



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**

**Forty-fourth Session**

**Dresden, Germany  
2 – 6 October 2024**

**DISCUSSION PAPER ON THE USE OF FRUCTANS, BETA-CAROTENE, LYCOPENE IN THE STANDARD  
FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR  
INFANTS (CXS 72-1981)**

*(Prepared by the Electronic Working Group Chaired by the United States of America)*

**SUMMARY**

1. At the 43rd session of CCNFSDU (CCNFSDU43), the Committee agreed to establish an EWG chaired by the United States of America with the following Terms of References (TORs):
  - Review the use of fructans (fructo-oligosaccharides and other relevant fructans in human milk), beta-carotene, lycopene in the context of optional ingredients in the *Standard for infant formula and formulas for special medical purposes intended for infants* (CXS 72- 1981);
  - Develop recommendations to CCNFSDU44 regarding the safety and suitability of these ingredients as optional ingredients in CXS 72-1981; and
  - Submit a report for discussion at CCNFSDU44.
2. The EWG was established in July 2023 and has 24 Members and Observers (20 Codex Members, one Codex Member Organization, and three Codex Observers). A list of participants can be found in Appendix II.
3. The EWG completed two rounds of consultation seeking to develop recommendations to CCNFSDU44 regarding the rationale to recommend that CCMAS endorse the methods of analysis for beta-carotene, lycopene, fructo-oligosaccharides (FOS), oligofructose (OF), and oligofructan. The methods of analysis referred from CCMAS41 back to CCNFSDU were as follows:
  - Beta-carotene: AOAC 2016.13 / ISO DIS 23443
  - Lycopene: AOAC 2016.13 / ISO DIS 23443
  - Fructo-oligosaccharides, oligofructose, oligofructan: AOAC 2016.14 / ISO DIS 22579 | IDF 241
4. The first consultation received 13 responses from 10 Codex Members, one Member Organization, and two Observer Organizations. The second consultation received 11 responses from 10 Codex Members and one Member Organization.
5. The first consultation paper requested responses from EWG members regarding the safe use, and suitability of FOS, OF, and oligofructan and the second sought additional information on the use, safety, and suitability of lycopene in infant formula as no consensus on lycopene emerged in the first consultation. Consistent with the TORs, the EWG completed a review of the use of beta-carotene, FOS, OF, and oligofructan, and lycopene and developed recommendations to CCNFSDU44. The full report of the EWG is presented in Appendix I and includes the consultation questions as well as the summary and analysis of responses towards the development of recommendations to CCNFSDU44.

**RECOMMENDATIONS**

6. CCNFSDU44 is invited to consider informing CCMAS:
  - i. beta-carotene is a suitable optional ingredient as defined in CXS 72-1981 and listed in the *Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young*

- children* (CXG 10-1979), and requesting CCMAS to endorse AOAC 2016.13 / ISO DIS 23443 (beta-carotene and lycopene) for use with beta-carotene in the CXS 72-1981 as a Type II method;
- ii. FOS, OF, and oligofructan are nutrient compounds consistent with the provisions established in CXG 10-1979 and suitable optional ingredients as defined in CXS 72-1981, and requesting CCMAS to endorse AOAC 2016.14/ISO DIS 22579 | IDF 241 (Fructans) for use with CXS 72-1981 as a Type II method; and
  - iii. CCNFSDU could not determine a rationale to endorse the method of analysis AOAC 2016.13 / ISO DIS 23443 (beta-carotene and lycopene) for use with lycopene at this time.

