refrigeration".

Furthermore, for FC 08.2.2, the adopted provisions in the GSFA for lauric arginate ethyl ester are such that its use is excluded from products conforming to the Standard for Cooked Cured Ham (CODEX STAN 96-1981) and the Standard for Cooked Cured Pork Shoulder (CODEX STAN 97-1981) by way of the inclusion of notes XS96 and XS97 respectively. As with products conforming to the standards associated with FC 08.3.2, a number of products falling within the scope of the standards associated with FC 08.2.2 are available as ready-to-eat products that require refrigeration to ensure their safety during their shelf life. Lauric arginate ethyl ester provides additional protection for such products against the growth of pathogenic organisms and this can be of particular benefit in developing countries where access to stable refrigeration may be limited and in developed countries consumers may not follow appropriate where (refrigerated) storage conditions.

The use of ethyl lauric arginate ethyl ester is permitted for use in products falling under both FC 08.2.2 and 08.3.2 in a number of countries worldwide (e.g. Australia, New Zealand, Canada, USA), without further restriction on its use in products conforming with the relevant Codex commodity standards. These products are also available in international trade. For example, in Australia and New Zealand, lauric arginate ethyl ester is permitted to be used in the broader national food categories 08.2 Processed meat, poultry and game products in whole pieces or cuts, and 08.3 Processed comminuted meat, poultry and game products, at levels of 200mg/kg and 315mg/kg respectively. As such, consideration should be given to revising the provisions of the GSFA to reflect the acceptable use of lauric arginate ethyl ester as a preservative in these products in numerous countries, particularly when these products are ready-to-eat and require refrigeration to ensure safety.

Safe use of additive: Dietary intake	Table 3 additive:
assessment (as appropriate)	□ Yes
	No (Please provide information on dietary intake assessment below)
	The use of lauric acid ethyl ester (INS 243) in meat products that fall under Codex food categories 08.2.2 and 08.3.2 (and without restriction of its use in standardised products), as well as its use in a broad range of other foods, was considered as part of the review of its safety in use as a food additive, and no concerns over dietary intake were identified for Australian and New Zealand consumers.
	In addition, consumption of meat products falling within these food categories was taken into consideration as part of the JECFA assessment of the safety of the additive in 2007.
Justification that the use does not mislead consumer	The use of lauric arginate ethyl ester (INS 243) would be indicated on the label of cured meat products falling within FC 08.2.2 and 08.3.2 that are ready-to-eat and that require refrigeration. These products are cured and by their very nature contain additives, and the presence of additives in these products is expected by consumers.

Colombia				
LA PROPUESTA ES PRESENTADA POR:	Colombia			
IDENTIFICACIÓN DEL ADITIVO ALIMENTARIO: T	OCOFEROLES			
NombredeladitivoalimentarioSegún figura en la lista de Nombresgenéricossistema internacional de numeración para aditivoalimentarios (SIN) - CAC/GL 36-1989	Tocoferol d-alfa-	Tocoferol, d-alfa-		
Número del SIN	307 a, b, c			
Clase funcional Según figura en la lista de Nombres genéricos Sistema internacional de numeración para aditivo alimentarios (SIN) - CAC/GL 36-1989		Antioxidante		
USOS PROPUESTOS DEL ADITIVO	La propuesta de			
ALIMENTARIO ⁽¹⁾ :	🗆 una nueva disposición; o			
Los renglones que figuran a continuación puede	revisar una disposición existente; o			
copiarse cuantas veces sea necesario.	■ uso y niveles de uso de tocoferoles (SIN 307a, b, c) como antioxidante en la CA 01.3.1 "Leche condensada (natural/simple)", y			
	□ uso y niveles de uso de alginato de propilenglicol (SIN 405) y ésteres de sacarosa de ácidos grasos (SIN 473) como emulsionantes en la CA 05.1.4 "Productos de cacao y chocolate".			
N.º de la categoría de alimento ⁽²⁾ Nombre de la categoría de alimento ⁽²⁾	Dosis máxima de uso ⁽³⁾	Observaciones ⁽⁴⁾		
0.1.3.1 Leche condensada (natural/simple)	200 mg/kg			
¿Está la propuesta relacionada con una CA con l	as correspondientes normas	de productos?		
(En caso afirmativo, indique la CA pertinente) SI				
01.3.1 "Leche condensada (natural/simple)"				

¿La propuesta tiene también como objetivo revisar los productos cubiertos por las normas sobre productos?
(En caso afirmativo, indique las normas de productos pertinentes) NO

EVALUACIÓN DEL JECFA:			
	Año: 1986		
Referencia a la evaluación del JECFA (incluyendo el			
año y la reunión de evaluación del JECFA; IDA completa (numérica o "no especificada"); monografía	Report:		
de especificaciones).	TRS 751-JECFA 30/18		
	Tox Monograph:		
	FAS 21-JECFA 30/55		
	Specification:		
	COMPENDIUM ADDENDUM 11/FNP 52 Add. 11/89 (METALS LIMITS) (2003). R; FAO JECFA Monographs 1 vol.3/535 Previous Years:		
	2000, COMPENDIUM ADDENDUM 8/FNP 52 Add.8/121. R		
	SEE dl-alpha-TOCOPHEROL		
	1986, FNP 37-JECFA 30/137;		
	COMPENDIUM/1509. N,T		
Justificación para su uso y necesidad tecnológica Información de apoyo basada en los criterios que figuran en la sección 3.2 del preámbulo de la Norma General para los Aditivos Alimentarios (es decir, ofrece alguna ventaja, no presenta riesgos apreciables para la salud de los consumidores,	productos lácteos. Los tocoferoles están naturalmente presentes en la grasa láctea. Protegen a las grasas y también a los carotenos de la		
desempeña una función tecnológica).	Tiene una IDA establecida, por lo cual se requiere especificar una Dosis Máxima de Uso. Actualmente la subcategoría 01.3.2 ya tiene establecida una DMU numérica.		
	Tiene una función tecnológica similar a la que desempeña en la categoría:		
	- 01.3.2 Blanqueadores de bebidas		
Uso inocuo del aditivo: evaluación de la ingestión alimentaria (según proceda)	Cuadro 3 aditivos: ■ Si		
	No (Sírvanse proporcionar información sobre la evaluación de la ingesta alimentaria)		
Justificación de que el uso no resulta engañoso para el consumidor	Su uso es para es como antioxidante, ayudando a mantener la estabilidad del producto durante su vida útil, por lo que no hay ninguna intención de engaño al consumidor.		

India			
PROPOSALS FOR NEW FOOD ADDITIVE PROVISIONS IN THE GSFA			
THE PROPOSAL IS SUBMITTED BY: India			
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989	1) Erythrosine		
INS Number	127		

¹ Alais, C., (2004), *Ciencia de la leche. Principios de técnica lechera*, Barcelona, España: Editorial Reverté. p99.

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 proposal for ■ a new provision; or □ 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 Categ	ory Name (2)	Maximum Use Level (3)	Comments (4)	
01.1.4	Flavoured fluid milk drinks		50 mg/kg		
01.7	Dairy-based desserts (e.g. yoghurt)	pudding, fruit or flavoured	50 mg/kg		
04.1.2.5	Jams, jellies, marmalades		100 mg/kg	-	
05.2	Confectionery including has etc. other than food catego	rd and soft candy, nougats, ries 05.1, 05.3 and 05.4	50 mg/kg		
06.5	Cereal and starch based de tapioca pudding)	esserts (e.g. rice pudding,	50 mg/kg		
07.2.1	Cakes, Cookies and pies (types)	eg. Fruit filled or custard	50 mg/kg		
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks		50 mg/kg		
14.1.4.2	Non-carbonated water-based flavoured drinks, including punches and ades		100 mg/kg		
EVALUATION B	Y JECFA:				
Evaluation by JECFA		ERYTHROSINE: Prepared at the 41st JECFA (1993), published in FNP 52 Add 2 (1993) superseding specifications prepared at the 37th JECFA (1990), and published in FNP 52 (1992). Metals and arsenic specifications revised at the 59th JECFA (2002). An ADI of 0-0.1 mg/kg bw was established at the 37th JECFA (1991).			
JUSTIFICATION:					
Justification for use and technological need		Erythrosine is a reddish-pink synthetic food dye used globally in various foods and food ingredients, ingested drugs and as a biological stain. The technological function of food colourings is to add or restore colour to food products. The intent of the proposed extension for the use of erythrosine is to improve the visual appearance of the products. Foods containing erythrosine possess superior colouring characteristics to alternative red colours including; colour strength, longevity and quality of the finished product.			
Safe use of additive: Dietary intake assessment		Table 3 additive: □ Yes ■No JECFA found that the national estimates of erythrosine dietary exposures were below the ADI of 0.1 mg/kg body weight.			
Justification that the use does not mislead consumer		The proposed use of Erythrosine is to improve its organoleptic properties and not to change the nature or quality of the food so as to deceive the consumer. Also, the addition of colours will be clearly labelled in the package in which the food is packed so that it will not mislead consumers.			

