

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



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Agenda Item 5b

CX/FA 19/51/8  
January 2019

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**  
**CODEX COMMITTEE ON FOOD ADDITIVES**  
**Fifty-first Session**  
**GENERAL STANDARD FOR FOOD ADDITIVES (GSFA)**

**PROPOSALS FOR NEW AND/OR REVISION OF FOOD ADDITIVE PROVISIONS**

Replies to CL 2018/27-FA of Brazil, China, Japan, Senegal, EFEMA, EU Specialty Food Ingredients and ICGMA

Brazil

<b>THE PROPOSAL IS SUBMITTED BY:</b>		Brazil		
<b>IDENTITY OF THE FOOD ADDITIVE:</b>				
<b>Name of the Additive</b> <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Annatto extracts, bixin-based		
<b>INS Number</b>		160b(i)		
<b>Functional Class</b> <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Colour		
<b>PROPOSED USE(S) OF THE FOOD ADDITIVE:</b> <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").		
<b>Food Category No.</b>	<b>Food Category Name</b>	<b>Maximum Level (')</b>	<b>Use</b>	<b>Comments</b>
12.2.2	Seasonings and condiments	600 ppm		Annatto extract provides the red or orange color, depending on the amount used. It does not provide flavour or taste to the product, which is an important advantage of this colour.
<b>EVALUATION BY JECFA:</b>				
<b>Evaluation by JECFA</b> <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not</i>	The 67 <sup>th</sup> JECFA (2006) established new ADI for bixin: ADI of 0-12 mg/kg b.w., with the exception of oil-processed bixin. Specification monograph for annatto extracts (solvent-extracted bixin) (INS 160b(i)) was published in the 80 <sup>th</sup> JECFA meeting report.			

specified"); specifications monograph).	
<b>JUSTIFICATION:</b>	
<p><b>Justification for use and technological need</b> <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>This request is for food category 12.2.2 (Seasonings and condiments) of the Codex Stan 192-1995 (General Standard for Food Additives), to allow more possibilities of products development, considering the biggest advantage of annatto extracts: to provide color (red or orange) without changing the flavor, an important advantage over other colours. Furthermore, it is one of the most commonly used natural colour in the food industry.</p> <p>For the category of seasoning and condiments, the color requirement is very important for consumers. It is important to highlight that the use of this type of product is in "dilution", that is, the consumer will not consume the product (seasoning/condiment) in the form in which it is available for sale, but will consume through addition in culinary preparations.</p> <p>The annatto is a Brazilian natural raw material widely used in the Northeast region of the country, mainly as an ingredient to improve the coloring of homemade culinary preparations.</p> <p>In this region of the country, mainly because the culture and eating habits, the color is an attribute of extreme importance and that influences in the sensorial perception of the culinary preparations.</p> <p>As in this region it is common the consumption of preparations with strong and spicy flavors, so dark/intense colors are required for a complete sensorial acceptance of the product.</p> <p>In this region, predominantly, but also in other regions of Brazil, it is very common to use a typical Brazilian product called "colorific" (product made by mixing corn flour, cassava flour, annatto extract (bixin-based) and oil, added with salt and edible oils or not).</p> <p>This product (colorific) is sold directly to the consumer in Brazil, and its use does not have a maximum limit established by Brazilian legislation.</p> <p>Thus, in Brazil, prepared seasonings/condiments <b>provide adequate and desired</b> flavors (strong/spicy) for preparations, <b>but do not give proportional (and expected) color for sensory acceptance</b>. So, together with the seasoning/condiment, consumers add "colorific" directly in the preparations, to complement the color that seasonings/condiments cannot achieve by the currently approved limit in legislation for this food category (100 ppm).</p> <p>Therefore, we understand that the best way to manage the risk of bixin consumption is to avoid the use of colorific added to the preparations by consumers, and providing its proper use as food additive.</p> <p>For this, we need appropriate limits of use in seasonings/condiments that comply with the technological needs, to provide products that suit the Brazilians consumer habits.</p>
<p><b>Safe use of additive: Dietary intake assessment</b> (as appropriate)</p>	<p>During its sixty-first meeting, the Committee performed an assessment of dietary exposure based on typical use levels (provided by industry) of extracts expressed as bixin and norbixin. Combining those levels with various average levels of food consumption resulted in dietary exposures ranging from 0.03 to 0.4 mg/day. Combining the use levels reported by industry with 97.5th percentiles of consumption by United Kingdom (UK) consumers of foods potentially containing annatto resulted in a dietary exposure of 1.5 mg/day of total bixin plus norbixin.</p> <p>If all the pigment ingested were bixin, the estimated dietary exposure of 1.5 mg/day would result in an intake of bixin of 26 µg/kg b.w. per day, corresponding to approximately 0.2% of the ADI (0–12 mg/kg b.w). (WHO FAS 58, 67th JECFA Meeting; WHO Technical Report Series 940, 67th Report JECFA).</p> <p>Some simulations were done in order to verify the impact that the proposed 600 ppm limit would have on the IDA.</p>

For example, considering a hypothetical situation in which a person eats 10 g of a seasoning/condiment containing 600 ppm of annatto extracts (bixin-based) daily. This consumption will provide an ingestion of 6 mg of annatto extracts (bixin-based) per day. This amount of seasoning/condiment prepares 8 portions of food, considering the manufacturer instructions (5 g of seasoning/condiment to prepare 400 g of food, or 4 servings).

Thus, considering the ADI established by JECFA of 12 mg/kg b.w. for bixin and a 60 kg consumer, the ingestion of 10 g of seasoning/condiment containing 600 ppm of annatto extract (bixin-based) will contribute with 0.8% of the ADI.