## Appendix I

**Report of the EWG on Methods of Analysis for the provisions in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981)*****BACKGROUND**

1. At the 30th session of the CCNFSDU (CCNFSDU30, 2008), the EWG on methods of analysis for infant formula recommended the Committee periodically review and update the infant formula methods listed in the *Recommended Methods of Analysis and Sampling (CXS 234-1999)*. Since 2009, the Codex Committee on Methods of Analysis and Sampling (CCMAS) has endorsed several methods of analysis for nutrients in the *Standard for infant formulas and formulas for special medical purposes intended for infants (CXS 72-1981)* based on the available methods at the time; these methods were adopted by the Codex Alimentarius Commission (CAC) and are included in CXS 234-1999.
2. At the 41st session of CCNFSDU (CCNFSDU41, 2019, REP20/NFSDU Rev 2020) the Committee discussed methods of analysis provisions for CXS 72-1981. The Committee agreed to refer to CCMAS for typing and endorsement several methods including methods for beta-carotene and lycopene (AOAC 2016.13/ISO DIS 23443) and Fructans (AOAC 2016.14/ISO DIS 22579 | IDF 241).
3. The 41st session of CCMAS (CCMAS41, 2021) considered a referral from CCNFSDU41 regarding methods of analysis for beta-carotene, lycopene, and fructans as provisions in CXS 72-1981. CCMAS41 agreed to inform CCNFSDU that the methods for fructans, beta-carotene and lycopene were not endorsed as there were no accompanying provisions in CXS 72-1981 and to request CCNFSDU to provide a rationale to support their proposal for methods for these ingredients/nutrients.
4. At CCNFSDU43 (2023), the in-session working group on methods of analysis considered the request from CCMAS41 related to fructans (fructo-oligosaccharides, oligofructose, and oligofructan), beta-carotene, and lycopene in infant formulas but was unable to reach a conclusion, and the Committee agreed to establish an EWG to further deliberate on the rationale for CCMAS to endorse the methods of analysis for these nutrients. The [CCNFSDU43 report](#) (REP23/NFSDU) summarizes the Committee's discussion on this agenda item (paragraphs 120 – 125). CCNFSDU43 agreed to establish an EWG chaired by the United States of America to:
  - Review the use of fructans (fructo-oligosaccharides and other relevant fructans in human milk), beta-carotene, lycopene in the context of optional ingredients in CXS 72-1981;
  - Develop recommendations to CCNFSDU44 regarding the safety and suitability of these ingredients as optional ingredients in CXS 72-1981; and
  - Submit a report for discussion at CCNFSDU44.
5. The EWG conducted two rounds of consultation to inform the recommendations to CCNFSDU44. The first paper gathered information on whether beta-carotene, lycopene, and fructo-oligosaccharides met the criteria for optional ingredients in CXS 72-1981 and/or for inclusion in the *Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CXG 10-1979)* with the objective of providing a basis to CCNFSDU44 for a recommendation to CCMAS regarding endorsement and typing of methods for the three nutrients. The second round of consultation sought additional information regarding the use of lycopene in infant formulas for EWG Members' feedback.

**SUMMARY OF FIRST CONSULTATION**

6. 10 Codex Members, one Member Organization, and two Observers submitted responses to the first EWG consultation.
7. Regarding **beta-carotene**, the consultation posed the following question to the EWG members: Do you support recommending to CCNFSDU that it inform CCMAS that beta-carotene is listed for use as a vitamin compound in the *Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CXG 10-1979)* for use in infant formulas (Parts A and B) and request CCMAS to endorse and type AOAC 2016.13 / ISO 23443 (beta-carotene and lycopene) for use with the *Standard for infant formula and formulas for special medical purposes intended for infants (CXS 72- 1981)*?

Of the 13 responses received regarding beta-carotene, 11 responded in support of recommending to CCNFSDU that it inform CCMAS that beta-carotene is a safe and suitable ingredient and is listed in CXG 10-1979 for use as a vitamin compound, and request CCMAS to endorse the above method for use with the CXS 72-1981. There was broad agreement that the recommendation should be made to the committee on the basis that beta-carotene is already listed for use in the CXG 10-1979. Among the responses not in favor, one Member stated that additional scientific evidence was needed to substantiate the benefits of beta-carotene for infants and a Member Organization considered that there was no scientific evidence to support that adding beta-

carotene to formulas is beneficial for infants and the criteria for its use as an optional ingredient had not been met.

