**Only the Slovak text is authentic**

**REGULATION No. 399/2005 Coll.,**

**of the Ministry of Environment of the Slovak Republic**

of August 8th, 2005,

to implement the Act No. 151/2002 Coll., on the use of genetic technologies and genetically modified organisms, **as amended by** the Regulation No. 312/2008 Coll., of July 21st 2008, by the Ministry of Environment of the Slovak Republic, amending and supplementing the Regulation No. 399/2005 Coll., by the Ministry of Environment of the Slovak Republic,

and **Regulation No. 86/2013 Coll. of 28th March 2013**

Pursuant to the Article 39, of the Act No. 151/2002 Coll., on the use of genetic technologies and genetically modified organisms as amended by the Act No. 587/2004 Coll., Act No. 77/2005 Coll., Act No. 100/2008 Coll. **and Act No. 448/2012 Coll.** (hereinafter referred to as „the Act“) the Ministry of Environment of the Slovak Republic (hereinafter referred to as „the Ministry“) stipulates:

**Art. 1**

**Scope of the Regulation**

**(1)** This Regulation sets out details of

a) emergency plan content,

b) requirements for the contained GMO facilities of the user (hereinafter referred to as "GMO facilities") where genetic technologies and genetically modified organisms will be used,

c) expertise of the person responsible for the project safety (hereinafter referred to as "project head") and his further education,

d) environmental risk assessment of genetic technologies and genetically modified organism usage (hereinafter referred to as „risk“) as well as procedure and criteria for classification of used genetic technologies and genetically modified organisms into risk categories, and content of the protection levels,

e) procedure for evaluation of direct and indirect, immediate and delayed impacts of introduction of genetically modified organisms into the environment and for performance of analysis of cumulative long-term impacts of genetically modified organisms to humans and the environment,

f) content of the dossier of using of genetic technologies and genetically modified organisms (hereinafter referred to as „dossier“) as well as procedures for its keeping and archiving,

g) content of the report on the results of introduction of the genetically modified organism into the environment (hereinafter referred to as „introduction report“),

h) requirements to the individual notifications and evaluation of their content,

i) requirements to the applications for permit,

j) content of the evaluation report,

k) criteria for safety of genetically modified microorganisms that will not be covered by the provisions of the contained use (hereinafter referred to as „contained use“).

**(2) The provisions of this regulation relating to the use of genetically modified organisms, apply equally to the use of genetically modified micro-organisms.**

**Art. 2**

**Content of the emergency plan**

(1) Emergency plan includes

a) identification data of the user,

b) identification data of the research, development or production facility of the user (hereinafter referred to as „GMO facility“) that contains GMO facility, or identification data of the ground where the genetically modified organisms are introduced into the environment,

c) identification data of bodies and persons intended to remove consequences of an accident, to ensure health care for persons injured by the accident, to disinfect etc.,

d) facility plan or plan of the ground with marked important sites for reduction of the accident consequences,

e) data on amount as well as species of genetically modified organisms that could be released during an accident, or that could unexpectedly be spread into the environment,

f) description of protective measures for accident prevention,

g) description of an accident that can happen in the facilities or in site where genetic technologies and genetically modified organisms are used, in parallel with description of the recommended procedure of removal of accident consequences, especially methods and means for physical disposal of genetically modified organisms in form of scenarios of model accident types.

(2) Scenarios of model accident types comprise

a) plans for both, human health and environmental protection in case of accident,

b) methods for separation of areas impacted by release,

c) methods for decontamination of impacted areas,

d) methods and procedures for control of genetically modified organisms in case of accident,

e) description of potential accident consequences and its immediate particular external effects to the employees of user, as well as the citizens and the environment,

f) methods for disposal or remediation of especially plants, animals, soil that were exposed to influence of genetically modified organisms during and after the accident,

g) description of recommended behaviour of the employees of the facility and the citizens in its vicinity, area and ground where genetic methods and genetic techniques are used for case of their contact with genetically modified organisms released during the accident.

