

USDA Foreign Agricultural Service

# GAIN Report

Global Agricultural Information Network

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Required Report - public distribution

**Date:** 2/5/2014

**GAIN Report Number:**

## Kenya

### Food and Agricultural Import Regulations and Standards - Narrative

### FAIRS Country Report

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**Report Highlights:**

This report provides updated technical information for import requirements and regulations on food and agricultural products as are currently required by the Government of Kenya (GOK). Sections updated are part of Section I, III, V, VI, Appendix I, and II.

## **Section I. Food Laws:**

[FAIRS Country Report 2012](#) is still valid. FAIRS Country Report 2013 provides updated information on part of Section I, III, V, VI, Appendix I, and II.

The Government of Kenya (GOK) does not have a specific food law that applies to imported foodstuffs and feedstuffs. Instead, the food regulatory system is multi-sectorial and embodied in various statutes that are implemented by various government ministries/departments and regulatory agencies. Due to inadequate coordination among these institutions, a National Food Safety Policy has been developed that proposes the formation of a National Food Safety Authority. Kenya's food regulatory system is consistent with sanitary and phytosanitary agreement of the World Trade Organization (WTO/SPS) and other international treaties (CODEX, OIE, and IPPC).

The GOK encourages export certification of almost all foods before they are exported to Kenya for human and animal consumption. Exporters and consolidators of U.S. food products may obtain a certificate of conformity (COC) through the GOK's PVoC. The GOK maintains inspection contracts with Société Générale De Surveillance S.A. (SGS) and Intertek International Ltd to operate its PVoC program for North American exports.

Exporters and consolidators can ship products covered under the PVoC to Kenya without receiving a COC, but these exports will be subject to inspection at the port of entry. The cost of the inspection will be approximately 15 percent of the CIF value of the product/s. The GOK will also require that the exporter post a bond equal to 15 percent of the CIF value.

The GOK excludes some products like fresh fruits, seeds, nuts and vegetables from the PVoC (check [http://www.kenyaPVoC.com/Product\\_Inquiry/](http://www.kenyaPVoC.com/Product_Inquiry/) for the full list). Nonetheless, the PVoC-excluded products/goods must meet all relevant Kenyan standards at the port of entry. However, for these foods that do not require a COC, exporters and consolidators may still request a COC from the PVoC agent, as a means of minimizing potential port-of-entry problems.

FAS Nairobi has identified 22 major Acts of Parliament governing food safety that are administered principally by the Kenya Plant Health Inspectorate Service (KEPHIS), the Kenya Bureau of Standards (KEBS), the Department of Veterinary Services (DVS), Pest Control and Product Board (PCPB), the National Biosafety Authority (NBA), and the Ministry of Health (MOH). The PVoC agent evaluates U.S. exports to Kenya vis-à-vis the following Acts:

### **Major Food Laws**

1. Public Health Act Cap.242<sup>1</sup>
2. Radiation Protection Act Cap.243 (In the case of irradiated Foods)<sup>1</sup>
3. Food, Drugs and Chemical Substances Act Cap. 254<sup>1</sup>
4. The Agriculture Act Cap 318<sup>2</sup>
5. The Agriculture Produce (Export) Act Cap.319<sup>2</sup>
6. Plant Protection Act Cap.324 (In case of Fruits & Vegetables)<sup>2</sup>
7. The Seed and Plant Variety (NPT) Regulations, 2009<sup>2</sup>
8. Suppression of Noxious Weeds Act 325<sup>2</sup>
9. The Seeds & Plant Varieties Act Cap. 326 (Imported seeds or seed crops with potential to grow when planted)<sup>2</sup>

10. Dairy Industry Act Cap. 336<sup>3</sup>
11. Meat Control Act Cap. 356<sup>4</sup>
12. Animal Diseases Act Cap. 364<sup>5</sup>
13. Customs & Excise Act Cap. 472<sup>6</sup>
14. The Standards Act Cap 496<sup>7</sup>
15. Weights and measures Acts Cap.513<sup>8</sup>
16. The Industrial Property Act Cap. 509<sup>8</sup>
17. Trademarks Act Cap. 506<sup>8</sup>
18. Pest Control Products Act Cap. 346<sup>9</sup>
19. Fisheries Act Cap. 378<sup>10</sup>
20. Biosafety Act 2009<sup>11</sup>
21. Alcoholic Drinks Control Act, 2010<sup>12</sup>
22. Fertilizers and Animal Feedstuff Act Cap 345<sup>13</sup>

