HUNGRÍA

LAW ON BIOTECHNOLOGY ACTIVITIES OF MARCH 16th, 1998*

CHAPTER I
GENERAL PROVISIONS

Scope of the Act

Article 1

(1) This Act shall apply to the genetic modification of natural organisms, to the contained use, to the deliberate release into the environment, to the commercialization, to the import, to the export and to the transportation of genetically modified organisms and products thereof (hereinafter referred together as biotechnology activity).

(2) In case of the modification of human genes and genome the provisions set forth in the Act on Public Health shall apply.

(3) For game or protected natural organisms the provisions of this Act shall apply with regard to the provisions of the Act on Nature Protection.

(4) Protected organisms shall not be modified by biotechnology. Protection of certain species shall not be changed due to biotechnology related reasons.

Definitions

Article 2

For the purpose of this Act:

a) "Natural organism" is any biological entity, with the exception of humans, which is capable of replication or of transferring the genetic material;

b) "Genetic engineering" means a method by which a gene or any part thereof is removed from a cell and transplanted into another cell, and hence the natural genetic material or any part thereof alters.

c) "Genetically Modified Organism" means an organism in which the genetic material has been altered by genetic engineering, including the offspring of such organisms to which the characteristics developed due to such engineering have been passed on.

d) "Contained use" means any place which eliminates the contact of genetically modified organisms, or any part thereof, or products thereof with the environment and their escape into the environment.

e) "Experiment" means any form of genetic engineering carried out on any organism in contained use in favor of scientific development, which does not support the direct production. Gene engineering carried out for research purposes shall be regarded as experiment.

f) "Deliberate release" means any intentional introduction into the envi-

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ronment of genetically modified organisms, or any part thereof, or a combination of genetically modified organisms. Genetic modification carried out in non-contained use, as well as the non-contained use of a genetically modified organism shall be regarded as deliberate release.

g) "Commercialization" means any distribution of genetically modified organisms or the products derived therefrom to agricultures, to processes, to retailers, to consumers or to other users.

h) "Neutralization" means the mitigation of the environmentally polluting effect of wastes and of waste components, exclusion or elimination of their environmentally damaging effects by isolating them from the elements of the environment, or by changing their material quality.

i) "User" means a natural person, legal entity or business association without having a legal entity which sets up a biotechnology laboratory, modifies natural organisms by biotechnology, engages in the contained use, deliberate release into the environment of genetically modified organisms and products derived therefrom or places them into the market.

CHAPTER II
PERMITTING AND REGISTRATION

Biotechnology Permits

Article 3

(1) A permit shall be obtained for:

a) The establishment of a biotechnology laboratory.

b) The genetic modification of natural organisms, with the exception of experimental modification.

c) The contained use, the deliberate release into the environment, the commercialization, the import and the export of genetically modified organisms and products derived therefrom, with the exception of contained use for research purposes.

(2) Permit shall not be issued for the genetic modification of natural organisms specified by the Government in a separate law.

Biotechnology Authorities

Article 4

(1) The establishment of biotechnology laboratories shall be authorized taking into consideration the opinion of the Committee for Evaluating Biotechnology Procedures (hereinafter referred as Biotechnology Committee).

a) By authorities specified by the Government in a separate law if the genetically modified organism is to be used in the field of human health care, human pharmaceutics or cosmetics.

b) By authorities specified by the Minister of Agriculture in a separate law if the genetically modified organism is to be used for the purpose of plant cultivation, plant protection, animal husbandry, food or fodder production.

c) By authorities specified by the Minister of Industry, Trade and Tourism in a separate law if the genetically modified organism is to be used for purposes not listed in items a) and b).

(2) The genetic modification of natural organisms, with the exception of modifications for experimental purposes, shall be authorized taking into

consideration the opinion of the Biotechnology Committee.

a) by authorities specified by the government in a separate law if the genetically modified organism is to be used in the field of human health care, human pharmaceutics or cosmetics, or for the production of chemicals that get into direct contact with the human body, or as processing aid in food production.

b) By authorities specified by the minister of Agriculture in a separate law if the genetically modified organism is to be used for the production of plants, plant protection products, seeds, plant propagation materials as well as microorganisms, animals and animal propagation materials, raw and processed food products, food raw materials, fodder, fodder raw materials, fodder complements and fodder additives.

c) By authorities specified by the minister of Industry, Trade and Tourism in a separate law if the genetically modified organism is to be used for purposes not listed in items a) and b).

