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Slovakia

Biotechnology

English text of Implementing Legislation and Act 2002

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Report Highlights: A new 'Act' (No. 151/2002 On the Use of Genetic Technologies and Genetically Modified Organisms) was adopted by the Slovak Parliament on February 19, 2002, and came into force on April 1, 2002. However, implementing regulations for this law only came into force on June 1, 2002. An English 'working version' of the implementing regulations was recently made available. A copy of these rules, as well as the Act, are provided in this report.

Slovak biotechnology rules are based on EU legislation. Slovakia is also expected to ratifying the Cartagena Protocol by the end of 2002.

Background: About 60 ‘premises’ are working with genetically modified organisms in Slovakia. Most are educational research facilities working with micro-organisms but there is also some work being done on plants and animals and several companies are active in the field. No approvals has been issued until now and field trials have been carried out.

The Ministry of the Environment (MoE) is the Competent Authority. A small Biosafety Department was established in the MoE on April 1, 2002, and regulators are being trained. In accordance with the Act, a Biosafety Committee was established some time ago as an advisory body for the MoE. Members of the Biosafety Committee come from the Ministries of Agriculture, Defense, and Health, and representatives from scientific centers, NGOs and business associations.

The Ministry of Environment is obliged to publicize applications for the use or release of GMOs.

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DECREE**of the Ministry of Environment of the Slovak Republic**of 30th April 2002,**implementing the Act on use of genetic technologies and genetically modified organisms**

The Ministry of Environment of the Slovak Republic (hereinafter referred to as "the Ministry" only) according to Article 39 of the Act No. 151/2002 Coll. on use of genetic technologies and genetically modified organisms sets out:

Article 1
Subject of regulation

This decree shall lay down the details on

- a) content of emergency response plan,
- b) requirements for a containment facility of a user, in which genetic technologies shall be used (hereinafter referred to as "facility" only),
- c) professional qualification of heads of the projects regarding contained use of genetic technologies (hereinafter referred to as "head of the project" only) and on their professional training,
- d) environmental risk assessment of using genetic technologies (hereinafter referred to as "risk" only) and on procedure and criteria for assignment of genetic technologies to risk classes and on the content of containment levels,
- e) procedure for evaluation of direct and indirect, immediate and delayed effects of introduction of genetically modified organisms into the environment and at the performance of analysis of cumulative long-term effects of genetically modified organisms on humans and environment,
- f) content of a dossier of a usage of genetic technologies and genetically modified organisms (hereinafter referred to as "dossier" only) and on the manner of its recording and storage,
- g) content of a report on the introduction of genetically modified organisms into the environment,
- h) content and keeping of the records of used genetic methods and genetic techniques and used modified genes,
- i) proprieties of particular notifications and on evaluation of their content,
- j) other proprieties of applications on entering the register of facilities and issuing of consents
- k) content of evaluation report.

Article 2

Content of emergency response plan

- m) data relating to the enforcement of responsibilities

(1) An emergency response plan, worked out for an event of the accident in the facility, in particular the leak of genetically modified organisms from the facility, shall include:

- a) identification data on facility, in which the genetic methods and genetic techniques are used,
- b) representation of the safety committee and identification data on the head of the project,
- c) data on the quantity and species of genetically modified organisms, which are capable of leaking in the event of an accident in the facility,
- d) identification of usage of genetic technologies in the facility, which could result in the accident,
- e) data on the commencement and presumed termination of the use of the genetically modified organisms, which could result in the accident,
- f) description of the proprieties of the genetically modified organisms, which are capable of leaking in the event of an accident in the facility,
- g) description of possible effects of an accident and its immediate particular outside effects on employees of the facility, as well as on the population and environment, in case of spread outside the borders of the facility,
- h) description of protective measures to prevent the occurrence of an accident,
- i) description of the measures for elimination of occurred accident in particular the methods and means for physical eradication of genetically modified organisms leaked from the facility,
- j) description of recommended behaviour for employees in the facility and population in the vicinity of the facility upon the contact with genetically modified organisms leaked from the facility,
- k) description of recommended procedure for elimination of accident consequences,
- l) identification data on authorities and persons designated for elimination of the consequences of the accident, for provision of medical care for persons affected by the accident, for disinfection etc.,

for incurred damage and provision of

compensation thereof.

(2) The emergency response plan for an event of the accident after introduction of genetically modified organisms into the environment shall include

- a) identification data on the user and on the area to which the genetically modified organisms have been introduced,
- b) data on the species and quantity of the genetically modified organisms introduced into the environment,
- c) identification of the user's activity, which could lead to accident at introduction or after introduction of genetically modified organisms into the environment,
- d) data on time of commencement and expected termination of the introduction, especially the data on particular phases of step by step introduction and on natural life cycle of genetically modified organisms being introduced,
- e) description of natural and foreseen characteristics of genetically modified organisms being introduced,
- f) description of possible characteristics of genetically modified organisms capable of endangering humans or causing harm to the environment, as well as description of their possible external manifestations and consequences, in case the symptoms occur on humans, animals and plants after the introduction,
- g) description of measures carried out for restriction of propagation and spread control of introduced genetically modified organisms,
- h) description of measures for elimination of incurred accident, in particular the measures and methods for destruction of genetically modified organisms, which show the proprieties capable of endangering humans or causing a harm to the environment, and for protection from the effects thereof on population, domestic animals and environment, as well as measures for reclamation of soil and reconstruction of the environment,
- i) description of recommended behaviour of user's employees and population in the vicinity of the place of introduction,
- j) identification data on authorities and persons designated for the elimination of accident consequences, for provision of medical care of persons affected by the accident, for evacuation of population, disinfection, reclamation of soil etc.
- k) data relating to the enforcement of responsibilities for incurred damage and provision of compensation thereof.

(3) The emergency response plan for an event of the accident after placing of the products on the market shall include:

- (1) The professional qualification of the head of the

- a) identification data on the producer and importer of the product,
- b) description of the product and data on its composition, purpose and proprieties,
- c) description of purpose-designation of the product, including the manual for its use, if it is not clear from the product itself, its function or purpose,
- d) data on negative proprieties of the product, which could represent a health risk to certain customers' groups or domestic animals, on external signs (symptoms) of these proprieties on humans and animals,
- e) instruction for disposal of packaging, remnants of the product after use and product itself when defective, with damaged packaging and after expiry date,
- f) guidance on procedure (first aid) after misuse, after use of defective product or after detecting of symptoms of negative proprieties of the product,
- g) information of license of the product, in particular the information on the authority, which has issued the licence for manufacturing or import of the product, the date and number of the licence,
- h) the list of authorities and persons to be notified on the accident,
- i) data relating to the enforcement of responsibilities for incurred damage and provision of compensation thereof..

Article 3

Requirements on facilities

(1) The facilities must comply with the requirements allowing the application of such containment levels, that correspond to the assignment of genetic technologies to the risk class.

(2) The requirements for application of level containment for

- a) microbiologic laboratories shall be laid down in Annex 1,
- b) glasshouses and growth-rooms shall be laid down in Annex 2,
- c) isolators, cells and animal units shall be laid down in Annex 3,
- d) other contained rooms shall be laid down in Annex 4.

Article 4

Professional qualification of heads of projects

project in the facility shall be:

- a) second degree university education,
- b) practice at least
 1. three years in genetic engineering and modern biotechnology including
 2. two years in contained use of genetic methods and genetic techniques,
- c) regular participation in professional training.

(2) The time of scientific preparation, PhD studies and teaching in the field genetic engineering and modern biotechnology shall count as the practice according to paragraph 1 letter b) point 1; shall not count as the practice according to paragraph 1 letter b) point 2.)