In the table below we show the acceptable daily intake of bixin, considering different body weights, and their respective contribution to ADI (%):

Body Weight (kg)	15	60
Acceptable Daily Intake (mg) of bixin considering the body weight	180	720
With the consumption of 10 g of seasoning/condiment with 600 ppm of annatto extract (bixin-based), the percentage of ADI of bixin that would be reached by consuming this product would be:	3,33	0,83

According to the data in Table 1.1 of the Brazilian Household Budget Survey 2008-2009 (POF, 2008) (Average food consumption per capita and percentage of consumption outside the household in relation to the total consumed, by sex, according to food), the food consumption average per capita in the category "sauces and condiments" is 0.5 g/day and the highest consumption observed is for men (0.7 g/day) and lower in women (0.3 g/day).

Even if we consider that all the consumption of 0.7g/day was only of seasonings/condiments containing 600 ppm of annatto extract (bixin-based) we would have the following situation:

Body Weight (kg)	15	60
Acceptable Daily Intake (mg) of bixin considering the body weight	180	720
With the consumption of 0.7 g of seasoning/condiment with 600 ppm of annatto extract (bixin-based), the percentage of ADI of bixin that would be reached by consuming this product would be:	0,233	0,058

At the 61<sup>st</sup> meeting (2006), through the data reported to JECFA, it was estimated a daily intake of 1.5 mg/day that resulted in an intake of bixin of 26 µg/kg b.w./day, corresponding approximately 0.2% of the ADI (0-12 mg / kg b.w.).

World production of annatto was estimated at 14,500 tons at the time of the preparation of Chemical and Technical Assessments (CTA), prepared by JECFA at 67th meeting.

Table 1. Estimated World Production (in Metric Tonnes) of Annatto seed\*

PRODUCERS		IMPORTERS	
Brazil	5,000	(either as seed or its equivalent in extract)	
Peru			
Ecuador		North America	3,000
Colombia		Europe	2,500
Bolivia	3,000	Japan	1,500
		Other	500
Kenya		Total	7,500
Tanzania	2,500		
Guatemala			
Mexico			
Caribbean	2,000		
Ivory Coast			
Ghana	1,500		
India, Asia	500		
Total	14,500		
Of which:			
Domestic consumption**	7,000		
Available for export	7,500		
	14,500		

\* Adapted from UNCTAD / GATT (1990), Wood *et al.* (1991), Green *et al.* (1995) and Dinesen (1999).

\*\* within the producer countries.

If we consider the current data on annual annatto production, we have:

- Brazil: 12,000 tons ~ 57% of world production
- Peru: 6,000 tons ~ 31%
- Ivory Coast and Ghana: 5,000 tons
- Kenya: 2,000 tons
- Guatemala: 1,500 tons
- Dominican Republic: 900 tons
- Bolivia: 500 tons
- Ecuador: 400 tons
- India: 300 tons
- Mexico: 200 tons

World production estimate (2015): 21,052 tons/year

*Brazil is responsible for 57% of world annatto production this year, estimated at between 10,000 t and 12,000 t annually (but has already reached 16,000 t). "The harvest of 2015 will not be enough to meet the demand of the Brazilian industries, which will have to import the product," predicts Eliane. According to her, other important world producers are Peru with 31% (6,000 t), Ivory Coast and Ghana (5,000 t), Kenya (2,000 t), Guatemala (1,500 t), Dominican Republic, Ecuador (400 t), India (300 t) and Mexico (200 t)".*

Site news: <http://www.sna.agr.br/demanda-por-corantes-naturais-aquece-mercado-brasileiro-de-urucum/>

Source of data used in the news: Instituto Agronômico de Campinas (IAC)

Thus, we observed that, in 2015, there was an increase around 50% of the world production of annatto in relation to the data reported in the CTA.

Considering that all this additional world production of annatto was directed to the food industry (overestimation) and making a correlation with the intake estimation made by JECFA in 2006, currently, the daily intake of annatto extract (bixin-based) would correspond to 0.4% of ADI (0-12 mg/kg b.w).

In 1998, a study carried out in Brazil about national intake of bixin, evaluated the consumption of annatto in the Northeast, the region that presents the highest consumption of annatto through the "colorific" product. The study demonstrated a

daily intake of bixin (by the amount of the annatto additive available on the market) from 0.14 mg/kg b.w. to a person of 60 kg, based on data available at the time.

In this study, the consumption of bixin through colorific (containing 0.28% bixin) was 112.61 tons. Considering the population of the Northeast (at that time) of 44,662,273, the daily consumption per capita of bixin through colorific represented 6.9 mg bixin.

*Reference: Toledo, C.F. National intake assessment of the intake of bixin in Brazil. Faculty of Food Engineering, University of Campinas, Campinas. Submitted to FAO, 1999.*

According to more recent data\*, the Northeast region presents a colorific consumption of approximately 9,200 tons per year. This represents more than 60% of national consumption.

\*Reference: <https://www.ourucum.com.br/mercado>

Considering the same percentage of bixin the of study carried out by Toledo (1998) (0.28%), we would have a current consumption of bixin through colorific of 25.76 tons per year, which would represent a daily per capita consumption of bixin of 1.1 mg.