<sup>1</sup>Implemented by Ministry of Health (Department of Public Health) at the ports of entry

<sup>2</sup>Implemented by KEPHIS at the ports of entry

<sup>3</sup>Implemented by the Kenya Dairy Board at the ports of entry

<sup>4</sup>Implemented by DVS and KEBS at the ports of entry

<sup>5</sup>Implemented by DVS and Department of Public Health at the ports of entry

<sup>6</sup>Implemented by the Kenya Revenue Authority at the ports of entry

<sup>7, 8</sup>Implemented by KEBS at the ports of entry

<sup>9</sup>Implemented by the PCPB

<sup>10</sup>Implemented by the Department of Fisheries

<sup>11</sup>Implemented by NBA (Ministry of Education, Science & Technology) and KEBS at the ports of entry

<sup>12</sup>Implemented by the National Authority for the Campaign against Alcohol and Drugs Abuse (NACADA)

<sup>13</sup>Animal Feedstuff Act is implemented by DVS

## **Section II. Labeling Requirements:**

### **A. General Requirements**

The GOK requires an English and/or Kiswahili label on all consumer-ready foods, which should include metric measurements and packaged in even numbers, a brand/trade name, common name, list of ingredients, date of manufacture, expiry date/sell by, net content, storage instructions, name and address of manufacturer, country of origin and grade designation where applicable.

Here below please find frequently asked questions and responses that will help the reader understand Kenyan import requirements as applied by the PVoC agent.

**Q:** What languages(s) are required and/or permitted on the product label?

**A:** The GOK requires English on the label, but permits any other language, or a combination of languages. In Kenya it is common to see imported food products with English and Arabic or Chinese Language labeling.

**Q:** Can U.S. consumer-ready products enter the Kenyan market without altering the U.S. label under which the product would normally be marketed in the United States?

**A:** In addition to all of the information provided by the U.S. label, the GOK requires the products to carry an Import Standardization Mark (ISM) that KEBS provides free-of-charge once the product

qualifies for a COC.

Q: Can the ISM or any other additionally-required labeling be affixed, or must it be incorporated into the original label for the product?

A: The GOK permits stick-on labels as noted in the above photograph.

Q: Must stick-on labels be applied before product export or may they be applied at the port of import or at the point of sale?

A: The stick-on labels may be applied at any point prior to retail sale.

Q: Are there instances where standard U.S. labels or claims thereon might be considered false or misleading?

A: To this date, there has not been a single reported incident of a standard U.S. food-product label having been deemed false or misleading.

Q: U.S. food product labels will carry a “best before date” (shelf life) but does the GOK require that the product enter Kenya with a predetermined percent of that shelf life remaining for marketing to Kenyan consumers?

A: All imported food products must have a minimum remaining shelf life of 75 percent of the shelf life indicated on the label upon arrival in Kenya.

Q: Does the GOK grant exceptions to their labeling regulations?

A: There are a great variety of different labels, label content, and style on imported food product in Kenya, but all seem to carry the standard Kenyan labeling requirements. There may be exceptions, but we are not aware of a formal process whereby an exporter might ask for an exception.

## **B. Other Specific Labeling Requirements**

For this section, “Other Specific Labeling Requirements” will include nutritional labeling, health claims made on labels, and any requirement to notify a specific process used to produce the consumer-ready food product.

Q: U.S. consumer-ready food products meet at least specific minimal nutritional-labeling requirements. Are the U.S. minimal nutritional labels sufficient for the Kenyan market?

A: The GOK requires nutritional labeling based on a uniform 100 grams of product. U.S. consumer-ready food product producers label nutrition based on portion size. However, the GOK has not insisted that U.S. nutritional labels be changed to reflect the nutritional content per 100 grams.

Q: Are subjective nutrient content claims (i.e. low in saturated fat) or absolute descriptors (i.e. high fibre, low fat) permitted in GOK labeling regulations?

A: The GOK requires that, where a consumer-ready food product carries a subjective or descriptive claim, it must be supported by a nutritional breakdown of the specific attribute being described i.e. “this product is low in saturated fat, containing only three grams of saturated fat per 100 grams of total fat.”

Q: Does the GOK permit health claims on labels, i.e. “heart healthy?”

A: At this time, the GOK does not preclude any such health claims on consumer-ready labels.

Q: Does the GOK require that foods produced using novel processes be labeled to reflect the process?

A: Irradiated foods must be so designated on the food container.

