DRAFT KENYA STANDARD

DKS 2571:2020

ICS 67.120

Second Edition

Food fortification premix and fortificants — Requirements for supply in Kenya



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Egerton University
Ministry of Health –Food Safety Division
Ministry of Health – Division of Nutrition and Dietetics
Kenya Industrial Research and Development Institute
Kenya Medical Research Institute
Ministry of Industrialization
Directorate of Dietetics and Nutrition
Government Chemist
DSM Nutritional Products
Capwell Industries Ltd
Mühlenchemie
Mombasa Maize Millers
Nestle Food Kenya Limited
Kenya Bureau of Standards — Secretariat

REVISION OF KENYA STANDARDS

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

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Foreword

This Kenya Standard was developed by the Technical Committee on Processed Cereals and Pulses under the guidance of the Standards Projects Committee, and it is in accordance with the Procedures of the Kenya Bureau of Standards.

The Government of Kenya through the Ministry of Health is implementing mandatory food fortification on salt, wheat flour, maize flour and edible fats/oils as one of the strategies to addressing the micronutrient deficiencies in Kenya. This has led to increased interest in the supply of premix in the country. To ensure appropriate control, the Ministry of Health in Kenya is registering all suppliers of premixes and fortificants in Kenya. It is on the basis of this the Ministry found the need to have standardised requirements which will be based for registration process which resulted to development of this standard.

This standard, provides the minimum requirements to which suppliers of premix both imported and locally produced should comply to so as to supply local industries. These requirements may also be used by local manufacturers of the final products for their direct procurement of their premix.

The revision of the first edition was aimed at aligning these requirements to premix and fortificant specification standard as well as enhance clarity on handling of premixes or fortificants where a local industry opts to directly import.

The edition therefore cancels and replaces first edition, KS 2571:2014, of the standard

Food fortification premix and fortificants — Requirements for supply in Kenya

1 Scope

- **1.1** This Draft Kenya Standard provides the requirements for registration of suppliers of food fortification premix and fortificants to industry producing products to which mandatory food fortification has been declared in Kenya.
- **1.2** The standard applies to both manufacturers and suppliers of premix as well as food industries such as millers or edible oil refineries that may seek to directly import premix for both internal use and sale.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 2890, Food fortification premix and fortificants - Specification

KS ISO 17025, General requirements for the competence of testing and calibration laboratories

KS ISO 22000, Food safety management system

3 Terms and definitions

For the purposes of this document, the following term and definition apply:

3.1

food fortification

practice of deliberately adding essential micronutrients in a food so as to improve the nutritional quality of the food and to provide a public health benefit with minimal risk to health

3.2

Fortificant

a compound which contains the specified micronutrient intended to be added to a food vehicle

3.3

food fortification premix (premix)

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

3.4

food grade containers

Containers whose food contact materials will not permit or introduce any food hazard to the premix or fortificant

3.5

supplier

any business, person or company in the business of manufacturing, importing, storing, distributing and or marketing of premix

4 Requirements

4.1 General requirements

4.1.1 The quality and safety requirements of the premix and fortificant shall comply with the requirements KS 2890.

Note: The particle size (granule size) of the premix has a direct effect to both mixing and appearance of the final product. In the case of bigger granules, spots are observed in the final product while the difference in particle size between the final product and the premix may result in uneven distribution of premix in the final product. As a result, the manufacturer should ensure that the granules are in such a size that the premix will blend well with the final product to avoid such spots in the final product. The spots may also be due to the nature of the fortificant used.

4.1.2 The liquid form of premix shall be stable, blend well, mix homogenously and shall not separate in the final product.

4.2 Specific requirements for qualification to supply premix and fortificants in Kenya

Supplier of premix and fortificants in Kenya shall comply with all the requirements under this clause.

4.2.1 Registration of company or business

A supplier shall be legally registered in accordance to the relevant laws of Kenya. Where renewal of registration/permit of trade is applicable, the company shall demonstrate compliance of such requirement.

Note: Local registered firms such as millers or edible oil refineries opting to import premix or fortificant for exclusive internal use need not to register as a premix/fortificant supplier but should have evidence in their possession for the consignment received that their exporting supplier is registered at the country of origin

4.2.2 Health clearance

A supplier shall have a certificate of health as prescribed in the Food, Drugs and Chemicals Substances Act, Cap. 254 of the laws of Kenya.

4.2.3 Conformity to quality and safety requirements

- **4.2.3.1** The supplier shall demonstrate that the premix is safe and that it is in compliance KS 2890 and has been approved for placement in Kenyan market such as evidence of Certificate of Conformity issued in reference to KS 2890.
- **4.2.3.2** The supplier shall provide material safety data sheet at registration and shall be updated on annual basis.
- **4.2.3.3** The supplier shall have a Certificate of Analysis (CoA) indicating the composition of all the nutrients in the premix as required in KS 2890 for each batch imported. The CoA should be issued by a laboratory accredited to ISO 17025 or as may be directed or requested by regulatory body in Kenya.
- **4.2.3.4** The supplier shall provide a copy of the certificate of analysis (CoA) indicated in clause 4.2.3.3 to their customer before or at the time of supplying the premix.
- **4.2.3.5** In addition, where applicable, the importing supplier shall have evidence of compliance with any other conformity assessment requirement set by the regulatory authorities in Kenya.

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4.2.4 Declaration of source of premix or fortificants

- **4.2.4.1** The supplier shall declare in descriptive terms the source of the premix including but not limited to manufacturer, importer (in case where one is distributing on behalf of an importer), country of origin, physical address. Evidence of this information shall be availed on during registration.
- **4.2.4.2** Where a supplier is an appointed local agent of a firm outside the country, they shall provide a company sealed letter as evidence of such appointment.
- **4.2.4.3** The supplier shall declare and update the relevant division or directorate responsible for food fortification in the Ministry of Health either through correspondence or by uploading through the Ministry's food fortification data base (or as guided by the Ministry) the quantities for every consignment imported or produced in the country. On a quarterly basis, the supplier shall provide information on the distribution indicating the firms and quantities of premix supplied.

4.2.5 Packaging, labelling and storage of premix

4.2.5.1 Packaging

The premix shall be packaged in food grade containers that shall ensure the safety and quality of the premix is maintained throughout the shelf life.

4.2.5.2 Labelling

The labelling of the containers shall comply with KS 2890.

4.2.5.3 Storage

The premix shall be stored in compliance to storage instruction as provided by the manufacturer and in compliance to the Public Health Act, Cap. 242 of the Laws of Kenya.

5 Certification

A manufacturer of premix shall possess a valid certificate from a recognized certification body demonstrating that the company is implementing a food-related quality system such as ISO 22000 or HACCP. A copy of this certificate shall be provided to the local agents or importers.

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