Professional training of heads of projects

Article 5

- (1) The professional training of the heads of the projects shall consist generally of three-day training courses repeated in a three-year period. The content of professional training shall be lectures, workshops and case studies related to knowledge of
- a) the content of legal provisions on genetic technologies, on use of genetic methods and genetic techniques, on principles of occupational safety and health protection when working with genetically modified organisms and on keeping of dossier,
 - b) the application of the principles of good laboratory practice and rules of microbiological work,
 - c) used modified genes, in particular on their properties, applicability in genetic engineering and on their recording,
 - d) international experience and knowledge in usage of genetic technologies,
 - e) procedures and rules concerning the preparation, coordination and assessment of projects with contained use of genetic methods and genetic techniques,
 - f) procedures in risk assessment, on assignment of used genetic technologies to risk classes and on the re-evaluation of the assignment,
 - g) containment levels in connection with assignment of genetic technologies to risk classes and on use of containment measures,
 - h) preparation of emergency response plans and the contents, publication and modification thereof,
 - i) procedures for a case of emergency.

(2) The professional training shall be designed for the heads of projects recorded in a register kept by the Ministry.

(3) A head of the project shall participate in a professional course upon being sent by the user in a period set out in Ministry's call.

Article 6

- (1) The professional training shall be organised by the

Ministry. Details on the organisation of a training course and on the schedule of professional training shall be published not later than three weeks before the planned commencement of training course.

(2) The certificate issued to a head of the project after finishing any training course shall entitle her for performance of activities related to heads of the projects until the next training course.

Article 7

(1) The users shall submit the proposals for entering of heads of the projects into the register of the heads of projects (hereinafter referred to as "list" only) and for deletion. The proposal shall include data necessary for keeping of the list.

(2) Following data shall be entered into the list:

- a) the name and surname of the head of the project,
- b) company name and address of the user,
- c) data on professional qualification of the head of the project
- d) address of the facility, in which the head of the project performs the activities belonging to her scope of work,
- e) projects, in which the head of the project performs the activities belonging to her scope of work,
- f) registration number of the head of the project
- g) data on professional training and on issuing of the certificate.

(3) Data laid down in the list need not to be stated in the notification on the contained use in the facility, in the application for the consent on contained use or deliberate release of genetically modified organisms into the environment, nor to be proved in proceedings for issuing of the consent; it shall be sufficient to specify the registration number of the head of the project.

(4) The data laid down in the list shall be publicly available. Every person may make a copy of the data in the list or request the making of an abstract from the list.

Article 8

Risk assessment

(1) The risk assessment shall be aimed at detection of all existing and possible future adverse effects on humans or environment, which may arise from use of genetic technologies in facilities and after deliberate release into the environment of genetically modified organisms.

(2) The aim of the risk assessment is to determine possible harmful effects of genetically modified

organisms on

- a) humans, in particular the allergenic and toxic effects and effects compromising medical or prophylactic treatment, for example resistance to antibiotics used in human or veterinary medicine,
- b) animals and plants, in particular effects caused by natural transfer of inserted genetic material to other organisms and effects of their introduction in the environment or spread therein.

(3) The report from the risk assessment concerning the contained use of genetic technologies in the facility shall include

- a) the identification of all possible harmful effects of genetically modified organisms in relation to
 1. the recipient organism,
 2. the inserted genetic material originating in the donor organism
 3. the vector
 4. the donor organism as long as the genetic method or genetic technique is being used
 5. the resulting genetically modified organism
- f) characteristics of the activities, in which a genetic technique should be used
- g) data on magnitude of the consequences of possible harmful effects
- h) the likelihood of potentially harmful effects being realised.

(4) When assessing the risk, in the case of application for the consent on use of the genetically modified organism, which contains genes expressing resistance to antibiotics

- a) the following shall be assessed:
 1. the direct influence of the enzyme expressing resistance
 2. the potential transfer of antibiotic resistance to cells of enteric epithelium
 3. the potential transfer of antibiotic resistance to micro-organisms in enteric tract,
 4. the potential transfer of antibiotic resistance to micro-organisms in the environment
- e) the following criteria shall be followed:
 1. whether that antibiotics plays an important role in medical applications,
 2. whether it is used often,
 3. whether it is used orally,
 4. whether it is unique,
 5. what is the level of spread of resistance to monitored antibiotics in bacterial population.

Article 9

Procedure and criteria for assignment of genetic technologies to risk classes and content of containment

(4) Based on the result of assessment pursuant

levels

(1) When assessing the risk of a use of genetic technologies in the facility, the following order of particular steps in the assessment shall be followed:

- a) to identify the harmful impacts of the recipient organism and if appropriate, the donor organism,
- b) to identify the harmful effects of the vector and inserted genetic material, including every modification of a recipient organism's characteristics,
- c) to examine the sanitary, foodstuff and other provisions in relation to genetic methods and genetic techniques and genetically modified organisms, in order to obtain essential data for risk assessment
- d) to use international classification systems and their reviews performed on the basis of new scientific data and achieved technical progress, both classification systems assigning to risk classes the micro-organisms as biological agents according to their effect on a healthy mature human and classification systems related to plant and animal pathogens.

(2) The user shall define the level of the risk by the procedure referred to in paragraph 1, make the preliminary assignment to a risk class of the use in the facility and choose the set of containment measures, which are adequate to the preliminary assignment and required level of containment.

(3) When choosing the set of the containment measures, the user shall take into account

- a) the characteristics of the environment in the facility, which is to be exposed to the effects of genetically modified micro-organisms, in particular whether there is a presence of any other live organisms, which might be adversely affected by the micro-organisms used in the facility,
- b) the scope and characteristics of the activities to be performed using genetic techniques,
- c) all unusual actions, which have to be taken into consideration, e.g. inoculation by genetically modified micro-organisms of animals, production of aerosols in the facility,
- d) the established containment level corresponding to the risk class.

to paragraphs 1 to 3, the use of genetic

technologies in the facility shall be definitely assigned to the risk class.

(5) The use of genetic technologies may be definitely assigned to the risk class 1 only after it has been proved, that the used genetically modified organisms have following proprieties:

- a) the recipient or parental organism should not cause harm to human health, nor to the health of animals and plants being exposed to its effects,
 - b) the nature of the vector and inserted genetic material does not constitute a phenotype for genetically modified organism, which would be capable of causing harm to human health, harm to the health of animals and plants, which would be exposed to its effects or which would be capable of harmful effects on the environment and
 - c) there is a supposition that the genetically modified organism shall not cause a disease to humans and disease to animals and plants in the environment, which would be exposed to its effects and that it should not have harmful effects on the environment.
- (6) Should not the proprieties of the genetically modified organism according to paragraph 5 be proved, the use of genetic technologies may be assigned to
- a) risk class 2, in case of a small risk, which can be easily eliminated by generally known containment measures, in particular physical barriers,
 - b) risk class 3, in case of a medium risk, which can be eliminated only by particularly stringent containment measures, or
 - c) risk class 4, in case of major risk representing permanent effects, which can not be wholly eliminated even by use of particularly stringent containment measures.

Article 10

Procedure for evaluation of direct and indirect, immediate and delayed effects and for performance of analysis concerning cumulative long-term effects

- (3) When assessing the risk of genetic technologies for the introduction of genetically modified organisms into the environment, the following order of particular steps in assessment shall be followed:
- a) to identify the characteristics related to the genetic modification, which could have adverse effects on humans or the environment,
 - b) to compare the identified characteristics of genetically modified organisms and their use, which are capable of causing adverse effects with those organisms, from which the genetically modified organism has been derived and under

- corresponding conditions of its use,
- c) to evaluate the possible effects of every adverse effect, of which occurrence is being probable,
- d) to evaluate the probability of occurrence of adverse effects depending on characteristics of the environment, to which the genetically modified organism is being planned to be released and on the manner of such deliberate release,
- e) to estimate the risk posed by each identified characteristic of the genetically modified organism, which has a potential to cause adverse effects, taking into account the state of art technique by combining the likelihood of the adverse effect occurring and the magnitude of the consequences, if it occurs,
- f) to define a strategy for the management of the identified risk.

