



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



**World Health
Organization**

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 5c

**CX/FA 23/53/9
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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 2019/55-FA)

(Australia, Colombia, Egypt, New Zealand, Peru, Senegal, FoodDrinkEurope, FIVS, IADSA, IFAC and NATCOL)

Australia

In response to CL 2021/55-FA, Australia would like to submit a request for an amendment to the current provisions in the GSFA for Lauric arginate ethyl ester (LAEE) (INS 243). This would apply in particular to food categories, where footnotes have been introduced (or in once case retained) during the alignment exercise which restrict the use of LAEE in food categories but where the use of other preservatives is considered acceptable. We consider the footnotes restricting the use of LAEE that were introduced or retained during the alignment working group’s review should now be revisited following the review of the standards and acceptance that the use of preservatives is justified in foods conforming to the standards.

The specific requests concern the continued presence of following footnotes, associated with the use of LAEE in three food categories, which appears to be a consequence of the work of the e-WG on alignment.

Food Category 01.6.1 “Unripened Cheese, including fresh cheese”

Footnote XS221 “Excluding products conforming to the Group Standard for *Unripened Cheese including Fresh Cheese* (CXS 221-2001)”

Footnote XS273 “Excluding products conforming to the *Standard for Cottage Cheese* (CXS 273-1968)”

Footnote XS275 “Excluding products conforming to the *Standard for Cream Cheese* (CXS 275-1973)”

Food Category 01.6.2.1 “Ripened Cheese, includes rind”

Footnote XS278 “Excluding products conforming to the *Standard for Extra Hard Grating cheese* (CXS 278-1978)”

Footnote XS283 “Excluding products conforming to the *General Standard for Cheese* (CXS 283-1978)”

Food Category 02.2.2 “Fat spreads, dairy fat spreads and blended spreads”

Footnote 215 “Excluding products conforming to the *Standard for Fat Spreads and Blended Spreads* (CODEX STAN 256-2007)”

Full details explaining why we consider the association of these footnotes with LAEE provisions requires amendment are included in the attached draft proposed responses to CL 2021/55-FA.

I. Food Category 01.6.1 “Unripened Cheese, including fresh cheese”

THE PROPOSAL IS SUBMITTED BY:	Australia
IDENTITY OF THE FOOD ADDITIVE:	
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>	Lauric arginate ethyl ester
INS Number	243
Functional Class	Preservative

<i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>			
PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i>		The proposal for: <input type="checkbox"/> a new provision; or <input checked="" type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input type="checkbox"/> 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)
01.6.1	Unripened Cheese, including fresh cheese	200 mg/kg	Note XS221 Note XS273 Note XS275 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 01.6.1 Group Standard for Unripened Cheese including Fresh Cheese (CXS 221-2001) Standard for Cottage Cheese (CXS 273-1968) Standard for Cream Cheese (CXS 275-1973)			
Is the proposal also intended to revise the products covered by the commodity standards? (if yes indicate the relevant commodity standards) Yes, to revise products covered by the commodity standards listed above to <i>re-permit</i> the use of lauric arginate ethyl ester (INS 243) (LAEE).			
EVALUATION BY JECFA:			
Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i>		Evaluation 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-N α -Lauroyl-L-Arginate	
JUSTIFICATION:			
Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i>		Based on Section 3.2 of the Preamble of the <i>General Standard for Food Additives</i> , the main technological need for the use of LAEE in food category 01.6.1 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 01.6.1 at a level of 200 mg/kg. The provisions were adopted without any footnotes restricting the use of the additive in products falling under this food category. However, following the completion of the latest phase of the realignment exercise undertaken by the CCFA e-WG, the outcome of which was endorsed by CCFA 52 and subsequently adopted by CAC in 2021, three new footnotes have been assigned to the provisions for INS 243 in Food Category 01.6.1 to restrict its use in certain foods conforming with three commodity standards, namely:	

XS221: Excluding products conforming to the *Group Standard for Unripened Cheese including Fresh Cheese* (CXS 221-2001)

XS273: Excluding products conforming to the *Standard for Cottage Cheese* (CXS 273-1968)

XS275: Excluding products conforming to the *Standard for Cream Cheese* (CXS 275-1973)

The current request is to reverse the adoption of these newly introduced footnotes from the provision for INS 243 proposed by the working group on alignment. We do not consider it was intended to further restrict the use of preservatives already listed under FC 01.6.1 given the working group concluded that the use of preservatives used in accordance with Tables 1 and 2 of the *General Standard for Food Additives* (CXS 192-1995) in Food Category 01.6.1 is justified in foods conforming to these Codex Standards. Other preservatives permitted for use in these standardised foods include sorbates, nisin and natamycin. LAEE has been permitted to be used in products under Food Category 01.6.1. at a level of 200 mg/kg for several years and previously footnotes were not assigned to this entry in the GSFA. The use of LAEE provides an effective alternative to the use of other preservatives in products falling under these standards.

Technological effect of Lauric arginate ethyl ester in cheese

LAEE is a preservative that is also used in products that conform to these corresponding standards associated with FC 01.6.1. 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 01.6.1. 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.

Unripened cheeses benefit from the addition of preservatives. They 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 flavour, 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 01.6.1) include the following:

LAEE is effective at low and near-neutral pH. In contrast, some other preservatives are only effective at low pH.

	<p>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</p> <p>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</p> <p>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.</p> <p><u>Efficacy</u></p> <p>The efficacy of LAEE as an antimicrobial preservative for use on cheese has been demonstrated in studies previously referred to the committee. For example, an internal study examined effect of LAEE on fresh cheese (50 ppm and 100 ppm) (Internal study VED-EC-22). Treating fresh cheeses with LAE did not change their taste and general appearance. The study also found that LAEE reduces the concentration of the standard microbiological contamination present in the samples (<i>E. coli</i>, 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.</p> <p><u>International authorisation of LAEE</u></p> <p>The use of lauric arginate ethyl ester (LAEE) is permitted for use in products falling under FC 01.6.1 in a number of countries worldwide, 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 reverse the introduction of the new footnotes in the GSFA to reflect the acceptable use of LAEE as a preservative in these products in numerous countries.</p>
<p>Safe use of additive: Dietary intake assessment (as appropriate)</p>	<p>Table 3 additive:</p> <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below)</p> <p>The use of lauric acid ethyl ester (INS 243) in cheese products that fall under Codex food category 01.6.1, 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.</p>
<p>Justification that the use does not mislead consumer</p>	<p>When used as a preservative, the use of LAEE would be in the list of ingredients on the label of the products.</p>

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.

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the use of natamycin (E 235) as a food additive. *EFSA Journal* 2009;7(12):1412 [25 pp.].

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-22. Technical report of Efficacy test. Lauric Arginate as Preservative for Fresh Cheese. Laboratorios Miret S.A. Lamirsa. 22 February 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.

II. Food Category 01.6.2.1 “Ripened Cheese, includes rind”

THE PROPOSAL IS SUBMITTED BY:		Australia	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Lauric arginate ethyl ester	
INS Number		243	
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Preservative	
PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i>		The proposal for: <input type="checkbox"/> a new provision; or <input checked="" type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input type="checkbox"/> 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 XS278 Note XS283 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 Extra Hard Grating cheese (CXS 278-1978) General Standard for Cheese (CXS 283-1978)			
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 standard listed above to <i>re-permit</i> the use of lauric arginate ethyl ester (INS 243) (LAEE).			
EVALUATION BY JECFA:			
Evaluation by JECFA		Evaluation date: 2008 Report: TRS 952-JECFA 69/27	

<p>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or “not specified”); specifications monograph).</p>	<p>Tox Monograph: FAS 60-JECFA 69 Specifications: FAO JECFA Monographs 7 (2009) ADI 0-4 mg/kg bw for Ethyl-Nα-Lauroyl-L-Arginate</p>
<p>JUSTIFICATION:</p>	
<p>Justification for use and technological need</p> <p><i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i></p>	<p>Based on Section 3.2 of the Preamble of the <i>General Standard for Food Additives</i>, 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’.</p> <p>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.</p> <p>The thirteen footnotes adopted were as follows:</p> <p>XS263: Excluding products conforming to the <i>Standard for Cheddar</i> (CXS 263-1966)</p> <p>XS264: Excluding products conforming to the <i>Standard for Danbo</i> (CXS 264-1966)</p> <p>XS265: Excluding products conforming to the <i>Standard for Edam</i> (CXS 265-1966)</p> <p>XS266: Excluding products conforming to the <i>Standard for Gouda</i> (CXS 266-1966)</p> <p>XS267: Excluding products conforming to the <i>Standard for Havarti</i> (CXS 267-1966)</p> <p>XS268: Excluding products conforming to the <i>Standard for Samsø</i> (CXS 268-1966)</p> <p>XS269: Excluding products conforming to the <i>Standard for Emmental</i> (CXS 269-1967)</p> <p>XS270: Excluding products conforming to the <i>Standard for Tilsiter</i> (CXS 270-1968)</p> <p>XS271: Excluding products conforming to the <i>Standard for Saint-Paulin</i> (CXS 271-1968)</p> <p>XS272: Excluding products conforming to the <i>Standard for Provolone</i> (CXS 272-1968)</p> <p>XS274: Excluding products conforming to the <i>Standard for Coulommiers</i> (CXS 274-1969)</p> <p>XS276: Excluding products conforming to the <i>Standard for Camembert</i> (CXS 276-1973)</p> <p>XS277: Excluding products conforming to the <i>Standard for Brie</i> (CXS 277-1973)</p> <p>CCFA 52 adopted as new work (at Step 2) a request to remove footnotes associated with the use of LAEE in products conforming to a number of the food standards listed above and for which the use of preservatives is considered justified. In all the Committee agreed to take forward new work to remove the following ten footnotes:</p> <p>XS263: Excluding products conforming to the <i>Standard for Cheddar</i> (CXS 263-1966)</p> <p>XS264: Excluding products conforming to the <i>Standard for Danbo</i> (CXS 264-1966)</p> <p>XS265: Excluding products conforming to the <i>Standard for Edam</i> (CXS 265-1966)</p>