(3) Taking into consideration the opinion of the Biotechnology Committee, the contained use, the deliberate release, the commercialization of genetically modified organisms and products derived therefrom, with the exception of contained use for research purposes, shall be authorized.

a) By authorities specified by the government in a separate law if the genetically modified organism is to be used in the field of human health care, human pharmaceutics or cosmetics, or for the production of chemicals that get into direct contact with the human body, or as processing aid in food production.

b) By authorities specified by the minister of Agriculture in a separate law, according to separate laws relating to the given product type, if the genetically modified organism is to be used for the production of plants, plant protection products, seeds, plant propagation materials as well as microorganisms, animals and animal propagation materials, raw and processed food products, food raw materials, fodder, fodder raw materials, fodder complements and fodder additives.

c) By authorities specified by the minister of Industry, Trade and Tourism in a separate law if the genetically modified organism is to be used for purposes not listed in items a) and b).

(4) Taking into consideration the opinion of the Biotechnology Committee, the import and export of genetically modified organisms and products derived therefrom, with the exception of the import and export for research purposes, shall be authorized.

a) By authorities specified by the government in a separate law if the genetically modified organism is to be used in the field of human health care, human pharmaceutics or cosmetics, or for the production of chemicals that get into direct contact with the human body, or as processing aid in food production.

b) By authorities specified by the minister of Agriculture in a separate law if the genetically modified organism is to be used for the production of plants, plant protection products, seeds, plant propagation materials as well as microorganisms, animals and animal propagation materials, raw and processed food products, food raw materials, fodder, fodder raw ma-

terials, fodder complements and fodder additives.

c) By authorities specified by the minister of Industry, Trade and Tourism in a separate law if the genetically modified organism is to be used for purposes not listed in items a) and b).

(5) Authorities specified by the minister of Environmental Protection and Regional Development in a separate law shall agree with the issuance of permits listed in Paragraphs (1) through (4), while authorities specified by the Government in a separate law shall agree with the issuance of permits listed in items b) and c) of Paragraph (1), in items b) and c) of Paragraph (2), in items b) and c) of Paragraph (3), and in items b) and c) of Paragraph (4) in the capacity of special authorities.

(6) Special authorities shall make their decision on the issuance of the permit specified in Paragraph (2), as well as on the issuance of the permits for the contained use, deliberate release, commercialization, import and export of genetically modified organisms within sixty days.

(7) Provisions of a separate law shall apply to the genetic modification of natural organisms for experimental purposes, as well as to the contained use, the import and the export of genetically modified organisms and products derived therefrom for research purposes.

Biotechnology Committee

Article 5

(1) The biotechnology authority shall decide on the application for the permit taking into consideration the opinion of the Biotechnology Committee. The biotechnology authority may reject the application for the permit despite the opinion of the Biotechnology Committee.

(2) The Biotechnology Committee shall consist of representatives appointed by

a) The Hungarian Academy of Sciences.

b) The minister of Agriculture.

c) The minister of Industry, Trade and Tourism.

d) The minister of Environmental Protection and Regional Development,

e) The minister of Culture and Education.

f) The Minister of Public Welfare.

g) The managing director of the National Committee for Technological Development, as well as of representatives elected by.

h) Social organizations of environmental and health protection purposes in a way determined by these organizations.

The professional interest organization of the user shall also attend the sessions of the Biotechnology Committee with the right to participate in the discussions. The operational conditions of the Biotechnology Committee shall be provided for by the minister of Agriculture, who shall ask the members of the Biotechnology Committee for the participation in the work of the Committee.

(3) Members of the Biotechnology Committee shall not be civil servants of the ministries. Members of the Biotechnology Committee shall not have neither direct, nor indirect financial interest in biotechnology activities.

(4) The president of the Hungarian Academy and Sciences shall delegate

five, the ministers and the managing director of the National Committee for Technological Development shall delegate one representative each, the social organizations of environmental protection purpose shall altogether delegate four representatives, and the social organizations of health protection purpose shall altogether delegate two representatives to the Biotechnology Committee.

(5) The Biotechnology 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.

(6) Other rules regarding the organization and operation of the Biotechnology Committee shall be specified in a separate law.

Permit Fee and Validity

Article 6

(1) Applications for permits specified in article 3 shall be submitted to the biotechnology authority by the user. Responsibilities and rights specified in the permit shall be assumed and exercised by the user.

(2) Fee (hereinafter referred as permit fee) specified in a separate law shall be paid when applications for the permits specified in article 3 and applications for renewing permits are submitted.

Article 7

(1) Taking into consideration the opinion of the Biotechnology Committee, the biotechnology authority shall grant permits specified in Paragraphs (1)-(4) of Article 4 for five years, but these permits shall be renewed annually in compliance with the provisions specified in a separate law.

