Act No. XXVII of 1998

on gene technology activities

Recognising the possibilities and risks related to genet activities affecting the human environment and to genetically modified organisms, and in order to preserve the balance in nature, to protect human health, to ensure scientific and economic development, as well as to enforce the provisions of the Convention on Biological Diversity announced by Act No. LXXXI of 1995 and the Cartagena Protocol on Biosafety signed on 24 May 2000 in Nairobi and announced by Act No. CIX of 2004, the Parliament hereby adopts the following Act:

Chapter I

GENERAL PROVISIONS

Scope

Article 1

(1) This Act shall apply to
a) the genetic modification of natural organisms,
b) the establishment of premises performing gene technology activities,
c) the following in relation to genetically modified organisms and products derived there from
1. contained use,
2. release for any other purposes than for placing on the market,
3. placing on the market,
4. disposal,
5. imports from countries outside the European Economic Area (hereinafter referred to as "third countries") (hereinafter referred to as "imports"),
6. exports to third countries (hereinafter referred to as "exports"),
7. transports between the countries of the European Economic Area (hereinafter referred to as "transports"), [a), b) and c) together hereinafter referred to as "gene technology activities"], and

d) side by side cultivation of genetically modified plants and plants cultivated by conventional and organic methods in a given region (hereinafter referred to as "co-existence").
(2) As regards the modification of human genes and genetic material, the provisions of the Healthcare Act shall apply.
(3) As regards wild animals or protected natural organisms, the provisions of this Act shall apply save as otherwise provided for in the Nature Conservation Act.
(4) Protected natural organisms should not be genetically modified. The protection status of species cannot be altered due to gene technology reasons.

Definitions

Article 2

For the purposes of this Act:
a) a natural organism means any biological entity, with the exception of human beings, capable of reproducing and transferring its genetic material, except for humans;
b) a genetically modified organism means a natural organism in which the genetic material has been altered by genetic modification, including the progeny of such organisms carrying the properties appearing as a result of these modifications;
c) a microorganism means any microbiological entity, cellular or non-cellular, capable of replication or of transferring its genetic material, including viruses, viroids, plant and animal cells in culture; if not specifically identified by their name, microorganisms are included in the definition of natural organisms;

b) a genetically modified microorganism means a microorganism in which the genetic material was altered in a way which does not occur naturally by mating and/or natural recombination;
e)
f) a premise performing genetic modification means a laboratory or other place where genetic modification or contained uses are performed;
g) genetic modification means a method defined by the relevant law issued under the authorisation of this Act which extracts a gene or any part thereof from the cells and transplants it into another cell, or introduces synthetic genes or gene fragments into a natural organism to alter the genetic material of the recipient;
h) contained use means any activity in which microorganisms are genetically modified or in which such genetically modified microorganisms are cultured, stored, transported, destroyed, disposed of or used in any other way, , and for which specific containment measures are used as defined by the relevant law issued under the authorisation of this Act in order to limit their contact with, and to provide a high level of safety for, the general population and the environment;
i) release for any other purposes than placing on the market means any release other than for the purpose of placing on the market;
j) deliberate release means any intentional introduction into the environment of genetically modified organisms or parts or combinations thereof for which the specific containment measures defined by the relevant law issued under the authorisation of this Act were not used in order to limit their contact with, and to provide a high level of safety for, the general population and the environment; non-contained gene technology activities and non-contained uses of genetically modified organisms are considered as deliberate releases;
k) placing on the market means releases during which genetically modified organisms and products derived therefrom are delivered to processing entities, wholesalers, consumers or other users in any way;
l) disposal means the elimination of genetically modified organisms, the wastes generated during their production, and the adverse environmental effects of the components of genetically modified organisms, excluding or eliminating their damaging environmental effects via containment from the environmental compartments or via altering their material quality;
m) user means natural persons, legal persons or business entities without legal personality establishing premises performing genetic modification, genetically modifying natural organisms and engaging in the contained use of the genetically modified organisms and the product derived therefrom or deliberately releasing them into the environment or placing them on the market, i.e., whoever is responsible for such activities.
n) a genetically modified product means a preparation consisting of or containing a genetically modified organism, or a combination of genetically modified organisms which is placed on the market;
o) environmental risk assessment means an evaluation of the risks to human health and the environment, whether direct or indirect, immediate or delayed, carried out in accordance with the relevant law issued under the authorisation of this Act or with the provision laid down in the relevant directly applicable legal act of the European Union with general scope, which is justifiable due to the contained use, deliberate release and placing on the market of genetically modified organisms;
p) an accident means any incident during which or as a result of which significant and unintended release of genetically modified organisms in the course of their contained use and their release occur, which could present an immediate or delayed hazard to human health or the environment ;
q) a buffer zone means a safety distance laid down in the relevant law issued under the authorisation of this Act or in the relevant directly applicable legal act of the European Union with general scope which serves as a means to avoid physical mixing, pollen contamination, foreign pollination from volunteers, drifting or other pollution from any directions, and which separates the areas cultivated with genetically modified organisms from those cultivated with conventional and organic farming, as well as from protected, highly protected and sensitive natural areas, Natura 2000 sites and gene bank areas;
r) a refuge zone means an area sowed with non-genetically modified plants of the same species as the given genetically modified plant species around the area cultivated with the genetically modified plant;
s) a zone free from genetically modified plant varieties means an agricultural area under cultivation in which farmers voluntarily avoid growing genetically modified plant species.

Chapter II

AUTHORISATION AND REGISTRATION

Gene technology authorisations

Article 3

(1) With the exceptions laid down in Articles 13(1) and 15(1), gene technology activities are subject authorisation.
(2) The genetic modification of the natural organisms defined in the relevant law issued by the Government under the authorisation of this Act cannot be authorised.
(3) The format and content requirements for the applications for such authorisations shall be laid down in the relevant law issued under the authorisation of this Act or in the relevant directly applicable legal act of the European Union with general scope.
(4) In the framework of public administration procedures, no appeals can be filed against the decisions made during the authority procedure defined in Chapters II and III.

Gene technology authorities

Article 4

(1) On the basis of the opinion elaborated in accordance with Article 8 of a Gene Technology Advisory Committee (hereinafter referred to as "Gene Technology Committee"), gene technology activities shall be authorised
a) in case of gene technology activities related to human health, to the production of human pharmaceutical products and to cosmetics in direct contact with the human body, by the Healthcare Gene Technology Authority,
b) in the case of gene technology activities in the agricultural and food sector (including process additives used in food production) and in contained use, as well as in the case of other industrial gene technology activities, by the Environmental, Agricultural and Industrial Gene Technology Authority – upon taking into account environmental and agricultural considerations – (the Healthcare Gene Technology Authority and the Environmental, Agricultural and Industrial Gene Technology Authority hereinafter collectively referred to as the "Gene Technology Authority"), provided that the authorisation procedure occurs at a national level.
(2) At Union-level authorisation procedures, the responsibilities of the national authorities are undertaken by the Gene Technology Authority, which shall consult with the Gene Technology Committee in the framework of its operation, except for in relation to administrative tasks. In relation to Union-level authorisation procedures for food and feed products, the Environmental, Agricultural and Industrial Gene Technology Authority shall consult with the Healthcare Gene Technology Authority. In relation to Union-level authorisation procedures, the Healthcare Gene Technology Authority shall consult with the Environmental, Agricultural and Industrial Gene Technology Authority.
(3) In the authorisation procedures in the fields referred to in paragraph 1b and in paragraph 1a, the Healthcare Gene Technology Authority and the Environmental, Agricultural and Industrial Gene Technology Authority shall act as the Special Technical Authority, respectively.
(4) The rules of involving the Special Technical Authority in the authorisation procedures referred to in paragraph 1 shall be governed by the relevant law issued under the authorisation of this Act.

