FOOD AND DRUGS AUTHORITY

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GUIDELINES FOR LABELLING FOOD/FEED DERIVED FROM GENETICALLY MODIFIED ORGANISMS (GMOs), AND FOOD/FEED CONTAINING GENETICALLY MODIFIED (GM) INGREDIENTS

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-	01	Initial issue

Guidelines for Labelling Food/Feed Derived from Genetically Modified Organisms, And Food/Feed Containing Genetically Modified Ingredients

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Executive Summary

The Food and Drugs Authority (FDA) has developed Guidelines to regulate the labelling of food/feed derived from GMOs and GM ingredients. These Guidelines aim to ensure industry compliance with Part Seven, Section 103 of the Public Health Act, 2012, and provide guidance for accurate labelling of GM food and ingredients. The Guidelines define terms like GMOs, GM food, highly processed food, ingredients, labels among others. They outline mandatory labelling requirements for various categories of GM food and ingredients, with exemptions for low-level GM presence, and requirements for non-GMO claims. Non-compliance with these Guidelines shall result in regulatory sanctions. The FDA expects strict compliance to ensure accuracy and transparency for the benefit of the general public.

1.0 Introduction (background)

In exercise of the powers conferred on the Food and Drugs Authority (FDA) by the Public Health Act, 2012 (Act 851), Part Seven, Section 148(2)(b)(iv)(vi), the Biosafety Act, 2011 (Act 831), Sections 1 and 31 (1), and the Biosafety Regulations, 2019 (LI 2383), this guidelines are made to regulate the labelling of Food/Feed obtained from Genetically Modified Organisms (GMOs), Food/Feed containing Genetically Modified (GM) ingredients.

1.1. Legal Basis

The purpose of this Guidelines is to provide guidance for the labelling of food/feed which are obtained from or contain GMOs; and to ensure industry compliance with Part Seven, Section 103 of the Public Health Act, 2012 (Act 851).

This Guidelines should be used in conjunction with other guidance document available from the FDA, including the Guidelines for the Labelling of Prepackaged Foods (FDA/FERD/GL-LAB/2013/02).

This Guidelines is hereby made for the information, guidance and strict compliance by all concerned.

1.2. Scope

This Guidelines apply to all food/feed derived from GMOs, and food/feed containing GM ingredients intended for sale that are:

a) Locally manufactured or produced
b) Imported
c) Exported

and have been approved by the National Biosafety Authority.

2. Definitions and Abbreviations

For the purpose of this guidelines:

"*Claim*" means any representation which states, suggests, or implies that a food has particular qualities relating to its origin, nutritional properties, nature, production, processing, composition, or any other quality [1].

"***Food***" includes water, a food product, a live animal or live plant, and;

a) a substance or a thing of a kind used, capable of being used or represented as being for use, for human or animal consumption, where it is live, raw, prepared or partly prepared,
b) a substance or a thing of a kind used, capable of being used or represented as being used, as an ingredient or additive in a substance or a thing referred to in paragraph (a)
c) a substance used in preparing a substance or a thing referred to in paragraph (a)
d) chewing gum or an ingredient or additive in chewing gum or a substance used in preparing chewing gum, and
e) a substance or a thing declared by the Minister to be a food.

"***Genetically Modified Organism (GMO)***" means an organism that has been transformed by the insertion of one or more genes, or regulatory elements, or an organism that has had its own genes modified without the insertion of any new genes and their products [2].

"***Genetically Modified (GM) Food***" means food derived from organisms whose genetic material (DNA) has been modified in a way that does not occur naturally through the introduction of a gene from a different organism. Eg. GM corn[3]

"***Highly Processed food***" refers to food which 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 a food and present in the final product although possibly in a modified form[1].

"***Label***" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, or impressed on, or attached to, a container of food[1].

"Low Level Presence" refers to the situation where a food contains unintended traces of a GM material that has been authorized for commercial use in one or more countries but not yet authorized in an importing country.

"***Non-GMO***" means food that are not derived from GMOs or food products that do not contain genetically modified ingredients.

"Non prepackaged GM food" means food obtained from Genetic Modification or food containing GM ingredients which is placed on the market without packaging; can be packaged at the point of sale at the consumer's request; or can be *ad hocly* packaged for direct sale.

