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from 19 February 2002

on use of genetic technologies and genetically modified organisms

The National Council of the Slovak Republic has passed the following Act:

PART ONE
GENERAL PROVISIONS

Article 1
The scope of regulation

This Act stipulates rights and responsibilities of users using genetic technologies and genetically modified organisms and competence of state administration authorities.

Article 2
Genetic technologies

(1) Genetic technologies shall be activities of genetic engineering and modern biotechnology, which create and use live genetically modified organisms including micro-organisms, parts and products from thereof.

(2) Use of genetically modified technologies:
a) must not restrain biological diversity of wild species, nor affect the balance of natural biological chain of organisms in nature,
b) must not include implementing genes expressing resistance of humans and animals to antibiotics in use for human and veterinary medicine, into products intended for introduction into the environment or placing on the market.

(3) The content of a genetical technology shall be a use of genetic method and genetic technique on a genetic fund[1]) of a living organism.

Article 3
Genetic methods and genetic techniques

(1) Genetic methods and genetic techniques shall be particularly aimed methods and techniques, by which a genetic material of one organism (hereinafter referred to as "donor" only) is inserted into a genetic material of another organism (hereinafter referred to as "recipient" only) using a vector, or by which the part of natural genetic material of an organism is deleted or modified, resulting in genetically modified organism.

(2) Genetic techniques shall be

a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced outside an organism into any virus, bacterial plasmid or other vector system and their incorporation into a recipient in which they do not naturally occur but in which they are capable of continued propagation,

b) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection, micro-encapsulation and other invasive techniques,

c) cell fusion including protoplast fusion and hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells from different families and that do not occur naturally.

(3) Genetic methods and genetic techniques shall not be those, which result in genetic modification
a) without the use of recombinant nucleic acid molecules,
b) by natural processes, in particular in vitro fertilisation, conjugation, transduction, transformation, polyploidy induction, mutagenesis and plant cell fusion using traditional breeding methods or
c) involving the use of organisms genetically modified by
   1. cell fusion of prokaryotic species of microorganisms that exchange genetic material by known physiological processes including protoplast fusion,
   2. cell fusion of cells of any eukaryotic species of microorganisms including protoplast fusion, production of hybridomas and plant cell fusions or
   3. self-cloning consisting in the removal of nucleic acid sequences from a cell, which may be followed by reinsertion of all or part of that nucleic acid or synthetic equivalent with or without prior enzymic or mechanical steps into cells of phylogenetically closely related species which can exchange genetic material by natural physiological processes.

[1]) Article 3 of the Act No. 287/1994 Coll. on nature and landscape protection. The Act No. 194/1998 Coll. on breeding of farm animals and on change and amendment of the Act No. 455/1991 Coll. on trades (trades licensing act) as amended.

(4) Self-cloning shall be a genetic technique, in which the donor and recipient belong to the same biological species. Self-cloning according to paragraph 3 letter c) third point may include the use of recombinant vectors with an extended history of safe use of micro-organisms.

(5) Genetic techniques may be used in genomes of all organisms including micro-organisms; it shall be prohibited to implement them on human genomes.

Article 4
Genetically modified organism

(1) Genetically modified organism shall be an organism, of which genetic material has been altered in a way that does not occur naturally by sexual reproduction and natural recombination.

(2) Organism shall be any biological organism capable of replication or of transferring genetic material in other way. For the purposes of this Act the human organism shall not be considered as the organism.

(3) Micro-organism shall be any cellular or non-cellular entity capable of replication and of transferring genetic material, including viruses, viroids, animal cells and plant cells in culture.

(4) Genetic material shall be deoxyribonucleotic acid or ribonucleotic acid.

Article 5
Environmental risk assessment

(1) Environmental risk assessment (hereinafter referred to as "risk" only) shall be an evaluation of possible harmful effects of genetically modified organisms on humans and environment.[2])

(2) According to the prevention and precautionary principle in an environmental risk assessment, scientifically proved data, available experience and work conducted on international field in use of genetic technologies and genetically modified organisms shall be followed.

(3) An environmental risk assessment shall be carried out for every use of genetic technologies and every use of genetically modified organisms.

(4) The outcome of the risk assessment shall be an opinion in writing, which forms a part of the user's dossier (Article 39)

Article 6
Emergency response plan

(1) Emergency response plan shall be a document in writing, in which the measures and procedures designated for controlling of further spread of leaked genetically modified organisms and for elimination or mitigation of accident effects upon humans and environment are laid down for case of emergency. The emergency response plan shall be drawn up by a user for every use of genetic technologies and for every use of genetically modified organisms.

(2) For the purposes of this Act accident shall mean any incident, in which a leak of genetically modified organisms occurred and which presents a hazard to humans and environment.

(3) The content of emergency response plan shall be drawn up according to the use of genetic technologies, species of leaked genetically modified organisms and level of risk hazard to humans and environment.

(4) The emergency response plan must include the manner of elimination of accident effects, liability for inflicted damage and provision of reimbursement for damage caused therewith.

Article 7
Manners of use of genetic technologies and genetically modified organisms.

(1) Genetic technologies and genetically modified organisms may be used

a) in contained facilities employing containment measures (hereinafter referred to as "contained use" only),
b) in deliberate release without employing containment measures (hereinafter referred to as "deliberate release" only).

(2) Containment measures shall be physical barriers, combined, if appropriate, with biological and chemical barriers and specific control and safety measures designed to prevent the exposure of population and environment to genetically modified organisms.

PART TWO

CONTAINED USE

Article 8
Facilities

(1) Contained use shall be any activity, in which organisms are genetically modified or by which genetically modified organisms are cultivated, stored, transferred, eradicated, disposed of or used in other manner employing protective measures.

(2) The containment rooms shall be laboratories, hothouses, cultivating rooms and other containment facilities preventing the leak of genetically modified organisms in user's research, development or production facilities (hereinafter referred to as "facility" only).

(3) The facility must be entered into the register [Article 24, par. 1 letter d)]. The facility may be entered into the facility register only if complying with construction and technical equipment requirements and requirements concerning its location, internal operational arrangements, laboratory procedures and system of work in

[2]) Article 2 and 9 of the Act No. 17/1992 Coll. on Environment as amended by the Act No. 287/1994 Coll.

contained rooms and the waste handling[3]) and waste water treatment[4]).

Responsibilities of users

Article 9

(1) User shall be any legal or natural person using genetic technologies and genetically modified organisms; it shall not be a final consumer of products placed on the market.

