

## SCIENTIFIC OPINION

# Statement on the exposure assessment of sodium stearoyl-2-lactylate and calcium stearoyl-2-lactylate including exposure resulting from extension of the authorisation of sodium stearoyl-2-lactylates<sup>1</sup>

## EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)<sup>2, 3</sup>

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### ABSTRACT

Following a request by the European Commission, the Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS) carried out an exposure assessment of sodium stearoyl-2-lactylate (E 481) and calcium stearoyl-2-lactylate (E 482) as a food additive, including an extension of the uses to use the additives in emulsified cooked meat products (e.g. mortadella, pâté). Reflecting the data on actual use levels provided by food industry, the combined exposure to sodium stearoyl-2-lactylate and calcium stearoyl-2-lactylate is in the range of 29-92 mg/kg bw/day for toddlers, 28-81 mg/kg bw/day for children, 13-32 mg/kg bw/day for adolescents, 8-21 mg/kg bw/day for adults, and 5-15 mg/kg bw/day for the elderly at the mean level. For exposure at high levels, ranges of 69-223 mg/kg bw/day for toddlers, 44-190 mg/kg bw/day for children, 21-59 mg/kg bw/day for adolescents, 19-53 mg/kg bw/day for adults, and 16-31 mg/kg bw/day were calculated for the elderly. The extension of the authorisation for the use of sodium stearoyl-2-lactylate in emulsified cooked meat products (e.g. mortadella, pâté) would not lead to an increase of exposure based on the approach taken for the exposure assessment for the two food additives.

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### KEY WORDS

Sodium stearoyl-2-lactylate, calcium stearoyl-2-lactylate, E 481, E 482, exposure.

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## SUMMARY

Following a request by the European Commission, the Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS) carried out an exposure assessment of sodium stearyl-2-lactylate (E 481) (SSL) and calcium stearyl-2-lactylate (E 482) (CSL) as a food additive including extension of the uses to use in emulsified cooked meat products (e.g. mortadella, paté).

In April 2011 the application for the extension of the use of sodium stearyl-2-lactylate (E 481) was limited to emulsified cooked meat products (e.g. mortadella, paté) by proposing a maximum limit of 3 g/kg food in combination with iota carrageenan (stabilizer E 407, which belongs to group I of food additives used at *quantum satis*), that is 2.2 g/kg food of E 481 and 0.8 g/kg food of iota carrageenan. The applicant has indicated that sodium stearyl-2-lactylate is one of the emulsifiers with the highest hydrophilic-lipophilic balance and is therefore an excellent emulsifier for fat in water emulsions. An important synergy between sodium stearyl-2-lactylate emulsifier and the stabilizer iota carrageenan (E 407) has recently been discovered and has been patented (European Patent No. 1488 701 A1). As sodium stearyl-2-lactylate is authorised to be used individually or in combination with calcium stearyl-2-lactylate it does not seem justified to make the exposure assessment only to sodium stearyl-2-lactylate and it is therefore preferable to perform exposure assessments for both substances included in the group of lactylates.

On 13 April 2012, the European Commission requested EFSA to perform an exposure assessment of the food additives SSL (E 481) and CSL (E 482) due to the request for an extension of use of this substance.

Currently, SSL/CSL is an authorised emulsifier in the EU with MPLs ranging from 2000 to 10 000 mg/kg in foods. An extension of authorisation to the use of SSL has been requested for the use in emulsified cooked meat products (e.g. mortadella, paté) within food category 08.2.2 Heat-treated processed meat at a proposed use level of 2200 mg/kg food in combination with iota carrageenan (E 407) at a level of 0.8 g/kg food.

Information about the actual levels in use has been provided by the European Food Emulsifier Manufacturers' Association (EFEMA) and from a data collection by the Confederation of the Food and Drink Industries of the EU (CIAA, now FoodDrinkEurope). For calculation of chronic exposure, intake statistics have been calculated based on individual average consumption over the total survey period excluding surveys with only one day per subject. High level consumption was only calculated for those foods and population groups where the sample size was sufficiently large to allow calculation of the 95<sup>th</sup> percentile. The Panel estimated chronic exposure for the following population groups: toddlers, children, adolescents, adults and the elderly. Calculations were performed using individual body weights. Exposure to SSL and CSL from its use as food additive has been calculated by using MPLs combined with national consumption data for the five population groups.