"***Prepackaged***" means packaged or made up in advance in a container, ready for offer to the consumer, or for catering purposes [1].

"Processing aid" means a substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product [1].

"***Product-based approach***" refers to an approach to labelling GM Foods where labelling is based on the scientific detectability of novel genetic material in foods.

3. Requirements

3.1 All GM food and/or ingredients manufactured, imported, exported, distributed, sold or supplied or exposed for sale shall be registered by the FDA.

3.2 Food and food ingredients derived from GMOs shall comply with the Guidelines for the Labelling of Prepackaged Foods (FDA/FERD/GL-LAB/2013/02).

3.3 Processed food containing GM ingredients shall comply with the Guidelines for the Labelling of Prepackaged Foods (FDA/FERD/GL-LAB/2013/02).

3.4 Labelling of GM Food and ingredients shall be based on a product-based approach.

4.0 Mandatory Labelling Requirements

4.1 All prepackaged:

a) GM Food (e.g. GM Soybean),
b) Food ingredients derived from GMOs, (e.g. Soy lecithin).
c) Processed food derived from GMOs (e.g. Grits from GM Maize),
d) Processed food containing GM ingredient(s) (e.g. Cornflakes), shall be labelled

4.2 Non-prepackaged GM food shall be labelled.

4.3 Where food or food ingredients derived from GMOs are as intended significantly different from the conventional counterparts, with respect to composition, nutritional value, or its use, such a food or ingredient shall be labelled to indicate the significant change in addition to “Produced from GMO (name of GMO)”.

5.0 Presentation of Mandatory Labelling Requirements

5.1 Where food consists of a single ingredient, the words

a) “Produced from GMO (name of GMO)”, or
b) “Product of Genetic Modification” or other similar wordings subject to approval by the regulator, shall appear clearly and prominently on the label.

5.2 Where the food consists of more than one ingredient, the words "Genetically Modified" or "Produced from Genetically Modified (name of the ingredient)" shall appear in the

list of ingredients in parentheses immediately following the GM ingredient or shall be marked with an asterisk and indicated prominently as a footnote.

Eg. List of ingredients: flour, soy flour (derived from genetically modified Soybean), water, sugar, butter and walnuts.

List of ingredients: flour, soy flour*, water, sugar, butter and walnuts.

* Derived from Genetically Modified Soybean

5.3 Non-prepackaged GM foods displayed for sale shall be labelled in the following manner:

a) the name of the product shall be affixed to the display container; or
b) the name of the product written on a plaque and placed in close proximity to the product; or
c) in any other manner that shall be prescribed by the Food and Drugs Authority from time to time

6.0 Exemptions

6.1 Despite the requirements from 4.1 to 4.3, the following foods are exempted from mandatory labelling:

a) Foods or ingredients with low level presence of no more than 5%.
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;
d) Minor ingredients which make up not more than 5% of food;
e) Flavours that are present in amounts of no more than 0.1%;
f) Meat or meat products of animals fed on feed derived from Genetically Modified Organism;
g) Foods fermented using GM microorganisms where the GM microorganism is no longer present in the final product; and
h) Foods for catering purposes including those foods for use in hotels, restaurants, canteens, street vendors, schools, hospitals, and similar institutions where food is offered for immediate consumption.

7.0 Non-Gmo Labelling or Claims

7.1 Labelling of non-GMO foods and ingredients, such as “Non-GMO” or other similar labels shall:

a) Be voluntary.

b) Not be misleading, deceptive or false as regards in character, nature, value additives, substance, quality, quantity, composition, merit or safety.

c) Not be made for foods or ingredients which do not have GM counterparts.

7.2 Manufacturers or importers shall substantiate Non-GMO claims by documentation and/or by testing for the presence of GM materials.

8.0 Penalties

Any person or corporate body who fails to comply with any of the requirements of these Guidelines commits an offence and shall be liable to a fine in accordance with Part Seven, Section 110 (1) of the Public Health Act, 2012 (Act 851).

References

1. General Standard for the Labelling of Prepackaged Foods CXS1-1985. Adopted in 1985. Amended in 1991, 1999, 2001, 2003, 2005, 2008 and 2010. Revised in 2018.
2. Biosafety Act, 2011 Act 831 (44-Interpretation)
3. WHO (2020). [Accessed online: https://www.who.int/health-topics/food-genetically-modified#tab=tab_1]