(2) After the expiration date the permit can be renewed upon payment of the permit fee, if the activity described in Paragraphs (1) through (4) of article 4 complies with the provisions of this Act and of separate laws.

(3) When evaluating the application for renewing permits, the biotechnology authority shall, within eight days following receipt of the renewal application, forward the documentation attached to the renewal application, as well as the documentation attached to the original permit application to the Biotechnology Committee for review. Depending on the results of the review, the Biotechnology Committee shall form an opinion on the application and shall forward this opinion to the biotechnology authority within thirty days following receipt of the application. The biotechnology authority shall decide on the renewal of the permit on the basis of the opinion of the Biotechnology Committee.

(4) If there are such professional and scientific reasons, the biotechnology authority and the Biotechnology Committee shall evaluate the application for renewing permits according to the provisions of articles 8-14.

Article 8

(1) Applications for permits together with the documentation specified in a separate law shall be submitted to the biotechnology authority. The biotechnology authority shall:

a) Examine whether the format and content of the application complies with the provisions of this Act and of the separate laws.

b) Forward the application and the documentation specified in a separate law to the Biotechnology Committee.

(2) The Biotechnology Committee shall:

a) Examine the documentation specified in item b) of Paragraph (1).

b) Evaluate the risks posed by the activity described in the application.

c) accept the results of environmental and biological impact assessments conducted in the member states of the European Union, but, in well justified cases, it shall recommend to the biotechnology authority to carry out further control experiments and examinations, including especially environmental and biological impact assessments.

d) Concludes an opinion on approving, conditionally approving or opposing the activity described in the application.

(3) To fulfill the tasks specified in Paragraph (2) the Biotechnology Committee may also ask for an expert's opinion.

(4) When preparing the opinion, the Biotechnology Committee shall in compliance with Paragraph (2) study the effects of the use of genetically modified organisms, including especially concomitant changes in the human and natural organisms, primarily in the DNA structure and resistance, the transfer material (vector) used for the generation of new traits as well as its effect on the generation and insertion of the new material into the human and other natural organisms, with special regard to health risks, concomitant changes in the populations of natural organisms, with special regard to the possibility of spontaneous crossing and its effect on biodiversity, the new effect originating from the natural change.

(5) Costs of the control experiments and examinations mentioned in item c) of Paragraph (2) shall be borne by the user. Costs of the participation of experts specified in Paragraph (3) shall be covered from the budgetary allocation of the Ministry of Agriculture.

Genetic Modification, Contained Use

Article 9

(1) The biotechnology authority shall decide on the application for a permit for the genetic modification of natural organisms, as well as for the contained use of genetically modified organisms and products derived therefrom within ninety days following receipt of such application. This deadline shall be extended with the time necessary for the control experiments and examinations; however, it shall not be later than the thirtieth day following the completion of the examinations.

(2) The biotechnology authority shall forward the application, within five days after it is received, to the Biotechnology Committee upon the fulfillment of tasks specified in item a) of Paragraph (1) of Article 8 or it shall notify the applicant that the application fails to comply with the relevant legal regulations, and shall return the application to the applicant for correction.

(3) The Biotechnology Committee shall forward its opinion on the appli-

cation to the biotechnology authority within thirty days (hereinafter referred as opinion forming deadline) following receipt of the application. Based on the opinion of the Biotechnology Committee, the biotechnology authority shall rule on the approval of the application for a permit within ten days following receipt of the opinion (hereinafter referred as ruling deadline).

(4) The biotechnology authority shall publish the draft permit in its official journal within forty-five days following receipt of the application (hereinafter referred as publishing deadline). Comments on the draft permit can be submitted to the Biotechnology Committee and to the biotechnology authority within thirty days after the publication of the draft permit (hereinafter referred as commenting deadline). The Biotechnology Committee shall examine the comments within ten days following receipt thereof and forward its opinion to the biotechnology authority (hereinafter referred as forwarding deadline). On the basis of the opinion of the Biotechnology Committee, the biotechnology authority shall finalize or amend the draft permit, or reject the application within five days following receipt of the opinion (hereinafter referred as decision-making deadline).

(5) The biotechnology authority shall publish an announcement in its official journal on the permit for the genetic modification of natural organisms, as well as for the contained use of genetically modified organisms and products derived therefrom. In the announcement the authority shall also indicate the name of the entity engaged in genetic modification, the name of the user, the permit number, the object of utilization, the genes used for genetic modification, as well as the social benefits and potential risks inherent in the genetic modification.

(6) When calculating the five-day period mentioned in Paragraph (2), the time during which the biotechnology authority is awaiting additional information from the applicant shall not be considered.

