



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 - www.codexalimentarius.org

Agenda Item 3(b)

CX/FA 19/51/4 Add.1

February 2019

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-first Session

PROPOSED DRAFT SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 86TH JECFA MEETING

Comments at Step 3 (Replies to CL 2018/95/OCS-FA)

Comments of Iraq, Japan, Malaysia, Saint Lucia, EFEMA and IUFOST

Background

1. This document compiles comments received, in response to CL 2018/95/OCS-FA issued in December 2018 with a deadline of 31 January 2019. Annex I contains the comments received through Codex Online Commenting System (OCS).

Explanatory notes on the appendix

2. The comments submitted are hereby attached as **Annex I** and are presented in table format.

Comments on the Step 3 on the Proposed draft Specifications for the Identity and Purity of Food Additives

General Comment	Member/Observer
We agree with proposed	Iraq
<p>Japan recognizes that each specification is discussed in detail on the JECFA Meeting. However, Japan submits comments that some proposed modifications may need confirmation of current market situations as described below:</p> <p>-Citric and fatty acid esters of glycerol (INS 472c) In Monograph 22, some changes in the definition (fatty acid composition), Solubility and Total glycerol of the CITREM (INS 472c) specification were proposed. However, in the markets, many products complying with the current INS 472c are selling, and thus, the proposed changes may cause confusions in the markets.</p> <p>Japan observes that the such proposals in the specification are tentative. Japan is of opinion that prior to consider proposals to the INS 472c specification, it is recommended that marketing situation on the CITREM complying with the current specification should be confirmed.</p> <p>-Flavouring agents</p> <p>In addition, Japan submits comments on requests for reconsideration to the proposed draft flavouring agents specifications at the 86th JECFA Meeting.</p> <p>Regarding flavouring agents, different specification values from the actual status of distribution in Japan have been confirmed, including specifications other than draft proposed at 86th JECFA Meeting.</p> <p>Some substances have the specification values for Refractive index and Specific gravity set at the measurement temperature below the melting point or freezing point. The substances from natural sources, such as Myrcene, have a variety of purity are distributed in the market, and there are many substances not to conform to JECFA standard specifications. Therefore, it's recommended to reconsider JECFA specifications.</p> <p>If there is an opportunity to propose draft revisions, Japan is prepared to propose draft revisions for a part of JECFA specifications to other flavouring agents that have the same issue.</p>	Japan
Malaysia has no objection to the recommendation for CCFA51 to forward for adoption of the specification for food additives designated as 'Full' by the CAC42.	Malaysia
Saint Lucia accepts the new and revised specifications presented from the 86th Session of the JECFA. There are no technical deviations proposed at this time.	Saint Lucia
<p>EFEMA comments on tentative revised specifications for Citric and fatty acid esters of glycerol (CITREM - INS 472c) Footnote 3 "3 The Committee did not receive a replacement method for the obsolete packed column gas chromatographic method for the determination of total citric acid, in its specifications monograph. The Committee noted further that the method for total glycerol still uses chloroform. The Committee encouraged the submission of a method for total glycerol that eliminates the use of chloroform. Specifications were revised and made tentative pending the availability of data. Specifications will be withdrawn if suitable information is not provided by December 2019".</p> <p>EFEMA, the European Food Emulsifiers Manufacturers Association, noted the 86th JECA's conclusions and recommendations about INS 472c. We are happy to confirm that it provided the JECFA secretariat with the following information about Citric and fatty acid esters of glycerol (INS 472c) in December 2018:</p>	EFEMA

General Comment	Member/Observer
<ul style="list-style-type: none"> • Suitable validated method for citric acid and performance characteristics (data on at least five batches) • Method for total glycerol that eliminates the use of chloroform. <p>In connection with the EFEMA application for a change of the specification to also make it possible to use milder acting salts for neutralization of INS 472c, EFEMA also provided JECFA with additional data about INS 472c, its characteristics and manufacturing process.</p> <p>We remain accessible for any further information.</p> <p>EFEMA's comments on JECFA's definition for INS 472c (Monograph 22 - page 155 - lines 4 to 9 of the 'Definition' section - see link: http://www.fao.org/3/ca2330en/CA2330EN.pdf):</p> <p>EFEMA would like to suggest an alternative wording for this sentence: "The mono- and di-glycerides may include fatty acids found in edible oils."</p> <p>This would be in alignment with the definition in the current JECFA Monograph for INS 472c and with the definition in the EU specifications for citric acid esters of mono-and diglycerides of fatty acids. (Regulation 231/2012 - see link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012R0231).</p> <p>Maximum limit for lead when INS 472c is used in infant formula</p> <p>EFEMA would like to remind that the maximum limit for lead when INS 472c is used in infant formula should be 0.5 mg/kg and not 0.1 mg/kg.</p> <p>At its 82nd meeting, JECFA established a specific maximum limit for lead of 0,5 mg/kg when CITREM is used in infant formula. Indeed, the following sentence can be found on page 14 of the Summary and conclusions of the 82nd JECFA meeting (see link: http://www.fao.org/3/a-bl839e.pdf): "The current limit of 2 mg/kg for lead in the CITREM specifications monograph was maintained for general use, and a limit of 0.5 mg/kg was included for use in infant formula".</p> <p>However, we noted that in the FAO JECFA MONOGRAPHS 19 document (see link: http://www.fao.org/3/a-i6413e.pdf) the specifications for INS 472 c initially read: "Lead (Vol. 4): Not more than 2 mg/kg.</p> <p>(Not more than 0.1 mg/kg for use in infant formula and formula for special medical purposes intended for infants)".</p> <p>After EFEMA officially raised the issue, the 84th JECFA accepted to include the correction in the Mongraph 20 (see link:http://www.fao.org/3/i8147en/I8147EN.pdf) and the specifications for INS 472c were corrected accordingly (see link: http://www.fao.org/3/a-bt053e.pdf).</p> <p>We would really appreciate if this could also be corrected in the JECFA Monograph 22.</p>	
<p>IUFOST fully supports CCFA action on adopting JECFA food additive specifications as Codex specifications. This should be automatic and does not need CCFA step processes which are in this case a waste of time for all Member Countires, take up time in CCFA plenary sessions, and do not provide any additional validity to the existing JECFA spifications.</p>	<p>IUFOST</p>