8. Regarding **fructo-oligosaccharides (FOS), oligofructose (OF), and oligofructan**, the consultation posed the following questions to EWG members:
  - i. Do you support recommending to CCNFSDU that it inform CCMAS that FOS, OF, and oligofructan are considered by CCNFSDU to be nutrient compounds (dietary fibres) consistent with the provisions established in the *Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children* (CXG 10-1979) for use in infant formulas (Parts A and B) and request CCMAS to endorse and type AOAC 2016.14/ISO DIS 22579 | IDF 241 (Fructans) for use with the *Standard for infant formula and formulas for special medical purposes intended for infants* (CXS 72-1981)? If you support the action in Question 4, do you support recommending to CCNFSDU that the Codex Secretariat update the CXG 10-1979 to include FOS, OF, and oligofructan as nutrient compounds with a function of dietary fibres?
  - ii. Do you support recommending to CCNFSDU that FOS, OF, and oligofructan are suitable optional ingredients as defined in CXS 72-1981 section 3.2.1 as a nutritional benefit to assure infant formulas provide sole source nutrition or a functional benefit to infants similar to those provided by human milk for use in infant formulas (Parts A and B), that CCNFSDU inform CCMAS that fructo-oligosaccharides (FOS), oligofructose (OF), and oligofructan are considered by CCNFSDU to be an optional ingredients and request CCMAS to endorse and type AOAC 2016.14/ISO DIS 22579 | IDF 241 (Fructans) for use with the *Standard for infant formula and formulas for special medical purposes intended for infants* (CXS 72-1981)? If you support the action in Question 5, do you support recommending to CCNFSDU that the Codex Secretariat update the CXS 72-1981 to include fructo-oligosaccharides (FOS), oligofructose (OF), and oligofructan as an optional ingredient?
9. Of the 13 responses received, 11 supported recommending to CCNFSDU that CCNFSDU inform CCMAS that it considers FOS, OF, and oligofructan to be nutrient compounds consistent with the provisions established in the CXG 10-1979 and suitable optional ingredients as defined in CXS 72-1981. While supporting the recommendation to the Committee of the ingredients' suitability, six respondents either noted that they would not support explicitly adding FOS, OF, and oligofructan to the CXG 10-1979 and/or CXS 72-1981 or suggested that the Committee discuss how to approach inclusion of additional nutrients or ingredients in the respective texts, highlighting that optional ingredients do not need to be added to a specific list to be used and expressing that maintaining a positive list of optional ingredients was not necessary.
10. One Member and one Member Organization did not support the proposals in the questions regarding FOS, OF, and oligofructan. One of these comments noted concerns that fructans were outside of the scope of the EWG. The comments opposed considered that there is no scientific evidence to support adding fructans to infant formulas and noted that scientific evidence is needed to substantiate the benefits for FOS used alone.
11. In general, there was widespread agreement in the first consultation to develop a recommendation to CCNFSDU44 regarding the use, safety, and suitability of beta-carotene and fructo-oligosaccharides, oligofructose, and oligofructan and a recommendation to CCMAS to endorse methods related to these.
12. Regarding **lycopene**, the consultation posed the following questions to EWG members:
  - i. Do you support recommending to CCNFSDU that it inform CCMAS that lycopene is considered by CCNFSDU to be a nutrient compound consistent with the provisions established in the *advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children* (CXG 10-1979) and request CCMAS to endorse and type AOAC 2016.13 / ISO DIS 23443 (beta-carotene and lycopene) for use with the *Standard for infant formula and formulas for special medical purposes intended for infants* (CXS 72- 1981)? If you support the action in Question 2, do you support recommending to CCNFSDU that the Codex Secretariat update CXG 10-1979 to include lycopene?
  - ii. Do you support recommending to CCNFSDU that lycopene, the main carotenoid in human milk, is a suitable optional ingredient as defined in CXS 72-1981 section 3.2.1 as a nutritional benefit to assure infant formulas provide sole source nutrition or a functional benefit to infants similar to those provided by human milk for use in infant formulas (Parts A and B) , that CCNFSDU inform CCMAS that lycopene is considered by CCNFSDU to be an optional ingredient, and request CCMAS to endorse and type AOAC 2016.13 / ISO DIS 23443 (beta-carotene and lycopene) for use with CXS 72-1981? If you support the action in Question 3, do you support recommending to CCNFSDU that the Codex Secretariat update CXS 72-1981 to include lycopene as an optional ingredient?