Article 10

(1) Activities aiming at the genetic modification of organisms can only be pursued by users fulfilling the technical, technological, environmental, nature protection and health requirements specified in a separate law.

(2) Within the users' organization, activities aiming at the genetic modification of organisms can be pursued independently only by persons having a university degree and scientific experience in the given field.

Release, Marketing

Article 11

(1) The biotechnology authority shall decide on the application for a permit for the release or commercialization of genetically modified organisms and products derived therefrom within one-hundred-eighty days following receipt of the application.

(2) During the evaluation of the application by the authority, the provisions of article 9 shall apply with the exception that:

a) The opinion forming deadline specified in paragraph (3) of article 9 shall be one-hundred days, and the ruling deadline shall be fifteen days.

b) The publishing deadline specified in Paragraph (4) of article 9 shall be one-hundred-twenty days, the commenting deadline shall be forty days, the forwarding deadline shall be fifteen days and the decision-making deadline shall be five days.

(3) The biotechnology authority shall publish in its official journal the permit for the release or commercialization of genetically modified organisms, and products derived therefrom, and it shall indicate the name of the releasing and commercializing organization, the permit number, the object of release and commercialization, as well as the genes used for genetic modification. The announcement shall also indicate to what extent the product contains genetically modified organisms.

Package Labeling

Article 12

(1) The producer, distributor shall indicate on the packaging of the product consisting of or fully or partially containing genetically modified organisms, as well as on the product's quality certificate that the product contains genetically modified organism. If the product was produced from genetically modified organism, however it does not contain genetically modified organisms the producer, distributor shall indicate the fact of gene engineering on the packaging of the product and on the product's quality certificate. The label shall show what genetically modified organism the product contains, or from what genetically modified organism it was derived from.

(2) In other aspects the commercialization and labeling of genetically modified organisms and products fully or partially containing of such organisms shall be governed by provisions specified in a separate law.

(3) The group of products to be such labeled, the content and method of labeling, as well as the date for the application of the provisions relating to the labeling shall be specified in a separate law by the minister competent in the given product group.

(4) In terms of Paragraph (1), products shall include, apart from other things, plants and plant protection materials, seeds and plant propagation materials, animals and animal propagation materials, food products, food raw materials, fodder, fodder raw materials, fodder complements and fodder additives.

Import, Export

Article 13

(1) The biotechnology authority shall decide on the application for the permit for the import or export of genetically modified organisms, or products derived therefrom within sixty days following receipt of the application.

(2) The evaluation of the application by the authority shall be governed by the provisions of article 9, with the exception of the fact that after the fulfillment of the tasks specified in paragraph (3) of article 9, the biotechnology authority shall send its ruling on the application for the permit to the applicant within three days after such ruling is made, and that Paragraphs (4) and (5) of article 9 shall not apply.

(3) Concurrently with the notification of the applicant about its ruling, the biotechnology authority shall publish an announcement in its official journal on the permit for the import of genetically modified organisms or products derived therefrom, indicating the name, brand name, producer, importer and distributor of the imported genetically modified organism or of the product derived therefrom.

Separate Permits

Article 14

(1) The issue of permits for genetically modified organisms, specified in separate laws, especially the state registration of genetically modified plant species, as well as the state registration of genetically modified animal species, can only take place after the completion of the permitting procedure specified in articles 8 through 13.

(2) In contrast to Paragraph (1), permits for the commercialization of genetically modified organisms and products derived therefrom can be issued only after the state registration of genetically modified plant species, the state registration of genetically modified animal species or the state quality control and registration of products derived from genetically modified organisms, specified in separate laws.

(3) For the purpose of agricultural production, the contained production of products derived from genetically modified organisms can be authorized under conditions specified in a separate law, however, commercialization of genetically modified organisms as new species can only be authorized after the fulfillment of the provisions specified in Paragraph (2).

(4) If the Biotechnology Committee requires the biotechnology authority to perform environmental and biological impact assessments in compliance with item c) of Paragraph (2) of article 8 for the evaluation of the application for permit, permits for the release and commercialization of genetically modified organisms and products derived therefrom can only be issued after the issuance of separate permits specified in a separate law.

(5) When calculating the deadline for the permitting procedure for the commercialization of genetically modified organisms and products derived therefrom, the period of the state registration of genetically modified plant species, the state registration of genetically modified animal species, as well as the state quality control and registration required by separate laws of products derived from genetically modified organisms shall not be considered.

Transportation

Article 15

(1) In order to ensure the safety of biotechnology activities and to protect the environment, the biotechnology authority may prohibit, or specify the conditions for the transportation of genetically modified organisms and products derived therefrom in the permit issued in pursuance of Paragraphs (3) and (4) of article 4.