The exposure estimates based on reported use levels are in a range of 29-92 mg/kg bw/day for toddlers, 28-81 mg/kg bw/day for children, 13-32 mg/kg bw/day for adolescents, 8-21 mg/kg bw/day for adults, and 5-15 mg/kg bw/day for the elderly at the mean level.

To perform a preliminary evaluation on the impact of impurities, an exposure estimation was performed on the basis of a daily ingestion of 20 mg/kg bw SSL or CSL (the current ADI value) and the maximum permitted levels of the impurities. The comparison with the tolerable daily intake of these impurities showed no toxicological concern after ingestion of the current ADI of 20 mg/kg bw/day of SSL or CSL (individually or in combination). The extension of the authorisation of sodium stearyl-2-lactylate to the use in emulsified cooked meat products would not result in a substantial increase of exposure based on the scenario of exposure assessment in this opinion. At present, sodium stearyl-2-lactylate is authorised in the food category "heat-treated processed meat" (08.2.2) for minced and diced canned meat products. The EFSA Comprehensive Food Consumption Database however does not provide data specifically on the consumption of these foods. Therefore, the

data on the consumption of the top level category 08.2.2 had to be used for the exposure assessment. The exposure resulting from the extension of use to emulsified cooked meat products is already included in this conservative approach.

The Panel concluded that an extension of the authorisation for the use of sodium stearyl-2-lactylate in emulsified cooked meat products (e.g. mortadella, pâté) would not lead to an increase of exposure based on the approach taken for the exposure assessment for the two food additives.

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## BACKGROUND AS PROVIDED BY EFSA

Originally, the applicant wanted to extend the use of sodium stearyl-2-lactylate (E 481) and calcium stearyl-2-lactylate (E 482) to a number of applications under Directive No 95/2EC<sup>5</sup> of the European Parliament and Council Directive on food additives other than colours and sweeteners. In April 2011 the applicant indicated that he wanted to limit the scope to emulsified cooked meat products (e.g. mortadella, pâté). The applicant proposes a maximum limit of 3 g/kg in combination with iota carrageenan (stabiliser E 407 which belongs to group I of food additives used at *quantum satis*) that is 2.2 g/kg of E 481 and 0.8 g/kg of iota-carrageenan.

The European Commission in consultation with the Member States experts consider that the requested extension of use may result in a significant contribution to the total intake.

The applicant has indicated that sodium stearyl-2-lactylate is one of the emulsifiers with the highest hydrophilic-lipophilic balance and is therefore an excellent emulsifier for fat in water emulsions. An important synergy between sodium stearyl-2-lactylate emulsifier and the stabilizer iota carrageenan (E 407) has recently been discovered and has been patented (European Patent No 1488705 A1) under the registered trademark *Premultex*®.

As sodium stearyl-2-lactylate (E 481) is authorised to be used individually or in combination with calcium stearyl-2-lactylate (E 482), it does not seem justified, according to EFSA, to make the exposure assessment of only sodium stearyl-2-lactylate (E 481) and it would be preferable to perform an exposure assessment for both substances included in the group of lactylates (E 481-482).

## TERMS OF REFERENCE AS PROVIDED BY EFSA

For the reasons described in the letter and in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002<sup>6</sup>, the European Commission asks the European Food Safety Authority to provide a scientific opinion on the exposure assessment of both lactylates (sodium stearyl-2-lactylate and calcium stearyl-2-lactylate).

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<sup>5</sup> European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners., OJ L 61, 18.03.1995, p. 53.

<sup>6</sup> Commission Regulation (EU) No 178/2002 of the European Parliament and of the Council of 28 January 2012 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 12.2002, p. 24.

## EVALUATION

### 1. Introduction

Following a request by the European Commission on 13 April 2012, the Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS) carried out an exposure assessment of sodium stearoyl-2-lactylate (E 481) (SSL) and calcium stearoyl-2-lactylate (E 482) (CSL) as food additives including extension of the uses to use in emulsified cooked meat products (e.g. mortadella, paté).

