CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5b **CX/FA 20/52/8**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-second Session

GENERAL STANDARD FOR FOOD ADDITIVES (GSFA)

PROPOSALS FOR NEW AND/OR REVISION OF FOOD ADDITIVE PROVISIONS

Replies to CL 2019/40-FA of Australia, Uganda and Food Drink Europe

Australia

THE PROPOSAL IS SUBMITTED BY:		Australia	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive *As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989*		Lauric arginate ethyl ester	
INS Number		243	
Functional Class *As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989*		Preservative	
PROPOSED USE(S) OF THE FOOD ADDITIVE ([1]): *The rows below may be copied as many times as needed.*		The proposal for: ☐ a new provision; or **X** revising an existing provision in Tables 1 and 2 of the GSFA; or ☐ revising an existing provision in Table 3 of the GSFA (skip to "Is the proposal intended to revise products covered by the commodity standard").	
Food Category No. ([2])	**Food Category Name ([2])**	**Maximum Use Level ([3])**	**Comments ([4])**
01.6.2.1	Ripened Cheese, includes rind	200 mg/kg	~~Note XS263~~ ~~Note XS264~~ ~~Note XS265~~ ~~Note XS266~~ ~~Note XS267~~ ~~Note XS268~~ ~~Note XS269~~ ~~Note XS270~~ ~~Note XS271~~ ~~Note XS272~~ Remove these exclusions from the lauric arginate ethyl ester provisions

Is the proposal related to a FC with corresponding commodity standards? (if yes indicate the relevant FC) Yes. FC 01.6.2.1 Standard for Cheddar (CXS 263-1966) Standard for Danbo (CXS 264-1966) Standard for Edam (CXS 265-1966) Standard for Gouda (CXS 266-1966) Standard for Havarti (CXS 267-1966) Standard for Samsø (CXS 268-1966) Standard for Emmental (CXS 269-1967) Standard for Tilsiter (CXS 270-1968) Standard for Saint-Paulin (CXS 271-1968) Standard for Provolone (CXS 272-1968)	
Is the proposal also intended to revise the products covered by the commodity standards? (if yes indicate the relevant commodity standards) Yes, to revise the products covered by the commodity listed above to permit the use of lauric arginate ethyl ester (INS 243) (LAEE).	
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 date: 2008 Report: TRS 952-JECFA 69/27 Tox Monograph: FAS 60-JECFA 69 Specifications: FAO JECFA Monographs 7 (2009) ADI 0-4 mg/kg bw for Ethyl-Nα-Lauroyl-L-Arginate
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).*	Based on Section 3.2 of the Preamble of the General Standard for Food Additives, the main technological need for the use of LAEE in food category 01.6.2.1 is 3.2(c) 'To enhance to keeping quality or stability of a food'. Provisions were adopted at Step 8 in 2011 for LAEE (INS 243) in food category 01.6.2.1 at a level of 200 mg/kg. The provisions were adopted with footnotes that restrict the use of the additive in products conforming to corresponding commodity standards associated with this category. The thirteen footnotes adopted were as follows: **XS263:** Excluding products conforming to the Standard for Cheddar (CXS 263-1966) **XS264:** Excluding products conforming to the Standard for Danbo (CXS 264-1966) **XS265:** Excluding products conforming to the Standard for Edam (CXS 265-1966) **XS266:** Excluding products conforming to the Standard for Gouda (CXS 266-1966) **XS267:** Excluding products conforming to the Standard for Havarti (CXS 267-1966) **XS268:** Excluding products conforming to the Standard for Samsø (CXS 268-1966) **XS269:** Excluding products conforming to the Standard for Emmental (CXS 269-1967) **XS270:** Excluding products conforming to the Standard for Tilsiter (CXS 270-1968) **XS271:** Excluding products conforming to the Standard for Saint-Paulin (CXS 271-1968)