### C. Genetically Modified Organisms (GMOs) Labeling Regulations

This section addresses the GOK's mandatory labeling requirements for GMOs. These requirements and precise labeling language are found in Appendix III and the Kenya standard KS 2225:2010 Labeling of food and feed.

[http://www.biosafetykenya.go.ke/index.php?option=com\\_content&view=article&id=163:biosafety-labeling-regulations-2012&catid=84&Itemid=498](http://www.biosafetykenya.go.ke/index.php?option=com_content&view=article&id=163:biosafety-labeling-regulations-2012&catid=84&Itemid=498)

Q: Which products are covered under these regulations?

A: These regulations apply to food, feed or ingredients containing GMOs or products derived from Live Modified Organisms (LMOs).

Q: What are the labeling requirements for processed products containing GMOs?

A: In the list of ingredients the words "genetically modified" must follow each of the ingredients that have been derived from LMOs or combined with GMOs. The following is an example:

#### Product Ingredients

Maize Meal (genetically modified)

Soybean Meal (genetically modified)

Salt

Sugar

Q: Does the GOK require any additional labeling for GMOs.

A: Please see Appendix III for information related to possible other labeling requirements for foods containing GMOs.

### **Section III. Packaging and Container Regulations:**

Kenya has no special packaging or container size requirements. Due to purchasing power constraints, most consumers prefer small pack sizes at the retail level. However, wholesale outlets offer foodservice size packaging.

The following section treats potential technical barriers to trade associated with Kenya's packaging and container size or material requirements and the recycling thereof.

Q: Many U.S. consumer-ready foods are marketed in containers specific to the U.S. market based on a certain number of ounces, pounds, for fluid ounces. Can Kenyan importers of these products market them in the same containers, or must a specific container be used to comply with GOK container/packaging requirements?

A: Kenyan importers may market U.S. consumer-ready product in its original packaging/container without alteration regardless of the container or package size.

Q: Are there any special municipal waste disposal laws or product-packaging recycling regulations that U.S. exporters need to be aware of, or prepared for, in the Kenyan marketplace?

A: Neither the GOK nor the regional local Governments currently require consumer-product package

recycling.

Q: Does the GOK restrict or limit any packaging materials for consumer-ready products?

A: The GOK regulates the wood pallets often-times used to ship food products, but not the materials in which the food are packaged.

GOK requires solid wood packaging material be treated or fumigated (International Standards for Phytosanitary Measures #15).

#### **Section IV. Food Additives Regulations:**

Food additives and the regulation thereof remain an important variable when considering a country's openness to trade within the context of protecting the health of its population. Recent protein-adulteration cases have highlighted the importance of understanding the role and disclosure of additives.

But not all developing countries have the capability to regulate and monitor additives in food.

Q: Has the GOK established specific regulations to regulate additives in food?

A: KEBS regulates food additives through the Food, Drugs and Chemicals Substances Act [http://www.kenyalaw.org/kenyalaw/klr\\_home/](http://www.kenyalaw.org/kenyalaw/klr_home/) and KS 660 series (Guidelines to the safe use of food additives) found at [http://www.kebs.org/catalog\\_results.php](http://www.kebs.org/catalog_results.php). Where there are no specific GOK guidelines, KEBS follows the CODEX approved food additives as references to regulate food additives.

Q: Does Kenya maintain a positive and/or negative list of food additives?

A: Kenya has both positive and negative lists for food additives. The lists are not yet available "on line," but may be purchased from any regional or national KEBS office.

Q: Are there any special use requirements or restrictions for additives on the positive list?

A: The GOK restricts on the use of all food additives in baby food. Food additives used as oxidants, sweeteners, colorants, curing agents, flavor enhancers, flavorings or preservatives, in a given food stuff must appear on the label. The common chemical name of the product should be used on the label.

Q: Will the GOK accept the list of CODEX-approved food additives for imported consumer-ready food products?

A: Where an additive isn't listed in GOK regulations, KEBS relies, and requires that the PVoC agent rely on the CODEX list.

#### **Section V. Pesticides and Other Contaminants:**

The Pest Products Control Act mandates Pest Control Products Board (PCPB) to regulate importation, exportation, manufacture, distribution and use of pesticides in Kenya. PCPB is also in charge of pesticide registration and maintains a list of registered products, restricted and banned pesticides. One can access the list online at an annual subscription fee of US\$ 12 (Kshs. 1,000). PCPB refers to CODEX standards for tolerance levels.