*Data:*

*Northeast population: 64,549,493 (IBGE, 2016)*

*[Amount of colorific for use/ (Total Northeast population x 365)]*

Using this daily per capita consumption of bixin through colorific together with POF 2008-2009 data, even if we consider that all consumption of 0.7 g/day was only of seasonings/condiments containing 600 ppm of annatto extract (bixin-based), we would have the following situation:

Body Weight (kg)	15	60
Acceptable Daily Intake (mg) of bixin considering the body weight	180	720
With the daily consumption of 0.7 g of seasoning/condiment with 600 ppm of annatto extract (bixin-based) = 0,42 mg bixin/day plus the daily consumption per capita of bixin of the "colorific", the percentage of ADI that would be reached by consuming this product would be: (1,52 mg total bixin)	0,844	0,211

We emphasize that there is no maximum level established by the Brazilian legislation for the use of annatto extract (bixin-based) in the domestic production of colorific. As it is in the Northeast, the colorific is a homemade seasoning/condiment and, for this reason, we assumed the value used in the Toledo (2008) study (0.28% bixin in colorific).

Even if we consider the ADI of 6 mg/kg b.w. for bixin established by EFSA in 2016, in which was assessed the extension of use for 16 food categories and concluded that the estimated uses do not exceed the current ADI, the proposed new limit of 600 ppm for seasoning/condiment would also not exceed the ADI of 6 mg/kg b.w.

Body Weight (kg)	15	60
Acceptable Daily Intake (mg) of bixin considering the body weight	90	360
With the daily consumption of 0.7 g of seasoning/condiment with 600 ppm of annatto extract (bixin-based) = 0,42 mg bixin/day plus the daily consumption per capita of bixin the of "colorific", the percentage of ADI that would be reached by consuming this product would be: (1,52 mg total bixin)	1,69	0,422

**Thus, we request that the limit of 600 ppm for annatto extracts (bixin-based) (160b(i)) for the category 12.2.2 - Seasonings and Condiments with the functional class of colour at the next CCFA Session.**

<b>Justification that the use does not mislead consumer</b>	In Brazil, consumers are familiarized to the use of seasonings that give color and taste to food, and this is more evident in the Northeast and North regions, although it is a reality for the entire country.  Furthermore, the declaration of the additive is mandatory in the list of ingredients. In this way, consumers will be correctly informed that the annatto extract colour is one of the components of food.
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## China

<b>THE PROPOSAL IS SUBMITTED BY:</b>		China		
<b>IDENTITY OF THE FOOD ADDITIVE:</b>				
<b>Name of the Additive</b> <i>As listed in Class Names and the International Numbering System (INS) -CAC/GL 36-1989</i>		Nisin		
<b>INS Number</b>		234		
<b>Functional Class</b> <i>As listed in Class Names and the International Numbering System (INS) -CAC/GL 36-1989</i>		Preservative		
<b>PROPOSED USE(S) OF THE FOOD ADDITIVE (1):</b> <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")		
<b>Food No. (2)</b>	<b>Category</b>	<b>Food Category Name (2)</b>	<b>Maximum Use Level (3)</b>	<b>Comments (4)</b>
12.6.1		Emulsified sauces & dips	5.0 mg/kg	Note 233 'As Nisin'
12.6.2		Non-emulsified sauces	5.0 mg/kg	Note 233 'As Nisin'
12.6.4		Clear sauces	5.0 mg/kg	Note 233 'As Nisin'
12.7		Salads & Sandwich spreads	5.0 mg/kg	Note 233 'As Nisin'
<b>Is the proposal related to a FC with corresponding commodity standards?</b> <i>(if yes indicate the relevant FC)</i>				
12.6.2 CODEX STAN 306R-2011 Regional Standard for Chilli Sauce				
12.6.4 CODEX STAN 302-2011 Standard for Fish Sauce				
<b>Is the proposal also intended to revise the products covered by the commodity standards?</b> <i>(if yes indicate the relevant commodity standards)</i>				
No				
<b>EVALUATION BY JECFA:</b>				
<b>Evaluation by JECFA</b> <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i>		Evaluation year: 2013 ADI: 0–2 mg/kg bw <a href="http://apps.who.int/food-additives-contaminants-jecfadatabase/">http://apps.who.int/food-additives-contaminants-jecfadatabase/</a>		
<b>JUSTIFICATION:</b>				
<b>Justification for use and technological need</b> <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard</i>		Consumer demand for convenient, less processed and/or healthier sauce, dressing & prepared salad options are driving the development of new products		

<p>for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</p>	<p>with lower oil content, serving &amp; storage formats and a wide range of recipe ingredients. These changes can impact product microbial stability. Nisin provides an alternative to preservatives such as sodium diacetate &amp; benzoate. It inhibits gram positive spoilage bacteria and in refrigerated products, can help inhibit <i>Listeria</i>.</p>
<p><b>Safe use of additive: Dietary intake assessment</b> (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 2013 JECFA review includes a dietary intake discussion for US, Japan, Australia and New Zealand. From Food Standards Australia New Zealand (FSANZ), the estimated consumers-only mean dietary exposures to nisin from consumption of cheese, cream, meat products, sauces, toppings and mayonnaise were 0.009 mg/kg bw per day (all ages) and 0.02 mg/kg bw per day (2- to 6-year-olds). Estimated consumers-only 95th percentile dietary exposures to nisin were lowest for New Zealanders aged 15 years and above, at 0.03 mg/kg bw per day, and highest for Australian children aged 2–6 years, at 0.07 mg/kg bw per day. The consumers-only dietary exposure estimate from the USA from consumption of cheese spreads, dressings, egg products and processed meat products was 0.04 mg/kg bw per day at the mean. The Japanese per capita estimate was from consumption of cheeses, buns, meat and egg products, tofu and miso and was reported as 2.06 mg/person per day or approximately 0.04 mg/kg bw per day for a 50 kg individual. (WHO Food Additives Series 68, JECFA 77, page 108)</p> <p>Additionally, based on per capita consumption of products in the proposed food categories in China, daily intakes are estimated by 0.0005 mg/kg bw (50 kg bw basis) for China. This value assumes that nisin is added at the ML of 5 mg/kg in all sauces, dressings and prepared salads produced and consumed (GB 2760).</p>
<p><b>Justification that the use does not mislead consume</b></p>	<p>The presence of nisin would be declared on product labels</p>

