



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

Forty-fourth Session

Dresden, Germany

(Comments by United States of America)

**AGENDA ITEM 8 DISCUSSION PAPER ON USE OF FRUCTANS, BETA-CAROTENE, LYCOPENE IN
STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES
INTENDED FOR INFANTS (CXS 72-1981)**

The United States, as chair of the EWG, has reviewed the *Comprehensive guidance for the process of submission, consideration and endorsement of methods for inclusion in CXS 234*. According to the guidance document, information required for the presentation of methods for incorporation into CXS 234 includes, among other requirements, "An attribute in a Codex standard with a limit/range of values or a characteristic (authenticity)."

In light of this, the United States has prepared information on the ranges of these ingredients used in infant formula for discussion during this agenda item. Table 1 provides an overview of the ranges of Human Milk Oligosaccharides (HMOs) and β -carotene found in human milk. Table 2 presents the proposed maximum values for the purposes of endorsing an analytical method for fructans and β -carotene in infant formula which the Committee should consider in conjunction with its recommendations to CCMAS. Table 2 represents maximum levels for use in infant formulas for referral to CCMAS. The information that follows Table 2 provides general information and sources used to derive the maximum values in Table 2.

Table 1. Ranges for HMOs (g HMOs/100g human milk) and β -carotene in human milk (μ g β -carotene/100g human milk)

Human Milk	Lowest Mean	Highest Mean
Human Milk Oligosaccharides ¹	0.5	2.0
β -carotene in Human Milk	0.97 ²	4.34 ³

Table 2. Proposed levels for referral to CCMAS for fructans and β -carotene in commercial infant formula and based on regulatory limits: fructans (g fructans/100g product) and β -carotene (μ g β -carotene/100g product)

Product	Maximum
Fructooligosaccharides	0.80
Oligofructose	0.68
Oligofructan/Inulin	0.68
Fructans (general class)	0.80
β -carotene	21.0

Select types of fructans can be measured in commercial infant formula or are allowed by regulatory authorities in the range of 0.0250 – 0.8 g fructans/100ml product (see Table 3). β -carotene can be measured in commercial infant formula in the range of 0 – 21 μ g β -carotene/100ml product (see Table 4).

¹ Okburan, Gozde, and Serap Kiziler. "Human milk oligosaccharides as prebiotics." *Pediatrics & Neonatology* 64.3 (2023): 231-238.

² Meneses, Flavia, and Nadia MF Trugo. "Retinol, β -carotene, and lutein+ zeaxanthin in the milk of Brazilian nursing women: associations with plasma concentrations and influences of maternal characteristics." *Nutrition Research* 25.5 (2005): 443-451.

³ Zaidi, Yusuf, Rachel Stroh, and Nancy E. Moran. "Systematic review of carotenoid concentrations in human milk and infant blood." *Nutrition Reviews* 80.9 (2022): 2029-2050.

Ranges of Fructans and β -carotene in Commercial Infant Formula

Table 3. Ranges in commercial infant formula for fructans (g fructans/100ml product)

Product ⁴	Minimum	Maximum	Mean
Ready to feed infant formula	0.209	0.367	0.300
Infant formula powder fructooligosaccharide/ galacto-oligosaccharides-based	0.0250	0.0371	0.0308
Infant formula powder milk-based	0.204	0.309	0.264
Regulatory Limits	Minimum	Maximum	Mean
U.S. FDA regulatory limits (fructooligosaccharides) ^{5,6}		0.4 g	
U.S. FDA regulatory limits (oligofructose) ⁷		0.3 g	
U.S. FDA regulatory limits (Short-chain fructooligosaccharides) ^{8,9}		0.4 g	
U.S. FDA regulatory limits (long-chain inulin) ¹⁰		0.8 g	
U.S. FDA regulatory limits (9:1 oligofructose & inulin) ¹¹		0.68 g	
Canada regulatory limits (short-chain fructooligosaccharide)		0.25 g	
Canada regulatory limits (long-chain fructooligosaccharide 1:9 FOS:GOS)		0.8 g	

Table 4. Ranges in commercial infant formula for β -carotene¹² (μ g β -carotene/100g product)

Product	Minimum	Maximum	Mean
Various products (n=8): Beba 0, Humana 0, Beba Pre, Aptamil Pre, Pre Aletemil, PreAponti, Humana HA, Aletemil HA	0	20	-
PBM Products, store brand, soy, ready-to-feed	-	-	37
Mead Johnson, ENFAMIL, premium, infant, ready to use	-	-	0
Mead Johnson, ready-to-feed	-	-	2.0
Similar advance, Abbott Nutrition, ready to eat	-	-	1.3
Similar Advance with OptiGRO, Abbott Nutrition, ready-to-feed	-	-	1.2
Preterm formula, Abbott Nutrition, ready-to-feed	-	-	7.1
Transitional formula, Abbott Nutrition, ready-to-feed	-	-	6.4
Term standard formula, Abbott Nutrition, ready-to-feed	-	-	2.5
Several infant food formulas	0.2	21.0	-

⁴ Spichtig, Véronique, et al. "Determination of Fructans in Infant Formula and Adult/Pediatric Nutritional Formula by Anion-Exchange Chromatography with Pulsed Amperometric Detection after Enzymatic Treatment: Collaborative Study, Final Action 2016.14." *Journal of AOAC International* 103.5 (2020): 1301-1317.

⁵ GRAS notices [no. 797](#).

⁶ GRAS notices [no. 623](#).

⁷ GRAS notices [no. 392](#).

⁸ GRAS notices [no. 990](#).

⁹ GRAS notices [no. 537](#).

¹⁰ GRAS notices [no. 477](#).

¹¹ GRAS notices [no. 576](#).

¹² Bohn, Torsten. "Determinants and determination of carotenoid bioavailability from infant food formulas and adult nutritionals including liquid dairy products." *Journal of AOAC International* 102.4 (2019): 1044-1058.