



Food and Agriculture
Organization of the
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Organization

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Agenda Item 3(b)

CX/FA 21/52/4 Add.3¹

August 2021

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON FOOD ADDITIVES

Fifty-second Session

PROPOSED DRAFT SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 87TH AND 89TH JECFA MEETINGS

Comments at Step 3

(Replies to CL 2019/118/OCS-FA of Egypt, Iraq, Malaysia, Paraguay, USA, CCTA, EFEMA, ISA and ISC
and

Replies to CL 2021/34/OCS-FA of Cuba, Colombia, Malaysia, Panama, Peru and Philippines)

Background

1. This document compiles comments received, in response to:
 - CL 2019/118/OCS-FA issued in December 2019 with a deadline of 15 February 2020; and
 - CL 2021/34/OCS-FA issued in May 2021 with a deadline of 31 July 2021.
2. 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.

¹ This document is an updated version of CX/FA 20/52/4 Add.1 and comments in reply to CL 2021/34/OCS-FA have been included.

Comments on the Step 3 on the Proposed draft Specifications for the Identity and Purity of Food Additives**Part A: Replies to CL 2019/118/OCS-FA****General Comments**

General Comment	Member/Observer
Egypt agrees with the proposed specifications in this document.	Egypt
we are agree with proposed draft without any comments.	Iraq
Malaysia has no objection to the recommendation for CCFA52 to forward for adoption of the specification for food additives designated as 'Full' by the CAC43	Malaysia

Specific comments

Specific comments	Member/Observer
Brilliant Black (Black) (Black PN) (INS 151)	CCTA
Citric and fatty acid esters of glycerol (CITREM) (INS 472c) (R)	CCTA
Citric and fatty acid esters of glycerol (CITREM) (INS 472c) (R)	<p>EFEMA</p> <p>EFEMA's comments on JECFA's definition for INS 472c (monograph 23, page 31, lines 6 to 11 of the 'Definition' section): EFEMA would like to suggest an alternative wording for this sentence: "The mono- and di-glycerides may include fatty acids found in edible oils." 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). Furthermore, many CITREM products currently on the market are based on unsaturated oils, and would hence not be in conformance to the fatty acid distribution given in the text.</p> <p>EFEMA's comment on Sulphated ash (Vol. 4) (monograph 23, page 32): the differentiation in the specification for sulphated ash between partially and wholly neutralized CITREM is complicated to manage as these terms are not defined. This would imply that it would be unclear under which conditions the lower or higher limit is valid. Furthermore, the spectrum going from a partially neutralized to fully neutralized product is continuously and it would appear that the proposed specification only permits for CITREM which is slightly neutralized or wholly neutralized, but not in between. Therefore, EFEMA suggests reverting to the old specification for Sulphated ash: Partially or wholly neutralized products: not more than 10%.</p>

