

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
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WORLD  
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Agenda Item 10(b)

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES

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#### PROPOSALS FOR ADDITION AND/OR AMENDMENTS TO THE INTERNATIONAL NUMBERING SYSTEM FOR FOOD ADDITIVES (IN RESPONSE TO CL 2006/40-FA, PART 2)

The following comments have been received from: Canada and U.S.A

#### **Canada:**

INS 306, Mixed tocopherols concentrate has no specifications established by JECFA or Food Chemicals Codex. Instead, there are three types of tocopherols under the number INS 307, namely:

INS 307 a (used also as 307) – d-alpha-Tocopherol, concentrate

INS 307 b – Tocopherol concentrate, mixed

INS 307 c – dl-alpha-Tocopherol

May we suggest that the list of additives be updated with all three entries for Tocopherols of INS 307. Furthermore, INS 306 and INS 307 b have almost identical names, which may be a source of confusion. We therefore suggest either deletion of INS 306 from the list of additives or preparation of specifications for this substance which would clearly indicate differences between INS 306 and INS 307b.

INS 322, Lecithin. There are two lecithins bearing the same INS number and therefore Canada proposes to create a general number 322 for Lecithins with INS 322(i) for Lecithin and INS 322(ii) for Partially hydrolyzed lecithin.

#### **U.S.A:**

#### **General Comment**

The INS uses a hierarchical set of numbers, letters, and numerical subscripts (i.e., (i), (ii), etc.) to identify food additives. According to the principles laid out in Section 1 of *Class Names and the International Numbering System for Food Additives* (CAC/GL 36), the identification number for an additive for labeling purposes usually consists of a three or four digit number and in some cases a letter (e.g., 307a). The additive may be further identified by a numerical subscript (e.g., (i), (ii)), which is used to distinguish additive sub-classes that have different specifications. These principles are taken into account in our proposals below.

#### **Tocopherols**

The 38<sup>th</sup> Codex Committee on Food Additives and Contaminants (CCFAC) decided to postpone until the next session the clarification of the INS numbers of tocopherol derivatives because of noted inconsistencies between the INS numbers in the Codex Guideline and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) specifications (ALINORM 06/29/12, para. 103).

The following table presents the tocopherol names and associated INS numbers currently found in the JECFA specification monographs ([http://apps3.fao.org/jecfa/additive\\_specs/foodad-q.jsp](http://apps3.fao.org/jecfa/additive_specs/foodad-q.jsp)):

INS Number	Codex Guideline (CAC/GL-36)	JECFA Specification Monograph
INS 306	Mixed Tocopherols Concentrate	No reference
INS 307	Alpha-tocopherol	d-alpha-Tocopherol concentrate (55 <sup>th</sup> JECFA, 2000)
INS 307a	No listing	d-alpha-Tocopherol, concentrate (30 <sup>th</sup> JECFA, 1986)
INS 307b	No listing	Tocopherol concentrate, mixed (30 <sup>th</sup> JECFA, 1986)
INS 307c	No listing	dl-alpha Tocopherol (30 <sup>th</sup> JECFA, 1986)

First, the INS numbers 307a and 307, respectively, referenced in the 1986 and 2000 JECFA specifications clearly refer to the same substance, “d-alpha-tocopherol concentrate”.

Second, we have concluded that INS 306 (“mixed tocopherols concentrate”) in the INS list and INS 307b (“tocopherols concentrate, mixed”) in the 1986 JECFA specifications monograph refer to the same substance. This conclusion is based on the following: 1) the assay for “tocopherols concentrate, mixed” evaluated by JECFA in 1986 is the same as in the specifications for “tocopherols concentrate, mixed” published in 1972 in the 2<sup>nd</sup> Edition of the Food Chemicals Codex (FCC); and 2) chronologically, the 1972 FCC listing for “tocopherols concentrate, mixed” likely corresponds to “mixed tocopherols concentrate,” which was toxicologically evaluated by JECFA in 1973 (WHO Technical Report Series no. 539).

