DRAFT KENYA STANDARDS **DKS 2890:2019**

ICS 67.020

Food fortification premix and fortificants — Specification

First Edition 2019

TECHNICAL COMMITTEE REPRESENTATION

The following organizations were represented on the Technical Committee:

Egerton University – Department of Human Nutrition

Jomo Kenyatta University of Science & Technology – Department of Food Science and Technology

Ministry of Health – Nutrition and Dietetics Unit

Ministry of Health – Food Safety Unit

Kenyatta National Hospital

Nestle foods

Danone Ltd

Kenya Association of Manufacturers

Government Chemist

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Unga Limited

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Kenya Bureau of Standards — Secretariat

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In order to keep abreast of progress in industry, Kenya standards shall be regularly reviewed. Suggestion for improvements to published standards addressed to the Managing Director, Kenya Bureau of Standards, are welcome.

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Food fortification premix and fortificants - Specification

KENYA BUREAU OF STANDARDS (KEBS)

Head Office: P.O. Box 54974, Nairobi-00200, Tel.: (+254 020) 605490, 602350, Fax: (+254 020) 604031

E-Mail: info@kebs.org, Web:http://www.kebs.org

Coast Region	**Lake Region**	**North Rift Region**
P.O. Box 99376, Mombasa-80100	P.O. Box 2949, Kisumu-40100	P.O. Box 2138, Nakuru-20100
Tel.: (+254 041) 229563, 230939/40	Tel.: (+254 057) 23549, 22396	Tel.: (+254 051) 210553, 210555
Fax: (+254 041) 229448	Fax: (+254 057) 21814	

Foreword

This Kenya Standard was prepared by a joint committee of Processed Cereals and Pulses and Nutrition and Foods for Special Dietary Uses TC under the guidance of the Standards Project Committee, and it is in accordance with the procedures of the Kenya Bureau of Standards.

These specifications are intended to ensure the quality of premix and fortificants are produced in a manner that will provide all the required nutrients and ensure final products comply with the respective standards. The specification will assist quality assurance at industries in ensuring consistency and compliance to the standards. They are developed taking into account the final product specifications as well as expected normal factory overages.

During the preparation of this standard, reference was made to the following documents

Guidelines on food fortification with micronutrients, 2006, WHO/FAO.

CAC/GL 09 – 1987: General principles for the addition of essential nutrients to foods.

Vitamin and Mineral requirements in Human Nutrition, WHO/FAO, 2004, 2nd Edition.

Acknowledgement is hereby made for the assistance derived from the above sources.

Food fortification premix and fortificants - Specification

1 Scope

This Draft Kenya Standard specifies the requirements, method of test and sampling of food fortification premix and fortificants.

It applies to premixes and fortificants intended for use in wheat flour, maize flour, composite flours, sugar, fat spreads and edible oils and fats

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

KS EAS 38, Labelling of pre-packaged foods — General requirements

KS EAS 39**,** Code of practice for hygiene in the food and drink manufacturing industry

KS ISO 20633 Infant formula and adult nutritionals -- determination of vitamin e and vitamin a by normal phase high performance liquid chromatography

AOAC SMPR 2015.002 Standard Method Performance Requirements (SMPRs) for Total Vitamin B1 (Thiamin) in Infant and Adult/ Pediatric Nutritional Formula

AOAC SMPR 2015.003 Standard Method Performance Requirements (SMPRs) for Total Vitamin B2 (Riboflavin) in Infant and Adult/ Pediatric Nutritional Formula

AOAC SMPR 2015.004 Standard Method Performance Requirements (SMPRs) for Total Vitamin B3 (Niacin) in Infant and Adult/ Pediatric Nutritional Formula

AOAC 961.15 Official Methods for Vitamin B_6

AOAC 2004.05 Total Folates in Cereal

KS ISO 27085 Animal feeding stuffs -- determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum, arsenic, lead and cadmium by ICP-AES

KS ISO 6869 Animal feeding stuffs -- determination of the contents of calcium, copper, iron, magnesium, manganese, potassium, sodium and zinc -- method using Atomic Absorption Spectrometry

AOAC 960.45 official method for Vitamin A in margarine

Public Health Act, Cap. 242

3 Definition

For the purposes of this standard, the following definitions shall apply:

3.1

diluent

suitable, inert, edible food-grade carrier for micronutrients

3.2

fortification

practice of deliberately adding micronutrient(s), i.e. vitamins and minerals (including trace elements) in a food, so as to improve the nutritional quality of the food supply and provide a public health benefit with minimal risk to health

3.3

fortification premix

blend of fortificants and diluents formulated to provide specified and determinable amounts of micronutrients

3.4

fortificant

The micronutrient that is intended to be added to food vehicle

3.5

food vehicle

food products intended to be used for fortification such as wheat flour, maize flour, composite flour, fat spreads, sugar and edible oils and fats

3.6

micronutrient

A natural or synthesized vitamin, mineral or a trace element that is essential for normal growth, development and maintenance of life and of which a deficiency will be detrimental to health

3.7

overage

refers to the additional amount of fortificant added to the premix/ food to compensate for losses that do occur during processing, distribution and storage, which will ensure the fortified food delivers the targeted level of nutrients at the time the food is used.

