52nd Codex Committee on Food Additives

WORKING GROUPS & PRE-SESSION MEETINGS,
21-25 June 2021 Virtual

PLENARY, 1-10 September 2021, Virtual

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

IADSA CODEX | CCFA52

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SPECIFICATIONS FOR IDENTITY AND PURITY OF FOOD ADDITIVES

The Committee will be asked at its Plenary session to recommend the endorsement at Step 5/8 of newly developed or revised specifications prepared by JECFA at their 87th and 89th meeting. Some specifications cover food additives used in food supplements.

ON TRACK | ENDORSEMENT OF THE SPECIFICATIONS FORESEEN AT STEP 5/8 FOR ADOPTION AT CAC

Brilliant Black (Black PN) (INS 151) (R)
Limits in FC13.6 tabled for discussion
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 a 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 was changed to "practically insoluble or insoluble in ethanol"

+

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. The temporary ADI will be withdrawn if no studies are submitted, This implies that no provisions in the GSFA could be established in the future for the additive.

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

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MATTERS OF INTEREST THAT AROSE AT THE 87TH (2019) & 89TH (2020) MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)

Multi-sectorial issues impacting FC13.6

ACTIONS FORESEEN | MULTI-SECTORIAL ISSUES IMPACTING FC13.6

Carotenoids (beta-apo-8'- (INS 160e), carotenes, beta-, synthetic (INS 160a(i)), carotenes, beta-, Blakeslea trispora (INS 160a(iii)), βcarotene-rich extract from Dunaliella salina (INS 160a(iv)) (R) - Limits in FC13.6 tabled for discussion
Endorsement of the revised specifications foreseen at Step 5/8 for adoption at CAC

However, the 87th JECFA meeting noted it was very unlikely that it will be possible to establish a group ADI because data from the population in heavy smokers cannot be gathered ethically. The 87th JECFA also noted that no adverse health effects were observed in the general population. The group ADI of 0-5 mg/ kg bw was nevertheless withdrawn.

A withdrawal of an ADI will generally lead to the removal of all provisions for the additive from the GSFA and could potentially impact its use at national level where the GSFA is used as a reference.

Discussions will be taking place this year to encourage a revision of the provisions or a postponement of decisions regarding this additive to a future meeting in order to address JECFA concerns.

Sorbitan esters of fatty acids (INS 491, INS 492 and INS 495) 10000 mg/kg in FC13.6

The Committee recommended that a new call for data be issued in order to proceed with an updated safety evaluation and specifications for the five sorbitan esters of fatty acids ((INS 491, INS 492, INS 493, INS 494, and INS 495) at the same time. IADSA input may be required for supplement intakes.

Sucrose esters of fatty acids (INS 473) (SEFs) and sucrose oligoesters type I and type II (INS 473a) (SOEs) 20000 mg/kg mg/kg in FC13.6

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.

JECFA therefore recommended that more refined dietary exposure estimates should be provided. A deadline of 2 years is proposed. IADSA input may be required for supplement intakes.

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

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SPECIFICATIONS FOR IDENTITY AND PURITY OF FOOD ADDITIVES

INS 1205 BASIC METHACRYLATE COPOLYMER (BMC)

&

GENERAL STANDARD FOR FOOD ADDITIVES (GSFA)

The adoption of the provision for INS 1205 into Table 3 of the GSFA (covering FC13.6) is also foreseen this year. The additive has a JECFA ADI of "not specified and there is therefore no safety concern for its use at GMP level.

FOR INFORMATION | PROPOSED 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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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 proposal of the eWG of the GSFA held in 2019 in which IADSA was involved.

These provisions will be reviewed in June under the chairmanship of the US delegation in the physical Working Group on GSFA before being proposed for endorsement at the Plenary session next September and adoption at the next CAC.

WHAT IS EXPECTED: Proposed levels could again be challenged by the EU specifically that have raised concerns on the new proposed provisions during the eWG consultation. These comments have so far been disregarded.

Securing the current draft provisions for some of the key colours will be the main IADSA priority to ensure maintenance of current market conditions.

Additive	INS	Max Level Current draft provision (mg/kg)	Final EWG Proposal
ANNATTO EXTRACTS, BIXIN BASED	160b(i)	60	Adopt
ANNATTO EXTRACTS, NORBIXIN BASED	160b(ii)	100	Adopt
AZORUBINE (CARMOISINE)	122	300	Adopt at 1500 mg/kg
BETA- CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	300	Hold pending discussion of 87th JECFA report
BRILLIANT BLACK (BLACK PN)		300	Adopt at 530 mg/kg
BROWN HT	155	300	Adopt
CARAMEL II- SULFITE CARAMEL	150b	35000	Adopt at 7500 mg/kg
CHLOROPHYLLS	140	25000	Discontinue; Chlorophylls is a Table 3 additive with a JECFA ADI of "not specified." As this food category is not in the Annex to Table 3, Chlorophylls is already permitted for use in this food category at GMP.
CURCUMIN	100(i)	300	Adopt; New Note, Except for use in film coated tablets at 3000 mg/kg
LUTEIN FROM TAGETES ERECTA	161b(i)	300	Hold this provision until the additive has been considered for inclusion in Table 3 (proposal included in Appendix 2 of the EWG on the GSFA).
LYCOPENE, TOMATO	160d(ii)	50000	Discontinue; Lycopene, Tomato is a Table 3 additive with a JECFA ADI of "not specified." As this food category is not in the Annex to Table 3, Lycopene, tomato is already permitted for use in this food category at GMP.
PAPRIKA EXTRACT	160c(ii)	20	Adopt
QUINOLINE YELLOW	104	300	Adopt; New Note, Except for use in hard capsules and film coated tablets at 1800 mg/kg
TARTRAZINE	102	300	Adopt; New Note, Except for use in hard capsules at 1710 mg/kg and film coated tablets at 3000 mg/kg
ZEAXANTHIN, SYNTHETIC	161h(i)	300	Hold this provision until the additive has been considered for inclusion in Table 3 (proposal included in Appendix 2 of the EWG on the GSFA).