F	PROPOSALS FOR NEW FO	OD ADDITIVE PROVISIONS	IN THE GSFA	
	IS SUBMITTED BY:	India		
IDENTITY OF TH	E FOOD ADDITIVE:			
Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989		2) Annatto (Annatto extracts, bixin-based & Annatto extracts, norbixin-based)		
INS Number		160b(i) & 160b(ii)		
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 proposal for ■ a new provision; or □ 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 Categ	ory Name (2)	Maximum Use Level (3)	Comments (4)
1.1.4	Flavoured Fluid Milk Drinks	6	100 mg/kg	
1.7	Dairy-based desserts (e.g. yoghurt)	pudding, fruit or flavoured	100 mg/kg	
4.1.2.5	Jams, jellies, marmalades		GMP	
4.1.2.6	Fruit-based spreads (e.g. chutney) excluding products of food category 04.1.2.5		GMP	
5.1.4	Cocoa and chocolate products		100 mg/kg	
5.1.5	Imitation chocolate, chocolate substitute products		100 mg/kg	
5.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4		200 mg/kg	
5.2.1	Hard candy		GMP	
5.2.2	Soft candy		GMP	-
5.3	Chewing gum		GMP	-
6.4.3	Pre-cooked pastas and not	odles and like products	GMP	
07.2.1	Cakes, Cookies and pies (types)	eg. Fruit filled or custard	GMP	
12.6.1	Emulsified sauces and dips (e.g. mayonnaise, salad dressing, onion dips)		GMP	
12.6.2	Non-emulsified sauces (e.g cream sauce, brown gravy)		GMP	
12.6.3	Mixes for sauces and gravi	les	GMP	
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks		100 mg/kg	
14.1.4.2	Non-carbonated water-based flavoured drinks, including punches and ades		200 mg/kg	
EVALUATION BY	Y JECFA:			
Evaluation by JECFAANNATTO EXTRACTS (SOLVENT-EXTRACTED BIXII (INS 160b(i)): Prepared at the 80th JECFA and published FAO JECFA Monographs 17 (2015) supersedir specifications prepared at the 67th JECFA (2006) published in FAO JECFA Monographs 3 (2006). An ADI for bixin of -12 mg/kg bw was established at the 67th JECFA (2006).			d published in superseding 06) published for bixin of 0	

1	ANNATTO EXTRACTS (SOLVENT-EXTRACTED
	NORBIXIN) (INS 160b(ii)) : Prepared at the 80 th JECFA and published in FAO JECFA Monographs 17 (2015) superseding specifications prepared at the 67th JECFA (2006) published in FAO JECFA Monographs 3 (2006). A group ADI for norbixin and its disodium and dipotassium salts of 0 –0.6 mg/kg bw expressed as norbixin was established at the 67 th JECFA (2006).
JUSTIFICATION:	
Justification for use and technological need	Annatto extracts are food colours of natural origin that provide yellow, orange and orange-red colour shades. Annatto seeds and extracts have been used for over 200 years to impart a yellow to red colour to foods. The chemical properties of the colouring principles bixin and norbixin, lead to a solubility profile that distinguishes annatto extracts from other carotenoids. Bixin-based annatto extracts are used extensively to impart colour in bakery products, biscuit fillings, popcorn and snack foods, sauces, dressings and cream desserts. Norbixin-based annatto extracts are claimed to be suitable in acidic foodstuffs having a matrix or solid structure. The amphoteric nature of norbixin makes it suitable in products where the pigment is absorbed by protein and/or starch, stabilising it thereby and making it less soluble in water. These characteristics make norbixin-based extracts suitable for products like cheese, smoked fish and breakfast cereals.Bixin and norbixin have good heat stability during food processing compared with other carotenoids. Annatto is a commonly consumed colorant in foods. Bixin, which is oil soluble typically is used in higher fat foods like snacks, baked goods, sauces, dressings and cream
	used in high protein products. Additives such as emulsifiers may be used in conjunction with annatto to produce a colorant that is more stable to the effects of other food components such as acids, metal ions and salts.
Safe use of additive: Dietary intake assessment	 Table 3 additive: Yes No Annatto extract does not exert any genotoxicity, subacute and chronic toxicity, reproductive toxicity or carcinogenicity. The acceptable daily intake (ADI) estimated from a long-term study in the rat, however, is quite low at 0–0.065 mg/kg/day, because of the low concentration of carotenoid in the annatto extract used in previous studies (JECFA, 1982). Annatto pigments are absorbed and rapidly eliminated from the blood in the rat (JECFA, 1982). It was also reported that norbixin could no longer be detected in plasma 24 hours after ingestion of bixin in human volunteers. The combined data on use level of annatto extracts was used to estimate the concentration of bixin/norbixin in foods. Concentrations in food ranged from less than 1–163% of the acceptable daily intake.
Justification that the use does not mislead consumer	The proposed use of Annatto is to improve its organoleptic properties and not to change the nature or quality of the food so as to deceive the consumer. Also, the addition of colours will be clearly labelled in the package in which the food is packed so that it will not mislead consumers.

F	PROPOSALS FOR NEW FO	OD ADDITIVE PROVISIONS	IN THE GSFA	
THE PROPOSAL	IS SUBMITTED BY:	India		
IDENTITY OF TH	E FOOD ADDITIVE:			
Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989		3) Curcumin		
INS Number		100(i)		
Functional Class As listed in Class International Num CAC/GL 36-1989	Names and the bering System (INS) -	Colour		
PROPOSED USE(S) OF THE FOOD ADDITIVE (1):		The proposal for ■ a new provision; or □ 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 Categ	ory Name (2)	Maximum Use Level (3)	Comments (4)
1.1.4	Flavoured Fluid Milk Drinks	3	100 mg/kg	
1.7	Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt)		100 mg/kg	
4.1.2.5	Jams, jellies, marmalades		GMP	
4.1.2.6	Fruit-based spreads (e.g. chutney) excluding products of food category 04.1.2.5		GMP	
4.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds		GMP	
5.1.4	Cocoa and chocolate products		100 mg/kg	
5.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4		GMP	
5.3	Chewing gum		GMP	
07.2.1	Cakes, Cookies and pies (eg. Fruit filled or custard types)		GMP	
7.2	Fine bakery wares (sweet, salty, savoury) and mixes		GMP	
12.2.2	Seasonings and condiments		GMP	
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks		100 mg/kg	
14.1.4.2	Non-carbonated water-based flavoured drinks, including punches and ades		200 mg/kg	
EVALUATION B	Y JECFA:			
Evaluation by JE	ECFA	CURCUMIN: Prepared a published in FNP 52 a specifications prepared at 5 in FNP 52 Add 9 (2001). A was established at the 61 st .	Add 11 (2003), 57 th JECFA (2001) a n ADI of 0-3 mg/kg	superseding nd published

JUSTIFICATION:		
Justification for use and technological need	Curcumin is the main natural polyphenol found in the rhizome of Curcuma longa (turmeric) and in others Curcuma spp. Curcuma longa has been traditionally used in Asian countries as a medical herb for several pathologies due to its antioxidant, anti-inflammatory, anti-mutagenic, antimicrobial and anticancer properties. In relation to the solubility properties, curcumin is soluble in alkali or in extremely acidic solvents. It is a crystalline compound with a bright orange-yellow colour so it is used as food colorant. It is a keto-enol tautomeric compound with a predominant keto-form in acid or neutral solutions and the enol-form is predominant in alkalis solutions with good properties as chelator of metal ions.	
	Curcumin (E100) is an orange-yellow pigment used mainly for colouring purposes of a wide variety of snacks. Curcumin is occasionally used in blends with annatto colorant. The orange-yellow colour of curcumin is very useful for colouring many bakery products and snacks in which an egg-colour shade is required.Curcumin is soluble in alcohols and other polar solvents, but it is degraded in alkaline solution and is light-sensitive. Curcumin exhibits a good stability at pH <7. It has very good stability to heat.	
Safe use of additive: Dietary intake assessment	 Table 3 additive: Yes No The EFSA Panel noted that intake of curcumin from the normal diet amounts to less than 7% of the ADI of 3 mg/kg bw/day, resulting from an average exposure to curcumin of 0.1 mg/kg bw/day from the intake of turmeric and curry powder each for both children and adults. 	
Justification that the use does not mislead consumer	The proposed use of Curcumin is to improve its organoleptic properties and not to change the nature or quality of the food so as to deceive the consumer. Also, the addition of colours will be clearly labelled in the package in which the food is packed so that it will not mislead consumers.	

