52nd Codex Committee on Food Additives

PLENARY, 1-10 September 2021, Virtual

KEY PRIORITIES
for the food supplement category (FC13.6)

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International Alliance of Dietary/
Food Supplement Associations

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SPECIFICATIONS FOR IDENTITY AND PURITY OF FOOD ADDITIVES

The Committee was asked at its Plenary session to recommend the endorsement at Step 5/8 of revised specifications prepared by JECFA at their 87th and 89th meetings. Specifications on this page cover food additives used in food supplements.

A specification that cannot be finalised could be revoked and lead to a withdrawal of the related additive from the GSFA

CCFA AGREED TO FORWARDED TO CAC44 SPECIFICATIONS FORWARDED FOR FINAL ADOPTION

Brilliant Black (Black PN) (INS 151) (R) New limits agreed this year

JECFA noted that based on the estimated exposure for the additive, its use should not present safety concerns. The previous ADI of 0 - 1 mg/ kg bw is maintained.

CITREM (INS 472c) (R) Table 3 additive = GMP for FC13.6

The ADI 'not specified 'has been reconfirmed. The additive should remain in Table 3 additive, allowing its use in supplements at GMP level.

Magnesium stearate (INS 470(iii) (R) Table 3 additive = GMP for FC13.6

For the assay of magnesium, the ICP-AES method reference was replaced with a general term to read as 'use a method appropriate to the specified level'.

Polyvinyl alcohol (INS 1203 (R) 45000 mg/kg in FC13.6

The solubility criteria were changed to "practically insoluble or insoluble in ethanoxl"

+

Rosemary extract (INS 392) (R) No provisions established for food categories

A temporary ADI of 0 – 0.3 mg/kg bw has been retained pending the submission by end of 2021 of new studies incl. data on the developmental toxicity of the additive. One Observer confirmed that data would be available by 2022.

(N) new specifications; (R) revised specifications; (T) tentative specifications

PROVISIONS IN TABLE 3 OF THE GSFA

DECISION: The Committee endorsed the recommendation of the Virtual WG to adopt at Step 5/8 the draft provisions for **lecithin, partially hydrolyzed (INS 332(ii)), basic methacrylate copolymer (INS 1205), lutein from Tagetes erecta (INS 161b(i)), and zeaxanthin (synthetic) (INS 161(h))** in Table 3.

Table 3 additives are permitted for use in food in general at levels consistent with good manufacturing practices (GMP)

BACKGROUND :

For basic methacrylate copolymer (INS 1205), lutein from Tagetes erecta (INS 161b(i)), and zeaxanthin (synthetic) (INS 161(h): The 86th JECFA (2018) established an acceptable daily intake (ADI) of "not specified" for the three additives that were included, as a result, in Table 3 of the GSFA at Step 3.

Lecithin, partially hydrolyzed (INS 332(ii): The additive had received an ADI of "not limited" from the 17th JECFA and CCFA47 agreed to enter a provision for this additive in Table 3 of the GSFA. CCFA51 requested the EWG on the GSFA to CCFA52 to circulate these provisions for comment at Step 3.

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INS 1205 BASIC METHACRYLATE COPOLYMER (BMC)

CCFA52 AGREED - CORRECTIONS TO THE SPECIFICATIONS

Basic methacrylate copolymer (INS 1205) Will also be applied to anionic methacrylate copolymer (INS 1207) and neutral methacrylate copolymer (INS 1206)	In section Definition: "Basic methacrylate copolymer is used as a coating and glazing agent for food supplements and foods for special medical purposes."	Sentence deleted.	Deletion requested by CCFA51[6]; sentence provided only marginal information

FOR INFORMATION
The 2 specifications for INS 1206 and 1207 are still tentative

Neutral methacrylate copolymer (NMC) (INS 1206)
Suitable method of assay required
Data provider: No commitment

Anionic methacrylate copolymer (AMC) (INS 1207)
Safety evaluation (missing data to finalise evaluation)
Data provider: No commitment

BACKGROUND: Concerns were raised at CCFA51 by the European Union on the appropriateness of the sentence "*Basic methacrylate copolymer is used as a coating and glazing agent for food supplements and foods for special medical purposes"* in the definition section of the BMC specifications. It was notably highlighted that the sentence would tend to limit the use of the additive to food supplements (FS) and foods for special medical purposes (FSMP) in solid forms solely while an ADI 'not specified' in Table 3 was established permitting its use in a wide variety of foods. The EU reminded the Committee that it was also unusual to refer to uses in JECFA specifications and requested JECFA to clarify the scope of the assessment.