The Gene Technology Committee

Article 5

(1) The Gene Technology Authority shall decide on the applications for authorisations taking into account the opinion of the Gene Technology Committee. The Gene Technology Authority may reject the application for authorisation or issue approval against the opinion of the Gene Technology Committee.
(2) The Gene Technology Committee shall consist of representatives delegated by
a) the Hungarian Academy of Sciences (one delegate from each field of genetics, environmental sciences, medical sciences, agricultural sciences, law and veterinary science, a total of six delegates),
b) the Minister responsible for agricultural policy (one delegate from each field of agriculture and industry),
c) the Minister responsible for nature protection (one delegate from each field area of environment and nature protection),
d) the Minister responsible for healthcare (one delegate from the field of health),
e) the Minister responsible for education (one delegate from the field of education),
f) the Minister responsible for Research and Development and Technological Innovation (one delegate),

g) social organizations of environmental protection purpose (four delegates altogether),
h) social organizations of health and consumer protection purposes (two delegates altogether).

(3) Membership of the Gene Technology Committee takes for four years, after which the sending institution, ministry, or organization designates or elects new member. The term of membership may be extended once for a period of four years. The sending institution, ministry, or organization may initiate the recall of the designated or elected member from the Gene Technology Committee, providing detailed technical explanation, by designation or election of a new member.

(4) The members of the Gene Technology Committee shall not be individuals in government service at Ministries. Members of the Gene Technology Committee shall not have either direct or indirect financial interest in gene technology activities. The members declare conflicting interest statements before participating in the work of the Gene Technology Committee, which will be published in the website of the Gene Technology Authority.

(5) The user, invited by the Committee, may also attend the sessions of the Gene Technology Committee with the right to participate in the discussions. The operational conditions of the Gene Technology Committee shall be provided for by the Minister responsible for agricultural policy together with the Minister responsible for Research and Development and Technological Innovation and with the Minister responsible for healthcare in proportion of their field of expertise. The Minister responsible for agricultural policy shall ask the members of the Gene Technology Committee for the participation in the work of the Committee.

(6) The Gene Technology Committee shall elect a chairman from among its members by secret ballot, with a simple majority of votes. The chairman shall remain in office for two years. The work of the Committee shall be assisted by a secretary elected from among the members. The term of office of the chairman and the secretary may not be extended more than four years.

(7) Other rules regarding the organization and activity of the Gene Technology Committee shall be specified in a separate law under the authorisation of this Act.

General rules of authorisation

Article 6

(1) The applications for approval as specified in Article 3 shall be submitted to the Gene Technology Authority by the user. The obligations and rights laid down in the consents shall be assumed and exercised, respectively, by the user.
(2) Unless otherwise provided for in the relevant law issued under the authorisation of this Act or in the relevant directly applicable legal act of the European Union with general scope, the Gene Technology Authority shall issue the authorisation defined in Article 3(1) in view of the nature and purposes of the gene technology activities in question, and for a proposed time period identified in the consent and not exceeding ten years, and on the basis of identical criteria within a given activity.

Article 7

(1) In case the user wishes to continue the gene technology activities beyond the time period defined in the consent,
a) at the latest 120 days before the expiry of the consent, for consents for release for any other purposes than for placing on the market,
b) at the latest 270 days before the expiry of the consent, for consents for release for the purpose of placing on the market,
he should submit an application to the Gene Technology Authority for the renewal of the consent.
(2) For the assessment of the applications for renewal, the rules of issuing authorisations shall otherwise apply.
(3) When submitting an application for the authorisation defined in Article 3(1) or for the renewal of the consent, an administration permit fee defined in the relevant law issued under the authorisation of this Act should be paid and these fees may be used by the Gene Technology Authority issuing the authorisations for covering its costs arising in connection with its tasks as defined in this Act and other laws.
(4) Release of genetically modified organisms for any other purposes than for placing on the market and for placing on the market shall not be authorised when they contain genes expressing resistance to antibiotics in use for medical or veterinary treatment or when they may have adverse effects on human health and the environment.

(5) The Gene Technology Authority and the Authority Entitled to Control shall ensure that gene technology activities are pursued in compliance with the provisions of the relevant law and of the consent.

Article 8

(1) The applications for authorising gene technology activities – together with the documentation specified in the relevant law issued under the authorisation of this Act – shall be submitted to the Gene Technology Authority. The Gene Technology Authority shall

a) send a notice to the client that the application has been received in accordance with rules of notifying clients regarding their applications laid down in the Act on the general rules of administrative proceedings and services,

b) examine within eight days whether the format and the content of the application complies with provisions of this Act and the relevant law issued under the authorisation of this Act; in case the application fails to meet the relevant legal requirements, the authority shall return it for completion indicating the additional information required for the assessment of the application as well as the reason for requiring such submissions,

c) forward the application to the Gene Technology Committee - with the exception of the applications for import and export authorisations defined in Article 13(2) and for transport authorisations defined in Article 15(2), provided that the application meets the relevant legal requirements.

(2) The Gene Technology Committee shall

a) examine the application and the documentation attached thereto,

b) evaluate the risks posed by the activities described in the application,

c) accept the results of the environmental and biological impact assessments conducted in the Member States of the European Union; however, if it is required for due reasons, it shall propose that the Gene Technology Authority requires further control experiments and studies to be conducted – in particular, environmental and biological impact assessments –determined in the decision of the Gene Technology Authority,

d) elaborate an opinion approving, conditionally approving or opposing the activities described in the application.

(3) The Gene Technology Committee may require an expert opinion for meeting the provisions of paragraph 2.

(4) When preparing the opinion, the Gene Technology Committee shall – in accordance with the provisions of paragraph 2 – examine the direct or indirect, immediate or delayed effects of genetically modified organisms, such as in particular:

- the resulting changes in humans and natural organisms, primarily in the DNA structure and in resistance,
- the transferring material (vector) used for the generation of new traits as well as its effects on the generation and insertion of the new material into humans and natural organisms, with special regard to health risks,
- the resulting changes in the communities of natural organisms, with special regard to the possibility of spontaneous crossing and to its effects on biological diversity,
- the new effect resulting from the natural change thereof.

(5) Costs of the control experiments and studies defined in point c paragraph 2 shall be borne by the user. Costs of the contributing experts defined in paragraph 3 shall be covered from the budgetary allocation of the Ministries led by the Ministers responsible for nature conservation, for research and development and technical innovation, for healthcare, and for education, respectively, as appropriate.

(6) The Gene Technology Committee shall forward its opinion on the given application to the Gene Technology Authority within 30 days following its receipt.