(2) The user shall define the overall level of the risk of the planned deliberate release by the procedure referred to in paragraph 1, and choose the set of protective measures, which are adequate to the preliminary assignment.

(3) When choosing the set of the protective measures, the user shall take into account

- a) characteristics of the environment, to which the genetically modified organisms are to be introduced, in particular whether the other live organisms, which could be adversely affected are present,
- b) the scope and characteristics of the deliberate release,
- c) possible effects on the environment in case of
 1. genetically modified organisms other than higher plants,
 2. genetically modified higher plants.

(4) Higher plants shall be the plants which belong to the taxonomic group Spermatophytæ.

(5) The overall risk level of planned deliberate release shall be definitely established according to the results of risk assessment according to paragraphs 1 to 3.

(6) The report from the risk assessment of deliberate release to the environment of the genetically modified organisms shall include

- a) the identification of all possible direct and indirect, immediate and delayed effects of genetically modified organisms on humans and the environment,
- b) the analysis of cumulative long term effects of genetically modified organisms on human health and the environment,
- c) the identification of resistance to antibiotics

used in human and veterinary medicine.

(7) The identification of the characteristics according to paragraph 1 letter a) and possible effects according to paragraph 6 point a) shall be understood as the assignment to

- a) direct effects: all primary effects on human health or the environment, which are a result of direct acting of genetically modified organism and which do not occur through a causal chain of events;
- b) indirect effects: all effects on human health or on the environment, occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management; they are usually observed in a delay,
- c) immediate effects: all effects on human health or the environment which are observed during the period of the release of the genetically modified organisms; they may be direct or indirect;
- d) delayed effects: all effects on human health or the environment which may not be observed during the period of the release of the genetically modified organisms, but become apparent as a direct or indirect effect either at a later stage or after termination of the release,
- e) cumulative long term effects: all accumulated effects on human health and the environment, including inter alia flora and fauna, soil fertility, purity of organic material, the feed/food chain, biological diversity, animal health and resistance problems in relation to antibiotics used in human or veterinary medicine.

The content of the dossier Article 11

- (1) The dossier on the use of genetic technologies in the facilities shall include
 - (a) the identification data on the facility and on the particular contained room, in which the activities using genetic techniques are being carried out,
 - (b) the composition of safety committee and identification data on the head of the project,
 - (c) the data on the quantity of organisms used on genetic technologies,
 - (d) the identification of genetic method and genetic technique being used,
 - (e) the data on the commencement, course and termination of the activity, in particular the data on time, temperature, air humidity and other physical data, during which the activities has been carried out,
 - (f) the description of the course and the result of use of genetic methods and genetic techniques,
 - (g) the data on the quantity of final genetically modified organisms,

- (h) the description of proprieties of the genetically modified organisms,
 - (i) the identification of the modified genes and used genetic material,
 - (j) the data on the storage, propagation, elimination or other use of genetically modified organisms,
 - (k) data on the quantity and category of waste or waste water and its disposal.
- (2) The dossier according to paragraph 1 shall be prepared in three written copies, of which one shall be stored within the user's and two shall be submitted to the authority, which has issued the consent for use of genetic technologies in the facility.
- (3) The documentation according to paragraph 1 shall be signed by:
- a) the statutory representative of the user,
 - b) the members of the safety committee,
 - c) the head of the project and
 - d) at least one of the workers who directly used the genetic method or genetic technique.

Article 12

- (1) The dossier on the introduction of the genetically modified organisms into the environment shall include
 - a) the documentation according to the Article 11 par. 1, if introduced genetically modified organisms originate from the use of genetic technologies in a facility,
 - b) the report from the risk assessment with definition of overall risk level of planned introduction
 - c) a copy of the application for issuing of the consent for introduction of the genetically modified organisms into the environment and a copy of the issued consent,
 - d) the plan of the introduction containing the description of particular phases in step by step introduction of genetically modified organisms into the environment, from the experiment to the complete introduction,
 - e) the description of circumstances of the introduction and its course according to particular phases of the step by step introduction and evaluation of particular phases of step by step introduction together with a operational diary,
 - f) the description of the place of the introduction and operational order in the place of the introduction,
 - g) the evaluation of the lifecycle of genetically modified organisms being introduced,
 - h) the emergency response plan,
 - i) the report on the result of introduction into the

environment of the genetically modified organisms (hereinafter referred to as "report on the result of the introduction" only).

(2) The dossier according to paragraph 1 shall be prepared in four written copies, of which one is stored by the user, three shall be submitted to the authority, which has issued the consent for introduction into the environment.

Article 13

(1) The dossier on the introduction of the product on the market shall include

- a) the identification data on the producer and on the product,
- b) the report on the result of the introduction, if the introduction of genetically modified organisms into the environment has taken place prior to the commencement of the manufacturing of the product,
- c) the copy of the application for consent with placing of the product on the market and copy of the issued consent with placing of the product on the market and in case the product is being exported, also the copy of consent issued by the national authority of the country to which the product is being exported,
- d) data on the distribution of the product, in particular the identification of purchasers and sales persons and exporters if appropriate,
- e) characteristics of the product's proprieties and its detailed description,
- f) data on the specific use of the product and on the way of its recommended use, including the user's manual, if it is a part of the product's packaging,
- g) the emergency response plan
- h) the monitoring plan
- i) the data on a training of the sellers' employees, if appropriate.

(2) The documentation according to paragraph 1 shall be prepared in four written copies, of which one is stored by the user and three shall be submitted to the authority, which has issued consent for placing of the product on the market.

Article 14

Report on the result of introduction

(1) Then report on the result of the introduction shall include

- a) the identification data on the species and quantity of the genetically modified organisms, which have been introduced into the environment
- b) the report from the risk assessment with definition of overall risk level
- c) a copy of the application for issuing of the consent for introduction of the genetically modified organisms into the environment and a copy of the issued consent,
- d) the description of the circumstances of each phase

of the introduction, its course and evaluation,
e) the description and operational order of the place of the introduction,

- f) the data on performed research and development activities in relation to the introduction of the genetically modified organisms into the environment and knowledge obtained thereby, in particular the evaluation of the lifecycle of the genetically modified organisms being introduced,
- g) detected possible harmful impacts and negative effects of introduced genetically modified organisms on humans, animals and plants,
- h) potential risks for users, proposed possible use or handling of genetically modified organisms, if they are to be perspective used in or as a product.

(2) The report according to paragraph 1 shall be prepared in three written copies, of which one shall be stored by the user and two shall be submitted to the Ministry.

Article 15

Recording of genetic methods and genetic techniques

(1) The genetic methods used in facilities on the basis of notification by the user and issued consent for use shall be entered into the recordings of genetic methods and genetic techniques.

(2) The following data shall be entered into the recordings:

- a) the description of a genetic method and genetic technique,
- b) the marking of the user's person, who has used the genetic method or genetic technique, in particular her company name, identification number and address,
- c) the result of the risk assessment and final assignment of genetic technologies to a risk class,
- d) the address and description of the facility, in which the genetic method or genetic technique has been used,
- e) the description of the organism, on which the genetic method or genetic technique has been used,
- f) data on the vector and genetic material
- g) the way of possible use of the resulting genetically modified organism.

