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Federal Act on Non-Human Gene Technology (Gene Technology Act, GTA)

of 21 March 2003 (Status as of 1 January 2018)

The Federal Assembly of the Swiss Confederation,

based on Articles 74 paragraph 1, 104 paragraphs 2 and 3 letter b, 118 paragraph 2 letter a and 120 paragraph 2 of the Federal Constitution^{1,2}
in implementation of the Convention of 5 June 1992³ on Biological Diversity and the Cartagena Protocol of 29 January 2000⁴ on Biosafety to the Convention on Biodiversity,
and having considered the Dispatch of the Federal Council dated 1 March 2000⁵
and the Report of the Council of States' Committee for Science, Education and Culture dated 30 April 2001^{6,7}

decrees:

Chapter 1 General Provisions

Art. 1 Purpose

¹ The purpose of this Act is:

- a. to protect human beings, animals and the environment from abuses of gene technology;
- b. to serve the welfare of human beings, animals and the environment in the application of gene technology.

² In particular, it shall:

- a. protect the health and safety of human beings, animals and the environment;

AS 2003 4803

¹ SR 101

² Amended by No I of the FA of 16 June 2017, in force since 1 Jan. 2018 (AS 2017 6667; BBI 2016 6521).

³ SR 0.451.43

⁴ SR 0.451.431

⁵ BBI 2000 2391

⁶ Official Bulletin of the Federal Assembly (AB), enclosures, Council of States Summer Session 2001, p. 22.

⁷ Amended by No I of the FA of 19 March 2010, in force since 1 Aug. 2010 (AS 2010 3233; BBI 2009 5435).

- b. conserve biological diversity and the fertility of the soil permanently;
- c. ensure respect for the dignity of living beings;
- d. enable freedom of choice for consumers;
- e. prevent product fraud;
- f. promote public information;
- g. take account of the significance of scientific research on gene technology for human beings, animals and the environment.

Art. 2 Precautionary and polluter-pays principles

¹ Early precautions shall be taken to prevent hazards or harm that may be caused by genetically modified organisms.

² Any person who causes measures to be taken under the provisions of this Act shall bear the costs.

Art. 3 Area of validity

¹ This Act applies to the handling of genetically modified animals, plants and other organisms, as well as their metabolic products and wastes.

² For products obtained from genetically modified organisms, only the regulations on labelling and provision of public information (Art. 17 and 18) apply.

Art. 4 Reservation of other laws

More detailed provisions in other federal laws concerning the protection of human beings, animals and the environment from hazards or harm caused by genetically modified organisms are reserved.

Art. 5 Definitions

¹ *Organisms* means cellular or non-cellular biological entities capable of replication or of transferring genetic material. Mixtures, articles and products that contain such entities are also regarded as organisms.

² *Genetically modified organism* means organisms in which the genetic material has been altered in a way that does not occur under natural conditions by crossing or natural recombination.

³ *Harm* means any harmful effect or nuisance caused by genetically modified organisms to human beings, animals or the environment.

⁴ *Handling* means any activity undertaken in connection with organisms, in particular their production, experimental release, putting into circulation, import, export, keeping, use, storage, transport or disposal.

⁵ *Putting into circulation* means any supply of organisms to third parties in Switzerland, in particular by sale, exchange, giving as a gift, renting, lending or sending on

approval, as well as their import; supply for activities in contained systems or experimental release does not count as putting into circulation.

⁶ *Installations* means buildings, traffic routes and other fixed installations, as well as modifications to the land. Appliances, machines, vehicles, ships and aircraft are also regarded as installations.

Chapter 2 Handling Genetically Modified Organisms

Section 1 General Principles

Art. 6 Protection of human beings, animals, environment and biological diversity

¹ Genetically modified organisms may only be handled in such a way that they, their metabolic products or wastes:

- a. cannot endanger human beings, animals or the environment;
- b. do not harm biological diversity or the sustainable use thereof.

² Genetically modified organisms may be released for experimental purposes if:

- a. the information sought cannot be obtained through experiments in contained systems;
- b. the experiment also contributes to research on the biosafety of genetically modified organisms;
- c. they do not contain genes inserted by gene technology which cause resistance to antibiotics used in human or veterinary medicine; and
- d. according to the current state of knowledge, the dispersal of these organisms and their new traits can be excluded and the principles of paragraph 1 cannot otherwise be contravened.

³ Genetically modified organisms lawfully intended for use in the environment may only be put into circulation if they do not contain gene technologically inserted resistance genes to antibiotics used in human or veterinary medicine, and if experiments in contained systems and field trials have shown that they:

- a. do not harm the population of protected organisms or organisms that are important for the ecosystem in question;
- b. do not lead to the unintended extinction of a species of organism;
- c. do not severely or permanently harm the material balance of the environment;
- d. do not severely or permanently harm any important functions of the ecosystem in question, and in particular the fertility of the soil;
- e. do not disperse or spread their traits in an undesired way; and
- f. do not otherwise contravene the principles of paragraph 1.

⁴ Hazards and harm must be evaluated both individually and as a whole and in terms of their interaction; connections to other hazards and harm from causes other than genetically modified organisms should also be considered.

Art. 7 Protection of production without genetically modified organisms and freedom of choice

Genetically modified organisms may be handled only in such a way that they, their metabolic products or wastes do not impair production that does not involve genetically modified organisms, or limit consumers' freedom of choice.

Art. 8 Respect for the dignity of living beings

¹ In animals and plants, modification of the genetic material by gene technology must not violate the dignity of living beings. In particular, violation is deemed to have occurred if such modification substantially harms species-specific properties, functions or habits, unless this is justified by overriding legitimate interests. In evaluating the harm, the difference between animals and plants must be taken into consideration.

² Whether the dignity of living beings has been respected is determined on a case-by-case basis, by evaluating the severity of the harm suffered by animals or plants against the significance of the legitimate interests. Legitimate interests are, in particular:

- a. human and animal health;
- b. guaranteeing food security;
- c. the reduction of harm caused to the environment;
- d. the preservation and improvement of environmental conditions;
- e. securing a substantial economic, social or environmental benefit for society;
- f. increasing knowledge.

³ The Federal Council determines the conditions under which genetic modifications to the genetic material are exceptionally permissible without a weighing of interests.

Art. 9 Genetic modification of vertebrates

Genetically modified vertebrates may only be produced and put into circulation for purposes of research, therapy, or diagnostics in human or veterinary medicine.

Art. 10 Activities in contained systems

¹ Any person who handles genetically modified organisms which may not be released for experimental purposes (Art. 11) nor put into circulation (Art. 12) is required to take all containment measures necessary in particular due to the hazards for human beings, animals or the environment that these organisms represent.

² The Federal Council shall introduce a notification or authorisation procedure for activities in contained systems.

Art. 11 Experimental releases

¹ Any person who intends to release for experimental purposes genetically modified organisms which may not be put into circulation for use in the environment (Art. 12) requires federal authorisation.

² The Federal Council determines the requirements and the procedure. In particular, it regulates:

- a. the consultation of experts;
- b. the guarantee of funding for measures with which any hazards or harm can be identified, averted or eliminated;
- c. the provision of information for the public.

Art. 12 Putting into circulation

¹ Genetically modified organisms may be put into circulation only if the Confederation has granted authorisation.

² The Federal Council determines the requirements and the procedure, and regulates the provision of information to the public.

Art. 12a⁸ Opposition procedure

¹ Applications for authorisations for experimental releases of genetically modified organisms and for putting into circulation genetically modified organisms for lawful use in the environment are published by the authorising authority in the Official Federal Gazette and made available for public inspection for 30 days.

² Any person who is a party in accordance with the Federal Act of 20 December 1968⁹ on Administrative Procedure may file opposition with the authorising authority during the inspection period. A party who fails to file opposition is excluded from subsequent proceedings.

Art. 13 Inspection of authorisations

¹ Authorisations are regularly inspected to determine whether they may continue to apply.

² Authorised persons must voluntarily inform the authorising authority of new findings that could lead to a re-evaluation of hazards or harm as soon as they become aware of these findings.

⁸ Inserted by No I of the FA of 19 March 2010, in force since 1 Aug. 2010 (AS 2010 3233; BBl 2009 5435).

⁹ SR 172.021