Special rules of the authorisations of genetic modification and contained uses

Article 8/A

(1) Genetically modified microorganisms shall be classified in relation to their risks to present to the human health and the environment, on the basis of the provisions of the relevant law issued under the authorisation of this Act.

(2) On the basis of the evaluation criteria and procedures laid down in the relevant law issued under the authorisation of this Act, the user shall classify the contained uses as regards the risks to human health and the environment and shall use the appropriate safety containment levels.

(3) Where there is doubt as to which class is appropriate for the proposed contained use, the more stringent protective measures shall be applied unless; the Gene Technology Authority has sufficient evidence to justify the application of less stringent measures.

Article 9

(1) In the authorisation procedure in case of genetic modification of natural organisms as well as of contained uses of genetically modified organisms and products derived therefrom, the administrative time limit is ninety days unless a shorter period is defined in the relevant law or in the relevant directly applicable legal act of the

European Union with general scope. The time required for the control experiments and studies shall be excluded from the administration time limit.
(2)-(3)
(4) The Gene Technology Authority shall publish the draft consent in its official journal and website for public consultation with the exception of confidential business information, copyright information and information regarding variety protection. Comments on the draft consent may be submitted to the Gene Technology Authority within 30 days after publication in the official journal and such comments shall be forwarded to the Gene Technology Committee for opinion. The Gene Technology Committee shall assess such comments and forward its opinion to the Gene Technology Authority within 10 days of its receipt. Upon receiving the opinion of the Gene Technology Committee, the Gene Technology Authority shall finalise or amend the draft consent or reject the application.
(5) When calculating the time limit for the procedure, the period during which the Gene Technology Authority conducts the public consultation shall not be considered.
(6) The final consent of the genetic modification of natural organisms as well as of contained uses of genetically modified organisms and products derived therefrom,– with the exception of confidential business information, copyright information and information regarding patents and plant variety protection – shall also be published in the official journal of the Gene Technology Authority and of the Ministry led by the Minister directing the Gene Technology Authority; and the name of the entity engaged in genetic modification, the name of the user, the consent number, the subject of the genetic modification and the subject of use, the genes used for genetic modification, as well as the social benefits and potential risks inherent in the genetic modification should also be indicated.

Article 10

(1) Activities aiming at the genetic modification of a natural organism shall only be pursued by users fulfilling the technical, technological, environmental, nature conservation and health requirements specified in the relevant law issued under the authorisation of this Act.
(2) Within the user's organisation, activities aiming at the genetic modification of a natural organism shall only be independently pursued by persons having a university degree and with scientific experience in the given field.

Special rules of the authorisation of the releases for any other purposes than placing on the market

Article 10/A

(1) As regards authorisations for releases of genetically modified organisms or products derived therefrom for any other purposes than placing on the market, the Gene Technology Authority shall make a decision within 90 days of the receipt of the application, after conducting the procedure specified in Articles 9(4) and (5).
(2) The final consent for the releases of genetically modified organisms and products derived therefrom for any other purposes than placing on the market – with the exception of confidential business information, copyright information and information regarding patents and plant variety protection – shall also be published in the official journal of the Gene Technology Authority and of the Ministry led by the Minister directing the Gene Technology Authority, and the name of the releasing entity and the genetically modified trait should also be indicated.
(3) The user may only pursue releases for any other purposes than placing on the market if he possesses the final consent according to Article 3(1) and until the expiry of the time period specified in the said consent. In cases specified in the relevant law issued under the authorisation of this Act, in order to evaluate the environmental effects in the given area, the Environmental, Agricultural and Industrial Gene Technology Authority may require in the consent that supplementary control assessments in accordance with the relevant law issued under the authorisation of this Act be conducted and may specify detailed conditions thereto, or may conduct such assessments.
(4) For the purposes of the assessments to be conducted by the Environmental, Agricultural and Industrial Gene Technology Authority specified in paragraph 3, the user shall provide the Environmental, Agricultural and Industrial Gene Technology Authority with samples of the propagation material of the genetically modified plant and with samples of the propagation material of the non-modified version of the same plant to be used as control in said assessments, in the quantities required by the consent and in a manner specified in the relevant law issued under the authorisation of this Act, and within 30 days of the entry into force of the approval. In case user fails to meet these obligations, the Environmental, Agricultural and Industrial Gene Technology Authority shall withdraw the consent.
(5) The Environmental, Agricultural and Industrial Gene Technology Authority shall use the samples provided according to paragraph 4 or transfer them to third parties – while respecting intellectual property rights – only for the purposes of the supplementary control assessments specified in the relevant law issued under the

authorisation of this Act. Within 30 days after the expiry of the time period specified in the consent or after the withdrawal of the said consent, the Environmental, Agricultural and Industrial Gene Technology Authority shall return the unused parts of the samples to the user.
(6) When submitting applications for releases for any other purposes than placing on the market, applicants should enclose a detailed plan of the experiment, as specified in the relevant law issued under the authorisation of this Act.

Review of releases for any other purposes than placing on the market

Article 11

(1) During the time period specified in the consent for releases for any other purposes than placing on the market, the user shall submit a report (hereinafter referred to as the "annual report") to the Gene Technology Authority each year, by the 30th day after terminating the releases – or in the case of genetically modified higher plants, after harvesting –, in the format and with the contents specified in the relevant directly applicable legal act of the European Union with general scope and in the consent for releases for any other purposes than placing on the market. In case the user does not wish to continue the approved activities in the following year, the annual report should also include a statement to this effect with the supplementary information detailing whether he wishes to terminate the said activities definitively or wishes to continue at a later date within the time period specified in the consent. In the latter case, the user should notify the Gene Technology Authority on the continuation of the releases, within 30 days before initiating it.
(2) On the basis of the annual report, the Gene Technology Authority shall review the releases for any other purposes than placing on the market, and shall take into account the control reports of the field visits submitted during the year by the Authority Entitled to Control during said review.
(3) The Gene Technology Authority shall forward the annual report and the statement specified in paragraph 1 to the Gene Technology Committee for opinion and to the Special Technical Authority, specified by the Government Decree issued under the authorisation of this Act, involved in the authorisation procedure to formulate a technical authority's resolution. The Gene Technology Committee shall forward its opinion on the report and its possible proposal for amending or repealing the consent to the Gene Technology Authority within 30 days of the receipt of the report.
(4) In case the review concludes that the conditions and circumstances taken into consideration at the time of granting the authorisation have changed, the Gene Technology Authority shall – upon asking for the opinion of the Gene Technology Committee – amend the consent. However, if as a result of the changed conditions or circumstances the conditions of granting the authorisation no longer prevail or the releases fail to meet the legal requirements or the terms of the consent, the Gene Technology Authority shall – upon asking the opinion of the Gene Technology Committee – withdraw the consent.

Special rules of placing on the market

Article 11/A

(1) The first placing on the market within the territory of the European Economic Area of genetically modified organisms or combinations genetically modified organisms as or in products shall be subject to authorisation; thereafter, they are freely marketable within the territory of the European Economic Area except as specified in Article 11/B.
(2)
(3) As regards authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified organisms, for food and feed uses, the provisions of the relevant directly applicable legal act of the European Union with general scope shall apply.
(4) In connection with genetically modified organisms with final consent for placing on the market according to paragraph 1, the Gene Technology Authority and the Authority Entitled to Control shall check compliance with the monitoring requirements specified in the relevant directly applicable legal act of the European Union with general scope during placing on the market.