(3) If it will be recognised according to the risk assessment and final classification of using of genetic technology or genetically modified organisms into the risk category that due to uncontrolled release of genetically modified organisms can not cause an accident, emergency plan can be replaced by operating rules.

**Art. 3**

**Requirements for GMO facilities**

(1) GMO facilities should meet requirements that allow for implementation of protective level corresponding to the classification of using of genetic technologies and genetically modified organisms into risk categories.

(2) Requirements for implementation of protective level for

a) laboratories are listed in Annex 1,

b) greenhouses and growing chambers are listed in Annex 2,

c) cells for animals are listed in Annex 3,

d) other GMO facilities are listed in Annex 4.

**Art. 4**

**Training of project heads**

(1) Training of project heads comprises training course that is performed in three-year intervals as minimum requirement. Content of the training course for project heads is formed by lectures, workshops and case studies related to knowledge and experience in

a) content of legislative requirements on genetic technologies, on using of genetic methods and genetic techniques, on principles of safety and health protection during work with genetically modified organisms, as well as record keeping,

b) international experience and knowledge of using of genetic technologies,

c) procedures of risk assessment, classification of using of genetic technologies and genetically modified organisms into risk categories, and of classification re-evaluation,

d) protective levels related to risk categories of using of genetic technologies and genetically modified organisms, and application of protection measures,

e) elaboration of emergency plans, their content, publication and amendments,

f) procedures in case of accident.

(2) Head of project participates on training course on a basis of nomination by the user, in the time period set out in Ministry call.

(3) Details of the training course organisation are published not later than three weeks before its planned commencement.

**Art. 5**

**Risk assessment**

(1) Risk assessment is focused in identification of all existing or potential future unfavourable effects to humans or the environment that could emerge during contained use or deliberate release of genetically modified organisms to the environment.

(2) Risk assessment is aimed in identification and evaluation potential adverse effects of genetic technologies and genetically modified organisms in each individual case onto

a) human beings, especially allergenic and toxic effects and effects blocking treatment of existing disease, or provision of effective prevention, e.g. resistance to antibiotics applied in human treatment or veterinary medication,

b) fauna and flora, especially effects caused by natural transfer of inserted genetic material to other organisms, and influence of their introduction into the environment or their spread in the environment.

(3) Risk assessment in case of application for issuing of permit for using of genetically modified organism containing gene that causes resistance to antibiotics

a) evaluates

1. direct impact of enzyme encoded by the resistance,

2. potential transfer of antibiotic resistance to intestine epithelial cells,

3. potential transfer of antibiotic resistance to intestine microorganisms,

4. potential transfer of antibiotic resistance to microorganisms in the environment,

b) follows the criteria below:

1. whether the assessed antibiotic is important in the medical applications,

2. whether it is used frequently,

3. whether it is administered orally,

4. whether it is unique,

5. what is the extent of resistance spread in the bacterial population against the assessed antibiotic.

**Procedure and risk assessment report**

**Art. 6**

**Procedure of contained use risk assessment**

(1) The following steps of evaluation should be performed during the contained use risk assessment:

a) to identify harmful characteristics of the recipient organism, and also of the donor, if applicable,

b) to identify harmful characteristics related to vector or inserted genetic material including each change of properties of recipient organism,

c) to investigate hygienic, food related and other regulations related to genetic methods and genetic techniques as well as genetically modified organisms in order to gain data necessary for the risk assessment,

d) to apply international classification systems and other national classification systems and their revisions performed on the basis of newly received scientific knowledge and technical progress, first, classification systems for risk categorisation of microorganisms as biological agents according to their effects to the healthy human adults, second, classification systems related to plant and animal pathogens.

(2) The user identifies the risk level according to the procedure set out in par. 1, he pre-classifies the contained use into risk category, and he selects the set of protection measures adequate to the pre-classification and requested protective level.