In order to address these duplicate INS numbers we propose that in the INS list:

1. INS 306 should be deleted; and
2. INS 307 should be renamed as “Tocopherols” so that it becomes a “parent” listing for individual tocopherols that are listed as follows:

INS 307      Tocopherols  
INS 307a    d-alpha-Tocopherol Concentrate  
INS 307b    Tocopherol Concentrate, Mixed  
INS 307c    dl-alpha-Tocopherol

As a consequence, the group additive listing for “Tocopherols” in the GSFA should be modified by removing INS 306 and adding INS 307a, 307b, and 307c. We also note that any changes to the INS numbers for tocopherols will have consequential effects on Codex commodity standards that contain provisions for tocopherols (see below).

### Carotenes

The 38<sup>th</sup> CCFAC decided to postpone the consideration of the INS numbers for all compounds currently listed under INS 160a (Carotenes) until the next session (ALINORM 06/29/12, para. 103).

The INS currently lists “INS 160a Carotenes,” “INS 160a(i) Beta-carotene (synthetic),” and “INS 160a(ii) Natural extracts.” There are several issues related to these INS listings:

First, the JECFA specifications ([http://apps3.fao.org/jecfa/additive\\_specs/foodad-q.jsp](http://apps3.fao.org/jecfa/additive_specs/foodad-q.jsp)) list INS 160a(ii) as both “carotenes (algae)” and “carotenes (vegetable).” In 1993, the 41<sup>st</sup> JECFA did not allocate an ADI to “carotenes (algae),” but concluded that the use of “carotenes (vegetable),” was acceptable, provided that the level of use does not exceed the level normally found in vegetables.

Second, in 2001, the 57<sup>th</sup> JECFA assigned beta-carotene from *Blakeslea trispora* a group ADI with beta-carotene (synthetic) (INS 160a(i)) of 0 – 5 mg/kg bw. In 1974, the 18<sup>th</sup> JECFA assigned a group ADI of 0 – 5 mg/kg bw to beta-carotene (synthetic) (INS 160a(i)), beta-apo-8'-carotenal (INS 160e), and beta-apo-8'-carotenoic acid, methyl and ethyl esters (INS 160f). Therefore, beta-carotene from *Blakeslea trispora* is part of the group ADI for “Carotenoids,” which includes INS 160a(i), 160e, and 160f. In 2003, the 61<sup>st</sup> JECFA developed specifications for beta-carotene from *Blakeslea trispora*, listed as “INS 160a,” that were different from those already established for beta-carotene (synthetic) (INS 160a(i)). In 2003, the 35<sup>th</sup> CCFAC assigned INS 160a(ii) to beta-carotene from *Blakeslea trispora* (ALINORM 03/29, para. 96 and Appendix VII).

Thus, INS 160a(ii) now corresponds to three distinct substances: carotenes (algae), carotenes (vegetable), and beta-carotene from *Blakeslea trispora*. Each of these substances has a different specification monograph and ADI. Therefore, they should be distinguished in the INS.

To resolve this inconsistency, we propose the following changes to the listing of INS 160 in the INS list:

INS 160a Carotenes, beta- (Synthetic)

INS 160a(i) and 160a(ii) would be deleted

INS 160b through INS 160f would remain as currently listed in the INS

The following new INS entries would be added:

INS 160g Carotenes, beta- (Natural Extracts)

INS 160g(i) Carotenes, beta- (*Blakeslea trispora*)

INS 160g(ii) Carotenes (Vegetable)

INS 160g(iii) Carotenes (Algae)

The GSFA contains two major listings for carotene derivatives. If accepted, the above proposal would have the following effect on the listings in the GSFA:

1. The INS number for “carotenes, vegetable” should be changed from INS 160a(ii) to INS 160g(ii).
2. The group additive listing for “Carotenoids” that includes beta-carotene (synthetic) (INS 160a(i)), beta-apo-8'-carotenal (INS 160e), beta-apo-8'-carotenoic acid, methyl and ethyl esters (INS 160f), and beta-carotene from *Blakeslea trispora* (INS 160a(ii)) would have the INS numbers for beta-carotene (synthetic) changed from INS 160a(i) to INS 160a, and for beta-carotene (*Blakeslea trispora*) changed from INS 160a(ii) to INS 160g(i).

