Kenya: Biosafety Act, 2009 (No. 2 of 2009).
Long title: An Act of Parliament to regulate activities in genetically modified organisms, to establish the National Biosafety Authority, and for connected purposes.
Date of text: 2009.
Entry into force notes: This Act shall come into operation on such date as the Minister may, by Notice in the Gazette, appoint (1 July 2011 (L.N. No. 71 of 2011)).
Type of text: Legislation

Available web site: www.kenyalaw.org
Full text available (English): ken89675.doc

Implemented by:
☐ Biosafety (Contained Use) Regulations, 2011 (L.N. No. 96 of 2011). - 15 July 2011 [LEX-FAOC104833]

☐ Biosafety (Import, Export and Transit) Regulations, 2011 (L.N. No. 97 of 2011). - 15 July 2011 [LEX-FAOC104834]

☐ Biosafety (Environmental Release) Regulations, 2011 (L.N. No. 98 of 2011). - 15 July 2011 [LEX-FAOC104836]

☐ Biosafety (Labeling) Regulations, 2012 (L.N. No. 40 of 2012). - 25 May 2012 [LEX-FAOC115311]

FAOLEX No: LEX-FAOC089675

25th May, 2012

LEGAL NOTICE NO. 40

THE BIOSAFETY ACT, 2009
(No. 2 of 2009)

IN EXERCISE of the powers conferred by section 51 of the Biosafety Act, 2009, the Minister for Higher Education, Science and Technology, makes the following Regulations: —

THE BIOSAFETY (LABELING) REGULATIONS, 2012

ARRANGEMENT OF REGULATIONS

Regulations

THE BIOSAFETY (LABELING) REGULATIONS, 2012

Citation.
1. These Regulations may be cited as the Biosafety (Labeling) Regulations, 2012.

Interpretation.
2. In these Regulations unless the context otherwise requires—

"altered characteristic" of a genetically modified food means that when the genetically modified food is compared to its conventional counterpart, it is different in: 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;

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

"competent authority" means an agency of a country outside Kenya responsible under its national law for the control or regulation of genetically modified organisms;

"conventional counterpart" means a related organism or variety, its components or products for which there is experience of establishing safety based on common use as food, feed or for processing;

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

"genetic modification-free " means the complete absence of any genetically modified material, or use of a genetic modification process, in a food or food product and "non-genetically modified organism" shall be construed accordingly;

"genetically modified food or feed" means food or feed that is, or contains as an ingredient, including a processing aid, produced using modern biotechnology which—

(a) contains novel DNA 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;

"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 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 these Regulations;

Objective.
3. The objective of these Regulations is—

(a) to ensure that consumers are made aware that food, feed or a product is genetically modified so that they can make informed choices; and

(b) to facilitate the traceability of genetically modified organism products to assist in the implementation of appropriate risk management measures where necessary.

Application.
4. The labeling requirements shall include, but not be limited to—

(a) products consisting of, or containing, genetically modified organisms; or

(b) food or feed produced from genetically modified organisms, placed on the market in accordance with the Act.

Exemptions.
5. These Regulations shall not apply to—

(a) food, feed or their ingredients containing approved genetically modified organisms and derived products where there is inadvertent presence of genetically modified material in proportions of less than 1% of the total weight;

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

(c) a processing aid or food additive, except where novel DNA 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;

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

Food safety assessment before Labelling.
6. Labelling 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 Act.

Labelling and Packaging requirements.
7. (1) In labelling products consisting of or containing genetically modified organisms, operators shall ensure that—

(a) for pre-packaged products, the words 'genetically modified (name of ingredient)' or 'genetically modified (name of food)' appears on the label;

(b) for non-pre-packaged products the words 'genetically modified organisms' or 'genetically modified (name of organism)' shall appear on, or in connection with, the display of the product.

(2) In addition to the inclusion of the words 'genetically modified' as required under sub-regulation (1), there shall be additional labeling and information requirements for genetically modified 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 or feed or ingredient thereof not produced using modern biotechnology techniques;

(b) the level of anti-nutritional factors or natural toxicants that 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 that 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 if it is different from the existing counterpart food produced using gene technology; or

(e) the food derived from genetically modified organisms which contains any other characteristics or properties that differ from the conventional counterpart not mentioned in paragraph (a) to (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.

Claims.
8. (1) Genetically modified organisms shall not be described or labeled in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding their character in any respect.

(2) Any claim on a label that a product is genetic modification free shall have a clear printed statement indicating that the claim is true and not misleading, and shall be supported by validated testing and documentation of the handling practices and procedures.

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

Traceability.
9. An operator shall at all stages of placing on the market a product consisting of or containing genetically modified organisms, including bulk quantities, ensure that the following information is transmitted in writing to the subsequent operator—

(a) that it contains or consists of genetically modified organisms; and

(b) the unique identifier assigned to those genetically modified organisms in accordance with these Regulations.

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

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

(4) Each operator shall maintain a register describing the systems and procedures for each transaction to be kept for a minimum period of five years.

(5) The Authority shall establish a mechanism for development and assignment of unique identifiers where such identifiers are useful in traceability of genetically modified organisms.

Monitoring Inspection and Compliance.
10. (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 labelled in accordance with Regulation 7, the inspector shall serve the operator with a notice in writing—

(a) prohibiting the placing on the market of the product until it is correctly labelled;

(b) prohibiting the removal of the product from the premises described in the notice other than to facilitate the correct labelling of the product;

(c) requiring that the product be labelled in accordance with these Regulations within such period as the inspector may deem reasonable.

(3) A notice under sub-regulation (1) may contain such conditions as the inspector is satisfied are reasonable and may be amended, suspended or revoked by a further notice in writing by the inspector at any time.

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

(5) If a notice under this regulation, or an action required by the notice to be taken, 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 from the operator on whom the notice was served.

(6) Where the product has been placed on the market prior to the date of the notice, the inspector may require the withdrawal of the product within such period as he may reasonably believe to be necessary.

Genetically modified organisms labeling register.
11. The Authority shall maintain a register of all applications made to, and decisions made by, the Authority on labelling of genetically modified organisms.

Offences and penalties.
12. 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.