(3) The user reflects the following parameters during the selection of control and other protective measures that should be based on the risk level linked to genetically modified organism:

a) characteristics of the environment inside the contained use that could be exposed to the effects of genetically modified microorganisms, especially whether other living organisms are present that could be adversely affected by microorganisms used in the facility,

b) extent and characteristics of the activities to be performed with application of genetic techniques,

c) each potential non-standard activities, e.g. inoculation of animals by genetically modified microorganisms, generation of aerosols in the GMO facility,

d) defined protective level corresponding to the risk category.

(4) The contained use will be categorised into risk category according to the results of assessment pursuant to par. 1 to 3.

(5) Contained use can be categorised as risk category 1 only if it will be shown that the used genetically modified organisms have the following properties:

a) receiving organism or donor organism should not harm the human health or harm health of animals or plants in the environment possibly exposed to its influence,

b) nature of vector as well as inserted material do not give a phenotype to the genetically modified organism that could cause harm to human health, harm to animal or plant health in the environment possibly exposed to its influence, or that could have cause adverse effects to the environment, and

c) an assumption exists that genetically modified organism will not cause illness of human beings, nor illness of animals and plants in the environment that could be exposed to its influence, and that it could not deteriorate the environment.

(6) If the properties of the genetically modified organism according to the par. 5 will not be proved, the contained use can be classified into

a) risk category 2, in case of low risk easily removable by protective measures, especially physical barriers,

b) risk category 3, in case of medium risk removable by special demanding protective measures, or

c) risk category 4, in case of high risk leaving permanent consequences that can not be completely removed even by especially demanding protective measures.

**Art. 7**

**Risk assessment report of contained use**

(1) Risk assessment report of contained use includes

a) identification of all harmful effects of genetically modified organisms,

b) characteristics of activities intended to use genetic technique,

c) data on potential harmful effects intensity,

d) probability assessment of potential appearance of harmful effects.

(2) Identification of all possible harmful effects according to par. 1 a) related to

a) recipient organism, it contains data on

1. character of pathogenicity and virulence, infectivity, allergenicity, toxicity and disease transfer vector,

2. character of indigenous vectors and random agents in cases when they could mobilise inserted genetic material, as well as on mobilisation frequency,

3. character and stability of blocking mutations,

4. all previous genetic modifications,

5. extent of hosts,

6. all important physiological characteristics that could be changed in the final genetically modified organism, and if appropriate also their stability,

7. natural biotopes and geographical distribution,

8. important involvement into environmental processes, e.g. nitrogen fixation or pH regulation,

9. interaction with other organisms in the environment and influence to them including probable competitive, pathogenic or symbiotic properties,

10. potential to create structures for survival ability, e.g. spores or sclerotia,

b) donor organism, it contains data on

1. character of pathogenicity and virulence, infectivity, allergenicity, toxicity and disease transfer vector,

2. character of indigenous vectors (sequence, mobilisation and specificity frequency),

3. extent of hosts,

4. other related physiological characteristics,

c) vector, it contains data on

1. vector character and source,

2. structure and amount of nucleic acid of any vector or donor that remains in the final construction of modified organism,

3. mobilisation frequency of inserted vector if it is present in the final modified microorganism, or genetic material transfer potential,

d) inserted material, it contains data on

1. individual identity and function of inserted material (genes),

2. expression level of inserted genetic material,

3. source of genetic material, donor organism identity and its characteristic,

4. history of former genetic modifications, if appropriate,

5. site where genetic material was inserted (possibility of activation or deactivation of host genes by insertion),

e) resulting genetically modified organism, it contains data on

1. expected toxic or allergenic effects of genetically modified organism or its products,

2. comparison of modified organism with recipient organism or donor organism as regards its pathogenicity,

3. expected colony forming potential,

4. infectious dose, diseases that it causes, survival capacity out of human host, biological stability, antibiotics resistance profiles, allergenicity, toxigenicity, availability of appropriate therapy and profylactic measures if the organism is pathogenic for immunocompetent human beings,

5. ecosystems where organism could be unintentionally released from the contained use,

6. expected survival potential, reproduction and spread capacity of modified organism in the indentified ecosystems,

7. predicted results of interactions among modified organism and organisms or microorganisms that could be exposed to its influence in case of unintentional release into the environment

8. known or predicted effects to plants and animals as pathogenicity, toxicity, allergenicity, vector of certain pathogene, changed antibiotic resistance profiles, changed tropism or host specificity, colonisation,

9. known or predicted involvement into biogeochemical processes.