In addition to PCPB, other government institutions that enforce pesticide/contaminant regulations include:

- KEPHIS monitors and analyzes pesticide residues in their accredited analytical chemistry laboratory;

- KEBS sets the standards and monitors compliance;
- DVS checks on pesticide residues in animal products, feed and animal health drugs;
- Department of Public Health and KEBS examines for microbial and chemical contamination of food as guided by the Food, Drugs, and Chemical Substances Act, Cap 254.

Pesticide and contaminant regulation in food varies from continent-to-continent and from country-to-country, even when those countries form part of a bigger trade block. Many developing countries lack the technical expertise and appropriate technology to regulate and/or test for pesticides and contaminants in food.

Q: Has the GOK formulated pesticide contaminant regulations for food?

A: The GOK promulgated pesticides and contaminants regulations for consumer-ready foods and commissioned KEBS and/or KEPHIS to oversee this aspect of Kenya's food safety.

Q: Does the GOK use both positive and negative lists as with the case for food additives?

A: Kenya does regulate on the basis of both positive and negative lists that are available at regional and national KEBS and KEPHIS offices, but not yet available "on line."

Q: For the pesticides appearing on the positive list, does the GOK establish maximum residue levels (MRLs)?

A: Where the GOK does not list pesticides and contaminants MRLs, KEBS and KEPHIS use CODEX MRLs.

## **Section VI. Other Regulations and Requirements:**

The GOK facilitates the importation of consumer-oriented products through a Certificate of Conformity.

To obtain a CoC, an imported product must satisfy Kenyan import requirements, as evaluated by the Société Générale of Surveillance (SGS) or Intertek International Ltd., pre-export verification of conformity (PVoC) agents appointed by GOK. Once SGS or Intertek has issued a CoC, the importer may present the CoC to KEBS for clearance of the goods and to receive the Import Standardization Mark (ISM), a stick-on-label to be affixed to each retail container.

There are three routes for certification namely:

**Route A:** Products shipped under this route must be tested and physically inspected to demonstrate conformity to relevant standards. This route is open to all products being exported by either traders or manufacturers and mainly for first time exporters.

**Route B:** Products shipped under this route must be registered with an authorized PVoC agent. The Product Registration is valid for a period of one year. Shipments of registered products are exempted from mandatory testing, and certification may be based on physical inspection only. However, random testing of registered product is still required to ensure product conformity throughout the registration period. Frequent exporters of homogenous products mainly use Route B.

The following products are however not eligible for registration under Route B (i.e. are subject to certification under Route A only);

- Sugar
- Cereals and pulses such as Rice, wheat, beans, Maize etc
- Animal and Fishery products (fresh and frozen- not further processed)

- Dairy Products
- Fresh horticultural products

**Route C:** allowed to only manufacturers with a quality management system in their production process. It involves auditing of such production processes and licensing of products manufactured thereof by authorized PVoC agent(s) in line with ISO Guide 28: 2004. If successful, the manufacturer will be presented with a License for the relevant products valid for a period of one year. Licensed products shall be subject to random physical inspection by authorized PVoC agent(s) prior issuance of Certificate of Conformity and subsequent shipping of the same. However, the PVoC agent(s) shall carry out limited testing during the license valid period.

The PVoC agent(s) reviews the Request for Certification (RFC) received from the exporter before determining the most appropriate certification route and the applicable standard to be used in the certification process.

Additional information can be found at: <http://www.kebs.org/?opt=qai&view=pvoc>

Non-tariff barriers can be imposed at varying points along the farm-to-fork food chain and with great imagination. This section identifies “other” regulations that might have potential to impede trade in agricultural products.

Q: What are the GOK’s inspection requirements at the point imported food reaches Kenyan borders?

A: The level of inspection required by the GOK at the port of entry depends on the food and whether the food product has received a COC. Food products that enter with a COC do not require inspection, even though they may be inspected at random.

Q: Does the GOK require that consumer-ready food products be registered before being sold in the domestic market?

A: The GOK provides that a food product with homogeneous production methods be registered annually with the PVoC agent, so that shipments within that year need only be inspected randomly by the PVoC agent, but otherwise does not provide for or require product registration.

Q: Do all consumer-ready food products and food commodities require laboratory testing to ensure conformity with Kenya import standards?

A: For products covered under the PVoC, the PVoC agent makes the determination in accordance with the contract with the GOK. The GOK requires that a food product meet all Kenyan standards before qualifying for a COC, and, therefore, product testing should be expected.

Q: Are product samples shipped via express mail or parcel post subject to import regulations?

