

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 5b

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fiftieth Session

GENERAL STANDARD FOR FOOD ADDITIVES (GSFA): PROPOSALS FOR NEW AND/OR REVISION OF FOOD ADDITIVE PROVISIONS

Comments of Australia

Australia

Updated submission from Australia including the additional information that was orally provided to the Physical WG of the GSFA at the 50th sessions of the CCFA

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:		Australia	
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>		Lauric arginate ethyl ester	
INS Number		243	
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>		The proposal for: <input type="checkbox"/> a new provision; or <input checked="" type="checkbox"/> revising an existing provision; or <input type="checkbox"/> use and use levels of tocopherols (INS 307a, b, c) as antioxidant in FC 01.3.1 "Condensed milk (plain)"; or <input type="checkbox"/> use and use levels of propylene glycol alginate (INS 405) and sucrose esters of fatty acids (INS 473) as emulsifier in FC 05.1.4 "Cocoa and chocolate products".	
Food Category No. (2)	Food Category Name (2)	Maximum Use Level (3)	Comments (4)
08.2.2	Heat-treated processed meat, poultry, and game products in whole pieces or cuts	200 mg/kg	Note XS96 Note XS97

			<i>Insert new note, which reads ““For products conforming to the Standard for Cooked Cured Ham (CODEX STAN 96-1981) and the Standard for Cooked Cured Pork Shoulder (CODEX STAN 97-1981), use is limited to ready-to-eat products which require refrigeration</i>
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	200 mg/kg	Note XS98 Note XS88 Note XS89 Note 377
<p>Is the proposal related to a FC with corresponding commodity standards? (if yes indicate the relevant FC)</p> <p>Yes</p> <p>FC 08.2.2 Standard for Cooked Cured Ham (CODEX STAN 96-1981). Standard for Cooked Cured Pork Shoulder (CODEX STAN 97-1981).</p> <p>FC 08.3.2 Standard for Corned Beef (CODEX STAN 88-1981) Standard for Luncheon Meat (CODEX STAN 89-1981) Standard for Cooked Cured Chopped Meat (CODEX STAN 98-1981)</p>			
<p>Is the proposal also intended to revise the products covered by the commodity standards? (if yes indicate the relevant commodity standards)</p> <p>No</p>			
EVALUATION BY JECFA:			
<p>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></p>		<p><i>Evaluation date: 2008</i> <i>Report: TRS 952-JECFA 69/27</i> <i>Tox Monograph: FAS 60-JECFA 69</i> <i>Specifications: FAO JECFA Monographs 7 (2009)</i> <i>ADI 0-4 mg/kg bw for Ethyl-N^o-Lauroyl-L-Arginate</i></p>	
JUSTIFICATION:			
<p>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></p>		<p><i>Provisions were adopted at Step 8 in 2016 for lauric arginate ethyl ester (LAEE) (INS 243) in food categories 08.2.2 and 08.3.2 at a level of 200 mg/kg in each category. Each of these provisions was adopted with footnotes that restricted the use of the additive in products conforming to corresponding commodity standards associated with the respective categories. The footnotes adopted for each of the categories are as follows:</i></p> <p><u>FC 08.2.2</u> <i>XS96 Excluding products conforming to the Standard for Cooked Cured Ham (CODEX STAN 96-1981).</i> <i>XS97 Excluding products conforming to the Standard for Cooked Cured Pork Shoulder (CODEX STAN 97-1981).</i></p> <p><u>FC 08.3.2</u> <i>XS88 Excluding products conforming to the Standard for Corned Beef (CODEX STAN 88-1981).</i> <i>XS89 Excluding products conforming to Standard for Luncheon Meat (CODEX STAN 89-1981).</i> <i>XS98 Excluding products conforming to the Standard for Cooked Cured Chopped Meat (CODEX STAN 98-1981).</i></p> <p><u>TECHNICOLOGICAL JUSTIFICATION</u> <i>Lauric arginate ethyl ester (LAEE) (INS 243) has demonstrated activity against a broad range of Gram-negative and Gram-positive bacteria, yeasts and moulds.</i></p>	

Provisions for LAEE in FC 08.2.2

As explained above, LAEE is currently permitted only in non-standardised foods falling under FC 08.2.2, of the GSFA i.e. "Heat-treated processed meat, poultry, and game products in whole pieces or cuts" at 200 mg/kg. Its use is excluded from products conforming to the Standard for Cooked Cured Ham (CODEX STAN 96-1981) and the Standard for Cooked Cured Pork Shoulder (CODEX STAN 97-1981). Both standardised and non-standardised products under this category can be prepared such that after heat treatment (which is not a sterilisation step) they are handled, sliced and packaged in the supply chain. They are then further handled by the consumer in the home following purchase. A number of these products are prepared ready to eat and require refrigerated storage. There are numerous opportunities for inadvertent post-processing contamination of these ready to eat products either in the supply chain or in the home following purchase. The use of LAEE in ready-to-eat products requiring refrigeration provides an advantage in developing countries where access to stable refrigeration may be limited or in developed countries where the final consumer may not adhere to storage instructions.

