



AFDC 11 (6527) P3  
ICS 07.080

## DRAFT TANZANIA STANDARD

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**Biotechnology - Genetically modified organisms and derived products – Requirements for labelling of food, feed and ingredients.**

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**TANZANIA BUREAU OF STANDARDS**

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## 0 Foreword

This Tanzania standard provides requirements for labeling of food, feed and ingredient derived from genetically modified organisms (GMOs). The labeling provides clear and factual information to protect consumer's health and ensure fair practices in trade. It also helps consumers to make informed choices and handling of the products. The labeling information should be provided in a manner that does not mislead consumers.

The standard permits verification of claims by several processes including audit tracking (identity preservation, traceability) as well as chemical analysis.

During the preparation of this standard, reference was made to the following documents:

- The Environmental Management (Biosafety) Regulations, 2009
- Standard 1.5.2, Food Produced Using Gene Technology Issue 112; Australia New Zealand Food Standards Authority
- Regulation (EC) No 1829/2003 of the European parliament and the Council on Genetically Modified Food and Feed
- KS 2225: 2009 genetically modified organisms and derived products – Labelling of food and feed
- The Tanzania Food and Drugs Authority, food regulation 2006

## 1 Scope

This Tanzania standard provides requirements for labeling of genetically modified organisms (GMOs) and derived products intended for use as food, feed or ingredients. The standard shall not apply to food, feed or their ingredients containing genetically modified organisms and derived products in proportions of less than 0.9% of the total weight of the product.

## 2 Normative references

The following referenced documents are indispensable in the application of this Tanzania standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies:

TZS 538/EAS 38 Labelling of pre-packaged foods — General requirements

TZS 2070, Principles for the risk analysis of foods derived from modern biotechnology-Code of practice

TZS 2071, Biotechnology - Guideline for the conduct of food safety assessment of food derived from Recombinant DNA plants - Code of practices

TZS 2072, Biotechnology - Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA micro-organisms - code of practice

TZS 2073, Biotechnology-Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA Animals-Code of practice

AFDC 11 (6528) P1 Biotechnology - handling, transfer and use of genetically modified organisms and derived products - Code of practice

AFDC11 (5385) P1- ISO 21572:2019 Foodstuffs - Molecular biomarker analysis -Immunochemical methods for the detection and quantification of proteins

TZS 482/ EAS 804 - Claims – General Requirements

TZS 550/EAS 805 - Use of nutrition and health claims - Requirements

FTZS 2414/ISO 24276 Foodstuffs- Methods of analysis for the detection of genetically modified organisms and derived products- General requirements and definitions

FTZS 2411/ISO 21569 Foodstuffs- Methods of analysis for the detection of genetically modified organisms and derived products- Qualitative nucleic acid based methods.

FTZS 2412/ISO 21570 Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Quantitative nucleic acid based methods

FTZS 2413/ISO 21571 Foodstuffs- Methods of analysis for the detection of genetically modified organisms and derived products- Nucleic acid extraction

### **3 Terms and definitions**

For the purpose of this standard and in addition to the terms defined in TZS 538/EAS 38 and AFDC 11 (6528) P1, the following definitions shall apply:

#### **3.1 claim**

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

#### **3.2 Conventional counterpart**

shall be a 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.

#### **3.3 Denomination**

Shall be common, scientific/or commercial name of GMO.

#### **3.4 Food, feed or ingredient derived from genetically modified organism**

shall be a food, feed, or ingredient produced from, in whole or in part from genetically modified organisms.

#### **3.5 Food/feed additives**

are substances added to food/feed for specific technical and/or functional purposes during processing, storing or packaging.

#### **3.6 Ingredient**

shall mean any substance, including additives and enzymes, used in the manufacture or preparation of feed/foodstuffs and still present in the finished products even if in altered form.

#### **3.7 Genetic modification**

shall be a collection of techniques which are used to alter the heritable genetic material of living cells or organisms in a way that does not occur naturally by multiplication and/or recombination.

Note: the term genetically modified organisms is synonymous to genetically engineered organisms and living modified organisms.

### **3.8 Label**

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

### **3.9 Unique identifier**

shall be a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorised transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO.