A report published in 1978 by the SCF endorsed the group acceptable daily intake (ADI) of 20 mg/kg bw/day as established by JECFA. In April 2011 the application for the extension of the use of sodium stearoyl-2-lactylate (E 481) was limited to emulsified cooked meat products (e.g. mortadella, paté) by proposing a maximum limit of 3 g/kg food in combination with iota carrageenan (stabilizer E 407, which belongs to group I of food additives used at *quantum satis*), that is 2.2 g/kg food of E 481 and 0.8 g/kg food of iota carrageenan. The applicant has indicated that sodium stearoyl-2-lactylate is one of the emulsifiers with the highest hydrophilic-lipophilic balance and is therefore an excellent emulsifier for fat in water emulsions. An important synergy between sodium stearoyl-2-lactylate emulsifier and the stabilizer iota carrageenan (E 407) has recently been discovered and has been patented (European Patent No 1488 701 A1). As sodium stearoyl-2-lactylate is authorised to be used individually or in combination with calcium stearoyl-2-lactylate it does not seem justified to make the exposure assessment only to sodium stearoyl-2-lactylate and it is therefore preferable to perform exposure assessments for both substances included in the group of lactylates.

### 2. Case of need and proposed uses

Maximum Permitted Levels (MPLs) of SSL and CSL have been defined in the Commission Regulation (EU) No 1129/2011<sup>7</sup> on food additives for use in foodstuffs, with MPLs ranging from 2000 to 10 000 mg/kg in foods.

Table 1 summarises foods that are permitted to contain SSL and CSL and the corresponding MPLs as set by Commission Regulation (EU) No 1129/2011. An extension of authorisation to the use of SSL has been requested for the use in emulsified cooked meat products (e.g. mortadella, paté) within food category 08.2.2 Heat-treated processed meat at a proposed use level of 2200 mg/kg food in combination with iota carrageenan (E 407) at a level of 0.8 g/kg food.

**Table 1:** MPLs of SSL and CSL in foods according to the Commission Regulation (EU) No 1129/2011

Category number	Foods	Restrictions/exception	Maximum level (mg/L or mg/kg as appropriate)
01.4	Flavoured fermented milk products including heat-treated products		5000
01.8	Dairy analogues, including beverage whiteners	only beverage whiteners	3000
02.2.2	Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions		10 000 <sup>1</sup>

<sup>7</sup> Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council establishing a Union list of food additives. The Panel noted that the Commission Regulation (EU) No 1129/2011 of 11 November 2011 will enter into force on June, 1<sup>st</sup> 2013 but confirms the approved uses of SSL and CSL as food additive as described in previous directive still active until end of May 2013:

– Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners.

Category number	Foods	Restrictions/exception	Maximum level (mg/L or mg/kg as appropriate)
04.2.4.1	Fruit and vegetable preparations excluding compote	only mostarda di frutta	2000 <sup>1</sup>
05.2	Other confectionery including breath freshening microsweets	only sugar confectionery	5000 <sup>1</sup>
05.3	Chewing gum		2000 <sup>1</sup>
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4		5000 <sup>1</sup>
06.3	Breakfast cereals		5000 <sup>1</sup>
06.7	Pre-cooked or processed cereals	only quick-cook rice	4000 <sup>2</sup>
07.1	Bread and rolls	except products in 7.1.1 and 7.1.2	3000 <sup>1</sup>
07.2	Fine bakery wares		5000 <sup>1</sup>
08.2.2	Heat-treated processed meat	only minced and diced canned meat products	4000 <sup>1,3</sup>
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)		2000 <sup>1</sup>
14.1.4	Flavoured drinks	only powders for the preparation of hot beverages	2000 <sup>1</sup>
14.1.5	Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products other than coffee and coffee extracts	only powders for the preparation of hot beverages	2000 <sup>1</sup>
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	only emulsified liqueurs	8000 <sup>1</sup>
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol	only flavoured drinks containing less than 15% of alcohol	8000 <sup>1</sup>
15.1	Potato-, cereal-, flour- or starch-based snacks	only cereal-based snacks	2000 <sup>1</sup>
16	Desserts excluding products covered in categories 1, 3 and 4		5000 <sup>1</sup>

<sup>1</sup> The additives may be added individually or in combination

<sup>2</sup> The maximum level is applicable to the sum and the levels are expressed as the free acid

<sup>3</sup> As requested in the authorisation to the use of SSL, levels in addition to the use of iota carrageenan (E 407) of 0.8 g/kg

### 3. Reported use levels or data on analytical levels of SSL and CSL

SSL and CSL are used at levels of about 0.5 % (based on flour weight) in baked goods. SSL is used at a level of approximately 0.5 % in both dairy and non-dairy whipped toppings and desserts, and to 0.2 % in non-dairy coffee creamers. CSL is used at a level of approximately 0.5 % as an egg-white whipping aid (SCF, 1978).