(2) The user shall be obliged to
a) to establish a safety committee for contained use (hereinafter referred to as "safety committee" only) at each facility,
b) to designate a head of the project for each use of genetic technologies and genetically modified organisms.

(3) The task of the safety committee shall be to control the use of genetic technologies and genetically modified organisms in the facility, particularly to check the correctness of the risk assessment and of the risk class assignment, to evaluate the compliance with containment measures corresponding to the assigned class and effectivity of the containment level, review the emergency response plan, cooperate with the head of the project and submit the proposals to the principal employees of the user for performance of measures necessary for remedy of detected shortcomings. The safety committee shall have at least five members, the majority being not the user's employees.

(4) The task of the head of the project is to ensure the safety and protection of health of the employees at work and supervision of the good microbiological practice during the use of genetic technologies and genetically modified organisms and to secure the cooperation with the safety committee.

(5) The user shall appoint
a) as a member of the safety committee only a person with integrity, university education in relevant field and three year experience in using of genetic technologies and genetically modified organisms,
b) as the head of the project only a person with integrity and professional qualification.

(6) For the purposes of this act the person with integrity shall mean a person that has not been convicted of a willful crime or a crime that represents a threat to population or environment,[5]) if the court has not decided on conditional suspension of execution of punishment, the fact, which is to be proved by criminal record abstract not older than three months.

(7) Professional qualification of the head of the project shall mean a university education in relevant field, at least three-year experience in genetic engineering and modern biotechnology and regular participation in professional education.

(8) A user shall be obliged to secure the implementation of following principles as regards the occupational safety and health protection and good microbiological practice in facilities:
a) exposure of facility's workplace to genetically modified microorganisms must be kept to the lowest practicable level
b) protective measures must be exercised at the source of danger and must be supplemented, if necessary according to the containment level corresponding to assignment to risk class, by personal protective equipment,
c) the facility equipment must be maintained adequately to the containment level corresponding to assignment to risk class,
d) in case that failure of containment measures is suspected, the presence of used viable microorganisms outside the primary physical containment must be tested,
e) disinfection and decontamination procedures must be available in case of leak of genetically modified microorganisms from containment facility,
f) effective disinfectants and hygienic and decontamination preparations and mechanisms must be available,
g) local codes of practice for the safety of user's personnel must be formulated and implemented,
h) biohazard signs must be displayed in the facility and its surrounding,
i) the professional education of employees in the facility must be facilitated
j) detailed documentation on activities in the facility must be kept
k) eating, drinking, smoking, applying cosmetics or storing of food for human consumption must be prohibited in the work area
l) mouth pipetting must be prohibited
m) written standard operating procedures must be provided, where appropriate, to ensure safety
n) safe storage for contaminated laboratory equipment and material must be provided.

(9) Documentation according to paragraph 8 letter j) shall include the data on all substantial circumstances concerning the contained use.

Article 10

(1)Prior to the beginning of any contained use the user shall be obliged to

[3]) The Act No. 223/2001 Coll. on waste and on change and amendments of certain acts as amended.

[4]) The Act No. 138/1973 Coll. on water (Water Act) as amended.

[5]) e.g. Articles 181a to 181g of Criminal Code.

a) execute measures for averting of possible harmful effects to humans and environment, that may be resulting from such use,
b) to assess the risk arising from planned contained use, in particular as regards the possible harmful effects to humans and environment,
c) on the basis of result of the risk assessment to assign the prepared use of genetic technology to a risk class (paragraph 3),
d) to provide the level of protection corresponding to the risk class and its relevant requirements on contained use and particular protective measures,
e) to draw up the emergency response plan (Article 6) and make it available via internet, or in other appropriate manner,
f) to provide the substantial information on the content of the emergency response plan to persons likely to be affected in case of accident,
g) to submit a notification (Article 12) or submit an application for consent with contained use (Article 13).

(2) The user must identify the following possible harmful effects in risk assessment:
a) allergenic and toxic effects of genetically modified organisms to humans,
b) effects of genetically modified organisms to animal and plant health,
c) effects causing resistance to antibiotics used in human and veterinary medicine,
d) effects deleterious for providing of effective prophylaxis
e) effects due to the natural transfer of inserted genetic material to other organisms.

(3) The user shall assign any planned contained use to one of the following risk class:
a) risk class 1 – activities of no or negligible risk, for which level 1 containment is appropriate,
b) risk class 2 – activities of low risk, for which level 2 containment is appropriate,
c) risk class 3 – activities of moderate risk, for which level 3 containment is appropriate
d) risk class 4 – activities of high risk, for which level 4 containment is appropriate.

(4) In case of doubt the higher risk class shall be applied to the proposed use, unless the reason for applying lower risk class is justified.

(5) Level of containment shall be a set of containment measures (Article 7 par. 2) and system of work in facility corresponding to the particular risk class according to paragraph 3.

(6) Information on the content of emergency response plan must be updated by the user when changing the contained use, emergency response plan and if issued consent with contained use is being changed. Information provided for persons likely to be affected by accident shall be provided also for the Ministry of Environment of the Slovak Republic (hereinafter referred to as "Ministry" only) as the basis for consultation with authorities of other countries.

(7) The assignment to risk class need not be performed for transport of genetically modified organisms by road, rail, water and air.

Article 11
Review of the assignment

(1)The user shall be obliged during the contained use to regularly review the assignment to risk class. She must reassess it every time he finds out that:
a) the containment measures applied are no longer adequate for the required containment level of user's employees,
b) the assignment to the risk class is no longer adequate to the containment level or it does not correspond any longer to the result of risk assessment,
c) there is reason to suspect that the performed risk assessment is no longer appropriate judged in the light of new scientific knowledge and state of art of genetic methods or techniques.

(2)The review of the assignment must take into account
a) the level of waste disposal and waste water disposal,
b) the content of the genes in genetically modified organisms expressing resistance to antibiotics used in human or veterinary medicine.

(3) The user shall perform containment measures necessary for protection of humans and environment, should the review of assignment prove it to be necessary.

(4) The user shall be obliged to keep the references from risk assessment (Article 5 par. 4) and records from review of the assignment ten years from the day of the assignment to risk class or review of this assignment.

Article 12
Notification

(1)The notifier shall be a person, which has according to this act a duty to make a notification according to paragraph 2 or to submit a request for issuing of consent (Article 13, 17 and 21).