Japan

<p><b>THE PROPOSAL IS SUBMITTED BY:</b></p>	<p>Japan</p>
<p><b>IDENTITY OF THE FOOD ADDITIVE:</b></p>	
<p><b>Name of the Additive</b> <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i></p>	<p>Tamarind seed polysaccharide</p>
<p><b>INS Number</b></p>	<p>437</p>
<p><b>Functional Class</b> <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i></p>	<p>Thickener, Stabilizer, Emulsifier, Gelling agent</p>

<b>PROPOSED USE(S) OF THE FOOD ADDITIVE (1):</b> <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").	
<b>Food Category No. (2)</b>	<b>Food Category Name (2)</b>	<b>Maximum Use Level (3)</b>	<b>Comments (4)</b>
01.2.1.1	Fermented milks (plain), not heat-treated after fermentation	GMP	Note 234 "For use as a stabilizer or thickener only." Note 235 "For use in reconstituted and recombined products only."
01.2.1.2	Fermented milks (plain), heat-treated after fermentation	GMP	Note 234 "For use as a stabilizer or thickener only."
01.4.1	Pasteurized cream (plain)	GMP	Note 236 "Excluding products conforming to the Standard for Cream and Prepared Creams (reconstituted cream, recombined cream, prepackaged liquid cream) (CODEX STAN 288-1976)."
01.4.2	Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)	GMP	Note 236 "Excluding products conforming to the Standard for Cream and Prepared Creams (reconstituted cream, recombined cream, prepackaged liquid cream) (CODEX STAN 288-1976)."
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	GMP	—
06.4.1	Fresh pastas and noodles and like products	GMP	Note 211 "For use in noodles only."
06.4.2	Dried pastas and noodles and like products	GMP	Note 256 "For use in noodles, gluten-free pasta and pasta intended for hypoproteic diets only."
09.2.4.1	Cooked fish and fish products	GMP	Note 241 "For use in surimi products only." Note 327 "For use in fish products cooked in soy sauce."
11.4	Other sugars and syrups (e.g. xylose, maple syrup, sugar toppings)	GMP	Note 258 "Excluding maple syrup."
14.1.3.1	Fruit nectar	GMP	—

14.1.3.2	Vegetable nectar	GMP	—
14.1.3.3	Concentrates for fruit nectar	GMP	—
14.1.3.4	Concentrates for vegetable nectar	GMP	—
<p><b>Is the proposal related to a FC with corresponding commodity standards?</b> (if yes indicate the relevant FC)</p> <p><b>Yes</b></p> <p><b>FC 01.2.1.1, FC 01.2.1.2</b> - Standard for Fermented Milks (CXS 243-2003)</p> <p><b>FC 01.4.1, FC 01.4.2</b> - Standard for Cream and Prepared Creams (CXS 288-1976)</p> <p><b>FC 04.2.2.7</b> - Standard for Edible Fungi and Fungus Products (CXS 38-1981) - Standard for Kimchi (CXS 223-2001) - Standard for Pickled Fruits and Vegetables (CXS 260-2007) - Regional Standard for Gochujang (CXS 294R-2009)</p> <p><b>FC 14.1.3.1, FC14.1.3.3</b> - General Standard for Fruit Juices and Nectars (CXS 247-2005)</p>			
<p><b>Is the proposal also intended to revise the products covered by the commodity standards?</b> (if yes indicate the relevant commodity standards)</p> <p><b>Yes.</b></p> <p>CXS 243-2003, CXS 288-1976, CXS 223-2001, CXS 247-2005 (as stabilizers and thickeners), and CXS 294R-2009 (as stabilizers).</p>			
<b>EVALUATION BY JECFA:</b>			
<p><b>Evaluation by JECFA</b></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>Tamarind seed polysaccharide was evaluated and an ADI “not specified” was established at the 84th JECFA (2017).</p> <p>The specification was prepared at the 84th JECFA (2017) and published in FAO JECFA Monographs 20 (2017).</p>	
<b>JUSTIFICATION:</b>			
<p><b>Justification for use and technological need</b></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>Tamarind seed polysaccharide shows stable viscosity in a wide range of pH. Its viscosity changes only slightly by heating or freeze-thawing and is hardly affected by salts.</p> <p><u>Thickener and Stabilizer</u></p> <p>Tamarind seed polysaccharide is mainly used as a thickener and stabilizer in sauces, beverages (fruit and vegetable nectars), fermented milks (plain), cream (plain), pickles, tsukudani (boiled foods in sweetened soy sauce), fermented vegetables (kimchi, gochujang), spreads/fillings, and flour products. It is also used as an ice crystal stabilizer in frozen desserts such as ice cream.</p> <p><u>Emulsifier</u></p> <p>Tamarind seed polysaccharide is used as an emulsifier in dressings and mayonnaise to prevent separation of fat and oil.</p> <p><u>Gelling agent</u></p>	

	<p>Tamarind seed polysaccharide forms a gel when mixed with sugars, dextrin, sugar alcohols, alcohols and catechin, and it is used as a gelling agent in fruit preserves and desserts. In these applications, it also prevents syneresis.</p> <p>Tamarind seed polysaccharide is compatible with other hydrocolloids.</p> <p>Tamarind seed polysaccharide in higher amounts results in higher viscosity, which places limitations on its addition (self-limitation) and thus precludes it from being added in excessive amounts.</p>
<b>Safe use of additive: Dietary intake assessment</b> ( <i>as appropriate</i> )	<p>Table 3 additive:</p> <p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No (Please provide information on dietary intake assessment below)</p>
<b>Justification that the use does not mislead consumer</b>	The above-mentioned use does not affect nature and quality of the food that would be expected by consumers.

