CODEX ALIMENTARIUS COMMISSION

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VITAMIN A IN RUTF

Comments by UNICEF

Proposal for Codex Guideline for RUTF: Vitamin A minimum, maximum and upper limits

Background on Vitamin A recommendation from WHO

WHO's most recent guideline recommends that children with severe acute malnutrition (SAM) should receive the daily recommended nutrient intake of vitamin A throughout the treatment period of about 5000 IU (1.5mg)[1] vitamin A daily, either as an integral part of therapeutic foods or as part of a multi-micronutrient formulation provided as part of the treatment protocol[2]. In these updated guidelines, WHO revised the previous recommendation of routinely providing an additional high dose of vitamin A as a supplement on the basis that ready-to-use therapeutic food (RUTF) given in the treatment of SAM contain sufficient vitamin A. The current dose of vitamin A in one sachet of RUTF is approximately 2500IU (0.75mg), so consuming an average of 2 sachets per day will provide the Vitamin A 5000 IU (1.5mcg) daily.

Previously children with SAM were be given a high dose of vitamin A (50 000 IU/166mg; 100 000 IU/333mg or 200 000 IU/666mg, depending on age) routinely on admission to hospital, however, this is now only recommended in some cases of complicated SAM or if the food used for treatment is without vitamin A fortification.[3]

Levels of Vitamin A in RUTF

During assessments of RUTF products, UNICEF and other procuring partners have noted frequent issue with low levels of vitamin A present in RUTF test reports from suppliers, particularly in the shelf life studies. Results are often below the target value that WHO recommend in the most recent guideline, of 5000IU (1.5mg).

Stability of Vitamin A during Shelf life

Vitamin A is incorporated in RUTF in the form of multivitamin premix consisting of vitamin and minerals and then blended with excipients such as maltodextrin. The premix is added to the other bulk ingredients in RUTF as a fortificant. Vitamin A is a one of the most unstable vitamins and degrades due to several external factors including exposure to oxygen, humidity, light. Temperatures over 25°C accelerate vitamin A degradation.[4,5]

Significant degradation of vitamin A occurs in commercial premixes, with 10-30 % losses observed in just 3 months of storage of premix[6,]. Vitamin A levels in both the premix and the finished RUTF product are further reduced through the supply chain i.e. during transportation and storage of the premix, RUTF processing (i.e. due to heat generated while processing), and excursions in temperature during transport and storage of finished product (RUTF).

UNICEF routinely tests every batch of RUTF products for vitamin A levels prior to distribution, and the aggregated data collected from 2018 revealed a total of 55% of suppliers' levels below 0.9mg per 100 grams

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[1] Using the conversion factor of IU to mcg: IU/3.33 = mcg
https://dietarysupplementdatabase.usda.nih.gov/ingredient_calculator/help.php#

[2] World Health Organization; 2013. Guideline: updates on the management of severe acute malnutrition in infants and children. Geneva Switzerland.

[3] Op.cit

[4] Gadient, M. 1986. Effect of pelleting on nutritional quality of feed. In "Proc. 1986 Maryland Nutrition Conference Feed Manufacturers," College Park, Maryland.

[5] Scrimshaw N et.al Food and Nutrition Bulletin Volume 19, Number 2, 1998 (UNU, 1998, 100 pages), The United Nations University

[6]Frye, T.M. 1994. The performance of vitamins in multicomponent premixes. Proc. Roche Technical Symposium, Jefferson, Georgia

in their freshly produced product. While this level is within the current specification limits of 0.8mcg and 1.1mcg, as the level of 0.9mcg is at the start of shelf life and is insufficient to reach the required 24 months shelf life.

Based on feedback from suppliers, the estimated loss during production due to the heat generated by production is 0.24 mg/100g, or 20%. Analysis of the Vitamin A losses from stability data (shelf life data) after 24 months at 30°C from suppliers demonstrated an estimated loss during storage at 30°C of about 29%. The estimated loss during storage at 40°C is 55%. As RUTF is often sent to destinations where conditions are over 30°C and humid, the product needs to be able to withstand these conditions to maintain its therapeutic properties.

Temperature conditions	**Storage and transport loss**	**Production loss**	**Total estimated losses**
30°C	**29%**	**20%**	**49%**
40°C	**55%**	**20%**	**75%**

Taking both loss directly after production (20%) and losses during shelf life and storage (29-55%), into consideration, the allowance of overages for manufacturers needs to be 75%. Using the midpoint (0.9mg) of the vitamin A in the RUTF composition (0.8-1.1mg) and averaging this result with the aggregated level of vitamin A at fresh production(0.9mg) a target value of 0.925mg vitamin A can be used to then apply the 75% loss rate to generate an upper limit. This value can be included in the RUTF guideline to accommodate the processing and shelf life losses and provide a guide to manufacturers.

Proposed limits for Vitamin A:

To take into consideration the manufacturing and supply chain constraints of achieving the WHO recommended 5000IU (750mcg) daily dose, UNICEF proposes that the maximum level of vitamin A is 1.2mg and a guided upper limit of 1.6mg.

	Min	Max	GUL
Mg RE/100g	0.8	1.2	1.6