Specific comments	Member/Observer
	<p>EFEMA's comment on Method for total Glycerol (monograph 23, pages 32-33):the method given for total Glycerol has not been replicated correctly from the methods supplied by EFEMA. EFEMA would therefore like to point out that the temperature column should indicate 20 degrees Celsius instead of 35 degrees Celsius.</p> <p>EFEMA's comment on Method for Total citric acid (monograph 23, pages 33-34): EFEMA would like to point out that there is a mistake in the replication of the method: the 10 µl in the text should be replaced by 20 µl.</p>
Steviol glycosides (R, N) ²	<p>Paraguay</p> <p>The JECFA 87th meeting report recognises in relation to the specifications for steviol glycosides INS 960a that the major components in the leaves from the Stevia rebaudiana Bertoni plant are stevioside and rebaudioside A; the proportions of rebaudioside D and M, which are of the order of 2% and 1%, are negligible (2015), however the final product obtained by this process does not reflect the composition of the leaves.</p> <p>More information about the origin of leaves is needed; while the extraction method is the same, it is remarkable that the proportions of minor components in the final product are very high.</p> <p>It should be noted that the number 960a has been assigned to steviol glycosides obtained from the leaves without genetic modification, since the strength of this additive is related to the natural origin, in order not to mislead consumers.</p>
Steviol glycosides (R, N) ²	<p>USA</p> <p>The United States would like to seek clarification from the JECFA Secretariat as to the status of the Framework for Developing Specifications for Steviol Glycosides by the 87th JECFA. In addition, we request clarification from the Codex Secretariat as to next steps to be taken by the Codex Committee on Food Additives (CCFA) in response to the publication of full specifications for several Steviol Glycosides under the Framework for Steviol Glycosides.</p> <p>We note that the Report of the 87th JECFA meeting (WHO Technical Report Series, No. 1020), the JECFA Summaries and Conclusions document for the 87th JECFA, and CX/FA 20/52/4 Rev. 1 (Agenda Item 3(b) document for the 52nd CCFA) all indicate that the Framework for Specifications for Steviol Glycosides was adopted by JECFA. Likewise, all three documents indicate that the Framework consists of three full sets of specifications (Annex 1: Steviol Glycosides from Stevia Rebaudiana Bertoni; Annex 2: Steviol Glycosides from Fermentation; and Annex 3: Enzyme Modified Steviol Glycosides), and one tentative set of specifications (Annex 4: Enzyme Modified Glucosylated Steviol Glycosides).</p>

Specific comments	Member/Observer
	<p>However, we note that the recently published FAO JECFA Monographs 23 lists the entire Framework for Steviol Glycosides as tentative. We would request clarification from the JECFA Secretariat on our understanding that the Framework for Steviol Glycosides in its entirety is not tentative, but rather that only one Annex of the framework is tentative (Annex 4) pending further information on analytical methods.</p> <p>In addition, as noted in the Report of the 87th JECFA (WHO Technical Report Series, No. 1020) when referring to Steviol glycosides produced by the four methods included in the Framework for Steviol glycosides: "...the Committee determined that no safety issues exist for steviol glycosides produced by any one of these methods resulting in products with \geq 95% steviol glycosides as per existing specifications. The Committee indicated that the ADI of 0–4 mg/kg bw established at the sixty-ninth meeting of JECFA for steviol glycosides (expressed as steviol) (Annex 1, reference 190) applies to steviol glycosides produced by the four methods indicated in the annexes of the specifications monograph produced at the current meeting."</p> <p>As Steviol glycosides are considered under a group header within the General Standard for Food Additives (GSFA) we are requesting clarification from the Codex Secretariat as to the next steps to be taken by CCFA in order to include the Steviol Glycosides from Annexes 1, 2, and 3 into the GSFA. Based on the three sets of full specifications in the Framework for Steviol Glycosides and the inclusion of the Steviol glycosides from the different manufacturing methods in the existing group ADI for Steviol glycosides, it is our understanding that CCFA should take the following actions:</p> <ol style="list-style-type: none"> 1. Maintain INS 960a in the GSFA group header for Steviol glycosides (based on the full specifications from "Annex 1: Steviol Glycosides from Stevia Rebaudiana Bertoni" of the Framework). 2. Include INS 960b "Steviol glycosides from fermentation" in the GSFA group header for Steviol glycosides (based on the full specifications from "Annex 2: Steviol Glycosides from Fermentation" of the Framework). <ol style="list-style-type: none"> a. We would also like to seek clarification from the JECFA Secretariat regarding the status of the specifications for INS 960b(i) (Rebaudioside A from multiple gene donors expressed in <i>Yarrowia lipolytica</i>). It appears that the specifications for INS 960b(i) may have been subsumed by Annex 2 of the Framework for Steviol glycosides (Steviol glycosides from fermentation). If this is the case, once INS 960b has been added to the GSFA group header