**Art. 8**

**Risk assessment of deliberate release, identification of effects and analysis of cumulative long-term effects**

(1) Effects of deliberate release of genetically modified organisms into the environment can be

a) direct, as all primary effects to human health or to the environment that result from direct influence of genetically modified organism, i.e. that do not result from chain of causation,

b) indirect, as all effects to human health or to the environment that result from random chain of causation via mechanisms, e.g. interaction with another organisms, genetic material transfer, changed use or management; observations of indirect effects will probably be consecutive,

c) immediate, as all effects to human health or to the environment that are observable as early as genetically modified organisms are released; they can be direct or indirect,

d) delayed, as all effects to human health or to the environment that are not observable during genetically modified organisms release, but that will express as direct effect or indirect effect in a later phase of release or even after its termination,

e) cumulative long-term, as all effects to human health or to the environment including effects to flora and fauna, soil fertility, purity of organic material, food chain, biological diversity, animal health, resistance to antibiotics used in human therapy or veterinary medication when they are important from the market placement point of view.

(2) In compliance with prevention principle, the following fundaments apply during risk assessment of deliberate release:

a) identified characteristics of genetically modified organism and its application that are able to cause adverse effects are compared with those that are present in non-modified organisms from which the genetically modified organism was derived, and with its use under equivalent conditions,

b) risk assessment will be performed by scientifically applicable and transparent way based on available scientific and technical data,

c) risk assessment will be performed for each particular case, thus requested information could change according to the type of related genetically modified organisms, intended use and receiving environment,

d) if new information become available regarding the genetically modified organism and its effects to human health or to the environment, risk assessment will be re-evaluated in order to recognise whether the risk has changed or whether it is necessary to adjust risk management,

e) analysis of cumulative long-term effects will be elaborated, relevant to introduction into the environment and placing on the market.

(3) Risk assessment of deliberate release reflects scientific and technical data related to the characteristics of

a) each recipient or donor organism,

b) each genetic modification, regardless whether it is insertion or extraction of genetic material, and related information on vector and donor,

c) genetically modified organism,

d) intended release,

e) possible receiving environment and interactions between them.

(4) Risk assessment report of the deliberate release of genetically modified organisms into the environment includes

a) identification of effects related to genetic modification that could cause adverse effects to human health or the environment,

b) comparison of identified characteristics of genetically modified organisms and their use that could cause adverse effects with organisms from which the genetically modified organism was derived, and with its use under comparable conditions,

c) probability assessment of occurrence of adverse effect in relation to characteristics of environment where the genetically modified organism is intended to be released deliberately, as well as to the type of deliberate release,

d) evaluation of possible consequences of each adverse effect, if it is probable that it can occur,

e) risk assessment for each identified characteristic of the genetically modified organism that has potential to cause adverse effects, reflecting the technique state-of-the-art according to the combination of adverse effect occurrence probability and extent of consequences, if it occurred,

f) development of strategy for identified risk management of deliberate release of the genetically modified organism into the environment,

g) identification of the total risk of the genetically modified organism.

(5) The following will be reflected during selection of the battery of protective measures

a) characteristics of the environment where genetically modified organisms are intended to be released deliberately, especially whether another living organisms are present that could be adversely affected,

b) extent and characteristics of deliberate release of genetically modified organisms into the environment,

c) possible effect to the environment, if the following is concerned

1. genetically modified organisms that are not higher plants belonging to taxonomical group Spermatophytae (hereinafter referred to as „higher plants“),

2. genetically modified higher plants.

(6) The final total risk level of the deliberate release of genetically modified organisms to the environment will be identified according to the results of assessment based on par. 1 to 4.

