



## MINISTRY OF HEALTH MALAYSIA

### GUIDELINES ON LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH MODERN BIOTECHNOLOGY

(Regulations 11(3A), 11(6) and 11(7), Food Regulations 1985)

#### 1.0 PURPOSE:

These guidelines were prepared:

- 1.1 To fulfill the requirements of Regulations 11(3A), 11(6) and 11(7) of the Food Regulations 1985;
- 1.2 As a guidance to the food industries, consumer and authorised officers under the Food Act 1983;
- 1.3 The Regulations are as follows:

#### **Regulation 11(3A)**

**For the purpose of subregulation (3), the origin of food and food ingredients obtained through modern biotechnology shall be stated as follows:**

**“gene derived from (common name of such animal)”**

*(3) For the purposes of paragraphs (1)(e) and (g), where the ingredients of the food, or the food additives added to such food, are derived from animal, the common name of such animal shall also be stated on the label of that food:*

*Provided that it shall not be necessary to indicate the name of the animal from which the ingredient or food additive is derived if it can be inferred from the appropriate designation of such ingredient of food additive.*

### **Regulation 11(6)**

**For the purpose of paragraph (ea) of subregulations (1) and (5), the origin of food and food ingredients obtained through modern biotechnology shall be stated as follows:**

**“gene derived from (origin)”.**

*(1)(ea) where the food contains an ingredient known to cause hypersensitivity, a statement indicating that the food may cause hypersensitivity;*

*(5) For the purpose of paragraph (ea) of subregulation (1), the specific food or ingredients known to cause hypersensitivity are as follows:*

- (a) cereal containing gluten including wheat, rye, barley and oat;*
- (b) nut and nut product including peanut and soybean;*
- (c) fish and fish product;*
- (d) milk and milk product (including lactose); and*
- (e) egg and egg product.*

### **Regulation 11(7)**

**Food and food ingredients obtained through modern biotechnology shall be labelled as follows:**

- (a) in the case of food and food ingredients are composed of or contains genetically modified organisms, the words “genetically modified (name of the ingredient)” shall appear on the label;**
- (b) in the case of food and food ingredients are produced from, but does not contain genetically modified organisms, the words “produced from genetically modified (name of the ingredient)” shall appear on the label;**
- (c) for the purpose of paragraphs (a) and (b), in the case of single-ingredient foods, the information shall appear on the principal display panel in close proximity with the name of the food and shall be in not less than 10 point lettering;**
- (d) for the purpose of paragraphs (a) and (b), in the case multi-ingredient foods, the information shall appear in the list of ingredients immediately following the ingredients; and**

- (e) for the purpose of paragraph (d), the statement “contains genetically modified ingredient” shall be stated on the principal display panel in close proximity with the name of the food and shall be in not less than 10 point lettering.

## 2.0 INTERPRETATION

“Genetically modified organism (GMO)” means an organism in which the genetic material has been changed through modern biotechnology in a way that it does not occur naturally by multiplication or natural recombination or both.

“Highly refined foods” means food or food ingredient that are highly refined and where the processing removes all novel DNA and/or novel protein.

“Processing aid” means any 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 fulfill 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.

## 3.0 REQUIREMENTS OF LABELLING

3.1 The labelling requirements shall only apply to the three (3) main ingredients in the ingredient list.

3.2 Threshold level:

The labelling requirements shall **not apply** to foods which contains, consists of or produced from GMO in a proportion **not more than 3%** of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

3.3 Exemptions:

- Highly refined foods e.g. refined oil, plant sterol, boiled sweet, sugar, corn syrup, honey and dextrin (other than that with \*altered characteristics).

- The following are exempted when novel DNA and/or novel protein is not present in the final food:
    - Processing aids and food additives (e.g. dextrin).
    - Acidic foods (e.g. pickles and vinegar).
    - Salty foods (e.g. soy sauce).
  - Food from animals fed with GM animal feed (e.g. meat, milk, eggs).
  - Foods produced from fermentation using GMM (Genetically Modified Microorganisms) not present in the final products (e.g. vitamins, amino acid).
  - Foods produced with GM enzyme (e.g. cheese, bakery products produced with amylase).
- 3.4 For the purpose of requirements 3.1 to 3.3, only those events that have been approved by the National Biosafety Board are deemed to be the permitted events for foods and food ingredients obtained through modern biotechnology.

*Please refer to the list of events that have been approved by the National Biosafety Board at <http://www.biosafety.nre.gov.my>:*

