

CODEX ALIMENTARIUS COMMISSION



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 3a and 3b

CRD17

Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-Second Session

Virtual, 1-10 September 2021

Matters of Interest arising from FAO/WHO and from the 87th and 89th Meetings of the Joint
FAO/WHO Expert Committee on Food Additives (JECFA)

Proposed draft Specifications for Identity and Purity of Food Additives arising from the 87th, 89th
and 91st JECFA Meetings

Comments of the Republic of Korea and NATCOL

Agenda Item 3a

NATCOL (Natural Food Colours Association)

Beta-carotene is widely present in the human diet and has been used as a food colour for more than five decades. It is still the most widely used colour giving yellow-orange shade to food and beverages¹. It is also the **most important source of vitamin A** in the human diet.

JECFA found that, besides heavy smokers², ***“the high exposure to β -carotene (...) from its current uses as a food additive, in addition to background exposure from the diet, would not be expected to be a safety concern”***. This conclusion included synthetic β -carotene 160a(i), β -carotene derived from *B. trispora* 160a(iii) and β -carotene-rich extract from *Dunaliella salina* 160a(iv).

The high exposure of 6 mg/day in adults and 9 mg/day in children as a food colour reported by JECFA is in the range of intake of β -carotene naturally present from various dietary sources³.

Therefore, in line with the recommendations from JECFA, **NATCOL supports the revision of the provisions** of β -carotene INS160a(i) and IN160a(iii), and the inclusion of provisions for β -carotene from *Dunaliella salina* INS 160a(iv), in the GSFA.

Such revision should also consider that **all the β -carotene-based colours under INS 160a – including INS 160a(ii) - may be used substitutionally**, and should therefore ensure that the **maximum use levels are uniformly expressed on β -carotene basis**, which is the main pigment in all colours, and are also applicable to the combination of the four different sources of β -carotene by use of specific notes in the GSFA⁴.

NATCOL looks forward to support such revision with appropriate, technologically justified data, reflecting industry practices.

Agenda Item 3b

Republic of Korea

The Republic of Korea supports the adoption of the specifications for steviol glycosides evaluated by JECFA.

¹ In the last five years, more than 29'600 new products were launched with β -carotene, which represents 17% of all new yellow-orange-colored food and drinks launched worldwide during this period. Source: MINTEL — GNPD.

² JECFA quotes two large intervention studies in smokers (ATBC and CARET studies), which investigated very high doses (20 and 30 mg/day respectively) of β -carotene taken as dietary supplement in addition to background dietary intake. WHO Technical Report Series, No. 1020, 2019, pp. 32-47.

³ Surveys in the United States, European Union, China, Japan or Latin America report average intakes of in the range of 2-3 mg/day, and up to 5.6 mg/day in some countries.

⁴ NATCOL calls for a harmonized risk management approach to all β -carotene sources, although it notes that different ADI have been allocated. β -carotene rich-extract from *D. salina* INS160a(iv) has an ADI “not specified”, based on the fact that **“total dietary exposure to β -carotene will not increase”** (WHO Food Additives Series, No. 75). Also, following JECFA evaluation in 1993, no numerical ADI could be established for vegetable carotene INS 160a(ii), but the committee considered that the use was acceptable, provided that use as food colour did not exceed the level normally present in vegetables (FAS 32-JECFA 41/87). An ADI “not specified” is also allocated.

NATCOL (Natural Food Colours Association)

NATCOL welcomes the proposal for new specification for β -carotene, synthetic INS 160a(i). We noticed two typos that would need to be corrected, in line with the previous specification adopted in 2011.

In the “purity test”, “procedure” section, the impurity at relative retention time of 0.85 currently reads “all-trans- α -carotene”. It should read “all-trans- γ -carotene”.

In the “purity test”, “calculation” section, the formula is wrong: the multiplication sign should be replaced by a subtraction sign; it should read as follows:

Carotenoids other than β - carotenes (% w/w)

$$= \left(\frac{A_{\text{total}} - A_{\beta\text{-carotenes}}}{A_{\text{total}}} \right) \times 100$$