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FOOD AND DRUGS AUTHORITY GUIDELINES FOR LABELLING FOOD DERIVED FROM GENETICALLY MODIFIED ORGANISMS, AND FOOD CONTAINING GENETICALLY MODIFIED INGREDIENTS

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26 **1.0 INTRODUCTION**

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

32 These guidelines apply to all food and/or food ingredients derived from GMOs, and food
33 containing GM ingredients that are:

- 34 a) Locally manufactured or produced
- 35 b) Imported
- 36 c) Exported

37 and are intended for sale.

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

41 **2.0 GLOSSARY**

42 For the purpose of these guidelines:

43 **“Claim”** means any representation which states, suggests, or implies that a food has particular
44 qualities relating to its origin, nutritional properties, nature, production, processing, composition,
45 or any other quality ¹.

46 **“Food”** includes water, a food product, a live animal or live plant, and;

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

55 “**Ingredient**” means any substance, including a food additive, used in the manufacture or
56 preparation of a food and present in the final product although possibly in a modified form ¹.

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

60 “**Genetically Modified (GM) Food**” means food derived from organisms whose genetic material
61 (DNA) has been modified in a way that does not occur naturally through the introduction of a gene
62 from a different organism. Eg. GM corn³

63 “**Label**” means any tag, brand, mark, pictorial or other descriptive matter, written, printed,
64 stenciled, marked, embossed, or impressed on, or attached to a container of food ¹.

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

68 “**Non GMO**” means food that are not derived from GMOs or food products that do not contain
69 genetically modified ingredients.

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

73 “**Prepackaged**” means packaged or made up in advance in a container, ready for offer to the
74 consumer, or for catering purpose ¹.

75 “**Processing aid**” means a substance or material not including apparatus or utensils and not
76 consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods
77 or its ingredients to fulfill a certain technological purpose during treatment or processing, and
78 which may results in the non-intentional but unavoidable presence of residues or derivatives in the
79 final products ¹.

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

82 **3.0 REQUIREMENTS**

83 **3.1 GENERAL REQUIREMENTS**

84 3.1 All GM food and/or ingredients manufactured, imported, exported, distributed, sold or supplied
85 or exposed for sale shall be registered by the FDA.

86 3.2 Food and food ingredients derived from GMOs shall comply with the General Labelling
87 Guidelines for Prepackaged Foods (FDA/FERD/GL-LAB/2013/02).

88 3.3 Processed food containing GM ingredients shall comply with the General Labelling Guidelines
89 for Prepackaged Foods (FDA/FERD/GL-LAB/2013/02).

90 3.4 Labelling of GM Food and ingredients shall be based on a product-based approach.

91 **3.2 MANDATORY LABELLING REQUIREMENTS**

92 4.1 All prepackaged:

- 93 a) GM Food (GM Soybean),
- 94 b) Food ingredients derived from GMOs, shall be labeled (e.g. Soy lecithin).
- 95 c) Processed food derived from GMOs (e.g. Oil from GM Soybean),
- 96 d) Processed food containing GM ingredient(s) (e.g. Cornflakes),

97 4.2 Non-prepackaged GM food shall be labelled.

98 4.3 Where food or food ingredients derived from GMOs are significantly different from the
99 conventional counterparts, with respect to composition, or nutritional value, allergenicity, or
100 its intended use, such a food or ingredient shall be labelled to indicate the significant change
101 in addition to “Produced from GMO (name of GMO)”.

102 **3.3 PRESENTATION OF MANDATORY LABELLING REQUIREMENTS**

103 5.1 Where food consists of a single ingredient, the words

- 104 a) “Produced from GMO (name of GMO)”, or

105 b) "Product of Genetic Modification" or other similar wordings subject to approval by the
106 regulator, shall appear clearly and prominently on the labelling.

107 5.2 Where the food consists of more than one ingredient, the words "Genetically Modified" or
108 "Produced from Genetically Modified (name of the ingredient)" shall appear in the list of
109 ingredients in parentheses immediately following the GM ingredient or shall be marked with
110 an asterisk and indicated prominently as a footnote.

111 Eg. List of ingredients: flour, soya flour (genetically modified), water, sugar, butter and
112 walnuts.

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

114 * Genetically Modified

115 5.3 Non-prepackaged GM foods displayed for sale shall be labelled in the following manner:

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

120 **3.4 EXEMPTIONS**

121 6.1 Despite the requirements from 4.1 to 4.3, the following foods are exempted from mandatory
122 labelling:

- 123 a) Foods or ingredients with low level presence of no more than 5%.
124 b) Highly processed foods, except where the food has been genetically modified with
125 respect to composition, nutritional value, allergenicity, or its intended use;
126 c) Processing aids;
127 d) Minor ingredients which make up not more than 5% of food;
128 e) Flavors that are present in amounts of no more than 0.1%;
129 f) Meat or meat products of animals fed on Genetically Modified feed; and
130 g) Foods fermented using GM microorganisms where the GM microorganism is no longer
131 present in the final product;

132 h) Foods for catering purposes including those foods for use in hotels, restaurants,
133 canteens, street vendors, schools, hospitals, and similar institutions where food is
134 offered for immediate consumption.

135 **3.5 NEGATIVE LABELLING OR CLAIMS**

136 7.1 Negative labelling of non-GMO foods and ingredients, such as “Non GMO” or other similar
137 labels shall:

- 138 a) Be voluntary.
- 139 b) Not be misleading, deceptive or false.
- 140 c) Not be made for foods or ingredients which do not have GM counterparts.

141 7.2 Manufacturers or importers shall substantiate negative claims by documentation and/or by
142 testing for the presence of GM materials.

143 **3.6 PENALTIES**

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

147 **APPENDIX 1**

148 **REFERENCES**

- 149 1. General Standard for The Labelling of Prepackaged Foods CXS1-1985. Adopted in
150 1985. Amended in 1991, 1999, 2001, 2003, 2005, 2008 and 2010. Revised in 2018.
- 151 2. Biosafety Act, 2011 Act 831 (44-Interpretation)
- 152 3. WHO (2020). [Accessed online: [https://www.who.int/health-topics/food-genetically-](https://www.who.int/health-topics/food-genetically-modified)
153 [modified](https://www.who.int/health-topics/food-genetically-modified)]