## Senegal

<b>THE PROPOSAL IS SUBMITTED BY:</b>	Senegal		
<b>IDENTITY OF THE FOOD ADDITIVE:</b>			
<b>Name of the Additive</b> <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>	Methacrylate copolymer, basic		
<b>INS Number</b>	1205		
<b>Functional Class</b> <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>	Glazing agent, Carrier (request is pending decision by the INS working group).		
<b>PROPOSED USE(S) OF THE FOOD ADDITIVE (1):</b> <i>The rows below may be copied as many times as needed.</i>	<p>The proposal for:</p> <p><input checked="" type="checkbox"/> 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>		
<b>Food Category No. (2)</b>	<b>Food Category Name (2)</b>	<b>Maximum Use Level (3)</b>	<b>Comments (4)</b>
06.2.1	Flours	GMP	
12.5.2	Mixes for soups and broths	GMP	
12.1.1	Salt	GMP	
<b>Is the proposal related to a FC with corresponding commodity standards?</b>			
(if yes indicate the relevant FC)			
Yes ( <i>Flours, 6.2.1; Mixes for Soups and Broths, 12.5.2</i> )			

<p><b>Is the proposal also intended to revise the products covered by the commodity standards?</b></p> <p>(if yes indicate the relevant commodity standards)</p> <p>Yes (Wheat flour, Codex Stan 152; Bouillon and Consommés, Codex Stan 117) – We are particularly interested in these two products. We understand that BMC would be included in Table 3 and Food Category 12.5.2 is not in the Annex to Table 3. We are, however, very interested in Bouillons and Consommés, and therefore would want Codex Stan 117 to be included in the listing for BMC, Table 3, last column.</p>	
<p><b>EVALUATION BY JECFA:</b></p>	
<p><b>Evaluation by JECFA</b></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>JECFA Eighty-sixth meeting Geneva, 12–21 June 2018</p> <p>The Committee established an ADI “not specified” for basic methacrylate copolymer.</p> <p>Full monograph and specifications not yet published.</p>
<p><b>JUSTIFICATION:</b></p>	
<p><b>Justification for use and technological need</b></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 additive is used to coat and protect various micronutrients used in food fortification to protect them from degradation due to adverse environmental conditions (heat and humidity) during storage and cooking of fortified food products. This use does not present an appreciable health risk and should improve the nutrient status of individuals at risk of malnutrition. Use of the additive has no effect on the food itself.</p>
<p><b>Safe use of additive: Dietary intake assessment (as appropriate)</b></p>	<p>Table 3 additive:</p> <p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No (Please provide information on dietary intake assessment below)</p> <p>The use levels in food will be determined by the amount of the polymer required to coat the quantity of each micronutrient required to be added to the fortified food product to achieve the desired level of fortification for the anticipated consumption level of the particular food product. The level of fortification will be guided by WHO’s 2006 “Guidelines on food fortification with micronutrients.”</p> <p>We have identified 12 micronutrients for which use of the additive would improve their stability in fortified foods. The currently proposed use of the additive (BMC) with all of these micronutrients was evaluated by JECFA in its recent assessment. As noted in the “Summary and Conclusions” for that meeting:</p> <p><i>“The Committee evaluated exposure to BMC for the copolymer and its monomers (n-butyl methacrylate, 2-(dimethylamino)ethyl methacrylate and methyl methacrylate). Estimated exposures to BMC range from 3.0 to 135 mg/kg bw per day. The total monomeric content of BMC is less than 0.3%. The Committee concluded that the toxicological data on the residual monomers do not give rise to concerns when taking into account the low dietary exposures.”</i></p>
<p><b>Justification that the use does not mislead consumer</b></p>	<p>Studies show that coating of micronutrients with the additive protects them from degradation due to conditions, such as boiling for 2 hours, that results in loss of potency</p>

	of unprotected micronutrients (e.g., vitamins A, C & D), while not affecting the food to which it is added.
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**EFEMA (European Food Emulsifier Manufacturers' Association)**