Safeguard clause

Article 11/B

(1) Where the Gene Technology Authority, has new or additional information revealed after the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge – in relation to a genetically modified organism as or in a product having written consent for placing on the market, the Gene Technology Authority shall evaluate whether the genetically

modified organisms as or in a product may constitute a risk to human health or the environment as defined in the relevant law issued under the authorisation of this Act (hereinafter referred to as "risk").
(2) In case the Gene Technology Authority concludes that the genetically modified organism as or in a product is considered to constitute a risk to human health or the environment, it shall immediately inform –via the liaison specified in the relevant law issued under the authorisation of this Act –the European Commission and other Member States of the following:
a) restriction or prohibition of the placing on the market or use in the territory of Hungary for the duration of the safeguard clause procedure,
b) the new or additional scientific information on which its measures specified in point a are based,
c) the supposed risks and their reasons, including the review of the environmental risk assessment, and
d) its proposal to amend or repeal the approval.
(3) In parallel with the notification of paragraph 2, the Minister responsible for agricultural policies shall issue a decree to
a) specify the list of genetically modified organisms as or in products and which are under safeguard clause, and
b) specify the safety measures required for the duration of the safeguard clause, in particular the restriction or prohibition of imports, exports, transports, production, placing on the market and use of genetically modified organisms as or in products, their removal from the market, separation of the products during storage or destruction of the plant culture.
(4) Pursuant to the decree specified in paragraph 3, in relation to genetically modified plant varieties under safeguard clause
a) no cultivation authorisation shall be granted,
b) cultivation authorisation already granted shall be withdrawn.

State recognition of plant varieties and animal breeds

Article 11/C

(1) During recognising genetically modified plant varieties and genetically modified animal breeds, the provisions of the law on the state recognition of plant varieties and on the breed recognition of animal breeds shall apply together with the provisions of this Article.
(2) In case of genetically modified plant varieties, the experimental studies required for recognition by the state may only be initiated after the entry into force of the authorisation for any other purposes than for placing on the market of the Gene Technology Authority.
(3) The Authority Responsible for the State Recognition of Plant Varieties may forward the results of the variety studies of the plant varieties applying for a recognition by the state to the Variety Evaluation Committee provided that genetically modified organism has an authorisation for placing on the market and that applicant has submitted it to the Authority Responsible for the State Recognition of Plant Varieties.
(4) One condition of the breed recognition procedure of genetically modified animal breeds is the submission by the entity applying for such breed recognition of the authorisation for placing on the market to the Authority Responsible for the Breed Recognition of Animal Breeds.
(5) In case placing on the market of the genetically modified organism is restricted or prohibited according to Article 11/B (2), no decision on state recognition or breed recognition can be issued.

Package labelling

Article 12

(1) The producer and the distributor of a genetically modified product or of a food or feed product produced from genetically modified organisms, as specified in the relevant directly applicable legal act of the European Union with general scope, shall label the packaging of the product and the accompanying documents as specified in the relevant directly applicable legal act of the European Union with general scope, with the exception provided for in paragraph 2.
(2) The provisions of paragraph 1 shall not apply to the presence provided that it is adventitious or technically unavoidable and is below the relevant threshold as specified in the relevant directly applicable legal act of the European Union with general scope.

Imports and exports

Article 13

(1) The imports from third countries of genetically modified organisms with written consent for placing on the market shall not be subject to special authorisation without affecting the requirements laid down in the relevant directly applicable legal act of the European Union with general scope.
(2) The imports from or exports to third countries of genetically modified organisms not having written consent for placing on the market or any parts thereof (including parts capable of reproducing the genetic material or transferring it by inheritance) are subject to authorisation. The applications for authorisation shall be submitted to the Gene Technology Authority by the Hungarian addresses of the consignment or by the sender. The Gene Technology Authority shall decide on the application for authorisation within 90 days of the receipt. In the authorisation, the Gene Technology Authority shall specify the conditions of imports and exports and – in case of genetically modified organisms and products derived therefrom falling under the scope of the laws on the transport of dangerous goods – in accordance with such laws.
(3) As regards the exports of genetically modified organisms intended for deliberate release into the environment, food or feed uses or processing, contained use and as regards the unintended exports and imports of genetically modified organisms, the provisions of the relevant directly applicable legal act of the European Union with general scope shall apply.
(4) The imports and exports of genetically modified organisms and products derived therefrom falling under the scope of the laws on the transport of dangerous goods shall be authorised by the provisions of such laws.

Article 14

Transport

Article 15

(1) Genetically modified organisms and products derived therefrom or containing them which are freely marketable in the territory of the European Economic Area in accordance with Article 11/A may be transported from Hungary to the Member States of the European Economic Area and from the Member States of the European Economic Area to Hungary without special authorisation.
(2) The transport from Hungary to the Member States of the European Economic Area and from the Member States of the European Economic Area to Hungary of genetically modified organisms and products derived therefrom without a written consent for placing on the market shall be subject to special authorisation. The applications for transport authorisations shall be submitted to the Gene Technology Authority by the Hungarian addressee of the consignment or by the sender.
(3) The Gene Technology Authority shall decide on the application within the general administration time limit laid down in the Act on the general rules of administrative proceedings and services. In case of genetically modified organisms and products derived therefrom falling under the scope of the laws on the transport of dangerous goods, the Gene Technology Authority shall specify the conditions of transport in the consent in accordance with such laws. The consignment should be accompanied by a copy of the transport consent.
(4) The provisions applicable in case of unintended transport are contained in the relevant directly applicable legal act of the European Union with general scope.
(5) The transport of genetically modified organisms and products derived therefrom falling under the scope of the laws on the transport of dangerous goods shall be governed by the provisions of such laws.

Establishment of premises performing genetic modification

Article 16

(1) In the authorisation procedure for establishing premises performing genetic modification by, the administration time limit is 45 days.
(2)

Waste management

Article 17

(1) On the basis of the resolution of the special technical authority involved in the authorisation procedure in cases specified in the relevant law issued under the authorisation of this Act, the Gene Technology Authority – in order to evaluate the environmental risks – may require that a biological impact assessment be prepared relating to the wastes generated upon the gene technology activities or the death and disposal of genetically modified organisms and products derived therefrom and relating to the waste management. The Gene Technology Authority may require the preparation of the biological impact assessment, and the labelling, treatment, transport or disposal of the wastes in the consent for genetic modification, for the contained uses of

genetically modified organisms and products derived therefrom, for deliberate releases for any other purposes than placing on the market or for placing on the market, or in the consent for exports or imports of genetically modified organisms or products derived therefrom. The biological impact assessment shall be prepared by the user or by the disposing entity. The wastes shall be labelled, treated, transported and disposed in accordance with the procedure specified in the consent.
(2) The provisions of paragraph 1 shall not apply to genetically modified organisms that may be used in food production as raw materials or as additives in accordance with the authorisation of the Gene Technology Authority, and these shall be treated in accordance with the procedure specified in the law laying down the conditions and methods of destroying food products and in the relevant directly applicable legal act of the European Union with general scope.
(3) The treatment, transport and disposal of wastes originating from gene technology activities which are considered as hazardous wastes pursuant to the law on hazardous wastes shall be governed by the provisions of the law on the treatment, transport and disposal of hazardous wastes.