In response to the EU question, JECFA indicated that the safety assessment was based on supplements, FSMP and micronutrient encapsulation for food fortification but the conclusion was not specific to those categories. It was stressed that the available toxicological data on BMC indicated low absorption and did not indicate any adverse health effects even at the highest doses tested. Noting that the sentence had caused misunderstandings, JECFA suggested to take the sentence out of the specifications. The Committee also noted that the current safety evaluation of BMC would not be changed.

The European Union requested that the following comments be recorded in the report: "In the EU, BMC was authorized for use only in food supplements with a maximum use level (ML) of 100.000 ppm, and that this level was appropriate to achieve the technological function, and thus corresponded to a use level in accordance with Good Manufacturing Practice". The US Delegation requested that the EU comments were about EU and not the view of the Committee. It was noted that the EU intervention was for information.

This issue raised by the EU led to heated discussions in Plenary with Senegal, who had introduced draft provisions for fortification at GMP levels worrying that these provisions could be in jeopardy. Senegal highlighted the humanitarian benefits provided by BMC for the country and requested the Committee to consider the adoption of BMC in the GSFA at its next meeting.

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JECFA PRIORITY LIST

TITANIUM DIOXIIDE : RE-EVALUATION AGREED

BACKGROUND: In response to a reassessment of the safety of titanium dioxide by the European Food Safety Authority (EFSA) that concluded that its use is unsafe as a food additive, the JECFA Secretariat anticipates issuing a call-for-data for purposes of conducting its own re-evaluation. Comments from Australia, Canada, Colombia, EU, Peru, UK and USA, provided in advance of CCFA, were supportive of this re-evaluation.

One Member noted that although new specifications for titanium dioxide were established in 2012, the last toxicological assessment was conducted in 1969. Further, it was noted that titanium dioxide is a widely used additive and so the expected revocation of the use of titanium dioxide as a food additive in the European Union presents a significant potential for a disruption in trade.

NEXT: JECFA aims first to establish criteria for the data necessary for the re-evaluation of titanium dioxide (likely in 2022) and then issue a corresponding call for data (likely in 2023), with the risk assessment that would begin in 2024 at the earliest.

Given the potential impact on trade if titanium dioxide is removed from EU market based on EFSA's recent opinion, Canada urged the JECFA Secretariat to consider every possible option to expedite the risk assessment by JECFA. The JECFA Secretariat stated stated that it would do its best to expedite the process.

SORBITAN ESTERS OF FATTY ACIDS (INS 491, 492 & 495)

BACKGROUND: A request was made to revise the specifications for INS 491, 492 and 495 to replace the congealing range identification method as reported in the JECFA monographs for INS 491, 492 and 495 with the identification test "acid value, iodine value, gas chromatography".

However, JECFA recommends that a call for data be issued to conduct a safety re-evaluation of the group Sorbitan esters of fatty acids (INS 491 to 495). The specifications for the group can be revised pending the outcome of the safety re-evaluation. z

TIMELINE:

Data availability: To be confirmed at CCFA53
Data provider: To be confirmed at CCFA53

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GENERAL STANDARD FOR FOOD ADDITIVES (GSFA)

ADVANCING PROVISIONS FOR COLOURS IN FC 13.6

BACKGROUND: CCFA50 has agreed to advance the draft provisions for colours as part of its new work. This work represents a major step forward for the Committee.

Colours have often been a trade barrier for many sectors notably in countries basing their additives legislation solely on the Codex GSFA. The Category 13.6 (food supplements) was considered a priority category to be addressed at CCF52. The table summarises the provisions endorsed by CCFA for adoption at Step 8 or Step 5 by CAC44

DECISION

Food Category No.	13.6	Food supplements			
Additive	INS	Step	Year	Max Level	Notes
ANNATTO EXTRACTS, BIXIN-BASED	160b(i)	5/8	2021	200 mg/kg	8 & B6
ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	5/8	2021	100 mg/kg	185 & B6
AZORUBINE (CARMOISINE)	122	8	2021	300 mg/kg	B6 & B7
BRILLIANT BLACK (BLACK PN)	151	8	2021	530 mg/kg	B6
BROWN HT	155	8	2021	300 mg/kg	B6
CARAMEL II - SULFITE CARAMEL	150b	5/8	2021	7500 mg/kg	
CURCUMIN	100(i)	8	2021	300 mg/kg	B6
PAPRIKA EXTRACT	160c(ii)	5/8	2021	100 mg/kg	39 & B6
QUINOLINE YELLOW	104	8	2021	300 mg/kg	B6 & B8
TARTRAZINE	102	8	2021	300 mg/kg	B6

Note 8 As bixin.
Note 39 On a total carotenoid basis.
Note 185 As norbixin.
Note B6 For use in solid **forms** as sold to the consumer only.
Note B7 Except for use at 100 mg/kg in **liquid forms as sold to the consumer only.**
Note B8 Except for use in hard capsules and film coated tablets at 1800 mg/kg.