(2) If the genetically modified organisms and the products derived therefrom are regarded hazardous under

a separate law, for the transportation thereof the provisions of a separate law shall apply.

Establishment of Biotechnology Laboratory

Article 16

(1) The biotechnology authority shall rule on the application for a permit for the establishment of a laboratory performing genetic modification within forty-five days following receipt of the application.

(2) In other aspects, the application for a permit for the establishment of a laboratory performing genetic modification shall be evaluated by the authority in compliance with the provisions of article 9, with the exception that the biotechnology authority within ten days following receipt of the opinion of the Biotechnology Committee shall rule on the application for a permit and shall forward its ruling to the applicant, and that Paragraphs (4) and (5) of article 9 shall not apply.

Waste Management

Article 17

(1) Based on the opinion of special authorities, the biotechnology authority, to study environmental risks, may require the preparation of a biological impact assessment relating to the wastes generated upon the biotechnology activity or the death and neutralization of genetically modified organisms and products derived therefrom, and to the treatment thereof. The biotechnology authority may call for the preparation of a biological impact assessment, the marking, treatment, transportation and neutralization of waste materials in the permit for genetic modification, the contained use, release, or commercialization of genetically modified organisms and products derived therefrom, or in the permit for the import, export of genetically modified organisms and products derived therefrom. The biological impact assessment shall be prepared by both the user or the neutralizer. Waste materials shall be marked, treated, transported and neutralized in compliance with the procedure described in the permit.

(2) In case of genetically modified organisms that can be used as raw materials or additives in food production in compliance with the permit issued by the biotechnology authority, the provisions specified in Paragraph (1) shall not apply. Such organisms shall be treated in compliance with the procedure specified in a separate law.

(3) The treatment, transportation and neutralization of wastes originating from biotechnology activities and regarded hazardous under a separate law, shall be governed by the provisions of a separate law.

Biotechnology Inspector

Article 18

To pursue their activities, users shall employ a biotechnology inspector (hereinafter referred as inspector). The inspector shall control that the user complies with the provisions of this Act and a separate law, and shall assist in securing that the user's activity should not be hazardous for the human health and the environment.

Registration Procedure

Article 19

(1) Genetic modifications used in plant cultivation, plant protection, animal husbandry, food production, fodder production, the industry and other fields of use, as well as information on the contained use, release and commercialization of genetically modified organisms and products derived therefrom, and the lists of laboratories engaged in genetic modification and of the heads responsible for such laboratories shall be registered by an agency (hereinafter referred as registration agency) appointed by the minister of Agriculture.

(2) Part of the information registered in compliance with Paragraph (1) that refers to the release and commercialization of genetically modified organisms, as well as the lists of laboratories engaged in genetic modification and of the heads responsible for such laboratories shall be regarded as information of public interest.

Article 20

(1) The biotechnology authority shall forward the permits for the genetic modification of natural organisms, as well as for the contained use, release and commercialization of genetically modified organisms and products derived therefrom, and the related documentation to the registration agency.

(2) The rules relating to the registration and accessibility of information listed in Article 19, and the fee for data shall be specified in a separate law.

(3) The registration agency shall provide information to the Biotechnology Committee and the biotechnology authority free of charge.

Article 21

(1) The biotechnology authority shall prepare annual reports for the Biotechnology Committee on the control of the contained use, release and commercialization of genetically modified organisms and products derived therefrom.

(2) The Biotechnology Committee shall prepare annual summary reports on the basis of the reports specified in Paragraph (1), and shall publish such reports in the official journal of the Hungarian Academy of Sciences.

CHAPTER III
SUPERVISION AND MEASURES TAKEN BY THE AUTHORITIES

Article 22

The genetic modification of natural organisms, the contained use, release, commercialization, import and export of genetically modified organisms and products derived therefrom shall be supervised by the biotechnology authority at the scene of the biotechnology activity.

Revoking the Permit

Article 23

(1) The biotechnology authority shall, e*x officio* or upon the recommendation of the special authorities participating in the permitting procedure, revoke the permit from the producer, user, releasing organization, distributor, importer or exporter ordering the immediate termination of the activity, or impose a biotechnology fine, if the genetic modification of the natural or-

ganisms, the contained use, release, commercialization, import and export of genetically modified organisms and products derived therefrom violate the provisions specified in this Act, in separate laws or in the permit, especially if the biotechnology activity poses a threat to the environment and to the human health.