A: Product samples (except live plants or seeds) shipped via express mail or parcel post are not subject to import regulations but are subject to custom handling charges that are based on the value of product.

Q: Does the GOK monitor food products at wholesale or retail distribution points?

A: Reportedly KEBS conducts random surveillance and requires non-conforming products to be recalled by the producer.

## **Specific documentation and certification Requirements**

### Pre-Shipment Documents

- Plant Import Permit (PIP) for bulk commodities issued by the Kenya Plant Health Inspectorate Service (KEPHIS). The PIP form can be found at <http://www.kephis.org/online-forms-mainmenu-38.html>
- Import Declaration Form (IDF) issued by the Kenya Revenue Authority (KRA) found at [http://www.revenue.go.ke/customs/pdf/Import\\_Declaration\\_Fee\\_%20FORM.pdf](http://www.revenue.go.ke/customs/pdf/Import_Declaration_Fee_%20FORM.pdf)

### Post-Shipment Documents

- Certificate of Conformity (CoC)
- Phytosanitary Certificate (PC) containing the required Additional Declarations for bulk commodities (corn, wheat, pulses, rice, sorghum, barley, etc.).
- Non-Genetically Modified Organisms (GMO) Certificate
- Bill of Lading (three original B/L plus non-negotiable copies)
- Commercial Invoice
- Packing List
- Customs Entry Form
- Certificate of Origin
- Health Certificates (Cleanliness, Weight, and Quality)
- Insurance Certificate

Other Documents requested depending on the agricultural commodity or food product:

- Fumigation Certificate
- Radiation Certificate
- Noxious Weed Certificate
- Free from Karnal Bunt Certificate

## **Section VII. Other Specific Standards:**

Non-tariff barriers are often imposed through specific and unique standards. This section treats “Specific Standards” that might impede trade in agricultural products.

Q: Are there any special standards, legislation, or ordinances that might impede or increase the cost of importing food?

A: The GOK requires non-scientifically based import permits for meat, dairy, poultry and their products.

## **Section VIII. Copyright and/or Trademark Laws:**

Intellectual property rights (IPR) laws and regulations are a rarity in developing countries, and where they exist, they are poorly enforced. Exporters must be aware that IPR protection can be difficult-to-impossible and that includes in Kenya.

Q: Does the GOK have laws that protect trademarks and brand names of foreign-produced food products?

A: The GOK provides for trademark and brand name registration in Kenya. Kenya Industrial Property Institute (KIPI) <http://www.kipi.go.ke/index.php/about-trademarks> registers product via an application.

Q: Is there a statute of limitations on trademarks and brand names?

A: Trademarks are registered for ten years initially and may be renewed indefinitely upon request.

### **Section IX. Import Procedures:**

While an exporter may comply with each and every regulation on the books of a given country, exporting may still be exceedingly difficult, if the final port of entry import procedures are designed to make importing difficult or expensive.

Q: Once I have complied with all the testing and labeling requirements, and received my COC, what should I expect at the Kenyan port of import?

A: Below, please find a description of the expected import procedures flow:

The importer will notify a clearing agent (CA) of arrival date of cargo;

The CA notifies the Kenya Revenue Authority (KRA) via its on-line clearing system (Simba). The importer must use a KRA appointed CA;

The CA obtains the arrival date and manifest number and enters into the Simba;

The CA sends the manifest number to KRA, who posts number to the specified Kenyan bank;

The CA pays the relevant taxes using HS Codes and VAT rates where applicable;

The KRA agent clears and confirms entry of the cargo to the CA;

The CA uses KRA confirmation to pay the various port charges at the Kenya Ports Authority (KPA);

The CA uses the KPA documents and any related import permits to request clearance from KEPHIS, KEBS, Port Health and the local police; and,

The KPA conducts a final physical verification of the cargo before releasing it into the domestic market.

The entire customs clearance process takes a minimum of three days. Should an exporter/importer be dissatisfied, KRA has an appeals system <http://www.kra.go.ke/vat/vatassessments.html>

### **Appendix I. Government Regulatory Agency Contacts:**

Kenya Bureau of Standards (KEBS)

The Managing Director

P.O. Box 54974 Nairobi, Kenya

Tel: 254-20-6948000 or 69028201/401/410

Fax: 254-20-609660/6004031

Email: [info@kebs.org](mailto:info@kebs.org)

Website: [www.kebs.org](http://www.kebs.org) and [www.kenyapvoc.com](http://www.kenyapvoc.com)

Kenya Plant Health Inspectorate Service (KEPHIS)

