GUIDELINES FOR LABELLING OF GENETICALLY MODIFIED ORGANISMS (GMOs) AND THEIR DERIVED PRODUCTS IN KENYA

JANUARY, 2025

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FOREWORD

The labelling of approved GMOs and their derived products by NBA ensures informed choice and traceability. These are crucial aspects of consumer rights and food safety. It also signifies that the product has been assessed and has been found to be safe. Labelling of these products allows consumers to make informed decisions about the products they purchase and consume. Traceability ensures that GMOs can be tracked at all stages of production and distribution chain, providing transparency and accountability. This system helps verify labelling claims and supports regulatory compliance, ensuring that consumers have access to accurate information by enabling informed choices, labelling and traceability contributes to consumer autonomy and trust in the food supply. These labelling measures can help mitigate unanticipated health and environmental concerns associated with GMOs through implementation of appropriate risk management measures where necessary. To address these objectives, it is essential to have a robust system for labeling GMOs and their derived products.

These guidelines are designed to establish a clear and consistent approach to labeling GMOs and their derived products. They specify the requirements for labeling of GMOs and their derived products.

By setting these requirements the guidelines aim to create a framework that shall be recognized across the country. This will not only enhance consumer confidence but also facilitate trade and regulatory compliance.

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ABBREVIATIONS

BCH	-Biosafety Clearing House
CBD	-Convention on Biological Diversity
DNA	-De-oxy ribonucleic acid
GM	-Genetically Modified
GMO	-Genetically Modified Organisms
NBA	-National Biosafety Authority

DEFINITION OF TERMS

For the purpose of this guideline, the following definitions shall apply;

Claim refers to any representation that states, suggests, or implies that a food has particular qualities relating to its origin, nutritional properties, nature, processing, composition, or any other quality

Conventional counterpart refers to a non-modified counterpart, related organism/variety, its components, and/or products for which there is experience of establishing safety based on common use as food, feed, or ingredient.

Denomination refers to a name or designation given to a variety, which is its generic designation to enable it to be identified as registered by the registering authority.

Food, feed, or ingredient derived from genetically modified organisms refers to food, feed, or ingredient produced from, in whole or in part genetically modified organisms.

Genetically modified organism: means an organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques; 'modern Biotechnology' includes the application of-

- *in-vitro* nucleic acid techniques including the use of recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or
- fusion of cells beyond the taxonomic family, that overcome natural physiological, reproductive, and recombinant barriers and which are not techniques used in traditional breeding and selection.

Labeling: shall be any written, printed, or graphic matter that is present on the label, accompanies the food, or is displayed near the food including that for the purpose of promoting its sale or disposal.

Highly Processed food refers to food that has been processed or refined to such an extent that foreign genetic material (DNA or protein) is no longer functional or has been denatured.

Ingredient means any substance, including a food additive, used in the manufacture or preparation of food and present in the final product although possibly in a modified form.

Non-GMO means food that is not derived from GMOs or food products that do not contain genetically modified ingredients. Where a product is declared to be GMO-free, there shall be proof that no GMO is detected at the level of less than 0.1% of total ingredients.

Non-prepackaged means food obtained from Genetic Modification, or food containing GM ingredients which is placed on the market without prior packaging; and can be packaged at the point of sale at the consumer's request.

Prepackaged means packaged or made up in advance in a closed container, packet, sachet, tin, or any other enclosure.

Product-based approach refers to an approach to labeling GM Foods where labeling is based on the scientific detectability of the GM content in foods.

Unique identifier refers to a simple numeric or alphanumeric code that serves to identify a genetically modified organism based on the authorized transformation event from which it was developed and provides the means to retrieve specific information pertinent to that genetically modified organism.

CHAPTER ONE

THE NATIONAL BIOSAFETY AUTHORITY

1.1 Background

The National Biosafety Authority (NBA) is a state corporation in Kenya established pursuant to the provisions of the Biosafety Act, 2009 to regulate all activities involving genetically modified organisms (GMOs) in food, feed, research, industry, trade, and environmental release. Being the national focal point on biosafety matters, the NBA fulfills its mandate by ensuring and assuring the safe development, transfer, handling, and use of GMOs to ensure the safety of human and animal health as well as the provision of adequate protection of the environment. NBA has made great strides in establishing a strong Biosafety regulatory framework in Kenya by developing and publishing the implementing Biosafety Regulations namely; The Biosafety (Contained Use) Regulations, 2011; the Biosafety (Environmental Release) Regulations, 2011; the Biosafety (Import, Export and Transit) Regulations, 2011; and the Biosafety (Labeling) Regulations, 2012. These regulations lay down a clear procedure for handling GMOs whether plants, animals, or microorganisms. NBA is the National Focal Point for the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD) and is mandated to implement the provisions of the Cartagena Protocol on all Biosafety matters pertaining to GMOs.

1.2 Vision Statement

A World-class Biosafety Agency

1.3 Mission Statement

To ensure and assure safe development, transfer, handling, and use of genetically modified organisms (GMOs) in Kenya.

1.4 Our Core Values

a) Integrity
b) Professionalism
c) Transparency
d) Accountability

1.5 Our Objectives

a) To facilitate responsible research and minimize risks that may be posed by genetically modified organisms;

b) To ensure an adequate level of protection in the development, transfer, handling, and use of genetically modified organisms that may have an adverse effect on the health of the people and the environment; and
c) To establish a transparent, science-based, and predictable process for reviewing and making decisions on the development, transfer, handling, and use of genetically modified organisms and related activities.