(2) The notifier shall be obliged to notify Ministry on
a) the data on the head of the project and on members of the safety committee, as well as the changes in these data,
b) the commencement of the activity assigned to risk class 1 in facility, for which first consent for contained use has been issued,
c) the commencement of the activity assigned to risk class 2 in facility, for which the consent for contained use in activities assigned to classes 2 to 4 has been already issued and for which all requirements of this consent have been met,
d) the finding out of new information concerning the activities that may have significant impact on risk.

(3) After first notification according to paragraph 2 letter c) the further use of facility for the activities assigned to risk class 1 need not be notified.

(4) The notifier shall be obliged to submit a notification
a) without delay after the reason for notification has arisen and
b) at least seven days before commencement of the activity, should the notification be according to paragraph 2 letter c) and d)

Article 13
Consent for contained use

(1) The consent of the Ministry [Article 24 par. 1 letter b)first point] shall be needed for contained use should it be
a) first use of the facility for genetic technologies,
b) activities assigned to risk class 2, if the consent has been issued only for activities assigned to risk class 1 or if all conditions laid down in issued consent have not been met,
c) activities assigned to risk class 3 and 4,
d) the change of the assignment from risk class 3 or 4 to a lower risk class,
e) the continuation of the activities, which have been suspended upon the inspection of the facility.

(2) Should the containment facility have been used for activities assigned to risk class 2 to 4 on the basis of consent according to paragraph 1 and should all conditions laid down in this consent be met, the notification (Article 12) shall be sufficient for further use for activities assigned to risk class 2 in the facility. The notifier may, however, ask for issue of the consent according to paragraph 1 also in this case.

(3) Should the containment facility have been used for activities assigned to risk classes 2 to 4 without notification (Article 12) or without the consent according to paragraph 1, it may be further used for activities assigned to risk class 2 only upon the consent. However, should the consent be not issued up to 45 days, the containment facility may be used for activities assigned to risk class 2 without this consent, after expiration of 45 days from the day of submission of application for consent.

(4) The activities according to paragraph 1 letter c) to e) may be performed only on the basis of consent for contained use.

Article 14
Emergency procedures

(1) Should the accident have occurred (Article 6 par. 2) the user shall be obliged without delay
a) to submit a notification on emergency to the Ministry,
b) to notice imminently endangered persons in vicinity of the facility and in case of accident with transboundary impact the authorities of endangered countries,
c) to carry out safety measures according to emergency response plan,
d) to provide information on the accident and performed measures to the public in an appropriate manner.

(2) The notice according to par. 1 point b) shall include
a) the description of accident circumstances
b) the identification and quantity of genetically modified organisms that has got out of control,
c) the information needed for assessment of accident effects to humans and environment,
d) the information on adopted measures.

(3) Should transboundary impacts of possible emergency be taken into account, the user shall provide information according to paragraph 2 to the Ministry as well, as the basis for informing the authorities of foreign countries and for consultation within bilateral interstate relationships.

(4)The user shall be obliged to collect all available data on accident, analyse its cause, identify effects, prepare proposals for measures to prevent similar accidents in future and for reduction of effects thereof.

PART THREE
DELIBERATE RELEASE

Article 15
Initial provisions

(1)Deliberate release shall be any intentional introduction into the environment of a genetically modified organism or a combination of genetically modified organisms (hereinafter referred to as ”introduction into the environment” only) or its placing on the market, for which no containment measures have been used to limit their contact with population and environment with the aim to provide high level of safety.

(2)Introduction into environment according to paragraph 1 shall be every use of genetically modified organisms in environment, particularly seeding, planting, farming and release into wild nature.

(3) Placing on the market for the purposes of this act shall be every requited or unrequited accessing of the products according to paragraph 4 to third persons on the market with the exception of accessing of the genetically modified organisms including culture collections for contained use or introduction into the environment.

(4) The product shall be a preparation consisting of genetically modified organism, or parts thereof, or a preparation containing a genetically modified organisms or a combination of them, which is placed on the market.

(5) The deliberate release shall not be a transport of genetically modified organisms by road, rail, water or air.

(6) The provisions on deliberate release shall be the premise for application of special provisions regulating:

a) licensing and control of drugs used in human and veterinary medicine,[6])
b) protection of and care for genetic sources of plants,[7])
c) production of foodstuffs, manipulation with foodstuffs and their placing into circulation, [8])
d) registration of varieties and protection of rights regarding new plant and animal varieties, [9])
e) assessment of proposals for introduction of new foodstuffs for special nutritive purposes and new foodstuffs into circulation. [10])

Article 16
General responsibilities of the user

(1) Prior to beginning of every deliberate release the user shall be obliged to
a) carry out measures for prevention of possible adverse effects on humans and environment, which could be caused by the deliberate release,
b) assess the risk arising from planned deliberate release, in particular to identify and evaluate direct and indirect, immediate and delayed effects of genetically modified organisms on humans and environment,
c) perform the analysis of cumulative long term effects of genetically modified organisms on humans and environment,
d) decide on the need for risk management (paragraph 3) and on the use of the most suitable genetic method,
e) draw up the emergency response plan (Article 6) and make it available via the Internet, or, if appropriate in other manner.
f) provide substantial information on the content of emergency response plan to the persons that are likely to be affected in case of an accident,
g) to assess every case of possible adverse effects arising from direct or indirect transfer of genes from genetically modified organisms to other organisms,
h) to apply for a consent (Article 17 and 21) and comply with the requirements laid down in the issued consent.

(2) In analysis of cumulative long term effects [paragraph 1 point c)] the user shall be obliged to determine the effects of genetically modified organisms on human, animal and plant health, soil fertility, food/feed chain, ecosystems, biological diversity of plants and animals and resistance in relation to antibiotics used in human and veterinary medicine.

(3) The risk assessment [paragraph 1 point d)] shall be the observation of imported or newly evolved live genetically modified organism using containment measures prior to its introduction into environment for at least one life-cycle or one generation with aim to verify the performed risk assessment (Article 5).

(4)The information on the content of the emergency response plan [paragraph 1 point f)] must be regularly updated upon modification of the emergency response plan and modification of issued consent (Article 17 and 21). Substantial information provided to persons, who could be affected by an accident are simultaneously provided to the Ministry as the basis for consultation with authorities of other countries.

Introduction into the environment

Article 17
Consent for introduction into the environment

(1) Consent of the Ministry for introduction into the environment shall be required for
a) first and every other introduction of a genetically modified organism or a combination of genetically modified organisms into the environment,
b) change of introduction of a genetically modified organism, several genetically modified organisms and a combination of genetically modified organisms, which could have significant effect on humans or environment or which could give rise to new knowledge of such effects,
c) import of genetically modified organisms designed for the introduction into the environment.