(2) The biotechnology authority shall immediately notify the registration agency and the special authorities participating in the permitting procedure on the revocation of the permit specified in paragraph (1).

Article 24

(1) Against entities that damage human health, the environment and nature including especially protected natural territories by means of the genetic modification of natural organisms, the contained use, release and commercialization of genetically modified organisms, the provisions specified in separate laws shall apply.

(2) For the protection of the nature, the biotechnology authority may order users to set up a genetic protection zone specified in a separate law.

Restriction and Prohibition of Biotechnology Activity

Article 25

(1) If any new information on the risks inherent in the activity permitted under this Act including especially information according to which the activity poses a threat to human health and to the environment becomes available to the biotechnology authority, the biotechnology authority may restrict or prohibit the activity. The biotechnology authority shall notify the Biotechnology Committee on the measures and reasons thereof immediately after the measures are taken.

(2) The Biotechnology Committee shall comment on supporting the measure specified in Paragraph (1) and shall forward its opinion to the biotechnology authority within thirty days following receipt of the notification of such measure. The biotechnology authority shall decide on supporting the measure taking into consideration the opinion of the committee.

(3) If the activity is prohibited, following receipt of the opinion of the Biotechnology Committee on supporting the measure, the biotechnology authority shall order the immediate destruction of the genetically modified organisms. Destruction shall be carried out at a place specified by the biotechnology authority and shall be supervised by said authority.

(4) The deadline specified in Paragraph (2) shall be extended with the time needed for the study considered essential by the Biotechnology Committee to make a decision.

(5) If the user applying for, or holding a permit has a new information specified in Paragraph (1) on the genetically modified organism described in the application, he shall immediately report such information to the biotechnology authority. Concurrently, the user shall immediately take safety and other measures required for the new circumstances relating to the genetically modified organism that have emerged as a result of the new information. The biotechnology aut-

hority shall proceed in compliance with the provisions of Paragraph (1) following receipt of such notification. The user shall review, amend if necessary and forward the documentation submitted with the application for a permit to the biotechnology authority within fifteen days after forwarding the notification.

Article 26

Authorities appointed in pursuance of article 4 by the Government, the minister of Agriculture, the minister of Industry, Trade and Tourism, and the minister of Environmental Protection and Regional Development, shall mutually participate as special authorities in the legal procedures specified in Articles 22 through 25.

Liability for Damages Originating from Biotechnology Activity

Article 27

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

Article 28

In case the biotechnology user ceases to exist without a legal successor, in order to discover and mitigate possible damages caused by the activity, the provisions relating to the environmental protection of the Act on bankruptcy proceedings, liquidation proceedings and final accounting procedures shall appropriately apply during the liquidation or final accounting procedure.

Financial Coverage for Tasks Specified in This Act

Article 29

(1) Permit issuance, as well as taking measures and proceedings by the authority specified in Articles 21 through 25 and Articles 36 and 37 are state tasks and the costs thereof shall be funded from the central budget.

(2) The establishment and operation of the registration system specified in Articles 19 and 20, as well as the information supply shall be funded in part from the central budget.

Education, Training, Information

Article 30

In the course of fulfilling state tasks, the Government shall ensure that within the framework of school and not school based education, training and information supply the users and consumers of genetically modified organisms receive information about the essence and applications of biotechnology as well as about the environmental, health, economic and social effects and risks of the use of organisms modified in this manner.

Article 31

The provisions of the Act on the general rules of public administration procedures shall apply with regard to the different provisions specified in this Act.

CHAPTER IV
MISCELLANEOUS AND CLOSING PROVISIONS

Effective Date

Article 32

This Act enters into force on January 1, 1999.

Laws Amending

Article 33

(1) Simultaneously with the effectuation of this Act Paragraph (1) of Article 14 of the Law Decree num. 2 of 1988 on plant protection shall be amended as follows:

"(1) Plant protection products, biological plant protection products or products serving the purpose of plant protection, but not regarded as plant protection or biological plant protection products, growth enhancing materials, products derived from the different development stages of *articulata* of the parasite and predatory type, as well as equipment serving the purpose of plant protection (hereinafter referred together as product subject to permitting) can be commercialized and used for domestic purposes in compliance with the provisions specified in the permit for commercialization and use (hereinafter referred as permit) of the ministry, specified in a separate law and issued with regard to the opinion of the Ministry of Public Welfare and the Ministry of Environmental Protection and Regional Development".

(2) Simultaneously with the effectuation of this Act, Article 20 of Act XCI of 1995 on animal health shall be completed with the following Paragraph (2), and at the same time numbers of Paragraphs (2) and (3) shall change to Paragraphs (3) and (4):

"(2) Veterinary products containing genetically modified organisms can be produced, tested, imported, commercialized and used only in compliance with the provisions of the separate law".