	<p>XS266: Excluding products conforming to the <i>Standard for Gouda</i> (CXS 266-1966)</p> <p>XS267: Excluding products conforming to the <i>Standard for Havarti</i> (CXS 267-1966)</p> <p>XS268: Excluding products conforming to the <i>Standard for Samsø</i> (CXS 268-1966)</p> <p>XS269: Excluding products conforming to the <i>Standard for Emmental</i> (CXS 269-1967)</p> <p>XS270: Excluding products conforming to the <i>Standard for Tilsiter</i> (CXS 270-1968)</p> <p>XS271: Excluding products conforming to the <i>Standard for Saint-Paulin</i> (CXS 271-1968)</p> <p>XS272: Excluding products conforming to the <i>Standard for Provolone</i> (CXS 272-1968)</p> <p>However, alongside agreeing to take forward work removing these footnotes, the outcome of a separate review undertaken by electronic working group on alignment (CX/FA 21/52/6) was also agreed by CCFA 52. This work on alignment resulted in the introduction of two new footnotes associated with the provisions for INS243 in FC 01.6.2.1, namely:</p> <p><u>XS278: Excluding products conforming to the Standard for Extra Hard Grating cheese (CXS 278-1978)</u></p> <p><u>XS283: Excluding products conforming to the General Standard for Cheese (CXS 283-1978)</u></p> <p>However, in the same review, the working group on alignment also concluded that preservatives used in accordance with Tables 1 and 2 of the <i>General Standard for Food Additives</i> (CXS 192-1995) in food category 01.6.2.1 (Ripened cheese, includes rind) are acceptable for use in foods conforming to both of these standards. The use of LAEE provides an effective alternative to the use of other preservatives in products falling under these standards.</p> <p><u><i>The acceptability of the use of LAEE in a range of cheeses conforming to a number of Codex Standards is currently being recognised formally through the new work to remove footnotes in the GSFA that limit these uses. As such it perhaps seems the introduction of the new footnotes suggested by the eWG on alignment is an unintended consequence of their review. Indeed the new notes will introduce quite considerable new restrictions for the use of LAEE at a time when removal of a number of existing restrictions is being considered by CCFA. As such we request that consideration is given to the reversal of the introduction of these two new footnotes.</i></u></p> <p><u>Technological effect of Lauric arginate ethyl ester in cheese</u></p> <p>If further technological justification is required to support the reversal of the introduction of the footnotes, the following can be considered:</p> <p>LAEE is a preservative that is also used in products that conform to these 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.</p>
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	<p>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. Pasteurisation may eliminate many spoilage microorganisms originating from milk production and processing, but post-process contamination of milk and cheese can still occur.</p> <p>Use of the currently authorised preservatives in cheese has some disadvantages. For example, 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 flavour, 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).</p> <p>The technological advantages of LAEE over other preservatives for use in cheeses (i.e. FC 01.6.2.1) include the following:</p> <ul style="list-style-type: none"> • 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. <p><u>International authorisation of LAEE</u></p> <p>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.</p>
<p>Safe use of additive: Dietary intake assessment (as appropriate)</p>	<p>Table 3 additive:</p> <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below)</p> <p>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.</p>
<p>Justification that the use does not mislead consumer</p>	<p>When used as a preservative, the use of LAEE would be in the list of ingredients on the label of the products.</p>

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.

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.

III. Food Category 02.2.2 “Fat spreads, dairy fat spreads and blended spreads”

THE PROPOSAL IS SUBMITTED BY:		Australia		
IDENTITY OF THE FOOD ADDITIVE:				
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Lauric arginate ethyl ester		
INS Number		243		
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Preservative		
PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i>		The proposal for: <input type="checkbox"/> a new provision; or <input checked="" type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input type="checkbox"/> 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 No. (2)	Food Category	Food Category Name (2)	Maximum Use Level (3)	Comments (4)
02.2.2		Fat spreads, dairy fat spreads and blended spreads	200 mg/kg	Note XS215 Remove this exclusion 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 02.2.2 Standard for Fat Spreads and Blended Spreads (CODEX STAN 256-2007))				
Is the proposal also intended to revise the products covered by the commodity standards? (if yes indicate the relevant commodity standards) Yes, to revise products covered by the commodity standard listed above to permit the use of lauric arginate ethyl ester (INS 243) (LAEE).				
EVALUATION BY JECFA:				
Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of</i>			Evaluation date: 2008 Report: TRS 952-JECFA 69/27	

evaluation; full ADI (numerical or “not specified”); specifications monograph).	Tox Monograph: FAS 60-JECFA 69 Specifications: FAO JECFA Monographs 7 (2009) ADI 0-4 mg/kg bw for Ethyl-N α -Lauroyl-L-Arginate
JUSTIFICATION:	
<p>Justification for use and technological need</p> <p><i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i></p>	<p>Based on Section 3.2 of the Preamble of the <i>General Standard for Food Additives</i>, the main technological need for the use of LAEE in food category 02.2.2 is 3.2(c) ‘To enhance to keeping quality or stability of a food’.</p> <p>Provisions were adopted at Step 8 in 2011 for LAEE (INS 243) in food category 02.2.2 at a level of 200 mg/kg. The provisions were adopted with Footnotes 214 and 215 restricting the use of the additive in products conforming with the <i>Standard for Dairy Fat Spreads</i> (Codex Stan 253-2006) and the <i>Standard for Fat Spreads and Blended Spreads</i> (CODEX STAN 256-2007) falling under this food category. However, following the completion of the latest phase of the realignment exercise undertaken by the CCFA e-WG, the outcome of which was endorsed by CCFA52 and subsequently adopted by CAC in 2021, it has been accepted that the use of preservatives is justified in products conforming with the <i>Standard for Fat Spreads and Blended Spreads</i> (CODEX STAN 256-2007). The e-WG on alignment is due to review the provisions contained in the <i>Standard for Dairy Fat Spreads</i> (Codex Stan 253-2006) ahead of CCFA 53.</p> <p>When footnotes 214 and 215 were assigned to the provisions for LAEE in FC 02.2.2 in 2011, the justification given was that the relevant commodity committee had not reviewed the provisions in relation to the use of the additive in the respective standards.</p> <p>It should be recognised that the report of CCFA 43¹, at which the provisions for LAEE were adopted, records that “<i>the representative of FAO stated that the inclusion of Notes in the GSFA excluding existing related commodity standards might result in unwarranted restrictions in the use of new food additives, which had been evaluated by JECFA at the request of the Codex Alimentarius Commission</i>”.</p> <p>The current request is to remove footnote 215 (Excluding products conforming to the Standard for Fat Spreads and Blended Spreads (CODEX STAN 256-2007)) from the provision for INS 243 in the GSFA. As noted by the FAO representative at CCFA 43, the use of LAEE in foods, including those conforming with Codex Stan 256-2007 were evaluated by JECFA. Furthermore the working group on alignment has agreed that the preservatives used in accordance with Tables 1 and 2 of GSFA FC 0.2.2.2 are acceptable in foods conforming with Stan 256-2007. As such LAEE should be considered to be acceptable in these products at a use level of 200 mg/kg. The use of LAEE provides an effective alternative to the use of other preservatives in products falling under these standards.</p> <p><u><i>Given the use of LAEE in products conforming to Codex Stan 256-2007 was only restricted in 2011 because the relevant commodity committee had not reviewed the use in the standardised food, and since the use of preservatives is considered justified in foods conforming with the standard following the assessment of the e-WG on alignment, it would appear that the retention of the footnote 215 for LAEE in FC 02.2.2 is an unintended consequence of the alignment exercise.</i></u></p> <p><u>International authorisation of LAEE</u></p>

¹ https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-711-43%252FREP11_FAe.pdf

	The use of lauric arginate ethyl ester (LAEE) is permitted for use in products falling under FC 02.2.2 in a number of countries worldwide, without further restriction on its use in products conforming to the relevant Codex commodity standard. These products are also available in international trade. As such, consideration should be given to remove footnote 215 associated with the provisions for LAEE in 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: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below) The use of lauric acid ethyl ester (INS 243) in products that fall under Codex food category 02.2.2, 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.		

Colombia

I. Jagua (Genipin-Glycine) Blue

THE PROPOSAL IS SUBMITTED BY:		Colombia	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Jagua (Genipin-Glycine) Blue	
		Synonyms: Jenipapo (genipapo) , Blue jenipapo (genipapo blue) , Azul de jagua (jagua blue), Azul de huito (huito blue), Huito, Jagua	
INS Number		INS 183 (adopted by the 44 th CAC)	
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Colour	
PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i>		The proposal for: <input checked="" type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input type="checkbox"/> 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 Number	Food Category Name	Maximum use Level	Notes
01.1.4	Flavoured fluid milk drinks	160 mg/kg	Note 52: Excluding chocolate milk Note x On a blue polymer basis.
01.6.4.2	Flavoured processed cheese, including containing fruit, vegetables, meat, etc.	44 mg/kg	Note x On a blue polymer basis.