(2) One consent for introduction into the environment may be issued for the introduction of the same genetically modified organism or the same combination of genetically modified organisms to the same place or to various places but for the same purpose at the same time.

Article 18
Principles of introduction into the environment

(1) Introduction into the environment shall be carried out according to the ”step by step” principle. Firstly it shall be done as testing, with significant reduction of propagation and dissemination of genetically modified organisms and only consequently, after the sufficient evaluation of the testing, using state of art science and technology, when no adverse effects on humans and environment are expected on the basis of such evaluation, the full scale introduction with control of propagation and dissemination of genetically modified organisms in environment may be carried out.

(2) If no adverse effects on humans and environment are expected in accordance with state

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[6]) The Act No. 140/1998 Coll. On drugs and health-care equipment, on change of the Act No. 455/1991 Coll. on trades (Trades Licensing Act) as amended and on the change and amendment of the Act No. 220/1996 Coll. on advertising as amended.

[7]) The Act No. 215/2001 Coll. on protection of genetic sources of plants for nutrition and agriculture

[8]) The Act No. 152/1995 on foodstuffs as amended.

[9]) The Act No. 291/1996 Coll. on varieties and seeds.

The Act No. 132/1989 Coll. on the protection of rights to new plant and animal varieties, as amended

[10]) Article 27 par. 2 point c) of the Act No. 272/1994 Coll. on protection of human health as amended by the Act No. 514/2001 Coll.

of art science and level of genetic technology prior to the introduction into environment during the risk assessment, the full scale introduction into environment may be carried out on the basis of issued consent for introduction into environment, without any testing.

Article 19
Responsibilities of user at the introduction into the environment

(1) The user shall be obliged to
a) notify without delay the Ministry upon every detected modification of introduction into environment or deviation from its expected course, which could have adverse effects on humans and environment and if necessary, submit an application for change of the issued consent or for an issue of a new consent,
b) to verify during the introduction into the environment the sufficiency and completeness of safety measures according to emergency plan (Article 6) and if the need be, to change without delay the emergency response plan.
c) to keep a detailed documentation on the introduction into the environment (Article 39)
d) to submit a report on the result of the introduction into the environment (Article 20) to the Ministry.

(2) If modifications, which could have adverse consequences on humans or environment have been detected during the introduction into the environment, the user shall be obliged to carry out without delay safety measures according to emergency response plan needed for protection of humans and environment, to review the safety measures and to notify the Ministry upon the changes.

(3) The notification according to paragraph 2 shall include
a) the description of modifications detected during the introduction into the environment,
b) the identification and quantity of genetically modified organisms, which are affected by the modification,
c) the knowledge, data and information needed for assessment of consequences of the modification, from the point of view of risk assessment (Article 5),
d) adopted measures including the content of performed revision of safety measures (Article 7 par. 2).

(4) According to paragraph 1 point c) the user shall be obliged to record the data on the circumstances regarding the introduction into the environment, in particular the plan of introduction containing the phases of step by step introduction, description of circumstances of introduction and its course, the description of the place of introduction and evaluation of the life-cycle of introduced genetically modified organisms; details on the content of the dossier shall be set out in generally binding regulation (Article 39).

Article 20
Report on the result of introduction into the environment

(1) The user shall be obliged to prepare a report on the result of the introduction aimed at detecting the risk to human, animal and plant health and submit it to the Ministry, after the introduction of a genetically modified organism as well as after every finished testing or after any other phase of step by step introduction designated in the issued consent for introduction into the environment. The report shall include the knowledge, data and information obtained from research and development activities at introduction into the environment and from risk assessment (Article 5).

(2) Should the final purpose of introduction into the environment be a preparation of a product, with a view of placing it on the market, the report shall state the potential risks arising from the future use of the product and proposed conditions for the use and handling of the product as the basis for the decision-making of the authorities regarding the handling and introduction of the food products into the circulation.

Placing on the market

Article 21
Consent with placing of the product on the market

(1) The consent of the Ministry for placing of the product on the market shall be required for
a) first placing of a new product on the market,
b) repeated placing of the same product on the market if it is intended for other use,
c) substantial change of the product placed on the market,
d) import of the product, which has to be placed on the market for the first time.

(2) The duty according to paragraph 1 shall be applied to products, which contain genetically modified organisms or parts thereof capable of transferring the genetic information.

(3) The consent according to paragraph 1 shall not be required for placing on the market of
a) the product consisting exclusively from raw materials and products, for which the consent is not required or for which such consent has already been issued,
b) the imported product, for which the consent has been issued by relevant foreign authority, if it is designated by international treaty.

(4) If it is discovered, after placing on the market, that the product represents greater risk than has been expected at its placing on the market or that it presents a threat to humans or environment if used in ordinary manner or according to the producer's instructions, the state inspection authority according to Article 25 shall suspend or prohibit its further placing on the market and order its withdrawal from the market.

(5) The producer shall have the rights and duties of the user at the placing of a product on the market, in case of the imported product it shall be the first importer.

(6) The consent according to paragraph 1 may be issued only for a definite period, 10 years at most, from the date of entry into force of the decision on the consent according to paragraph 1. Should the consent be for placing on the market of the seed of a genetically modified organism or its offspring, the first consent may be issued for 10 years at most.

(7) The state inspection authority may decide that the genetically modified organisms which have been

introduced to the environment without consent, the products which have been imported without consent or the products which have been placed on the market without consent shall be destroyed on the costs of the user, an appeal to such decision shall not have a dilatory effect.

Article 22
The responsibilities of the user after placing of the product on the market

(1) The user shall be obliged to ensure that
a) products placed on the market have been packaged in accordance with safety requirements for transport and storage in accordance with the purpose of the use and conditions laid down in issued consent for placing of the product on the market,
b) the text "This product contains genetically modified organisms" is placed on the product, its packaging or in accompanying documentation of the product,
c) the labeling of the product and accompanying documentation contains
1. the description of recommended use or instructions for use, if the product usage is not clear from its construction or function, or if it is not generally known
2. the data on non-permissible usage of the product together with the instructions for protection of humans and environment in case of non-permissible use,
3. the data on recommended storage conditions of the product and on handling and disposal of non-used remnants or packaging,
4. the data on the producer, and in case of imported product also the data on importer,
5. the period of usability,
6. other data according to special regulations.