In France, 179 food products containing stearoyl lactylates as an emulsifier were identified (Bemrah et al., 2008). Breakfast cereals, milk-based desserts, flavoured desserts, peeled potatoes, powdered hot beverages, fine bakery products, canned meat products, and rice account for approximately 80 % of the dietary exposure. Thus, the current use spectrum seems to be broader than described by the SCF in 1978. The average concentrations in foods containing the additive were 664.3 mg/kg in 9 breads and 1079.8 mg/kg in 5 fine bakery products.

According to Commission Regulation (EU) No 1129/2011 the maximum level of the permitted uses for SSL and CSL is restricted (Table 1: These additives may be added individually or in combination according to Annex II to Commission Regulation EC No 1333/2008<sup>8</sup> as amended by Commission Regulation (EU) No 1129/2011 i.e. the sum of both additives may not exceed the maximum level). Furthermore, two new food categories are included in Commission Regulation (EU) No 1129/2011: “Flavoured fermented milk products including heat-treated products” and “Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4”, with maximum levels of each 5000 mg/kg.

Most food additives in the EU are authorised at a specific MPL. However, a food additive may be used at a lower level than the MPL. In the framework of Regulation (EC) No 1333/2008 on food additives and of Regulation (EU) No 257/2010<sup>9</sup> regarding the re-evaluation of approved food additives, EFSA issued a public call for scientific data on SSL and CSL (E 481 and E 482) including present use and use patterns (i.e. which food categories and subcategories, proportion of food within categories/subcategories in which it is used, and actual use levels (typical and maximum use levels).

#### **Summarised data on reported use levels in foods from industries and other sources**

Information about the actual levels in use has been provided by the European Food Emulsifier Manufacturers’ Association (EFEMA). According to the questionnaire from ELC (Federation of European Food Additives, Food Enzymes and Food Cultures Industries), stearoyl-2-lactylate salts are typically used in bread at a level of 0.14-0.21 % (unpublished report), which is about 30 % lower than recommended by EFEMA in commercial data sheets. In addition, the level recommended in commercial technical data sheets by EFEMA for both bread and beverage whiteners are 0.2-0.3 %. Furthermore use levels are given in the questionnaire for SSL and CSL in bread, beverage whiteners, fine bakery wares, quick-cook rice, breakfast cereals, emulsified liqueur, cereal-based snacks, potato powders for mashed potato meals, fat emulsions, desserts, sugar confectionery, cereal- and potato-based snacks, minced and diced canned meat products, powders for the preparation of hot beverages, dietetic foods intended for special medical purposes - dietetic formulae for weight control intended to replace total daily food intake or individual meal, and *Mostarda di frutta* (specific Italian food within the food category “Fruit and vegetable preparations excluding compote” - 4.2.4.1)..

A data collection from the Confederation of the Food and Drink Industries of the EU resulted in the information given in Table 2 (CIAA, 2009, unpublished report). However, there is no information given on usages by beverages. Table 2 provides data on the use levels of SSL and CSL in foods as reported by industries. Table 2 also shows the levels used for the refined exposure assessment identified by the Panel.

<sup>8</sup> Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, OJ L 354, 311.2.2008, p. 33.

<sup>9</sup> Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up the program for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives, OJ L 80, 26.03.2010, p. 19-27.