(3) The data entered into the recordings shall be available to users.

Article 16

Recording of used modified genes

(1) All known used genes, which have been isolated and modified by a genetic technique shall be entered into the recordings of used modified genes.

(2) The following data shall be entered into the professional qualification (Article 6), recordings pursuant to paragraph 1:

- a) the name and identification data of the modified gene,
- b) the scientific and national taxonomic name of the organism, from which the gene has been isolated,
- c) the genetic method and genetic technique, by which the gene has been modified and used,
- d) the result of risk assessment from its use
- e) the marking of the user's person, who has used the gene, in particular her company name, identification number and address,
- f) the characteristics and known effects of the modified gene,
- g) actual and possible use of the modified gene in modern biotechnologies.

c) the marking of the used recipient, donor or parental organism and also the marking of the used system host-vector if needed,

d) data on the source and intended function of the genetic material included into the genetic modification,

e) data on the identity and characteristics of the genetically modified organism,

f) the purpose of the use of the genetic technologies, including the expected results,

g) the information on planned quantity of organisms in culture to be used,

h) the description of protective measures to be used, including the data on the waste management including the waste to be produced, its modification, final form and destination.

Proprieties of notifications

Article 17

(1) The notification of the first use of the facility for use of genetic technologies shall include:

- (a) the identification of the person, who is the user, in particular her business name, identification number and the address of the site,
- (b) the identification of the person, who is the head of the project and data on her professional qualification,
- (c) the address of the facility and its general description,
- (d) the data on the members of the safety committee,
- (e) the description of the activities, in which the genetic methods and genetic techniques should be used,
- (f) the risk class, to which the use of genetic technologies has been definitely assigned.

(2) In case the use of genetic technologies is being assigned to risk class 1, the annex to the notification shall be

- a) the report from the risk assessment
- b) data on the waste management in the facility,
- c) the opinion of the head of the project,
- d) the emergency response plan.

Article 18

(1) The notification of the first and any other use of genetic technologies assigned to risk class 2 shall include

- a) the data of the submission of the notification on the first use of the facility (Article 17),
- b) the data on the head of the project and on her

(2) The annex to the notification shall be

- a) the report from the risk assessment from the notification on first use of the facility,
- b) the opinion of the head of the project.
- c) the emergency response plan.

(3) Should the head of the project be entered into the list kept by the Ministry, the data according to paragraph 1 letter b) may be replaced by the name and surname of the head of the project and her registration number.

Article 19

(1) The notification on the planned export of the genetically modified organisms or products thereof shall include

- a) the identification data on inland exporter and on foreign importer
- b) the identification data on genetically modified organism with domestic classification of the biohazard level,
- c) the planned date of the export, the route and border crossing,
- d) the taxonomic classification, common name, place of collecting or acquisition and characteristics of the recipient, donor or parental organism in relation to biological safety,
- e) data on the centre of origin and centres of genetic diversity of the recipient and parental organism, if known and the description of habitat, in which the

- organism may live or propagate itself,
- f) the description of nucleic acids or conducted genetic modification, used genetic technique and resulting proprieties of live genetically modified organism,
- g) the planned utilization of the genetically modified organism or a product thereof, in particular the processed materials originating in live genetically modified organism and containing detectable unusual combinations of genetic material, obtained by the use of modern biotechnology,
- h) the previous or current report from the risk assessment,
- i) the quantity or volume of live genetically modified organisms, which are to be exported,
- j) the purpose and the result of other notifications provided in relation to export of another country,
- k) data on the result of the assessment of the genetically modified organism, in particular whether it is not prohibited together with a reason for the prohibition, or whether its use is not restricted, together with a reason for the restriction, or whether it has been approved for general use,
- l) the proposal of methods for safe use, for storage, transport, utilization including the packaging, labelling and documentation, for disposal and emergency procedures,
- m) the affidavit that the data laid down in the notification are actually correct,
- n) the signature of the statutory body of the exporter, together with her name and position.
- (2) The notification shall be submitted in one copy to the Ministry, the second copy shall be submitted directly to the foreign authority competent to issue the import consent.
- Further proprieties of applications for issuing of consents
- Article 20
- (1) The application for entering of the facility in the register of facilities shall include except of general proprieties of the submission
- a) data on the location of the facility to be entered in the register of facilities,
- b) the description of genetic technologies to be used in the facility,
- c) the description of equipment in the facility, in particular the information on the laboratories, glasshouses, growth rooms and other contained rooms for use of genetic technologies, the level of control for which they are equipped as regards the technical construction and materials, whether the contained rooms allow for compliance with principles of good laboratory and microbiological practice and performance of containment measures arising from the assignment of planned use to a risk class, as well as connection of the facility to public transport and technical facilities of the territory and possibilities of waste and waste water disposal in the facility,
- d) the information on the species and quantity of organisms, including micro-organisms, which shall be genetically modified in the facility,
- e) data on the number, structure, and qualification composition of the employees, who shall use the genetic technologies in the facility,
- f) data on statutory bodies of the user and on heads of the projects.
- (2) The annex to the application shall be
- a) the abstract from the companies register or trade licence register, if the user is the entrepreneur,
- b) the certified copy of the charter or similar document, proving the legal status of the user and tasks for which it has been established or come into existence, if the user is not an entrepreneur,
- c) abstracts from criminal records of the members of the user's statutory body,
- d) the plan of the internal construction - technical and operational arrangement of the facility, in particular the situation of contained rooms and their securing from the leak of genetically modified organisms during the operation or at the accident,
- e) certifications, attests, certificates and other documents proving the data stated in the application or supporting the capacity of the facility for use of genetic technologies,
- f) the list of research tasks carried out in the facility, which have a relation to the use of genetically modified organisms,
- g) the reference of scientific literature from the employees, who should use genetic technologies and that is related to the planned

use of genetically modified organisms in the facility,

h) the operational order in the facility.

Article 21

(1) The application for issuing of the consent with first and every other use of genetic technologies in the facility, which has been finally assigned to the risk classes 3 and 4 shall include except of general proprieties of the submission

- a) the date of submission of the notification on the first use of the facility,
- b) data on the head of the project and her professional qualification,
- c) the marking of the recipient and parental organism to be used,
- d) the marking of the used system host-vector,
- e) data on the source and intended function of the genetic material included into the genetic modification,
- f) data on the identity and characteristics of the genetically modified organism,
- g) the information on planned volumes of the cultures of organisms to be used,
- h) the description of protective measures to be used, including the data on the waste management including the waste to be produced, its modification, final form and destination.
- i) the purpose of the use of the genetic technologies, including the expected results,
- j) the description of the parts of the facility, in particular the laboratories, glasshouses and growth rooms,
- k) data on the prevention of an accident and on the emergency response plan, including the data on hazards resulting from the location of the facility,
- l) the description of preventive measures, in particular the security equipment of the facility, alarm system and control methods,
- m) the description of procedures and plans to verify the permanent effectiveness of protective measures,
- n) data on the content and type of information, which has been provided to the user's employees,
- o) data essential for appraisal of the content of the emergency response plan.

(2) The annex to the application shall be

- a) the report from the risk assessment,

b) the opinion of the head of the project,

c) the emergency response plan.

(3) Should the head of the project be entered into the list kept by the Ministry, the data according to paragraph 1 letter b) may be replaced by the name and surname of the head of the project and her registration number.

Article 22

(1) The application for issuing of the consent with introduction of genetically modified organisms, other than higher plants, shall include except of general proprieties of the submission

- a) the name of the project, in framework of which the introduction should occur,
- b) data on the head of the project,
- c) data related to the characteristics of the genetically modified organism,
- d) data related to the characteristics of donor, recipient and, if appropriate, the parental organism,
- e) data related to the characteristics of the vector,
- f) the description of characteristics affecting the survival, propagation and dissemination of genetically modified organisms,
- g) data related to the conditions of the introduction and receiving environment,
- h) data on the monitoring plan, on conducting of the control of the introduction, waste processing and on emergency response plans.