Gene technology inspector

Article 18

For the purpose of pursuing their activities, users shall employ a gene technology inspector (hereinafter referred to as "inspector"). The responsibilities of the gene technology inspector shall control that the user complies with the provisions of this Act and that of the relevant law issued under the authorisation of this Act and shall assist that the user's activity should not be hazardous to human health and the environment.

Registers and data management

Article 19

(1) An institution appointed by the Government (hereinafter referred to as "Registering Body") shall maintain registers of the following and shall make them available on its website without limitation and in a searchable format:
a) a general description of the genetically modified organism or organisms, the name and address of the user, the purpose and location of the release, the intended uses, the environmental risk assessment, and the methods and plans for monitoring of genetically modified organisms and for emergency measures among the data of the documentation specified in the relevant law issued under the authorisation of this Act as well as in the applications for authorisation for genetic modification of natural organisms, for the contained uses of genetically modified organisms and products derived therefrom, for releases for any other purposes than placing on the market or for placing on the market,
b) the final consent, and
c) a list of the names of the laboratories performing genetic modifications and the responsible managers thereof.
(2) The members of the Gene Technology Committee shall maintain the confidentiality of the data received in the framework of the operation of the Gene Technology Committee and may only disclose such data to third parties upon obtaining the consent of the applicant. This provision shall apply even if the user withdraws the submitted application.
(3) The Gene Technology Authority shall forward the data specified in paragraph 1 to the Registering Body, and in case of data specified in paragraph 1a, shall publish the draft consent at the same time.
(4) Among the data submitted for registering purposes, those related to user's rights to confidential business information or patents or variety protection shall not be public provided that user requests the Gene Technology Committee or the Gene Technology Authority to treat such data in this manner.
(5) The Registering Body shall maintain the registers for 10 years after the expiry of the time period specified in the consent.
(6) In case of withdrawal of the consent, the Registering Body shall delete the data specified in paragraph 1afrom its registers.

Article 20

(1)-(2)
(3) The detailed rules relating to the registration and the accessibility of information specified in Article 19(1) shall be laid down by the relevant law issued under the authorisation of this Act.

Article 21

(1) The Authority Entitled to Control shall prepare annual reports to the Gene Technology Authority on the control of the contained uses of genetically modified organisms and products derived therefrom and releases thereof, and shall also forward it to the Gene Technology Committee for their information.
(2) The chairman and secretary of the Gene Technology Committee shall prepare annual summary reports regarding the discharging of the duties related to its activities and the annual reports specified in paragraph 1 shall be included in the annual summary reports which shall be published by the Ministry led by the Minister responsible for agricultural policies in its official journal and website.

Accidents

Article 21/A

(1) In order to prevent accidents, the user shall prepare an emergency plan in accordance with the provisions of the relevant law issued under the authorisation of this Act. In case of accident, the user shall immediately alert the Authority Entitled to Control without delay and provide it with the data specified in the relevant law issued under the authorisation of this Act.
(2) The Gene Technology Authority and the Authority Entitled to Control shall take all the necessary measures and shall collect all the information necessary for a full analysis of the accident and shall make recommendations to avoid similar accidents in the future and to limit the effects thereof.

Chapter III

Co-existence rules

Article 21B

(1) In order to prevent any contamination or crossing of genetically modified plants with plants cultivated by traditional and/or by ecological farming, genetically modified plants may only be produced with a valid consent of the Cultivation Authority.
(2) The natural person, legal person or business entity without legal personality producing genetically modified plants (hereinafter referred to as "producer") shall submit the application for a cultivation consent to the Cultivation Authority at least 90 days before the foreseen date of sowing and shall enclose its own certificate or the certificate of an employee thereof, as specified in the relevant law issued under the authorisation of this Act, which confirms that the skills required for coexistence have been obtained. The application for cultivation consent shall be subject to a fee specified in the provisions of a separate legal prescription.
(3) Multiple producers may submit joint applications provided that their lands where they wish to cultivate genetically modified plants are adjacent to each other. When calculating the size of the buffer zone and determining the other terms of production in such cases, the Cultivation Authority shall consider the lands as one unit and issue a decision regarding the authorisation of the production. In case of joint applications, the Cultivation Authority shall only grant the authorisation provided that each producer separately complies with the conditions required by law; in other cases, the authority shall reject the application for each producer.
(4) The application shall include
a) the name or company name and the address or legal abode of the producer,
b) producer's client registration number as specified in the law on the provisions of the legal procedure of agricultural and rural development supports and its implementing norms,
c) the location of the cultivation including cadastral number, size, and block identification numbers of land sections, as well as
d) the plant variety intended to be cultivated and its unique identifier in the European Union, as well as the modified trait.
(5) The Cultivation Authority
a) shall confirm the receipt of the application for a cultivation authorisation the applicant in writing, and shall publish the contents (applicant's name, plant species and variety, area, MEPAR[1] identifier and cadastral number) of the submitted application in its national database at the same time.
b)-c)
(6) The Cultivation Authority shall issue a preliminary consent regarding the size of the buffer zone to be established for the cultivation of genetically modified plants and the other terms of cultivation within 40 days from the receipt of the application. The preliminary consent shall not be interpreted as a final consent for starting cultivation.

[1] Agricultural Parcel Identifier System

(7) Based on local natural, geographical and other characteristics affecting the cultivation, the Cultivation Authority may establish a distance larger than the minimum size of buffer zone between the genetically modified plants and the plants cultivated by traditional and/or organic farming, as specified in the relevant law issued under the authorisation of this Act. The Cultivation Authority may also establish a distance larger than the minimum size of buffer zone, as specified in the relevant law issued under the authorisation of this Act, in cases where the distance between the boundaries of protected areas, highly protected areas, sensitive natural areas, NATURA 2000 sites and gene bank areas and the boundaries of cultivation areas of genetically modified plants is shorter than the double of the minimum size of the buffer zone. The size of the buffer zone specified by the Cultivation Authority shall not exceed double the minimum size.
(8) The Cultivation Authority may stipulate special cultivation conditions in order to comply with the legal provisions ensuring compliance with the legal acts of the European Union on the conservation of natural habitats, and of wilds fauna and flora and on the conservation of wild birds, and with the requirements of the laws granting protections and of the laws on sensitive natural areas. In case these requirements cannot be met even in this way, the cultivation shall not be authorised.
(9) It is not allowed to cultivate in the buffer zone any species that is sexually compatible with the genetically modified plants, and all weeds that are suitable for cross-pollination shall be eradicated in accordance with the Best Farming Practices.
(10) In the case of cultivating a genetically modified insect-resistant plant, in order to avoid the appearance of resistant insects, the Cultivation Authority determines in its preliminary consent the size of the refuge area to be established around the area cultivated with the genetically modified plant. This size depends on the requirements specified in the relevant law issued under the authorisation of this Act and is between 10% and 20% of the area indicated in the application as being sown by genetically modified plants. The refuge zone shall be established within the area indicated in the application as being sown by genetically modified plants. The refuge zone shall not be part of the buffer zone. The crops cultivated in the refuge zone shall be labelled as genetically modified crops, unless the unique test performed by an accredited laboratory at the request of the producer makes unnecessary (for the crop grown in the refuge area) the labelling requirements specified in the relevant directly applicable legal act of the European Union with general scope related to genetically modified organisms.
(11) After the preliminary expert opinion has been issued, the applicant shall install a sign-board in accordance with the relevant law issued under the authorisation of this Act, stating that an authorising procedure on cultivating genetically modified plants on the area concerned is under way.
(12) For the training courses related to coexistence and the corresponding examinations and certification, a fee specified in the relevant law issued under the authorisation of this Act shall be paid.

