



**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](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

**Agenda Item 5(b)**

**CX/FA 17/49/8**

January 2017

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES

#### Forty-ninth Session

**Macao SAR, China, 20-24 March 2017**

#### GENERAL STANDARD FOR FOOD ADDITIVES (GSFA):

#### USE LEVELS FOR ADIPIC ACID (INS 355) IN VARIOUS FOOD CATEGORIES

**Replies to CL 2016/9-FA of Brazil, Chile, Costa Rica, Cuba, European Union, Japan, United States of America, ICA, ICGA and IFAC**

#### Brazil

Food Category No. (1)	Food Category Name (1)	Maximum Use Level (2)	Comments (3)
<b>THE PROPOSAL IS SUBMITTED BY:</b>			
<b>USE LEVELS FOR ADIPIC ACID (INS 355):</b> The rows below may be copied as many times as needed.			
05.1.	Cocoa products and chocolate products including imitations and chocolate substitutes	Coverage: 10.000 mg/kg Fillings: 2000 mg/kg	
05.2 05.3	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4 Chewing gum	Minimum use level: 1000 mg/kg Typical Average Use level: 6534 mg/kg Maximum use level: 9818 mg/kg	
01.6.1	Unripened cheese (cream cheese)	no comments	
01.7	Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt)	4500 mg/kg	
04.1.2.9	Fruit-based desserts, incl. fruit-flavoured water-based desserts	6000 mg/kg	
07.1.2 07.2.1 15.1	Crackers, excluding sweet crackers Cakes, cookies and pies (e.g. fruit-filled or custard types) Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	2000 mg/kg	
14.1.4.3	Concentrates (liquid or solid) for water-based flavoured drinks	10.000 mg/kg	

(1) Food category number and name, as listed in Annex B of the GSFA.

(2) For consistency, the maximum use level should be reported on the same basis as the ADI.

(3) Comments on specific restrictions on the use of the food additive to be included as Notes (e.g., limitation of use to specific products in a food category).

### Chile

The CCFA subcommittee of Chile appreciates the possibility of submit information on use levels for adipic acid (INS 355) in various food categories.

Attached form with information on the use level.

<b>THE PROPOSAL IS SUBMITTED BY:</b>		Chile	
<b>USE LEVELS FOR ADIPIC ACID (INS 355):</b>			
Food Category No. (1)	Food Category Name (1)	Maximum Use Level (2)	Comments (3)
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4 Chewing gum	Typical Average Use level: 6534 mg/kg	
05.3		Maximum use level: 9818 mg/kg	

(1) Food category number and name, as listed in Annex B of the GSFA.

(2) For consistency, the maximum use level should be reported on the same basis as the ADI.

(3) Comments on specific restrictions on the use of the food additive to be included as Notes (e.g., limitation of use to specific products in a food category).

### Costa Rica

<b>THE PROPOSAL IS SUBMITTED BY:</b>			
<b>USE LEVELS FOR ADIPIC ACID (INS 355):</b> The rows below may be copied as many times as needed.			
Food Category No. (1)	Food Category Name (1)	Maximum Use Level (2)	Comments (3)
05.1.	Cocoa products and chocolate products including imitations and chocolate substitutes	Coverage: 10.000 mg/kg Fillings: 2000 mg/kg	
05.2 05.3	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4 Chewing gum	Minimum use level: 1000 mg/kg  Typical Average Use level: 6534 mg/kg Maximum use level: 9818 mg/kg	
01.6.1	Unripened cheese (cream cheese)	no comments	
01.7	Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt)	4500 mg/kg	
04.1.2.9	Fruit-based desserts, incl. fruit-flavoured water-based desserts	6000 mg/kg	
07.1.2 07.2.1 15.1	Crackers, excluding sweet crackers Cakes, cookies and pies (e.g. fruit-filled or custard types) Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	2000 mg/kg	
14.1.4.3	Concentrates (liquid or solid) for water-based flavoured drinks	10.000 mg/kg	

(1) Food category number and name, as listed in Annex B of the GSFA.

(2) For consistency, the maximum use level should be reported on the same basis as the ADI.