<b>THE PROPOSAL IS SUBMITTED BY:</b>		EFEMA, the European Food Emulsifier Manufacturers Association	
<b>IDENTITY OF THE FOOD ADDITIVE:</b>			
<b>Name of the Additive</b> <i>As listed in Class Names and the International Numbering System (INS) – CAC/GL 36-1989</i>		Mono- and diglycerides	
<b>INS Number</b>		471	
<b>Functional Class</b> <i>As listed in Class Names and the International Numbering System (INS) – CAC/GL 36-1989</i>		Antifoaming agent, Emulsifier, Stabilizer	
<b>PROPOSED USE(S) OF THE FOOD ADDITIVE (1):</b>  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 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 stanard")	
<b>Food category No. (2)</b>	<b>Food Category Name (2)</b>	<b>Maximum Use Level (3)</b>	<b>Comments (4)</b>
02.1.2	Vegetable oils and fats	10000 mg/kg	With new note xx – For use in frying oils and fats only
<b>Is the proposal related to a FC with corresponding commodity standards?</b> <i>(if yes indicate the relevant FC)</i> Yes. Food category 02.1.2 corresponds to the following Commodity Standards: 33-1981 Olive Oil, Virgin and Refined, and Refined Olive Pomace Oil, Olive Oils and Olive Pomace Oils 210-1999 Named Vegetable Oils 325R-2017 Unrefined Shea Butter (Regional Standard)			
<b>Is the proposal also intended to revise the products covered by the commodity standards?</b> <i>(if yes indicate the relevant commodity standards)</i> Yes. We intend to have the Codex Standard 210-1999 revised.			
<b>EVALUATION BY JECFA:</b>			
<b>Evaluation by JECFA</b> <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 17 <sup>th</sup> JECFA (1973), published in FNP 4 (1978) and in FNP 52 (1992). Metals and arsenic specifications revised at the 55 <sup>th</sup> JECFA (2000). An ADI "not limited" was established at the 17 <sup>th</sup> JECFA (1973)  Monograph 1 (2006)  See: <a href="http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/detail/en/c/137/">http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/detail/en/c/137/</a>	
<b>JUSTIFICATION:</b>			

<p><b>Justification for use and technological need</b></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>Certain mono- and diglycerides within the JECFA specification for INS 471 have shown to reduce the formation of foam during the frying process. When foaming is reduced during frying the risk for oxidation of the oil will also be reduced. This both prevents the development of unwanted oxidized by-products in the oil and the oils will have a longer shelf life.</p>
<p><b>Safe use of additive: Dietary intake assessment</b> (as appropriate)</p>	<p>Table 3 additive:</p> <p><input checked="" type="checkbox"/> yes</p> <p><input type="checkbox"/> No (Please provide information on dietary intake assessment below)</p>
<p><b>Justification that the use does not mislead consumer</b></p>	<p>The proposed use of Mono- and diglycerides (INS 471) in frying oils and fats is to prevent foaming during frying and it does not change the nature or quality of the oil as to deceive the consumer. Also, the use INS 471 in frying oils and fats must be indicated on the product label.</p>

#### EU Specialty Food Ingredients

<b>THE PROPOSAL IS SUBMITTED BY:</b>		EU Specialty Food Ingredients		
<b>IDENTITY OF THE FOOD ADDITIVE:</b>				
<p><b>Name of the Additive</b></p> <p><i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i></p>		<p><math>\beta</math>-Carotene-rich extract from <i>Dunaliella salina</i></p>		
<p><b>INS Number</b></p>		<p>New INS 160a(v) or replacement of INS 160a(iv)</p> <p>See first draft of INS EWG (51th CCFA-2019) dated 31.10.2018</p>		
<p><b>Functional Class</b></p> <p><i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i></p>		<p>Colour</p>		
<p><b>PROPOSED USE(S) OF THE FOOD ADDITIVE (1):</b></p> <p><i>The rows below may be copied as many times as needed.</i></p> <p><b>Comment:</b></p> <p><b>The colour principle of <math>\beta</math>-Carotene-rich extract from <i>Dunaliella salina</i> is beta-carotene, therefore same food categories and maximum use levels as for beta-carotenes, synthetic (INS 160a(i)) and beta-carotenes from <i>Blakeslea trispora</i> (INS 160a(iii)) are proposed for table 1 and 2 of GSFA (2018), maximum use levels based on beta-carotene</b></p>		<p>The proposal for:</p> <p><input type="checkbox"/> <b>X</b> 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>		
<p><b>Food Category No. (2)</b></p>	<p><b>Food Category Name (2)</b></p>	<p><b>Maximum Level (3) mg/kg</b></p>	<p><b>Use</b></p>	<p><b>Comments (4)</b></p>
01.1.4	Flavoured fluid milk drinks	150		Notes GSFA 52 & 402
01.3.2	Beverage whiteners	100		
01.4.4	Cream analogues	20		
01.5.2	Milk and cream powder analogues	100		Notes GSFA 209
01.6.1	Unripened cheese	100		
01.6.2.1	Ripened cheese, includes rind	100		

01.6.2.2	Rind of ripened cheese	500	
01.6.2.3	Cheese powder (for reconstitution; e.g., for cheese sauces)	100	
01.6.4	Processed cheese	100	
01.6.5	Cheese analogues	200	
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	100	
02.1.2	Vegetable oils and fats	25	Notes GSFA 232
02.1.3	Lard, tallow, fish oil, and other animal fats	25	
02.2.1	Butter	25	Notes GSFA 146 & 291
02.2.2	Fat spreads, dairy fat spreads and blended spreads	35	
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	200	
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	150	
03.0	Edible ices, including sherbet and sorbet	200	
04.1.2.3	Fruit in vinegar, oil, or brine	1000	
04.1.2.4	Canned or bottled (pasteurized) fruit	200	Notes GSFA 161 & 104
04.1.2.5	Jams, jellies, marmelades	200	
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	500	
04.1.2.7	Candied fruit	200	
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	100	Notes GSFA 161 & 182
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	150	
04.1.2.10	Fermented fruit products	500	
04.1.2.11	Fruit fillings for pastries	100	
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	500	Notes GSFA 4, 16 & 161
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	1000	Notes GSFA 161
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	50	Notes GSFA 161
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	50	Notes GSFA 161
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)	50	Notes GSFA 161
04.2.2.6	Vegetable (including mushrooms	50	Notes GSFA 92 & 161