Article 21/C

(1) Upon granting the preliminary consent, applicant shall – for the purposes of the authorisation procedure for the cultivation of genetically modified plants – obtain
a) prior consents in writing of land owners within the buffer zone designated in the preliminary consent, and
b) in case lands within the buffer zone are not being used by the land owner, the prior consent in writing of the land user shall also be procured [the individuals specified in points a and b hereinafter collectively referred to as "land owners or land users within the buffer zone"], and
c) in case applicant is not the owner of the land where the cultivation of genetically modified plants is intended, also the prior written consent of the owner of the land concerned shall be submitted.
(2) In case the owner of the land specified in paragraph 1 is the Hungarian State, the prior written consent of the property management organisation or, in the absence thereof, the organisation possessing the ownership rights shall be submitted.
(3) At the same time of written consent, the land owner or land user within the buffer zone shall declare – as an integral part of said consent – concerning their awareness of the obligation that plants sexually compatible with the genetically modified plants may not be cultivated within the buffer zone during the time period specified in the cultivation consent. This consent may not be substituted by court. In the absence of such consents, no cultivation authorisation shall be granted. The format and data content of the written consent to the production of genetically modified plants shall be laid down in the relevant law issued under the authorisation of this Act.
(4) Applicants shall submit the consents to the Cultivation Authority by the 20th day before the foreseen date of sowing at the latest. The Cultivation Authority shall decide on the applications for cultivation authorisation within 15 days from their submission.
(5) The validity of the cultivation authorisation shall expire in the case of arable plants at the end of sowing cycle, in other cases at the deadline specified in the consent; an application for a new authorisation shall be submitted after expiry thereof.
(6) Upon granting the cultivation authorisation, the Cultivation Authority shall maintain registries of the cultivation-related data included in the application and shall make such data available as a national database on its website and on the government portal without limitation and in a searchable format. The Cultivation Authority shall forward the decision to the Authority Entitled to Control. Applicant or the consent holder shall

notify the Cultivation Authority of the changes occurring after the submission of the application within 5 days and in writing.
(7) The consent holder shall forward copies of the labels of the sown propagation material to the Cultivation Authority by the 30th day after the date of sowing at the latest.
(8) In case of a joint authorisation as specified in Article 21/B (3), producers shall be responsible for complying with the requirements of the decision and the relevant laws in relation to their own lands and own cultivation activities.
(9) During the authorisation and the registration procedures, the Land Registration Authority and the Land Survey and Mapping Authority shall provide the Cultivation Authority with data free of charge.
(10) The detailed technical rules and conditions of co-existence and the treatment, transport, storage and marketing of the crops shall be laid down in the relevant law issued under the authorisation of this Act.

Article 21/D

(1) Compliance with the provisions of the cultivation consent and the relevant laws shall be controlled by the Authority Entitled to Control consent holders and land owners or land users within the buffer zone shall cooperate with the Authority Entitled to Control.
(2)
(3) Articles 22(1), (2) and (3a) to (6), and Article 23 with the exception of the requirements related to the Gene Technology Committee and the Special Technical Authorities, as well as Article 24/A and the first sentence of Article 25(1) shall also apply to co-existence with the provision that instead of gene technology co-existence, instead of Gene Technology Authority, Cultivation Authority, and instead of Authority Entitled to Control the gene technology activities, Authority Entitled Control co-existence, and instead of user, consent holder shall be understood.
(4) In case the controls conclude that land owner or land users within the buffer zone fail to comply with the prohibition specified in Article 21/B (9), on the basis of a notification by the Authority Entitled to Control Co-existence, the Cultivation Authority shall oblige the trespasser to destroy the plants produced against such prohibition.
(5) With the exception specified in paragraph 6, liability for damages caused during co-existence shall be governed by Articles 345 and 346 of the Civil Code. (6) In case the aggrieved party has – in accordance with Article 21/C (1) and (2) – given its prior written consent to the cultivation of genetically modified plants, Article 339 through Articles 342 and 344 of the Civil Code shall apply to the liability for the damage caused during coexistence.

Article 21/E

(1) The distributor of the propagation material of the genetically modified plants shall provide the Cultivation Authority with data regarding the quantity of genetically modified propagation materials, including the name of the plant species and plant variety, 60 days before selling the given lot of propagation material of genetically modified plants at the latest, and shall also indicate the names or business names and the addresses and legal abode.
(2) In order to ensure the traceability of genetically modified organisms, the distributor of the propagation material of the genetically modified plant shall maintain the registers specified in the relevant directly applicable legal act of the European Union with general scope, and such registers shall contain data on the type of the propagation material, its metallic seal number and identifier, the quantities concerned, the date of selling and the name and address or company name and legal abode of the buyer. The distributor shall maintain its register for 5 years. The registers shall be controlled by the Authority Entitled to Control.
(3) Each year, the distributor shall supply data to the cultivation authority about the actually traded reproductive material quantity of the genetically modified plant in the current year, also specifying the data required by paragraph 1 herein. The deadline for providing this data is as follows: until 31 January for plants that are sown in the autumn, and until 31 August for plants that are sown in the spring.
(3a) The Cultivation Authority shall register of the data provisions specified in paragraphs 1 and 3 and said registries shall include the name or company name and the address or legal abode of distributor. Except for personal information, the complete range of data in the registers shall be made available on the website of the Cultivation Authority and on the government portal without limitation and in a searchable format.
(4) Before the buying, distributor shall inform the buyer that the use of the propagation material is subject to cultivation consent. The fact that the information obligations have been met by distributor shall be confirmed by the buyer by signing a statement.
(5) The provisions of this Article shall also apply to the selling of propagation materials of genetically modified plants in the framework of transboundary services provided by a service provider entitled to freely provide services in accordance with the Act on the general rules on taking up and pursuit of service activities.

Article 21/F

If natural or legal entities, and/or entities without legal personality agree to establish a zone free of genetically modified plants, the Cultivation Authority, at the request of farmers operating in that particular zone and based on their voluntary data supply, shall publish on its website, as well as on the government portal, the data of the particular zone and farmers indicated in the application.

Chapter IV

OFFICIAL CONTROLS AND MEASURES

Article 22

Compliance with the provisions of the laws related to gene technology activities and of the final consent shall be checked by the Authority Entitled to Control at the site of said activities. During the on-control, the Authority Entitled to Control shall suspend the activities until a decision by the Gene Technology Authority made in accordance with Article 25(1), provided that

a) the activities are different from those described and specified in the consent and the relevant laws,

b) non-authorised gene technology activities are observed,

c) any new information on increased risks related to the authorised activity becomes available to it, especially if connected to the level of the risks posed for human health and the environment.