(2) The data according to paragraph 1 letter c) shall include

- a) data on methods used in the genetic modification,
- b) data on methods used for setting up and introduction of the inserted genetic material to the recipient or for deletion of a sequence,
- c) the description of the combination of the insert and vector
- d) data on the cleanness of the inserted genetic material in relation to each unknown sequence and on the extent in which the inserted sequence is limited in relation to deoxyribonucleic acid, which is required for performance of the intended function of the organism,

- e) the description of methods and criteria used for the selection,
- f) the description of the sequence, functional identity and location of the altered, deleted nucleic acid segment, with particular reference to any known harmful sequence,
- g) the description of genetic trait or phenotypic characteristics of the genetically modified organism, in particular any new traits and characteristics, which may be expressed or no longer expressed,
- h) data on the structure and amount of any vector and donor nucleic acid in the final construction of the genetically modified organism,
- i) data on the stability of the genetically modified organism in terms of genetic traits,
- j) data on rate and level of expression of the new genetic material and on method and sensitivity of measurement;
- k) the description of the activity of the proteins,
- l) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector and sensitivity, reliability (in quantitative terms) and specificity of those techniques,
- m) history of previous releases and other uses of genetically modified organisms,
- n) description of considerations for human, animal and plant health in particular
1. data on toxic and allergenic effects of the genetically modified organism or its metabolic product,
 2. comparison of the genetically modified organism to the donor, recipient or parental organism regarding pathogenicity,
 3. description of capacity for colonisation,
 4. data on pathogenicity to humans who are immunocompetent, in particular data on diseases caused and mechanism of pathogenicity including invasiveness and virulence, communicability, infective dose, host range and possible alternate hosts, possibility of survival outside of human host, presence of vectors or means of dissemination, biological stability, antibiotics resistance patterns, allergenicity and on availability of appropriate therapies,
 5. data on other detected or possible hazards.
- (3) Data according to paragraph 1 letter d) shall include
- a) scientific name of the organism,
 - b) taxonomic classification of the organism
 - c) other names of the organism, in particular usual name, strain name, etc,
 - d) phenotypic and genetic markers of the organism,
 - e) degree of relatedness between donor and recipient or between parental organisms,
 - f) description of identification and detection techniques and their sensitivity, reliability and specificity in quantitative terms,
 - g) description of the geographic distribution and of the natural habitat of the organism, including information on natural predators, preys, competitors, symbionts and hosts,
 - h) definition of organisms with which transfer of genetic material is known to occur under natural conditions,
 - i) data on verification of the genetic stability of the organisms and factors affecting it,
 - j) data on pathological, ecological and physiological traits:
 1. classification of hazard according to existing rules concerning the protection of human health and the environment,
 2. generation time in natural ecosystems, sexual and asexual reproductive cycle,
 3. capacity for survival including seasonability and the ability to form survival structures,
 4. pathogenicity, in particular infectivity, toxigenicity, virulence, allergenicity, carrier of pathogen, possible vectors, host range including non-target organisms, possible activation of latent viruses and proviruses and ability to colonise other organisms,
 5. antibiotic resistance and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy,
 6. involvement in environmental processes: primary production, nutrition turnover, decomposition of organic matter, respiration, etc.
 - k) data on nature of indigenous vectors, sequence, frequency of mobilisation, specificity and presence of genes which confer resistance,
 - l) history of previous genetic modification.
- (4) The information according to paragraph 1 letter e) shall include data on
- a) nature and source of the vector,
 - b) sequence of transposons, vectors and other

- non-coding genetic segments used to construct the genetically modified organism and to make the introduced vector and insert function in the organism,
- c) frequency of mobilisation of inserted vector and genetic transfer capabilities and methods of determination,
 - d) the degree to which the vector is limited to deoxyribonucleotic acid required to perform the intended function.
- (5) Data according to paragraph 1 letter f) shall include
- a) description of biological features which affect survival, multiplication and dispersal,
 - b) data on known or predicted environmental conditions which may affect survival, multiplication and dissemination of genetically modified organisms (in particular wind, water, soil, temperature, pH, etc.)
 - c) data on sensitivity of genetically modified organisms to specific agents,
 - d) description of predicted habitat of the genetically modified organisms,
 - e) studies of the behaviour and characteristics of the genetically modified organisms and their ecological impact carried out in simulated natural environments e.g. greenhouses, growth rooms,
 - f) data on postrelease genetic transfer capability
 1. from genetically modified organism into organisms in affected ecosystems,
 2. from indigenous organisms to the the genetically modified organisms,
 - g) data on likelihood of postrelease selection leading to the expression of unexpected and undesirable traits in the genetically modified organism,
 - h) description of measures employed to ensure and to verify the genetic stability, description of genetic traits, which may prevent or minimise dispersal of genetic material and methods to verify genetic stability,
 - i) data on routes of biological dispersal, known or potential modes of interaction with the dissemination agent, including inhalation, ingestion, surface contact, burrowing, etc.,
 - j) description of ecosystems, to which the genetically modified organisms could be disseminated,
 - k) data on potential for excessive population increase in the environment,
 - l) description of competitive advantage of the genetically modified organism in relation to the unmodified recipient or parental organism,
- m) identification and description of
 1. target organisms if anticipated
 2. non-target organisms, which may be adversely affected by the release and anticipated mechanisms of any identified adverse interaction,
 - n) description of anticipated mechanism and result of interaction between the deliberately released genetically modified organisms and the target organisms,
 - o) information on likelihood of postrelease shifts in biological interactions or in host range,
 - p) description of known or predicted interactions of genetically modified organisms with non-target organisms in the environment, including predators, competitors, preys, hosts, symbionts, parasites and pathogens,
 - r) description of known or predicted involvement in biochemical processes,
 - s) description of other potential interactions of genetically modified organisms with the environment.
- (6) Data according to paragraph 1 point g) shall include:
- a) description of the proposed release including three purpose and foreseen products,
 - b) information on the foreseen dates of the release and time planning of the experiment including frequency and duration of releases,
 - c) description of a preparation of the site previous to the release,
 - d) information on the size of the site,
 - e) description of the methods to be used for the release into the environment,
 - f) information on the quantity of genetically modified organisms to be released,
 - g) description of the possible disturbances on the site of the release into the environment, in particular the type and method of cultivation, mining, irrigation, or other activities,
 - h) description of worker protection measures taken during the release,
 - i) description of treatment of the release site,
 - j) data on techniques foreseen for elimination or inactivation of the genetically modified organisms at the end of the experiment,