13. Of the 13 responses received, 10 respondents either elected to reserve their position on these questions until more information on the use of lycopene and/or scientific data on its benefits in infants were available or answered that they did not support recommending to CCNFSDU that it inform CCMAS that lycopene is a nutrient compound consistent with the provisions established in CXG 10-1979 or a suitable optional ingredient as defined in CXS 72-1981 and further did not support recommending to CCNFSDU that it request CCMAS endorse the associated method.
14. Two Observers supported recommending to CCNFSDU that it inform CCMAS that lycopene is both a nutrient compound consistent with the provisions established in CXG 10-1979 and a suitable optional ingredient as defined in CXS 72-1981, but did not support recommending to CCNFSDU that the Codex Secretariat update either text, recalling that optional ingredients do not need to be included in a specific list to be used. One Member responded in favour of the proposals in questions 2 and 3 while suggesting that CCNFSDU seek more data on lycopene in infant formulas.
15. Based on the multiple requests for additional information regarding lycopene, the Chair of the EWG decided to seek additional input from EWG members on lycopene in infant formulas in a second consultation to inform a recommendation to CCNFSDU regarding a response to CCMAS on the suitability of lycopene as an optional ingredient in infant formulas.

### **SUMMARY OF SECOND CONSULTATION**

16. The second paper summarized Members' responses to the questions in the first paper and posed additional questions regarding the use of lycopene in infant formulas for Members' feedback. The questions were as follows:
  - i. Do your country's national regulations allow lycopene to be added to infant formulas and formulas for special medical purposes intended for infants?
  - ii. If so, at what levels is lycopene added to infant formulas and formulas for special medical purposes intended for infants, and what is nutritional basis for its use?
  - iii. Do you have any additional information/data on or basis for the nutritional role of lycopene in infants? For example, extrapolation of the benefits demonstrated in the general population to infants.
17. The second consultation received 10 responses from Codex Members and one from a Codex Member Organization. All 11 respondents indicated that their countries either do not have provisions in their regulations for the use of lycopene in infant formulas or currently do not allow its use. Those members who responded that their national regulations require premarket assessments to be conducted prior to lycopene's approval and use indicated that they have not received any requests regarding lycopene.
18. Based on the information obtained in both rounds of consultation, the EWG members indicated there is not currently a basis to recommend that CCNFSDU inform CCMAS of lycopene's use or suitability in infant formulas.

### **RECOMMENDATIONS**

19. CCNFSDU44 is invited to consider informing CCMAS:
  - i. beta-carotene is a suitable optional ingredient as defined in CXS 72-1981 and is listed in the *Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children* (CXG 10-1979), and requesting CCMAS to endorse AOAC 2016.13 / ISO DIS 23443 (beta-carotene and lycopene) for use with beta-carotene in the CXS 72-1981 as a Type II method;
  - ii. FOS, OF, and oligofructan are nutrient compounds consistent with the provisions established in the CXG 10-1979 and suitable optional ingredients as defined in CXS 72-1981, and requesting CCMAS to endorse AOAC 2016.14/ISO DIS 22579 | IDF 241 (Fructans) for use with CXS 72-1981 as a Type II method; and
  - iii. CCNFSDU could not determine a rationale to endorse the method of analysis AOAC 2016.13 / ISO DIS 23443 (beta-carotene and lycopene) for use with lycopene at this time.

**LIST OF PARTICIPANTS****Chair**

United States of America

**Codex Members**

Australia

Brazil

Canada

Djibouti

European Union

Germany

Guatemala

India

Indonesia

Iran

Japan

Malaysia

Morocco

New Zealand

Norway

Panama

Saudi Arabia

South Africa

Thailand

Uganda

**Codex Observers**

Federation of European Specialty Food Ingredients Industries (EUSFI)

Global Organization for EPA and DHA Omega-3s (GOED)

International Special Dietary Foods Industries (ISDI)