01.7	Dairy-based desserts (e.g. pudding, fruit or flavored yoghurt)	120 mg/kg	Note xx Use in frozen dairy confections and novelties at a maximum of 400 mg/kg to achieve the desired color Note x On a blue polymer basis.
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	160 mg/kg	Note x On a blue polymer basis.
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	200 mg/kg	Note xxx Use in non-dairy frozen confections and novelties at a maximum of 400 mg/kg to achieve the desired color Note x On a blue polymer basis.
03.0	Edible ices, including sherbet and sorbet	120 mg/kg	Note x On a blue polymer basis.
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	120 mg/kg	Note 182: Excluding coconut milk Note x On a blue polymer basis.
04.1.2.5	Jams, jellies, marmalades	120 mg/kg	Note x On a blue polymer basis.
04.1.2.11	Fruit fillings for pastries	120 mg/kg	Note x On a blue polymer basis.
04.1.2.9	Fruit-based desserts, incl. fruit-flavoured water-based desserts	120 mg/kg	Note x On a blue polymer basis.
05.1.4	Cocoa and chocolate products	800 mg/kg	Note 183: For use in surface decoration only Note x On a blue polymer basis.
05.2	Confectionary including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4	800 mg/kg	Note XS309R: Excluding products conforming to the Codex Regional Standard for Halawa Tehenia (CODEX STAN 309R-211) Note x On a blue polymer basis.
05.3	Chewing gum	800 mg/kg	Note x On a blue polymer basis.
05.4	Decorations (e.g. for fine bakery wares), toppings (non-fruit) and sweet sauces	120 mg/kg	Note x On a blue polymer basis.
06.3	Breakfast cereals, including rolled oats	2000 mg/kg	For use in ready-to-eat multi-colored cereal only; the 2000 mg/kg is for individual pieces of cereal Note x On a blue polymer basis.
06.5	Cereal and starch based desserts (e.g. rice pudding, tapicoa pudding)	84 mg/kg	Note x On a blue polymer basis.
11.4	Other sugars and syrups (e.g. xylose, maple syrup, and sugar toppings)	120 mg/kg	Note x On a blue polymer basis.
12.2.2	Seasonings and condiments	600 mg/kg	Note x On a blue polymer basis.
13.4	Dietetic formulae for slimming purposes and weight reduction	64 mg/kg	Note x On a blue polymer basis.
13.5	Dietetic foods (e.g. supplementary foods for dietary use) excluding products of food categories 13.1-13.4 and 13.6	64 mg/kg	Note x On a blue polymer basis.
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	80 mg/kg	Note x On a blue polymer basis.
15.1	Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	1200 mg/kg	For use in blue/purple tortilla chips only. Note x On a blue polymer basis.

15.2	Processed nuts, including coated nuts and nut mixtures (with e.g. dried fruit)	800 mg/kg	For use in yoghurt coating of yoghurt-covered nuts only. Note x On a blue polymer basis.
Is the proposal related to a FC with corresponding commodity standards? No			
Is the proposal also intended to revise the products covered by the commodity standards? No			
EVALUATION BY JECFA:			
Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i>		89 th meeting JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (Safety evaluation of certain food additives) 1-2 June 2020. ADI of 0-11 mg/kg bw was established by the Committee for Jagua Blue, on a blue-polymer basis. During this evaluation, the Committee concluded that: the estimated dietary exposure to Jagua Blue, on a blue polymer basis, does not represent a health concern.	
JUSTIFICATION:			
Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i>		Since Jagua Blue is a colorant, its use improves the organoleptic properties of foods. Experts have shown that colour plays an important role in the taste and desirability of foods. Colour is considered to be a major quality factor of food. As the JECFA evaluation concluded, Jagua Blue does not present a health concern. Colours are already permitted in the categories listed for the proposed uses.	
Safe use of additive: Dietary intake assessment (as appropriate)		Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below) An ADI of 0-11 mg/kg bw was established by the committee for Jagua Blue on a blue-polymer basis. This ADI was based on the absence of treatment –related long-term toxicity and of reproductive and developmental toxicity in the 12-month rat dietary study with in-utero exposure, in which the NOAEL was identified as 1127 mg/kg bw per day of the blue polymer, the highest dose tested. The ADI was established by applying and uncertainty factor of 100 to the NOAEL. The Committee noted that the upper end of the high-level dietary exposure estimate for Jagua blue, on a blue-polymer basis, for infants and toddlers of 11.5 mg/kg bw per day is in the region of the upper bound of the ADI. In view of the conservative nature of the dietary exposure assessments, in which it was assumed that all foods contained Jagua blue on a blue-polymer basis at the maximum use level, and because the ADI was based on a NOAEL that was the highest dose tested, the Committee concluded that the estimated dietary exposure to Jagua blue, on a blue-polymer basis, does not represent a health concern. <i>(From the Summary Report of the 89th JECFA Meeting, pages 3-4).</i>	
Justification that the use does not mislead consumer		Other colours are already permitted in the food categories listed for Jagua Blue. Therefore, consumers are accustomed to colours being in these foods. Further, foods containing Jagua Blue would be labelled. Thus, consumers would not be misled.	

II. Titanium Dioxide

THE PROPOSAL IS SUBMITTED BY:		Colombia	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Titanium Dioxide Synonyms: Titania; CI Pigment white 6; CI (1975) No. 77891; INS No. 171	
INS Number		INS No. 171	
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Colour	
PROPOSED USE(S) OF THE FOOD ADDITIVE (!): <i>The rows below may be copied as many times as needed.</i>		The proposal for: <input type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input checked="" type="checkbox"/> 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 Number	Food Category Name	Maximum use Level	Notes
01.1.4	Flavoured fluid milk drinks	GMP	N/A
01.3	Condensed milk and analogues (plain)	GMP	N/A
01.4.3	Clotted cream (plain)	GMP	N/A
01.4.4	Cream analogues	GMP	N/A
01.5	Milk powder and cream powder and powder analogues (plain)	GMP	N/A
01.6.1	Unripened cheese	GMP	N/A
01.6.2	Ripened cheese	GMP	N/A
01.6.4	Processed cheese	GMP	N/A
01.6.5	Cheese analogues	GMP	N/A
01.7	Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt)	GMP	N/A
01.8.1	Liquid whey and whey products, excluding whey cheeses	GMP	N/A
02.2.2	Fat spreads, dairy fat spreads and blended spreads	GMP	N/A
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	GMP	N/A
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	GMP	N/A
03.0	Edible ices, including sherbet and sorbet	GMP	N/A
04.1.2	Processed fruit	GMP	N/A
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and	GMP	N/A

	aloe vera), seaweeds, and nuts and seeds		
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soybean sauce	GMP	N/A
04.2.2.4	Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	GMP	N/A
04.2.2.5	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	GMP	N/A
04.2.2.6	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g. vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	GMP	N/A
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	GMP	N/A
05.0	Confectionery	GMP	N/A
06.3	Breakfast cereals, including rolled oats	GMP	N/A
06.4.3	Pre-cooked pastas and noodles and like products	GMP	N/A
06.5	Cereal and starch based desserts (e.g. rice pudding, tapioca pudding)	GMP	N/A
06.6	Batters (e.g. for breading or batters for fish or poultry)	GMP	N/A
06.7	Pre-cooked or processed rice products, including rice cakes (Oriental type only)	GMP	N/A
06.8	Soybean products (excluding soybean-based seasonings and condiments of food category 12.9)	GMP	N/A
07.0	Bakery wares	GMP	N/A
08.2	Processed meat, poultry, and game products in whole pieces or cuts	GMP	N/A
08.3	Processed comminuted meat, poultry, and game products	GMP	N/A
08.4	Edible casings (e.g. sausage casings)	GMP	N/A
09.3	Semi-preserved fish and fish products, including mollusks,	GMP	N/A

	crustaceans, and echinoderms		
09.4	Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	GMP	N/A
10.2.3	Dried and/or heat coagulated egg products	GMP	N/A
10.3	Preserved eggs, including alkaline, salted, and canned eggs	GMP	N/A
10.4	Egg-based desserts (e.g. custard)	GMP	N/A
11.6	Table-top sweeteners, including those containing high-intensity sweeteners	GMP	N/A
12.2.2	Seasonings and condiments	GMP	N/A
12.3	Vinegars	GMP	N/A
12.4	Mustards	GMP	N/A
12.5	Soups and broths	GMP	N/A
12.6	Sauces and like products	GMP	N/A
12.7	Salads (e.g. macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.5 and 05.1.3	GMP	N/A
12.8	Yeast and like products	GMP	N/A
12.9	Soybean-based seasonings and condiments	GMP	N/A
12.10	Protein products other than from soybeans	GMP	N/A
13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	GMP	N/A
13.4	Dietetic formulae for slimming purposes and weight reduction	GMP	N/A
13.5	Dietetic foods (e.g. supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	GMP	N/A
13.6	Food supplements	GMP	N/A
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	GMP	N/A
14.2.1	Beer and malt beverages	GMP	N/A
14.2.2	Cider and perry	GMP	N/A
14.2.4	Wines (other than grape)	GMP	N/A
14.2.5	Mead	GMP	N/A
14.2.6	Distilled spirituous beverages containing more than 15% alcohol	GMP	N/A
14.2.7	Aromatized alcoholic beverages (e.g. beer, wine and spirituous cooler-type beverages, low	GMP	N/A

	alcoholic refreshers)		
15.0	Ready-to-eat savouries	GMP	N/A
16.0	Prepared foods	GMP	N/A
Is the proposal related to a FC with corresponding commodity standards? No			
Is the proposal also intended to revise the products covered by the commodity standards? No			
EVALUATION BY JECFA:			
Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or “not specified”); specifications monograph).</i>		Prepared at the 76th JECFA (2012) and published in FAO JECFA Monographs 13 (2012), superseding specifications prepared at the 73rd JECFA (2010) and published in FAO JECFA Monographs 10 (2010). An ADI “not limited” was established at the 13th JECFA (1969).	
JUSTIFICATION:			
Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i>		<p>Since titanium dioxide is a colorant, its use improves the organoleptic properties of foods.</p> <p>PROPOSALS FOR ADDITIONS AND CHANGES TO THE PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA (REPLIES TO CL 2019/41-FA AND CL 2020/37) (Agenda item 7)</p> <p>Canada introduced the item, noting that no in-session WG on Priority was held due to the virtual meeting format. He explained that, based on CX/FA 21/52/12 Add.1 (Replies to CL 2021/61-FA) and other relevant documents, a report (CRD6) which addressed the Priority List of Substances Proposed for Evaluation by JECFA has been prepared. He proposed that the Committee consider CRD6 as the basis for discussion. (...) <u>Discussion</u> <i>Titanium dioxide (INS 171)</i> In response to the request for clarification on the timeline for the call for data and re-evaluation of titanium dioxide (INS 171), Canada clarified that even though titanium dioxide was put on the priority list, it would be in 2023 when a call for data would be issued.</p> <p>One Member stressed a potential impact on trade if titanium dioxide is removed from EU market based on EFSA’s recent opinion and given the fact that titanium dioxide is widely used as a food additive and that the risk assessment by JECFA would begin in 2024 at the earliest. He urged the JECFA Secretariat to consider every possible option to expedite the risk assessment by JECFA.</p> <p>The JECFA Secretariat, in response to the concern, stated that JECFA would do its best to expedite the process.</p> <p>SCIENTIFIC OPINION: Safety assessment of</p>	

titanium dioxide (E171) as a food additive

(ADOPTED: 25 March 2021)

1. Updated safety assessment of the food additive titanium dioxide (E 171) based on new relevant scientific evidence considered by the Panel to be reliable, including data obtained with **TiO₂ nanoparticles (NPs)** and data from an **extended one-generation reproductive toxicity (EOGRT) study**.
2. Less than 50% of constituent particles by number in E 171 have a minimum external dimension <100 nm. Constituent particles <30 nm amounted to less than 1% of particles by number.
3. The Panel concluded that although gastrointestinal absorption of TiO₂ particles is low, they **may accumulate** in the body.
4. Studies on general and organ toxicity **did not indicate adverse effects with either E 171 up to a dose of 1,000 mg/kg body weight (bw) per day or with TiO₂NPs (>30 nm) up to the highest dose tested of 100 mg/kg bw per day**. No effects on reproductive and developmental toxicity were observed up to a dose of 1,000 mg E 171/kg bw per day, the highest dose tested in the EOGRT study.
5. However, observations of potential immunotoxicity and inflammation with E 171 and potential neurotoxicity with TiO₂ NPs, together with the potential induction of aberrant crypt foci with E 171, may indicate adverse effects.
6. Genotoxicity, the Panel concluded that TiO₂ particles have the potential to induce DNA strand breaks and chromosomal damage, but not gene mutations.