**Dossier content**

**Art. 9**

(1) According to the Art. 9, par. 8 j) of the Act, the dossier includes

a) identification data of the facility and particular GMO facility where genetic technologies and genetically modified organisms are used,

b) copy of the application for permit for contained use or copy of notification,

c) decision on permit issuance for contained use, as well as change or withdrawal of such decision, and also decision on penalty,

d) composition of the Safety Committee as well as identification data of the project head,

e) risk assessment report and records from re-evaluation of classification of contained use into risk categories,

f) operation manual,

g) emergency plan,

h) operational logbook,

i) records of training of personnel and qualification improvement,

j) documented familiarization with operation manual,

k) records of checks and their results.

(2) According to the Art. 19, par. 1 c) of the Act, the dossier includes

a) documentation pursuant to par. 1, if the introduced genetically modified organisms originate from the contained use,

b) written risk assessment report with identification of the total risk level of planned introduction,

c) copy of application for permit for introduction of genetically modified organisms into the environment as well as copy of permit,

d) introduction plan containing description of the individual phases of gradual introduction of the genetically modified organisms into the environment, since the experiment until completed introduction,

e) description of circumstances of introduction and its progress according to the individual phases of gradual introduction, and evaluation of the individual phases of gradual introduction, as well as operational logbook,

f) description of introduction site as well as operation manual of this site,

g) operational logbook,

h) evaluation of life cycles of the introduced genetically modified organisms,

i) emergency plan,

j) report on introduction result,

k) records of training of personnel and qualification increase,

l) documented familiarization with operation manual of the introduction site,

m) records of checks and their results.

**Art. 10**

**Operational logbook and operation manual**

(1) Operational logbook that is kept during utilization of genetic technologies and genetically modified organisms includes

a) description of genetic technology and genetically modified organisms,

b) data on beginning, progress, termination and result of utilization of genetic technologies and genetically modified organisms,

c) data on amount of organisms used for genetic technologies,

d) data on amount of resulting genetically modified organisms,

e) identification of altered genes and used genetic material,

f) data on maintenance, reproduction, disposal or other utilization of genetically modified organisms,

g) data on amount and type of waste or waste water and their disposal,

h) records of all emergency situations and accidents,

i) records of all checks performed by state supervision bodies,

j) date of each record, name, surname and signature of person who wrote the record.

(2) If justified, the applicant can split the utilization of genetically modified organisms into several phases, aimed in obtaining partial results. Each phase can have its own logbook in such cases.

(3) Operation manual includes

a) description of operation rooms,

b) rules for work with genetically modified organisms,

c) procedure for storage of genetically modified organisms,

d) method for marking of genetically modified organisms,

e) method for disposal of genetically modified organisms,

f) conditions for transport of genetically modified organisms in contained use as well as in public areas,

g) description of safeguarding of GMO facilities against release of genetically modified organisms during their operation,

h) description of method for removal of genetically modified organisms in case of their uncontrolled release.

**Art. 11**

**Record keeping and archiving**

Documentation is written and it is fled, kept and archived in order to avoid its lost or damage. Documentation is a registry regulated by a separate Act.[[1]](#footnote-1)1)

**Art. 12**

**Introduction report**

(1) Report on result of introduction, unless it is introduction of higher plants, includes

a) identification data on species and amount of genetically modified organisms introduced into the environment,

b) risk assessment report with identification of total risk level,

c) number of application for permit on introduction into the environment and number of permit,

d) description of circumstances of each phase of introduction and its progress and evaluation,

e) description of introduction site and operation manual of the site,

f) data on realised research and development activities performed during introduction of genetically modified organisms into the environment, as well as obtained results, especially evaluation of life cycles of introduced genetically modified organisms,

g) identified potential adverse impacts and negative effects of introduced genetically modified organisms to humans, animals and plants,

h) possible risks for users, proposed possible utilization or handling of genetically modified organisms if they are intended to be used in product or as product introduced to the market in the future.