- k) data on and results of, previous releases or other uses of the genetically modified organisms, especially at different scales in different ecosystems,
- l) description of geographical location and grid reference of the site of release or areas of the use of the product,
- m) information on physical or biological proximity to humans and other significant biota,
- n) information on proximity of the site of release to significant biotopes, protected areas and drinking water supplies,
- o) data on climatic characteristics of the region likely to be affected by released genetically modified organisms,
- p) description of geographical, geological and pedological characteristics of the site of release,
- r) data on flora and fauna, including crops, livestock and migratory species at the site of release,
- s) description of target and non-target ecosystems likely to be affected by release of the genetically modified organisms into the environment,
- t) comparison of the natural habitat of the recipient organism with the proposed site of release,
- u) data on any known planned changes in land use in the territory, which could influence the environmental of the release.
- (7) Data according to paragraph 1 letter h) shall include:
- a) description of methods for tracing the genetically modified organisms and for monitoring their effects,
- b) data on the specificity of the identification of the genetically modified organisms and sensitivity and reliability of the monitoring techniques,
- c) description of the techniques for detecting transfer of the donor's genetic material to other organisms,
- d) information on duration and frequency of the monitoring,
- e) description of methods and procedures
1. to avoid or minimise the spread of the genetically modified organisms beyond the site of release or the designated area for use
 2. to protect the site of release from intrusion of unauthorised individuals and to prevent other organisms from entering the site,
3. to control the genetically modified organisms in case of unexpected spread,
- f) data on type of waste generated and its expected amount,
- g) description of waste treatment envisaged,
- h) description of methods for
1. decontamination of areas affected, for example eradication of the genetically modified organisms,
 1. disposal or sanitation of plants, animals, soils, that were exposed to the genetically modified organisms during the release or after the spread in the environment,
 2. for isolation of the area affected by the spread of genetically modified organisms,
- i) description of plans for protecting human health and the environment in case of the occurrence of an undesirable effect,
- j) final assignment to a risk class and level of protection and result of re-evaluation of assignment, if appropriate.
- (8) The annex to the application shall be
- a) the report from the risk assessment,
 - b) waste management plan,
 - c) emergency response plan,
 - d) dossier of documents concerning the data according to paragraphs 1 to 7.
- (9) The applicant may use in the application
- a) data and results from previous notifications and proceedings for consent,
 - b) references to scientific literature stating the authorities responsible for elaboration of studies,
 - c) reference to the standardized or internationally recognised genetic methods and genetic techniques.

Article 23

- (1) The application for issuing of consent with release of genetically modified higher plants into the environment shall include except of general proprieties of submission
- a) title of the project in framework of which the release into the environment should occur,

- b) data concerning the genetically modified plant,
- c) data concerning the higher plant donor and recipient and parental plants if appropriate, particularly
1. complete name including name of family, genus, species, subspecies, cultivar/breeding line and common name,
 2. information concerning reproduction, in particular the mode of reproduction, specific factors affecting reproduction of the plant and on generation time of the plant,
 3. data on survivability of the plant, in particular on its ability to form structures for survival or dormancy and on specific factors affecting survivability,
 4. data on dissemination of the plant, in particular on the ways and extent of natural dissemination, with estimation of how viable pollen and seeds declines with distance and on specific factors affecting dissemination, if any.
 5. data on geographical distribution of the plant,
 6. description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts, in case of plant species not normally grown in the territory of the Slovak Republic,
 7. description of other potential interactions of the genetically modified plant with organisms in the ecosystem, where it is usually grown, including information on toxic effects on humans, animals and other plants,
- d) information relating to the genetic modification of the plant, in particular
1. description of gene techniques used for the genetic modification,
 2. description of nature and source of the vector used,
 3. data on size and source name (of donor plant) and intended function of each constituent fragment intended for insertion,
- e) information relating to the site of release, in case of standard or simplified procedure, particularly
1. description of location and size of the release,
 2. description of the release site ecosystem, including climate, flora and fauna,
 3. information on presence of sexually compatible wild relatives or cultivated plant species,
 4. information on proximity to officially recognised biotopes or protected areas which may be affected by the released genetically modified plants,
- f) information relating to the release in case of standard or simplified procedure
1. purpose of the release,
 2. foreseen date and duration of the release,
 3. description of methods by which the genetically modified plants will be released into the environment,
 4. description of methods for preparing and managing the release site, prior to, during and postrelease, including cultivation practices and harvesting methods,
 5. information on approximate number of plants or plants per m²,
- g) information on plans for control of release, monitoring, postrelease and waste treatment
1. data on precautionary measures to prevent or minimise the possibility of dispersal of reproductive material, in particular the pollen, seeds and tuber and for sufficient distance from sexually compatible wild plant species or crops,
 2. description of methods for treatment of the release site,
 3. description of postrelease treatment methods for the genetically modified plants including wastes,
 4. description of monitoring plans and techniques,
 5. description of the content of emergency plans,
 6. description of methods and procedures to protect the release site.
- (2) Data according to paragraph 1 letter b) shall include
- a) description of the traits and characteristics which have been introduced or modified,
 - b) information on the sequences actually inserted or deleted, in particular
 1. data on size and structure of the insert and methods used for its characterisation including information on any parts of the vector introduced in the genetically modified plant and on carrier and foreign

- deoxyribonucleotic acid remaining in the genetically modified plant,
2. data on size and function of the deleted region,
 3. information on copy number of the insert,
 4. description of location of the insert in the plant cells and methods for its determination,
 - c) information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterisation and on parts of the plant, where the insert is expressed, for example in roots, stem, pollen, etc.
 - d) information on how the genetically modified plant differs from the recipient plant in mode and rate of reproduction, dissemination and survivability,
 - e) information on genetic stability of the insert and phenotypic stability of the genetically modified plant,
 - f) information on any change to the ability of the genetically modified plant to transfer genetic material to other organisms,
 - g) information on any toxic, allergenic or harmful effects on human health arising from the genetic modification of the plant,
 - h) information on the safety of the genetically modified plant to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the genetically modified plant is intended to be used in animal feedstuffs,
 - i) description of the mechanism of interaction between the genetically modified plant and target organisms,
 - j) description of potential changes in the interactions of the genetically modified plant with non-target organisms resulting from the genetic modification of the plant,
 - k) description of potential interactions with the abiotic environment,
 - l) description of detection and identification techniques for the genetically modified plant,
 - m) information on previous releases of the genetically modified plant, if applicable,
 - n) final assignment to a risk class with level of protection and result of re-evaluation of the assignment, if appropriate.
- (3) The annex to the application shall be
 - a) the report from the risk assessment,
 - b) waste management plan,
 - c) emergency response plan,
 - d) dossier of documents concerning the data according to paragraphs 1 and 2.
 - (4) The applicant may use in the application
 - a) data and results from previous notifications and proceedings for consent,
 - b) references to scientific literature stating the authorities responsible for elaboration of studies,
 - c) reference to the standardized or internationally recognised genetic methods and genetic techniques.

Article 24

- (1) An application for issuing of the consent with placing of the product made of genetically modified organisms on the market shall include the proprieties according to Article 5 and 6, depending on the fact, whether the product involves genetically modified higher plant or genetically modified organisms other than higher plants. Additionally, the application shall include except of general proprieties of submission
 - a) data and information on results of releases into the environment arising from the consents issued on the basis of applications according to Articles 5 and 6,
 - b) the result of the risk assessment and conclusions regarding potential effects of the product on the environment after placing on the market,
 - c) conditions for the placing on the market of the product including specific conditions of use and handling,
 - d) a proposed period for the consent, which should not exceed ten years,
 - e) a proposal for the time period of monitoring plan,
 - f) a proposal for labelling and packaging of the product,
 - g) a summary of the dossier.
- (2) The conclusions according to paragraph 1 letter b) shall include