Specific comments	Member/Observer
	<p>for Steviol glycosides, it may be appropriate to remove INS 960b(i) from the Steviol glycosides group header in the GSFA.</p> <p>3. Task the INS working group with generating an INS number for Enzyme Modified Steviol Glycosides (based on the full specifications from “Annex 3: Enzyme Modified Steviol Glycosides in the Framework”). The USA respectfully proposes that the additive be given the INS number “INS 960c” in keeping with the nomenclature structure for other Steviol glycosides already included in CXG 36-1989 (the INS). Once an INS number for the additive has been established, the additive can be added to the GSFA group header for Steviol glycosides.</p> <p>4. Request that the INS working group consider generating an INS number for Enzyme Modified Glucosylated Steviol Glycosides (based on the tentative specifications from “Annex 4: Enzyme Modified Glucosylated Steviol Glycosides”). Once JECFA has removed the tentative status for the specifications, the additive can be included in the GSFA group header for Steviol glycosides.</p>
Steviol glycosides (R, N) ²	<p>ISA</p> <p>The International Sweeteners Association would like to submit the below comments referring to steviol glycosides and in particular to the inconsistency between the report (full version and summary) of the 87th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the 23rd JECFA Monographs prepared at the said 87th meeting.</p> <p>The full report from the 87th JECFA meeting states that:</p> <p>A framework was adopted for developing specifications for steviol glycosides by four different methods of production. Specifications for steviol glycosides produced by different production methods were included as annexes, as below:</p> <ul style="list-style-type: none"> - Annex 1: Steviol Glycosides from Stevia rebaudiana Bertoni (revised from the specifications monograph for Steviol glycosides from Stevia rebaudiana Bertoni [INS 960a] prepared at the eighty-fourth meeting of JECFA [Annex 1, reference 236]). - Annex 2: Steviol Glycosides from Fermentation (specifications for Rebaudioside A from multiple gene donors expressed in Yarrowia lipolytica [INS 960b(i)] prepared at the eighty-second meeting of JECFA [Annex 1, reference 231] were revised to include other steviol glycosides from Saccharomyces cerevisiae and Yarrowia lipolytica). - Annex 3: Enzyme Modified Steviol Glycosides (new specifications). - Annex 4: Enzyme Modified Glucosylated Steviol Glycosides (new specifications, tentative pending further information concerning the analytical methods).

Specific comments	Member/Observer
	<p>It is our understanding that, as per the full report of the 87th JECFA meeting, JECFA adopted the framework for developing specifications for steviol glycosides and the three specifications set out in Annex 1, 2 and 3. Only the new specification for enzyme modified Glucosylated Steviol Glycosides was considered as 'tentative', pending further information concerning the analytical methods. The same rationale was reproduced in the Codex working document CX/FA 20/52/4 Rev.1 Proposed draft specifications for the identity and purity of food additives arising from the 87th JECFA meeting.</p> <p>As opposed to this, the 23rd JECFA Monographs prepared at the said 87th JECFA meeting states that the framework for developing specifications for steviol glycosides is 'tentative'.</p> <p>As no request for information or concern with regard to the framework for developing specifications for steviol glycosides as such was expressed in the JECFA 87th meeting report and the 23rd monograph, ISA understands that the framework was fully adopted by JECFA. Only the new specifications involving Enzyme Modified Glucosylated Steviol Glycosides were considered tentative pending further information concerning the analytical methods.</p> <p>Accordingly, ISA would like to ask for alignment of the 23rd Monographs with the reports from the 87th JECFA meetings and the amendment of the 23rd Monographs to include an indication that the framework for developing specifications for steviol glycosides is considered 'full'.</p>
Steviol glycosides (R, N) ²	<p>ISC</p> <p>The International Stevia Council (ISC) would like to make the following comments and request clarification on the JECFA 23 compendium specification monograph in relation to steviol glycosides.</p> <p>Firstly, there appears to be a disconnect and contradiction in terms of the JECFA 87th meeting report regarding the SG framework and specifications and the JECFA specification compendium 23. In both the summary and the full reports from the 87th JECFA meeting it clearly states that the SG framework for the safety evaluation was "adopted" by the Committee and that specifications for the New Technologies were subsequently prepared, with 3 specifications being adopted as "full" and only the Enzyme Modified Glucosylated steviol glycosides as being "tentative". In contradiction, the FAO JECFA Monograph 23, indicates that the SG framework and therefore the specifications are only considered to be "tentative". It is therefore unclear to the ISC as to how the 2 reports generated as a result of the outcome of the deliberations of the JECFA Committee could provide totally opposing opinions?</p> <p>The disconnect in terms of the specifications as laid down in monograph 23 as only being considered tentative is further highlighted in Agenda item 3(b) CX/FA 20/52/4 Rev.1 2019.</p>

