REPORT 1

EXPERT MEETING ON VITAMIN A LEVELS IN RUTF

UNICEF, Supply Division

2-3 SEPTEMBER 2019
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EXPERT PANEL MEETING PARTICIPANTS:

- Dr André Briend, Affiliated Professor, Department of Nutrition, Faculty of Science, University of Copenhagen, Denmark and Current Adjunct Professor at the University of Tampere, Department for International Health, Finland
- Mr. Gilbert Tshitaudzi, Deputy Director, Nutrition National Dept, South African Government, Pretoria, South Africa
- Ms. Gwenaelle Garnier, Nutrition in Emergency and Preparedness and Response Officer, World Food Programme (WFP)
- Prof. Henrik Friis, Professor, Department of Nutrition, University of Copenhagen, Denmark
- Dr Kirrily de Polnay, Leader of the Doctors Without Borders (MSF) Intersectional Nutrition Working Group, MSF (via skype)
- Ms. Maria Xipsiti, Nutrition Officer, Nutrition and Food Systems Division, Food and Agriculture Organization of the United Nations (FAO)
- Ms. Odile Caron, Food Quality Coordinator, MSF
- Ms. Peijie Yang, Food Technologist, WFP
- Dr Ruffo Perez, DCHA/FFP- Senior Food Technology Adviser, The United States Agency for International Development (USAID)
- Mr. Filiberto Beltran Velazquez, Technical Officer (Regulatory affairs), Evidence and Programme Guidance (EPG), World Health Organization (WHO)

UNICEF SUPPLY DIVISION PARTICIPANTS:

- Hanne Bak Pedersen, Deputy Director, Supply Programme
- Akthem Fourati, Chief, Medicines and Nutrition Centre
- Francisco Blanco, Chief, Quality Assurance Centre
- Mary Atieno Ojoo, Technical Manager, Medicines and Nutrition Centre
- Alison Feet, Technical Specialist, Medicines and Nutrition Centre, Meeting Facilitator
- Jan Debyser, Contracts Manager, Medicines and Nutrition Centre
EXECUTIVE SUMMARY

A technical meeting was held to discuss the needed information for procurement agencies to address concerns about vitamin A levels in RUTF as part of the development of the Codex Guidelines for Ready to Use Therapeutic Foods (RUTF).

The expert group considered the challenge procuring agencies face in maintaining vitamin A levels within the specified current limits (0.8-1.1 mg per 100 grams) in RUTF throughout the supply chain and during their shelf-life.

A comprehensive supply chain approach was suggested to address the decrease in vitamin A in RUTF. It was recommended promoting vitamin A testing firstly during premix goods receipt, before using the premix in manufacturing RUTF and, secondly, post-production (batch release). Increasing the upper limit in the specifications of vitamin A in RUTF was also discussed and the experts agreed that the maximum limit could be safely raised to 1.6 mg per 100 grams.

VITAMIN A LEVELS IN RUTF

This session addressed challenges in maintaining vitamin A levels within the specified current limits (0.8–1.1 mg per 100 grams) throughout the supply chain and shelf-life period. Based on the stability testing reports and feedback from RUTF manufacturers, the maximum vitamin A limits, set at the current limits (0.8–1.1 mg per 100 grams), were considered too narrow to remain within the specifications during the desired shelf-life.
Vitamin A in vitamin and mineral premix

Vitamin A is one of the most chemically unstable vitamins and degrades in the presence of external factors including temperature, oxygen, humidity and light, impacting on the shelf life. Of RUTF\(^1,2\).

Vitamin A is widely used in RUTF and is introduced by means of commercial vitamin and mineral premix. In commercial premixes it has been reported that vitamin A has a significant loss in efficacy with approximately 10–30 per cent of vitamin A is lost in premix when stored for three months\(^3,4\).

Vitamin A levels in RUTF are further reduced through the supply chain i.e., during transportation and storage of the premix, heat generated during RUTF processing, temperature excursion and storage of finished product (e.g., when stored in containers at ports in the Sub-Saharan region and Middle East where the temperature may exceed 40\(^\circ\)C) (see Figure 4).

In 2018, vitamin A levels in RUTF were tested during pre-delivery inspections (PDI) and a total of 55 per cent of suppliers had RUTF vitamin A levels below 0.9 mg per 100 grams of RUTF in freshly made stock (see Figure 5).

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Also, according to the analysis of various studies into RUTF stability over two years, at 30°C, 45 per cent of RUTF products were found to no longer meet their specifications (see Figure 6).

From the 2019 UNICEF tender, stability trend data at 30°C for vitamin A soft gel capsules containing vitamin E as an anti-oxidant was also used as a comparator to study the degradation pattern of vitamin A. This shows that, in spite of having a high level of anti-oxidant, there is significant degradation at around 18 months.

A nine-year (2010–2018) compiled stability data set shared by a supplier (Nutriset) shows that temperature alone has a huge impact on vitamin A levels in RUTF. The estimated vitamin A loss during storage at 30°C is 0.28 mg/100g, i.e. 29 per cent over 24 months, this loss is increased to 55 per cent during storage at 40°C. The technical experts considered that physical and chemical factors are the causes of low levels of vitamin A in RUTF, such as oxidation due to permeability in the packaging or other oxidative ingredients in the premix such as ferrous sulfate.

The group also discussed standardizing the methods for testing vitamin A across the supplier base to enable a uniform interpretation of results.

Historical vitamin A supplementation of 100000–200000 IU given to SAM children routinely, provided justification for the expert group to consider increasing the maximum levels of vitamin A in RUTF to ensure that the revised daily vitamin A level of 5000IU (1.5mcg) is achieved. The group discussed the possible revision of vitamin A specification level by an increase of 40–50 per cent for RUTF finished product. Experts advised building a case to propose increasing the specification levels in the Codex committee for nutrition and foods for special dietary uses (CCNFSDU) meeting in 2019 and to draft a conference room document outlining the discussion points and recommendations from the expert meeting.

The technical expert group recommended that UNICEF should provide guidance to suppliers on how to manage premix in their facilities:

- encouraging the testing of vitamin A in the premix - at goods receipt and before using it in manufacturing RUTF, if stored for more than one month
- ensuring premix is stored at. less than 25°C
• advising the adjustment of vitamin A levels and or its formulation (eg encapsulated vitamin A) in the premix specification.

The predelivery inspection reports indicate that the initial vitamin A input levels in the premix are too low. This could be addressed by procuring agencies stipulating that batch release levels of vitamin A in RUTF should be not less than 1.1 mcg per 100 grams.

CONCLUSION

Vitamin A levels in RUTF need to maintain a dose of 5000IU (1.5mcg) throughout the product’s shelf life. Suppliers can improve the consistency in delivering this level of vitamin A by monitoring and adjusting the premix for the finished product, and their release limits for the finished product.
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