Any changes to the INS numbers for carotenes will have consequential effects on Codex commodity standards that contain provisions for carotenes (see below).

### **Ammonium Citrates**

The INS list currently lists “INS 380 Ammonium Citrates.” JECFA has a specification monograph for “triammonium citrate (INS 380),” but not for “ammonium citrate” ([http://apps3.fao.org/jecfa/additive\\_specs/foodad-q.jsp](http://apps3.fao.org/jecfa/additive_specs/foodad-q.jsp)). However, in the “Summary of Evaluations Performed by JECFA” (<http://jecfa.ilsa.org>), “ammonium citrate” cross-references the summary for “triammonium citrate (INS 380),” but is not listed as a synonym for “triammonium citrate” in the summary (only “ammonium citrate, tribasic” is listed). There is no separate summary for “ammonium citrate.” JECFA assigned “triammonium citrate (INS 380)” an acceptable daily intake (ADI) of “not limited for citric acid and its bases.”

Based on this information, we believe that the listing for INS 380 should be revised from “Ammonium Citrates” to “Triammonium Citrate.”

As a consequence of this proposal, Table 3 of the GSFA should be revised to correct the duplicate entries for INS 380. Currently, both “INS 380 Ammonium Citrate” and “INS 380 Triammonium Citrate” appear in Table 3 of the GSFA. Thus, the entry for “INS 380 Ammonium Citrate” should be removed from Table 3 of the GSFA.

Any changes to the INS numbers for ammonium citrate will have consequential effects on Codex commodity standards that contain provisions for ammonium citrate (see below).

### **Calcium Citrates**

The INS currently lists INS 333 as “calcium citrates.” The JECFA monographs refer to “calcium citrate.” We believe that “calcium citrates” in the INS should be corrected to “calcium citrate,” so that the amended INS listing would be: “INS 333 Calcium Citrate.”

Consequently, the listing for INS 333 in Table 3 of the GSFA should be corrected to “calcium citrate.”

Any changes to the INS numbers for calcium citrates will have consequential effects on Codex commodity standards that contain provisions for calcium citrates (see below).

### **Annatto Extracts**

The INS currently lists “INS 160b Annatto Extracts.” JECFA has established different specification monographs for the various preparations of annatto extracts ([http://apps3.fao.org/jecfa/additive\\_specs/foodad-q.jsp](http://apps3.fao.org/jecfa/additive_specs/foodad-q.jsp)). The 67<sup>th</sup> JECFA (2006) revised the ADIs for the various preparations of annatto extracts. A group ADI for bixin of 0 – 12 mg/kg bw was assigned for solvent-extracted bixin ( $\geq 85\%$  bixin,  $\leq 2.5\%$  norbixin) and aqueous processed bixin ( $\geq 25\%$  bixin,  $\leq 7\%$  norbixin). A group ADI for norbixin and its sodium and potassium salts of 0 – 0.6 mg/kg bw was assigned for solvent-extracted norbixin ( $\geq 85\%$  norbixin), alkali processed norbixin, acid precipitated ( $\geq 35\%$  norbixin), and alkali processed norbixin, not acid precipitated ( $\geq 15\%$  norbixin).

In order to distinguish between the various preparations of annatto extracts that have different specifications and ADIs, we propose that the listing for “Annatto Extracts” be revised as follows:

INS 160b Annatto Extracts, Bixin-based

INS 160b(i) Annatto Extracts, Solvent-extracted Bixin

INS 160b(ii) Annatto Extracts, Aqueous-processed Bixin

INS 160c through INS 160f would remain as currently listed in the INS.