(3) Comments on specific restrictions on the use of the food additive to be included as Notes (e.g., limitation of use to specific products in a food category).

### Cuba

In response to the document CL 2016/9-FA requesting information about use levels of adipic acid (INS 355) in various food categories, adipic acid is not used in Cuba.

### European Union

The European Union (EU) welcomes the request for information on use levels for adipic acid (INS 355) for the purpose of exposure assessment to be performed by JECFA prior to the CCFA49.

Adipic acid has a relatively low ADI (0-5 mg/kg bw) compared to the proposed provisions included in the step process.

For the exposure assessment the EU would like to propose the following provisions:

THE PROPOSAL IS SUBMITTED BY:		European Union	
USE LEVELS FOR ADIPIC ACID (INS 355):			
Food Category No	Food Category Name	MaxLevel	Comments
01.7	Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt)	1000	Only dry powdered dessert mixes and fruit-flavoured desserts. Except for use in gel-like desserts at 6000 mg/kg
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	1000	Only dry powdered dessert mixes and fruit-flavoured desserts. Except for use in gel-like desserts at 6000 mg/kg
04.1.2.9	Fruit-based desserts, incl. fruit-flavoured water-based desserts	1000	Only dry powdered dessert mixes and fruit-flavoured desserts. Except for use in gel-like desserts at 6000 mg/kg
06.5	Cereal and starch based desserts (e.g. rice pudding, tapioca pudding)	1000	Only dry powdered dessert mixes and fruit-flavoured desserts. Except for use in gel-like desserts at 6000 mg/kg
05.4	Decorations (e.g. for fine bakery wares), toppings (non-fruit), and sweet sauces	2000	Only fillings and toppings for fine bakery ware
14.1.4.3	Concentrates (liquid or solid) for water-based flavoured drinks	10000	Only powders for home preparation of drinks. The ML is expressed on powder not as consumed!
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	10000	Only powders for home preparation of drinks. The ML is expressed on powder not as consumed!

### Japan

Food category No.	Food category name	Maximum use level (mg/kg)	Comments
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses)	100	To lower pH in freeze dried turnip greens which are used as an ingredient for topping to sprinkle on rice.
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	770	Adipic acid is used for following two types of foods. 1. Simmered vegetables and seaweeds Adipic acid is used to impart sour taste. Maximum use level is 210 mg/kg. 2. Simmered sea tangle with seasoning Adipic acid is used to prolong shelf life by lowering pH. Maximum use level is 770 mg/kg.
05.1.5	Imitation chocolate, chocolate substitute products	50	To impart sour taste to imitation chocolate containing fruit juice as an ingredients.
05.2.1	Hard candy	6500	To impart sour taste.
05.3	Chewing gum	8000	To impart sour taste.
09.2.4.1	Cooked fish and fish products	100	To prolong shelf life of steamed fish by lowering pH.
09.2.4.2	Cooked molluscs, crustaceans, and echinoderms	120	To prolong shelf life of cooked molluscs by lowering pH.
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms	570	To prolong shelf life of dried salted squids, salted molluscs by lowering pH.

Food category No.	Food category name	Maximum use level (mg/kg)	Comments
09.3.2	Fish and fish products, including molluscs, crustaceans and echinoderms, pickled and/or in brine	840	Adipic acid is used in following four types of foods to prolong shelf life by lowering pH. Name of the products and their maximum use level are as follows: 1. Soy sauce pickled squid Maximum use level is 840 mg/kg. 2. Soy sauce pickled cod herring Maximum use level is 320 mg/kg 3. Marinated sea urchin Maximum use level is 120 mg/kg 4. Koji-pickled salmon Maximum use level is 100 mg/kg
09.3.3	Salmon substitutes, caviar and other fish roe products	900	To prolong shelf life of seasoned cod roe by lowering pH.
12.2.2	Herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles)	30	To prolong shelf life of topping to sprinkle on rice by lowering pH.
15.1	Snacks – potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	100	To prolong shelf life of flour based snacks by lowering pH.