## **4 General requirements**

**4.1** Labelling of food, feed or ingredients containing genetically modified organisms or products derived from genetically modified organisms shall be considered after they have undergone appropriate food safety assessment in accordance with TZS 2070, TZS 2071, TZS 2072 and TZS 2073

**4.2** Food, feed or ingredient derived from genetically modified organisms offered to the consumer shall be authorized for use in Tanzania in accordance with AFDC 11 (6528) P1.

**4.3** Any person offering food, feed or ingredient derived from genetically modified organisms for sale shall demonstrate that it has been authorized in accordance with section 4.2.

**4.4** Claims about single-ingredient foods as well as to ingredients in a multi-ingredient food shall

- a) be permitted pursuant to the scope of this standard
- b) be clear, informative, not false, and not misleading;
- c) comply with all requirements of section 5.2;
- d) refer to ingredient(s) in a multi-ingredient food rather than to the multi-ingredient food itself; (For examples, see Appendix A: Claim Statements, paragraph. A2.1)
- e) contain a reference to an external, readily accessible source of further information, such as a Quick Response (QR) code, toll-free telephone number or a Web-page address, unless all the mandatory information required accompanies the claim;
- f) be accompanied by an explanatory statement if the claim alone is likely to result in misunderstanding or misinformation;
- g) be presented in a manner so that the claim is grouped together with any explanatory statements and sources of additional information. Explanatory text shall be placed in close proximity to the claim with no intervening material.
- h) be based upon a percentage by weight as offered for sale unless otherwise stated;

- i) not imply directly or indirectly an improvement that does not exist nor exaggerate the aspect of the food to which the claim relates;
- j) not imply that the food is endorsed or certified by an independent third-party organization, when it is not;
- k) not be made using absolute terms such as free or 100% or all;
- l) use such terms as entirely, completely and absolutely with care. When claims are modified by these terms, allowances for unintentional or unverifiable food or ingredients, as described in sections 6, cease to exist; (For examples, see Appendix A: Claim Statements, par. A1.3)
- m) comply with TZS 538 on use of signs or emblems, symbols and abbreviations n) be re-assessed and updated as necessary to reflect changes in technology or other circumstances that could alter the accuracy of the claim;
- o) use the terms genetically modified(name of product), (derived) from genetically engineered/modified (name of product), or the term product of genetic modification, which refers to either of the preceding terms and shall conform, in intent, to the examples and guidance found in Appendix A: Claim Statements;

## **5 Specific requirements**

### **5.1 Claims that food are products of genetic engineering**

#### **5.1.1 Claims about Single-Ingredient Foods (For examples, see Appendix A: Claim Statements, paragraph (A2.3))**

**5.1.1.1** If a claim is made that a single-ingredient food is a product of genetic engineering/modification, it must comply with the requirements of sub-clause 4.4 of this standard.

**5.1.1.2** Claims that a single-ingredient food is a product of genetic engineering shall be made only when more than 99% of the source of the single-ingredient food is a product of genetic engineering/modification.

#### **5.1.2 Claims about Ingredient(s) in a Multi-Ingredient Food (For examples, see Appendix A: Claim Statements, par. A2.3 and A2.4)**

**5.1.2.1** If a claim is made that an ingredient is a product of genetic engineering/modification or is a mixture of products of and not of genetic engineering/modification, it must comply with the requirements of sub-clause 4.4 of this standard.

**5.1.2.2** Claims that an ingredient in a multi-ingredient food is a product of genetic engineering/modification shall be made only when more than 99% of the source of the ingredient is a product of genetic engineering/modification.

### **5.2. Verification of claims**

**5.2.1** Prior to making a claim, verification methods shall be used to confirm the validity of the claim.

**5.2.2** A person making a claim in accordance with this standard shall ensure compliance with the requirements in sub-clause 4.4 and sub-clause 5.1 of this standard, as appropriate and shall be responsible for securing data necessary for the verification of the claim.

**5.2.3** Verification for claims about foods that are and are not products of genetic engineering/modification may include but are not limited to testing, detection methods, inspection, and audit tracking. No claim is permitted if it cannot be verified.

**5.2.4** Claims shall be verified in accordance with FTZS 2414, FTZS 2411, FTZS 2413, FTZS 2412 and AFDC11 (5385) P1.

**5.2.5** The verification shall be fully documented, and the documentation shall be retained by the claimant for the purposes of information disclosure.

