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DRAFT EAST AFRICAN STANDARD

Use of probiotics —Guidelines

EAST AFRICAN COMMUNITY

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Foreword

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in the East African Community. It is envisaged that through harmonized standardization, trade barriers that are encountered when goods and services are exchanged within the Community will be removed.

The Community has established an East African Standards Committee (EASC) mandated to develop and issue East African Standards (EAS). The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the public and private sector organizations in the community.

East African Standards are developed through Technical Committees that are representative of key stakeholders including government, academia, consumer groups, private sector and other interested parties. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the Principles and procedures for development of East African Standards.

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

The committee responsible for this document is Technical Committee EASC/TC 018, *Nutrition and Foods for Special Dietary Uses.*

Attention is drawn to the possibility that some of the elements of this document may be subject of patent rights. EAC shall not be held responsible for identifying any or all such patent rights.

Introduction

Most people who have access to a balanced diet can usually obtain all the nutrients they require from their normal diet. Because foods contain many substances that promote health, people should therefore be encouraged to select a balanced diet from food before considering any supplement.

Probiotics can be taken by children, adults, elderly, with specific formulation available for different age groups.

Probiotics are bacteria that help maintain the natural balance of microflora in the gastrointestinal tract. The normal human digestive tract contains about 400 types of probiotic bacteria that reduce the growth of harmful bacteria and promote a healthy digestive system.

Probiotics are usually bacteria, but certain types of yeasts can also function as probiotics. There are also other microorganisms in the gut that are being studied, including viruses, fungi, archaea, and helminths. Probiotics can be obtained from supplements, as well as from foods prepared through bacterial fermentation.

The most common probiotic bacteria are Lactobacillus and Bifidobacteria. Other common kinds are Saccharomyces, Streptococcus, Enterococcus, Escherichia, and Bacillus. Each genus comprises different species, and each species has many strains. Therefore, choosing the right type of probiotics is essential.

Probiotics are also available as dietary supplements (in capsules, powders, liquids, and other forms) containing a wide variety of strains and doses.

Some supplements, known as broad-spectrum probiotics or multi-probiotics, combine different species in the same product. Probiotics can be purchased as a food-grade health supplement.

Probiotics are measured in colony forming units (CFU), which indicate the number of viable cells. Amounts may be written on product labels as, for example, 1×10^9 for 1 billion CFU or 1×10^{10} for 10 billion CFU. Many probiotic supplements contain 1 to 10 billion CFU per dose, but some products contain up to 50 billion CFU or more. However, higher CFU counts do not necessarily improve the product's health effects.

Use of probiotics — Guidelines

1 Scope

This Draft East African standard provides guidelines on safety, quality and efficacy of probiotics and probiotics used in food products and probiotic supplements including, their production, characterization criteria, labelling.

2 Normative references

There are no normative references in this document

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
probiotics
live microorganisms which when administered in adequate amounts confer a health benefit on the host

3.2
shelf-life
period during which the Survival of adequate viable microorganisms confer health benefits to the host when stored under favorable or specified conditions

3.3
probiotic supplement
product containing live or viable microorganisms, which, when administered in adequate amounts, confer a health benefit on the host.

3.4
food grade packaging material
packaging material, made of substances which are safe and suitable for their intended use, and which will not impart any toxic substance or undesirable odour or flavour to the product

4 Requirements

4.1 Safety and characterization of the probiotics

4.1.1 Probiotics strains used in food products and supplements should be characterised for the following tests:

a) Determination of antibiotic resistance patterns

b) Assessment of metabolic activities

c) Assessment of side effects in human studies

d) Epidemiological surveillance of adverse incidents in consumers

e) Test for toxin production

f) Determination of haemolytic activity.

4.1.2 Probiotics should be taken as directed by healthcare professionals to avoid over dosing on certain nutrients, which could lead to toxicity

4.1.3 The probiotics should be present as:

a) viable cells preferably in numbers (not less than 10^9 CFU/g for supplements and not less than 10^7 CFU/g for food products

b) capable of exerting a beneficial effect on the host,

c) non-pathogenic,

d) non-mutagenic,

e) non-carcinogenic,

f) non-toxic,

g) Capable of surviving and metabolizing in the gut environment,

h) easily reproducible,

i) stable under storage and field conditions,

j) genetically stable with no plasmid transfer mechanism

4.2 Quality

4.2.1 Probiotic supplements and food products containing probiotics should be produced under conditions that ensure consistent quality, including the purity and potency of active ingredients.

4.2.2 Food products should comply with the relevant EAS for the product

4.2.3 Probiotic supplement and food products containing probiotics that is being produced commercially must have the highest possible yield, stability, and consistent performance for the intended application. It should be stable with the environmental conditions such as humidity, temperature, and pressure with rapid action without any significant delay

4.3 Efficacy

The efficacy to realise a claim attached to a probiotic strain should be supported by an independent third-party research/review.

5 Production of supplements and food production cultures

5.1 The manufacturing process should be very well controlled, so the strain can be consistently made with subsequent predictable performance.

5.2 Probiotics supplements should be produced through a multi-step process involving:

a) Strain selection;

b) Fermentation;

c) Concentration;

d) Stabilization; and

e) Formulation.

6 Packaging

Probiotic Supplements and food products containing probiotics should be packaged in food grade packaging material which will safeguard the hygienic, nutritional, technological, and organoleptic qualities of the products

7 Storage recommendations

7.1 Manufacturers should provide storage and handling instructions to customers, taking into account individual formulations and packaging. Instructions should be based upon data and experience with each product, and should take into account all of the environments in which the product will be reasonably expected to be held throughout its lifecycle (e.g., warehouse, shipping, retail and consumer shelves).

7.2 Probiotic organisms are generally sensitive to changes in temperature and humidity. The degree that an individual product is impacted by temperature and humidity is dependent on the probiotic strains in the product, formulation matrix and dosage form, and product packaging.

8 Labelling

8.1 General

In addition to the requirements in EAS 38, it should be applied the following specific provisions:

a) name of the microorganism(s) (genus, species and strain) mentioned in the list of ingredients;

b) amount of viable cells of total probiotic microorganisms (CFU/g);

c) serving size for food products containing probiotics

d) dosage for probiotic supplements

e) storage conditions for the viability of the probiotic strain used

8.2 Claims for probiotics

A claim that the product contains probiotics should only be applied when:

a) The product contains a minimum number of the specific probiotics strain as recommended in these guidelines

b) There should be independent evidence that the probiotic strain confers health benefits to the host

Annex A
(informative)

Stability test for probiotics

A.1 Stability testing should be conducted under real-time conditions to support the stated shelf life of the product. Use of accelerated or other testing in a program to support product release should be scientifically justified and documented.

A.2 The product and packaging conditions used in stability testing should be supported by scientifically sound evidence. Similar to the recommendation in the International Conference on Harmonization of technical requirements guideline, stability testing should be conducted under conditions that are representative of the finished product in the final packaging proposed for marketing.

A.3 Products should contain 100% of the quantity of probiotics declared on the product label at end of shelf life, except for any variability that is attributable to methods.

A.4 All stability testing methods, including proprietary testing methods, should be scientifically sound, repeatable, and reproducible. The specific testing method used should be documented.

Bibliography

[1] CXG 55: 2005 *Guidelines for Vitamin and Mineral Food Supplements*

[2] World Health Organization (WHO) Guidelines for the Evaluation of Probiotics in Food

[3] CX/NFSDU 19/41/11 Discussion paper on harmonized probiotic guidelines for use in foods and dietary supplements