

09/02/2015

**European Union comments on
Codex Circular Letter CL 2014/15-FA
Proposals for new and/or revision of adopted food additives provisions in
the GSFA**

European Union Competence.

European Union Vote.

The European Union would like to submit the following proposals for new additive provisions:

1. For the use of INS 242 Dimethyl dicarbonate in the category 14.2.7 Aromatized alcoholic beverages
2. For the use of INS 322(ii) Lecithin, partially hydrolysed as an alternative to the permitted uses of Lecithin INS 322(i)

Annex:

The forms containing the information requested for proposals for new additive provisions

Annex

Use of INS 242 Dimethyl dicarbonate in the category 14.2.7 Aromatized alcoholic beverages

THE PROPOSAL IS SUBMITTED BY:		European Union	
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Dimethyl dicarbonate	
INS Number		242	
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Preservative	
PROPOSED USE(S) OF THE FOOD ADDITIVE ⁽¹⁾: <i>The rows below may be copied as many times as needed.</i>			
Food Category No. ⁽²⁾	Food Category Name ⁽²⁾	Maximum Use Level ⁽³⁾	Comments ⁽⁴⁾
14.2.7	Aromatized alcoholic beverages	250 mg/kg	GSFA note 18: As added level; residue not detected in ready-to-eat food.
EVALUATION BY JECFA:			
Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i>	Evaluation year: 1990 ADI: ACCEPTABLE Comments: Acceptable for use as a cold sterilization agent in beverages when used according to good manufacturing practice up to a maximum concentration of 250 mg/l Meeting: 37 Specs Code: N Report: TRS 806-JECFA 37/23 Tox Monograph: FAS 28-JECFA 37/231 Specification: COMPENDIUM ADDENDUM 12/FNP 52 Add. 12/67 (METALS LIMITS) R; FAO JECFA Monographs 1 vol.1/473 Previous Years: 1990, COMPENDIUM/515. N		

JECFA SUMMARY: Dimethyl dicarbonate was considered acceptable for use as a cold sterilization agent for beverages when used in accordance with Good Manufacture Practice up to a maximum concentration of 250mg/l.	
JUSTIFICATION:	
Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i>	Dimethyl dicarbonate is used for cold sterilisation of beverages. It acts against fungi and bacteria and it is in particular useful to limit heat treatment by pasteurisation. This use allows an effective preservation of drinks without altering their flavour and taste. The use of dimethyl dicarbonate is cost effective and environmental friendly. The substance is currently permitted for the same use in several GSFA categories: 14.1.4, 14.1.5, 14.2.2, 14.2.3, 14.2.4 and 14.2.5.
Safe use of additive: Dietary intake assessment (as appropriate)	The substance is considered by JECFA to be of no toxicological concern at the proposed use level. In aqueous solutions it breaks down almost immediately after addition to beverages. The breaks down products are methanol, carbon dioxide and small amounts of other substances. The concentrations of methanol are similar to or less than those occurring naturally in many fruit juices and alcoholic beverages and are not of toxicological concern. The JECFA risk assessment refers to the use in fruit juices, soft drinks and wines. It is not expected that the extension of use to aromatized alcoholic beverages would be of safety concern. Consumption of aromatized alcoholic beverages is relatively modest comparing to the consumption of e.g. water based flavoured drinks.
Justification that the use does not mislead consumer	The use of Dimethyl dicarbonate fulfils the conditions listed in section 3.2 as regards preservation and keeping the stability of the product. Furthermore, it aids in the manufacture of the product. The use does not change the nature of the product and does not have any impact on the sensorial properties which would mislead the consumer (e.g. use of faulty raw materials).

Use of INS 322(ii) Lecithin, partially hydrolysed as an alternative to Lecithin INS 322(i)

THE PROPOSAL IS SUBMITTED BY:	European Union
IDENTITY OF THE FOOD ADDITIVE:	
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>	Lecithin, partially hydrolysed

INS Number		322(ii)	
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Antioxidant Emulsifier	
PROPOSED USE(S) OF THE FOOD ADDITIVE ⁽¹⁾: <i>The rows below may be copied as many times as needed.</i>			
Food Category No. ⁽²⁾	Food Category Name ⁽²⁾	Maximum Use Level ⁽³⁾	Comments ⁽⁴⁾
Table Three of the GSFA	Table Three of the GSFA	GMP	
EVALUATION BY JECFA:			
Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or “not specified”); specifications monograph).</i>	Evaluation year:	1973	
	ADI:	NOT LIMITED (i.e. not specified)	
	Meeting:	17	
	Specs Code:	S (1993)	
	Specification:	COMPENDIUM ADDENDUM 8/FNP 52 Add.8/203 (METALS LIMITS) (2000). R; FAO JECFA Monographs 1 vol.2/263	
	Previous Years:	1993, SPECIFICATIONS CONFIRMED. S 1990, COMPENDIUM/841 (FOR BOTH BLEACHED AND UNBLEACHED LECITHINS). R 1986, FNP 37-JECFA 30/69. N	
JECFA SUMMARY: Although fewer toxicological studies have been conducted than would normally be required for substances used as food additives, it is considered that nutritional and clinical experience with lecithin is sufficiently extensive to compensate for the incompleteness of the experimental data. Since many observations have been made in man it is not considered necessary to calculate the safe intake level from animal experiments.			
JUSTIFICATION:			
Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable</i>		Lecithins & partially hydrolyzed lecithin (INS 322 (ii)) are widely used as a dispersing agent/wetting agent, emulsifier or antioxidant (synergist) in various food categories (e.g. baked goods, confectionary, dairy products, dressings,	

<p><i>health risk, serves a technological function).</i></p>	<p>sauces, instant products etc.).</p> <p>Partially hydrolyzed lecithin 322 (ii) is hydrophilic while lecithin E 322 (i) is lipophilic. Thus, partially hydrolyzed lecithin is a better oil-in-water emulsifier, while lecithin generally cannot produce stable oil-in-water emulsions. Therefore, the permission of partially hydrolysed lecithin could, inter alia, provide an appropriate alternative in food applications for which lecithin (i) might not be so suitable.</p> <p>Partially hydrolyzed lecithin is used at very low levels. It is able to complex with starch, which makes it more functional in bakery applications than lecithin. It functions better than lecithin as an anti-spattering agent in low-salt containing margarines. It functions better than lecithin for improving the wettability and dispersibility of fat-containing powders while lecithin functions better for improving the wettability and dispersability of high protein powders.</p> <p>In condensed milk a better stability of the product is obtained with a lower dosage of partially hydrolyzed lecithin than when using standard grade lecithin.</p> <p>It should be noted that the food additive sections of several commodity standards refer to lecithins and do not specify their individual sub-classes. It is the EU understanding that the technological need for lecithins referred to in the commodity standards was scrutinised by the commodity committees and it would cover both lecithins (i) and (ii).</p>
<p>Safe use of additive: Dietary intake assessment <i>(as appropriate)</i></p>	<p>Lecithins are natural constituents of all cells in the human body and natural components of the diet. The average diet provides a daily intake of several grams of lecithins (approximately 1-5 g; JECFA, http://www.inchem.org/documents/jecfa/jecmono/v05je42.htm). It is considered that the intake of lecithins from food additive uses would not be of safety concern.</p>
<p>Justification that the use does not mislead consumer</p>	<p>Partially hydrolyzed lecithin is used commonly as an emulsifier to form and maintain a homogenous mixture of oil and water phases. Its use is not typically linked with issues related to the nature, freshness, quality of ingredients used or undesirable practices which would mislead the consumer.</p>