The Managing Director

P.O. Box 49592 Nairobi, Kenya  
Tel: 254-20-3536171/2 or 3597201/2/3  
Mobile: 254-722516221, 254-733874274  
Fax: 254-20-882265  
Email: [director@kephis.org](mailto:director@kephis.org)  
Website: [www.kephis.org](http://www.kephis.org)

Department of Veterinary Services (DVS)  
The Director  
P.O. Private Bag 00625 Kabete, Kenya  
Tel: 254-20-8043441631383/2231/1287  
Fax: 254-20-2026212  
Cell: 254-722376237  
Email: [veterinarydepartment@yahoo.com](mailto:veterinarydepartment@yahoo.com)

Ministry of Health  
The Chief Public Health Officer  
Public Health Department  
P.O. Box 30016-00100 Nairobi, Kenya  
Tel: 254-20-2717077  
Fax: 254-20-2710055  
Website: [www.publichealth.go.ke](http://www.publichealth.go.ke)

The Managing Director  
Pest Control Products Board  
Waiyaki Way, Opposite ABC Place  
P. O. Box 13794 - 00800 Nairobi, Kenya.  
Tel. +254 - 020 - 8021846/7/8  
Mobile: 0720480904/0735778743  
Fax: +254 - 020 - 8021865  
Email: [md@pcpb.or.ke](mailto:md@pcpb.or.ke) / [pcpboard@todays.co.ke](mailto:pcpboard@todays.co.ke)  
Website: [www.pcpb.or.ke](http://www.pcpb.or.ke)

National Biosafety Authority  
The Chief Executive Officer  
Commission for Higher Education Campus  
P.O. Box 28251-00100  
Nairobi, Kenya  
Tel. +254-20-2678667  
Email: [ceo@biosafetykenya.go.ke](mailto:ceo@biosafetykenya.go.ke)  
[www.biosafetkenya.go.ke](http://www.biosafetkenya.go.ke)

Customs and Excise Department  
The National Treasury

P.O.Box 30007 Nairobi, Kenya  
Tel: 254-20-715540  
Fax: 254-20-718417  
Website: [www.revenue.go.ke](http://www.revenue.go.ke) and [www.kra.go.ke](http://www.kra.go.ke)

Ministry of Industrialization and Enterprise Development  
The Managing Director  
Kenya Industrial Property Institute  
P.O. Box 51648-00200  
Nairobi, Kenya  
Tel: (254-20) 6002210/11  
Fax: (254-20)6006312  
Website: <http://www.kipi.go.ke/>  
Email: [info@kipi.go.ke](mailto:info@kipi.go.ke)

Kenya Ports Authority  
The Managing Director  
P.O. Box 95009-80104  
Mombasa, Kenya  
Tel: (254-41) 2112999/2113999  
Cell: (254-20) 720202424  
Email: [micd@kpa.co.ke](mailto:micd@kpa.co.ke)  
Website: <http://www.kpa.co.ke>

Kenya Revenue Authority  
Office of the Commissioner General  
Times Tower Building, 30th Floor  
P.O. Box 48240-00100 GPO  
Nairobi. Kenya  
Tel: (254-20) 310900/2810000  
Fax: (254-20) 341342  
Email: [cic@kra.go.ke](mailto:cic@kra.go.ke)  
Website: <http://www.kra.go.ke>

**Appendix II. Other Import Specialist Contacts:**

SGS North America Inc.  
236 32nd Avenue  
Brookings, SD 57006 USA  
Tel: 605-692-7611  
Fax: 605-692 -7617  
Website: [www.us.sgs.com/](http://www.us.sgs.com/)

Intertek International Ltd.

Tel: 305-513-3000

[www.intertek-gs.com/contactintertek/namerica/](http://www.intertek-gs.com/contactintertek/namerica/)

SGS Kenya Limited  
Victoria Towers, 2nd floor, Kilimanjaro Ave Upper Hill  
P.O. Box 72118-00200  
Nairobi, Kenya  
Tel: (254 -20) 272 7832/4  
Website: <http://www.sgs.co.ke>

Intertek - Government Services Kenya  
House of Vanguard, Chiromo Road, Westlands  
Nairobi, Kenya, 00621  
Tel: (254-20) 4449 132  
Fax: (254 -20) 4 49 212  
Email: [info.nairobi.gs@intertek.com](mailto:info.nairobi.gs@intertek.com)