	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		
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	50	
05.1.3	Cocoa-based spreads, including fillings	100	Notes GSFA 161 & XS86
05.1.4	Cocoa and chocolate products	100	Notes GSFA 183
05.1.5	Imitation chocolate, chocolate substitute products	100	
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	100	Notes GSFA XS309R
05.3	Chewing gum	100	
05.4	Decorations (e.g., for fine bakery wares), toppings (nonfruit) and sweet sauces	100	
06.3	Breakfast cereals, including rolled oats	200	
06.4.3	Pre-cooked pastas and noodles and like products	1200	Notes GSFA 153
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	150	
06.6	Batters (e.g., for breading or batters for fish or poultry)	500	
07.1.2	Crackers, excluding sweet crackers	1000	
07.1.3	Other ordinary bakery products (e.g., bagels, pita, English muffins)	100	
07.1.4	Bread-type products, including bread stuffing and bread crumbs	200	Notes GSFA 116
07.1.5	Steamed bread and buns	100	Notes GSFA 216
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	100	
08.1.2	Fresh meat, poultry, and game, comminuted	100	Notes GSFA 4 & 16
08.3.1.1	Cured (including salted) non-heat treated processed comminuted meat, poultry, and game products	100	Notes GSFA 16
08.3.1.2	Cured (including salted) and dried non-heat treated processed comminuted meat, poultry, and game products	20	Notes GSFA 16
08.3.1.3	Fermented non-heat treated processed comminuted meat, poultry, and game products	20	Notes GSFA 16
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	20	Notes GSFA 16, XS88, XS89 & XS98
08.4	Edible casings (e.g., sausage casings)	100	
09.1.1	Fresh fish	300	Notes GSFA 4
09.1.2	Fresh mollusks, crustaceans, and echinoderms	100	Notes GSFA 4, 16, XS292, XS312 & XS315

09.2	Processed fish and fish products, including mollusks, crustaceans, and echinoderms	100	Notes GSFA 95, 304, XS36, XS92, XS95, XS165, XS167, XS189, XS190, XS191, XS222, XS236, XS244, XS292, XS311, XS312 & XS315
09.3	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	100	Notes GSFA 96 & XS291
09.4	Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	100	Notes GSFA 95, XS3, XS37, XS70, XS90, XS94 & XS119
10.1	Fresh eggs	1000	Notes GSFA 4
10.4	Egg-based desserts (e.g., custard)	150	
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	50	Notes GSFA 217
12.2.2	Seasonings and condiments	500	
12.4	Mustards	300	
12.5	Soups and broths	300	Notes GSFA 341
12.6	Sauces and like products	500	Notes GSFA XS302
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	50	
13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	50	
13.4	Dietetic formulae for slimming purposes and weight reduction	50	
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	300	
13.6	Food supplements	300	
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	100	
14.2.2	Cider and perry	200	
14.2.4	Wines (other than grape)	200	
14.2.6	Distilled spirituous beverages containing more than 15% alcohol	200	
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	200	
15.1	Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	100	
15.2	Processed nuts, including coated nuts and nut mixtures (with e.g., dried fruit)	100	
<b>Is the proposal related to a FC with corresponding commodity standards?</b>			
Yes, see CODEX STAN 192-1995 General Standard for Food Additives, Annex C (cross-reference of the food category system and Codex commodity standards)			
<b>Is the proposal also intended to revise the products covered by the commodity standards?</b>			
No			

(if yes indicate the relevant commodity standards)	
<b>EVALUATION BY JECFA:</b>	
<p><b>Evaluation by JECFA</b></p> <p>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or “not specified”); specifications monograph).</p>	<p><b>84<sup>th</sup> JECFA session 2017 (WHO TRS 1007-JECFA 84/16):</b></p> <p>The Committee concluded that there was no health concern for the use of <math>\beta</math>-carotene-rich extract from <i>D. salina</i> when used as a food colour in accordance with the specifications established at this meeting.</p> <p>The Committee noted that the total dietary exposure to <math>\beta</math>-carotene is not expected to increase when <i>D. salina</i> d-limonene extract is used as a food colour.</p> <p><b><u>Specification/Monograph:</u></b></p> <p>FAO JECFA Monographs 20 – Compendium of Food Additive Specifications, 84<sup>nd</sup> JECFA session (2017)</p> <p><b><u>CCFA document CX-FA 18/50/3:</u></b></p> <p>Table 1 in this document lists <math>\beta</math>-Carotene-rich extract from <i>Dunaliella salina</i> with a “Recommended action by CCFA”:</p> <p>Request proposals for use levels of <math>\beta</math>-Carotene-rich extract from <i>Dunaliella salina</i> (used a colour only) in Table 1 and 2 of the GSFA (to be provided in response to the CL requesting proposals for new and/or revision of adopted food additives provisions in the GSFA).</p>
<b>JUSTIFICATION:</b>	
<p><b>Justification for use and technological need</b></p> <p>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>As a colour <math>\beta</math>-Carotene-rich extract from <i>Dunaliella salina</i> serve a technological function by adding or restoring colour to a food. There is a global need for natural food colours. <math>\beta</math>-Carotene-rich extract from <i>Dunaliella salina</i> is produced from a natural source. Its yellowish to redish colour hue is unique and suitable to supplement the colour spectrum achievable with other carotenoids.</p> <p><math>\beta</math>-Carotene-rich extract from <i>Dunaliella salina</i> does not present any appreciable health risk to consumers. The 2017 JECFA safety assessment of the substance at the Committees 84<sup>th</sup> session, which included dietary exposure, concluded on that there was no health concern for the use of <math>\beta</math>-carotene-rich extract from <i>D. salina</i> when used as a food colour.</p>
<p><b>Safe use of additive: Dietary intake assessment (as appropriate)</b></p>	<p>Table 3 additive:</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> X No (Please provide information on dietary intake assessment below)</p> <p><b>84<sup>th</sup> JECFA session 2017 (WHO TRS 1007-JECFA 84/16):</b></p> <p>The Committee considered dietary exposure to <math>\beta</math>-carotene from <i>D. salina</i> d-limonene extract assuming its uses as a food additive in the same food categories and at the same maximum use levels (<math>\beta</math>-carotene basis) as previously evaluated <math>\beta</math>-carotene additives. The Committee concluded that dietary exposure to <math>\beta</math>-carotene would not change, as the extract will provide <math>\beta</math>-carotene at a level equivalent to that from other <math>\beta</math>-carotene food additives.</p>

