

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 5a-e

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Original Language

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-eighth Session

Xi'an, China, 14-18 March 2016

Comments of Egypt and CEFIC

EGYPT

AGENDA 5A

We support the proposal to hold discussions while there is no definition on the development of Regional Standard for Non-fermented Soybean Products

AGENDA 5C

We supports Chile's recommendation to remove Note 168 from the adopted provision in the GSFA for Quillaia extract in 14.1.4 since both types of the extract have been evaluated for safety by JECFA and a revised specification of Type 2 was adopted by the 79th JECFA in 2014

AGENDA 5D

We support the uses of Paprika Extract INS 160c (ii) and recommends adoption of the maximum use levels as determined from a comparison between IACM and NATCOL proposals

EUROPEAN CHEMICAL INDUSTRY COUNCIL (CEFIC)

AGENDA 5E

CEFIC would like to submit the comments as a correction for the previous one that was published in the CX/FA 16/48/11

Annex I

FORM FOR THE SUBMISSION OF PROPOSALS FOR NEW AND/OR REVISION OF ADOPTED FOOD ADDITIVE PROVISIONS IN THE GSFA

In completing this form, only brief information is required. However, responsive information is required for each field. The form may be retyped if more space is needed under any one heading provided that the general format is maintained. A separate table should be completed for each food additive.

THE PROPOSAL IS SUBMITTED BY:		<i>Cefic (European Chemical Industry Council)</i>	
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>		<i>Magnesium Stearate</i>	
INS Number		<i>INS 470(iii)</i>	
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		<i>Functional class:</i>	<i>Technological purpose</i>
		<i>Anticaking agent</i>	<i>Anticaking agent, lubricant, release agent</i>
		<i>Emulsifier</i>	<i>Emulsifier</i>
		<i>Thickener</i>	<i>Thickener, binder</i>
PROPOSED USE(S) OF THE FOOD ADDITIVE (1): <i>The rows below may be copied as many times as needed.</i>		The proposal for <input checked="" type="checkbox"/> a new provision;	
Food Category No. (2)	Food Category Name (2)	Maximum Use Level (3)	Comments (4)

05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	13'000 mg/kg	Anticaking agent (lubricant) Thickener (binder) in hard candy, pressed mint and mint pastille
05.3	Chewing gum	20'000 mg/kg	Emulsifier, Anticaking agent and Drying agent
13.6	Food Supplements	30'000 mg/kg	Anticaking agent (anticaking/lubricant / release agent), emulsifier and thickener
07.0	Bakery wares	2'500 mg/kg	Emulsifier / Thickener (Binder) in rusks, baking powder
12.2.1	Herbs and Spices	10'000 mg/kg	Anticaking agent in hydrophobic powdered spices and herbs
Table 3	May be used in Table 3 foods under the conditions of good manufacturing practices (GMP) as outlined in the Preamble of the Codex GSFA.	GMP	Emulsifier / Anticaking agent / Thickener INS 470 (i) and INS 470 (ii) are both listed in Table 3.

EVALUATION BY JECFA:

<p>Evaluation by JECFA Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</p>	<p>Magnesium Stearate was evaluated by JECFA at the 80th session (Rome, 16–25 June 2015) and an ADI "not specified" was adopted. The summary report has been published (http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/) and the Chemical Technical Assessment is also available (http://www.fao.org/3/a-az648e.pdf).</p> <p>Specifications will be published in FAO JECFA Monographs 17 and are already available online at http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/</p>
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JUSTIFICATION:

<p>Justification for use and technological need Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</p>	<p>Anticaking agent (technical purpose: Lubricant / Release agent) Magnesium stearate is mainly used in the food industry for the production of food supplements and confectionery compressed tablets. In tablet technology, when added to the powder before compression, it acts as a lubricant and assists in the ejection of the tablet from the punch and die. It prevents parts of the tablet sticking to the punches. This function is essential with today's high speed tablet presses as debris build-up on the punches and dies can cause damage. The magnesium stearate also provides a smooth surface to the tablet. The amount of magnesium stearate used in a tablet formula is dependent on the 'stickiness' of the pre-compression granule, but would normally not exceed 3% w/w.</p> <p>Anticaking agent Magnesium stearate improves the flowability and continuity with its anti-caking effect in certain hydrophobic powdered foods (e.g. spices and herbs) to extend the shelf life of these powders.</p> <p>Emulsifier / Binder Magnesium stearate can be used as an emulsifier in bakery ware such as rusks and baking powder. It is also used to bind sugar in hard candies like mints.</p> <p>Magnesium stearate is used by tablet manufacturers worldwide. Over the years, a number of alternative substances have been tried but none is claimed to function as effectively as magnesium stearate. It has been estimated that it is used in around 75% of all food supplement tablets and capsules produced and in over 90% of confectionery tablets. In chewing gums it is estimated to be used up to 30%.</p> <p>In the European Union, magnesium stearate is included in E470b – Magnesium salts of Fatty Acids, as described by Regulation (EU) No. 231/2012. It can be generally used as additive in foodstuffs with no specific maximum level (quantum satis) as determined by Regulation (EC) No. 1333/2008 on food additives. Excluded are processed foods and foods for which the use of</p>
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	<p><i>additives is prohibited.</i></p> <p><i>In the Unites States, the affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use: The ingredient is used as a lubricant and release agent; a nutrient supplement; and a processing aid as defined. And, the ingredient is used in foods at levels not to exceed current good manufacturing practice (§ 184.1440 in CFR 1985).</i></p>
<p>Safe use of additive: Dietary intake assessment (as appropriate)</p>	<p>Table 3 additive: X Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below)</p>
<p>Justification that the use does not mislead consumer</p>	<p><i>None of the uses described above is imparting properties to the foods that would be expected by consumers due to other reasons. Magnesium stearate is part of the INS 470 group of salts of fatty acids which are used and regulated for various purposes without any reported potential to mislead consumers.</i></p>

- (¹) For proposed revisions of adopted provisions, the current adopted provision should be provided, with deletions noted in ~~strike through~~ text, and changes or additions noted in **bold** font.
- (²) Food category number and name, as listed in Annex B of the GSFA.
- (³) For consistency, the maximum use level should be reported on the same basis as the ADI. A numerical use level should be provided for a food additive assigned a numerical ADI. GMP or a numerical use level may be provided for a food additive assigned a non-numerical ADI (e.g., "not-specified").
- (⁴) 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).