(3) Simultaneously with the effectuation of this Act.

a) Item 16 of Article 2 of Act XC of 1995 on foodstuffs shall be replaced with the following provision:

"Item 16 novel food: processed food, raw food or food raw material not yet used for public consumption in the country.

a) In course of the production thereof a new process triggering significant changes in the composition of the food has been applied and that process affects the nutritional value, digestibility of the food or the level of undesirable substances in the food.

b) Which contains or consists of genetically modified organisms.

c) Which was produced from a genetically modified organism, but not containing such organism.

d) The primary molecular structure of any ingredient thereof is new, or has been intentionally modified.

e) Which consists of microorganisms, fungi or algae, or has been isolated therefrom.

f) which consists of plants grown with untraditional methods or which is isolated from plants grown with untraditional methods and has no history of safe food use, or which consists of raw material of animal origin isolated from animals bred with untraditional

methods and has no history of safe food use".

b) Article 19 of Act XC of 1995 on foodstuffs shall be completed with the following Paragraph (2), and at the same time number of Paragraph (2) shall change to Paragraph (3):

"(2) Apart from the information specified in Paragraph (1), the following information shall be visibly indicated on the packaging of novel foods, or on the sales premises in case of unpacked novel food, as well as in the accompanying document of food raw materials:

a) The food differs from existing, traditional foods in terms of compositional, perceptional and nutritional characteristics or of method of use, indicating the different compositional, perceptional and nutritional characteristics or method of use, as well as the process, method triggering such difference.

b) The food contains an ingredient which is not present in any existing traditional food and which may affect the health of certain groups of the population.

c) the food contains an ingredient which is not present in any existing traditional food and which may raise ethical problems in certain groups of the population that follow certain eating practices.

d) The food contains an organism produced by genetic modification specified in a separate law".

Empowerment

Article 34

Empowerment shall be granted

(1) To the Government to regulate in the form of a decree the application and use of living genetically modified organisms in human health care and pharmaceutics, the environmentally safe transportation of such organisms, the group of products to be labeled, the content and method of labeling, as well as the date after which such labeling provisions shall apply. The Government shall also regulate the technical, technological, environmental and nature protection, and sanitary conditions essential for pursuing biotechnology activities in human health care and pharmaceutics, and shall appoint the permit issuing authorities specified in item a) of paragraph (1) of article 4, in item a) of paragraph (2) of article 4, in item a) of Paragraph (3) of Article 4 and in item a) of paragraph (4) of article 4, as well as the participating authorities specified in paragraph (5) of article 4.

(2) To the Government to specify in a decree those natural organisms that shall not be genetically modified;

(3) To the minister of Agriculture, so that he shall, in agreement with the minister of Environmental Protection and Regional Development, the minister of Industry, Trade and Tourism, the minister of Transport, Communication and Water Management and the minister of Public Welfare, regulate in the form of a decree the production, contained use and release of genetically modified organisms for agricultural and food production purposes, the creation of a genetic protection zone, the environmentally safe transportation and commercialization of genetically modified organisms, the group of products to be labeled, the content and method of labeling, as well as the date after which said labeling provisions shall apply. Said minister shall also re-

gulate the technical, technological, environmental and nature protection, and sanitary conditions essential for pursuing biotechnology activities for agricultural and food production purposes and shall appoint the permit issuing authorities specified in item b) of paragraph (1) of article 4, in item b) of paragraph (2) of article 4, in item b) of paragraph (3) of article 4 and in item b) of paragraph (4) of article 4.

(4) To the minister of Industry, Trade an Tourism, so that he shall, in agreement with the minister of Agriculture, the minister of Environmental Protection and Regional Development, the minister of Transport, Communication and Water Management and the minister of Public Welfare, regulate in the form of a decree the industrial use not governed by the provisions of the decrees specified in Paragraphs (1) and (3) and the environmentally safe transportation of genetically modified organisms, the group of products to be labeled, the content and method of labeling, as well as the date after which said labeling provisions shall apply. Said Minister shall also regulate the technical, technological, environmental and nature protection, and sanitary conditions essential for pursuing biotechnology activities for industrial purposes, and shall appoint the permit issuing authorities specified in item c) of paragraph (1) of article 4, in item c) of paragraph (2) of article 4, in item c) of paragraph (3) of article 4 and in item c) of paragraph (4) of article 4.

(5) To the Minister of Industry, Trade an Tourism, so that he shall, in agreement with the minister of Agriculture, the minister of Environmental Protection and Regional Development, and the minister of Public Welfare, regulate in the form of a decree the import and export of genetically modified organisms.