(2) In addition to those described in paragraph 1, the Authority Entitled to Control may adopt the following measures taking into account the level and nature of the risks inherent to the non-compliance, in accordance with the provisions of the law implementing this Act and in proportion with the seriousness of the non-compliance revealed:

a) may prohibit the production, storage, transport, use, placing on the market, or imports or exports of genetically modified organisms, as well as the products derived therefrom having no authorisation, being under safeguard clause or failing to comply with the relevant requirements;

b) may prescribe the removal from the market or the destruction of the genetically modified organisms, as well as the products derived therefrom, having no authorisation, being under safeguard clause or failing to comply with the relevant requirements;

c) may prohibit the production or the harvest of plant varieties consisting of or containing genetically modified organisms having no authorisation, being under safeguard clause or failing to comply with the relevant requirements;

d) may prescribe the examination, separation or killing of the unauthorised genetically modified animals;

e) during the border control, may prescribe the measures described in the law implementing this Act and the relevant directly applicable legal act of the European Union with general scope be adopted.

(3) The Authority Entitled to Control shall require the payment of a gene technology penalty in case of non-compliance of

a) the provisions of points a and b of paragraph 1,

b) the prohibition or restriction pursuant to the decree specified in Article 11/B (3), or

c) the requirements of Chapter III.

(3a) When determining the penalty, the authority shall consider the seriousness of the illicit behaviour, the hazards of its consequences on the environment and human health, as well as whether it happened at first time or not and whether it happened accidentally. Non-compliance observed for the second time or more are defined as repeated infringements occurring within 5 years after observing the previous non-compliance. The amount of the penalty and the detailed rules of imposing it shall be laid down in the law implementing this Act.

(4) The Authority Entitled to Control shall notify the Gene Technology Authority of the measures adopted in case of an non-compliance within 3 days of making the decision by forwarding said decision, and shall propose the conditions be specified for the final consent for the gene technology activity on a national level or the consent to be amended, suspended or repealed, and, in case of authorisations granted by the European Union the amendment or the repeal of the consent shall proposed.

(5) In case of identifying non-compliance, the costs of the assessments conducted in connection with the controls shall be borne by the trespasser.

(6) The Gene Technology Authority shall publish the information regarding the controls on its website.

Requiring conditions for the authorisation, or amending, suspending or repealing the consent

Article 23

(1) In case the authorised gene technology activity represents increased risks in comparison with the risk assessment forming the basis of the authorisation, especially in relation to human health and the environment,

the Gene Technology Authority shall – *ex officio* or upon the recommendation of the Special Technical Authority involved in the authorisation procedure in the cases specified in the relevant law issued under the authorisation of this Act or by the Authority Entitled to Control, and on the basis of the opinion of the Gene Technology Committee –

a) shall require conditions for the authorisations for gene technology activities issued under its national competence, or amend, suspend or – in case the condition of granting the authorisation no longer prevail – repeal said authorisation,

b) in case of authorisation issued under European Union competence, shall propose the amending or repealing of the authorisation through the liaison specified in the relevant law issued under the authorisation of this Act.

(2) The Gene Technology Authority shall – in cases specified in Article 22(1)(a), upon the proposal by the Authority Entitled to Control, and in cases where the user fails to meet its annual reporting obligations specified in Article 11, *ex officio* –

a) repeal the authorisation for the gene technology activity issued under its national competence,

b) in case of authorisation issued under European Union competence, shall propose the repealing of the authorisation through the liaison specified in the relevant law issued under the authorisation of this Act.

(3) In addition to the entities specified in the Act on the general rules of administrative proceedings and services, the Gene Technology Authority shall also communicate its decision requiring conditions for, amending, suspending or repealing the authorisation issued under its national competence to the Registering Body.

(4) In cases specified by Article 22(1)(b), the Gene Technology Authority may ban the natural person or legal person or company entity without legal personality pursuing non-authorised gene technology activities from all gene technology activities ensuring that no authorisation for pursuing gene technology activities may be granted to them during the ban period.

Article 24

(1)

(2) In order to protect nature, the Gene Technology Authority may require users to establish a genetic protection zone as specified in the relevant law issued under the authorisation of this Act.

Article 24/A

In case the applicant applying for an authorisation for pursuing gene technology activities or the user receives important new information regarding the genetically modified organisms specified in the application or regarding the authorised activities, or wishes to modify its activity in a manner significantly increasing the associated risks, they shall immediately notify the Gene Technology Authority to take the measures that ensure the protection of human health and the environment. Applicant shall review the documentation submitted with the application for authorisation and shall amend or withdraw the application. User shall review the documentation submitted with the application for authorisation and shall submit an application to amend or withdraw the authorisation. Upon informing the user, the Gene Technology Authority shall proceed in accordance with Article 25(1).

Article 25

(1) In case of receiving a notification from the Authority Entitled to Control in accordance with Article 22(1) or of observing the events specified in Article 22(1), the Gene Technology Authority may restrict or prohibit the activities – in case of risks to human health or the environment – until a decision is made on the stipulation of conditions for, amending, suspending or repealing the authorisation. The Gene Technology Authority shall immediately notify the Gene Technology Committee of the measure and the reasons thereof after taking said measure.

(2) The Gene Technology Committee shall make an opinion as to whether the measure should be maintained and shall forward said opinion to the Gene Technology Authority within thirty days of the receipt of the notification regarding the measure. The Gene Technology Authority shall decide on the maintenance of the measure taking into account the opinion of the Gene Technology Committee.

(3) In case of the prohibition of the activity, the Gene Technology Authority shall – upon receiving the opinion of the Gene Technology Committee deeming the maintenance of the measure as justifiable – require the immediate destruction of the genetically modified organisms. The destruction shall be carried out at the location specified by the Gene Technology Authority and shall be controlled by the Authority Entitled to Control.

(4) The deadline specified in paragraph 2 shall be prolonged with the time required for the assessments as deemed necessary for making a decision by the Gene Technology Committee.

(5)

Article 26

(1) In case of infringing the legal requirements for gene technology activities in a manner which affects a large proportion of the general population, presents hazards to human life and health, impends with major economic or environmental damage, affects a large proportion of the livestock or presents hazards to animal health (hereinafter referred to as emergency GM events),
a) in emergency GM events falling under the scope of the Environmental, Agricultural and Industrial Gene Technology Authority, the Minister responsible for agricultural policies,
b) in case of emergency GM events falling under the scope of the Healthcare Gene Technology Authority, the Minister responsible for healthcare shall notify the general population of the information necessary for eliminating such hazards.
(2) When an emergency GM event occurs, the Minister responsible for agricultural policies and the Minister responsible for healthcare, respectively, shall – in their functions specified in paragraph 1 – adopt a decision
a) requiring data supply, including personal information such as names, addresses and other contact information,
b) suspending or prohibiting the use or marketing of the product or product group,
which shall be published in the official journal and website of the Ministries led by said Ministers, as well as through the national news agencies. Decisions thus published shall be implemented immediately regardless of any appeals. The disclosure date of the decisions shall be the date of the first publication.
(3) Instead of the personal data of the entitled or obliged client specified in the Act on the general rules of administrative proceedings and services, the decision shall contain the range of products and the range of individuals affected by the decision.