PROPOSALS FOR NEW FOOD ADDITIVE PROVISIONS IN THE GSFA				
THE PROPOSAL	IS SUBMITTED BY:	India		
IDENTITY OF TH	E FOOD ADDITIVE:			
Name of the AdditiveAs listed in Class Names and theInternational Numbering System (INS) -CAC/GL 36-1989		4) Azorubine (Carmoisine)	4) Azorubine (Carmoisine)	
INS Number		122		
Functional Class As listed in Class International Num CAC/GL 36-1989		Colour		
PROPOSED USE ADDITIVE (1):	E(S) OF THE FOOD The proposal for ■ a new provision a new provision a new provision a new provision or □ revising an existing provision 01.1.2 "Other fluid milks (plain)		ovision on in the new food	category
Food Category No. (2)	Food Category Name (2)		Maximum Use Level (3)	Comments (4)
1.7	Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt) 100 mg/kg			

4.1.2.5	Jams, jellies, marmalades		200 mg/kg	
5.1.4	Cocoa and chocolate products		100 mg/kg	
5.2	Confectionery including has etc. other than food catego	rd and soft candy, nougats, ries 05.1, 05.3, and 05.4	100 mg/kg	
5.3	Chewing gum		100 mg/kg	
07.2.1	Cakes, Cookies and pies (e types)	eg. Fruit filled or custard	100 mg/kg	
14.1.4	Water-based flavoured drin "energy," or "electrolyte" dr	iks, including "sport," inks and particulated drinks	100 mg/kg	
EVALUATION B	Y JECFA:			
Evaluation by JECFA(1984), published in FNP 3Metals and arsenic specifi (2002). An ADI of 0-4 m		AZORUBINE (CARMOISIN (1984), published in FNP 31 Metals and arsenic specific (2002). An ADI of 0-4 mg 27 th JECFA (1983).	I/1 (1984) and in FN ations revised at th	IP 52 (1992). e 59 th JECFA
JUSTIFICATION	:			
Justification for use and technological need		Carmoisine is a red shaded colour which can be used to make food more attractive, appealing, appetizing, and informative. It can be added to correct natural variations in colour and offset colour loss due to exposure to light, air, temperature and storage conditions. It also provide colour to colourless and "fun" foods and allow consumers to identify products on sight, like candy flavours.		
Safe use of additive: Dietary intake assessment		Table 3 additive: ☐ Yes ■ No Carmoisine is a nontoxic distributed into tissues and gastrointestinal tract. The calculated from the blood ra intravenous administration below 10% of the total intak colour in food systems may	efficiently excreted bioavailability of adioactivity curves a of Carmoisine was a. This further indic	d through the Carmoisine after oral and found to be
Justification that the use does not mislead consumer		The proposed use of 0 organoleptic properties an quality of the food so as to addition of colours will be c which the food is packe consumers.	d not to change the consun leceive the consun learly labelled in th	he nature or ner. Also, the e package in

PROPOSALS FOR NEW FOOD ADDITIVE PROVISIONS IN THE GSFA	
THE PROPOSAL IS SUBMITTED BY:	India
IDENTITY OF THE FOOD ADDITIVE:	
Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989	5) Tartrazine
INS Number	102
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 proposal for <a>The provision;

or \Box revising an existing provision

or \Box 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)
1.1.4	Flavoured Fluid Milk Drink	S	100 mg/kg	
1.7	Dairy-based desserts (e.g. yoghurt)	pudding, fruit or flavoured	100 mg/kg	
4.1.2.5	Jams, jellies, marmalades		200 mg/kg	
5.1.4	Cocoa and chocolate prod	ucts	100 mg/kg	
5.2	Confectionery including ha	rd and soft candy, nougats, pries 05.1, 05.3, and 05.4	100 mg/kg	
5.3	Chewing gum		100 mg/kg	
6.5	Cereal and starch based d tapioca pudding)		100 mg/kg	
07.2.1	Cakes, Cookies and pies (types)		100 mg/kg	
14.1.4	•••	rinks and particulated drinks	100 mg/kg	
14.1.4.2	Non-carbonated water-bas including punches and ade		200 mg/kg	
EVALUATION BY	Y JECFA:	TARTRAZINE: Prepared		
Evaluation by JE		and arsenic specifications r An ADI of 0-7.5 mg/kg wa (1964).	as established at t	he 8 th ĴECFÁ
Justification for use and technological need		dyes are a large category of colourings used in food an cosmetics. Tartrazine is also available as the wate insoluble Aluminium Lake. Some food products contain ver little free water, making it difficult to dissolve the colour. I these cases the insoluble lakes are used, with the colou absorbed onto a hydrated alumina substrate. Tartrazin appears reddish at alkaline pH. Tartrazine is stable to hea and light. Tartrazine can be found in a wide variety of food including desserts and candies, soft drinks, condiments and breakfast cereals.		the water- contain very the colour. In th the colour e. Tartrazine table to heat riety of foods
Safe use of additive: Dietary intake assessment		Table 3 additive: Yes No The EFSA Panel concluded levels of use, refined intake 7.5 mg/kg/bw. The Panel co to be able to elicit intolerand the exposed population. Th individuals may react to Tab ADI.	e estimates are belo oncluded that Tartra ce reactions in a sm e Panel also notes	ow the ADI of zine appears all fraction of that sensitive
Justification that the use does not mislead consumer The proposed use of Tartrazine is to organoleptic properties and not to change quality of the food so as to deceive the consu- addition of colours will be clearly labelled in which the food is packed so that it wi consumers.		he nature or ner. Also, the e package in		

P	ROPOSALS FOR	NEW FOOD ADDITIVE PROVISIONS	IN THE GSFA	
THE PROPOSAL BY:	IS SUBMITTED	D India		
IDENTITY OF TH ADDITIVE:	E FOOD			
Name of the Add As listed in Class International Num (INS) - CAC/GL 3	Names and the bering System	6) Anthocyanins		
INS Number		163(ii), 163(iii)		
Functional Class As listed in Class International Num (INS) - CAC/GL 3	Names and the bering System	Colour		
PROPOSED USE FOOD ADDITIVE		The proposal for ■ a new provision; or □ revising an existing provision or □ a food additive provision in the "Other fluid milks (plain)"	0,1	
Food Category No. (2)	Foo	od Category Name (2)	Maximum Use Level (3)	Comments (4)
14.1.4		lavoured drinks, including "sport," trolyte" drinks and particulated drinks	GMP	
EVALUATION B	/ JECFA:			
Evaluation by JECFA		 (1984), published in FNP 31/1 (1984) and in FNP 52 (1992). Metals and arsenic specifications revised at the 59th JECFA (2002). An ADI of 0-2.5 mg/kg bw was established at the 26th JECFA (1982). BLACKCURRANT EXTRACT (INS 163(iii)): Prepared at the 57th JECFA (2001) and published in FNP 52 Add 9 (2001), superseding tentative specifications prepared at the 55th JECFA (2000), published in FNP 52 Add 8 (2000). No ADI was allocated at the 30th JECFA (1986) 		
JUSTIFICATION:				
Justification for use and technological need		There has been an increased inter- colorants from natural sources. A occurring, water-soluble compounds red, magenta, violet, purple and blu- vegetables and plants. Plants rich is blackcurrant, chokeberry, cherry, c cabbage. The interest in anthocyar colouring effect but also from their anti-oxidising activity, improvement in vessels and prevention of thrombo anthocyanins as food colouring agen they provide the attractive colour to m preserves.	Anthocyanins are that impart many of ue colours to a vari in anthocyanins are eggplant, blue gra nins derives not or beneficial propertion the tightness of co pocyte aggregation. ts becomes very im	the naturally of the orange, riety of fruits, e blackberry, ape and red hly from their ies, including apillary blood The role of aportant since
Safe use of additive: Dietary intake assessment		Table 3 additive: ☐ Yes ■ No The exposure estimates of anthocy were higher than dietary intakes and from colouring foods. The major con- consumption of fruits and vegetables	that these did not in tribution of intake i	clude intakes s highly from

Justification that the use does not mislead consumer

The proposed use of Anthocyanins is to improve its organoleptic properties and not to change the nature or quality of the food so as to deceive the consumer. Also, the addition of colours will be clearly labelled in the package in which the food is packed so that it will not mislead consumers.