(2) The user shall be obliged
a) to make available for the authorities of state inspection according to Article 25 the control samples of the products placed on the market and facilitate the taking of the samples by the authorities,
b) to draw up a monitoring plan, to carry out the monitoring of the product on the market according to it and to evaluate the results of the monitoring,
c) to provide the training of the seller's employees if the use of the product requires knowledge or skills, which are not apparent from the function of the product or instructions for its use,
d) to prepare a report on the results of the monitoring and submit it to the authority, which issued the consent for placing on the market,
e) to make publicly available the results of the product monitoring on the market via the Internet or, if appropriate, in other adequate manner.

PART FOUR

STATE ADMINISTRATION

Article 23
The bodies of state administration

The bodies of state administration in matters covered by this Act shall be:
a) The Ministry
b) The Slovak Environmental Inspection (hereinafter referred to as "Inspection" only)

Article 24
Ministry

(1) The Ministry
a) shall be the central administration body in the matters related to the use of genetic technologies and genetically modified organisms,
b) shall be a procedural body competent to
   1. issue the consents according to Articles 13, 17 and 21,
   2. receive the notifications and assess their content (Articles 12 and 32),
   3. receive the notices on accidents (Article 14 par. 2) and on detected changes in deliberate release (Article 19 par. 3),
   4. to receive the applications according to Articles 33, 34 and 35,
c) shall keep a record of used genetic techniques, genetic methods and used altered genes,
d) shall keep a register of facilities including the records of users, safety committees and heads of the projects (Article 8 par. 3),
e) shall provide the users with information, methodic materials and professional guidance and organise the education of the heads of the projects (Article 9 par. 7).

(2) The Ministry shall be in matters of genetic technologies and modern biotechnology
a) the national notifier to the bodies of European Communities competent in particular to
   1. carry out the notification if the contained use or deliberate release has transboundary impacts or if an accident has or may have a transboundary effect.
   2. consult the content and performance of emergency response plans and knowledge gained from analysis of cause and effect of an accident;
   3. submit the yearly summary report on issued consents for contained use assigned to risk class 3 and 4, including the description, purpose and risks,
   4. draw up the evaluating report at placing of the products on the market,
b) the national centre for safety of genetic engineering and modern biotechnology.

(3) The Ministry shall be obliged to make publicly available via the Internet or, if appropriate in other adequate manner the substantial content of submitted notifiers' applications, reports on the result of introduction into the environment of genetically modified organisms, results of commission activities according to Article 27, reports on results of product monitoring on the market and evaluation reports for authorities of European Communities.

Article 25
Inspection

(1) The inspection as the body of state supervision over the use of genetic technologies and genetically

modified organisms (hereinafter referred to as "state supervision" only) shall
(a) perform the state supervision and
(b) impose the fines for procedural offences (Article 28 and 29) and resolves the infringements (Article 30).

(2) The Inspection shall not perform
a) the supervision in the field of human health protection and health risk assessment, which is being carried out by health protection authorities in accordance with special regulations, [11])
b) the veterinary supervision, which is being carried out by bodies of veterinary care in accordance with special regulations, [12])
c) the supervision in the field of plants, seeds and plantings and fytosanitary care, which is being carried out by state administration authorities in accordance with special regulations, [13])
d) the supervision over the products on the market, which is being carried out by state administration authorities in accordance with special regulations, [14]), [8])
e) the supervision over occupational safety and health protection, which is being carried out by bodies of labour inspection administration in accordance with special regulations. [15])

(3) The state supervision shall be the determination, how users comply with this Act, generally binding regulations, which have been issued for its execution and with responsibilities arising from issued decisions according to this Act.

(4) Should the inspection detect any violation of responsibilities or other shortcomings in user's activities or her facility, it notifies thereupon and impose a duty to remedy it in an adequate period. Should an activity of the user present an imminent danger of accident (Article 6 par. 2) threatening the human health outside of contained facility, the inspection shall prohibit the further use of genetic technologies or genetically modified organisms.

(5) The inspection employee (hereinafter referred to as "inspector" only) shall be entitled during the performance of state supervision in facility
a) to enter the premises and the facility sites including the laboratories, hothouses, storage rooms and other contained rooms in the facility area,
b) to perform needed survey including taking of control samples, making of photo- and video-documentation
c) to inspect the recordings, documents and other papers related to the use of genetically modified organisms and professional qualification of heads of the projects, to make extracts thereof and to require the making of the copies,
d) to require the explanations and true and concise data and information on all activities performed in the facility, which utilize genetic methods and genetic techniques.

(6) The user that is being controlled shall be obliged to facilitate the inspector, who proves his identity by a card issued by the inspection, to perform the authority according to paragraph 5.

(7) The basic rules for controlling activity [16]) shall be followed when performing the state supervision.

Article 26
Secrecy

(1) Following persons shall be obliged to keep the secrecy about the facts, data and information, which are subject to intellectual property law or trade secret of the notifier:
a) inspectors (Article 25), if they have learnt of it while performing the state inspection in facility,
b) employees of the Ministry and Inspection, if they have learnt of it from the notification or notice of the notifier or in proceedings according to this Act,
c) members of the Commission and board of experts according to Article 27, if they have learnt of it during the activities according to Article 27.

(2) The obligation of secrecy may be lifted by the notifier and in case of data and information needed for clarification and investigation of a criminal act also the Minister of Environment of the Slovak Republic.

(3) The notifier may mark the data or information made available during the performance of state inspection or set out in notification or in application for consent as the subject to intellectual property or trade secret and require that they not be published. The content of the proposal shall be assessed by the Ministry, which shall inform the notifier upon the result of the assessment.

(4) The data and information, which has been recognised by the Ministry as the subject to intellectual property or trade secret shall not be published, nor supplied to other persons and foreign state authorities even in case the notifier has drawn back the notification or application for issuing of the consent.

(5) The subject to intellectual property or trade secret shall not be following data and information:
a) the general characteristics (description) of a genetically modified organism,
b) commercial name and address of the notifier,

[11]) Article 24 and 26 of the Act No. 272/1994 Coll. as amended by the Act No. 95/2000 Coll.

[12]) Article 20 of the Act No. 337/1998 Coll. on veterinary care and on change and amendments of some other acts

[13]) e.g. the Act No. 285/1995 Coll. on fytosanitary care as amended by the Act No. 471/2001 Coll.; the Act No. 291/1996 Coll.; the Act No. 332/1996 Coll. on viticulture and ampeology and on change of the Act No. 61/1964 Coll. on plant production development as amended by the Act No. 132/1989 Coll., as amended by the Act No. 23/2002 Coll.