Specific comments	Member/Observer
	<p>Point number 5 within this document supports the opinion that the SG framework was adopted and that full specifications were set for 3 of the technologies with only the Enzyme Modified Glucosylated Steviol Glycosides being considered tentative pending further information. Agenda Item 3(b) indicates the following within Annex 1;</p> <p>“A framework was adopted for developing specifications for steviol glycosides by four different methods of production. Specifications for steviol glycosides produced by different production methods were included as annexes, as below:</p> <ul style="list-style-type: none"> • Annex 1: Steviol Glycosides from <i>Stevia rebaudiana</i> Bertoni (revised from the specifications monograph for Steviol glycosides from <i>Stevia rebaudiana</i> Bertoni prepared at the 84th meeting of JECFA (INS 960a)). • Annex 2: Steviol Glycosides from Fermentation (specifications for Rebaudioside A from multiple gene donors expressed in <i>Yarrowia lipolytica</i> (INS 960b(i)) prepared at the 82nd JECFA were revised to include other steviol glycosides from <i>Saccharomyces cerevisiae</i> and <i>Yarrowia lipolytica</i>). • Annex 3: Enzyme Modified Steviol Glycosides (new specifications). • Annex 4: Enzyme Modified Glucosylated Steviol Glycosides (new specifications, tentative pending further information concerning the analytical methods)”. <p>From a procedural perspective, if the framework was in fact only considered “tentative” at the JECFA meeting this would have precluded any in depth work on the specifications until the limitations had been resolved. This clearly was not the case. Furthermore, it is our understanding that if a JECFA opinion is considered “tentative”, then this is usually highlighted in the full report along with a request for what additional information is required to be supplied along with a submission date. As no such request was outlined in the full report of the 87th meeting, this further supports that the framework was adopted at the meeting and was not considered “tentative”.</p> <p>The ISC is therefore requesting a correction be made to the JECFA specification monograph 23, to remove the statement that the framework and therefore the specifications are considered “tentative”. It is understood that the only “tentative” outcome relates to the Enzyme Modified Glucosylated Steviol Glycoside specification.</p> <p>It would be important to align statement from the JECFA 87th report and the JECFA compendium specification monograph 23.</p>

Specific comments	Member/Observer
	<p>Furthermore, ISC identified another disconnect between the two documents that appears to be a mistake in the text:</p> <p>In the 87th JECFA Full Report, Annex 2 indicates Steviol Glycosides in the list of food additives under “Food additives considered for specifications only” with reference to note (e) (page 103). Reference to Steviol Glycosides is not present in the list of food additive under “Food additives considered for specifications only” in the JECFA 23rd Monograph while the note (e) appears in the text (page 102-103).</p> <p>ISC is requesting the correction of the chapter on “Toxicological and dietary exposure information and information on specifications” in the JECFA 23rd Monograph according to the JECFA 87th Full Report.</p> <p>Finally, we would also like to request further clarification on what are the next steps in relation to the INS for the steviol glycosides specifications which might be adopted at CCFA 52.</p>