CONCLUSION.

Based on all the evidence available, a concern for genotoxicity could not be ruled out, and given the many uncertainties, the Panel concluded that E 171 can no longer be considered as safe when used as a food additive.

COMMISSION REGULATION (EU) 2022/63 of 14 January 2022 amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the food additive titanium dioxide (E 171)

THE EUROPEAN COMMISSION, (...)
HAS ADOPTED THIS REGULATION:

Article 1

Annexes II and III to Regulation (EC) No 1333/2008 are amended in accordance with the Annex to this Regulation.

Article 2

Until 7 August 2022, foods produced in accordance with the rules applicable before 7 February 2022 may continue to be placed on the market. After that date, they may remain on the

	<p>market until their date of minimum durability or 'use by' date.</p> <p>Article 3 The Commission shall, following consultation on the European Medicines Agency, review the necessity to maintain titanium dioxide (E 171) or to delete it from the Union list of food additives for the exclusive use as colour in medicinal products in Part B of Annex II to Regulation (EC) No 1333/2008 within three years after the date of entering into force of this Regulation.</p> <p>Article 4 This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.</p> <p>According to said above, Colombia expresses its concern regarding the Scientific Opinion published by EFSA which, consequently, has resulted in the issuance of Regulation 2022/63 by the European Union. In this regard, Colombia respectfully requests to know the position of the Codex Alimentarius Commission on the "Codex General Standard for Food Additives" (GSFA, Codex STAN 192-1995), regarding the decision of the European Union to suspend the use of Titanium Dioxide as a colour additive in foods.</p>
<p>Safe use of additive: Dietary intake assessment (<i>as appropriate</i>)</p>	<p>Table 3 additive:</p> <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below)</p>
<p>Justification that the use does not mislead consumer</p>	<p>N/A</p>

Egypt

I. Allura red AC

THE PROPOSAL IS SUBMITTED BY:		EGYPT	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Allura red AC	
INS Number		129	
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Colour	
PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i>		The proposal for: <input checked="" type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input checked="" type="checkbox"/> 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)
14.1.3.1	Fruit Nectar	GMP	
14.1.3.2	Vegetable Nectar	GMP	
Is the proposal related to a FC with corresponding commodity standards?			
Yes Fruit & Vegetable Nectar			
Is the proposal also intended to revise the products covered by the commodity standards?			
Yes, CXS 247			
EVALUATION BY JECFA:			
Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i>		Evaluation year: 2016 ADI: 0-7 mg/kg bw https://apps.who.int/food-additives-contaminants-jecfa-database/Home/Chemical/2361	
JUSTIFICATION:			
Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i>		Provide better sensorial properties & enhance behavior of product throughout shelf life no matter the nature of the fruit/vegetable.	
Safe use of additive: Dietary intake assessment (as appropriate)		Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below)	
Justification that the use does not mislead consumer		Natural colour	

II. Annatto extracts

THE PROPOSAL IS SUBMITTED BY:		EGYPT	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Annatto extracts	
INS Number		160b	
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Colour	
PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i>		The proposal for: <input checked="" type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input checked="" type="checkbox"/> 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)
14.1.3.1	Fruit Nectar	GMP	
14.1.3.2	Vegetable Nectar	GMP	
Is the proposal related to a FC with corresponding commodity standards? <i>(if yes indicate the relevant FC)</i> Yes Fruit & Vegetable Nectar			
Is the proposal also intended to revise the products covered by the commodity standards? <i>(if yes indicate the relevant commodity standards)</i> Yes, CXS 247			
EVALUATION BY JECFA:			
Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i>		Evaluation year: 2006 ADI: BIXIN: 0-12 mg/kg bw; NORBIXIN AND ITS SODIUM AND POTASSIUM SALT: 0-0.6 mg/kg bw (group ADI, expressed as norbixin) https://apps.who.int/food-additives-contaminants-jecfa-database/Home/Chemical/2706	
JUSTIFICATION:			
Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i>		Provide better sensorial properties & enhance behavior of product throughout shelf life no matter the nature of the fruit/vegetable.	
Safe use of additive: Dietary intake assessment (as appropriate)		Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below)	
Justification that the use does not mislead consumer		Natural colour	

III. Calcium carbonate

THE PROPOSAL IS SUBMITTED BY:	EGYPT
IDENTITY OF THE FOOD ADDITIVE:	
Name of the Additive	Calcium carbonate

As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989			
INS Number		170(i)	
Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989		Colour	
PROPOSED USE(S) OF THE FOOD ADDITIVE (1): The rows below may be copied as many times as needed.		The proposal for: <input checked="" type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input checked="" type="checkbox"/> 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)
14.1.3.1	Fruit Nectar	GMP	
14.1.3.2	Vegetable Nectar	GMP	
Is the proposal related to a FC with corresponding commodity standards? (if yes indicate the relevant FC) Yes Fruit & Vegetable Nectar			
Is the proposal also intended to revise the products covered by the commodity standards? (if yes indicate the relevant commodity standards) Yes, CXS 247			
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: 1965 ADI: NOT LIMITED https://apps.who.int/food-additives-contaminants-jecfa-database/Home/Chemical/457	
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).		Provide better sensorial properties & enhance behavior of product throughout shelf life no matter the nature of the fruit/vegetable.	
Safe use of additive: Dietary intake assessment (as appropriate)		Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below)	
Justification that the use does not mislead consumer		Natural colour	

IV. Caramel

THE PROPOSAL IS SUBMITTED BY:	EGYPT
IDENTITY OF THE FOOD ADDITIVE:	
Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989	<u>caramel colour</u> CAMEL COLOUR, Class I CAMEL COLOUR, Class II CAMEL COLOUR, Class III CAMEL COLOUR, Class IV
INS Number	150a,b,c,d
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:

<i>The rows below may be copied as many times as needed.</i>		<input checked="" type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input checked="" type="checkbox"/> 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)
14.1.3.1	Fruit Nectar	GMP	
14.1.3.2	Vegetable Nectar	GMP	
Is the proposal related to a FC with corresponding commodity standards? (if yes indicate the relevant FC) Yes Fruit & Vegetable Nectar			
Is the proposal also intended to revise the products covered by the commodity standards? (if yes indicate the relevant commodity standards) Yes, CXS 247			
EVALUATION BY JECFA:			
Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i>		https://apps.who.int/food-additives-contaminants-jecfa-database/	
JUSTIFICATION:			
Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i>		Provide better sensorial properties & enhance behavior of product throughout shelf life no matter the nature of the fruit/vegetable.	
Safe use of additive: Dietary intake assessment (as appropriate)		Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below)	
Justification that the use does not mislead consumer		Natural colour	

V. Carmines

THE PROPOSAL IS SUBMITTED BY:		EGYPT	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Carmines	
INS Number		120	
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Colour	
PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i>		The proposal for: <input checked="" type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input checked="" type="checkbox"/> 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	Maximum Use Level (3)	Comments (4)

	Category Name ⁽²⁾		
14.1.3.1	Fruit Nectar	GMP	
14.1.3.2	Vegetable Nectar	GMP	
Is the proposal related to a FC with corresponding commodity standards? (if yes indicate the relevant FC) Yes Fruit & Vegetable Nectar			
Is the proposal also intended to revise the products covered by the commodity standards? (if yes indicate the relevant commodity standards) Yes, CXS 247			
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: 2000 ADI: 0-5 mg/kg bw (1982) https://apps.who.int/food-additives-contaminants-jecfa-database/Home/Chemical/1079	
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).		Provide better sensorial properties & enhance behavior of product throughout shelf life no matter the nature of the fruit/vegetable.	
Safe use of additive: Dietary intake assessment (as appropriate)		Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below)	
Justification that the use does not mislead consumer		Natural colour	

VI. Carotenes, beta

THE PROPOSAL IS SUBMITTED BY:		EGYPT	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989		Carotenes, beta-, vegetable	
INS Number		160a(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 rows below may be copied as many times as needed.		The proposal for: <input checked="" type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input checked="" type="checkbox"/> 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⁾
14.1.3.1	Fruit Nectar	GMP	
14.1.3.2	Vegetable Nectar	GMP	
Is the proposal related to a FC with corresponding commodity standards? (if yes indicate the relevant FC) Yes			

Fruit & Vegetable Nectar	
Is the proposal also intended to revise the products covered by the commodity standards? (if yes indicate the relevant commodity standards) Yes, CXS 247	
EVALUATION BY JECFA:	
Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).	Evaluation year: 1993 ADI: NOT SPECIFIED https://apps.who.int/food-additives-contaminants-jecfa-database/Home/Chemical/1320
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).	Provide better sensorial properties & enhance behavior of product throughout shelf life no matter the nature of the fruit/vegetable.
Safe use of additive: Dietary intake assessment (as appropriate)	Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below)
Justification that the use does not mislead consumer	