	XS272: Excluding products conforming to the Standard for Provolone (CXS 272-1968) **XS274:** Excluding products conforming to the Standard for Coulommiers (CXS 274-1969) **XS276:** Excluding products conforming to the Standard for Camembert (CXS 276-1973) **XS277:** Excluding products conforming to the Standard for Brie (CXS 277-1973) The current request is to authorize the use LAEE in the same cheese standards as many other preservatives, including lysozyme, sorbates, nisin, natamycin, nitrates and propionate. Therefore, it is sought to remove the following **ten** footnotes: **XS263:** Excluding products conforming to the Standard for Cheddar (CXS 263-1966) **XS264:** Excluding products conforming to the Standard for Danbo (CXS 264-1966) **XS265:** Excluding products conforming to the Standard for Edam (CXS 265-1966) **XS266:** Excluding products conforming to the Standard for Gouda (CXS 266-1966) **XS267:** Excluding products conforming to the Standard for Havarti (CXS 267-1966) **XS268:** Excluding products conforming to the Standard for Samsø (CXS 268-1966) **XS269:** Excluding products conforming to the Standard for Emmental (CXS 269-1967) **XS270:** Excluding products conforming to the Standard for Tilsiter (CXS 270-1968) **XS271:** Excluding products conforming to the Standard for Saint-Paulin (CXS 271-1968) **XS272:** Excluding products conforming to the Standard for Provolone (CXS 272-1968) The acceptability of the use of preservatives in these ten food standards is recognised in the GSFA by way of the inclusion of provisions permitting the use of various preservatives, including lysozyme, sorbates, nisin, natamycin, nitrates and propionates[1] in these standards. The use of LAEE provides an effective alternative to the use of such preservatives in products falling under these standards. <u>Technological effect of Lauric arginate ethyl ester in cheese</u> LAEE is a preservative that is also used in products that conform to these corresponding ten commodity standards associated with FC 01.6.2.1. The technical effect of LAEE in food is to inhibit microbial growth in the food to which it has been added, and it is effective in controlling the growth of potentially pathogenic organisms in products falling under 01.6.2.1. The active ingredient of LAEE, as a cationic surfactant, has a wide spectrum of activity against bacteria, yeasts and moulds. Specifically, LAEE affects negatively charged compounds such as microbial proteins present in cellular membranes or in enzyme systems. Both hard or ripened and soft or unripened cheese benefit from the addition of preservatives. Age-ripened cheese retain their quality for long periods due to comparatively low pH, low water activity and low redox potential. However, spoilage may occur through the action of fungi, lactic acid bacteria and spore-forming bacteria. Unripened

[1] Proprionates are not permitted for use in Emmental and have the following Note - XS269: Excluding products conforming to the *Standard for Emmental* (CXS 269-1967). But they are permitted in the other nine standards as described here.