Part B: Replies to CL CL 2021/34/OCS-FA**General Comments**

General Comment	Member/Observer
Cuba, in principle, supports what is described in the Proposed draft specifications elaborated by JECFA at its 89th session.	Cuba
<p>Adenosine 5'-monophosphate deaminase from <i>Streptomyces murinus</i> (N); D-Allulose 3-epimerase from <i>Arthrobacter globiformis</i> expressed in <i>Escherichia coli</i> (N)</p> <p>Colombia supports the proposal.</p> <p>Jagua (genipin-glycine) blue (R)</p> <p>Colombia supports the proposal. Colombia considers important to highlight that in CX/FA 21/52/4 Add.1, Annex I, INS 183, proposed for this additive, is not specified when mentioning Jagua (genipin-glycine) blue.</p> <p>Lipase from <i>Mucor javanicus</i> (N); Magnesium stearate (INS 470(iii) (R); Phosphatidylinositol-specific phospholipase C expressed in <i>Pseudomonas fluorescens</i> (PI-PLC) (N); Polyvinyl alcohol (INS 1203) (R); Flavours tested for new specifications; Flavours tested for revision of specifications only</p> <p>Colombia supports the proposed position</p>	Colombia
Malaysia has no objection to the recommendation for CCFA52 to forward for adoption of the specification for food additives designated as 'Full' by the CAC44.	Malaysia
Panama appreciates the work carried out and we agree with what is presented in this document, we have no negative comments, and we recommend its progress.	Panama
Peru supports the proposal for Jagua (genipin-glycine) blue, given that in 2020 JECFA89 established the ADI for Jagua blue.	Peru
<p>The Philippines supports the adoption of the specifications designated as "Full" for the following food additives:</p> <ol style="list-style-type: none"> 1. Adenosine 5'-monophosphate deaminase from <i>Streptomyces murinus</i> (N) 2. D-Allulose 3-epimerase from <i>Arthrobacter globiformis</i> expressed in <i>Escherichia coli</i> (N) 3. Jagua (genipin-glycine) blue (Jagua blue) (R) 4. Lipase from <i>Mucor javanicus</i> (N) 5. Magnesium stearate (INS 470(iii) (R) 6. Phosphatidylinositol-specific phospholipase C expressed in <i>Pseudomonas fluorescens</i> (PI-PLC) (N) 7. Polyvinyl alcohol (INS 1203) (R) <p>Also, the Philippines supports the adoption of the new specifications (N) of the following 12 flavouring agents:</p> <ol style="list-style-type: none"> 1. Betaine 2. N-Acetyl-glutamate 3. L-Cysteine methyl ester hydrochloride 4. Glutamyl-2-aminobutyric acid 5. Glutamyl-norvaline 	Philippines

<p>6. Glutamyl-norvalyl-glycine 7. (±)-Homoeriodictyol sodium salt 8. (±)-Naringenin 9. (2R)-3',5-Dihydroxy-4'-methoxyflavanone 10. 7,8-Dihydroxyflavone 11. (2S)-3',7-Dihydroxy-8-methyl-4'-methoxyflavan 12. 3-(3-Hydroxy-4-methoxyphenyl)-1-(2,4,6-trihydroxyphenyl)propan-1-one</p> <p>Rationale:</p> <p>JECFA has already established the ADIs for the 7 food additives and it was concluded at the 89th JECFA meeting (virtual online platform, on 1-12 June 2020) that the usage of these additives would not pose a health concern based on its genotoxicity test results and current estimated dietary exposures.</p> <p>Further, flavoring agents considered for new specifications were concluded to have no safety concern based on current estimated dietary exposure except for (2S)-3',7-Dihydroxy-8-methyl-4'-methoxyflavan (JECFA No. 2260) due to its genotoxicity data which raised concerns for potential genotoxicity.</p>	
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Specific comments

Specific comments	Member/Observer
Jagua (genipin-glycine) blue (Jagua blue) (R)	<p>Peru</p> <p>Peru supports the proposal for Jagua (genipin-glycine) blue given that in 2020 JECFA89 established the ADI for Jagua blue.</p>
Magnesium stearate (INS 470(iii)) (R)	<p>Peru</p> <p>Peru will not submit comments.</p>
Polyvinyl alcohol (INS 1203) (R)	<p>Peru</p> <p>Peru will not submit comments.</p>
Flavours tested for new specifications ¹	<p>Peru</p> <p>Peru will not submit comments</p>