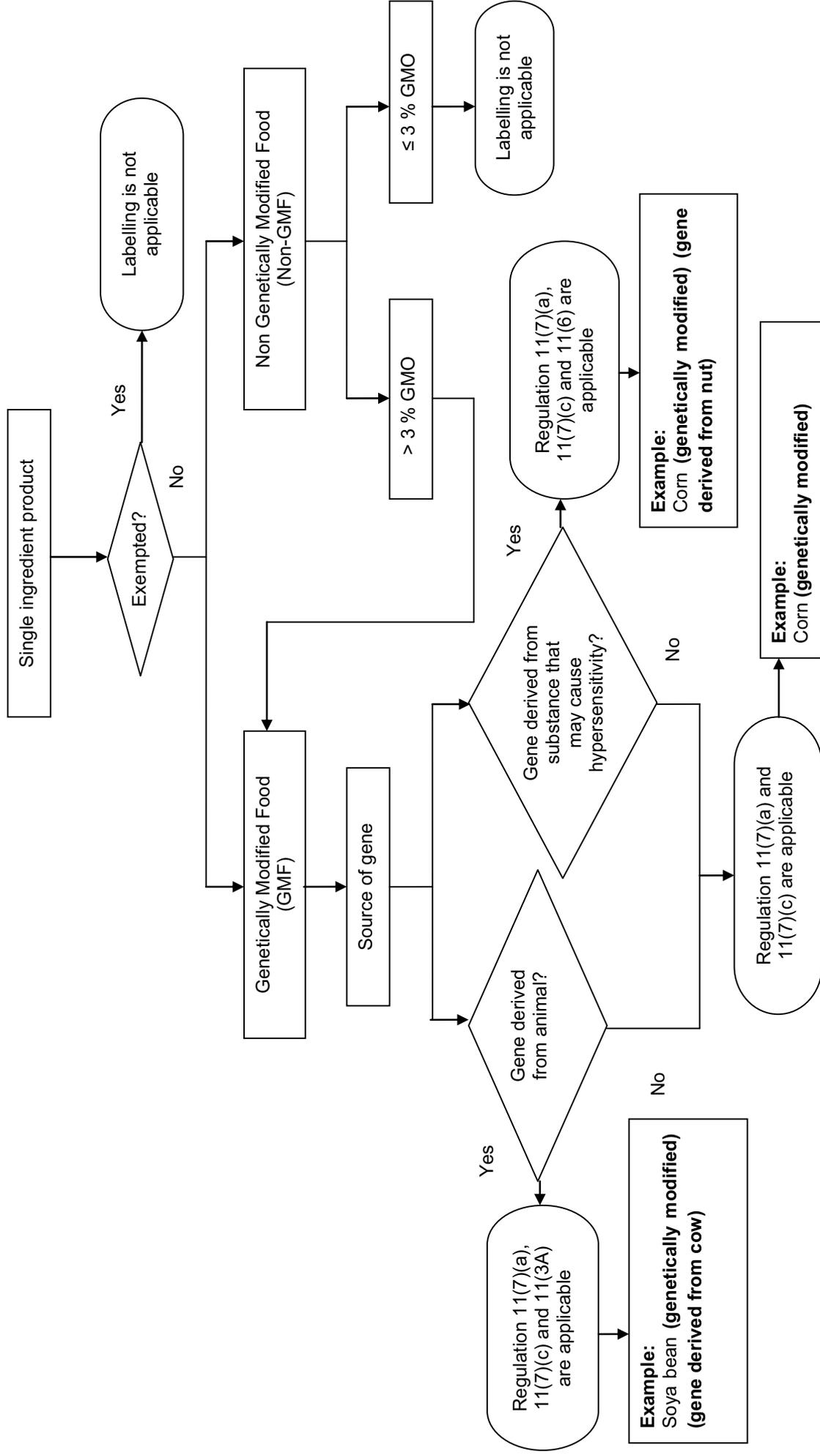
*(Home>Country's Decision>Approval for Food, Feed and Processing)*

- 3.5 Notwithstanding requirements 3.1 to 3.3, no exemption of labelling for foods which contains, consists of or produced from GMO if the gene is derived from animal or substance that may cause hypersensitivity.
- 3.6 Notwithstanding requirements 3.1 to 3.3, no exemption of labelling for highly refined foods with altered characteristics. \*Altered characteristics means –
- The genetic modification has resulted in one or more significant composition or nutritional parameters having values outside the normal range of values for existing counterpart food not produced using gene technology.
  - The level of anti-nutritional factors or natural toxicants are significantly different in comparison to the existing counterpart food not produced using gene technology.
  - The food produced using gene technology contains a new factor known to cause an allergic response in particular sections of the population.