**Table 2:** Usages data collection exercise for lactylates (E 481-482) (CIAA, 2009)

Foods	Maximum level (Reg (EU) 1129/2011)	Typical use level	Extreme use level	Comments	Level used for exposure assessment based on reported use levels
Fine bakery wares	5 g/kg	0.4-3 g/kg	0.4-5 g/kg	Partly representative of the European market	5 g/kg
Panification sèche		2-2.7 g/kg	2-2.7 g/kg	Partly representative of the French market	
Biscuits		0.7-0.8 g/kg	0.7-0.8 g/kg	Partly representative of the French market	
Quick-cook rice	4 g/kg	Products not representatively covered by CIAA's membership			4 g/kg <sup>1</sup>
Breakfast cereals	5 g/kg	No data received so far from CIAA's Membership			5 g/kg
Cereal-based snacks	2 g/kg	No data received so far from CIAA's Membership			2 g/kg
Desserts	5 g/kg	0-3 g/kg	5 g/kg	Limited representation of the European market. Some producers reported that these additives are typically not used.	5 g/kg
Sugar confectionery	5 g/kg	No data received so far from CIAA's Membership			5 g/kg
Cereal- and potato-based snacks	5 g/kg	No data received so far from CIAA's Membership			5 g/kg
Dietetic foods intended for special medical purposes - Dietetic formulae for weight control intended to replace total daily food intake or individual meal	2 g/kg	No data received so far from CIAA's Membership			2 g/kg
Bread (except that referred to in Annex II)	3 g/kg	1-2.6 g/kg	0.7-3 g/kg	Partly representative of the European market	3 g/kg

<sup>1</sup> When no data was available the Panel used the maximum level.

## 4. Exposure assessment

### 4.1. Food consumption data used for exposure assessment

In 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been built from existing national information on food consumption at a detailed level. Competent authorities in the European countries provided EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of EFSA 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a).

Overall, the food consumption data gathered at EFSA were collected by different methodologies and thus direct country-to-country comparison should be made with caution.

For calculation of chronic exposure, intake statistics have been calculated based on individual average consumption over the total survey period excluding surveys with only one day per subject. High level consumption was only calculated for those foods and population groups where the sample size was sufficiently large to allow calculation of the 95<sup>th</sup> percentile (EFSA, 2011a). The Panel estimated chronic exposure for the following population groups: toddlers, children, adolescents, adults and the elderly. Calculations were performed using individual body weights.

Thus, for the present assessment, food consumption data were available from 26 different dietary surveys carried out in 17 different European countries as mentioned in Table 3:

**Table 3:** Population groups considered for the exposure estimates of SSL and CSL

Population	Age range	Countries with food consumption surveys covering more than one day
Toddlers	from 12 up to and including 35 months of age	Bulgaria, Finland, Germany, Netherlands
Children <sup>10</sup>	from 36 months up to and including 9 years of age	Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden
Adolescents	from 10 up to and including 17 years of age	Belgium, Cyprus, Czech Republic, Denmark, France, Germany, Italy, Latvia, Spain, Sweden
Adults	from 18 up to and including 64 years of age	Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Spain, Sweden, UK
The elderly <sup>10</sup>	Older than 65 years	Belgium, Denmark, Finland, France, Germany, Hungary, Italy

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from FoodEx classification system has been linked to the Food Classification System as presented in the Commission Regulation (EU) No 1129/2011, part D, to perform exposure estimates.

#### 4.2. Exposure to SSL and CSL from their use as food additives

Exposure to SSL and CSL from their use as food additives has been calculated by using MPLs as listed in Table 1 combined with national consumption data for the five population groups (Table 3). Since data on reported use levels were the same as MPLs no exposure estimates have been performed with reported use levels.

High level exposure (typically 95<sup>th</sup> percentile of consumers only) was calculated by adding the 95<sup>th</sup> percentile of exposure from one food group (i.e. the one having the highest value) to the mean exposure resulting from the consumption of all other food groups.

This is based on the assumption that an individual might be a high level consumer of one food category and would be an average consumer of the others. This approach has been tested several times by the Panel in re-evaluation of food colours and has shown reasonable correlation with high level total intakes when using the raw food individual consumption data. Therefore, this approach was preferred for the calculations based on the MPLs and maximum reported use levels in order to avoid excessively conservative estimates.

However, the Panel noted that its estimates should be considered as being conservative as it is assumed that all processed foods contain SSL and CSL added at the MPLs or the maximum reported use levels.

Exposure was estimated using the food additives intake model (FAIM), available on the EFSA website<sup>11</sup>.

The Panel noted uncertainties in its exposure estimates based on the inability to calculate exposure for several food categories at a more detailed level as insufficiently robust data on food consumption is

<sup>10</sup> The terms “children” and “the elderly” correspond respectively to “other children” and the merge of “elderly” and “very elderly” in the Guidance of EFSA on the ‘Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment’ (EFSA, 2011b).