- a) in the case of product made of genetically modified organisms other than higher plants,
1. likelihood of the genetically modified organism to become persistent and invasive in natural habitats under the conditions of the proposed release,
 2. description of any selective advantage or disadvantage conferred to the genetically modified organism and the likelihood of its occurrence under the conditions of the proposed release,
 3. potential for gene transfer to other species under conditions of the proposed release and any selective advantage or disadvantage conferred to those species,
 4. description of potential immediate or delayed environmental impact of the direct and indirect interactions between the genetically modified organisms and target organisms or non-target organisms, including impact on population level of predators, competitors, prey, hosts, symbionts, parasites and pathogens,
 5. description of possible immediate and delayed effects on human health resulting from potential direct and indirect interactions of the genetically modified organisms and persons coming into contact with them or in the vicinity of deliberate release,
 6. description of possible immediate and delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the genetically modified organisms and any products derived from it, if it is intended to be used as animal feed,
 7. description of possible immediate and delayed effects on biochemical processes resulting from potential direct and indirect interactions of the genetically modified organisms and target and non-target organisms in the vicinity of the release.
 8. description of possible immediate and delayed, direct and indirect environmental impacts of the specific techniques used for the management of the genetically modified organisms, on the environment, where these are different from the techniques used for organisms not genetically modified,
- b) in the case of genetically modified plants
1. likelihood of the genetically modified plant becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats,
 2. data on any selective advantage or disadvantage conferred to the genetically modified plant,
 3. data on potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the genetically modified plant and any selective advantage or disadvantage conferred to those plant species,
 4. description of potential immediate and delayed environmental impact resulting from direct and indirect interactions between the genetically modified plants and target organisms, such as predators, competitors, parasitoids, and pathogens, if applicable and with non-target organisms, including impact on population levels of predators, competitors, herbivores, symbionts, parasites and pathogens,
 5. description of possible immediate and delayed effects on human health resulting from potential direct and indirect interactions of the genetically modified plants and persons working with, coming into contact with or in the vicinity of the release,
 6. description of possible immediate and delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the genetically modified plants and any products derived from them, if it is intended to be used as animal feed,
 7. description of possible immediate and delayed effects on biochemical processes resulting from potential direct and indirect interactions of the genetically modified plants and target and non-target organisms in the vicinity of the release.
 8. description of possible immediate and delayed, direct and indirect environmental impacts of the specific cultivation, raising and harvesting techniques used in relation with genetically modified organisms on the environment, where these are different from those used for plants not genetically modified.
- (3) The proposal according to paragraph 1 letter f) shall include
- a) commercial names of the products and identification of genetically modified organisms contained therein, and any specific identification, name or code used by the user to identify the genetically modified organism,
 - b) name and full address of the person, who is responsible for the placing on the market, e.g. the manufacturer, the distributor, the importer,

- c) name and full address of the supplier of control samples,
 - d) description of how the product is to be used, in particular the differences in use or handling of the genetically modified organism compared to similar non-genetically modified products should be highlighted,
 - e) description of the geographical area and types of environment where the product is intended to be used, including estimated scale of use in each area,
 - f) intended categories of users of the product e.g. industry, agriculture and trade, consumer use by public at large,
 - g) information on the genetic modification for the purposes of determination of identifier, which can be used for the detection and identification of genetically modified organism in product to facilitate post-marketing control and inspection, including the lodging of samples or genetic material and details of nucleotide sequences and results of experiments in confidential part of the register,
 - h) proposed labelling on a label or in an accompanying document with the information on commercial name of the product and the information how to access the information in the publicly accessible part of the register,
 - i) description of measures to take in case of unintended release or misuse of the genetically modified organism,
 - j) specific instructions or recommendations for storage and handling of the product,
 - k) instructions for carrying out monitoring and reporting to the user on any adverse effect,
 - l) information on how product may be used and for what purposes,
 - m) proposed packaging,
 - n) estimated production or import,
 - o) proposed additional labelling of the product.
- b) description of the result of the genetic modification in the genetically modified organism.
 - c) assessment of whether the genetic modification has been characterised sufficiently for the purpose of assessing any risks to human health and the environment.
 - d) identification of any new risks to human health and the environment that may arise from the release of the genetically modified organism as compared to the release of the corresponding non-modified organism, based on the risk assessment,
 - e) conclusions on whether
 1. the genetically modified organism should be placed on the market in or as a product and under which conditions,
 2. the genetically modified organism should not be placed on the market,
 3. the views of other authorities should be sought in case of specific aspects be identified in risk assessment.
- (6) The conclusion should address the proposed use of the genetically modified organism and the monitoring plan proposed.
 - (7) The conclusion of the assessment report stating that the the genetically modified organisms should not be placed on the market shall be justified.

Article 27

(1) The objective of a monitoring plan is to confirm the corectness of assumptions arising from assessment of risk regarding the occurrence and impact of potential adverse effects of the genetically modified organisms or its use and to identify the occurrence of adverse effects of the genetically modified organisms or its use on human health or the environment which were not anticipated in the risk assessment.

(2) Monitoring shall take place after the consent to the placing of a product on the market. The data collected by monitoring, in particular changes observed in the environment shall be the reason and basis for re-evaluation of risk assessment and of appropriateness and suitability of protective measures to observe, whether they are result of deliberate release or other environmental factors, which are not related to the deliberate release of the genetically modified organisms.

Article 25

The way of submitting notifications and applications

The notifications and applications according to Articles 17 to 24 shall be submitted to the Ministry in three written copies and in electronic form.

Content of assessment report

Article 26

- (1) The assessment report shall include
 - a) Identification of the characteristics of the recipient non-modified organism which are relevant to the assessment of any known risks resulting from the genetically modified organism to human health and the environment at the release into the environment.

- (3) The monitoring plan shall
- a) be detailed on a case by case basis taking into account the result of risk assessment,
 - b) take into account the characteristics of the genetically modified organisms, the scale of its intended use and the range of relevant environmental conditions where the genetically modified organisms may be released,
 - c) incorporate rules for general surveillance of unanticipated adverse effects and, if necessary, rules for specific monitoring focusing on adverse effects identified in the risk assessment for a sufficient time period to detect immediate and direct as well as, where appropriate, delayed or indirect effects, using already established routine surveillance practices such as the monitoring of agricultural cultivars, plant protection, or effects of veterinary and medical products,
 - d) facilitate the observation, in a systematic manner, of the release of a genetically modified organism in the receiving environment and the interpretation of these observations with respect to safety to human health or the environment,
 - e) identify who and when is obliged to
 1. carry out the various tasks pursuant to the monitoring plan,
 2. set the monitoring plan into place and

- carry it out appropriately,
3. ensure that the user and authority issuing the consent will be informed on any observed adverse effects on human health and the environment,
 - f) give consideration to the mechanisms for identifying and confirming any observed adverse effects on human health and environment, of the genetically modified organisms and enable the user and the authority, that has issued the consent to take the measures necessary to protect human health and the environment.

Article 28
Entry into force

This decree shall enter into force on June 1, 2002.

László Miklós s. m.

Annex 1
to the Decree No. 252/2002 Coll.

Containment and other protective measures for laboratory activities

Specifications		Containment levels			
		1	2	3	4
1	Laboratory suite: isolation ¹⁾	Not required	Not required	Required	Required
2	Laboratory: sealable for fumigation	Not required	Not required	Required	Required

Equipment (of a laboratory)

3	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required (bench)	Required (bench)	Required (bench, floor)	Required (bench, floor, ceiling, walls)
4	Entry to lab via airlock ²⁾	Not required	Not required	Optional	Required
5	Negative pressure relative to the pressure of the immediate environment	Not required	Not required	Required except for ³⁾	Required
6	Extract and input air from the laboratory should be HEPA-filtered	Not required	Not required	Required (HEPA) ⁴⁾ — extract air except for ³⁾	Required (HEPA) ⁵⁾ — input and extract air
7	Microbiological safety post	Not required	Optional	Required	Required
8	Autoclave	On site	In the building	En suite ⁶⁾	In lab = double-ended

System of work

9	Restricted access	Not required	Required	Required	Required
1	Biohazard	Not required	Required	Required	Required

0	sign on the door				
111	Specific measures to control aerosol dissemination	Not required	Required minimise	Required prevent	Required prevent
13	Shower	Not required	Not required	Optional	Required
14	Protective clothing	Suitable protective clothing	Suitable protective clothing and (optional) footwear	Suitable protective clothing	Complete change of clothing and footwear before entry and exit
15	Gloves	Not required	Optional	Required	Required
16	Efficient vector control (e.g. for rodents and insects)	Optional	Required	Required	Required

Waste

17	Inactivation of genetically modified micro-organisms in effluent from hand-washing sinks or drains and showers and similar effluents	Not required	Not required	Optional	Required
18	Inactivation of genetically modified micro-organisms in contaminated material	Optional	Required	Required	Required

	and waste				
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Other measures

19	Laboratory to contain its own equipment	Not required	Not required	Optional	Required
20	An observation window or alternative is to be present so that occupants can be seen	Optional	Optional	Optional	Required

1) Isolation = the laboratory is separated from other areas in the same building or is in a separated building.