PROPOSALS FOR NEW FOOD ADDITIVE PROVISIONS IN THE GSFA THE PROPOSAL IS SUBMITTED BY: India **IDENTITY OF THE FOOD ADDITIVE:** Name of the Additive As listed in Class Names and the 7) Paprika Oleoresin International Numbering System (INS) -CAC/GL 36-1989 **INS Number** 160c **Functional Class** As listed in Class Names and the Colour, Flavouring agent International Numbering System (INS) -CAC/GL 36-1989 The proposal for **a** new provision; **PROPOSED USE(S) OF THE FOOD** or revising an existing provision ADDITIVE (1): or \Box a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)" Food Category Maximum Use Comments Food Category Name (2) No. (2) Level (3) (4) 6.4.3 Pre-cooked pastas and noodles and like products GMP Processed meat, poultry, and game products in whole GMP 8.2 pieces or cuts Emulsified sauces and dips (e.g. mayonnaise, salad GMP 12.6.1 dressing, onion dips) Non-emulsified sauces (e.g. ketchup, cheese sauce, GMP 12.6.2 cream sauce, brown gravy) **EVALUATION BY JECFA:** Paprika Oleoresin: Prepared at the 35th JECFA (1989), published in FNP 49 (1990) and in FNP 52 (1992). Metals and arsenic specifications revised at the 59th JECFA (2002). **Evaluation by JECFA** An ADI 'acceptable' was established at the 14th JECFA (1970)JUSTIFICATION: A natural dye with capsanthin and capsorubin being the principle colouring compounds. It has an extensive use in food industry as a natural colouring agent for foods such as spicy culinary, meat products, cheese food coatings, Justification for use and technological popcorn, oil & cheeses. Depending on the nature of the food need (moisture, fat content, texture, background colour) colour saturation is achieved and increasing the quantity of paprika extract has no further benefit, neither for the appearance nor for the taste of the food. As a result, the use of paprika extract as a colour is self-limiting.

	The advantages of paprika oleoresin include: easy to store and transport; More stable when heated; More economical to use; Easier to control for quality and cleaner than the equivalent ground spices; Free from contamination; Concentrated form reduces storage space and bulk handling and transport requirements; Longer shelf life due to minimal oxidative degradation or loss of flavour. Paprika, besides imparting pungency and a red color to dishes, is a rich source of pro-vitamin A and vitamins B, C and E, and minerals like K, Ca, P, Fe, Na and Cu in trace amounts.
Safe use of additive: Dietary intake assessment	Table 3 additive: □ Yes ■ No Considering the widespread consumption of paprika extract and the absence of reports on allergic and intolerance reactions, it could be concluded that the food additive paprika extract (E 160c) is unlikely to represent a safety concern as regards allergenicity and immunotoxicity. Paprika oleoresin is unlikely to pose a reproductive/developmental hazard.
Justification that the use does not mislead consumer	The proposed use of Paprika oleoresin is to improve its organoleptic properties and not to change the nature or quality of the food so as to deceive the consumer. Also, the addition of colours will be clearly labelled in the package in which the food is packed so that it will not mislead consumers.

PROPOSALS FOR NEW FOOD ADDITIVE PROVISIONS IN THE GSFA				
THE PROPOSAL	IS SUBMITTED BY:	India		
IDENTITY OF TH	E FOOD ADDITIVE:			
Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989		8) Disodium Pyrophosphate		
INS Number		450(i)		
Functional ClassAs listed in Class Names and the InternationalNumbering System (INS) - CAC/GL 36-1989		Raising agent, buffering	Raising agent, buffering agent, sequestrant	
PROPOSED USE(S) OF THE FOOD ADDITIVE (1):		The proposal for ■ a new provision; or □ 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)
7.1	Bread and ordinary baker	y wares and mixes	5000	Allowed
EVALUATION B	EVALUATION BY JECFA:			
DISODIUM PYROPHOSPHATE: Prepared a JECFA (1993), published in FNP 52 Add superseding specifications prepared at the 37 (1990) published in FNP 52 (1992). Metals ar specifications revised at the 55th JECFA (2000 MTDI of 70 mg/kg bw, as phosphorus from sources, was established at the 26th JECFA (2001)		dd 2 (1993) e 37 th JECFA s and arsenic 000). A group from all food		

JUSTIFICATION:	
Justification for use and technological need	Most baked goods are made with chemical leavening agents. Sodium acid pyrophosphate is used as an acid to react with sodium bicarbonate (baking soda). This produces a very controlled release of Carbon dioxide that leavens the baked goods. The biggest challenge in formulating a baked good is to control the release rate of CO ₂ so that it is produced at right time during the manufacturing process. SAPP provides that flexibility and control to the manufacturing process.
	Table 3 additive: □ Yes ■ No
Safe use of additive: Dietary intake assessment	Protein-rich foods are especially high in phosphorus; these include dairy products (100–900 mg/100 g), meats (200 mg/100 g), fish (200 mg/100 g) and grain products (100–300 mg/100 g). The average intake from foods in adults is estimated to be between 1000 and 2000 mg/day. Bioavailability of phosphorus depends on the food sources. In plants, phosphorus is largely present in the form of phytate, a form which is not bioavailable in humans because they lack the enzyme phytase, which is necessary to release phosphorus. Phosphorus in meat is typically found as intracellular organic compounds which can be easily hydrolyzed to release inorganic phosphate. In addition to the naturally occurring phosphorus, a number of food additives containing phosphorus in the form of inorganic phosphate salts are approved for use in many foods.
Justification that the use does not mislead consumer	The proposed use of Disodium Pyrophosphate is to provide aids in the processing and preparation of food and the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of the manufacturing activities. Also, the addition of additives will be clearly labelled in the package in which the food is packed so that it will not mislead consumers.

PROPOSALS FOR NEW AND REVISION OF ADOPTED FOOD ADDITIVE PROVISIONS IN THE GSFA		
THE PROPOSAL IS SUBMITTED BY:	India	
IDENTITY OF THE FOOD ADDITIVE:		
Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989	9) Polyglycerol Esters of Interesterified Ricinoleic Acid	
INS Number	476	
Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989	Emulsifier	
PROPOSED USE(S) OF THE FOOD ADDITIVE (1):	The proposal for ■ a new provision; or ■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)
5.1.5	Imitation chocolate, chocolate substitute		5000 mg/kg	Revision of existing provision of 3000
	products			mg/kg (Allowed at 5000)
5.3	Chewing gum		GMP	Allowed at GMP
EVALUATION BY	Y JECFA:			
Evaluation by JECFA		Polyglycerol Esters of Interesterified Ricinoleic Acid: Prepared at the 17 th JECFA (1973), published in FNP 4 (1978) and in FNP 52 (1992). Metals and arsenic specifications revised at the 55 th JECFA (2000). An ADI of 0-7.5 mg/kg bw was established at the 17 th JECFA (1973)		
JUSTIFICATION:				
JUSTIFICATION: JUSTIFICATION: Safe use of additive: Dietary intake assessment		 (1973) The main application of PGPR in the chocolate in is to maintain flow properly during the enrobing proved addition of PGPR, which improves the characteristics of molten chocolate by reducing the value(which represents the viscosity of chocolate shear rate). An additional property of PGPR in chois is ability to limit fat bloom. Emulsifiers also plubrication, in part through dispersion of the fat for ease in processing and ease in consumplichewing and bubble gum, emulsifiers act as plas of the gum base and also provide a hydration during chewing. Polyglycerol poly ricinoleate is important wate emulsifier that is manufactured from the esterification of castor oil fatty acids with Polygl PGPR is widely known as an excellent wate emulsifier in the food industry, because it form stable emulsions even when the water content high. Therefore, PGPR is used as emulsier greasing emulsions for the baking trade. PGP strong water-in-oil emulsifier sare: improved dough ha improved rate of hydration, improved crumb strincreased uniformity in cell size.Bakery product also contain chocolates filled in to it. The PGPR is used in bakery products to avoid fat blooming. 		the enrobing process. be achieved by the improves the flow e by reducing the yield ity of chocolate at low of PGPR in chocolate nulsifiers also provide sion of the fat phase, e in consumption. In iers act as plasticizers de a hydration effect moortant water in oil ed from the inter- tids with Polyglycerol. excellent water-in-oil because it forms very water content is very as emulsier in tin- ng trade. PGPR is a to manufacture stable industry. In generally, facteristics which are oved dough handling, oved crumb structure, Bakery products may it. The PGPR used in properly during the additives shall also be
		addition, growth, fo Organ we kidney we mice. His	ogenic effect of PGP dietary PGPR had no od consumption, longev ight analysis revealed a ight in both male and fe tological analysis of related adverse effects.	o adverse effect on vity and haematology. n increase in liver and emale rats and female tissues revealed no

	The proposed use of Polyglycerol Esters of
Justification that the use does not mislead consumer	Interesterified Ricinoleic Acid is to provide aids in the processing and preparation of food and the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of the manufacturing activities. Also, the addition of additives will be clearly labelled in the package in which the food is packed so that it will not mislead consumers.