	cheeses spoil more rapidly than aged cheeses, and typical spoilage microorganisms include psychrotrophs, coliforms, fungi and lactic acid bacteria (Ledenbach and Marshall, 2009). Pasteurisation may eliminate many spoilage microorganisms originating from milk production and processing, but post-process contamination of milk and cheese can still occur. Use of the currently authorised preservatives in cheese has some disadvantages. When used to prevent mould growth on the surface of cheese, sorbates tend to diffuse into the cheese decreasing the surface concentration and thereby decreasing their preservative effect, and also modifying the favour, appearance and ripening process of the cheese (de Ruig and van den Berg, 1985). In addition, some moulds that grow on cheese are capable of metabolising sorbic acid and sorbate to trans-1,3-pentadiene, which causes an off-odour and flavour (Ledenbach and Marshall, 2009; Sensidoni et al., 1994). In addition, the near neutral pH of fresh cheese is not optimal for the antimicrobial activity of sorbates. The use of other preservatives on cheese also have disadvantages, such as natamycin which is a polyene fungicide and is not active against pathogenic bacteria such as *L. monocytogenes* (EFSA, 2009). Nisin has a narrow spectrum of activity against only gram-positive bacteria and does not inhibit gram-negative bacteria, yeasts or moulds (EFSA, 2006). In addition, some strains of bacteria, including some strains of *L. monocytogenes* have been shown to develop gradual resistance against nisin (Soni et al., 2010). The technological advantages of LAEE over other preservatives for use in cheeses (i.e. FC 01.6.2.1) include the following: • LAEE is effective at low and near-neutral pH. In contrast, some currently approved preservatives are only effective at low pH. • LAEE is similarly effective against bacteria (Gram +ve and Gram –ve), yeasts and moulds. Other preservatives must be combined to enhance their antimicrobial efficacy because they cannot inhibit the growth of such a wide range of micro-organisms by themselves • The minimum inhibitory concentrations (MICs) of LAEE are considerably lower than the MICs of the other preservatives against the same micro-organisms. This means that the effective application dose is lower for LAEE than for other food preservatives • On ingestion, LAEE can be easily and rapidly metabolised to common, natural constituent metabolic compounds. This implies a lack of adverse effects because it is a unique food preservative that is metabolically decomposed into constituent products. <u>Efficacy</u> The efficacy of LAEE as an antimicrobial preservative for use on cheese has been demonstrated in a number of studies. Some of these studies are now described: An internal study examined effect of LAEE on fresh cheese (50 ppm and 100 ppm) (Internal study VED-EC-21). Treating fresh cheese with LAE did not change their taste and general appearance. Found that LAEE reduces the concentration of the standard microbiological contamination present in the samples (*E. coli*, Coliform bacteria and yeasts). The antimicrobial activity increases with higher concentrations of LAEE. At 50 ppm there is a clear reduction effect, while at 100 ppm the reduction increases significantly. A separate internal study examined the effect of LAEE on blue cheese to prevent the presence of *Listeria monocytogenes* without affecting the technological characteristics of this type of product (Internal study VED-EC-22). During ripening, soaking of blue cheeses was done using a 1% LAEE solution. Soaking was carried out 4 times during ripening. Treating blue cheeses with solutions of LAE during ripening period did not change their general appearance. LAEE surface

	treatment reduces the population of *Listeria spp.* in blue cheese and prevents the presence of *Listeria monocytogenes* on the surface of blue cheese. International authorisation of LAEE The use of lauric arginate ethyl ester (LAEE) is permitted for use in products falling under FC 01.6.2.1 in a number of countries worldwide (e.g. Australia, New Zealand, Canada, and the USA), without further restriction on its use in products conforming to the relevant Codex commodity standards. These products are also available in international trade. As such, consideration should be given to revising the provisions of the GSFA to reflect the acceptable use of LAEE as a preservative in these products in numerous countries.
Safe use of additive: Dietary intake assessment (*as appropriate*)	Table 3 additive: ☐ Yes **X** No (Please provide information on dietary intake assessment below) The use of lauric acid ethyl ester (INS 243) in cheese products that fall under Codex food category 01.6.2.1, as well as its use in a broad range of other foods, was taken into consideration as part of the JECFA assessment of the safety of the additive in 2009.
Justification that the use does not mislead consumer	When used as a preservative, the use of LAEE would be in the list of ingredients on the label of the products.

REFERENCES

De Ruig, WG and van den Berg G. (1985). Influence of the fungicides sorbate and natamycin in cheese coatings on the quality of the cheese. *Neth. Milk Dairy J. ,*39, 165-172.

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EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food. Scientific Opinion on the use of nisin (E 234) as a food additive. Question number EFSA-Q-2005-031. Adopted on 26 January 2006. The EFSA Journal (2006) 314, 1-16.

Internal study - VED-EC-21. Technical report of Efficacy test. Lauric Arginate as Preservative for treatment of Blue Cheese. Laboratorios Miret S.A. Lamirsa. 15 September 2008.