1.6 Our Core Functions
The Biosafety Act no.2 of 2009 lists the functions of the NBA as follows:

a) Consider and determine applications for approval for the development, transfer, handling, and use of genetically modified organisms, and related activities in accordance with the provisions of the Biosafety Act;
b) Co-ordinate, monitor, and assess activities relating to the safe development, transfer, handling, and use of genetically modified organisms to ensure that such activities do not have adverse effects on human health and the environment;
c) Co-ordinate research and surveys in matters relating to the safe development, transfer, handling, and use of genetically modified organisms, and collect, collate, and disseminate information about the findings of such research, investigation, or survey;
d) Identify national requirements for manpower development and capacity building in biosafety;
e) Advise the Government on legislative and other measures relating to the safe development, transfer, handling, and use of genetically modified organisms;
f) Promote awareness and education among the general public in matters relating to biosafety;
g) Establish and maintain a Biosafety clearing house (BCH) to serve as a means through which information is made available to facilitate the exchange of scientific, technical, environmental, and legal information on, and experience with, genetically modified organisms; and
h) To exercise and perform all other functions and powers conferred on by the Act.

CHAPTER TWO

INTRODUCTION

2.1 Scope and Objective

2.1.1 Scope

These guidelines apply to all GMOs and their derived products which have been approved by the Authority intended for environment release, imports and placing on the market.

2.1.2 Objective

The purpose of these guidelines is to provide requirements for the labeling of GMOs and their derived products and to ensure industry compliance with the Biosafety Act and the Biosafety (Labeling) Regulations. This system aims to achieve the following:

a) Assurance of safety of approved GMOs
b) For regulatory compliance
c) Consumer rights
d) Traceability
e) Transparency and trust

2.3 Mandatory Labelling Requirements

a) Where GMOs and their derived products are displayed for sale, whether pre-packaged or non-packaged, the labelling shall include a graphic presentation indicating "Contains Approved GMO or Contains Approved GM (Name of product)" and shall appear on every product approved by the NBA e.g. **Figure 1**.
b) Where products derived from GMOs are as intended significantly different from the conventional counterparts, concerning composition, nutritional value, or its use, such as food or ingredient, shall be labeled to indicate the significant change in addition to the standard labeling requirement.

2.4 Exemptions

Notwithstanding the labeling requirements above, the following foods/feeds/ingredients are exempted from mandatory labeling:

a) Foods, feeds, or ingredients with inadvertent presence of no less than 1% of total GM content.

b) Highly processed foods, except where the food has been genetically modified with respect to composition, nutritional value, or its intended use;
c) Processing aids or food additives except where novel DNA is detectable above 1%;
d) Animal products (meat, milk, eggs, etc.) of animals fed on feed derived from Genetically Modified Organism or vaccinated with GM vaccines;
e) Foods fermented using GM microorganisms where the GM microorganism is no longer present in the final product; and
f) Foods intended for immediate consumption or catering purposes including those foods for use in hotels, restaurants, canteens, street vendors, schools, hospitals, and similar institutions.

2.5 Labeling Procedures of GM Products

a) The manufacturer, operator, and sales agent are responsible for ensuring that GM products are labeled according to these guidelines before their placement in the market.
b) Where a food or feed consists of a single ingredient or where there is no list of ingredients; the words "genetically modified" or "produced from genetically modified (name of the ingredient or organism)'' shall be in the labeling information. For example, maize flour (Genetically modified maize).
c) Where a food or feed consists of more than one ingredient the words "genetically modified" or "produced from genetically modified (name of the ingredient) shall appear on the list of ingredients to indicate the ingredient that is genetically modified. For example, Ingredient: Soy protein isolate (genetically modified).
d) Where the words GM/GMO are declared on the label, they shall be in the same font size as other listed ingredients or the name of the food.
e) A graphic presentation indicating NBA approval shall also appear on every product approved by the NBA e.g. **Figure 1**.
f) A catalog or database of labeled GM products shall be maintained by the NBA.

Figure 1: Sample of a label of approved GM product

2.5 Unique Identifiers of GMOs and their Derived Products

a) The Authority shall issue unique identification numbers for each GM product for sale in the Kenyan market.
b) In addition to the NBA unique number, where a product already has a designated unique identifier or a denomination or any other internationally accepted identifier, that identity may be indicated in the label.
c) Labelling of GM food, feed, and/or ingredients will be done by a backbone of digit code (unique identifier) with a minimum of eleven digits issued by the NBA. The exact code of each product shall be issued by the Authority and data maintained in a register.

2.6 Non-GMO Labelling or Claims

a) Labelling of non-GMO and ingredients, as GMO- Free or other similar labels shall:
    i. Be voluntary.
    ii. Not be misleading, deceptive, or false as regards character, nature, value additives, substance, quality, quantity, composition, merit, or safety.
    iii. include a graphic presentation indicating "GMO Free" **Figure 2**
b) Manufacturers or importers shall substantiate non-GMO claims by documentation and/or by testing for the presence of GM materials. Where a product is declared to be GMO-free, there shall be proof that no GMO is detected at the level of less than 0.1% of total ingredients.

Figure 2 : Graphic presentation of the "GMO free" label

2.7 Prohibition on Claims

The following types of claims shall not be made on the label:

a) Claims which cannot be substantiated;

b) Claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer.