

Federal Law relating to Non-human Gene Technology (Gene Technology Law, GTL)

of 21 March 2003

The Federal Assembly of the Swiss Confederation,

in pursuance of Articles 74, 118 and 120 of the Federal Constitution¹,
in implementation of international agreements²,
having considered the Opinion of the Federal Council of 1 March 2000³
and the Report of the Council of States' Committee for Science, Education and
Culture of 30 April 2001⁴,

ordains:

Chapter 1: General provisions

Art. 1 Purpose

¹ The purpose of this law is:

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

² In particular, it shall:

- a. protect the health and safety of humans, animals and the environment;
- 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 into account the significance of scientific research on gene technology for humans, animals and the environment.

¹ SR 101

² SR 0.451.43, BBl 2001 4099

³ BBl 2000 2391

⁴ Official Bulletin of the Federal Assembly (AB), enclosures, Council of States Summer Session 2001, p. 22.

Art. 2 Precautionary and polluter-pays principles

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

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

Art. 3 Area of validity

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

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

Art. 4 Reservation of other laws

Further provisions in other federal laws concerning the protection of humans, animals and the environment from hazards or impairment caused by genetically modified organisms are reserved.

Art. 5 Terminology

¹ *Organisms* shall mean any cellular or noncellular biological entity able to replicate or transfer genetic material, in particular animals, plants and microorganisms; these include mixtures and objects that contain such entities;

² *Genetically modified organism* shall mean any organism in which the genetic material has been altered in a way that does not occur under natural conditions by crossing or natural recombination;

³ *Impairment* shall mean any harmful effect or nuisance caused by genetically modified organisms to humans, animals or the environment.

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

⁵ *Marketing* shall mean any transfer 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; transfer in association with contained use or release for experimental purposes does not count as marketing.

⁶ *Installations* shall mean buildings, highways and other fixed installation, as well as modifications of the land. Appliances, machines, vehicles, ships and aircraft shall also be regarded as installations.

Chapter 2: Handling genetically modified organisms

Section 1: General principles

Art. 6 Protection of humans, animals, environment and biological diversity

¹ Genetically modified organisms shall be handled in such a way that they, their metabolites or wastes:

- a. cannot endanger humans, animals or the environment;
- b. do not impair biological diversity or the sustainable use thereof.

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

- a. the desired findings cannot be obtained by means of experiments in contained systems;
- b. the experiment also contributes to research on the biosafety of genetically modified organisms;
- c. they do not contain gene technologically inserted resistance genes 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 intended for use in the environment may only be marketed if they do not contain gene technologically inserted resistance genes to antibiotics used in human or veterinary medicine, and if experiments in contained systems or field trials have shown that they:

- a. do not impair 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 cause severe or permanent impairment of the material balance of the environment;
- d. do not cause severe or permanent impairment of any important functions of the ecosystem in question, in particular the fertility of the soil;
- e. do not disperse, or their traits do not spread in an undesired way; and
- f. do not otherwise contravene the principles of paragraph 1.

⁴ Hazards and impairment must be evaluated both singly and as a whole and in terms of their interaction; connections to other hazards and impairment 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 metabolites or wastes do not impair production that does not involve genetically modified organisms, or consumers' freedom of choice.

Art. 8 Respect for the dignity of living beings

¹ In animals and plants, genetic modification of the genetic material may not lead to lack of respect for the dignity of living beings. Respect is lacking in particular if species-specific traits, functions or habits are substantially impaired and if this is not justified by preponderant legitimate interests. In evaluating the impairment, the difference between animals and plants should be taken into consideration.

² Whether lack of respect has been shown to the dignity of living beings shall be judged on a case-by-case basis, weighing up the severity of the impairment of animals and plants against the significance of the legitimate interests. Legitimate interests are, in particular:

- a. human and animal health;
- b. the securing of sufficient food;
- c. the reduction of ecological impairment;
- d. the conservation and improvement of ecological living conditions;
- e. a substantial benefit to society at the economic, social or ecological level;
- f. the increase of knowledge.

³ The Federal Council shall determine the conditions under which genetic modifications of the genetic material shall exceptionally be permissible without an evaluation of interests.

Art. 9 Genetic modification of vertebrates

Genetically modified vertebrates may only be produced and marketed for purposes of research, therapy and diagnostics on/for humans and animals.

Art. 10 Contained use

¹ Any person who handles genetically modified or pathogenic organisms which may not be released for experimental purposes (Art. 11) or marketed (Art. 12) shall be required to take all containment measures necessary due to the hazards for humans, 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 Release for experimental purposes

¹ Any person who intends to release for experimental purposes genetically modified organisms which may not be marketed for use in the environment (Art. 12), shall require a Federal licence.

² The Federal Council shall determine the requirements and the procedure. In particular, it shall regulate:

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

Art. 12 Marketing

¹ Genetically modified organisms may be marketed only if the Confederation has issued a licence.

² The Federal Council shall determine the requirements and the procedure, and regulates the provision of information for the public.

Art. 13 Inspection of licences

¹ Licences shall be regularly inspected to determine whether they can be maintained.

² Licence holders must voluntarily inform the licensing authorities of new findings that could lead to a re-evaluation of hazards or impairment, as soon as they become aware of these findings.

Art. 14 Exceptions to the notification or authorisation requirement;
self-supervision

¹ The Federal Council may simplify the requirement to notify or obtain a licence or may grant exemptions if, according to the current state of knowledge or experience, a contravention of the principles of Articles 6–9 can be excluded.

² As long as there is no authorisation requirement for a contained use or for the marketing of certain genetically modified organisms, the person or company responsible shall monitor adherence to the principles of Articles 6–9 him/herself. The Federal Council shall enact regulations covering the form, extent and monitoring of the self-supervision.

Section 2: Special provisions

Art. 15 Informing of the recipient

¹ Any person placing genetically modified organisms on the market must:

- a. inform the recipient of the properties that are significant for the implementation of Articles 6–9;
- b. instruct the recipient in such a way that the appropriate handling of the organisms will not endanger the principles of Articles 6–9.

² Instructions from producers and importers must be followed.

³ The passing to agricultural or forestry enterprises of genetically modified organisms that are subject to a labelling requirement shall require the written permission of the enterprise owner.

Art. 16 Product flow segregation

¹ Any person handling genetically modified organisms must take appropriate care to avoid undesired mixing with non-genetically modified organisms.

² The Federal Council shall enact regulations on product flow segregation and on measures to prevent contamination, taking into consideration international recommendations and external commercial relations.

Art. 17 Labelling

¹ Any person marketing genetically modified organisms must label them as such for the benefit of the recipient, in order to ensure freedom of choice for the consumer under Article 7 and to prevent product fraud. The labelling must contain the words "genetically modified". The Federal Council shall determine the details.

² The Federal Council shall lay down threshold values below which labelling is unnecessary for mixtures, articles and products that unintentionally contain traces of genetically modified organisms.

³ Traces of genetically modified organisms shall be considered to be unintentional if the person responsible for providing labelling proves that the product flows have been carefully monitored and recorded.

⁴ The Federal Council shall regulate the labelling of products, in particular of foodstuffs and additives obtained from genetically modified organisms.

⁵ It shall regulate how organisms that are not genetically modified can be labelled as such when they are marketed. It shall also enact regulations concerning protection from any misuse of such labelling.

⁶ In enacting the provisions of this Article the Federal Council shall take into consideration international recommendations and external commercial relations.

Art. 18 Access to files and public information

¹ On application to the responsible authority, every person has the right of access to information which has been gathered in the enforcement of this law, or other federal law, or international agreements on the handling of genetically modified organisms or products obtained from them. This right does not pertain if it is precluded by overwhelming private or public interests.

² After consulting the affected party the authorities may publish information gathered during enforcement (Art. 24 para. 1) and results from surveys or monitoring, insofar as these are of general interest. They may pass on this information in accordance with a federal law or international agreement to a foreign authority or international organisation. Manufacturing and trade secrecy are reserved.

Art. 19 Further Federal Council regulations

¹ The Federal Council shall enact further regulations governing the handling of genetically modified organisms, their metabolites and wastes if, due to their properties, methods of use or quantities used, the principles of Articles 6–9 could be contravened.

² In particular, it may:

- a. regulate their transport, import, export and transit;
- b. ban or restrict the handling of certain organisms or establish an authorisation procedure for handling them;
- c. prescribe measures to combat certain organisms or to prevent their occurrence;
- d. prescribe measures to prevent the impairment of biological diversity and the sustainable use thereof;
- e. prescribe long-range studies of the handling of certain organisms;
- f. hold public consultations in connection with licensing procedures.

Chapter 3: Enforcement

Art. 20 Enforcement competencies

¹ The Confederation shall enforce this law. The Federal Council shall enact implementing regulations.

² The Federal Council may pass on certain tasks of enforcement, especially those concerning the handling of articles and products, to the cantons, as long as these tasks have not already been allocated to the cantons under other federal laws.

³ The Federal Council may also pass on certain enforcement tasks to organisations and persons under public or private law.

⁴ The costs of measures that the authorities take to avert immediate hazard or impairment, as well as costs incurred in the determination and remediation thereof, shall be passed on to the perpetrator.

Art. 21 Coordination of enforcement

¹ The federal authority carrying out the enforcement of regulations on genetically modified organisms on the basis of another federal law or a state treaty, is also responsible in doing so for enforcing this law. The federal authorities shall make its decisions with the agreement of the other affected federal agencies and, where federal law provides, after consulting the affected cantons.

² Insofar as the handling of genetically modified organisms is also subject, in addition to the notification and licensing procedure of federal authorities, to the planning and licensing procedures of cantonal authorities, the Federal Council shall designate a competent authority to coordinate the procedure.

Art. 22 Swiss Expert Committee for Biosafety

¹ The Federal Council shall appoint a Federal Expert Committee for Biosafety, comprising experts from the various interested sectors. The interests of protection and use must be appropriately represented.

² The Expert Committee advises the Federal Council on issues of biosafety that arise in enacting regulations, and the authorities on their enforcement. It is consulted on licence applications. It may publish recommendations on these applications; in important and justified cases it can commission expert opinions and inquiries.

³ It collaborates with other federal and cantonal committees concerned with issues of biotechnology.

⁴ It engages in public dialogue, and makes periodic reports to the Federal Council about its activities.

Art. 23 Swiss Ethics Committee on Non-human Gene Technology

¹ The Federal Council shall appoint a federal Ethics Committee on Non-human Gene Technology. It is composed of ethicists from outside the government and other persons from a range of subject areas who have scientific or practical knowledge of ethics. Different ethical approaches must be represented in the Committee.

² The Committee pursues and evaluates from an ethical point of view the developments and applications of biotechnology and issues Statements on associated scientific and social issues from an ethical point of view.

³ It advises:

- a. the Federal Council in enacting regulations;
- b. federal and cantonal authorities on enforcement. In particular, it issues Statements on licence applications or planned research of fundamental or exemplary significance; for this purpose it may view documents, request information and consult further experts.

⁴ It collaborates with other federal and cantonal committees concerned with issues of biotechnology.

⁵ It engages in public dialogue about ethical issues of biotechnology, and makes periodic reports to the Federal Council about its activities.

Art. 24 Duty to provide information; confidentiality

¹ Every person shall be obliged to provide the information required for enforcement to the authorities and if necessary to carry out or permit inquiries.

² The Federal Council may require registers with details of the type, quantity and evaluation of genetically modified organisms to be kept, stored and made available at the request of the authorities.

³ The Confederation shall carry out surveys of the handling of genetically modified organisms. The Federal Council shall determine which details about genetically modified organisms, recorded in pursuance of other federal laws, should be provided to the federal authority carrying out the survey.

⁴ Where there is a legitimate interest in keeping details secret, such as information about trade and manufacturing secrets, they shall be treated confidentially.

Art. 25 Fees

The Federal Council shall set the fees for enforcement by the federal authorities and may determine the framework for cantonal fees. It may grant exemptions from fee payment.

Art. 26 Promotion of research, public dialogue and education

¹ The Confederation may commission or support research and technology assessments.

² It shall promote the knowledge of the population and public dialogue concerning the uses as well as the opportunities and risks of biotechnology.

³ It may promote the basic or advanced training of persons entrusted with tasks under this law.

Chapter 4: Judicial practice

Art. 27 Appeal procedure

¹ The appeal procedure is governed by the Federal Law of 20 December 1968⁵ relating to Administrative Procedure and the Federal Law relating to the Organisation of Federal Judicial Practice of 16 December 1943⁶.

² An appeal may be lodged against a decision by a federal office in application of this law to the responsible appeals body. The same applies to decisions of the highest cantonal authorities or third parties carrying out enforcement tasks.

³ The responsible appeals body shall consult the federal offices in question before making its decision.

Art. 28 Appeal by organisations

¹ National environmental protection organizations shall also have the right of appeal against authorisations of the marketing of genetically modified organisms intended for use in the environment, provided that the organizations were set up at least 10 years before lodging the appeal.

² The Federal Council shall designate the organisations with right of appeal.

⁵ SR 172.021

⁶ SR 173.110

Art. 29 Appeal by the authorities

¹ The Swiss Agency for the Environment, Forests and Landscape shall have the right to avail itself of cantonal and federal law in contesting decisions by cantonal authorities in application of this law and its implementing regulations.

² The same right of appeal is also accorded to the cantons, insofar as impairment of their territory from neighbouring cantons is disputed.

Chapter 5: Liability

Art. 30 Principles

¹ Any person subject to the notification or authorisation requirement, who handles genetically modified organisms in contained systems, releases such organisms for experimental purposes or markets them without permission is liable for damage that occurs during this handling that is a result of the genetic modification.

² The person subject to authorisation is solely liable for damage that occurs to agricultural or forestry enterprises or to consumers of products of these enterprises through the permitted marketing of genetically modified organisms, that is a result of the modification of the genetic material, if the organisms:

- a. are contained in agricultural or forestry additives; or
- b. stem from such additives.

³ In the liability under paragraph 2 recourse to persons who have handled such organisms inappropriately or have otherwise contributed to the occurrence or exacerbation of the damage is reserved.

⁴ If damage is caused by any other permitted marketing of genetically modified organisms as a result of the modification of the genetic material, the person subject to authorisation is liable if the organisms are faulty. He or she is also liable for a fault which, according to the state of knowledge and technology at the time when the organism was marketed, could not have been recognised.

⁵ Genetically modified organisms are faulty if they do not provide the safety that is to be expected, taking into consideration all situations; in particular the following should be considered:

- a. the way in which they are presented to the public;
- b. the use that can reasonably be expected;
- c. the time at which they were marketed.

⁶ A product made from genetically modified organisms is not considered faulty for the sole reason that an improved product has later been marketed.

⁷ The damage must have been caused as a result of:

- a. the new properties of the organisms;
- b. the reproduction or modification of the organisms; or
- c. the transmission of the modified genetic material of the organisms.

⁸ A person is exempt from liability if he or she can prove that the damage was caused by an Act of God or through gross misconduct of the injured party or of a third party. .

⁹ Articles 42–47 and 49–53 of the Swiss Code of Obligations⁷ shall apply.

¹⁰ The Confederation, cantons and communes shall also be liable in accordance with paragraphs 1–9.

Art. 31 Damage to the environment

¹ The person who is liable for handling genetically modified organisms must also reimburse the costs of necessary and appropriate measures that are taken to repair destroyed or damaged components of the environment, or to replace them with components of equal value.

² If the destroyed or damage environmental components are not the object of a right in rem or if the eligible person does not take the measures that the situation calls for, the damages shall be awarded to the community responsible.

Art. 32 Statute of limitations

¹ The right to claim damages expires after three years from the time when the injured party becomes aware of the damage and of the person liable, but at the latest after 30 years from:

- a. the time that the event that caused the damage occurred in the company or installation, or ended; or
- b. the date on which the genetically modified organisms were marketed.

² The right to recourse is also limited under paragraph 1. The three-year term begins as soon as damages have been paid in full and the person who shares liability is known.

Art. 33 Simplification of proof

¹ It is the responsibility of the person claiming damages to prove cause.

² If this proof cannot be provided with certainty or if production of proof cannot be expected of the claimant, the court may be satisfied with overwhelming probability. The court may also have the facts determined *proprio motu*.

Art. 34 Guarantee

The Federal Council may, to protect the injured party:

- a. require the person subject to notification or authorisation to provide a guarantee for their liability by taking out insurance or in some other way;
- b. set the scope and duration of this guarantee or leave this to the authority to decide on a case-by-case basis;

⁷ SR 220

- c. require those providing a guarantee for the liability to notify the enforcement authority of the existence, suspension or cessation of the guarantee;
- d. prescribe that the guarantee shall not be suspended or cease until 60 days after receipt of the notification.

Chapter 6: Penalties

Art. 35

¹ Imprisonment or a fine are the penalties for any person who deliberately

- a. handles genetically modified organisms in such a way that the principles of Articles 6–9 are contravened;
- b. in handling genetically modified or pathogenic organisms fails to take all necessary containment measures (Art. 10);
- c. releases genetically modified organisms for experimental purposes, or markets them, without permission (Art. 11 para. 1 and 12 para. 1);
- d. puts genetically modified organisms on the market without informing and instructing the customer appropriately (Art. 15 para. 1);
- e. handles genetically modified organisms contrary to instructions (Art. 15 para. 2);
- f. contravenes provisions on product flow segregation and on the precautions to prevent contamination (Art. 16);
- g. puts genetically modified organisms on the market without labelling them as such for the customer (Art. 17 para. 1);
- h. contravenes the provisions on the labelling of products obtained from genetically modified organisms (Art. 17 para. 4);
- i. puts genetically modified organisms on the market and labels them as “not genetically modified” (Art. 17 para. 5);
- j. contravenes special provisions on the handling of genetically modified organisms (Art. 19).

² If humans, animals or the environment are endangered, the penalty shall be imprisonment.

³ If the offender is negligent, the penalty is up to six months’ imprisonment or a fine.

Chapter 7: Final provisions

Art. 36 Amendments to existing statutes

The amendment of existing law is regulated in the Appendix.

Art. 37 Transitional period for the use of antibiotic resistance genes
Resistance genes to antibiotics used in human and veterinary medicine may be used in field trials until 31 December 2008.

Art. 38 Referendum and entry into force

¹ This law is subject to optional referendum.

² The Federal Council shall determine when this law enters into force.

Council of States, 21 March 2003

National Council, 21 March 2003

President: Gian-Reto Plattner

President: Yves Christen

Secretary: Christoph Lanz

Secretary: Christophe Thomann

Date of publication: 1 April 2003⁸

Deadline for referendum: 10 July 2003

⁸ BBl 2003 2778

Amendments to existing statutes

The statutes below shall be amended as follows:

1. Swiss Federal Penal Code⁹

*Art. 230^{bis}*¹⁰

Endangerment
through
genetically
modified or
pathogenic
organisms

¹ Any person who deliberately releases genetically modified or pathogenic organisms or disturbs the operation of an installation for their research, storage or production or disturbs their transport, shall be penalised by imprisonment if he or she knows or should know that these actions:

- a. endanger human life and limb; or
- b. severely endanger the natural composition of the communities of animals and plants or their habitats.

² If the offender is negligent, the penalty shall be imprisonment.

2. Federal Law of 1 July 1966¹¹ on the Protection of Nature and the National Heritage

Ingress

in accordance with Article 24^{sexies} of the Federal Constitution¹²,

...

⁹ SR 311

¹⁰ When the amendment of 13 December 2002 of the Federal Penal Code comes into force (BBl 2002 8240), Article 230^{bis} will be in the following form:

Art. 230^{bis}

Endangerment
through
genetically
modified or
pathogenic
organisms

¹ Any person who deliberately releases genetically modified or pathogenic organisms or disturbs the operation of an installation for their research, storage or production or disturbs their transport, shall be penalised by imprisonment of between one and up to ten years, if he or she knows or should know that these actions:

- a. endanger human life and limb; or
- b. severely endanger the natural composition of the communities of animals and plants or their habitats.

² If the offender is negligent, the penalty shall be imprisonment of up to three years or a fine.

¹¹ SR 451

¹² This provision corresponds to Article 78 of the Federal Constitution of 18 April 1999 (SR 101).

Art. 1 letter d

¹ The purpose of this law, subject to the authority of the Confederation pursuant to Article 24^{sexies} paragraphs 2–5 of the Federal Constitution¹³, is:

- d. to protect indigenous animal and plant communities as well as their biological diversity and their natural habitat;

Art. 2 para. 1 introductory sentence

¹ Fulfilment of federal responsibilities pursuant to Article 24^{sexies} paragraph 2 of the Federal Constitution¹⁴ shall principally be taken to mean: ...

Art. 20 para. 1 second sentence

¹ ... Likewise it can take appropriate measures to protect specific animal species at risk, or otherwise deemed worthy of protection.

Art. 25c **Judicial Practice**

¹ The appeals procedure shall be according to the Federal Law of 20 December 1968¹⁵ on Administrative Procedure and according to the Federal Law on the Organisation of Judicial Practice of 16 December 1943¹⁶.

² Appeal may be made to the Appeals Commission DETEC against decisions by SAEFL in application of this law and against third parties carrying out enforcement on behalf of SAEFL.

³ The highest legal authority shall consult the federal office in question before making its decision.

3. Federal Law on Animal Protection of 9 March 1978¹⁷

Ingress

in accordance with Articles 64, 80, 120 and 123 of the Federal Constitution¹⁸, in implementation of several European agreements¹⁹, having considered the Opinion of the Federal Council of 9 February 1977²⁰,
ordains:

¹³ This provision corresponds to Article 78 paragraphs 2–5 of the Federal Constitution of 18 April 1999 (SR **101**).

¹⁴ This provision corresponds to Article 78 paragraph 2 of the Federal Constitution of 18 April 1999 (SR **101**).

¹⁵ SR **172.021**

¹⁶ SR **173.110**

¹⁷ SR **455**

¹⁸ SR **101**

¹⁹ SR **0.452, 0.454, 0.456, 0.457, 0.458**

²⁰ BBl **1977 I 1075**

All section headings are given in figures (e.g. Section One becomes Section I).

Art. 2 para. 3

³ No one may cause unjustified pain, suffering, fear or injury to an animal, or fail to respect its dignity in another way.

Section 2a: Breeding and genetic modification of animals

Art. 7a Breeding and production of animals

¹ The application of natural or gene technological or other artificial methods of breeding and reproduction may not cause, in the parent animals or their offspring, any pain, suffering, injury or behavioural disorders as a consequence of the breeding aims or linked to them; the provisions on animal experiments are reserved.

² The Federal Council shall issue regulations on the breeding and production of animals and shall determine the criteria for evaluation the permissibility of breeding aims and reproductive methods; taking into consideration the dignity of living beings. It can prohibit the breeding, production or keeping of animals with particular properties.

Art. 7b Authorisation requirement for genetically modified animals

¹ The production, breeding, keeping, trading or use of genetically modified animals shall require cantonal authorisation. The authorisation procedure shall be in accordance with the provisions on animal experiments and the Gene Technology Law of 21 March 2003²¹.

² The Federal Council may, after consulting the interested parties, the Swiss Ethics Committee on Non-human Gene Technology, the Swiss Expert Committee on Biosafety and the Federal Committee on Animal Experiments (Art. 19), lay down criteria for the weighing up of interests in production, breeding, keeping, trading and use of genetically modified animals.

³ It may make exceptions to the authorisation requirement or simplify the authorisation procedure, in particular if it is clear that the animals show no pain, suffering, injury or behavioural disorders caused by their production or breeding, and that the dignity of living beings is taken into consideration in other ways.

Art. 7c Prohibition of abnormal animals

The Federal Council may prohibit the production, breeding, keeping, trading or use of animals with abnormalities of anatomy or behaviour.

²¹ SR ...; AS ... (BBI 2003 2778)

Art. 12 para. 2

² Activities according to Article 7b paragraph 1 shall be equivalent to animal experiments in terms of procedure.

Art. 19 Federal Committee for Animal Experiments

¹ The Federal Council shall establish an expert committee, the Federal Committee for Animal Experiments, to advise the Federal Veterinary Office of experts. It shall also be available to advise the cantons on matters of principle and in disputed cases.

² The Federal Committee for Animal Experiments shall collaborate with the Swiss Ethics Committee on Non-human Gene Technology.

Art. 19a Heading and para. 4

Documentation centre, statistics and information

⁴ The Federal veterinary Office shall provide public information about animal experiments, especially those involving genetic modifications of animals.

Art. 22 para. 3

³ The Federal Council may prohibit further activities on animals, particularly if they fail to respect the dignity of living beings.

Art. 29 number 1 letters ^{abis}, ^{ater} and ^{aquater}

1. Any person who deliberately

^{abis}. breeds or produces animals in contravention of the regulations (Art. 7a);

^{ater}. produces, breeds, keeps, trades or uses genetically modified animals in contravention of the regulations (Art. 7b);

^{aquater}. produces, breeds, keeps, trades or uses animals with abnormalities of anatomy or behaviour in contravention of the regulations (Art. 7c);

4. Federal Law relating to the Protection of the Environment of 7 October 1983²²

Ingress

in accordance with Articles 24^{septies} and 24^{novies} para. 1 and 3 of the Federal Constitution²³,

...

²² SR 814.01

²³ These provisions correspond to Articles 74 and 120 of the Federal Constitution of 18 April 1999 (SR 101).

Art. 1 para. 1

¹ The purpose of this law is to protect humans, animals and plants, their biological communities and habitats against harmful effects or nuisances and to conserve natural resources permanently, in particular biological diversity and the fertility of the soil.

Art. 4 para. 2

² Regulations relating to the handling of substances and organisms affecting the environment, which are based on other Federal laws, shall be in conformity with the principles governing substances (Art. 26–28) and organisms (Art. 29a–29h).

Art. 7 para. 1, 5^{bis}, 5^{ter}, 5^{quater} and 6^{ter}

¹ Effects means air pollution, noise, vibration, radiation, water pollution or other interference in waters, soil pollution, modification of the genetic material of organisms or of biological diversity, caused by the construction or operation of installations, by the handling of substances, organisms or wastes or by the cultivation of the soil.

^{5^{bis}} *Applies only to the French text.*

^{5^{ter}} *Applies only to the French text.*

^{5^{quater}} Pathogenic organisms means organisms capable of causing diseases.

^{6^{ter}} Handling means any activity in connection with substances, organisms or wastes, in particular, the manufacture, import, marketing, use, storage, transport or disposal thereof.

Chapter 3 receives the following version:

Chapter 3: Handling of organisms

Art. 29a Principles

¹ Organisms may be handled only in such a way that they, their metabolites or wastes:

- a. cannot endanger the environment or humans;
- b. do not impair biological diversity and the sustainable use thereof.

² Handling genetically modified organisms is regulated by the Gene Technology Law of 21 March 2003²⁴.

³ Provisions in other federal laws that require protection of human health from the immediate hazards of organisms are reserved.

²⁴ SR ...; AS ... (BBI 2003 2778)

Art. 29b Contained use

¹ Any person who handles genetically modified or pathogenic organisms, which he or she is allowed neither to release for experimental purposes (Art. 29c) nor to market for use in the environment (Art. 29d), shall be required to take all containment measures that are necessary due to the threat to the environment represented by these organisms.

² The Federal Council shall introduce a notification or authorisation procedure for the handling of pathogenic organisms.

³ For particular pathogenic organisms and activities it may simplify the requirement to notify or obtain a licence or grant exemptions to it if, according to the current state of knowledge or experience, a contravention of the principles of Article 29a can be excluded.

Art. 29c Release for field trials

¹ Any person who intends to release for experimental purposes (field trials) genetically modified or pathogenic organisms, which may not be marketed for use in the environment (Art. 29d), shall require a Federal licence.

² The Federal Council shall enact regulations concerning the requirements and the procedure for issuing licences. In particular, it shall regulate:

- a. the consultation of experts;
- b. the financial coverage of measures with which any harmful effects or nuisances can be identified, averted or eliminated;
- c. the provision of information for the public.

³ For particular pathogenic organisms it may simplify the requirement for a licence or make exemptions to it if, according to the current state of knowledge or experience a contravention of the principles of Article 29a can be excluded.

Art. 29d Marketing

¹ Organism may not be marketed for applications in which the principles of Article 29a are contravened if the organisms are handled as intended.

² For this purpose, the manufacturer or importer shall carry out self-supervision. The Federal Council shall enact regulations regarding the form, extent and monitoring of the self-supervision.

³ Pathogenic organisms may be marketed for use in the environment only if the Confederation has issued a marketing licence.

⁴ The Federal Council shall determine the requirements and provision of information for the public. It may simplify or grant exemptions from the requirement for a licence in the case of certain pathogenic organisms if, according to latest knowledge or experience, a contravention of the principles of Article 29a can be excluded.

Art. 29e Information for customers

¹ Any person who puts organisms on the market shall be required to:

- a. inform the customer about the properties which are relevant to applying the principles of Article 29a;
- b. provide instructions so that, when the organisms are handled correctly, the principles of Article 29a are not contravened.

² Manufacturers' or importers' instructions shall be complied with.

Art. 29f Further Federal Council regulations

¹ The Federal Council shall enact further regulations governing the handling of organisms if, due to their properties, methods of use or quantities used, the principles of Article 29a could be contravened.

² In particular, it may:

- a. regulate the transport, import, export and transit of the organisms;
- b. ban or restrict the handling of certain organisms or establish an authorisation procedure for handling them;
- c. prescribe measures to combat certain organisms or to prevent their occurrence;
- d. prescribe measures to prevent the impairment of biological diversity and the sustainable use thereof;
- e. prescribe long-range studies for the handling of certain organisms;
- f. hold public consultations in connection with licensing procedures.

Art. 29g Consultative committees

The Swiss Expert Committee for Biosafety and the Swiss Ethics Committee on Non-human Gene Technology (Art. 22 and 23 Gene Technology Law of 21 March 2003²⁵) shall advise the Federal Council on the issuing of regulations and on the enforcement of provisions concerning organisms.

Art. 29h Access to files

Each person has the right, on application to the enforcing authority, to receive information gathered in the enforcement of this law, other laws or international agreements about the handling of pathogenic or, pursuant to Article 29f, specially regulated organisms. This right shall not pertain if it is precluded by overwhelming private or public interests.

Art. 33 para. 1

¹ For the long-term preservation of soil fertility, measures against chemical and biological soil pollution shall be laid down in the implementing regulations on the

²⁵ SR ...; AS ... (BBI 2003 2778)

laws relating to water pollution control of 24 January 1991²⁶, on disaster prevention, on air pollution control, on handling substances and organisms and on waste and incentive taxes.

Art. 41 para. 1

¹ The Confederation shall enforce Articles 12 paragraph 1 letter e (regulations on fuels and combustibles), 26 (self-supervision), 27 (information for customers), 29 (regulations on substances), 29a–29h (handling of organisms), 30b paragraph 3 (deposit compensation system), 30f and 30g (import and export of wastes), 31a paragraph 2 and 31c paragraph 3 (federal measures of waste disposal), 32a^{bis} (prepaid disposal fee), 32e paragraphs 1–4 (charge to finance remediation), 35a–35c (incentive taxes), 39 (implementation of regulations and international agreements), 40 (marketing of series-produced installations) and 46 paragraph 3 (information about substances and organisms); it may delegate certain tasks to the cantons.

Art. 44 para. 3

³ It shall decide what information concerning substances and organisms gathered in pursuance of the laws on gene technology, foodstuffs, medicines, chemicals, agriculture, epidemics and epizootic diseases, shall be made available to the Federal Office.

Art. 49 para. 2

² It may commission or support research or technology assessments.

Art. 54 para. 2 und 3

² Appeals may be made to the Appeals Commission DETEC against decisions by the Federal Office in application of this law or against third parties who carry out enforcement tasks on behalf of the federal office. If the decisions concern the handling of substances (Art. 26–29), the appeal may be made to the Appeals Commission for Chemicals.

³ The highest authorities shall consult the federal office before making their decision.

Art. 55 para. 1

¹ National environmental protection organizations shall also have the right of appeal against the following decisions, provided that the organizations were established at least 10 years before lodging the appeal, in cases where administrative appeal to the Federal Council or appeal under administrative law to the Federal Supreme Court is admissible against these decisions:

- a. by the Cantonal or Federal authorities concerning the planning, construction or alteration of fixed installations requiring environmental impact assessment (Art. 9);

²⁶ SR 814.20

- b. licensing by the federal authorities of the marketing of pathogenic organisms (Art. 29d para. 3 and 4), which are intended for use in the environment.

Art. 59a Heading and para. 1 second sentence, 2 letters d and 4
General provisions

¹ ... For damage occurring through the handling of pathogenic organisms Article 59a^{bis} applies.

² As a rule, the following enterprises and installations shall be regarded as representing a special threat to the environment:

- d. those containing substances or organisms for which the Federal Council introduces a licensing requirement or enacts other special regulations.

⁴ Articles 42–47 and 49–53 of the Swiss Code of Obligations²⁷ shall apply.

Art. 59a^{bis} Pathogenic organisms

¹ Any person subject to the notification or authorisation requirement who handles pathogenic organisms in contained systems, releases such organisms for experimental purposes or markets them without permission, is liable for damage that occurs during this handling.

² The person subject to authorisation is solely liable for damage that occurs to agricultural or forestry enterprises or to consumers from products of these enterprises through permitted marketing of pathogenic organisms, if the organisms:

- a. are contained in agricultural or forestry additives; or
- b. stem from such additives.

³ In liability under paragraph 2 recourse to persons who have handled such organisms inappropriately or have otherwise contributed to the occurrence or exacerbation of the damage is reserved.

⁴ If damage is caused by the permitted marketing of any other pathogenic organisms, the person subject to authorisation is liable if the organisms are faulty. He or she is also liable for a fault which, according to the state of knowledge and technology at the time when the organism was marketed, could not have been recognised.

⁵ Pathogenic organisms are faulty if they do not provide the safety that is to be expected, taking into consideration all aspects of the situation; in particular the following should be considered:

- a. the way in which they are presented to the public;
- b. the use that can reasonably be expected;
- c. the time at which they were marketed.

⁶ A product made from pathogenic organisms is not faulty for the sole reason that an improved product has later been marketed.

⁷ The damage must have occurred because of the pathogenicity of the organisms.

⁸ It is the responsibility of the person claiming damages to prove cause. If this proof cannot be provided with certainty or if production of proof cannot be expected of the claimant, the court may be satisfied with overwhelming probability. The court may also have the facts determined *proprio motu*.

⁹ The person subject to the notification or authorisation requirement must also reimburse the costs of necessary and appropriate measures that are taken to repair destroyed or damaged components of the environment or to replace them with components of equal value. If the destroyed or damaged environmental components are not the object of a right in rem or if the eligible person does not take the measures that the situation calls for, the damages shall be awarded to the community responsible.

¹⁰ A person is exempt from liability if he or she can prove that the damage was caused by an Act of God or through gross misconduct of the injured party or of a third party.

¹¹ Articles 42–47 and 49–53 of the Swiss Code of Obligations²⁸ shall apply.

¹² The Confederation, cantons and communes shall also be liable in accordance with paragraphs 1–11.

Art. 59b letter a

For the protection of injured parties, the Federal Council may:

- a. require owners of certain enterprises or installations as well as persons required to notify or who require a licence to handle pathogenic organisms, to provide a guarantee for their liability by taking out insurance or in some other way.

Art. 59c Statute of limitations

¹ The right to damages shall expire in accordance with Article 60 of the Swiss Code of Obligations²⁹.

² If the damage has occurred because of the handling of pathogenic organisms, the right to claim damages shall expire after three years from the time when the injured party becomes aware of the damage and of the person liable, but at the latest after 30 years from:

- a. the event that caused the damage occurred in the company or installation, or ended; or
- b. the date on which pathogenic organisms were marketed.

²⁸ SR 220

²⁹ SR 220

Art. 59d Statute of limitations for the right of recourse

Right of recourse expires under Article 59c. The three-year term begins as soon as the damages have been paid in full and the person sharing liability is known.

Art. 60 para. 1 letter e-l

¹ A person who deliberately

- e. contravenes the regulations on substances or organisms (Art. 29, 29b para. 2, 29f, 30a letter b and 34 para. 1);
- f. handles organisms in such a way that the principles of Article 29a paragraph 1 are contravened;
- g. in handling pathogenic organisms fails to take all necessary containment measures (Art. 29b para. 1);
- h. without a licence, releases pathogenic organisms for experimental purposes or markets them for use in the environment (Art. 29c para. 1 and 29d para. 3 and 4);
- i. markets organisms for which he or she knows or should know that certain uses thereof will contravene the principles of Article 29a paragraph 1 (Art. 29d para. 1);
- j. places organisms on the market without informing the customer appropriately or providing instructions (Art. 29e para. 1);
- k. handles organisms contrary to the instructions (Art. 29e para. 2);
- l. *Repealed*

shall be liable to imprisonment or a fine; the penalty shall be imprisonment if humans or the environment are seriously endangered.

Art. 65 para. 2 first sentence

² The Cantons may not prescribe any new impact thresholds, alarm levels or planning values nor enact any new regulations governing conformity tests for series-produced installations or on the handling of substances and organisms. ...

5. Federal Law relating to Water Pollution Control of 24 January 1991³⁰

Substitute terms:

¹ In Article 48 paragraph 1 second sentence, the term “Swiss Agency for the Environment, Forests and Landscape” will be replaced by the term “Swiss Agency for the Environment, Forests and Landscape (Agency)”.

² In Articles 48 paragraph 4, 49 paragraph 2, 62a paragraphs 4 and 67a paragraphs 1 and 2 the term “Swiss Agency for the Environment, Forests and Landscape” will be replaced by the term “Agency”.

³⁰ SR 814.20

Ingress

in accordance with Article 24^{bis} of the Federal Constitution³¹,

...

Art. 67 Judicial practice

¹ The appeals procedure shall be according to the Federal Law of 20 December 1968³² on Administrative Procedure and according to the Federal Law on the Organisation of Judicial Practice of 16 December 1943³³.

² Appeals may be made to the Appeals Commission DETEC against decisions by the federal office in application of this law or against third parties carrying out enforcement tasks on behalf of the federal office. If the decisions concern the handling of substances (Art. 48 para. 3), the appeal may be made to the Appeals Commission for Chemicals.

³ Appeals against decisions of the Federal Office for Agriculture can be made in accordance with Article 62a paragraph 4 to the Appeals Commission DEA.

⁴ The highest authorities shall consult the federal office before making their decision.

6. Federal Law on Food of 9 October 1992³⁴

Ingress

in accordance with Articles 32^{ter}, 64 and 69^{bis} of the Federal Constitution³⁵,

...

Art. 9 letter b

The Federal Council may limit or prohibit the following substances and processes if, according to the current state of knowledge, human health hazards cannot be excluded:

- b. physical, chemical, microbiological or gene technological procedures to produce or treat food or consumer articles; taking into consideration the provisions of the Gene Technology Law of 21 March 2003³⁶.

³¹ This provision corresponds to Article 76 of the Federal Constitution of 18 April 1999 (SR **101**).

³² SR **172.021**

³³ SR **173.110**

³⁴ SR **817.0**

³⁵ These provisions correspond to Articles 97 paragraph 1, 105, 118 paragraph 2 and 123 of the Federal Constitution of 18 April 1999 (SR **101**).

³⁶ SR ...; AS ... (BBI **2003** 2778)

7. Federal Law on Epidemics of 18 December 1970³⁷

Ingress

in accordance with Articles 95 paragraph 1, 118 paragraph 2, 119, 120 and 123 of the Federal Constitution³⁸.

...

Art. 1 para. 3 und para. 4

³ The Confederation and cantons shall furthermore take the necessary measures to protect humans from pathogens.

⁴ Insofar as pathogens are genetically modified organisms, the Gene Technology Law of 21 March 2003³⁹ shall also apply.

Art. 2 para. 3

Applies only to the French text.

Art. 29b para. 2

Repealed

Art. 29e

Expert Committee for Biosafety The Swiss Expert Committee for Biosafety, in pursuance of the Gene Technology Law of 21 March 2003⁴⁰, advises the Federal Council in issuing regulations and the authorities on the enforcement of the Law on epidemics.

Art. 35 para. 1 letter i

Repealed

8. Federal Law on Agriculture of 29 April 1998⁴¹

Ingress

in accordance with Articles 31^{bis}, 31^{octies}, 32 and 64^{bis} of the Federal Constitution⁴²,

³⁷ SR 818.101

³⁸ SR 101

³⁹ SR ...; AS ... (BBI 2003 2778)

⁴⁰ SR ...; AS ... (BBI 2003 2778)

⁴¹ SR 910.1

⁴² These provisions correspond to Articles 45, 46 paragraph 1, 102, 103, 104, 120, 123 and 147 of the Federal Constitution of 18 April 1999 (SR 101).

...

Art. 14 para. 1 letter e and para. 3

¹ In the interests of credibility and to promote quality and sales, the Federal Council may issue regulations on the labelling of agricultural produce and its processed products which:

- e. are produced without using certain procedures or do not have specific properties.

³ The provisions of the laws on gene technology and on food are reserved.

Section title before Art. 27a

Section 6: Gene technology

Art. 27a

¹ Genetically modified agricultural produce or additives may be manufactured, bred, imported, released experimentally or marketed only if the requirements of this law and, especially, those of the laws on gene technology, environmental protection, animal protection and food are fulfilled.

² Independently of any further provisions, especially those of the laws on gene technology, environmental protection and animal protection, the Federal Council may introduce an authorisation requirement or other measures for the production and sale of this produce.

Art. 146a Genetically modified livestock

The Federal Council may issue regulations on the breeding, import or marketing of genetically modified livestock.

9. Federal Law on Forests of 4 October 1991⁴³

Ingress

in pursuance of Articles 24, 24^{sexies}, 24^{septies} and 31^{bis} of the Federal Constitution⁴⁴,

...

⁴³ SR **921.0**

⁴⁴ These provisions correspond to Articles 74, 77, 78, 94 and 95 of the Federal Constitution of 18 April 1999 (SR **101**).

Art. 46 para. 1^{bis} and 1^{ter}

^{1bis} Appeals against the Agency's decisions and against third parties carrying out enforcement on the Agency's behalf, may be made to the Appeals Commission DETEC.

^{1ter} The highest authorities shall consult the Agency before making their decision.

10. Federal Law on Hunting of 20 June 1986⁴⁵

Ingress

in pursuance of Articles 24^{sexies} paragraph 4, 24^{septies}, 25 and 25^{bis} of the Federal Constitution⁴⁶,

...

Section title before Art. 24

Section 9: Enforcement and procedure

Art. 24 Heading

Enforcement by the Confederation

Art. 25 Heading

Enforcement by the cantons

Art. 25a Judicial practice

¹ The appeals procedure shall be according to the Federal Law of 20 December 1968⁴⁷ on Administrative Procedure and according to the Federal Law on the Organisation of Judicial Practice of 16 December 1943⁴⁸.

² Appeals against the Agency's decisions may be made to the Appeals Commission DETEC.

³ The highest authorities shall consult the Agency before making their decision.

11. Federal Law of 21 June 1991⁴⁹ on Fishing

Ingress

in accordance with Articles 24^{sexies} and 25 of the Federal Constitution⁵⁰,

...

Art. 26a Judicial practice

¹ The appeals procedure shall be according to the Federal Law of 20 December 1968⁵¹ on Administrative Procedure and according to the Federal Law on the Organisation of Judicial Practice of 16 December 1943⁵².

² Appeals against the Agency's decisions may be made to the Appeals Commission DETEC.

³ The highest authorities shall consult the Agency before making their decision.

Art. 26b

Previously Art. 26a

45 **SR 922.0**

46 These provisions correspond to Articles 74, 78 paragraph 4, 79 and 80 of the Federal Constitution of 18 April 1999 (SR **101**).

47 **SR 172.021**

48 **SR 173.110**

49 **SR 923.0**

50 These provisions correspond to Articles 78 and 79 of the Federal Constitution of 18 April 1999 (SR **101**).

51 **SR 172.021**

52 **SR 173.110**