### United States of America

This responds to CL 2016/9-FA (May 2016): Request for information on use levels for adipic acid (INS 355) in various food categories. The United States appreciates the opportunity to provide the following comments for consideration at the forthcoming 49th Session of the Codex Committee on Food Additives (CCFA).

Adipic acid (INS 355) is considered generally recognized as safe for use in all foods in the USA at GMP levels. Currently recognized GMP levels in the USA are listed in 21 CFR 184.1009(d) for specific uses. A general GMP level of 0.02% (200 mg/kg) is listed in 21 CFR 184.1009(d) for all other food uses for which a specific GMP level is not provided.

A search of consumer packaged good (CPG) label databases provided information on products currently for sale in the USA that list Adipic acid as an ingredient on their label. A large number of products are available in the USA that contain Adipic acid. The table, below, lists the GSFA food categories that correspond to foods found in the USA that contain Adipic acid. Maximum use levels reported in the table, below, correspond to the GMP levels listed in the USA regulation for Adipic acid (21 CFR 184.1009(d)). All of these food categories currently have provisions for Adipic acid at Step 7 in the GSFA.

The Proposal is submitted by:		The United States of America	
USE LEVELS FOR ADIPIC ACID (INS 355): The rows below may be copied as many times as needed			
Food Category No.	Food Category Name	Maximum Use Level	Comments
01.6.4	Processed Cheese	200 mg/kg	
01.6.5	Cheese analogues	4500 mg/kg	
01.7	Dairy-based desserts (e.g., pudding, fruit of flavoured yoghurt)	5500 mg/kg	
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	5500 mg/kg	
05.2	Confectionary including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	200 mg/kg	
05.3	Chewing gum	200 mg/kg	
07.0	Bakery wares	500 mg/kg	

### International Confectioners Association (ICA)

<b>THE PROPOSAL IS SUBMITTED BY:</b>		International Confectioners Association	
<b>USE LEVELS FOR ADIPIC ACID (INS 355):</b> <i>The rows below may be copied as many times as needed</i>			
Food Category No. (1)	Food Category Name (1)	Maximum Use Level (2)	Comments (3)
5.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3, and 05.4	12000 mg/kg	The Confectionery Industry supports a maximum use level of 20000 mg/kg for future innovations.
5.3	Chewing gum	3900 mg/kg	The Confectionery Industry supports a maximum use level of 10000 mg/kg for future innovations.

(1) Food category number and name, as listed in Annex B of the GSFA.

(2) For consistency, the maximum use level should be reported on the same basis as the ADI.

(3) Comments on specific restrictions on the use of the food additive to be included as Notes (e.g., limitation of use to specific products in a food category).

### International Chewing Gum Association (ICGA)

<b>THE PROPOSAL IS SUBMITTED BY:</b>		International Chewing Gum Association (ICGA)	
<b>USE LEVELS FOR ADIPIC ACID (INS 355):</b> <i>The rows below may be copied as many times as needed.</i>			
Food Category No. (1)	Food Category Name (1)	Maximum Use Level (2) reported by ICGA member companies in all regions	ICGA Comments (3)
05.3	Chewing gum	Some regions do not report any use (e.g. EU28). Other regions (Americas, Japan, etc.) report <b>maximum use levels ranging from 3900 to 9820 mg/kg.</b> The above use levels were received from ICGA member companies and these 2016 use levels reflect the ICGA comments made during the 2014/2015 electronic working group on GSFA and ICGA proposal to reduce the current draft Maximum Permitted Level included in the GSFA from 20000 mg/kg down to 10000 mg/kg in the food category 05.3 Chewing gum (see CCFA47 working document CX/FA 15/47/9 from January 2015).	<b>Technological justification (summary):</b> Adipic acid is not widely used across the chewing gum category. Adipic acid is used in very specific products for its contribution to fruit and sour tastes. Adipic acid provides a prolonged sour taste and increased saliva flow while having low solubility during chewing. It is therefore an essential component used to promote continuous release of sour fruit flavours during chewing, thereby providing consumers that unique organoleptic experience and expected pleasure.  More information was provided by ICGA to the CCFA47's 2014 electronic Working Group on the GSFA and may be provided again upon request.
		<b>ICGA recommends that CCFA should consider for adoption at step 8 a level of 10000 mg/kg in 05.3 Chewing gum, depending on the outcome of JECFA's dietary exposure assessment and any JECFA further recommendation(s) on main food categories contributing to the exposure.</b>	<b>Important note to JECFA experts</b> in the case of chewing gum there are several conservative hypotheses that would lead to an overestimate of exposure based on a single maximum reported use level figure: <ul style="list-style-type: none"> <li>• Adipic acid is not used in all chewing gum but only in just a few specific product types and only in some areas in the world</li> <li>• Adipic acid is generally not used at the maximum reported use level but at a lower level</li> <li>• Adipic acid is not chewed out entirely from the gum after normal chewing time.</li> </ul>

