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AIDS HELPLINE: 0800-0123-22 Prevention is the cure

GOVERNMENT NOTICES

GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH DEPARTEMENT VAN GESONDHEID

No. R. 25

16 January 2004

REGULATIONS RELATING TO THE LABELLING OF FOODSTUFFS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION

The Minister of Health, has in terms of section 15(1) of the Foodstuffs, Cosmetics and Disinfectants Act , 1972 (Act No. 54 of 1972), made the regulations in the Schedule.

SCHEDULE

Definitions

1. In these regulations any expression to which a meaning has been assigned in the Act shall bear that meaning and, unless the context indicates otherwise -

“**allergen**” means a substance that causes an allergic reaction;

“**certain techniques of genetic modification**” means the application of -

- (a) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or
- (b) fusion of cells beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

“**corresponding existing foodstuff**” means the original form of the foodstuff as it occurs in agriculture or trade prior to genetic modification;

“**food additive**” means any substance not normally consumed as a foodstuff by itself and not normally used as a typical ingredient of the foodstuff, whether or not such substance has

nutritional value, the intentional addition of which to a foodstuff for technological (including organoleptic) purposes in the manufacture, processing, preparation, treatment, packing, packaging, transport or storage of such foodstuff results, or may be reasonably expected to result, directly or indirectly, in such substance or the byproducts thereof becoming an ingredient of or otherwise affecting the characteristics of such foodstuff, excluding any substance added to foodstuffs to maintain or improve nutritional qualities, or any contaminants;

“food ingredient” means any substance, including a food additive or a component of a compound ingredient, used in the manufacture or preparation of a foodstuff and present in the final product, whether or not in a modified form;

“foodstuff obtained through certain techniques of genetic modification” means a foodstuff -

- (a) composed of a genetically modified organism or organisms;
- (b) containing a genetically modified organism or organisms;
- (c) produced from and containing protein or DNA resulting from such genetic modification;
- (d) produced from, but not containing, a genetically modified organism or organisms or protein or DNA resulting from such genetic modification; and includes food additives and food ingredients, but excludes a foodstuff derived from an animal which is not itself a genetically modified organism but has been fed on feed in the production of which genetic modification is used;

“genetically modified organism” means an organism in which the genetic material has been changed through certain techniques of genetic manipulation in a way that does not occur naturally by multiplication or natural recombination;

“organism” means a biological entity, cellular or non-cellular, capable of replication or of transferring genetic material;

“significantly different” means, in respect of a foodstuff obtained through certain techniques of genetic modification, that characteristics scientifically assessed through an appropriate analysis of data are different from those of a corresponding existing foodstuff, taking into account accepted limits of natural variation in that foodstuff;

“taxonomic family” means a group of organisms classified together on the basis of common features, in a classification system; and

“the Act” means the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972).

Labelling of a foodstuff significantly different in respect of the composition, nutritional value, mode of storage, preparation or cooking, allergenicity or human or animal origin

2. A foodstuff obtained through certain techniques of genetic modification shall not be sold unless if such foodstuff is labelled as follows:

- (a) If the composition of a foodstuff differs significantly from the characteristic composition of the corresponding existing foodstuff, the label shall contain such additional words or phrases as may be necessary to inform the consumer of its true composition;

- (b) if the nutritional value of a foodstuff differs significantly from the characteristic nutritional value of the corresponding existing foodstuff, the label shall contain such additional words or phrases as may be necessary to inform the consumer of its changed nutrient content; and
- (c) if the mode of storage, preparation or cooking of such a foodstuff differs significantly from that of the corresponding existing foodstuff, clear instructions for use shall be given on the label of such foodstuff;
- (d) if a foodstuff contains an allergen from any of the products listed in the Annexure that causes allergy, the label shall contain such additional words or phrases as may be necessary to inform the consumer of this fact;
- (e) if a foodstuff is derived from -
 - (i) plant material containing animal nucleic acid(s) or protein(s) derived from a human or from an animal;
 - (ii) animal material containing animal nucleic acid(s) or protein(s) derived from a human or from a different taxonomic animal family, it shall be labelled with such wording as may be necessary to inform the consumer as to the origin of the nucleic acid(s) or protein(s).

Enhanced-characteristic claim

3. The label of a foodstuff obtained through certain techniques of genetic modification may bear a claim with regard to improved or enhanced characteristics such as composition, nutritional value and reduced causation of allergenicity: Provided that -

- (a) the claim has been validated and certified by a competent body which is accredited to the South African National Accreditation Services;
- (b) the name of the certifying body appears on the label of the product bearing such a claim in close proximity to the claim;

- (c) the claim indicates that such an improved or enhanced characteristic has been achieved by certain techniques of genetic modification; and
- (d) the wording is limited to "genetically-enhanced foodstuff" or "genetically-improved foodstuff".

General

4. The labelling of a foodstuff obtained through certain techniques of genetic modification is also subject to the Regulations Governing the Labelling and Advertising of Foodstuffs published under Government Notice No. R. 2034 of 29 October 1993, made in terms of the Act.

ANNEXURE

Crustaceans

Egg

Fish

Groundnuts

Milk

Molluscs

Soya beans

Tree nuts

Triticum cultivars



M E TSHABALALA-MSIMANG

MINISTER OF HEALTH