Government Chemist – Nairobi  
The Director  
P.O. Box 30014-00100  
Nairobi, Kenya  
Tel: (254-20) 2725806/7  
Fax: (254-20) 2717567  
Email: [gchemist@wananchi.com](mailto:gchemist@wananchi.com)

Government Chemist – Mombasa  
Officer-in-charge  
P.O. Box 819, Mombasa, Kenya  
Tel: (254-20) 2080906

### **Appendix III. The Biosafety (Labeling) Regulations, 2011**

#### **ARRANGEMENT OF REGULATIONS**

##### **Regulation**

##### **PART I – PRELIMINARY**

1. Citation.
2. Preamble

3. Interpretation
4. Objective

## **PART II- APPLICATIONS**

1. Threshold
2. Scope of Labeling
3. Labeling and Packaging Requirements
4. Exemptions
5. Claims
6. Traceability
7. Monitoring inspection and compliance

## **PART III - MISCELLANEOUS**

1. Genetically modified organisms Labeling register
2. Offences and Penalties

### **THE BIOSAFETY ACT** *(No.2 of 2009)*

**IN EXERCISE** of the powers conferred by section 51 of the Biosafety Act, the Minister for Higher Education, Science and Technology makes the following Regulations

### **THE BIOSAFETY (LABELING) REGULATIONS, 2011** **PART I- PRELIMINARY**

- |          |   |
|----------|---|
| Citation | <b>1.</b> These Regulations may be cited as the Biosafety (Labeling) Regulations, 2011.   |
| Preamble | <b>2.</b> Labeling and packaging 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 the Biosafety Act |

of Kenya.

## Interpretation

**3.** In these Regulations unless the context otherwise requires-

‘Authority’ means the National Biosafety Authority established under section 5 of the Act;

“altered characteristic” of a GM food means that when the GM food is compared to its conventional counterpart, it is different in relation to: composition or nutritional values; anti-nutritional factors or natural toxicants; factors known to cause allergic responses in particular sections of the population; its intended use; or any other material differences;

‘competent authority’ means an agency of another country responsible under its national law for the control or regulation of genetically modified organisms;

“conventional counterpart” means 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 for processing;

“genetically modified food/feed” means food/feed that is, or contains as an ingredient, including a processing aid, produced using modern biotechnology which –

(a) contains novel DNA and/or novel protein; or

(b) has altered characteristics;

‘genetically modified organism’ means an organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques;

“GM-free/ non-GMO” means the complete absence of any genetically modified material, or use of a genetic modification process, in a food or food product;

“food, feed or ingredient derived from genetically modified organism” means a food, feed, or ingredient produced from, in whole or in part from genetically modified organisms;

“labeling” means any written, printed, or graphic matter that accompanies a food or is displayed near the food, including that for the purpose of promoting its sale or disposal;

“novel DNA and/or novel protein” means DNA or a protein which, as a result of the use of genetic modification, is different in chemical sequence or structure from DNA or protein present in counterpart food which has

not been produced using genetic modification;

“operator” means a natural or legal person who places a product on the market at any stage of the production and distribution chain, but does not include the final consumer;

“placing on the market” means making a genetically modified organism available for sale;

“product” means genetically modified food, feed and ingredients as defined under this particular regulation;

“traceability” means ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains;

“unique identifier” means a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorized transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO.

Objective

**4.** The objective of these Regulations is to ensure the traceability of products consisting of or containing genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objectives of facilitating accurate labeling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products.

## **PART II- APPLICATIONS**

Threshold

**5.** These regulations shall not apply to food, feed or their ingredients containing approved genetically modified organisms and derived products where there is inadvertent presence of GM material in proportions of less than 5% of the total weight.

Scope of Labeling

**6.** The labeling requirements shall apply but not limited to:  
(a) products consisting of, or containing, GMOs, placed on the market in accordance with Biosafety Act, 2009;  
(b) food produced from GMOs, placed on the market in accordance with the Biosafety Act, 2009;  
(c) feed produced from GMOs, placed on the market in accordance with the Biosafety Act, 2009

Labeling and Packaging requirements

**7.**  
(1) For products consisting of or containing GMOs, operators shall ensure that:

(a) for pre-packaged products, the words ‘genetically modified (name of ingredient)’ or ‘genetically modified (name of food)’ appear on a label;  
(b) for non-pre-packaged products the words ‘genetically modified organisms’ or ‘genetically modified (name of organism(s))’ shall appear on, or in connection with, the display of the product.