<b>Justification that the use does not mislead consumer</b>	$\beta$ -Carotene-rich extract from <i>Dunaliella salina</i> is intended to be used in line with the food colour definition in CAC/GL 36-1989.
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ICGMA (International Council of Grocery Manufacturers Associations)

<b>THE PROPOSAL IS SUBMITTED BY:</b>		International Council of Grocery Manufacturers Associations (ICGMA)	
<b>IDENTITY OF THE FOOD ADDITIVE:</b>			
<b>Name of the Additive</b> <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Lauric arginate ethyl ester	
<b>INS Number</b>		243	
<b>Functional Class</b> <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Preservative	
<b>PROPOSED USE(S) OF THE FOOD ADDITIVE (1):</b> <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").	
<b>Food Category No. (2)</b>	<b>Food Category Name (2)</b>	<b>Maximum Use Level (3)</b>	<b>Comments (4)</b>
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms	200 mg/kg	<del>Note XS244</del> <del>Note XS311</del> Remove these exclusions from the lauric arginate ethyl ester provisions
<b>Is the proposal related to a FC with corresponding commodity standards? YES</b> <i>(if yes indicate the relevant FC)</i> FC 09.2.5 Standard for Salted Atlantic Herring and Salted Sprat (CODEX STAN 244-2004) Standard for Smoked, Smoked-Flavoured Fish and Smoke-Dried Fish (CODEX STAN 311-2013)			
<b>Is the proposal also intended to revise the products covered by the commodity standards?</b> <i>(if yes indicate the relevant commodity standards)</i> NO			
<b>EVALUATION BY JECFA:</b>			
<b>Evaluation by JECFA</b> <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 <sup>α</sup> -Lauroyl-L-Arginate	
<b>JUSTIFICATION:</b>			

<p><b>Justification for use and technological need</b></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>Provisions were adopted at Step 8 in 2018 for lauric arginate ethyl ester (INS 243) in food category 09.2.5 at a level of 200 mg/kg. The provisions were adopted with footnotes that restrict the use of the additive in products conforming to corresponding commodity standards associated with this category. The footnotes adopted were as follows:</p> <p>XS244 Excluding products conforming to the Standard for Salted Atlantic Herring and Salted Sprat (CODEX STAN 244-2004).</p> <p>XS311 Excluding products conforming to the Standard for Smoked, Smoked-Flavoured Fish and Smoke-Dried Fish (CODEX STAN 311-2013)</p> <p>The acceptability of the use of preservatives in these food standards is recognized in the GSFA by way of the inclusion of provisions permitting the use of benzoates and sorbates in the standards. The use of lauric arginate ethyl ester provides an effective alternative to the use of either benzoates or sorbates in products falling under these standards.</p> <p><u>Background:</u></p> <p>At the 36<sup>th</sup> Session of CCFAC (2004), the benzoate preservatives were added in FC 09.2.5 of the GSFA at a maximum level of 200mg/kg, with no restrictions on its use in fish standards.</p> <p>At the 44<sup>th</sup> Session of CCFA (2012), the sorbate preservatives were included in FC 09.2.5 of the GSFA at a maximum level of 1000mg/kg, with no restrictions on its use in fish standards.</p> <p>At the 50<sup>th</sup> Session of CCFA (2018), the Committee accepted proposed amendments to the food additive provisions of Codex fish standards revisions and made the corresponding amendments to the GSFA. Although several fish standards were excluded from the provisions of benzoates and sorbates, the Committee agreed that the use of benzoates and sorbates were acceptable in products conforming to the Standard for Salted Atlantic Herring and Salted Sprat (CODEX STAN 244-2004) and the Standard for Smoked, Smoked-Flavoured Fish and Smoke-Dried Fish (CODEX STAN 311-2013).</p> <p>Lauric arginate ethyl ester (INS 243) is also a preservative that is used in products that conform to these corresponding commodity standards associated with FC 09.2.5. The additive is effective in controlling the growth of potentially pathogenic organisms in products falling under 09.2.5. This proposal for new work requests that consideration is given to modification of the adopted provisions for lauric arginate ethyl ester (INS 243) to bring its use in standards in line with the provisions applied to the benzoates and sorbates. As such, the current notes XS244 and XS311 would be deleted.</p>
<p><b>Safe use of additive: Dietary intake assessment (as appropriate)</b></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 fish products that fall under Codex food categories 09.2.5 (and without restriction of its use in standardised products), 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 2007.</p>
<b>Justification that the use does not mislead consumer</b>	<p>The use of lauric arginate ethyl ester (INS 243) would be indicated on the label of the products. The salted, smoked, and smoked-flavoured products falling within the standards by their very nature contain additives, and the presence of additives in these products is expected by consumers.</p>