LAEE also provides an effective alternative to the use of nitrites, and can provide additional protection when reduced levels of nitrites and/or salt are used in the standardised products under FC 08.2.2, particularly when these are ready-to-eat products that require refrigeration. As such this proposal for new work seeks the modification of the current footnotes associated with the use of LAEE in this food category to additionally permit its use in standardised foods that are ready-to-eat and require refrigeration.

Provisions for LAEE in FC 08.3.2

As with the provisions for LAEE in FC 08.2.2, its use in FC 08.3.3 is currently limited to non-standardised products under this food category. The footnotes XS88, XS 89 and XS 98 exclude its use in products conforming with the Standard for Luncheon Meat (CODEX STAN 89-1981), Standard for Cooked Cured Chopped Meat (CODEX STAN 98-1981), and Standard for Corned Beef (CODEX STAN 88-1981) respectively.

Again, both standardised and non-standardised products under this category can be prepared such that after heat treatment they are handled, sliced and packaged in the supply chain. They are then further handled by the consumer in the home following purchase. A number of these products are prepared ready-to-eat and require refrigerated storage, and numerous opportunities exist for inadvertent post process contamination, as well as for improper storage at elevated temperatures.

It should also be recognised that during the 49th Session of CCFA (2017), the Committee considered the use of the preservative nisin (INS 234) in food category 08.3.2 in general, and agreed that the use of nisin was acceptable in products conforming to the corresponding commodity standards in cases where the products are ready-to-eat and require refrigeration. Lauric arginate ethyl ester (INS 243) is also a preservative that is used in products that conform to the same corresponding commodity standards associated with FC 08.3.2. Given the use of an additional preservative in these ready-to-eat refrigerated products is now permitted under the GSFA, this proposal for new work requests that consideration is given to also modify the adopted provisions for lauric

	<p><i>arginate ethyl ester (INS 243) to permit its use in similar products. As such, the current notes XS88, XS 89 and XS 98 would be deleted and replaced with note 377 i.e. "For products conforming to the Standard for Luncheon Meat (CODEX STAN 89-1981), Standard for Cooked Cured Chopped Meat (CODEX STAN 98-1981), and Standard for Corned Beef (CODEX STAN 88-1981) use is limited to ready-to-eat products which require refrigeration".</i></p> <p><u><i>Authorisation of LAEE in Australia and New Zealand</i></u> <i>The use of ethyl lauric arginate ethyl ester is permitted for use in products falling under both FC 08.2.2 and 08.3.2 in a number of countries worldwide (e.g. Australia, New Zealand, Canada, USA), without further restriction on its use in products conforming with the relevant Codex commodity standards. These products are also available in international trade. For example, in Australia and New Zealand, lauric arginate ethyl ester is permitted to be used in the broader national food categories 08.2 Processed meat, poultry and game products in whole pieces or cuts, and 08.3 Processed comminuted meat, poultry and game products, at levels of 200mg/kg and 315mg/kg respectively. As such, consideration should be given to revising the provisions of the GSFA to reflect the acceptable use of lauric arginate ethyl ester as a preservative in these products in numerous countries, particularly when these products are ready-to-eat and require refrigeration to ensure safety.</i></p>
<p>Safe use of additive: Dietary intake assessment (as appropriate)</p>	<p><i>Table 3 additive:</i></p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No (Please provide information on dietary intake assessment below)</p> <p><i>The use of lauric acid ethyl ester (INS 243) in meat products that fall under Codex food categories 08.2.2 and 08.3.2 (and without restriction of its use in standardised products), as well as its use in a broad range of other foods, was considered as part of the review of its safety in use as a food additive, and no concerns over dietary intake were identified for Australian and New Zealand consumers.</i></p> <p><i>In addition, consumption of meat products falling within these food categories was taken into consideration as part of the JECFA assessment of the safety of the additive in 2007.</i></p>
<p>Justification that the use does not mislead consumer</p>	<p><i>The use of lauric arginate ethyl ester (INS 243) would be indicated on the label of cured meat products falling within FC 08.2.2 and 08.3.2 that are ready-to-eat and that require refrigeration. These products are cured and by their very nature contain additives, and the presence of additives in these products is expected by consumers.</i></p>

(¹) For proposed revisions of adopted provisions, the current adopted provision should be provided, with deletions noted in ~~strikethrough~~ 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).