[14]) e.g. Articles 2 to 4 of the Act No. 71/1986 Coll. on Slovak commercial inspection as amended by the Act No. 417/1991 Coll.

[15]) The Act No. 95/2000 Coll. on labour inspection and on change and amendment of some acts.

[16]) The Act No. 10/1996 Coll. on control in state administration as amended by the Act No. 502/2001 Coll.

c) commercial name of the user and in case of import, commercial name of foreign producer and importer,
d) the assignment to the risk class of the contained use and its respective level of containment,
e) the result of the risk assessment and its evaluation,
f) the evaluation of foreseeable effects, in particular harmful effects on humans or environment.

Article 27
Commission for biological safety and its board of experts

(1) The Ministry shall establish the Commission for biological safety (hereinafter referred to as "Commission" only) and its board of experts.

(2) The members of the Commission and experts for the board of experts shall be appointed and withdrawn by the Minister of the Environment of the Slovak Republic in co-operation with the Minister of Agriculture of the Slovak Republic, Minister of Defence of the Slovak Republic and Minister of Health of the Slovak Republic, with scientific centres, with entrepreneur's associations and with civic associations, of which aim is according to their statue the environmental or consumer protection.

(3) The task of the Commission shall be
a) to deal with the state of the scientific and technologic development in the field of genetic technologies in particular to gather the results of any contained use and deliberate release obtained from notifier's reports and notifications, to generalise it and compare to scientifically proved facts obtained on the international level,
b) to analyse, review and assess the content of submitted notifications and applications for issue of notifications from the point of view of science and available knowledge on genetic methods, genetic techniques and on risks arising from the use of genetically modified organisms,
c) to work out the recommendations as the professional basis for Ministry issuing the consents (Article 13, 17 and 21),
d) to analyse and assess the content of received comments from public,
e) to work out recommendations needed for determination of technical and organisational requirements on facilities, good laboratory practice, monitoring and evaluation of the use of genetic technologies,
f) to assess the proposals for entering the register of used genetic techniques, genetic methods and used modified genes.

(4) The board of experts shall work out the basis for the activities of Commission according to paragraph 3 letter b), e) and f).

(5) The statute and rules of procedure of the Commission regulating in detail the status and activities of the Commission and its board of experts shall be issued by the Minister of Environment of the Slovak Republic.

Article 28
Procedural offences

(1) The inspection may impose a fine up to 5 million SKK to the entrepreneur and other legal person which
a) has not made a notification or submitted a notice, although she was obliged to do that according to this Act (Article 12 and 19),
b) has used the genetic technologies or genetically modified organisms in contained facility, which is not recorded in the register of facilities or for which the consent has not been issued (Article 8 par. 3),
c) has performed the contained use of genetic technologies or genetically modified organisms in a facility without establishing the safety committee or without appointing a head of the project (Article 9),
d) has imported or used genetic technologies or genetically modified organisms without the consent or without the notification according to this Act (Article 13, 17 and 21),
e) has placed the product on the market without the consent according to this Act (Article 21).

(2) The Inspection may impose a fine up to 1 million SKK on entrepreneur and other legal person, who in spite of being warned by the Inspection
a) has not drawn up an emergency response plan (Article 6),
b) uses in facility working procedures, which do not comply with principles of good laboratory practice or activities which do not comply to technical and organisational requirements on facilities (Article 9, par. 8),
c) has not kept the dossier in prescribed extent or for required period (Article 9 and 19),
d) has not made publicly available essential information on an accident and measures carried out (Article 14 par. 1),
e) has not facilitated the participation of a head of the project in education organised by the Ministry (Article 24, par. 1)
f) has not submitted to the Ministry the reports and other documents according to this Act,
g) has not registered the facility (Article 8 par. 3).

Article 29
Imposing the fines

(1) The fine may be imposed on the entrepreneur and other legal person up to one year from the day the Inspection has learned of the infringement of the duty, but three years at latest from the day the infringement has occurred.

(2) The severity and period of unlawful acting and the extent of hazard to humans and the environment shall be taken into account when imposing the fine.

(3) In the decision on the imposing of the fine the inspection may impose a duty to carry out measures for remedy of the effects of unlawful acting, for which the fine has been imposed. Should not the user in the defined period carry out the measures, the Inspection may impose another fine, up to double of the upper fine limit.

(4) Should the fined person breach the duty, for which she has been fined in one year from the date of entry into the force of the decision on imposing of

the fine, the inspection shall impose another fine up to double of the upper fine limit.

(5) The payoff of the fine shall be the revenue of the state budget.

(6) The imposed fine shall be payable within 30 days from the date of entry into force of the decision on imposing, if no other payability period is determined in the decision.

Article 30
Infringements

(1) The infringement shall be committed by a person, who
a) has used the genetic technologies and genetically modified organisms without the consent or notification (Article 12, 13, 17 and 21),
b) has used the containment facility, which is not registered (Article 8, par. 3).

(2) The infringement according to paragraph 1 may be fined up to 50 000 SKK and by a prohibition of activity up to two years.

(3) The general regulations on infringements [18]) shall apply on infringements and their resolution.

PART FIVE
PROCEEDINGS

Article 31
Initial provisions

(1) For the proceedings according to this Act the general regulation on administrative procedure shall apply,[19]) if not provided otherwise in this Act.

(2) The general regulation on administrative procedure shall not apply on
a) the notification and assessment of notification (Article 12 and 32),
b) noticing on the accident (Article 14 par. 2) and on detected modifications in deliberate release (Article 19 par. 2).

Article 32
The assessment of notifications

(1) When assessing the notifications (Article 12) the Ministry
a) shall check the completeness of the notification in relation to the type and purpose of its submission,
b) shall assess the content of the notification by comparing it with the requirements for contained use according to this Act, in particular check and evaluate
   1. the completeness and exactness of the data and information laid down in notification,
   2. the correctness of risk assessment and assignment to the risk class,
   3. the suitability and correctness of protective measures corresponding to required level of containment,
   4. the content of emergency response plan and suitability of safety measures,
   5. proposed handling of the waste and waste water,
   6. assessment of potential risks
   7. technical, organisational and personal conditions of facility,
c) shall compare the data and information with available scientific knowledge and technical specifications,
d) may impose on the notifier the obligation to perform additional tests, measurements or other forms of testing,
e) shall request the Inspection to perform the state supervision in the notifier's facility.