**5.2.6** Retention of documents shall be for the period that the claim for the food or ingredient is being made, and for a reasonable period thereafter, taking into account the patterns of use of the food.

**5.2.7** Where there are no methods already in existence, the person making the claims may develop a method, provided it meets the other requirements of this standard and is subject for approval by regulatory authority.

### **5.3 Prohibitions on Claims**

**5.3.1** Claims which cannot be substantiated

**5.3.2** Claims that are not in conformity with the suitability of the food, feed or ingredient in conformity with TZS 550

**5.3.3** Claims which could give rise to doubt about the safety of similar food or which could arouse or trigger fear to consumers

### **5.4 Labeling requirements**

**5.4.1** Labeling of food, feed, or ingredients containing or derived from GMOs shall be consistent with the requirements of TZS 538/EAS 38, TZS 482 and TZS 550. Also shall comply with national regulations.

**5.4.2** Where food, feed or ingredient containing or derived from genetically modified organisms is displayed for sale, labelling shall include the statement “genetically modified”. The labeling shall be clearly indicated.

**5.4.3** The language on the label shall be “Kiswahili” or Kiswahili and English”. A second language may be used depending on the designated market.

**5.4.4** Labelling information shall indicate a change in composition, nutritional value, intended use, and any other characteristics or properties which the food, feed, or ingredient derived from genetically modified organism differs from the conventional counterpart.

**5.4.4.1** 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 labelling information. For example;

“Soybean (genetically modified)”

“Maize flour produced from genetically modified (maize)”

“Soy protein isolate (genetically modified)”

**5.4.4.2** 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:

**Ingredients:**

- i. Soy protein isolate (genetically modified)
- ii. Maltodextrin
- iii. Vegetable oil
- iv. Emulsifier
- v. Water

**5.4.4.3** Where food, feed or ingredient derived from genetically modified organism contains a new factor known to cause allergic response in particular sections of the population, the presence of the allergen shall be declared in the labelling information.

**5.4.4.4** Where the origin of genetic material used in the modifications may raise objections based on religious or cultural dietary restrictions, such origin may be declared.

**5.4.4.4** Where there is common knowledge on the identity of the product by way of a unique identifier or a denomination or any other internationally accepted identifier, that identity may be indicated.

**APPENDIX A: CLAIM STATEMENTS**

**Introduction**

This appendix contains explanatory text and examples of claims that are acceptable and unacceptable according to the standard.

The examples provided are meant to be illustrative of the consideration discussed in each section, and unless otherwise noted, are not meant to take into consideration all the requirements of the standard.

This Appendix does not contain an exhaustive list of the requirements of the standard and is therefore not meant to serve as a replacement for the text of the standard.

**A1. Use of terms**

**A1.1 Product of genetic engineering/modification** - The expression product of genetic engineering/modification refers to food consisting of organisms that have undergone genetic engineering/modification and to foods derived from these organisms. Care must be taken when using the terms genetic engineering/modification, genetically engineered/modified, or from genetically engineered/modified.

**Examples:**

These potatoes are a product of genetic engineering (GE)/modification, this maize oil is a product of genetic engineering/modification, and soybean oil (from a GE/non-GE blend of soybean) are acceptable claims if they are made in accordance with the standard. Genetically engineered/modified maize oil, however, is unacceptable, since it is the maize that is actually genetically engineered/modified.

**A1.2 Use of terms other than those identified in this Standard** - Certain terms are not used in this standard. For example, claims that a food does not contain genetically modified (GMO) are misleading in many cases, since most foods do not contain organisms. Seeds, nuts, and micro-organisms such as live bacterial cultures in yogurt are exceptions. It is also important to consider whether acronyms such as GEO are commonly understood by the consumer, before using them in claims.

**Examples:**

Non-GEO maize starch and non-GEO soybean oil are unacceptable statements, since neither maize starch nor soybean oil are, or contain, organisms.

**A1.3 Modifying Statements** - Care should be taken when using such terms as entirely, completely, and absolutely. Claims that are modified by these terms ignore the allowances for unintentional or unverifiable food or ingredients described in sub-clause 4.4 and 5.1. Claims using such terms should not be made when ingredients in a multi-ingredient food are of unverifiable origin, or when it cannot be verified that there are no unintentionally present and/or undeclared products of, or not of, genetic engineering/modification in this food.