INS 160g is a proposed new entry for “Carotenes, beta- (Natural Extracts)” (see “Carotenes,” above)

The following new INS entries would be added:

INS 160h Annatto Extracts, Norbixin-based

INS 160h(i) Annatto Extracts, Solvent-extracted Norbixin

INS 160h(ii) Annatto Extracts, Alkali-processed Norbixin, Acid-precipitated

INS 160h(iii) Annatto Extracts, Alkali-processed Norbixin, Not Acid-precipitated

If this proposal is accepted, we recommend that the group additive listing for “Annatto Extracts” in the GSFA be replaced with two new group additive listings that reflect the two new group ADIs for annatto extracts as follows:

Annatto Extracts, Bixin-Based (including proposed INS 160b(i) and 160b(ii))

Annatto Extracts, Norbixin-Based (including proposed INS 160h(i), 160h(ii), and 160h(iii))

As a result of this revision, the Committee may wish to consider requesting information on: (i) the use of the specific preparations of annatto extracts for inclusion in Tables 1 and 2 of the GSFA; and (ii) clarification as to which specific preparations are used in the food categories listed in the current provisions in Tables 1 and 2 of the GSFA.

Any changes to the INS numbers for annatto extracts will have consequential effects on Codex commodity standards that contain provisions for annatto extracts (see below).

### Lycopene

The INS currently lists “INS 160d Lycopene.” The 67<sup>th</sup> JECFA (2006) assigned a group ADI of 0 - 0.5 mg/kg bw to synthetic lycopene and lycopene from *Blakeslea trispora*. The 67<sup>th</sup> JECFA also developed different specifications for synthetic lycopene and for lycopene from *Blakeslea trispora*.

To align the INS with the two types of lycopene identified in the JECFA specifications, we propose that INS 160d be sub-divided as follows:

- INS 160 d            Lycopene
- INS 160 d(i)      Lycopene (synthetic)
- INS 160 d(ii)     Lycopene (from *Blakeslea trispora*)

As a result of JECFA assigning a group numerical ADI to “lycopene,” the 39<sup>th</sup> CCFA may wish to consider including in the GSFA the group additive listing “Lycopene,” which would include lycopene (synthetic) (INS 160d(i)) and lycopene (from *Blakeslea trispora*) (INS 160d(ii)). If so, the Committee may wish to request information on the use of these substances for inclusion in Tables 1 and 2 of the GSFA.

### Consequential Effects to Food Additive Provisions in Codex Commodity Standards

If the INS is amended there will be consequential effects to the food additive provisions in Codex commodity standards. The following tables summarize the commodity standards that would be affected by the revision of the INS numbers for tocopherols, carotenes, ammonium citrate, calcium citrates, and annatto extracts.

<b>Tocopherols</b>		
<b>Codex Standard Number</b>	<b>Codex Standard Title</b>	<b>INS Numbers Listed in Codex Standard</b>
019-1981	Fats and oils not covered by individual standards	306, 307, 308 (synthetic gamma-tocopherol), 309 (synthetic delta-tocopherol)
032-1981	Margarine	“Natural and synthetic tocopherols” (no INS No.)
033-1981	Olive oil, virgin and refined, and refined olive pomace oil, olive oils and olive pomace oils	Alpha-tocopherol (no INS No.)
072-1981	Infant formula	306
073-1981	Canned baby foods	Mixed tocopherol concentrate, alpha tocopherol (no INS No.)
074-1981	Processed cereal-based foods for infants and children	306, 307
087-2003	Chocolate and chocolate products	307
117-1981	Bouillon and consommés	306, 307
135-1981	Minarine	Natural and synthetic tocopherols (no INS No.)
156-1987	Follow-up formula	Mixed tocopherol concentrate, alpha tocopherol (no INS No.)
210-1999	Named vegetable oils	306, 307, 308 (synthetic gamma-tocopherol), 309 (synthetic delta-tocopherol)
211-1999	Named animal fats	306, 307, 308 (synthetic gamma-tocopherol), 309 (synthetic delta-tocopherol)
249-2006	Instant noodles	306, 307
253-2006	Dairy fat spreads	306, 307
A-02-1973	Milkfat products	306, 307
C-31-1973	Cream cheese (Rahmfrischkase)	306, 307