Liability for damage caused by gene technology activities

Article 27

Gene technology activities may have considerable hazards, therefore to liability for damages originating from such activity the provisions relating to the damage originating from hazardous operations of the Civil Code shall apply.

Article 28

In case the gene technology user ceases to exist without a legal successor, the provisions related to environmental protection criteria of the Act on bankruptcy, liquidation proceedings and winding-up proceedings shall apply *mutatis mutandis* during the liquidation or final accounting procedure in order to reveal and mitigate the damage potentially caused by said activity.

Financial coverage for the official tasks specified in this Act

Article 29

(1) Issuing the authorisations, as well as taking the measures specified in Articles 21 through 25 and Articles 36 and 37 and conducting the official procedures are state responsibilities and costs thereof shall be covered from central budget sources.
(2) The establishment and operation of the registration system specified in Articles 19 and 20 as well as the information supply shall be financed in part from the central budget.

Education, Training, Information

Article 30

In the course of fulfilling state tasks, the Government shall ensure that the users and consumers of genetically modified organisms are informed on the essential aspects and applications of gene technology, as well as on the environmental, health, economic and social effects and risks of the use of these modified organisms within the framework of the education, training and information supply in and outside the school system.

Article 31

Upon request, the authority specified in Article 4(1)(b) shall issue a certificate regarding the genetically modified plant varieties approved for public production in Hungary, or, in the absence thereof, regarding the fact of this absence. This official certificate cannot be used to certify the free status from genetically modified organisms of

the given lot intended for seed, vegetative propagating material, and food or feed purposes. This fact shall also be included as a text in the official certificate.

Article 31/A

The environmental, agricultural and industrial Gene Technology Authority shall organise non-school based training programs of official nature and examinations with regard to the co-existence, covering a general understanding of genetically modified plants, the production conditions prevailing in Hungary, legal aspects, and special cultivation technological and environmental considerations.

Chapter V

MISCELLANOUS AND FINAL PROVISIONS

Entry into force

Article 32

This Act shall enter into force on 1 January 1999.

Article 33

(1)
(2)
(3)

Authorisations

Article 34

(1)The Government is hereby authorised to regulate in a decree
a) the range of those natural organisms that shall not be genetically modified,
b) the authorization procedure of the gene technology activity as well as the liaison with the European Commission and the Member States
c) in case of products for direct processing, the identification of the threshold of technically unavoidable contamination by authorised genetically modified organisms under which the requirements related to the placing on the market, labelling and packaging of genetically modified organisms shall not apply,
d) in case of products for food or feed uses, or for processing, the genetically modified organisms having a favourable risk assessment outcome, the transitional measures related to adventitious and technically unavoidable occurrence of genetically modified organisms,
e) in relation to authorising releases for the purposes other than placing on the market, the cases, range and rules of conducting the assessments necessary for an evaluation of the environmental effects, as well as the rules of providing samples,
f) the amount of the gene technology penalties and the detailed rules of imposing such penalties
g) the rules of transboundary movements of genetically modified organisms.
(2) The Government shall be authorised to issue a decree to designate
a) the Gene Technology Authority and the Special Technical Authority involved in the procedures for authorising gene technology activities,
b) the Authority or Authorities Entitled to Control the gene technology activities,
c) the Cultivation Authority,
d) the Authority or Authorities Entitled to Control the Co-existence,
e) the Registering Body or Bodies,
f) the national information centre or centres, the authority or authorities discharging the responsibilities specified in the Cartagena Protocol on Biosafety signed on 24 May 2000 in Nairobi, as announced by Act No. CIX. of 2004, as well as the control authorities.
(3) In agreement with the Minister responsible for nature conservation, the Minister responsible for healthcare shall be authorised to adopt a decree to lay down the special technical rules and the technical, technological, environmental and nature conservation conditions of gene technology activities related to human-health, production of human medicines, and chemicals in contact with the human body (4) The Minister responsible for healthcare shall be authorised to adopt a decree to lay down the rules of, falling under the scope of the Healthcare Gene Technology Authority, *a)* the registering and supplying data as well as the documentation which shall be enclosed in the notification regarding the gene technology activity,

b) official control related to the gene technology activity , and the detailed rules of the measures that may be applied pursuant to this Act.
(5) The Minister responsible for agricultural policies shall be authorised to adopt a decree to lay down – in agreement with the Minister responsible for healthcare –
a) the technical rules of gene technology activities pursued in the agricultural and in the food sector (including process additives used in food production), in contained uses, and in other industrial fields, as well as the technical, technological, environmental, nature conservation and health-related conditions required to pursue such activities,
b) the procedures considered as genetic modification and those not considering as genetic modification.
(6) In agreement with the Minister responsible for healthcare and the Minister responsible for taxation policies, the Minister responsible for agricultural policies shall be authorised to adopt a decree to lay down the level of the administrative authorisation fees to be paid during the procedure of the Gene Technology Authority and the Cultivation Authority, and the rules of paying said fees.
(7) In agreement with the Minister responsible for taxation policies, the Minister responsible for agricultural policies shall be authorised to adopt a decree to lay down the level of the fees of official training programs and examinations related to the coexistence, and the rules of paying said fees.
(8) The Minister responsible for agricultural policies shall be authorised to adopt a decree to lay down
a) the rules of the registering and supplying data related to gene technology activities falling under the scope of action of the Environmental, Agricultural and Industrial Gene Technology Authority, as well as the contents of documentation which shall be enclosed in the application regarding the gene technology activity,
b) the rules of official control related to the gene technology activity falling under the scope of action of the Environmental, Agricultural and Industrial Gene Technology Authority, and the detailed rules of the measures that may be applied pursuant to this Act,
c) the technical rules and conditions of the coexistence, the minimum size of the buffer zone and the rules of the control of the coexistence,
d) the requirements related to the training programs and examinations regarding the coexistence,
(9) The Minister responsible for agricultural policies shall be authorised to adopt a decree to specify the list of genetically modified organisms as or in products which are under safeguard clause, and to specify the safety measures necessary for the duration of the safeguard clause.
(10) In agreement with the Minister responsible for Research and Development and Technological Innovation, with the Minister responsible for education and with the Minister responsible for healthcare, the Minister responsible for agricultural policies shall be authorised to adopt a decree on detailed rules of the organization and the activity of the Gene Technology Committee.

Article 35

Transitional provisions

Article 36

The Minister responsible for agricultural policies shall be authorised to issue a decree specifying the list of genetically modified organisms as or in a product affected by a safeguard clause ongoing at the time of the entry into force of Act No. LXXIV. of 2012 on the amendment of Act No. XXVII of 1998 on gene technology activities (hereinafter referred to as the "Amended Act") and the safety measures of Article 11./B. (3) (b) required in connection thereto as specified by the Amended Act.

Article 37

Compliance with the relevant European Union law

Article 38

(1) This Act ensures compliance with
a) Directive 2001/18/EC 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,
b) Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market,
c) Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified microorganisms.
(2) This Act lays down the provisions required for the implementation of the following European Union acts:
a) Article 18 of Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms,

b) Articles 5(2), 17(2), 29(1), 30(6) and (7), and 45 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed,
c) Articles 4(6) through 4(8), 9(1) and 11 of Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.