(2) The Ministry may put upon the notifier the obligation to
a) supplement the notification, if not completed
b) provide the more detailed information or other materials for assessment of the notification, if necessary,
c) perform additional measures for elimination of shortcomings in relation to prepared contained use,
d) to work out the additional notification or simplified notification for the purposes of its publication and informing the public on a prepared contained use,
e) to make publicly available substantial information on prepared contained use including containment measures and essential content of emergency response plan in a form comprehensive for public,
f) provide for public hearing and submit the evaluation to the Ministry.

(3) To secure the assessment according to paragraphs 1 and 2, the Ministry may request the notifier not to commence the contained use or in case he has already started not to continue with it in the period set out for assessment of the notification.

(4) On the basis of the assessment of the notification the Ministry shall inform the notifier that
a) it has no objections to notified activity or, if appropriate set out additional recommendations or
b) she may perform the notified activity only on the basis of the content (Article 13) and at the same time call the notifier to submit the application for beginning of the proceedings for issuing of such consent (Article 33).

(5) The Ministry shall assess the notifications received in the period of
a) 45 days, in case of repeated notification,
b) 90 days in other cases.

(6) The periods according to paragraph 5 shall not run
a) from the day of announcement of the call for the notifier to supplement the application or remove its shortcomings according to paragraph 2 and paragraph 4 letter b) until the day the requirement is met.
b) during the performance of additional tests, measurements or other forms of testing,
c) during the inspection in the notifier's facility.

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[18]) The Act No. 372/1990 Coll. on infringements as amended.

[19]) The Act No. 71/1967 Coll. on administrative procedure (Administration Order)

(7) Should the Ministry not act in the period according to paragraph 5, nor should it announce the notifier that the application needs to be submitted, it is presumed that it has no objections to notified activity.

(8) Should the notifier not meet the requirement of the Ministry according to paragraph 2 or paragraph 3, the Ministry may prohibit the notified activity or impose a disciplinal fine up to 10 000 SKK by a decision.

Proceedings on the consent

Article 33
Proceedings on the consent for contained use

(1) An application in writing shall be the proposal for beginning of the proceedings. The application shall contain except of general proprieties of motion[20]) also other proprieties, which shall be laid down in generally binding regulation (Article 39).

(2) The notifier shall be a participant of the proceedings, without prejudice to general regulation on administrative proceedings.[21]) The civic association, of which aim according to its provisions is environmental or consumer protection may be also the participant of the proceedings, if
a) it is registered as a civic association [22]) with aim according to this paragraph for at least one year to the date of submission of the application according to letter b)
b) applies for it in writing at the Ministry within 10 days from the publication of the application for consent according to this Act and
c) a part of the application according to letter b) is a petition[23]) signed by at least 100 natural persons supporting this application.

(3) The Ministry shall request for supplementing of the application with data on performed tests, measurements or other examinations and on results of a public hearing, if any has taken place.

(4) The Ministry shall
a) confirm in writing to the notifier the submission of the application,
b) make publicly available without delay data on submitted application via Internet, in professional press, and if appropriate in daily press together with a call for submission of comments and a period for their submission.

(5) The professional basis for the decision on the consent shall be the recommendation of the Commission established by the Minister as professional advisory body.

(6) The period for the decision on the consent shall be
a) 45 days, in case of issuing the consent for use of facility, for use of which the consent has been already issued for activities assigned to risk class 3 and 4 and if all requirements of issued consent has been met,
b) 90 days, in case of issuing the consent for other cases.

Article 34
Proceedings on the consent for introduction into the environment

(1) An application in writing shall be the proposal for beginning of the proceedings. The application shall contain except of general proprieties of motion[20])
a) technical documentation needed for verification of risk assessment and
b) opinion from the risk assessment performed by the user together with reference on scientific literature and used genetic methods and genetic techniques, as well as with knowledge, data and results from introduction performed by other notifiers,
c) other proprieties laid down in a generally binding regulation (Article 39).

(2) The notifier shall be a participant of the proceedings, without prejudice to general regulation on administrative proceedings.[21]) The civic association, of which aim according to its provisions is environmental or consumer protection may be also the participant of the proceedings, if
a) it is registered as a civic association[22]) with aim according to this paragraph for at least one year to the date of submission of the application according to letter b)
b) applies for it in writing at the Ministry within 10 days from the publication of the application for consent according to this Act and
c) a part of the application according to letter b) is a petition[23]) signed by at least 100 natural persons supporting this application.

(3) The Ministry shall
a) confirm in writing to the notifier the submission of the application,
b) make publicly available without delay data on submitted application via Internet, in professional press, and if appropriate in daily press together with a call for submission of comments and 60 days period for their submission.

(4) The professional basis for a decision on the consent shall be the recommendation of the Commission.

(6) The period for the decision on the consent shall be 90 days. This period shall not run from the date of publication on the Internet till the expiration period according to paragraph 3 letter b), but must not be longer than 120 days.

Article 35
Proceedings on the consent for placing of the product on the market

(1) An application in writing shall be the proposal for beginning of the proceedings. The application shall contain except of general proprieties of motion[20]) also other proprieties, which shall be laid down in generally binding regulation (Article 39).

(2) The notifier shall be the participant of the proceedings, without prejudice to general regulation on administrative proceedings.[21]) The civic association, of which aim according to its provisions is environmental or consumer protection may be also the participant of the proceedings, if

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[20]) Article 19 par. 2 of the Act No. 71/1967 Coll.

[21]) Article 14 of the Act No. 71/1967 Coll.

[22]) Act No. 83/1990 Coll. on associating of the citizens as amended

[23]) The Act No. 85/1990 Coll. on petition rights as amended by the Act No. 242/1998 Coll.

a) it is registered as a civic association[22]) with aim according to this paragraph for at least one year to the date of submission of the application according to letter b)
b) applies for it in writing at the Ministry within 10 days from the publication of the application for consent according to this Act and
c) a part of the application according to letter b) is a petition[23]) signed by at least 100 natural persons supporting this application.

(4) The Ministry shall
a) confirm in writing to the notifier the submission of the application,
b) make publicly available without delay data on submitted application via Internet, in professional press, and if appropriate in daily press together with a call for submission of comments and a period for their submission; during the period for giving opinion or public hearing the Ministry shall suspend the proceedings, for 60 days at most,
c) work out in 90 days from the date of completion of the application the evaluation report, which shall be delivered to the notifier first; the assessment report shall always include the conclusion, whether the product is to be or is not to be introduced on the market,
d) publish the evaluation report via the Internet or, if appropriate, in other adequate manner, together with a call for submission of the comments and with 30 days period for their submission,
e) deliver the evaluation report, supplemented by new data or an opinion of the notifier or public comments if appropriate, within 15 days from its delivery to the notifier but 105 days from the date of submission of the application at latest, to the authorities of European Communities, if in meantime the notifier has not withdrawn the application,
f) decide on issuing of the consent for placing of the product on the market after the delivery of the opinion of the authorities of European Communities on the evaluation report.