PROPOSALS FOR NEW AND REVISION OF ADOPTED FOOD ADDITIVE PROVISIONS IN THE GSFA		
THE PROPOSAL IS SUBMITTED BY:	India	
IDENTITY OF THE FOOD ADDITIVE:		
Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989	10) Ammonium Salts of Phosphatidic Acid	
INS Number	442	
Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989	Emulsifier	
PROPOSED USE(S) OF THE FOOD ADDITIVE (1):	The proposal for ■ a new provision; or ■ 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)
5.1.4	Cocoa and chocolate products		GMP	Revision of existing provision of 10000 mg/kg
5.1.5	Imitation chocolate, chocolate substitute products		GMP	Revision of existing provision of 10000 mg/kg
5.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4		GMP	
5.3	Chewing gum		GMP	
EVALUATION BY JECFA:				
Evaluation by JECFA 55 52		55 th JECFA supersedin JECFA (19	A (2000) and publishing tentative specifica (73) and published ir An ADI of 0-30 mg/k	tidic Acid: Prepared at the ed in FNP 52 Add 8 (2000), ations prepared at the 17 th n FNP 4 (1978) and in FNP g bw was established at the

JUSTIFICATION:

Justification for use and technological need	When ammonium phosphatides were added to confectioneries, the viscosity was reduced and remained unchanged even after 6 months of storage at 60°C. The exact mechanism behind the viscosity reduction effect is likely that they act in the same manner as lecithin. It has been hypothesised that, due to moisture, sugar particles in the confectioneries are aggregated through liquid bridges and phospholipids will be absorbed on the moist carbohydrate surface forming a film and thus promote the deagglomeration of the sugar particles.

	Neutral taste: Ammonium phosphatides are very neutral/bland in taste and smell opposite soy bean lecithin which is well known to have a distinct flavour which develop further over time and thus limit the level of use. Efficiency: Ammonium phosphatides in comparison with
	soy bean lecithin are more efficient in reducing the plastic viscosities of chocolate, and in chocolate containing PGPR as emulsifier the ammonium phosphatides exhibit a synergism in reducing the viscosity and yield values.
	Uniformity : Ammonium phosphatides exhibits an excellent uniformity from batch to batch, where soy lecithin is known to show significant variations.
	Table 3 additive: □ Yes ■ No
Safe use of additive: Dietary intake assessment	Based on the available toxicological database, the EFSA Panel concluded that the ADI is not exceeded in any population group, the Panel also concluded that the use of ammonium phosphatides (E 442) as a food additive, at the permitted or reported use and use levels, would not be of safety concern.
Justification that the use does not mislead consumer	The proposed use of Ammonium Salts of Phosphatidic Acid is to provide aids in the processing and preparation of food and the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of the manufacturing activities. Also, the addition of additives will be clearly labelled in the package in which the food is packed so that it will not mislead consumers.

PROPOSALS FOR NEW AND REVISION OF ADOPTED FOOD ADDITIVE PROVISIONS IN THE GSFA				
THE PROPOSAL IS SUBMITTED BY: India				
IDENTITY OF TH	E FOOD ADDITIVE:			
Name of the Add As listed in Class International Num CAC/GL 36-1989	Names and the bering System (INS) -	11) Citric	acid	
INS Number		330		
Functional Class As listed in Class International Num CAC/GL 36-1989		Acidity re flavouring		ıt, antioxidant synergist,
ADDITIVE (1):		The proposal for ■ a new provision; or ■ revising an existing provision or □ a food additive provision in the new food category 01.1.2 "Other fluid milks (plain)"		vision n in the new food category
Food Category No. (2)	Food Category Name (2)		Maximum Use Level (3)	Comments (4)
4.2.2	Processed vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds		GMP	
14.1.2.1	Fruit juice		GMP	Revision of existing provision of 300 mg/kg

EVALUATION BY JECFA:	EVALUATION BY JECFA:			
Evaluation by JECFA	Citric acid: Prepared at the 79 th JECFA (2014), published in FAO JECFA Monographs 16 (2014), superseding specifications prepared at the 53 rd JECFA (1999), published in FNP 52 Add 7 (1999). Group ADI "Not limited" for citric acid and its calcium, potassium, sodium and ammonium salts established at the 17 th JECFA in 1973.			
JUSTIFICATION:				
Justification for use and technological need	Citric acid is used as a food ingredient in the production of fruit products, juices, oils and fats, and for 40 many other food products where it functions as an acidulant, pH control, flavouring and sequestrant. It is also used as a dispersant in flavour or colour additive products.			
Safe use of additive: Dietary intake assessment	Table 3 additive: ■ Yes □No			
Justification that the use does not mislead consumer	The proposed use of Citric Acid is to preserve the nutritional quality of the food and to provide aids in the processing and preparation of food and the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of the manufacturing activities. Also, the addition of additives will be clearly labelled in the package in which the food is packed so that it will not mislead consumers.			

PROPOSALS FOR NEW AND REVISION OF ADOPTED FOOD ADDITIVE PROVISIONS IN THE GSFA		
THE PROPOSAL IS SUBMITTED BY:	India	
IDENTITY OF THE FOOD ADDITIVE:		
Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989	12) Ponceau 4 R	
INS Number	124	
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 proposal for ■ a new provision; or ■ 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)
4.1.2.5	Jams, jellies, marmalades	200 mg/kg	
5.2.3	Nougats and marzipans	200 mg/kg	Revision of existing provision of 100 mg/kg
6.5	Cereal and starch based desserts (e.g. rice pudding, tapioca pudding)	100 mg/kg	
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	100 mg/kg	Revision of existing provision of 50 mg/kg
14.1.4.2	Non-carbonated water-based flavoured drinks, including punches and ades	200 mg/kg	

EVALUATION BY JECFA:			
Evaluation by JECFA	Ponceau 4R: Prepared at the 74 th JECFA (2011) and published in FAO JECFA Monographs 11 (2011), superseding specifications prepared at the 28 th JECFA (1984), published in the Combined Compendium of Food Additive Specifications, FAO JECFA Monographs 1 (2005). An ADI of 0-4 mg/kg bw was established at the 27 th JECFA (1983) and maintained at the 74 th JECFA (2011).		
JUSTIFICATION:			
Justification for use and technological need	Ponceau 4R (E 124) is an azo dye which is a reddish-pink colour used globally in various foods and food ingredients. The technological function of food colourings is to add or restore colour to food products. The intent of the proposed extension for the use of Ponceau is to improve the visual appearance of the products. Foods containing Ponceau possess superior colouring characteristics to alternative red colours including; colour strength, longevity and quality of the finished product.		
Safe use of additive: Dietary intake assessment	Table 3 additive: ☐ Yes No The EFSA Panel concludes that the present database does give reason for re-definition of the ADI and derives an ADI of 0.7 mg/kg bw/day. The Panel concludes that at the maximum levels of use of Ponceau 4R, intake estimates for adults at the high percentile (97.5 th) and for 1- to 10-year old children at the mean and the high percentiles (95 th /97.5 th) are generally above the ADI of 0.7 mg/kg bw/day even in the refined intake estimates (Tier 2 and Tier 3). The Panel concludes that while some sensitivity reactions after Ponceau 4R intake have been reported, mostly when Ponceau 4R is taken within mixtures of other synthetic colours, no conclusion on the induction of sensitivity by Ponceau 4R could be drawn from the limited scientific evidence available. The Panel also notes that sensitive individuals may react at dose levels within the ADI.		
Justification that the use does not mislead consumer	The proposed use of Ponceau 4R is to improve its organoleptic properties and not to change the nature or quality of the food so as to deceive the consumer. Also, the addition of colours will be clearly labelled in the package in which the food is packed so that it will not mislead consumers.		

PROPOSALS FOR NEW AND REVISION OF ADOPTED FOOD ADDITIVE PROVISIONS IN THE GSFA		
THE PROPOSAL IS SUBMITTED BY:	India	
IDENTITY OF THE FOOD ADDITIVE:		
Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989	13) Carnauba wax	
INS Number	903	
Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989	Glazing agent, bulking agent, acidity regulator, carrier	

PROPOSED USE(S) OF THE FOOD ADDITIVE (1):		The proposal for ■ a new provision; or ■ 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)
4.1.2.5	Jams, jellies, marmalades		400 mg/kg	
5.1.4	Cocoa and chocolate produ	ucts	GMP	Revision of existing provision of 5000 mg/kg
5.1.5	Imitation chocolate, chocolassi substitute products	ate	GMP	Revision of existing provision of 5000 mg/kg
5.2.2	Soft candy		GMP	Revision of existing provision of 5000 mg/kg
5.3	Chewing gum		GMP	Revision of existing provision of 1200 mg/kg
15.0	Ready-to-eat savouries		GMP	Revision of existing provision of 200 mg/kg
EVALUATION B	Y JECFA:			
Evaluation by JECFA publis publis specifi publis publis		publishe specific publishe	Carnauba wax: Prepared at the 51 st JECFA (1998), published in FNP 52 Add 6 (1998) superseding specifications prepared at the 44 th JECFA (1995), and published in FNP 52 Add 3 (1995). ADI 0-7 mg/kg bw, established at the 39 th JECFA in 1992.	
Justification for use and technological need		The components of carnauba wax are rather inert and stable it can be assumed that degradation or reaction with food components will not take place at significant extent. Carnauba wax is a multi-functional additive which provides a horizon of uses in wide variety of foods.		
□ Yes Safe use of additive: Dietary intake assessment Adver the Pa food a		☐ Yes ■ No The EF carnaut margins Adverse the Par food ad		
Justification tha mislead consum	stification that the use does not slead consumer technic activitie labelled		ing and preparation of disguise the effects of undesirable (includin ues during the course s. Also, the addition	a wax is to provide aids in the of food and the additive is not the use of faulty raw materials g unhygienic) practices or of any of the manufacturing of additives will be clearly ich the food is packed so that