**Examples:**

Made entirely from non-genetically engineered/modified ingredients and ingredients used are absolutely not genetically engineered/modified are unacceptable claims if some of the ingredients used are of unverifiable origin.

This maize is completely non-genetically engineered/modified and these maize chips contain absolutely no genetically engineered/modified ingredients are also unacceptable claims if it could not be verified that there is no product of genetic engineering/modification unintentionally present in these foods.

**A2. Guidance related to specific sections of the standard**

**A2.1** Claims about ingredients in a multi-ingredient food - A statement that a multi-ingredient food is or is not a product of genetic engineering/modification is misleading, since it is actually the ingredients that are or are not products of genetic engineering/modification.

**Examples:**

This cake is not a product of genetic engineering, non-genetically engineered pizza, and genetically engineered/modified potato chips are unacceptable statements.

These chips are made from potatoes that are not a product of genetic engineering/modification and made with oil from soybean that is a product of genetic engineering/modification are acceptable statements.

**A2.2** Explanatory statements in some cases, explanatory statements are required to ensure that a claim is truthful and not misleading. In other cases, a manufacturer may want to provide further details. Any information provided in such statements must also be truthful and not misleading, must meet all the requirements of sub-clause 4.4 and 5.3, and must apply specifically to the food being labelled, unless given an appropriate context.

**Examples:**

Soybean oil from soybean genetically engineered/modified to increase crop yield, maize: product of genetic engineering/modification, this type of maize requires less pesticide use, and our potatoes are

genetically engineered/modified to reduce our use of pesticide are acceptable statements about why genetic engineering/modification was used as long as they are truthful and not misleading. Scientific data about specific crops may be required to support claims that, for example, pesticide use was reduced for the crop being sold.

Identity preservation systems are used to ensure that the soybeans we use are not genetically engineered/modified and non-genetically engineered/modified maize (tested) are also acceptable statements about the methods used to verify claims that foods are not products of genetic engineering/modification provided that they are truthful and not misleading.

Soybean oil. Product of genetic engineering/modification. Contains no genetically engineered/modified material is an acceptable statement for a product of genetic engineering/modification that contains no genetically engineered/modified material

High fructose maize syrup. Product of genetic engineering/modification. Contains less than 0.1 % genetically engineered/modified material is an acceptable statement for a product of genetic engineering/modification that contains less than 0.1 % genetically engineered/modified material.

### **A2.3 Claims about Foods that are products of genetic engineering/modification**

In addition to the considerations described above, the choice of appropriate expressions for claims about single-ingredient foods and ingredients that are products of genetic engineering/modification will depend on how much of the specific food has been produced through genetic engineering/modification.

#### **Examples:**

Papaya (product of genetic engineering/modification) and genetically engineered/modified potatoes are acceptable claims only if the food is obtained from sources (for example, a farmer's crop) that are more than 99% product of genetic engineering/modification.

Potatoes (partly a product of GE), tomatoes (combination of GE and non-GE), and squash (mixed non-GE and GE sources) are acceptable claims when between 1% and 99% of the source of the food or ingredient is a product of genetic engineering/modification.

### **A2.4 Claims about ingredients in a multi-Ingredient food**

**A2.4.1** when a claim is made that one or more ingredients in a multi-ingredient food are products of genetic engineering/modification or are a mixture of products of and not of genetic engineering/modification, the standard requires

a) That the manufacturer undertake steps to investigate the origin of all ingredients of the multi-ingredient food as offered for sale, and

b) That all known ingredients that are products of genetic engineering be identified in the list of ingredients.

#### **Example:**

The following is an acceptable claim and format. (The percentages listed refer to the weight of ingredients in the product as offered for sale. These are included here for instructional use and are not a requirement of the standard.)

Maize chips snack food: ingredients: maize Footnote 1 (70%), hydrogenated soybean oil Footnote 2 (25%), seasonings (4%), calcium hydroxide

**FOOTNOTES**

Footnote 1 - Not products of genetic engineering/modification.

Footnote 2 - From GE/non-GE crops.

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