Chlorophylls (140), Lycopene, tomato 160d(ii), Lutein from *Tagetes erecta* (INS 161b(i)), Zeaxanthin (synthetic) (INS 161(h)) have been discontinued since these additives are in Table 3 allowing their use at GMP in Food Supplements.

A BIT MORE BACKGROUND

In the version proposed for adoption, the notes B6 and B7 notes read:

- Note B6 For use in solid products as sold to the consumer only.
- Note B7 Except for use at 100 mg/kg in liquid forms

The committee decided to revise: Note B6 to read “For use in solid forms as sold to the consumer only”; and Note B7 to read “Except for use at 100 mg/kg in liquid forms as sold to the consumer only”;

Why?

Forms: In order to be consistent with the Guidelines for vitamin and mineral food supplements, IADSA suggested to replace the term “products” contained in the Notes B6 and B7 with the term “forms”. While the Committee was reminded that under Codex the word “product" should normally be used, the IADSA recommendation was agreed. Such a change will allow for greater clarity about food supplement dosage forms in future Codex discussions.

As sold to consumer only: Prior to the adoption of the provisions at the Plenary, IADSA had a series of exchanges with the US and EU delegations related to the inconsistency between Note B6 and B7. To address the issue, IADSA and EU suggested to add the term “as consumed” to B7 .This would have allowed limits required for effervescent forms to be covered. However it was clarified by the Chair of the GSFA in Plenary that Codex provisions apply to products "as sold to the consumer" which, it was argued, is key for the enforcement of the GSFA. The terminology “as sold to the consumer only” was therefore added to the Notes B6 and B7 to ensure no misinterpretation.

Effervescent and INS122: With solid forms covered under effervescent forms, IADSA suggested the inclusion of a new note associated with azorubine (INS 122) “except for use at 1100mg/kg in effervescent forms as sold to the consumer only” to address member needs. While there was no objection with the proposal, the Committee indicated that such a new Note could be addressed at a future meeting given the issue of dosage form was rather complicated.

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GENERAL STANDARD FOR FOOD ADDITIVES (GSFA)

FUTURE WORK

CAROTENOIDS ARE SAFE FOR THE GENERAL POPULATION

BACKGROUND
Noting that data from the population in heavy smokers cannot be gathered ethically, JECFA decided to withdraw the two group ADIs of 0–5 mg/kg bw for synthetic carotenoids:

- the sum of carotenoids including Beta-carotene, Beta-apo-8′- carotenal and Beta-apo-8′-carotenoic acid methyl and ethyl esters of Beta-apo-8'-carotenoic acid and (originally applicable to INS 160e, INS 160f);
- Beta-carotene (synthetic) and Beta-carotene derived from Blakeslea trisporae (originally applicable to INS 160a(i) and INS 160a(iii)).

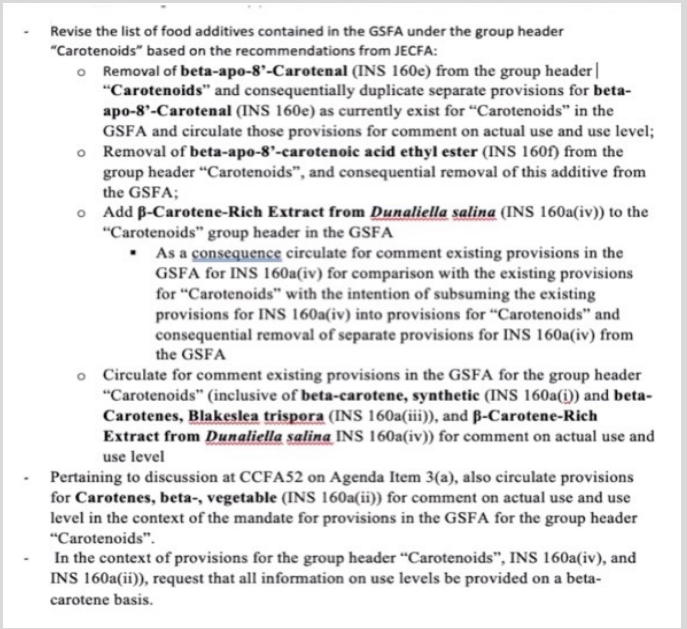
An ADI of 0-0.3 mg/kg bw for INS 160e was however established. No data was submitted for INS 160f.