PROPOSALS FOR NEW AND REVISION OF ADOPTED FOOD ADDITIVE PROVISIONS IN THE GSFA		
THE PROPOSAL IS SUBMITTED BY:	India	
IDENTITY OF THE FOOD ADDITIVE:		
Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989	14) Sulfite ammonia caramel	

<u>CX/FA 18/50/8</u>

				25
INS Number		150d		
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 proposal for \Box a new provision; or prevising an existing provision or \Box 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)
1.7	Dairy-based desserts (e.g. pudding, fruit or flavoured y	/oghurt)	3000 mg/kg	Revision of existing provision of 2000 mg/kg
EVALUATION BY	JECFA:			
Evaluation by JECFA		CARAMEL COLOURS: Prepared at the 74 th JECFA (2011) and published in FAO JECFA Monographs 11 (2011), superseding specifications prepared at the 55 th JECFA (2000), published in the Combined Compendium of Food Additive Specifications, FAO JECFA Monographs 1 (2005). An ADI for Class IV of 0-200 mg/kg bw (0-150 mg/kg bw on solids basis) was established at the 29 th JECFA (1985).		
JUSTIFICATION:				
Justification for use and technological need		In general the caramel colours are all heat and light-stable, although acid stability varies considerably, the negatively- charged caramel colours generally being more stable under acid conditions		
Safe use of additive: Dietary intake assessment		Table 3 additive: ☐ Yes Mo Class IV Sulphite Ammonia Caramel did not indicate mutagenic potential and that sub chronic studies did not show haematological effects. The Panel considered that the NOAEL in short term and sub chromic study was 6.25 g/kg bw/day, the highest dose tested. Overall the Panel concluded that there were no concerns regarding the genotoxic potential of caramel colours.		
Justification that the use does not mislead consumer		The proposed use of Caramel Colour is to improve its organoleptic properties and not to change the nature or quality of the food so as to deceive the consumer. Also, the addition of colours will be clearly labelled in the package in which the food is packed so that it will not mislead consumers.		

PROPOSALS FOR NEW AND REVISION OF ADOPTED FOOD ADDITIVE PROVISIONS IN THE GSFA				
THE PROPOSAL IS SUBMITTED BY: India				
IDENTITY OF THE FOOD ADDITIVE:				
Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989	15) Tartaric acid			
INS Number	334			
Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989	Synergist for antioxidants, Acidity regulator, sequestrant, flavouring agent			

PROPOSED USE(S) OF THE FOOD ADDITIVE (1):

The proposal for a new provision;

or revising an existing provision

or \Box 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)	
2.1.3	Lard, tallow, fish oil, and other animal fats		GMP		
4.1.2.5	Jams, jellies, marmalades		GMP		
4.1.2.6	Fruit-based spreads (e.g. chutney) excluding products of food category 04.1.2.5		GMP		
4.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds		GMP		
5.2.1	Hard candy		GMP	Revision of existing provision of 2000 mg/kg	
6.4.3	Pre-cooked pastas and not products	odles and like	GMP		
7.1	Bread and ordinary bakery mixes	wares and	GMP		
7.2.1	Cakes, cookies and pies (e.g. fruit-filled or custard types)		GMP		
12.2.2	Seasonings and condiment	ts	GMP		
12.6	Sauces and like products		GMP		
14.1.4.2	Non-carbonated water-based flavoured drinks, including punches and ades		GMP		
EVALUATION B	Y JECFA:		L	L	
Evaluation by JECFA		and published specifications p in NMRS 57 (19 mg/kg bw was	in FNP 52 Add repared at the 21 ^s 977) and in FNP	d at the 53 rd JECFA (1999) d 7 (1999), superseding ^t JECFA (1977), published 52 (1992). An ADI of 0-30 e 17 th JECFA (1973) and 977).	
JUSTIFICATION					
Justification for use and technological need		Tartaric Acid act as an Antioxidant and Acidity regulator it will control the oxidation (Which leads to pH fall) and at the same time maintain the acidity by regulating the pH of product. The sourness of Tartaric Acid dissipates quickly since it is hygroscopic solid. Hence it can be used in food products where natural taste is preferred.Tartrates apart from behaving as Acidity regulator also behaves as Antioxidants & Sequestrant hence act as a multitasking additive. Thus can reduce amount of different additives which will be required otherwise. In case of free fatty acid formation due to oxidation process, again tartaric acid are beneficial in two ways: - one counter attacking the oxidation process and other as regulation of Acidity.			
Safe use of additive: Dietary intake assessment		Table 3 additive ☐ Yes ■ No Tartrates are G	RAS as per 21 CF	R of USFDA [Tartaric Acid - 184.1801, Potassium	

Justification that the use does not mislead consumer	The proposed use of Tartaric Acid is to preserve the nutritional quality of the food and to provide aids in the processing and preparation of food and the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of the manufacturing activities. Also, the addition of additives will be clearly labelled in the package in which the food is packed so that it will not mislead consumers.
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PROPOSALS FOR NEW AND REVISION OF ADOPTED FOOD ADDITIVE PROVISIONS IN THE GSFA				
THE PROPOSAL IS SUBMITTED BY:	India			
IDENTITY OF THE FOOD ADDITIVE:				
Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989	16) TOCOPHEROLS			
INS Number	307a, 307b, 307c			
Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989	Antioxidant			
PROPOSED USE(S) OF THE FOOD ADDITIVE (1):	The proposal for ■ a new provision; or ■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)
2.1.3	Lard, tallow, fish oil, and other animal fats	GMP	
5.2.1	Hard candy	GMP	Revision of existing provision of 2000 mg/kg

EVALUATION BY JECFA:

	d- α -TOCOPHEROL, CONCENTRATE (INS 307a): Prepared at the 55 th JECFA (2000) and published in FNP 52 Add 8 (2000), superseding tentative specifications prepared at the 30 th JECFA (1986) and published in FNP 37 (1986) and in FNP 52 (1992). A group ADI of 0.15-2 mg/kg bw for dl- α -tocopherol and d- α -tocopherol, concentrate, singly or in combination, was established at the 30 th JECFA (1986).		
Evaluation by JECFA	TOCOPHEROL CONCENTRATE, MIXED (INS 307b): Prepared at the 30 th JECFA (1986), published in FNP 37 (1986) and in FNP 52 (1992). Metals and arsenic specifications revised at the 61 st JECFA (2003). A group ADI of 0.15-2 mg/kg bw for dl- α -tocopherol and d- α -tocopherol, concentrate, singly or in combination, was established at the 30 th JECFA (1986).		
	dl-α-TOCOPHEROL (INS 307c): Prepared at the 30 th JECFA (1986), published in FNP 37 (1986) and in FNP 52 (1992). Metals and arsenic specifications revised at the 61 st JECFA (2003). A group ADI of 0.15-2 mg/kg bw for dl- α -tocopherol and d- α -tocopherol, concentrate, singly or in combination, was established at the 30 th JECFA (1986).		

JUSTIFICATION:				
Justification for use and technological need	Tocopherol isomers are chain-breaking antioxidants. It breaks peroxyl chain propagation reactions and is an efficient lipid peroxyl radical scavenger. Vitamin E is may be regenerated form its radical form by redox reactions involving coenzyme Q, enhancing its role as an antioxidant. Alpha-Tocopherol is primarily recognized as a natural source of vitamin E. Vitamin E protects against lipid peroxidation, especially LDL cholesterol.			
Safe use of additive: Dietary intake assessment	Table 3 additive: ☐ Yes ■ No In USFDA, Tocopherols are Generally Recognized as Safe as per 21 CFR of USFDA [184.1890 - α-Tocopherols].			
Justification that the use does not mislead consumer	The proposed use of Tocopherols is to preserve the nutritional quality of the food. Also, the addition of additives will be clearly labelled in the package in which the food is packed so that it will not mislead consumers.			