(6) to the minister of Agriculture, so that he shall, in agreement with the minister of Industry, Trade and Tourism, the minister of Environmental Protection and Regional Development, the minister of Culture and Education, the minister of Public Welfare, as well as the President of the Hungarian Academy of Sciences, specify in the form of a decree the detailed rules of the organizational structure and operation of the Biotechnology Committee.

(7) To the minister of Culture and Education, so that he shall, in agreement with the minister of Agriculture, the minister of Industry, Trade and Tourism, the minister of Environmental Protection and Regional Development, as well as the minister of Public Welfare, specify in the form of a decree the rules relating to the scope of activities and qualifications of the biotechnology inspector.

(8) to the Minister of Agriculture, so that he shall, in agreement with the minister of Industry, Trade an Tourism, and the minister of Public Welfare, regulate in the form of a decree the order of registration of and data supply on the production, contained use, release and commercialization of genetically modified organisms, the fee to be paid for data, as well as the content of the documentation to be attached to the application for a biotechnology permit.

(9) To the minister of Agriculture, so that he shall, in agreement with the minister of Industry, Trade and Tourism, the minister of Public Welfare, and the minister of Finance, regulate in the form of a decree the permit fees.

(10) To the Government, so that it shall regulate in the form of a decree the biotechnology fine specified in article 23.

Approximation to the Laws of the European Communities

Article 35

In compliance with the provisions relating to the legal approximation of the Europe Agreement establishing an association between the Republic of Hungary and the European Communities and their Member States, signed in Brussels on 16 December 1991 and declared with Act I of 1994, this Act contains regulations compatible with the following laws of the European Communities:

a) Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

b) Council Directive 90/220/EEC completed with Commission Decision 92/146/EEC, and amended with Commission Directive 94/15/EC and Commission Decision 94/211/EC on the deliberate release into the environment of genetically modified organisms.

Provisional Measures

Article 36

(1) Simultaneously with the effectuation of this Act, natural organisms that were genetically modified before the effectuation of this Act, as well as genetically modified organisms that were used in contained systems, released into the environment, commercialized or imported to the territory of the Republic of Hungary within the frameworks of external trade, shall also be governed by the provisions of this Act, with regard to the differences specified in Paragraphs (2) through (6) hereunder.

(2) The contained use, release, commercialization or import of genetically modified organisms and products derived therefrom on the territory of the Republic of Hungary before the effectuation of this Act shall be reported by the producer, user, releasing organization, distributor or importer to the biotechnology authority within sixty days after this Act enters into force, with the documentation specified in Paragraph (1) of Article 8.

(3) The biotechnology authority shall check the report within 45 days following receipt of the report. If the genetic modification, or the contained use, release, commercialization or import of genetically modified organisms or products derived therefrom do not comply with the provisions specified in this Act and in separate laws, the biotechnology authority shall issue a resolution on the termination of genetic modification, the contained use, and release into the environment of genetically modified organisms and products derived therefrom, and shall order the concurrent restoration of the original condition of the environment, as well as on the recall and destruction of genetically modified organisms and products derived therefrom.

(4) In the case specified in paragraph (3), genetically modified organisms or products derived therefrom shall be recalled within fifteen days following receipt of the resolution of the biotechnology authority.

(5) The biotechnology authority shall supervise the termination of the

contained use, release, recall and destruction of genetically modified organisms or products derived therefrom, as well as the restoration of the original condition of the environment on the site.

(6) Food packaging materials manufactured before the effectuation of this Act which do not meet the requirements relating to labeling specified in this Act can be used for ninety days after this Act enters into force.

Article 37

(1) The provisions of article 36 shall not apply to the transportation of genetically modified organisms and products derived therefrom.

(2) The operation of any laboratory carrying out genetic modifications established before the effectuation of this Act shall be reported to the biotechnology authority by the founder or the operator within six months after this Act enters into force.

(3) In the laboratory specified in Paragraph (2), the biotechnology authority shall inspect whether the laboratory's operation complies with the provisions specified in this Act and in separate laws. In case of irregularities especially in the case of any severe violation of regulations relating to environmental, occupational health and labor safety the biotechnology authority may oblige the founder or operator of the laboratory to suspend or terminate said activity. The biotechnology authority shall authorize the reopening of the laboratory upon the fulfillment of requirements specified in separate laws. The biotechnology authority shall determine a period or date for the fulfillment of the requirements. After the expiration of said period or date without fulfillment, the biotechnology authority shall oblige the founder or operator of the laboratory to terminate the laboratory's activity.