

DEFINITIONS OF GMOs AND RELATED TERMS IN THE LEGISLATION OF DIFFERENT COUNTRIES

ARGENTINA

Cartagena Protocol on Biosafety

Article 3. Use of Terms

"Modern biotechnology" 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;

Resolution 701/2011

Art.2, bullet 19.

"Event" means "The joint and stable insertion into the plant genome of ONE (1) or more genes or DNA sequences that are part of a defined genetic construct".

(Unofficial translation from Spanish)¹

¹ Original legal text: "Evento de transformación individual, también referido como "evento": la inserción en el genoma vegetal en forma estable y conjunta, de UNO (1) o más genes o secuencias de ADN que forman parte de una construcción genética definida."

http://www.minagri.gob.ar/site/agricultura/biotechnologia/55-OGM_COMERCIALES/index.php

AUSTRALIA

The Gene Technology Act 2000

Section 10. Definitions

genetically modified organism means any of the following

- (a) an organism that has been modified by gene technology; or
- (b) an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; or
- (c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms;

but does not include:

- (d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or
- (e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.

Gene Technology Regulations 2001

Schedule 1A

Techniques that are not gene technology

Item Description of technique

- | Item | Description of technique |
|------|---|
| 1 | Somatic cell nuclear transfer, if the transfer does not involve genetically modified material. |
| 2 | Electromagnetic radiation-induced mutagenesis. |
| 3 | Particle radiation-induced mutagenesis. |
| 4 | Chemical-induced mutagenesis. |
| 5 | Fusion of animal cells, or human cells, if the fused cells are unable to form a viable whole animal or human. |
| 6 | Protoplast fusion, including fusion of plant protoplasts. |
| 7 | Embryo rescue. |

- 8 *In vitro* fertilisation.
- 9 Zygote implantation.
- 10 A natural process, if the process does not involve genetically modified material.

Examples

Examples of natural processes include conjugation, transduction, transformation and transposon mutagenesis.

Gene Technology Regulations 2001

Schedule 1

Organisms that are not genetically modified organisms

Item Description of organism

- 1 A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species).
- 2 A whole animal, or a human being, modified by the introduction of naked recombinant nucleic acid (such as a DNA vaccine) into its somatic cells, if the introduced nucleic acid is incapable of giving rise to infectious agents.
- 3 Naked plasmid DNA that is incapable of giving rise to infectious agents when introduced into a host cell.
- 6 An organism that results from an exchange of DNA if:
 - (a) the donor species is also the host species; and
 - (b) the vector DNA does not contain any heterologous DNA.
- 7 An organism that results from an exchange of DNA between the donor species and the host species if:
 - (a) such exchange can occur by naturally occurring processes; and
 - (b) donor species and the host species are micro-organisms that:
 - (i) satisfy the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 1; and
 - (ii) are known to exchange nucleic acid by a natural physiological process; and
 - (c) the vector used in the exchange does not contain heterologous DNA from any organism other than an organism that is involved in the exchange.

CANADA

Seeds Regulations Part V

“novel trait”, in respect of seed, means a characteristic of the seed that

(a) has been intentionally selected, created or introduced into a distinct, stable population of cultivated seed of the same species through a specific genetic change, and

(b) based on valid scientific rationale, is not substantially equivalent, in terms of its specific use and safety both for the environment and for human health, to any characteristic of a distinct, stable population of cultivated seed of the same species in Canada, having regard to weediness potential, gene flow, plant pest potential, impact on non-target organisms and impact on biodiversity; (caractère nouveau).

EUROPEAN UNION

Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms ²

Article 2

Definitions

For the purposes of this Directive:

(1) "organism" means any biological entity capable of replication or of transferring genetic material;

(2) "genetically modified organism (GMO)" means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;

Within the terms of this definition:

(a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;

(b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification;

Article 3

Exemptions

1. This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.

² Directive 2001/18/EC2 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration - OJ L 106, 17.4.2001, p. 1–39

Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms

ANNEX I A

TECHNIQUES REFERRED TO IN ARTICLE 2(2)

PART 1

Techniques of genetic modification referred to in Article 2(2)(a) are inter alia:

- (1) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;
- (2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;
- (3) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART 2

Techniques referred to in Article 2(2)(b) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Annex I B:

- (1) in vitro fertilisation,
- (2) natural processes such as: conjugation, transduction, transformation,
- (3) polyploidy induction.

ANNEX I B

TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

- (1) mutagenesis,
- (2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

JAPAN

Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Act No 97 of 2003)

Article 2 (Definitions)

- (1) In this Act, "living modified organism" shall mean an organism that possesses nucleic acid, or replicated product thereof, obtained through use of any of the following technologies.
- (i) Those technologies as stipulated in the ordinance of the competent ministries, for the processing of nucleic acid extracellularly
 - (ii) Those technologies as stipulated in the ordinance of the competent ministries, for the fusing of the cells of organisms belonging to different taxonomic families.

SOUTH AFRICA

Genetically Modified Organisms Act [No. 15 of 1997]

Definitions

1. In this Act, unless the context otherwise indicates-

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- i. "genetically modified organism" means an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both, and "genetic modification" shall have a corresponding meaning; (xiii)

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Application of Act

2. (1) This Act shall apply to-

- a. the genetic modification of organisms;
- b. the development, production, release, use and application of genetically modified organisms (including viruses and bacteriophages); and
- c. the use of gene therapy.

2. This Act shall not apply to techniques-

- a. involving human gene therapy;
- b. in which recombinant DNA molecules or genetically modified organisms are not employed-
 - i. in in vitro fertilisation in humans and animals;
 - ii. in conjugation, transduction, transformation or any other natural process: and
 - iii. in polyploidy induction;
- c. in which genetically modified organisms as recipient or parental organisms are not employed-
 - i. in mutagenesis;
 - ii. in the construction and use of somatic hybridoma cells; and
 - iii. in cell fusion (including protoplast fusion) of plant cells.

United States of America

Plant Protection Act

§ 340.1_Definitions

Plant pest. Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.

Regulated article. Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.