Japan				
THE PROPOSAL IS SUBMITTED BY:		Japan		
IDENTITY OF T	HE FOOD ADDITIVE:			
Name of the A	dditive	Sucrose esters of fatty acids		
	ss Names and the	Sucrose oligoesters, type I and type II		
International Nu - CAC/GL 36-1	umbering System (INS) 989	Sucroglycerides		
INS Number		INS 473		
		INS 473a		
		INS 474		
Functional Cla	SS	INS 473: Emulsifier, Foaming ag	ent, Glazing agent, Stabilizer	
As listed in Clas	ss Names and the	INS 473a: Emulsifier, Glazing ag	ent, Stabilizer	
International Nu - CAC/GL 36-1	umbering System (INS) 989	INS 474: Emulsifier		
	SE(S) OF THE FOOD	The proposal for:		
	The rows below may be	■ a new provision; or		
copied as many	times as needed.	□ revising an existing provision; or		
		□ use and use levels of tocopherols (INS 307a, b, c) as antioxidant in FC 01.3.1 "Condensed milk (plain))";or		
		use and use levels of propylene glycol alginate (INS 405) and sucrose esters of fatty acids (INS 473) as emulsifier in FC 05.1.4 "Cocoa and chocolate products".		
Food Category No. (²)	Food Category Name (²)	Maximum Use Level (³)	Comments (⁴)	
05.1.4	Cocoa and chocolate products	6,000 mg/kg	Note 348 "Singly or in combination: Sucrose esters of fatty acids (INS 473), sucrose oligoesters, type I and type II (INS 473a) and sucroglycerides (INS 474)"	
Is the proposal related to a FC with corresponding commodity standards? Yes. The proposal is related to FC 05.1.4 "Cocoa and chocolate products" which covers the Codex Standard for Chocolate and chocolate products (CXS 87-1981)				

Standard for Chocolate and chocolate products (CXS 87-1981).

Is the proposal also intended to revise the products covered by the commodity standards?

There is no need to change the corresponding commodity standard since CXS 87-1981, amended in 2016, permits to use emulsifiers in general in accordance with Tables 1 and 2 of the General Standard for Food Additives (CXS 192-1995) in FC 05.1.4 and its parent food categories.

It is noted that the Codex Committee on Cocoa Products and Chocolate has been adjourned sine die and thus the CCFA may revise food additive provisions in commodity standard under the purview of the adjourned committee.

EVALUATION BY JECFA:				
Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not	- A group ADI of 0-30 mg/kg bw for sucrose esters of fatty acids (INS 473), sucrose oligoesters type I and type II (INS 473a), sucroglycerides (INS 474), and sucrose monoesters of lauric, palmitic or stearic acid was established at 73 rd JECFA (2010).			
specified"); specifications monograph).	- The latest specifications for INS 473, 473a and 474 were prepared at the 84th JECFA (2017), 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).	Those food additives are used in chocolate products to uniformly disperse ingredients such as cocoa fat and cocoa mass and soften the products. They are also used as a crystallization inhibitor to prevent fat bloom in chocolate products.			
Safe use of additive: Dietary intake	Table 3 additive:			
assessment (as appropriate)	□ Yes			
	 No (Please provide information on dietary intake assessment below) 			
	The 73 rd JECFA estimated dietary intake of sucrose oligoesters, type I and type II (INS 473a) for which a group ADI has been set together with sucrose esters of fatty acids (INS 473) and sucroglycerides (INS 474). The summary of the dietary exposure assessment is as follows:			
	1. Dietary exposure based on poundage data			
	USA (assuming that sucrose oligoesters type I and type II captured 10% of the market for emulsifiers): 60 mg/day (3% of the upper bound of the ADI)			
	Japan (includes sucrose oligoesters and sucrose esters of fatty acids): 110 mg/day (6% of the upper bound of the ADI)			
	2. Dietary exposure based on national nutrition survey data			
	Japan: the mean dietary exposure to sucrose oligoesters 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 sucrose oligoesters 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 sucrose oligoesters 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			
Justification that the use does not mislead consumer	The proposed use of the food additives in food category 05.1.4 " Cocoa and chocolate products" does not change the nature of the food in any way to mislead the consumer.			

New Zealand				
THE PROPOSAL IS SUBMITTED BY:		New Zealand		
IDENTITY OF THE FOOD ADDITIVE:				
Name of the Add	itive		Sodium hydroxide	
As listed in Class International Num	Names and the bering System (INS) -			
CAC/GL 36-1989				
INS Number			524	
Functional Class			Acidity regulator	
As listed in Class International Num CAC/GL 36-1989	Names and the bering System (INS) -			
PROPOSED USE	(S) OF THE FOOD AD	DITIVE	E The proposal for:	
(¹):			a new provision; or	
	ay be copied as many		□ revising an existing provision	; or
times as needed.			□ use and use levels of tocophe antioxidant in FC 01.3.1 "Con	
			 □ use and use levels of propylene glycol alginate (INS 405) and sucrose esters of fatty acids (INS 473) as emulsifier in FC 05.1.4 "Cocoa and chocolate products". 	
Food Category	Food Category Name	e (²)	Maximum Use Level	Comments (⁴)
No. (²)		.,	(³)	
01.1.2	Other fluid milks (plain)	GMP	Note 227: For use in sterilized and UHT treated milks only
EVALUATION BY	JECFA:			
Evaluation by JE	CFA	Evalua	ition year: 1965	
Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph). Specifi (META vol.3/3 http://w		eting: 09 cs Code: R (1975) cification: COMPENDIUM ADDENDUM 10/FNP 52 Add.10/34 TALS LIMITS) (2002). R; FAO JECFA Monographs 1		
JUSTIFICATION:				
technological needagent).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).agent).FC 01. fermen FC 13. 2000 m		agent). stability The ne the GS	n hydroxide is widely used as an . It is used to adjust the pH of mill y of sterilized and UHT treated m w request is consistent with seve SFA including:	k, enhancing protein ilk. eral adopted provisions in
		fermen	C 01.2.1.2 Fermented milks (plain), heat treated after ermentation at GMP (adopted 2013);	
		C 13.1.1 Infant formula at 2000mg/kg (adopted 2013);		
		13.1.3 Formulae for special medical purposes for infants at 0 mg/kg (adopted 2013)		
			3.1.2 follow-up formulae at GMP (adopted 2015)	
			le 3 additive:	
intake assessme appropriate)	ent (as	∎ Ye	S	

	 No (Please provide information on dietary intake assessment below)
mislead consumer	The use of sodium hydroxide at GMP is technically justified and safe. Its use as a food additive does not change the nature of products or disguise the effects of the use of faulty raw materials which could mislead consumer.

Uganda			
THE PROPOSAL	IS SUBMITTED BY:	Uganda	
IDENTITY OF TH	E FOOD ADDITIVE:		
Name of the Add	litive		
As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989		AZORUBINE (CARMOISINE)	
INS Number		122	
Functional Class	6		
As listed in Class International Num CAC/GL 36-1989	nbering System (INS) -	COLOUR	
	(S) OF THE FOOD	The proposal for:	
as many times as	e rows below may be copied	a new provision; or	
as many umes as		revising an existing provision	; or
		□ use and use levels of tocoph antioxidant in FC 01.3.1 "Conde	
		□ use and use levels of propyle 405) and sucrose esters of fatty emulsifier in FC 05.1.4 "Cocoa	acids (INS 473) as
Food Category No. (²)	Food Category Name (²)	Maximum Use Level (³)	Comments (⁴)
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	50 mg/l	Maximum use level based on EFSA Journal 2009; 7(11): 1332
Is the proposal r	elated to a FC with correspo	onding commodity standards?	
(if yes indicate the	e relevant FC)		
NO			
	•	roducts covered by the commo	odity standards?
	e relevant commodity standar	ds)	
No	(15054		
EVALUATION B			
Evaluation by JE		27 th JECFA Meeting (19)	983)
	JECFA evaluation (including	• ADI: 0 – 4 mg/kg bw	
year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).		• FAS 18 – JECFA 27/15	i (monograph)
JUSTIFICATION:			
	use and technological		ts' organoleptic properties
need		The colourant is not mutagenic,	carcinogenic, or
Section 3.2 of th Standard for Fo advantage, does	nation based on the criteria in the Preamble of the General bod Additives (i.e. has an not present an appreciable is a technological function).	teratogenic and it produces no seffects (JECFA, 1983)	serious histopathological

Safe use of additive: Dietary intake assessment (as appropriate)	Table 3 additive: ■ Yes
	No (Please provide information on dietary intake assessment below)
Justification that the use does not mislead consumer	To be labelled on the finished product packaging

THE PROPOSAL IS SUBMITTED BY:		Uganda	
IDENTITY OF TH	E FOOD ADDITIVE:		
Name of the Add	litive		
As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989		UINOLINE YELLOW	
INS Number		104	
Functional Class	6		
As listed in Class International Nun CAC/GL 36-1989	nbering System (INS) -	COLOUR	
	E(S) OF THE FOOD	The proposal for:	
	e rows below may be copied	a new provision; or	
as many times as	needed.	□ revising an existing provision	; or
		□ use and use levels of tocopherols (INS 307a, b, c) as antioxidant in FC 01.3.1 "Condensed milk (plain))";or	
		□ use and use levels of propyle 405) and sucrose esters of fatty emulsifier in FC 05.1.4 "Cocoa	acids (INS 473) as
Food Category No. (²)	Food Category Name (²)	Maximum Use Level (³)	Comments (⁴)
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	100 mg/l	Maximum use level based on EFSA Journal 2009; 7(11): 1329
Is the proposal r	elated to a FC with correspo	onding commodity standards?	
(if yes indicate the	e relevant FC)		
NO			
	also intended to revise the p e relevant commodity standar	roducts covered by the commods) ds)	odity standards?
EVALUATION B	Y JECFA:		
Evaluation by JE	CFA	82 nd JECFA Meeting (2	016)
	JECFA evaluation (including	• ADI: 0 – 3 mg/kg bw	
year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).		FAO JECFA monograp	hs 19
JUSTIFICATION:			
Justification for need	use and technological	To enhance the produc	ts' organoleptic properties
Section 3.2 of the Standard for For advantage, does	nation based on the criteria in the Preamble of the General bod Additives (i.e. has an not present an appreciable s a technological function).		