VII. Chlorophylls

THE PROPOSAL IS SUBMITTED BY:		EGYPT	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989		Chlorophylls	
INS Number		140	
Functional Class As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989		Colour	
PROPOSED USE(S) OF THE FOOD ADDITIVE (1): The rows below may be copied as many times as needed.		The proposal for: <input checked="" type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input checked="" type="checkbox"/> 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)
14.1.3.1	Fruit Nectar	GMP	
14.1.3.2	Vegetable Nectar	GMP	
Is the proposal related to a FC with corresponding commodity standards? (if yes indicate the relevant FC) Yes Fruit & Vegetable Nectar			
Is the proposal also intended to revise the products covered by the commodity standards? (if yes indicate the relevant commodity standards) Yes, CXS 247			
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: 1969 ADI: NOT LIMITED https://apps.who.int/food-additives-contaminants-jecfa-database/Home/Chemical/369	

JUSTIFICATION:	
Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i>	Provide better sensorial properties & enhance behavior of product throughout shelf life no matter the nature of the fruit/vegetable.
Safe use of additive: Dietary intake assessment <i>(as appropriate)</i>	Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below)
Justification that the use does not mislead consumer	Natural colour

New Zealand

THE PROPOSAL IS SUBMITTED BY:		New Zealand	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Sorbates: Sorbic acid (200) Potassium Sorbate (202) Calcium sorbate (203)	
INS Number		INS 200, 202, 203	
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Preservative	
PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i>		The proposal for: <input type="checkbox"/> a new provision; or <input checked="" type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input type="checkbox"/> 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)
FC 01.6.1	Unripened Cheese	<i>Increase the ML from 1000mg/kg to 3000mg/kg:</i> 4000 mg/kg 3,000 mg/kg	<i>The following Notes have been taken from CRD003 of CCFA52 "Report of the 52nd CCFA's Virtual Working Group on endorsement and alignment" which includes some new Notes proposed out of the alignment work at CCFA52 and which was endorsed by CCFA52 and CAC43, but which have not as of the time of writing been implemented into the GSFA.</i> <i>Remove Note 223 because it becomes redundant if the ML is 3000mg/kg:</i> Note 223: Except for use in products containing added fruits, vegetables, or meats at 3 000 mg/kg <i>Maintain the other Notes:</i> Note 42: As sorbic acid Note H273275: For use in cheese mass only of products conforming to the Standard for Cottage Cheese (CXS 273-1968) and the Standard for Cream Cheese (CXS 275-1973): sorbic acid (INS 200), potassium sorbate (INS 202), calcium sorbate (INS 203). Note J221: For use in cheese mass and the surface treatment of sliced, cut, shredded and grated cheese products conforming to the Group Standard for Unripened Cheese including Fresh Cheese (CXS 221-2001): sorbic acid

			(INS 200), potassium sorbate (INS 202), calcium sorbate (INS 203).
FC 01.6.2	Ripened Cheese	3,000 mg/kg	<p><i>The following Notes have been taken from CRD003 of CCFA52 "Report of the 52nd CCFA's Virtual Working Group on endorsement and alignment" which includes some new Notes proposed out of the alignment work at CCFA52 and which was endorsed by CCFA52 and CAC43, but which have not as of the time of writing been implemented into the GSFA:</i></p> <p><i>Replace Note 457 with a new Note in order to allow the products listed in Note 457 to use sorbates at ML of 3000mg/kg:</i></p> <p>Note 457: Except for use in products conforming to the Standards for Cheddar (CXS 263-1966), Danbo (CXS 264-1966), Edam (CXS 265-1966), Gouda (CXS 266-1966), Havarti (CXS 267-1966), Samsø (CXS 268-1966), Emmental (CXS 269-1967), Tilsiter (CXS 270-1968), Saint-Paulin (CXS 271-1968) and Provolone (CXS 272-1968): at a maximum level of 1000 mg/kg for surface treatment only</p> <p>New Note1: For use in products conforming to the Standards for Cheddar (CXS 263-1966), Danbo (CXS 264-1966), Edam (CXS 265-1966), Gouda (CXS 266-1966), Havarti (CXS 267-1966), Samsø (CXS 268-1966), Emmental (CXS 269-1967), Tilsiter (CXS 270-1968), Saint-Paulin (CXS 271-1968) and Provolone (CXS 272-1968): for surface treatment only</p> <p><i>Delete Note C283 so that the ML is 3000mg/kg even for the products listed in Note C283:</i></p> <p>Note C283: For use in the cheese mass at 3000 mg/kg, and for surface or rind treatment of sliced, cut, shredded or grated cheese only at 1000 mg/kg, for products conforming to the General Standard for Cheese (CXS 283-1978): sorbic acid (INS 200), potassium sorbate (INS 202) and calcium sorbate (INS 203), as sorbic acid.</p> <p><i>Maintain the other Notes:</i></p> <p>Note 42: As sorbic acid</p> <p>Note XS274: Excluding products conforming to the Standard for Coulommiers (CXS 274-1969)</p>

			<p>Note XS276: Excluding products conforming to the Standard for Camembert (CXS 276-1973)</p> <p>Note XS277: Excluding products conforming to the Standard for Brie (CXS 277-1973)</p> <p>Note XS208: Excluding products conforming to the Standard for Cheese in Brine (CODEX STAN 208-1999)</p> <p>Note B278: Except for use in products conforming to the Standard for Extra Hard Grating Cheese (CXS 278-1978): sorbic acid (INS 200), potassium sorbate (INS 202) and calcium sorbate (INS 203), at 1000 mg/kg as sorbic acid in the final product.</p>
<p>Is the proposal related to a FC with corresponding commodity standards? (if yes indicate the relevant FC) Yes. FC 01.6.1, FC 01.6.2, and its subcategories</p>			
<p>Is the proposal also intended to revise the products covered by the commodity standards? (if yes indicate the relevant commodity standards) Yes. Products in the following commodity standards will be affected by the proposed change.</p> <p>FC 01.6.1: CXS 221-2001 Group Standard for Unripened Cheese, including Fresh Cheese CXS 262-2007 Standard for Mozzarella CXS 273-1968 Standard for Cottage Cheese CXS 275-1973 Standard for Cream Cheese CXS 283-1978 Standard for Cheese (unripened, including fresh cheese) –See also CODEX STAN 221-2001</p> <p>FC 01.6.2: CXS 263-1966 Standard for Cheddar CXS 264-1966 Standard for Danbo CXS 265-1966 Standard for Edam CXS 266-1966 Standard for Gouda CXS 267-1966 Standard for Havarti CXS 268-1966 Standard for Samso CXS 269-1967 Standard for Emmental CXS 270-1968 Standard for Tilsiter CXS 271-1968 Standard for Saint Paulin CXS 272-1968 Provolone CXS 283-1978 General Standard for Cheese (ripened, including mould ripened)</p>			
<p>EVALUATION BY JECFA:</p>			

<p>Evaluation by JECFA</p> <p><i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i></p>	<p>Evaluation year: 1973 ADI: 0-25 mg/kg-bodyweight As sum of sorbic acid and calcium, potassium and sodium sorbates (expressed as sorbic acid) Meeting: 17 Specs Code: R (1976) Specification: COMPENDIUM ADDENDUM 12/FNP 52 Add. 12/68 (METALS LIMITS) (2004). FAO JECFA Monographs 1 vol.3/401</p>
<p>JUSTIFICATION:</p>	
<p>Justification for use and technological need</p> <p><i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i></p>	<p>The request is for an increase of the existing ML for sorbates in cheese from 1000mg/kg to 3000mg/kg especially for shredded cheese.</p> <p>The proposed new level harmonises the MLs for sorbates applied as a surface treatment across unripened cheese and ripened cheese, whether they are standardised products or not, and in whichever format (e.g. shredded or not). The current discrepancy where different MLs apply does not relate to food safety considerations.</p> <p>Sorbates provide an important role for preventing mould growth, particularly for shredded cheese. MLs higher than 1000mg/kg are needed to be effective for a variety of reasons:</p> <p>The process of dosing sorbates on to shredded cheese is inherently variable, and in order for all portions of a batch to comply with an ML of 1,000 mg/kg, cheese is underdosed across a batch on average. This leads to other portions of a batch being underdosed to the extent that there is insufficient sorbate to prevent mould growth. This then leads to avoidable food waste.</p> <p>Mould needs oxygen for growth and, if present, is found on the surface of cheese. Shredded cheese requires higher dosage than block cheese due to the increased surface area. All the shred surfaces must be evenly coated with sorbate for sorbate to be effective. Any surfaces without sorbate are at risk of mould growth.</p> <p>While mould growth on a block of cheeses can be easily seen on the surface, mould on shredded cheese is harder to see and isolate, and there is a lot more surface area for growth. Shredded cheese can be contaminated by the shredding process. Mould growth can be disturbed and re-distributed throughout the shred during movement of the bags. Mould grows to high levels before it can be visually seen, and there may be off odours / flavours produced prior to visual spoilage</p> <p>It is common for gas flushed (fresh shred) products manufactured on 'form filled sealing machines' for small pinholes to occur on packaging within the process. The higher sorbate addition helps to minimise mould in these situations.</p> <p>Higher sorbate levels are also needed due to logistical impacts. Higher levels may be needed where the cheese is exported to warmer climates or where logistical movements cannot maintain the cool change as per recommended</p>