<sup>11</sup> (<http://www.efsa.europa.eu/en/topics/topic/additives.htm>).

available from the EFSA Comprehensive Food Consumption Database. In particular this applies to the use of SSL and CSL in food category 01.8 Dairy analogues, where the additive is authorised only for beverage whiteners, 08.2.2 Heat-treated processed meats, where the additive is authorised only for minced and diced canned meat products, and 15.1 Potato-, cereal-, flour- or starch-based snacks, where the additive is authorised only for cereal-based snacks. For these food categories it was assumed that the additive is used for all foods falling into this category, thus leading to an overestimation of exposure.

For the food categories 02.2.2 Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions, 04.2.4.1 Fruit and vegetable preparations, 06.7 Pre-cooked or processed cereals, 14.1.4 Flavoured drinks, 14.1.5 Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products other than coffee and coffee extracts, 14.2.6 Spirit drinks as defined in Regulation (EC) No 110/2008<sup>12</sup>, and 14.2.8 Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol it was assumed that the additive is not used at all since the authorisation applies only to a small part of these categories. Moreover, the food category 5.4 Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4 is not referenced in the FoodEx nomenclature and couldn't be taken into account in the present evaluation. This leads to a slight underestimation of exposure.

Table 4 summarises the estimated exposure to SSL and CSL from the use as food additives of all five population groups. The Panel noted that no differences were calculated for exposure estimates based on MPL and reported use levels due to the small number of use levels provided and the maximum reported use levels being at the MPL for all food categories.

**Table 4:** Summary of anticipated exposure to SSL and CSL from the use as food additives using MPLs in five population groups (mg/kg bw/day)

	Toddlers (12-35 months)	Children (3-9 years)	Adolescents (10-17 years)	Adults (18-64 years)	The elderly (>65 years)
<b>Estimated exposure using MPLs or reported use levels</b>					
• Mean	29-92	28-81	13-32	8-21	5-15
• High level <sup>13</sup>	69-223	44-190	21-59	19-53	16-31

Exposure estimates listed in Table 4 already include exposure resulting from the extension of the authorisation as requested by the petitioner to emulsified cooked meat products (e.g. mortadella, paté) as part of food category 08.2.2 Heat-treated processed meat as it was assumed that the entire food category processed meat contains the additive at the MPL of 4000 mg/kg food.

### 4.3. Main food categories contributing to exposure of SSL and CSL using MPLs

**Table 5:** Main food categories contributing to exposure to SSL and CSL using MPLs and number of surveys in which each food categories is contributing.

	Toddlers	Children	Adolescents	Adults	The elderly

<sup>12</sup> Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89, OJ L 39, 13.02.2008, p. 16-54.

<sup>13</sup> Typically 95<sup>th</sup> percentile of consumers only.

Category number	Foods	% contribution to total exposure (Number of Surveys)				
1.4	Flavoured fermented milk products including heat treated products	6-78 (4)	11-52 (13)	6-28 (10)	5-50 (13)	7-32 (6)
5.2.1	Other confectionery with added sugar		6-8 (4)	7-10 (2)	6-7 (2)	
6.3	Breakfast cereals	7 (1)	5-20 (8)	5-13 (7)	9-20 (4)	6-24 (2)
7.1	Bread and rolls	17-43 (3)	13-49 (14)	20-48 (12)	27-57 (14)	38-61 (6)
7.2	Fine bakery wares	12-40 (3)	12-42 (13)	5-39 (12)	6-30 (14)	7-29 (6)
8.2	Processed meat	6-14 (4)	8-22 (15)	10-22 (12)	12-33 (15)	13-37 (7)
16	Desserts excluding products covered in category 1, 3 and 4	13-16 (2)	6-14 (9)	6-10 (3)	8-10 (2)	8 (2)

#### 4.4. Uncertainty analysis

Uncertainties in the exposure assessment of SSL and CSL have been previously discussed in the present statement in section 4.2. According to the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and summarised below:

**Table 6:** Qualitative evaluation of influence of uncertainties

Sources of uncertainties	Direction *
Consumption data: different methodologies / representativeness / under reporting / misreporting / no portion size standard	+/-
Extrapolation from food consumption survey of few days to estimate chronic exposure	+
Linkage between reported use levels and food items in the consumption database: uncertainties on which precise types of food the use levels refer.	+/-
Occurrence data: maximum reported use levels within a food category	+
Exposure model: uncertainty in possible national differences in use levels of food categories, data set not fully representative of foods on the EU market, exposure calculations based on the maximum reported use levels (no use of typical use levels when available)	+

\* + = uncertainty with potential to cause over-estimation of exposure; - = uncertainty with potential to cause underestimation of exposure.