CLARIFICATION AT PLENARY

JECFA Secretariat clarified at CCFA52 that although it was not able to develop a group ADI for CAROTENOIDS, there were no safety concerns for the general population, and CCFA could address the recommendations in the JECFA assessment with appropriate risk management measures.

CCFA also noted that no ADI did not necessarily imply a withdrawal of the provision:
Section 1.1. of the Preamble to the GSFA allows for inclusions of additives without a JECFA ADI in the GSFA if they are determined by JECFA to be safe on the basis of other criteria.

CCFA52 agreed to task the GSFA EWG to consider this matter.



- Revise the list of food additives contained in the GSFA under the group header "Carotenoids" based on the recommendations from JECFA:
  - Removal of **beta-apo-8'-Carotenal** (INS 160e) from the group header | "**Carotenoids**" and consequentially duplicate separate provisions for **beta-apo-8'-Carotenal** (INS 160e) as currently exist for "Carotenoids" in the GSFA and circulate those provisions for comment on actual use and use level;
  - Removal of **beta-apo-8'-carotenoic acid ethyl ester** (INS 160f) from the group header "Carotenoids", and consequential removal of this additive from the GSFA;
  - Add **β-Carotene-Rich Extract from *Dunaliella salina*** (INS 160a(iv)) to the "Carotenoids" group header in the GSFA
    - As a consequence circulate for comment existing provisions in the GSFA for INS 160a(iv) for comparison with the existing provisions for "Carotenoids" with the intention of subsuming the existing provisions for INS 160a(iv) into provisions for "Carotenoids" and consequential removal of separate provisions for INS 160a(iv) from the GSFA
  - Circulate for comment existing provisions in the GSFA for the group header "Carotenoids" (inclusive of **beta-carotene, synthetic** (INS 160a(i)) and **beta-Carotenes, Blakeslea trispora** (INS 160a(iii)), and **β-Carotene-Rich Extract from *Dunaliella salina*** INS 160a(iv)) for comment on actual use and use level
- Pertaining to discussion at CCFA52 on Agenda Item 3(a), also circulate provisions for **Carotenes, beta-, vegetable** (INS 160a(ii)) for comment on actual use and use level in the context of the mandate for provisions in the GSFA for the group header "Carotenoids".
- In the context of provisions for the group header "Carotenoids", INS 160a(iv), and INS 160a(ii)), request that all information on use levels be provided on a beta-carotene basis.

A BIT MORE : The inclusion of beta carotenes in the JECFA priority list was also requested by Brazil to address the risk of heavy smokers at levels of intake expected from food additives use, the difference in toxicology between beta-carotenes from different sources, the relationship between the ADI and different sources of beta-carotenes, and JECFA advice relating to maximum levels for INS 160a(ii) in the GSFA. Brazil was invited to submit their request by replying to the Circular Letter on JECFA priorities that will be circulated after CCFA 52

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APPLICATION OF HORIZONTAL APPROACH TO SWEETENERS

BACKGROUND: For more than a decade, "Note 161: Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble" allowed for national exemptions from harmonizing with a Codex standard on sweeteners.

The note was introduced to adopt food additive provisions while recognising that countries may have different views on how food additives should be used nationally. The note resulted in different understandings of what is necessary to meet the criteria set in Section 3.2 of the Preamble on "Justification for the Use of Additives". This was specifically true for intense sweeteners. The note was assigned to a large number of them, which has led to the creation of trade barriers for the market of food categories containing these ingredients.

To address this issue, the Committee agreed to create a new electronic Working Group co-chaired by the European Union and US Delegations with the mandate to "develop wording of an alternative note which addresses concerns of Codex Members requiring significant energy reduction or food with no added sugar when sweeteners are used and those Codex Members requiring flexibility in the use of sweeteners."

In 2019, the Committee made significant progress by reaching consensus on two replacement notes below for sweeteners that do not refer to national legislation.