	<p>storage instructions. Additionally, due to the number of movements within the supply chain small stress fractures on the packaging can lead to small pin holes occurring allowing oxygen to enter and mould to grow. Again, a higher dosage rate will help minimise the risk.</p> <p>Therefore, it is recommended to increase the ML to 3000mg/kg especially for shredded cheese. A level of 3000mg/kg does not present an appreciable health risk as per the JECFA safety evaluation and the dietary exposure discussed below.</p>
<p>Safe use of additive: Dietary intake assessment (as appropriate)</p>	<p>Table 3 additive:</p> <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below)</p> <p>Dietary exposure to sorbates has been evaluated by Food Standards Australia New Zealand https://www.foodstandards.govt.nz/publications/documents/21st%20ATD%20Study%20report-Aug051.pdf. Highest exposure (as a % of ADI) was for 2–5-year-old males. The high 95th percentile consumers within this group had an intake at 40% of the ADI. Of this group's exposure, 17% came from cheese.</p> <p>Assuming a 16 kg bodyweight (actually for the 2–3-year-old males within this group), and ADI of 25 mg/kg-bodyweight, this allows for a total sorbate intake of 400 mg.</p> <p>Non-cheese foods will account for 83% of 40% of the ADI, i.e. $400 \text{ mg} \times 0.83 \times 0.40 = 132.8 \text{ mg}$. this means that sorbate exposure via cheese would need to be 267.2 mg to reach 100% of the ADI.</p> <p>Because Australian high 95th percentile cheese consumers within the 2–3-year-old population subgroup have a cheese intake of 0.082 kg-cheese/day, the cheese would need to contain $267.2 \text{ mg} \div 0.082 \text{ kg-cheese/day} = 3,258 \text{ mg/kg-cheese}$.</p> <p>Rounding down provides a ML of 3,000 mg/kg-cheese.</p>
<p>Justification that the use does not mislead consumer</p>	<p>The use of one or more of the sorbates as an additive will be labelled in the ingredients list to inform the consumer that it is present.</p> <p>Sorbates are already permitted in unripened and ripened cheeses, so this does not introduce any new additives into these products.</p> <p>Additionally, the use of sorbates is to prevent mould growth (permitted preservative function) rather than to alter the consumer's perception of the product in a way that is misleading.</p>

Peru			
THE PROPOSAL IS PRESENTED BY:		Peru	
FOOD ADDITIVE IDENTIFICATION:			
Name of the food additive <i>According to the list of Class names and the International Numbering System for Food Additives (INS) – CAC/GL 36-1989</i>		Polydimethylsiloxane	
INS number		900a	
Functional Class <i>According to the list of Class names and the International Numbering System for Food Additives (INS) - CAC/GL 36-1989</i>		Antifoaming agent	
PROPOSED USES OF THE ADDITIVE FOOD (¹): <i>The rows listed below can be copied as many times as necessary.</i>		The proposal of <input type="checkbox"/> a new provision; or <input type="checkbox"/> review an existing provision in GSFA tables one and two; or <input type="checkbox"/> review an existing provision in GSFA Table three (move to "Does the proposal also aim to review products covered by product standards?")	
Food Category No. (²)	Food Category Name (²)	Maximum level of use (³)	Comments (⁴)
04.1.2.5	Jams, jellies, marmalades	30 mg/kg in GSFA	Maximum level 10 mg/kg in CXS 296-2009 Standard for jams, jellies, marmalades
Is the proposal related to a food category (FC) with its corresponding product standards? Yes, to the Food Category 04.1.2.5 jams, jellies, marmalades			
Does the proposal also aim to review the products covered by the products standards? <i>(If yes, please indicate the relevant product standards)</i>			
JECFA EVALUATION:			
Evaluation of JECFA <i>Reference to JECFA evaluation (including year and meeting of JECFA evaluation; full ADI (numerical or "unspecified"); specifications monograph).</i>		In the 69th JECFA (2008), published in Monograph 5 (2008) replacing the specifications prepared in the 37th JECFA (1990). A temporary ADI of 0 – 0.8 mg/kg bw was established at the 69th JECFA meeting (2008); and at the 74th JECFA meeting (2011) an ADI of 0-1.5 mg/kg bw published in Monograph 11 (2011) was established.	
JUSTIFICATION:			
Justification for its use and technological need <i>Supporting information based on the criteria set out in Section 3.2 of the Preamble to the General Standard for Food Additives (i.e., it offers some advantage, does not present appreciable risks to consumer health, plays a technological role).</i>		Section 3.2 Criterion. From the GSFA Preamble: Increase the preservation quality or stability of a food. The use of an antifoaming agent in food is safe since it reduces the amount of foam in the product (food), in the case of jams, jellies (because it is a relatively prolonged cooking process of fruit and sugar release effect of vegetable protein, antifoaming agents are therefore necessary.	
Safe use of the additive: assessment of food intake (as applicable) NOT APPLICABLE		Table three additives: <input type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on food intake assessment)	
Justification that the use is not misleading to the consumer		The use of antifoaming agents in this category of food helps the quality of preservation or stability of the food so it can not be considered as deception to the consumer.	

Senegal

THE PROPOSAL IS SUBMITTED BY:		SENEGAL	
IDENTITY OF THE FOOD ADDITIVE: BASIC METHACRYLATE COPOLYMER (BMC)			
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		INS n°. 1205	
INS Number		1205	
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		CARRIER-ENCAPSULATING GLAZING AGENT INS 1205	
PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i>		The proposal for: <input checked="" type="checkbox"/> a new provision; or <input checked="" type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input checked="" type="checkbox"/> 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)
FC 06.1	Whole, Broken or Flaked Grain Including Rice	GMP	
FC 11.1.1	White Sugar	GMP	
FC 11.2	Brown Sugar, Excluding Products of Fc 11.1.3	GMP	
FC 11.1.2	Powdered Sugar – Powdered Dextrose	GMP	
Is the proposal related to a FC with corresponding commodity standards? <i>(if yes indicate the relevant FC)</i> NO			
Is the proposal also intended to revise the products covered by the commodity standards? <i>(if yes indicate the relevant commodity standards)</i> NO			
EVALUATION BY JECFA:		YES	
Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i>		BMC MONOGRAPH 22 (2018) CAS number 24938-16-17 INS number 1205	
JUSTIFICATION:			
Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i>		Fortification of sugar and rice (staple foods in Senegal and developing countries) to reduce micronutrients deficiencies in population. BMC will be used to encapsulate the micronutrients.	
Safe use of additive: Dietary intake assessment (as appropriate) ADI not specified		Table 3 additive: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below)	
Justification that the use does not mislead consumer		ADI not specified	

FoodDrinkEurope

THE PROPOSAL IS SUBMITTED BY:		FoodDrinkEurope	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Polyglycerol Esters of Interesterified Ricinoleic Acid	
INS Number		INS 476	
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Emulsifier	
PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i>		<p>The proposal for:</p> <p><input type="checkbox"/> a new provision; or</p> <p><input checked="" type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or</p> <p><input type="checkbox"/> revising an existing provision in Table 3 of the GSFA (skip to "Is the proposal intended to revise products covered by the commodity standard").</p>	
Food Category No. (2)	Food Category Name (2)	Maximum Use Level (3)	Comments (4)
12.6.1	Emulsified sauces and dips (e.g. mayonnaise, salad dressing, onion dip)	5,000 mg/kg 8,000 mg/kg (only emulsified sauces and dips with > 20% fat content)	Not applicable
Is the proposal related to a FC with corresponding commodity standards? <i>(if yes indicate the relevant FC)</i> No			
Is the proposal also intended to revise the products covered by the commodity standards? <i>(if yes indicate the relevant commodity standards)</i> No			
EVALUATION BY JECFA:			
Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i>		<p>Evaluation year: 1973</p> <p>ADI: 0 – 7.5 mg/kg bw</p> <p>Meeting: 17</p> <p>Report: NMRS 53/TRS 539-JECFA 17/20</p> <p>Tox Monograph: FAS 6/NMRS 53A-JECFA 17/246</p> <p>Specification: COMPENDIUM ADDENDUM 8/FNP 52 Add. 8/203 (METALS LIMITS) (2000). R; FAO JECFA Monographs 1 vol. 3/79</p>	
JUSTIFICATION:			
Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable</i>		INS 476 (PGPR) is known to be an excellent emulsifier that allows the production of lower fat emulsified sauces with improved sensory properties. Reducing the oil levels of emulsified sauces and dips can contribute to reduced fat intake of consumers.	

<i>health risk, serves a technological function).</i>	PGPR (E 476) has been evaluated by the European Food Safety Authority in 2017, with a new ADI being set at max. 25 mg/kg bw/d.
Safe use of additive: Dietary intake assessment (<i>as appropriate</i>)	<p>Table 3 additive:</p> <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below)</p> <p>A detailed exposure assessment has been undertaken using recent individual food consumption data from the United Kingdom (National Diet and Nutrition Survey (UK NDNS)) and Latin America - Brazil (Inquéritos Nacionais de Alimentação (INA)), and data from model diets from Europe (the European Food Safety Authority (EFSA) Comprehensive Food Consumption Database) and from global diets (the FAO/WHO Chronic Individual Food Consumption database – Summary statistics, CIFOcOss).</p> <p>Two scenarios of exposure were evaluated using these food consumption survey data. The first scenario considered all uses of INS 476 in line with the uses and use levels specified in the GSFA - the 'baseline' scenario. The second scenario considered the existing uses along with the proposed modification to the use of INS 476 in food category 12.6.1 described above – the 'modified' scenario. From the intake assessments conducted, the proposed modification to the use of INS 476 in food category 12.6.1 had little effect on exposure across all population groups examined (i.e., <7% increase in mean and 95th percentile intakes in the UK and Brazil, ≤ 10% increase in the EFSA Comprehensive database, and <2% increase in the CIFOcOss global diets).</p>
Justification that the use does not mislead consumer	<p>When PGPR is used as a technical additive, the consumer will be informed of its presence by its declaration in the product ingredients list, as per 4.2.1.2 of the <i>General Standard for the Labelling of Prepacked Foods (CXS 1-1985)</i>.</p> <p>In addition, many countries have standardized the most common product from FC 12.6.1, which is mayonnaise. As such, there will never be confusion between the regular product and the oil-reduced version containing PGPR, because the resulting reduction in total fat will no longer allow using the legal denomination of the standardized food.</p>

FIVS (Fédération internationale des vins et spiritueux)

By way of background, FIVS is a global trade federation for the alcohol beverage industry since 1951, and a Codex Observer. We are committed to providing a venue and developing tools to encourage social, environmental, and economic sustainability among our members and the wider sector, in keeping with the United Nations Sustainable Development Goals. Our membership includes producers, importers, exporters, and trade associations (currently accounting for 75% of the wine traded globally). We also welcome and collaborate effectively with affiliates from allied industries.