4 Requirements

4.1 General requirements

4.1.1 The addition rate for the premix or the fortificants in the final products shall be 500 g/MT

4.1.2 The fortificants may be mixed with diluents or carrier as appropriate to form a premix. The nutrients and diluents shall conform to either:

- British Pharmacopoeia (BP),
- Food Chemical Codex (FCC),
- Merck Index (MI),
- United States National Formulary (NF),

- European Pharmacopoeia (Ph. Eur),
- United States Pharmacopoeia (USP); or
- FAO/WHO Codex Alimentarius Commission (CAC).

4.2 Specific requirements

4.2.1 The food fortification premix and food fortificants shall be formulated so as to comply with Table 1, 2, 3 and 4 for the respective food vehicle.

4.2.2 The results of analysis shall be the nutrient content of the premix or fortificant as specified in the nutrient column of each table.

Note 1

The formulation takes into account 15 % and 20 % overage for minerals and vitamins respectively calculated from the minimum final product standard specifications

Table 1 – Premix for Maize milled products and Composite flour

Nutrient	**Nutrient Compound**	**g /kg of premix[1]**	**Method of test**
Vitamin A as Retinol	Vitamin A (Retinyl) palmitate , spray- dried or equivalent, 0.075 % retinol, min	1	KS ISO 20633
Vitamin B1	Thiamin Mononitrate, activity level, 81 %, min.	7	AOAC SMPR 2015.002
Vitamin B2	Riboflavin, activity level, 100 %, min.	5	AOAC SMPR 2015.003
Vitamin B3	Niacinamide, activity level, 99 %, min	36	AOAC SMPR 2015.004
Vitamin B6	Pyridoxine, activity level, 82 %, min.	5	AOAC 961.15
Folates	Folic acid, activity level, 100 %, min.	1	AOAC 2004.05
Vitamin B12	Vitamin B12 (Water soluble), activity level, 0.1 %, min.	0.02	AOAC 952.20
Iron	NaFeEDTA activity level, 13 % Fe, min.	21	KS ISO 27085 KS ISO 6869
Zinc	Zinc oxide, activity level, 80 %, min.	76	KS ISO 27085 KS ISO 6869
[1]Refer to clause 4.2.2			

Table 2 – Premix for wheat flour

Nutrient	**Nutrient Compound**	**g/kg of premix[1]**	**Method of test**

Vitamin A as Retinol	Vitamin A (Retinyl) palmitate , spray- dried or equivalent, 0.075 % retinol, min	1	ISO 20633
Vitamin B1	Thiamin Mononitrate, activity level, 81 %, min.	11	AOAC SMPR 2015.002
Vitamin B2	Riboflavin, activity level, 100 %, min.	8	AOAC SMPR 2015.003
Vitamin B3	Niacinamide, activity level, 99 %, min	72	AOAC SMPR 2015.004
Vitamin B6	Pyridoxine, activity level, 82 %, min.	7	AOAC 961.15
Folates	Folic acid, activity level, 100 %, min.	3	AOAC 2004.05
Vitamin B12	Vitamin B12 (Water soluble), activity level, 0.1 %, min.	0.02	AOAC 952.20
Iron	NaFeEDTA, activity level, 13 % Fe, min.	21	ISO 27085
	Ferrous fumarate activity level, 32 %, min		ISO 6869:2000
Zinc	Zinc oxide, activity level, 80 %, min.	92	ISO 27085 ISO 6869:2000
[1]Refer to clause 4.2.2			

Table 3 – Vitamin A fortificant for sugar

Nutrient	**Nutrient Compound**	**g/kg of premix[1]**	**Method of test**
Vitamin A as Retinol	Retinyl Palmitate 250 IU/g (dry)	12	ISO 20633
[1]Refer to clause 4.2.2			

Table 4 – Vitamin A fortificant for edible oils, fats and fat spreads

Nutrient	**Nutrient Compound**	**g/kg of premix[1]**	**Method of test**
Vitamin A as Retinol	Retinyl Palmitate 1.7 M IU/g oil	48	AOAC 960.45
[1]Refer to clause 4.2.2			

5 Contaminants

The premix and fortificants shall be practically free from heavy metals in amounts, which may represent a hazard to human health in fortified products

6 Hygiene

6.1 The premixes and fortificants shall be prepared and packaged in the premises built and maintained under hygienic conditions in compliance with the Public Health Act, Cap. 242, of the Laws of Kenya and KS EAS 39.

6.2 Premixes and fortificants shall not contain any pathogenic microorganisms in amounts that may present a health hazard to the consumer

7 Packaging

7.1 The Premix and fortificant shall be packaged in containers, which will safeguard the hygienic, nutritional, technological, and organoleptic qualities of the product.

7.2 The packaging materials shall be made of substances, which are safe and suitable for their intended use. They shall not impart any toxic substance or undesirable odour or flavour to the product.

8 Labelling

In addition to the provisions of KS EAS 38 the following information shall be inscribed on the external surface of the container or package;

a) name of the product: for flour premixes is shall be ‘wheat flour premix or maize/composite flour premix. For sugar and fats/oils it shall be lebel as “Vitamin A fortificant for XX’ where XX may either be sugar or oils

b) nutrient compound used;

c) addition rate declared as 500g/MT

d) storage condition

e) Instructions/direction for use