(4) The basis for the decision on the consent shall be a recommendation of the Commission and an opinion according to paragraph 3 letter f).

(5) The period for the decision on the consent shall be 120 days; this period shall not run
a) from the date of the announcement of the call for completion of the application or elimination of its shortcomings to the notifier till the date of meeting the requirement,
b) during the elaboration of the evaluation report, 90 days at most,
c) from the date of delivery of the evaluation report to the notifier till the date of delivery of the notifier's opinion, but 30 days at most,
d) during the discussing of the evaluation report by the authorities of European Communities, 105 days at most.

(6) The decision on the consent shall include except of general proprieties of the decision[24])
a) a definition of the extent of the consent, including the identity of the genetically modified organism in the product and its unique identifier,
b) a period of validity of the consent,
c) conditions for placing of the product on the market including the conditions for its use, handling and packaging and conditions for protection of eco-systems and geographical districts,
d) requirements for labeling of the product
e) requirements for monitoring of the product on the market including the monitoring schedule and vendors' responsibilities.

(7) The decision on the consent shall be published via the Internet, in Journal of the Ministry of Environment of the Slovak Republic, in professional press, and if appropriate in daily press as well.

Article 36
The change or repeal of the decision on consent

(1) The proceedings on the change or repeal of the decision on the consent shall begin upon the request of the notifier or Ministry's own initiative. Should it begin upon the request of the notifier, Articles 33, 34 or 35 shall be used respectively of the content of the application.

(2) The Ministry shall initiate the proceedings if
a) the notifier despite the notice and imposed fine does not comply with responsibilities according to this Act or with requirements laid down in the decision on the consent,
b) it is inevitable for the compliance with international obligations of the Slovak Republic including the hearing of objections of the authorities of European Communities from the evaluation report,
c) an unintentional modification of deliberate release has occurred, that might have harmful effects on humans and environment.

Article 37
Extension of validity of the decision on consent for placing on the market

(1) The extension of the validity of the decision on the consent issued in proceedings according to Articles 33 to 35 may be applied for at latest nine months before the expiration of validity date of issued consent.

(2) An application in writing shall be the proposal for beginning of the proceedings. The application shall contain except of general proprieties of motion the copy of issued decision on consent or, if appropriate, proposals for change of the content of the issued consent and in case of change of the decision on consent for placing of the product on the market the report on results of monitoring of the product on the market.

(3) The Ministry shall confirm in writing the submission of the application and if the application is complete, submit one copy to the authorities of the European Communities.

(4) The basis for the decision shall be a recommendation of the Commission and an evaluation report of the authorities of the European Communities.

(5) The period for the decision shall be 30 days from the date of delivery of the evaluation record according to paragraph 4. If there is a need on the basis of objections from the evaluation report to discuss detected problems, the period for the decision shall be 30 days from the date of termination of the discussion.

[24]) Article 47 of the Act No. 71/1967 Coll.

(6) The decision according to paragraph 1 may be issued only after the execution of requirements resulting from the evaluation report according to paragraph 4.

PART SIX

COMMON, TRANSITIONAL AND FINAL PROVISIONS

Article 38
Labeling of foodstuffs

The general provisions on foodstuffs[8]) shall apply for labeling of the foodstuffs being introduced into circulation.

Article 39
Enabling provision

The Ministry shall issue generally binding regulations setting out details on
a) the content of emergency response plan (Article 6),
b) requirements on the facilities (Article 8),
c) professional qualification of heads of the projects and on their professional education (Article 9),
d) risk assessment (Article 5) and on procedure and criteria for assignment to a risk class and on the content of containment levels (Article 10),
e) procedure for evaluation of direct and indirect, immediate and delayed effects and for performance of analysis of cumulative long term effects (Article 16),
f) the content of the dossier and the manner of its administration and storage (Article 5, 9 and 19),
g) the content of the report on the result of introduction into the environment (Article 20),
h) the content and administration of the register of used genetic methods and genetic techniques and used modified genes,
i) proprieties of particular notifications and on assessment of their content (Article 32),
j) other proprieties of the applications for entering into the register of facilities (Article 8) and for issuing of the consents (Articles 33 to 37),
k) the content of evaluation report (Article 35).

Article 40
Transitional provisions

(1) The entrepreneurs and other legal persons, who shall perform activities, in which they use genetic technologies or genetically modified organisms to the 1st of April 2002 may continue with these activities only if they meet following requirements till the 31st of March 2003:
a) adjusting of their position according to provisions of this Act on the user
b) modifying of the facilities in accordance with technical and organisational requirements on facilities according to this Act and a generally binding regulation (Article 39),
c) establishing of the safety committee and appointing the head of the project for each facility and each use of genetic technologies or genetically modified organisms,
d) the risk assessing,
e) working out of emergency response plan and
f) submitting of the application for issuing of the consent.

(2) Entrepreneurs and other legal persons, who shall not meet the requirements according to paragraph 1 shall be obliged to finish the performed activity to 31st of March 2003.

(3) The entrepreneurs and other legal persons shall be obliged to report to 30th of June 2002 the Ministry on data needed for keeping of the register of facilities, recordings of used genetic methods and genetic techniques and recordings of used modified genes.

(4) The Ministry may impose a fine up to 50 000 SKK to the entrepreneur or other legal person according to paragraph 1, who
a) shall not meet the requirements according to paragraph 1 or finish the performed activity in a period set out in paragraph 2,
b) shall not report the requested data in a period according to paragraph 3.

(5) Genetically modified organisms containing genes expressing resistance to antibiotics used in human and veterinary medicine must be
a) withdrawn from the market by the users to the 31st of December 2004.
b) eliminated from the introduction into the environment by the users to the 31st of December 2008.

Article 41
Entry into force

This Act shall enter into force on the 1st of April 2002 except of Article 35 par. 4 and Article 37 par. 4, which shall enter into force on the date of accession of the Slovak Republic to the European Union.

Rudolf Schuster s.m.

Jozef Migas s.m.

Mikulas Dzurinda s.m.