<b>Carotenes</b>		
<b>Codex Standard Number</b>	<b>Codex Standard Title</b>	<b>Codex Standard Listing</b>
019-1981	Fats and oils not covered by individual standards	Beta-carotene, INS 160a
032-1981	Margarine	Beta-carotene (no INS No.)
058-1981	Canned green peas	Beta-carotene (no INS No.)
115-1981	Pickled cucumbers (cucumber pickles)	Beta-carotene (no INS No.)
117-1981	Bouillon and Consommés	Natural extracts, INS 160a(ii)
135-1981	Minarine	Beta-carotene (no INS No.)
159-1987	Canned mangoes	Beta-carotene (no INS No.)
166-1989	Quick frozen fish sticks (fish fingers), fish portions and fish fillets - breaded or in batter	Beta-carotene (synthetic), INS 160a(i)
211-1999	Named animal fats	Beta-carotene, INS 160a
221-2001	Unripened cheese, including fresh cheese	160a(i), 160a(ii)
249-2006	Instant noodles	160a(i), 160a(ii)
253-2006	Dairy fat spreads	160a(i), 160a(ii)
A-01-1971	Butter	Beta-carotene (synthetic), INS160a(i); Carotenes (natural extracts), INS 160a(ii)
A-06-1978	Cheese	Beta-carotene (synthetic), INS160a(i); Carotenes (natural extracts), INS 160a(ii)
A-08a-1978	Named variety process(ed) cheese and spreadable process(ed) cheese	Beta-carotene (no INS No.)
A-08b-1978	Process(ed) cheese and spreadable process(ed) cheese	Beta-carotene (no INS No.)
A-08c-1978	Process(ed) cheese preparations (process(ed) cheese food and process(ed) cheese spread)	Beta-carotene (no INS No.)
C-01-1966 <sup>1</sup>	Cheddar	Beta-carotene (no INS No.)
C-03-1966	Danbo	Beta-carotene (no INS No.)
C-04-1966	Edam	Beta-carotene (no INS No.)
C-05-1966	Gouda	Beta-carotene (no INS No.)
C-06-1966	Havarti	Beta-carotene (no INS No.)
C-07-1966	Samsø	Beta-carotene (no INS No.)
C-09-1967	Emmental	No current listing
C-11-1968	Tilsiter	Beta-carotene (no INS No.)
C-13-1968	Saint Paulin	Beta-carotene (no INS No.)
C-15-1968	Provolone	No current listing
C-18-1969	Coulommiers	Beta-carotene (no INS No.)
C-31-1973	Cream cheese (Rahmfrischkase)	No current listing
C-33-1973	Camembert	Beta-carotene (no INS No.)
C-34-1973	Brie	Beta-carotene (no INS No.)

<b>Ammonium Citrates</b>	
<b>Codex Standard Number</b>	<b>Codex Standard Title</b>
A-18-1995	Edible casein products

<b>Calcium Citrates</b>	
<b>Codex Standard Number</b>	<b>Codex Standard Title</b>
013-1981	Canned tomatoes
066-1981	Table olives
074-1981	Processed cereal-based foods for infants and children
079-1981	Jams (fruit preserves) and jellies <sup>2</sup>

<sup>1</sup> The food additive provisions in the Draft Revised Standards for the cheese varieties (ALINORM 06/29/11, Appendices VI, VII, and IX – XXI) were revised and endorsed by the 38<sup>th</sup> CCFAC (ALINORM 06/29/12, Appendix IV), however, they were held at Step 8 by the 29<sup>th</sup> CAC (ALINORM 06/29/41, para. 88 and Appendix VI). The food additive provisions in these Draft Revised Standards include: Beta-carotene (synthetic), INS 160a(i); Beta-carotene (*Blakeslea trispora*), INS 160a(ii); and Carotenes, vegetable, INS 160a(ii).