2) Airlock = entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

3) Activities where transmission does not occur via airborne route.

4) HEPA = High efficiency particulate air.

5) Where viruses which are not retained by HEPA filters are used, extra requirements will be necessary for extract air.

6) With validated procedures, allowing the safe transfer of material into an autoclave outside the lab, and providing an equivalent level of protection.

**Annex 2
to the Decree No. 252/2002**

Coll.

Containment and other protective measures for glasshouses and growth-rooms

The terms "glasshouse" and "growth-room" refer to a structure with walls, a roof and a floor designed and used principally for growing plants in a controlled and protected environment.

All provisions of table in Annex 1 shall apply with the following additions/modifications:

Specifications	Containment levels			
	1	2	3	4

Building

1	Greenhouse: permanent structure ¹⁾	Not required	Required	Required	Required
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Equipment

3	Entry via a separated room with two interlocking doors	Not required	Optional	Optional	Required
4	Control of contaminated run-off water	Optional	Minimise (2) run-off	Prevent run-off	Prevent run-off

6	Measures to control undesired species such as insects, rodents, arthropods	Required	Required	Required	Required
7	Procedures for transfer of living material between the glasshouse/ growth-room, protective structure and laboratory shall control dissemination	Minimise dissemination	Minimise dissemination	Prevent dissemination	Prevent dissemination

	nation of genetic ally modifie d micro- organis ms				
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**Annex 3
to the Decree No. 252/2002**

Coll.

Containment and other protective measures for activities in animal units

All provisions of table in Annex 1 shall apply with the following additions/modifications:

Specifications	Containment levels			
	1	2	3	4

Facilities

1	Isolation of animal unit ³⁾	Optional	Required	Required	Required
2	Animal facilities ⁴⁾ separated by lockable doors	Optional	Required	Required	Required
3	Animal facilities designed to facilitate decontamination (waterproof and easily washable material (cages, etc.))	Optional	Optional	Required	Required
4	Floor and/or walls easily washable	Optional	Required (floor)	Required (floor and walls)	Required (floor and walls)
5	Animals kept in appropriate containment facilities such as cages, pens or tanks	Optional	Optional	Optional	Optional
6	Filters on isolators or isolated room ⁵⁾	Not required	Optional	Required	Required

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**Annex 4
to the Decree No. 252/2002**

Coll.

Containment and other protective measures for other activities

Specifications	Containment levels				
	1	2	3	4	
1	Viabile micro-organisms should be contained in a system which separates the process from the environment (closed system)	Optional	Required	Required	Required
2	Control of exhaust gases from the closed system	Not required	Required, minimise dissemination	Required, prevent dissemination	Required, prevent dissemination
3	Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	Optional	Required, minimise dissemination	Required, prevent dissemination	Required, prevent dissemination
4	Inactivation	Optional	Required, by validated	Required, by	Required, by

	of bulk culture fluids before removal from the closed system		means	validated means	validated means
5	Seals should be designed so as to minimise or prevent release	No specific requirement	Required, minimise dissemination	Required, prevent dissemination	Required, prevent dissemination
6	The controlled area should be designed to contain spillage of the entire contents of the closed system	Optional	Optional	Required	Required

7	The controlled area should be sealable to permit fumigation	Not required	Optional	Optional	Required
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Equipment

8	Entry via airlock	Not required	Not required	Optional	Required
9	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required (bench, if any)	Required (bench, if any)	Required (bench, if any, floor)	Required (bench, floor, ceiling, walls)
10	Specific	Optional	Optional	Optional	Required

	measures to adequately ventilate the controlled area in order to minimise air contamination				
11	The controlled area should be maintained at an air pressure negative to the immediate surroundings	Not required	Not required	Optional	Required
12	Extract and input air from the controlled area should be HEPA filtered	Not required	Not required	Required (extract air, optional for input air)	Required (input and extract air)

System of work

13	Closed systems should be located within a controlled area	Not required	Optional	Required	Required
14	Access should be restricted to nominated personnel only	Not required	Required	Required	Required
15	Biohazard signs should be posted	Not required	Required	Required	Required

16	Personnel should	Not required	Not required	Optional	Required
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	shower before leaving the controlled area				
17	Personnel should wear protective clothing	Required (work clothing)	Required (work clothing)	Required	Complete change before exit and entry

Waste

18	Inactivation of genetically modified micro-organisms in effluent from handwashing sinks and showers or similar effluents	Not required	Not required	Optional	Required
19	Inactivation of genetically modified micro-organisms in contaminated material and waste including those in process effluent before final discharge	Optional	Required, by validated means	Required, by validated means	Required, by validated means

151**A C T**

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 fund¹⁾ 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

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.

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
(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)

which can exchange genetic material by natural physiological processes.

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,

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

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 contained rooms and the waste handling³⁾ and waste water treatment⁴⁾.

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

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.

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
- 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 relation-

ships.

(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

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.

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 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 phytosanitary 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

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 phytosanitary 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 ampelogy 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.

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,

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) 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,
- 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 statute the environmental or consumer protection.

(3) The task of the Commission shall be g) 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,
- h) 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,
- i) to work out the recommendations as the professional basis for Ministry issuing the consents (Article 13, 17 and 21),
- j) to analyse and assess the content of received comments from public,
- k) 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,
- l) 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

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

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

- 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.

(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 disciplinary 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 motion²⁰⁾ 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
- it is registered as a civic association²²⁾ with aim according to this paragraph for at least one year to the date of submission of the application according to letter 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
 - a part of the application according to letter b) is a petition²³⁾ 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
- confirm in writing to the notifier the submission of the application,
 - 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
- 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,
 - 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

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.

shall contain except of general proprieties of motion²⁰⁾

- technical documentation needed for verification of risk assessment and
- 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,
- 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

- it is registered as a civic association²²⁾ with aim according to this paragraph for at least one year to the date of submission of the application according to letter 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
- a part of the application according to letter b) is a petition²³⁾ signed by at least 100 natural persons supporting this application.

(3) The Ministry shall

- confirm in writing to the notifier the submission of the application,
- 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 motion²⁰⁾ 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

- it is registered as a civic association²²⁾ 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 petition²³⁾ 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 decision²⁴⁾

- 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 ecosystems 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

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

discuss detected problems, the period for the decision shall be 30 days from the date of termination of the discussion.

(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 foodstuffs⁸⁾ 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

Rudolf Schuster s.m.

Jozef Migas s.m.

Mikulas Dzurinda s.m.

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.

²⁾ The glasshouse shall consist of a permanent structure with a continuous waterproofed covering, located on a site graded to prevent entry of surface-water run-off having self-closing lockable doors.

²⁾ Where transmission can occur through the ground.

- ²1) Animal unit: a building, or separate area within a building containing facilities and other areas such as changing rooms, showers, autoclaves, food storage areas, etc.
- ²2) Animal facility: a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures.
- ²3) Isolators: transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.