Internal study - VED-EC-22. Technical report of Efficacy test. Lauric Arginate as Preservative for Fresh Cheese. Laboratorios Miret S.A. Lamirsa. 22 Febuary 2008.

Ledenbach, LH and Marshall, RT. (2009). Microbiological Spoilage of Dairy Products. In: Compendium of the Microbiological Spoilage of Foods and Beverages. Ed. Sperber, W.H. and Doyle, M.P. Food microbiology and Food Safety. Springer p.41-67

Sensidoni A, Rondinini G, Peressini D, Maifreni M, Bortolomeazzi R. (1994). Presence of an off-flavour associated with the use of sorbates in cheese and margarine. Ital. J. Food Sci. 2: 237-242.

Soni KA, Nannapaneni R, Schilling MW, Jackson V. (2010). Bactericidal activity of lauric arginate in milk and Queso Fresco cheese against Listeria monocytogenes cold growth. J Dairy Sci., Oct;93(10):4518-25.

Uganda

THE PROPOSAL IS SUBMITTED BY:	UGANDA
IDENTITY OF THE FOOD ADDITIVE:	
Name of the Additive *As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989*	Azorubine (Carmoisine)
INS Number	122

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: **X** a new provision; or ☐ revising an existing provision in Tables 1 and 2 of the GSFA; or ☐ revising an existing provision in Table 3 of the GSFA (skip to "Is the proposal intended to revise products covered by the commodity standard").

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	Labelling requirement: "may have an adverse effect on activity and attention in children"

Is the proposal related to a FC with corresponding commodity standards?

(*if yes indicate the relevant FC*)

No

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

(*if yes indicate the relevant commodity standards*)

No

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).*	• 27th JECFA (1983) • ADI: 0 – 4 mg/kg bw • FAS 18-JECFA 27/15 (monograph)

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).*	To enhance products' organoleptic properties. The colourant is not mutagenic, carcinogenic, or teratogenic and it produces no serious histopathological effects (JECFA, 1983)
Safe use of additive: Dietary intake assessment (*as appropriate*)	Table 3 additive: ☐ Yes **X** No (Please provide information on dietary intake assessment below)
Justification that the use does not mislead consumer	Products containing the food additive to conform to food labelling requirements for food additives in the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985)

THE PROPOSAL IS SUBMITTED BY:	UGANDA
IDENTITY OF THE FOOD ADDITIVE:	

Name of the Additive *As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989*	Quinoline yellow
INS Number	104
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: **General Standard for the Labelling of Prepackaged Foods** a new provision; or ☐ revising an existing provision in Tables 1 and 2 of the GSFA; or ☐ revising an existing provision in Table 3 of the GSFA (skip to "Is the proposal intended to revise products covered by the commodity standard").

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	10 mg/l	Labelling requirement: "may have an adverse effect on activity and attention in children"

Is the proposal related to a FC with corresponding commodity standards?

(*if yes indicate the relevant FC*)

No

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

(*if yes indicate the relevant commodity standards*)

No

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).*	• 82nd JECFA (2016) • ADI: 0 – 3 mg/kg bw • FAO JECFA monographs 19

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).*	To enhance products' organoleptic properties. Dietary exposure to quinoline yellow for children and all other age groups does not present a health concern. (WHO food additives series: 73, 2017)
Safe use of additive: Dietary intake assessment (*as appropriate*)	Table 3 additive: ☐ Yes X No (Please provide information on dietary intake assessment below) • EFSA (European Food Safety Authority), 2015. Refined exposure assessment for Quinoline Yellow (E 104). EFSA Journal 2015;13(3):4070, 33 pp., doi:10.2903/j.efsa.2015.4070 • Safety evaluation of certain food additives (JECFA, 2017)

Justification that the use does not mislead consumer	Products containing the food additive to conform to food labelling requirements for food additives in the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985)