Safe use of additive: Dietary intake assessment (as appropriate)	Table 3 additive: ■ Yes
	No (Please provide information on dietary intake assessment below)
Justification that the use does not mislead consumer	To be labelled on the finished product packaging

THE PROPOSAL IS SUBMITTED BY:		Uganda		
	E FOOD ADDITIVE:			
Name of the Additive		TARTR	AZINE	
As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989				
INS Number		102		
Functional Class	5			
As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989		COLOU	COLOUR	
	(S) OF THE FOOD ADDITIVE		The proposal for:	
	nay be copied as many times a	as	a new provision; or	
needed.			□ revising an existing	provision; or
				of tocopherols (INS 307a, FC 01.3.1 "Condensed
			□ use and use levels alginate (INS 405) and acids (INS 473) as em "Cocoa and chocolate	d sucrose esters of fatty nulsifier in FC 05.1.4
Food Category No. (²)	Food Category Name (²)		Maximum Use Level (³)	Comments (⁴)
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks		100 mg/l	Maximum use level based on EFSA Journal 2009; 7(11): 1331
Is the proposal r	elated to a FC with correspo	onding c	ommodity standards?	
(if yes indicate the		U	-	
NO				
• •	Ilso intended to revise the p e relevant commodity standard		covered by the comm	odity standards?
EVALUATION BY	Y JECFA:			
Evaluation by JECFA •		•	82 nd JECFA Meeting (2016)	
Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).		•		
		FAO JECFA monographs 19		
JUSTIFICATION:				
Justification for need	use and technological	•	To enhance the produc	ts' organoleptic properties

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).	
Safe use of additive: Dietary intake assessment (as appropriate)	 Table 3 additive: ■ Yes □ No (Please provide information on dietary intake assessment below)
Justification that the use does not mislead consumer	To be labelled on the finished product packaging

THE PROPOSAL IS SUBMITTED BY:		International Special Di	etary Foods Industries (ISDI)
IDENTITY OF TH	IE FOOD ADDITIVE:	1	
Name of the Add	litive		
As listed in Class Names and the		Ascorbyl Palmitate	
International Nun CAC/GL 36-1989	nbering System (INS) -		
INS Number		INS 304	
Functional Class	6		
As listed in Class	Names and the	Antioxidant	
International Nun CAC/GL 36-1989	nbering System (INS) -	Antioxidant	
	E(S) OF THE FOOD	The proposal for:	
ADDITIVE (1): The copied as many t	e rows below may be imes as needed	□ a new provision; or	
	ines as needed.	 revising an existing p 	provision; or
		□ use and use levels of tocopherols (INS 307a, b, c) as antioxidant in FC 01.3.1 "Condensed milk (plain))";or	
		405) and sucrose ester	f propylene glycol alginate (INS s of fatty acids (INS 473) as "Cocoa and chocolate products".
Food Category	Food Category Name (²)	Maximum Use Comments (⁴)	
No. (²)		Level (³)	
13.1.1	Infant Formulae		
	Ascorbyl Esters INS 304, 305	10 mg/kg	Notes 15, 72, & 187
			Note 15 On the fat or oil basis
			Note 72 On the ready-to-eat basis
			<i>Note 187</i> Ascorbyl palmitate (INS 304) only
13.1.2	Follow-up formula		
	Ascorbyl Esters INS304, 305	50mg/kg	Notes 15, 72, 187 & 315
			Note 15 On the fat or oil basis
			Note 72 On the ready-to-eat basis
			Note 187 Ascorbyl palmitate (INS 304) only

International Special Dietary Foods Industries (ISDI)

			Note 315 Singly or in combination: ascorbic acid (INS 300), sodium ascorbate (INS 301), calcium ascorbate (INS 302), and ascorbyl palmitate (IUNS 304)
13.1.3	Formulae for Special Medical Purposes for Infants		
	Ascorbyl Esters INS 304, 305	10 mg/kg	Notes 15, 72, & 187
			Note 15 On the fat or oil basis
			Note 72 On the ready-to-eat basis
			<i>Note 187</i> Ascorbyl palmitate (INS 304) only

Is the proposal related to a FC with corresponding commodity standards? (if ves indicate the relevant FC)

Yes. Ascorbyl palmitate (INS 304), listed in GSFA FC 13.1.1, FC 13.1.3 and FC 13.1.2, is included in the Infant Formula Standard (CX STAN 72-1981 Infant Formula and Formulas for Special Medical Purposes Intended for Infants), at the same maximum use level (10 mg/kg) and in the Follow-up Formula Standard (CX STAN 156-1987 For Follow-up Formula), at the same maximum use level (50mg/kg), respectively. The requested revision is to delete Note 15 ("On the fat or oil basis") in GSFA FC 13.1.1, 13.1.3 and 13.1.2 in order to align the provisions of the commodity standard (CX STAN 72-1981 Infant Formula and Formulas for Special Medical Purposes Intended for Infants) with those in the GSFA FC 13.1.1 and 13.1.3 and the provisions of the commodity standard (CX STAN 156-1987 Follow-up Formula) with those in the GSFA FC 13.1.2.

Is the proposal also intended to revise the products covered by the commodity standards? (*if yes indicate the relevant commodity standards*)

No. The proposal will correct the provisions in GSFA FC 13.1.1, 13.1.3 and 13.1.2, which will then be aligned with the provision in the commodity standard CX STAN 72-1981 Infant Formula and Formulas for Special Medical Purposes Intended for Infants and commodity standard CX STAN 156-1987 Follow-up Formula.

EVALUATION BY JECFA:

Evaluation by JECFA	Evaluation year: 1973
_	
Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI	ADI: 0-1.25 mg/kg bw
	Comments: As ascorbyl palmitate or ascorbyl stearate, or the sum of both
(numerical or "not specified");	Meeting: 17
specifications monograph).	Specs Code: R
	Report: NMRS 53/TRS 539-JECFA 17/18
	Tox Monograph: FAS 5/NMRS 53A-JECFA 17/146
	Specification: COMPENDIUM ADDENDUM 11/FNP 52 Add. 11/89 (METALS LIMITS) (2003); FAO JECFA Monographs 1 vol.1/117
	Previous Years: 1973, FNP 4-JECFA 17/184; COMPENDIUM/157. R
	1971, NMRS 50/TRS 488-JECFA 15/20, FAS 3/NMRS 50C- JECFA 15/38
	1969, NMRS 46/TRS 445-JECFA 13/21. 0-1.25. FU. S
	1961, NMRS 31/TRS 228-JECFA 6/25, TRS 228/NMRS 31- JECFA 6/26. 0-0.25 (0.25-0.50, CONDITIONAL). CO
	1958, NMRS VOL. I-III/71. N
	1958, NMRS VOL. I-III/71. N

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).	 Use of INS 304 as an antioxidant has an advantage in the manufacture of formulas for infants and young children. This substance prevents the oxidation of macronutrient ingredients as well as essential vitamins and minerals in the formula.
	 Ascorbyl palmitate does not present a health risk to the target population, as supported by the JECFA review noted above. In addition to its use as an antioxidant, ascorbyl palmitate is a permitted nutrient source for use in formulas for infants and FSMP for infants (CAC/GL 10- 1979).
	 The use of INS 304 in formulas for infants and young children serves the following technological functions (from Section 3.2 of GSFA Preamble):
	a Preserves the nutritional quality of the food;
	 Provides necessary ingredients or constituents for foods manufactures for groups having special dietary needs;
	c Enhances the keeping quality of food;
Safe use of additive: Dietary intake	Table 3 additive:
assessment (as appropriate)	□ Yes
	 No (Please provide information on dietary intake assessment below)
	This alignment of the GSFA with the Infant Formula Standard (72-1981) and the Follow-Up Formula Standard (56-1987) would not alter the current exposure assessment for ascorbyl palmitate, as there is no modification of allowable levels. Estimated exposure would remain the same, governed by the maximum allowable level of ascorbyl palmitate in the Infant Formula Standard (1 mg/100 mL, as-consumed), and the Follow-Up Formula Standard (5 mg/100 mL singly or in combination).
Justification that the use does not mislead consumer	The use of INS 304 in products defined in the commodity standard CX STAN 72-1981 and CX STAN 156-1987 will not mislead consumers. The substance when used will be labelled in a clear and transparent manner, consistent with the Labelling provisions in this and other related Codex standards.