- **For provisions for additives with the function of sweetener but not the function of flavour enhancer:** Note 477 - "Some Codex Members allow use of additives with sweetener function in all foods within this Food Category while others limit additives with sweetener function to those foods with significant energy reduction or no added sugars."
- **For provisions for additives with both sweetener and flavour enhancer function:** Note 478 - "Some Codex Members allow use of additives with sweetener function in all foods within this Food Category while others limit additives with sweetener function to those foods with significant energy reduction or no added sugars. This limitation may not apply to the appropriate use as a flavour enhancer."

However, during that exercise, it was noted that CCFA had not yet considered the horizontal approach for sweeteners that are not associated with Note 161.

NEXT: To address this inconsistency, CCFA agreed that the Codex Secretariat would undertake an administrative review of all adopted food additives provisions in the GSFA for additives with sweetener function but not associated with Note 161 and prepare a status paper for consideration at CCFA53. This work is not aimed to re-open discussions on any specific provision.

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GENERAL STANDARD FOR FOOD ADDITIVES (GSFA)

Creation of a group header in the GSFA for INS 473, 473a, and 474

BACKGROUND: CCFA50 requested the Codex Secretariat to undertake a review of all group food additives in the GSFA and prepare a comprehensive document for consideration at CCFA51.

As part of this exercise, the Codex and JECFA Secretariats noted that a group ADI of 0-30 mg/kg bw was established by the 71st JECFA (2009) for sucroglycerides, (INS 474), sucrose esters of fatty acids (INS 473), and sucrose oligoesters type I and type II (INS 473a) and subsequently recommended that CCFA should consider creating a group heading for these additives in the GSFA.

DECISION: The Committee endorsed the following Recommendations for FC13.6

1. Consolidate existing adopted provisions for Sucroglycerides, (INS 474), Sucrose esters of fatty acids (INS 473), and Sucrose oligoesters type I and type II (INS 473a) into a single provision under a group header.

2. Delete the Note 348: "Singly or in combination: Sucrose esters of fatty acids (INS 473), sucrose oligoesters, type I and type II (INS 473a) and sucroglycerides (INS 474)) given that the three additives would all be under a group heading.

CONCRETELY

Food Category No. 13.6 Food supplements

Additive	INS	Step	Year	Max Level	Notes
SUCROSE ESTERS	473, 473a, 474	8	2021	20000 mg/kg	

Re-evaluation of INS 473, 473a, and 474

BACKGROUND: At its 89th meeting, JECFA noted that the high dietary exposure estimate of the sum of SEFs and SOEs of 113 mg/kg bw per day for children aged 3–9 years exceeded the group ADI of 0–30 mg/kg bw per day. JECFA also noted that the dietary exposure estimates for some other age groups also exceeded the ADI. In order to refine the dietary exposure estimates, data will be required within two years on typical or mean and high use levels for foods in which the food additives are used; and foods (or food categories) in which the use of SEFs and/or SOEs is permitted but in which they are never used. In both cases, the information should be as specific as possible, and the foods should be classified according to the EFSA FoodEx2 classification system.

NEXT: Data to be gathered by Japan

The Committee also endorsed the development of a discussion paper on a new work proposal to map food categories of the GSFA to the FoodEx2 database. The paper will be co-authored by Canada, Australia and Japan and be present at the meeting held prior to December 2023.

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Steviol glycosides

The following changes were agreed for adoption by CAC44.

STEVIOL GLYCOSIDES IN THE GSFA

STEVIOL GLYCOSIDES*

Note: All additions are shown in **bold underlined** font; all deletions are shown in strikethrough font.

960a	Steviol glycosides from Stevia rebaudiana Bertoni (Steviol glycosides from Stevia)	Functional class: Sweetener
960b	**Steviol glycosides from fermentation**	**Functional class: Sweetener**
~~960b(i)~~	~~Rebaudioside A from multiple gene donors expressed in Yarrowia lipolytica~~	~~Functional class: Sweetener~~
960c	**Enzymatically produced steviol glycosides**	**Functional class: Sweetener**
960d	**Glucosylated steviol glycosides**	**Functional class: Sweetener**

** Depending on the adoption by CAC44 relating to the Specifications, INS numbers and functional classes.*

A BIT MORE: As INS 960b covers INS 960 b(i), deletion of INS number INS 960 b(i) will be required via a request to the Circular Letter on Class Names and the International Numbering System for Food Additives (CXG 36-1989)".

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