<b>Calcium Citrates</b>	
<b>Codex Standard Number</b>	<b>Codex Standard Title</b>
080-1981	Citrus marmalade
250-2006	Blend of evaporated skimmed milk and vegetable fat
252-2006	Blend of sweetened condensed skimmed milk and vegetable fat
XXX-XXXX	Mozzarella <sup>3</sup>
A-03-1971	Evaporated milks
A-04-1971	Sweetened condensed milks
A-09-1976	Cream and prepackaged creams
A-18-1995	Edible casein products
C-16-1968	Cottage cheese <sup>4</sup>
C-31-1973	Cream cheese (Rahmfrischkase)

<b>Annatto Extracts</b>	
<b>Codex Standard Number</b>	<b>Codex Standard Title</b>
019-1981	Fats and oils not covered by individual standards
032-1981	Margarine
115-1981	Pickled cucumbers (cucumber pickles)
135-1981	Minarine
166-1989	Quick frozen fish sticks (fish fingers), fish portions and fish fillets - breaded or in batter
211-1999	Named animal fats
221-2001	Unripened cheese, including fresh cheese
253-2006	Dairy fat spreads <sup>5</sup>
A-01-1971	Butter
A-06-1978	Cheese
A-08b-1978	Process(ed) cheese and spreadable process(ed) cheese
A-08a-1978	Named variety process(ed) cheese and spreadable process(ed) cheese
A-08c-1978	Process(ed) cheese preparations (process(ed) cheese food and porcess(ed) cheese spread)
C-01-1966	Cheddar <sup>6</sup>
C-03-1966	Danbo
C-04-1966	Edam
C-05-1966	Gouda
C-06-1966	Havarti
C-07-1966	Samso
C-11-1968	Tilsiter

<sup>2</sup> The commodity standards for Jams and Citrus Marmalade are currently under revision. The current standards list "sodium, potassium, and calcium salts of any acid listed." Since citric acid is listed in the standards, calcium citrate (INS 333) would be permitted for use.

<sup>3</sup> The food additive provisions in the Draft Standard for Mozzarella (ALINORM 06/29/11, Appendix XXII) were revised and endorsed by the 38<sup>th</sup> CCFAC (ALINORM 06/29/12, Appendix IV), and were held at Step 8 by the 29<sup>th</sup> CAC (ALINORM 06/29/41, para. 88 and Appendix VI).

<sup>4</sup> The current commodity standards for cottage cheese and for cream cheese do not provide for the use of calcium citrates (INS 333). The food additive provisions in the Draft Revised Standard for Cottage Cheese (ALINORM 06/29/11, Appendix XVII) and the Draft Revised Standard for Cream Cheese (ALINORM 06/29/11, Appendix XIX), which include a provision for the use of calcium citrates (INS 333), were revised and endorsed by the 38<sup>th</sup> CCFAC (ALINORM 06/29/12, Appendix IV), and were held at Step 8 by the 29<sup>th</sup> CAC (ALINORM 06/29/41, para. 88 and Appendix VI).

<sup>5</sup> The Draft Revised Standard for Dairy Fat Spreads (ALINORM 06/29/11, Appendix XXIII) contained a provision for the use of annatto extracts. However, the 38<sup>th</sup> CCFAC did not endorse this provision as annatto extracts had been assigned a temporary ADI prior to the 67<sup>th</sup> JECFA (ALINORM 06/29/12, Appendix IV). The Dairy Fat Standard was adopted at Step 8 by the 29<sup>th</sup> CAC (ALINORM 06/29/41, Appendix IV).

<sup>6</sup> The food additive provisions in the Draft Revised varietal cheese standards (ALINORM 06/29/11, Appendices VI, VII, IX - XII, XIV, XV, XVIII, XX, and XXI) contained a provision for the use of annatto extracts. However, the 38<sup>th</sup> CCFAC did not endorse the provision for annatto extracts, as this substance had been assigned a temporary ADI prior to the 67<sup>th</sup> JECFA. The Draft Revised Standards were revised and endorsed by the 38<sup>th</sup> CCFAC (ALINORM 06/29/12, Appendix IV), and were held at Step 8 by the 29<sup>th</sup> CAC (ALINORM 06/29/41, para. 88 and Appendix VI).

<b>Anatto Extracts</b>	
<b>Codex Standard Number</b>	<b>Codex Standard Title</b>
C-13-1968	Saint Paulin
C-18-1969	Coulommiers
C-33-1973	Camembert
C-34-1973	Brie