Please find attached our proposal for the inclusion of potassium polyaspartate in the GSFA as a new additive for winemaking.

THE PROPOSAL IS SUBMITTED BY:		FIVS	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive <i>As listed in Glass Names and the International Numbering System (JNS) - CACIGL 36-1989</i>		Potassium polyaspartate	
INS Number		456	
Functional Class <i>As listed in Glass Names and the International Numbering System (INS) - CACIGL 36-1989</i>		Stabilizer	
PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i> Stabilizer against tartrate crystal precipitation in wine		The proposal for: a new provision; or <input type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input type="checkbox"/> 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)
		300 mg/L in wine	100 mg/L in wine,
			in countries that follow
			the OIV indications
Is the proposal related to a FC with corresponding commodity standards? Not <i>(if yes indicate the relevant FC)</i>			
Is the proposal also intended to revise the products covered by the commodity standards? Not <i>(if yes indicate the relevant commodity standards)</i>			
EVALUATION BY JECFA:			
Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full AD/ (numerical or "not specified; specifications monograph).</i>		JECFA 87th meeting, 2019. Full specifications designated into FAO JECFA monograph 23	
JUSTIFICATION:			
Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e., has an advantage, does not present an appreciable health risk, serves a technological/ function).</i>		Serves a technological function (wine tartrate crystal stabilizer)	
Safe use of additive: Dietary intake assessment (as appropriate) www.efsa.europa.eu/efsajournal EFSA Journal 2016; 14(3):4435		Table 3 additive: i;a Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below)	
Justification that the use does not mislead consumer		Effective stabilizing agent that preserves the original wine composition.	

IADSA

THE PROPOSAL IS SUBMITTED BY:		International Alliance of Dietary/Food supplement Associations(IADSA)	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		AZORUBINE (CARMOISINE)	
INS Number		INS 122	
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Colour	
PROPOSED USE(S) OF THE FOOD ADDITIVE (¹): <i>The rows below may be copied as many times as needed.</i>		The proposal for: <input type="checkbox"/> a new provision; or <input checked="" type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input type="checkbox"/> 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)
13.6	Food Supplements	300 mg/kg	Note B6 For use in solid forms as sold to the consumer only. & Note B7 Except for use at 100 mg/kg in liquid forms as sold to the consumer only. Proposed revision: Inclusion of a New Note in addition to B6 & B7 : "Except for use at 1100mg/kg in effervescent forms as sold to the consumer only"
Is the proposal related to a FC with corresponding commodity standards? No			
Is the proposal also intended to revise the products covered by the commodity standards? No			
EVALUATION BY JECFA:			
Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i>		Year: 1983 Meeting 27 th (Geneva, 1983) ADI: 0-4 mg/kg bw Monograph: https://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/Additive-050.pdf	

	Specification: Compendium Addendum 10/FNP 52 Add.10/34 (Metals Limits) (2002); FAO JECFA Monographs 1 Vol.1/137
JUSTIFICATION:	
<p>Justification for use and technological need</p> <p><i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i></p>	<p><u>Technical needs</u></p> <p>Effervescent forms are solid forms sold to the consumer that are intended to be dissolved in a specific amount of liquid prior to consumption following the manufacturers' instructions.</p> <p>AZORUBINE (CARMOISINE) (INS122) is used as a colour in food supplements in effervescent tablet forms at levels up to 1100 mg/kg in the solid forms as sold to the consumers, corresponding to 36 mg/kg in the liquid form prior to consumption (1 effervescent tablet of 6.5g - corresponding to 7.15 mg of AZORUBINE - to be dissolved in a glass of water of 200 ml)</p> <p>In effervescent forms, AZORUBINE (CARMOISINE) (INS122) is used:</p> <ul style="list-style-type: none"> • To make the preparation more uniform in the tablet, • To colour the water quickly and ensure that visual interest generated during the effervescent reaction is not lost in the liquid form, and • To match the flavour in the liquid after the dissolution of the effervescent tablet. <p>It was clarified at the 52nd Session of CCFA (2021), that provisions for colours in FC13.6 apply to the forms as sold to consumers only.</p> <p>The inclusion of the new Note below for effervescent forms associated with AZORUBINE (CARMOISINE) (INS 122) is therefore required for the additive to perform its technological function in the food supplement ready for consumption, after the dissolution of the effervescent tablet in the liquid. Proposed New Note: "except for use at 1100mg/kg in effervescent forms as sold to the consumer only"</p>
<p>Safe use of additive: Dietary intake assessment (as appropriate)</p>	<p>Table 3 additive:</p> <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below)</p> <p>At the 52nd Session of CCFA (2021), provisions for AZORUBINE (CARMOISINE) (INS 122) were adopted in FC13.6 at a maximum level of 300 mg/kg in solid forms as sold to the consumer only (Note B6) and 100 mg/kg in liquid forms as sold to the consumer only (Note B7).</p>

	<p>Effervescent forms are solid forms sold to the consumer that are intended to be dissolved in a specific amount of liquid prior to consumption.</p> <p>36 mg/kg in the liquid form (prior to consumption following the dissolution of the effervescent form) is required to achieve the technical needs. This is equivalent to:</p> <ul style="list-style-type: none"> 36% of the ML adopted by CAC44 for liquid forms as sold to the consumer, corresponding to a ML of 1100 mg/kg in the solid form as sold to the consumer only.
Justification that the use does not mislead consumer	<p>The use of AZORUBINE (CARMOISINE) (INS122) fulfills the conditions listed in section 3.2.</p> <p>The use of AZORUBINE (CARMOISINE) (INS122) as a food additive would be indicated on the label of the food supplement together with the conditions of use to permit the dissolution of the effervescent form. The use of this colour would not affect the quality of the food supplement that would be expected by consumers.</p>

IFAC (International Food Additives Council)

IFAC is a global association representing manufacturers and end-users of food additives. IFAC has NGO Observer status before Codex Alimentarius and appreciates the opportunity to provide the following information.

IFAC is requesting that CCFA revise the food additive provisions for dimethyl dicarbonate (INS 242) to include the following Food Categories: FC 14.1.2 (Fruit and vegetable juices) and FC 14.1.3 (Fruit and vegetable nectars). Please find the enclosed Annex 1 containing the additional requested information. Thank you for your consideration. If you have any questions, please contact me.

THE PROPOSAL IS SUBMITTED BY:		International Food Additives Council (IFAC), 529 14 th Street NW, Suite 1280, Washington, DC 20045, USA	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) – CAC/GL 36-1989</i>		Dimethyl dicarbonate (DMDC)	
INS Number		242	
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Preservative	
PROPOSED USE(S) OF THE FOOD ADDITIVE <i>(¹): The rows below may be copied as many times as needed.</i>		<p>The proposal for:</p> <p><input checked="" type="checkbox"/> a new provision; or</p> <p><input type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or</p> <p><input type="checkbox"/> revising an existing provision in Table 3 of the GSFA (skip to “Is the proposal intended to revise products covered by the commodity standard”).</p>	
Food Category No. (²)	Food Category Name (²)	Maximum Use Level (³)	Comments (⁴)
14.1.2	Fruit and vegetables juices	250 mg/kg	Subject to national legislation of the importing country.

14.1.3	Fruit and vegetable nectars	250 mg/kg	Subject to national legislation of the importing country.
Is the proposal related to a FC with corresponding commodity standards? Yes <i>(if yes indicate the relevant FC)</i> FCs 14.1.2.1, 14.1.2.3, 14.1.3.1 and 14.1.3.3			
Is the proposal also intended to revise the products covered by the commodity standards? Yes <i>(if yes indicate the relevant commodity standards)</i> General Standard for Fruit Juices and Nectars (CXS 247-2005)			
VALUATION BY JECFA:			
Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i>		Evaluation year: 1990 ADI: Not specified Comments: Acceptable for use as a cold sterilization agent in beverages when used according to good manufacturing practice up to a maximum concentration of 250 mg/l Meeting: 37 Specs Code: N Report: TRS 806-JECFA 37/23 Tox Monograph: FAS 28-JECFA 37/231 Specification: COMPENDIUM ADDENDUM 12/FNP 52 Add. 12/67 (METALS LIMITS) (2004). R; FAO JECFA Monographs 1 vol.1/473 Previous Years: 1990, COMPENDIUM/515. N	
JUSTIFICATION:			
Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i>		DMDC is used as a microbial control agent and/or processing aid in non-alcoholic beverages and wine, according to national legislation. DMDC is added to the beverage package (such as bottle or can) before the filling process. The mode of action is to penetrate the cells of microorganisms and inactivating some of the key enzymes required for cell function. Excess DMDC hydrolyses in the presence of water to form small amounts of methanol and carbon dioxide, which are common constituents of beverages. DMDC protects beverages during the sensitive processing step of filling and hence, prolongs the shelf life of beverages without imparting flavor or color of the product. The use of DMDC is safe for human consumption according the proposed uses.	
Safe use of additive: Dietary intake assessment (as appropriate)		Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below) Current exposure estimates based on U.S. National Health and Nutrition Examination Survey (NHANES) and the European Food Safety Authority's (EFSA) Comprehensive European Food Consumption Database.	
Justification that the use does not mislead consumer		DMDC is used as a cold sterilizing agent during filling. Any excess DMDC is hydrolysed to carbon dioxide and methanol, thus DMDC is not present in the final beverage and several countries have decided to recognize DMDC as a processing aid. If a country has the need to label DMDC in the ingredient list this is possible based on the food additive status, but this may mislead the consumer as DMDC is not present in the finished product and no longer provides any preserving properties.	

NATCOL (Natural Food Colours Association)

The Natural Food Colours Association (NATCOL) appreciates the opportunity to submit a proposal for the inclusion of Riboflavin from *Ashbya gossypii* in the food additive group RIBOFLAVINS and the addition of RIBOFLAVINS to Table 3 of the GSFA. Both requests are based on the result of the 92nd JECFA.

To this end, please find enclosed Annex I of CL 2021/55-FA duly completed.

NATCOL is an international organization acting on behalf of the natural food colour industry and as observer, it is submitting this proposal for consideration at the CCFA53 meeting.

We are ready to answer questions and provide additional information as requested to meet GSFA's requirements.