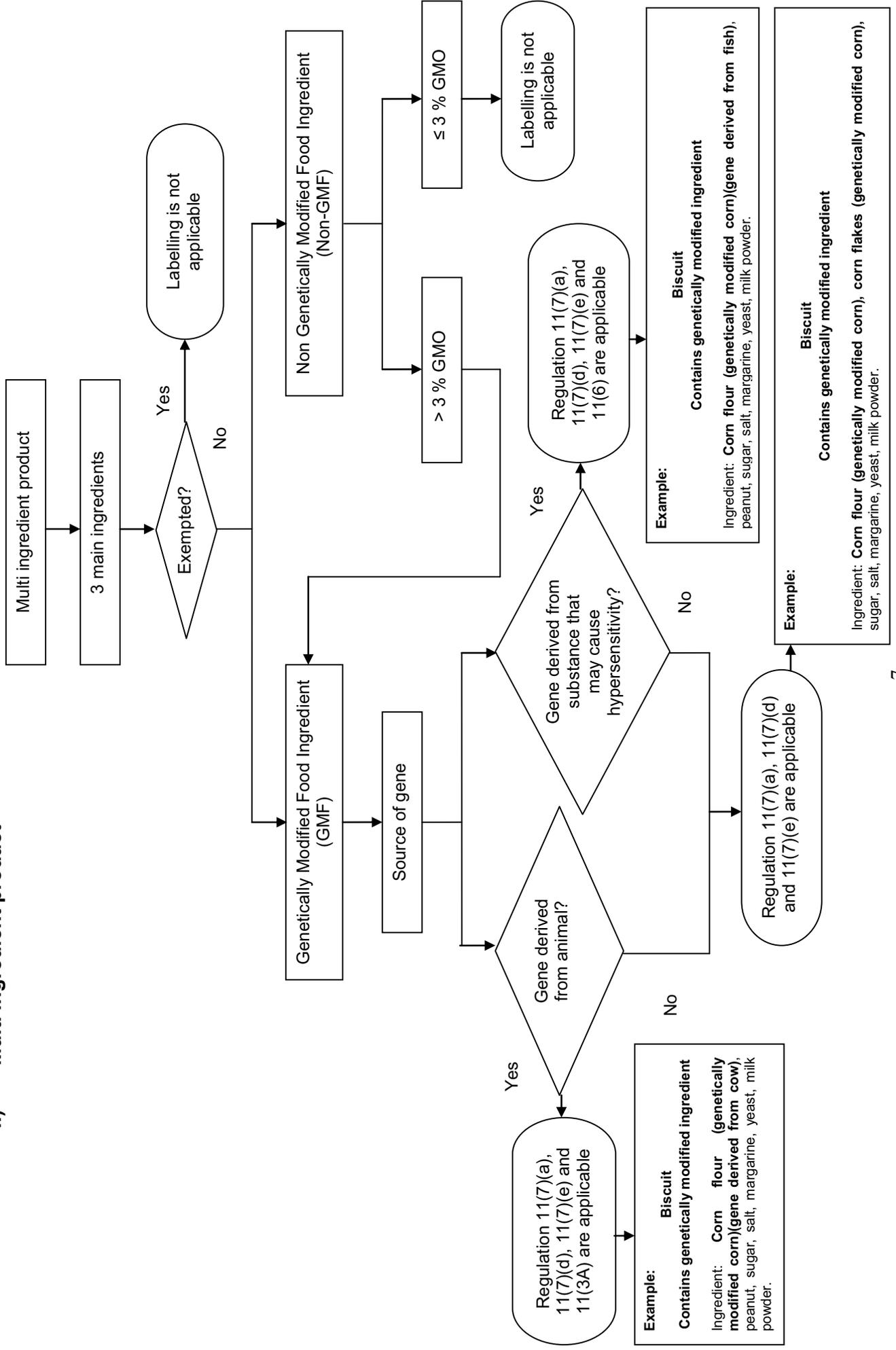
- The intended use of the food produced using gene technology is different to the existing counterpart food not produced using gene technology.
- 3.7 For the purpose of requirements 3.1 to 3.6, if the foods and food ingredients obtained through modern biotechnology are to be labeled, please refer to section 3.7.1. Please refer to section 3.7.2 for the examples of product label.

### 3.7.1 Flowchart

#### i) Single ingredient product



ii) Multi ingredient product



### 3.7.2 Examples of Product Label

#### i) Single ingredient product

<p><b>PQR®</b></p> <p><b>CORN</b></p> <p>(Genetically Modified)</p> <p>Storage instruction: Store in dry place.</p> <p><b>BEST BEFORE: 01/01/2013</b></p> <p>Packed by: PQR Sdn. Bhd. No.1, Jalan 123, Taman Perindustrian PQR, 58000 Kuala Lumpur</p> <p>Net weight: 1kg</p>
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<p><b>STU®</b></p> <p><b>SOYA BEAN</b></p> <p>(Genetically Modified) (Gene Derived from Cow)</p> <p>Storage instruction: Store in dry place.</p> <p><b>BEST BEFORE: 01/01/2013</b></p> <p>Packed by: MN Sdn. Bhd. No.1, Jalan 123, Taman Perindustrian XY, 58000 Kuala Lumpur</p> <p>Net weight: 1kg</p>
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ii) **Multi ingredient product**

**FGH®**  
**CORN BREAD**  
**Contains Genetically Modified Ingredient**

Nutrition Information  
Serving size: 60g  
Serving per package: 12

	Per 100g	Per serving 2 slices (60g)
Energy	252kcal	151kcal
Carbohydrate	48.5g	29.1g
Protein	8.3g	5.0g
Fat	2.4g	1.4g
Calcium	250mg	150mg

Ingredient: Wheat flour, corn flour (genetically modified corn), corn (genetically modified), yeast, non fat milk, corn oil, salt, butter.

Contains permitted preservative.  
Net weight: 360g  
Storage instruction: Store in dry place.

**BEST BEFORE: 01/01/2013**

Manufactured by:  
FGH Sdn. Bhd.  
No. 1, Jalan 123, Taman Perindustrian FGH,  
58000 Kuala Lumpur

**4.0 ENQUIRIES**

For further enquiries, please contact:

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