## 5. Discussion

The exposure to sodium stearoyl-2-lactylate and calcium stearoyl-2-lactylate is mainly resulting from the consumption of the food category flavoured fermented milk products, which contributes up to 78 % to the total exposure for toddlers. The second highest contributors are the food categories bread and rolls, fine bakery wares and processed meat. As the data on the actual use levels provided by the food industry are the same as the MPLs, exposure estimates based on reported use levels were not performed. The Panel noted that for some food categories no data were received from food industry or that food industry stated that the data provided were only of limited representation of the European market. Without any further details on the actual level of representation, the exposure estimates for those food categories are again based on the MPLs, as it cannot be assumed that those food categories do not contain the food additive at all. In view of the uncertainties in the exposure assessment identified in section 3.2, the Panel noted that its exposure estimates are conservative.

The exposure estimates based on MPLs are in a range of 29-92 mg/kg bw/day for toddlers, 28-81 mg/kg bw/day for children, 13-32 mg/kg bw/day for adolescents, 8-21 mg/kg bw/day for adults, and 5-15 mg/kg bw/day for the elderly at the mean level. At the high level, exposure estimates are in a range of 69-223 mg/kg bw/day for toddlers, 44-190 mg/kg bw/day for children, 21-59 mg/kg bw/day for adolescents, 19-53 mg/kg bw/day for adults, and 16-31 mg/kg bw/day for the elderly

The extension of the authorisation of sodium stearyl-2-lactylate to the use in emulsified cooked meat products would not result in a substantial increase of exposure based on the scenario of exposure assessment in this opinion. At present, sodium stearyl-2-lactylate is authorised in the food category “heat-treated processed meat” (08.2.2) for minced and diced canned meat products. The EFSA Comprehensive Food Consumption Database however does not provide data specifically on the consumption of these foods. Therefore, the data on the consumption of the top level category 08.2.2 had to be used for the exposure assessment. The exposure resulting from the extension of use to emulsified cooked meat products is already included in this conservative approach.

## CONCLUSIONS

In view of the data on actual use levels provided by food industry, the combined exposure to sodium stearyl-2-lactylate and calcium stearyl-2-lactylate is in the range 29-92 mg/kg bw/day for toddlers, 28-81 mg/kg bw/day for children, 13-32 mg/kg bw/day for adolescents, 8-21 mg/kg bw/day for adults, and 5-15 mg/kg bw/day for the elderly at the mean level. For exposure at high levels, ranges of 69-223 mg/kg bw/day for toddlers, 44-190 mg/kg bw/day for children, 21-59 mg/kg bw/day for adolescents, 19-53 mg/kg bw/day for adults, and 16-31 mg/kg bw/day for the elderly were calculated.

The Panel concluded that an extension of the authorisation for the use of sodium stearyl-2-lactylate in emulsified cooked meat products (e.g. mortadella, paté) would not lead to an increase of exposure based on the approach taken for the exposure assessment for the two food additives.

## DOCUMENTATION PROVIDED TO EFSA

1. CIAA (Confédération des Industries Agro-Alimentaires de l'UE), 2009. CIAA submission to Commission - intake data - September 2009. Submitted by EFEMA on stearyl-2-lactylate salts (E 481-E 482), unpublished report.

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## GLOSSARY AND ABBREVIATIONS

ADI	Acceptable Daily Intake
ANS	Scientific Panel on Food Additives and Nutrient Sources added to Food
bw	Body weight
CIAA	FoodDrinkEurope until June 2011 known as Confederation of the Food and Drink Industries of the EU
CSL	Calcium stearyl-2-lactylate
EC	European Commission
EFEMA	European Food Emulsifier Manufacturers' Association
EFSA	European Food Safety Authority
EU	European Union
MPL	Maximum Permitted Level
SCF	Scientific Committee on Food
SSL	Sodium stearyl-2-lactylate