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Steviol glycosides

- Steviol Glycosides from Stevia rebaudiana Bertoni (INS 960a)
- Steviol Glycosides from Fermentation 960b(i)
- Enzyme Modified Steviol Glycosides
- Enzyme Nodified Glucosylated Steviol Gycosides

BACKGROUND: At its 50th meeting, CCFA changed the way Steviol Glycosides are numbered in the INS in order to distinguish the different production methods of this additive (fermentation, bioconversion and enzymatic modification)

- The entry corresponding to INS 960 was set up as a parent category as "Steviol Glycosides".
- A new INS (INS960a) was assigned to Steviol glycosides from Stevia rebaudiana Bertoni.

Another two new entries were introduced in the INS:

- INS 960b as a sub-parent category of Steviol Glycosides to describe all steviol glycosides obtained "from fermentation". No functional class nor technological purpose were yet assigned to this entry.
- Under this new sub-parent category, a new entry as INS 960 b(i) Rebaudioside A from multiple gene donors expressed in Yorrowia lipolytica was created as sweetener and for the technological purpose of sweetener.

INS No.	Name of Food Additive	Functional class	Technological Purpose
960	Steviol glycosides	~~Sweetener~~	~~Sweetener~~
960a	Steviol glycosides from *Stevia rebaudiana Bertoni (Steviol glycosides from Stevia)*	Sweetener	Sweetener
960b(i)	Rebaudioside A from multiple gene donors expressed in *Yarrowia lipolytica*	Sweetener	Sweetener

NEXT : At the CCF52, the Committee will be asked:

To assign INS numbers for the two Steviol Glycosides produced by enzymatic modification:

- 960c for Enzyme Modified Steviol Glycosides
- 960d for Enzyme Modified Glucosylated Steviol Glycosides

To assign function class and technological purpose as sweetener for:

- the sub-parent category steviol glycosides obtained from fermentation, and
- the two additives produced by enzymatic modification.

To endorse all pending specifications for Steviol glycosides at Step 5/8 for adoption at CAC.

To add entries 960c and 960d to the GSFA with proposed limited of 2,500 mg/kg for FC13.6.

To eliminate the entry INS 960b(i) and replace it with INS 960b so as to be consistent with past practice: Name the INS after the name reflected in the JECFA specifications.

The above should allow the use of new forms of the addiive in supplements

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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.

NEXT: The Committee will ask to endorse the following recommendations for FC13.6:

1. To 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. To 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)

Existing provisions for Sucroglycerides, Sucrose esters of fatty acids, and Sucrose oligoesters type I and type II

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class
SUCROGLYCERIDES	474	20000	348	Adopted 2018	Emulsifier
SUCROSE ESTERS OF FATTY ACIDS	473	20000	348	Adopted 2018	Emulsifier, Foaming agent, Glazing agent, Stabilizer
SUCROSE OLIGOESTERS, TYPE I AND TYPE II	473a	20000	348	Adopted 2018	Emulsifier, Glazing agent, Stabilizer

Proposed Combined Provision for new group header Sucrose esters

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	Final EWG Proposal
SUCROSE ESTERS	473, 473a, 474	20000			Revoke existing provisions and adopt combined provision as listed.

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.

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CLARIFICATION OF THE USE OF THE TERM "ADI" NOT SPECIFIED"

PARTICULARTLY WITH RESPECT TO TABLE 3 ADDITIVES

Table 3 contains a list of additives that are permitted at GMP levels for many food categories including FC13.6 for supplements

At its 87th meeting JECFA confirmed that:

The definition of the term "ADI not specified' as a term applicable to a food substance of very low toxicity that, on the basis of the available chemical, biochemical and toxicological data as well as the total dietary intake of the substance (from its use at the levels necessary to achieve the desired effect and from its acceptable background in food), does not, in the opinion of the Joint FAO/WHO Expert Committee on Food Additives, represent a hazard to health. For that reason, and for reasons stated in individual evaluations, the establishment of an ADI expressed in numerical form is not deemed necessary. **An additive meeting this criterion must be used within the bounds of Good Manufacturing Practice:** that is, it should be technologically efficacious and should be used at the lowest level necessary to achieve this effect, it should not conceal inferior food quality or adulteration, and it should not create a nutritional imbalance."

& clarified that:

When an additive has been allocated an ADI "not specified" it could in principle, be allowed for use in foods in general with no limitation other than being in accordance with Good Manufacturing Practices (GMP). It should, however, be born in mind that ADI not specified ***does not mean that unlimited intake is acceptable***.

The term is used by JECFA in cases where "on the basis of the available data (chemical, biochemical, toxicological, and other) the total daily intake of the substance arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food does not, in the opinion of the Committee, represent a hazard to health. If, therefore, a substance is used in larger amounts and/or in a wider range of foods than originally envisaged by JECFA it may be necessary to consult JECFA to ensure that the new uses fall within the evaluation.

JECFA recommends that this definition of ADI "not specified" applies to Table 3 additives of the GSFA

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