		<ul style="list-style-type: none"> <li>Chewing gum daily serving is 3 grams per day at a global level (see JECFA flavouring evaluations based on SPET method) - It would mean that with a MPL of 10000 mg/kg, an amount of 30 milligrams of adipic acid is contained in 3 grams of chewing gum. Assuming this is what a 60 Kg adult would eat a day, it would represent only 0.5 mg/kg b.w./day, but this figure is already a significant overestimate compared to real exposure due to the safety factors explained above</li> </ul> <p><b>Additional information which may be relevant to JECFA experts:</b></p> <p>Please note that typical average reported use levels are ranging from 2100 mg/kg to 6600 mg/kg.</p> <p>Minimum reported use levels are generally oscillating between 1000 mg/kg and 2000 mg/kg, when adipic acid is used</p>
--	--	--

(1) Food category number and name, as listed in Annex B of the GSFA.

(2) For consistency, the maximum use level should be reported on the same basis as the ADI.

(3) Comments on specific restrictions on the use of the food additive to be included as Notes (e.g., limitation of use to specific products in a food category).

#### International Food Additives Council (IFAC)

The International Food Additives Council (IFAC) is responding to CL 2016/9-FA “Request for information on use levels for adipic acid (INS 355) in various food categories.” IFAC is a global association representing manufacturers of food ingredients, including food additives. IFAC strives to promote science-based regulations, standards and specifications for food ingredients worldwide. IFAC holds Codex non-governmental observer status and appreciates this opportunity to provide information on adipic acid (INS 355).

As requested, we have enclosed available usage information on adipic acid (see Annex 1). Please note, this information represents suggested usage levels. As an organization representing food additive manufacturers, we do not always have information on actual or maximum usage levels. However, we believe the information provided in the Annex is representative of actual usage levels although these may vary slightly by manufacturer.

We hope this information will be useful for the Joint FAO/WHO Expert Committee on Food Additives (JECFA) as it completes its exposure assessment on adipic acid. Please contact me with any questions.

Food Category No. (1)	Food Category Name (1)	Maximum Use Level (2)	Comments (3)
01.6.5	Cheese analogues	0.45%	Suggested usage level to achieve technical function.
01.7	Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt)	0.55%	Suggested usage level to achieve technical function.
02.1	Fats and oils essentially free from water	0.3%	Suggested usage level to achieve technical function.
04.1.2.5	Jams, jellies, marmalades	0.55%	Suggested usage level to achieve technical function.
07.2.3	Mixes for fine bakery wares (e.g. cakes, pancakes)	0.05%	Suggested usage level to achieve technical function.
12.6.2	Non-emulsified sauces (e.g. ketchup, cheese sauce, cream sauce, brown gravy)	5.0%	Suggested usage level to achieve technical function.
14.1.4	Water-based flavoured drinks, including “sport,” “energy,” or “electrolyte” drinks and particulated drinks	0.005%	Suggested usage level to achieve technical function.
15.1	Snacks – potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	1.3%	Suggested usage level to achieve technical function.

(1) Food category number and name, as listed in Annex B of the GSFA.

(2) For consistency, the maximum use level should be reported on the same basis as the ADI.

(3) Comments on specific restrictions on the use of the food additive to be included as Notes (e.g., limitation of use to specific products in a food category).