(2) In addition to the inclusion of the words ‘genetically modified’ as spelt out in (1), there may be additional labeling and/or information requirements for GM foods that have ‘altered characteristics’ in relation to:

(a) one or more significant composition or nutritional parameters having values outside the normal range of values compared to conventional counterpart food/feed or ingredient not produced using modern biotechnology techniques;

(b) the level of anti-nutritional factors or natural toxicants are significantly different in comparison to the existing counterpart food/ feed or ingredient not produced using gene technology;

(c) the food produced using modern biotechnology contains a new factor known to cause an allergic response in particular sections of the population;

(d) the intended use of the food produced using modern biotechnology is different to the existing counterpart food not produced using gene technology; or

(e) the food derived from GM contains any other characteristics or properties which differ from the conventional counterpart not mentioned in a-d above

(f) the genetic modification raises significant ethical, cultural and religious concerns regarding the origin of the genetic material used in the genetic modification.

Exemptions

(3) Suggested methods for packaging and handling of genetically modified organisms and/or derived products imported through conveyor shipment which shall comply with the relevant international and national requirements for repackaging and handling of conveyor shipped commodities.

Claims

**8.** These regulations shall not apply to:

(a) highly refined food, where the effect of the refining process is to remove novel DNA and/or novel protein;

(b) a processing aid or food additive, except where novel DNA and/or novel protein from the processing aid or food additive remains present in the food to which it has been added above the threshold level;

(c) food intended for consumption prepared and sold from food premises and vendors

**9.** (1) GMOs shall not be described or labeled in a manner that is false, misleading or deceptive or is likely to create an erroneous impression

Traceability

regarding their character in any respect.

(2) Any claim on the label that a product is “GM free” should substantiate the claim is true and not misleading. Validated testing and documentation of the handling practices and procedures will be required to support such claims.

(3) Validated testing shall be carried out in appropriate accredited laboratories and analytical procedures used shall be consistent with national and internationally laid down procedures and protocols

**10.** (1) An operator shall at all stages of placing on the market of a product consisting of or containing GMOs, including bulk quantities, ensure that the following information is transmitted in writing to the subsequent operators:

(a) that it contains or consists of GMOs;

(b) the unique identifier(s) assigned to those GMOs in accordance with these regulations;

(2) At all subsequent stages of the placing on the market of products referred to in paragraph 1, operators shall ensure that the information received in accordance with paragraph 1 is transmitted in writing to all other operators receiving the products along the supply chain.

Monitoring  
Inspection and  
Compliance

(3) In the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed or for processing, the information referred to in paragraph 1(b) may be replaced by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.

(4) Each operator shall maintain a register describing the systems and procedures for each transaction for providing information for a period of five years.

(5) The Authority shall establish a mechanisms for or development and assignment of unique identifiers where such unique identifier will be useful in traceability of GMOs

**11.** (1) The Authority shall liaise with the relevant regulatory agency to monitor any genetically modified organisms for compliance with the requirements of these Regulations.

(2) Where the Authority is satisfied that a product consisting of or containing genetically modified organisms has not been labeled in accordance with article 7 of these regulations, the inspector shall by notice in writing serve the operator

(a) prohibiting the placing on the market of the product until it has been

correctly labeled;

(b) where the product has been placed on the market prior to the date of the notice, require the withdrawal of the product within such period as the inspector may reasonably believe to be necessary;

(c) prohibiting the removal of the product from the premises described in the notice other than to enable the product to be labeled correctly;

(d) require the product to be labeled in accordance with these regulations within such period as the inspector may reasonably deem to be necessary.

(3) The notice may contain such conditions as the inspector is satisfied are reasonable and maybe amended, suspended or revoked by further notice in writing at any time.

(4) A notice under this regulation shall be complied with at the expense of the operator on whom the notice is served.

(5) If a notice under this regulation, or an action required to be taken by the notice, is not complied with within the period specified in the notice, an inspector may arrange for it to be complied with and all reasonable costs of taking such action shall be recoverable by the Authority as a penalty due by the operator on whom the notice was served.

### **PART III- MISCELLANEOUS**

Genetically  
modified organisms  
labeling register

**12.** The Authority shall maintain a register, which shall contain all applications made to, and decisions made by, the Authority on labelling genetically modified organisms.

Offences and  
penalties

**13.** A person who contravenes the provisions of these Regulations commits an offence and is liable on conviction to a fine not exceeding twenty million shillings or to imprisonment for a term not exceeding ten years or both.

Made on ....., 2011.

**MARGARET KAMAR,**  
**Minister for Higher Education, Science and Technology.**