THE PROPOSAL IS SUBMITTED BY:	Natural Food Colours Association (NATCOL)
IDENTITY OF THE FOOD ADDITIVE:	
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>	RIBOFLAVINS group: Riboflavin, synthetic Riboflavin 5'-phosphate sodium Riboflavin from <i>Bacillus subtilis</i> and Riboflavin from <i>Ashbya gossypii</i> (new; should be included in the group RIBOFLAVINS based on 92 nd JECFA)
INS Number	Riboflavin, synthetic INS 101(i) Riboflavin 5'-phosphate sodium INS 101(ii) Riboflavin from <i>Bacillus subtilis</i> INS 101(iii) Riboflavin from <i>Ashbya gossypii</i> INS 101(iv)
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>	Functional class "Colour" and technological purpose "colour"
PROPOSED USE(S) OF THE FOOD ADDITIVE (¹): <i>The rows below may be copied as many times as needed.</i>	<p>The proposal for: <input checked="" type="checkbox"/> a new provision; or <input checked="" type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or <input type="checkbox"/> revising an existing provision in Table 3 of the GSFA (skip to "Is the proposal intended to revise products covered by the commodity standard").</p> <p>Comment: Firstly: We propose inclusion of Riboflavin from <i>Ashbya gossypii</i> in the food additive group RIBOFLAVINS based on 92nd JECFA).</p> <p>Secondly: We propose based on 92nd JECFA, RIBOFLAVINS can be added to Table 3 of the GSFA. Meaning, that existing provisions for RIBOFLAVINS in Tables 1 and 2 would then either need to be discontinued (because covered via Table 3 if RIBOFLAVINS get listed in Table 3) or maintained unchanged in Table 1 and 2 provided respective food categories are not covered by Table 3 (i.e. those listed in the Annex to Table 3). Within Table 3, in column 5 (specific allowance in certain commodity standards), all those commodity standards would need to be added to that column where the commodity standard specifically allows RIBOFLAVINS. This means no change in any Commodity Standard as such, except indirectly for those that allow the technical class of colours per se.</p>

		<p>In a nutshell: Proposal is</p> <ul style="list-style-type: none"> - inclusion of Riboflavin from <i>Ashbya gossypii</i> in the food additive group RIBOFLAVINS based on 92nd JECFA - and inclusion of RIBOFLAVINS in Table 3 and adjustment of all other relevant provisions in the GSFA implied by that addition. The proposal otherwise aims at keeping the status quo of presently permitted RIBOFLAVIN uses in the GSFA. 	
Food Category No. (2)	Food Category Name (2)	Maximum Use Level (3)	Comments (4)
All Food categories covered by Table 3 GSFA	Riboflavin, synthetic, Riboflavin 5'-phosphate sodium, Riboflavin from <i>Bacillus subtilis</i> and Riboflavin from <i>Ashbya gossypii</i> Food categories-covered by Table 3 GSFA	GMP	ADI "not specified"
Table 1 and 2	<p>For all those food categories in Table 1 and 2 for which the use of Riboflavin, synthetic, Riboflavin 5'-phosphate sodium and Riboflavin from <i>Bacillus subtilis</i> is presently permitted and which are eligible for coverage via Table 3 upon inclusion of the RIBOFLAVINS group in Table 3, need be discontinued in Table 1 and 2. This concern 57 food categories. An overview of the 57 food categories is available and can be shared with the Committee.</p> <p>Those food categories that are not eligible for coverage via Table 3, and thus need remain in Table 1 and 2 as is and add for Riboflavin from <i>Ashbya gossypii</i> are listed in the following (12 food categories):</p>		
04.1.1.2	Surface-treated fresh fruit	300 mg/kg Notes 4 and 16	Existing Riboflavin, synthetic, Riboflavin-5'-phosphate sodium and Riboflavin from <i>Bacillus subtilis</i> provision in Table 1 and 2 but not covered by Table 3 should be kept
04.2.1.2	Surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	300 mg/kg Notes 4 and 16	Existing Riboflavin, synthetic, Riboflavin-5'-phosphate sodium and Riboflavin from <i>Bacillus subtilis</i> provision in Table 1 and 2 but not covered by Table 3 should be kept
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed products, excluding fermented soybean products of food categories 06.8.6, 06.8.7, 12.9.1, 12.9.2.1 and 12.9.2.3	500 mg/kg	Existing Riboflavin, synthetic, Riboflavin-5'-phosphate sodium and Riboflavin from <i>Bacillus subtilis</i> provision in Table 1 and 2 but not covered by Table 3 should be kept
09.2.1	Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	1000 mg/kg Notes 95, XS36, XS92, XS95, XS165, XS190, XS191, XS292, XS312, XS315	Existing Riboflavin, synthetic, Riboflavin-5'-phosphate sodium and Riboflavin from <i>Bacillus subtilis</i> provision in Table 1 and 2 but not covered by Table 3 should be kept

09.2.2	Frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	300 mg/kg Notes 16, XS166	Existing Riboflavin, synthetic, Riboflavin-5'-phosphate sodium and Riboflavin from Bacillus subtilis provision in Table 1 and 2 but not covered by Table 3 should be kept
09.2.3	Frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	300 mg/kg Note 16	Existing Riboflavin, synthetic, Riboflavin-5'-phosphate sodium and Riboflavin from Bacillus subtilis provision in Table 1 and 2 but not covered by Table 3 should be kept
09.2.4.1	Cooked fish and fish products	300 mg/kg Note 95	Existing Riboflavin, synthetic, Riboflavin-5'-phosphate sodium and Riboflavin from Bacillus subtilis provision in Table 1 and 2 but not covered by Table 3 should be kept
09.2.4.2	Cooked mollusks, crustaceans, and echinoderms	300 mg/kg	Existing Riboflavin, synthetic, Riboflavin-5'-phosphate sodium and Riboflavin from Bacillus subtilis provision in Table 1 and 2 but not covered by Table 3 should be kept
09.2.4.3	Fried fish and fish products, including mollusks, crustaceans, and echinoderms	300 mg/kg Note 16	Existing Riboflavin, synthetic, Riboflavin-5'-phosphate sodium and Riboflavin from Bacillus subtilis provision in Table 1 and 2 but not covered by Table 3 should be kept
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	300 mg/kg Notes 22, XS167, XS189, XS222, XS236, XS244, XS311	Existing Riboflavin, synthetic, Riboflavin-5'-phosphate sodium and Riboflavin from Bacillus subtilis provision in Table 1 and 2 but not covered by Table 3 should be kept
10.1	Fresh eggs	300 mg/kg Note 4	Existing Riboflavin, synthetic, Riboflavin-5'-phosphate sodium and Riboflavin from Bacillus subtilis provision in Table 1 and 2 but not covered by Table 3 should be kept
11.3	Sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products of food category 11.1.3	300 mg/kg	Existing Riboflavin, synthetic, Riboflavin-5'-phosphate sodium and Riboflavin from Bacillus subtilis provision in Table 1 and 2 but not covered by Table 3 should be kept

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

(if yes indicate the relevant FC)

Yes, those Commodity Standards that presently permit RIBOFLAVINS specifically, should be listed in column 5 of Table 3 according to presently applied Table 3 rules. All other remaining Commodity Standards either allow no colour use at all, allow colours per se, or permit only colours other than RIBOFLAVINS. The proposal would thus not change any provisions in existing Commodity standards.

<p>Is the proposal also intended to revise the products covered by the commodity standards? (if yes indicate the relevant commodity standards) No.</p>	
<p>EVALUATION BY JECFA:</p>	
<p>Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or “not specified”); specifications monograph).</p>	<p>92nd JECFA session 2021 (WHO Food Additives Series 83 and WHO TRS 1037): “The Committee at its present meeting noted that the toxicity database on riboflavin from various sources reviewed previously by the Committee does not indicate any adverse effects. The Committee at its present meeting established a group ADI “not specified” for riboflavin, riboflavin-5´-phosphate, riboflavin from <i>B. subtilis</i> and riboflavin from <i>A. gossypii</i> and withdrew the previous group ADI of 0–0.5 mg/kg bw. A toxicological and a dietary exposure monograph was prepared. New specifications and a Chemical and Technical Assessment were prepared.” Specifications/Monographs: Riboflavin, synthetic FAO JECFA Monograph 1 (2006) Riboflavin 5´-phosphate sodium FAO JECFA Monograph 1 (2006) Riboflavin from <i>Bacillus subtilis</i> FAO JECFA Monograph 1 (2006) Riboflavin from <i>Ashbya gossypii</i> FAO JECFA Monograph 27 (2021)</p>
<p>JUSTIFICATION:</p>	
<p>Justification for use and technological need Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</p>	<p>Riboflavins serve a technological function by adding or restoring colour to a food. Its yellowish to orange-yellowish colour hue is unique and suitable to supplement the colour spectrum achievable with other colours. Riboflavins do not present any appreciable health risk to consumers. The 2021 JECFA safety assessment of the substance at the Committees 92nd session, which included dietary exposure, concluded on an ADI “not specified” for this colour. It shall be used under conditions of good manufacturing practice (GMP) stated in Section 3.3 of the Preamble of the General Standard for Food Additives. RIBOFLAVINS are presently already permitted in the GSFA in numerous food categories in Table 1 and 2.</p>
<p>Safe use of additive: Dietary intake assessment (as appropriate)</p>	<p>Table 3 additive: X Yes -> ADI “not specified” <input type="checkbox"/> No (Please provide information on dietary intake assessment below)</p>
<p>Justification that the use does not mislead consumer</p>	<p>Riboflavins are intended to be used in line with the food colour definition in CAC/GL 36-1989. Food categories where colour use could be misleading to consumers, for example fluid buttermilk (plain), fats and oils essentially free from water, fresh fruit, fresh/dried pastas and noodles and like products to name a few, are excluded from Riboflavins colour use, see Annex to Table 3 GSFA. In addition, Riboflavins shall be used under conditions of good manufacturing practice (GMP) as defined in Section 3.3 of the Preamble of the GSFA. It is also noted that RIBOFLAVINS are already permitted in numerous food categories in Table 1 and 2.</p>