THE PROPOSAL IS SUBMITTED BY:		UGANDA	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive *As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989*		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 rows below may be copied as many times as needed.*		The proposal for: X a new provision; or ☐ revising an existing provision in Tables 1 and 2 of the GSFA; or ☐ revising an existing provision in Table 3 of the GSFA (skip to "Is the proposal intended to revise products covered by the commodity standard").	
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	Labelling requirement: "may have an adverse effect on activity and attention in children"
Is the proposal related to a FC with corresponding commodity standards? (*if yes indicate the relevant FC*) No			
Is the proposal also intended to revise the products covered by the commodity standards? (*if yes indicate the relevant commodity standards*) No			
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).*		• 82nd JECFA Report (2016) • ADI: 0 – 10 mg/kg bw • FAO JECFA Monographs 19	
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).*		To enhance products' organoleptic properties. Dietary exposure to tartrazine for the general population, including children, does not present a health concern (WHO Food Additive Series: 73, 2017)	

Safe use of additive: Dietary intake assessment (*as appropriate*)	Table 3 additive: ☐ Yes **X** No (Please provide information on dietary intake assessment below) (WHO/JECFA, 2017) Safety evaluation of certain food additives
Justification that the use does not mislead consumer	Products containing the food additive to conform to food labelling requirements for food additives in the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985)

Food Drink Europe

THE PROPOSAL IS SUBMITTED BY:		FoodDrinkEurope	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive *As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989*		Sucralose	
INS Number		955	
Functional Class *As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989*		Sweetener	
PROPOSED USE(S) OF THE FOOD ADDITIVE ([1]): *The rows below may be copied as many times as needed.* **Existing Authorisation in GSFA** **Table One** **Category 7.2 Fine Bakery Wares** **Sucralose 955 2008 700 mg/kg Notes 161 & 165**		The proposal for: ☐ a new provision; or **X** revising an existing provision in Tables 1 and 2 of the GSFA; or ☐ revising an existing provision in Table 3 of the GSFA (skip to "Is the proposal intended to revise products covered by the commodity standard").	
Food Category No. ([2])	**Food Category Name ([2])**	**Maximum Use Level ([3])**	**Comments ([4])**
07.2	Fine Bakery Wares	700 mg/kg	A new Note to be added "wafer paper only"
Is the proposal related to a FC with corresponding commodity standards? (*if yes indicate the relevant FC*) No			
Is the proposal also intended to revise the products covered by the commodity standards? (*if yes indicate the relevant commodity standards*) No			
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: 1990* *ADI: 0-15mg/kg bw* *Meeting: 37* *Specs Code: R (1993)* *Report: TRS 806-JECFA37/21* *Tox Monograph: FAS 28-JECFA 37/219* *Specification: Compendium Addendum 12/FNP 52 Add. 12/68 (Metals Limits) 2004. R;* *FAO JECFA Monographs 1 vol. 3/439*	

	2001, Compendium Addendum 9/FNP 52 Add.9/192 (Metals Limits) *1993, Compendium Addendum 2/FNP 52 Add.2/119. R* *1990, Compendium/1531. R* *1988, TRS 776-JECFA 33/20, FNP 38-JECFA 33/255, FAS 24-JECFA 33/45. 0-3.5 (Temporary). TE. N,T*
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).*	*A baking process with sugar is in the case of wafer papers technically not possible because the sugar will stick during the baking process to the baking plates.* *Therefore, in the case of wafer papers no alternative to Sweeteners. Sucralose is most suitable sweetener for wafer paper.*
Safe use of additive: Dietary intake assessment (*as appropriate*)	Table 3 additive: ☐ Yes **X** No (Please provide information on dietary intake assessment below) Wafer papers are absolute niche products and as a conclusion it can be stated that in the group of adults and children the ADI is not likely to be exceeded even for so called high-level consumers.
Justification that the use does not mislead consumer	*There are no sugar sweetened wafer papers on the market. Furthermore, the use of Sucralose is mentioned explicitly on the labelling.*