**(2) Introduction report is elaborated in two printouts, one of them is archived by the user and the other one is submitted to the Ministry, also electronically.** **Introduction report can be related only to one particular permit, and it shall be marked by a unique number of that particular application.**

**(3) Introduction report of higher plants is elaborated as the template[[2]](#footnote-2)2) and it is submitted by the end of the growing season in each year of introduction of the genetically modified higher plant.**

**Art. 13**

**Safety criteria of genetically modified microorganisms that are not covered by provisions on contained use**

(1) Safety criteria of the genetically modified microorganism according to Art. 8 par. 3 of the Act are as follows

a) justification or authentication of strain,

b) documented and indubitable proof of the organism safety and its genetic stability,

c) non-pathogenicity,

d) non-toxigenicity,

e) non-allergenicity,

f) safety for the environment after important and undeliberate release,

g) genetic material transfer must not cause infection or damage, nor it should be more intense than transfer of the other genes of the recipient or donor microorganisms,

h) absence of harmful additives as other active or latent microorganisms that exist inside the genetically modified microorganism or beside it and that could harm human health and the environment.

(2) Details of dossier content regarding the safety of genetically modified microorganisms not covered by provisions on contained use are shown in Annex 5.

(3) The proposal for incorporation of genetically modified microorganism among genetically modified microorganisms not covered by provisions on contained use includes identification of user, i.e. its title or trade name, identification number, address or domicile, as well as dossier according to par. 2.

**Art. 14**

**Registration of genetically modified organisms**

(1) Ministry enters genetically modified organisms ~~including microorganisms~~ that result from application of genetic technologies into genetically modified organisms register according to Art. 24 par. 1 c) of the Act.

(2) Following data are entered into register pursuant to par. 1:

a) scientific and national taxonometrical name of donor and recipient of genetic material,

b) name and identification data of altered gene,

c) genetic method or genetic technique by which the gene was altered and utilized,

d) classification into risk category,

e) properties of genetically modified organism that are expressed due to known effects of altered gene,

f) previous and possible future utilization of genetically modified organism in modern biotechnologies,

g) identification of the user, i.e. its title or trade name, identification number and address or domicile.

**Art. 15**

**Register of project heads and biological safety committees**

(1) Project heads and safety committees are entered into register of project heads and biological safety committees on the basis of user notification.

(2) Register of project heads includes

a) name and surname of project head **and the contact information, which includes phone number and email address,**

b) identification of the user, i.e. his title or trade name, identification number, address or domicile,

c) record number and date of entry into the register of project heads.

(3) Register of safety committees includes

a) name and surname of safety committee member,

b) identification of the user, i.e. his title or trade name, identification number, address or domicile,

c) date of entry into register of safety committees.

(4) Data recorded in the register pursuant to par. 2 are not listed in the contained use notification, application for issuance of permit for contained use nor deliberate release of the genetically modified organism into the environment, nor they are proved in permit issuance procedure; only registered number of project head is listed.

(5) Notification of data on project heads or safety committee members pursuant to Art. 12 par. 2 a) of the Act includes

a) name and surname of project head **and the contact information, which includes phone number and email address,** or name and surname of safety committee member, according to the subject of notification,

b) identification of the user, i.e. its title or trade name, identification number, address or domicile,

c) statement of criminal records not older than three months,

d) **information about the professional qualifications; attached with evidence of completion of university studies and a certificate of professional practice.**

**Requisites of notifications**

**Art. 16**

*Repealed from 15th April 2013.*

**Art. 17**

(1) Notification of beginning of contained use activities classified into risk category 2 that received permit for the first contained use and all permit conditions were met includes

a) date of submission of application for issuance of permit pursuant to Art. 13 par. 1 a) of the Act,

b) registration number of project head,

c) identification of GMO facility where utilization of genetic technologies and genetically modified organisms will be performed, e.g. laboratory, greenhouse, growing chamber, cell for animals,

d) identification of used recipient, donor or parental organism, and if applicable also identification of host-vector system,

e) data on source and intended function of genetic material involved into the genetic alteration,

f) data on identity and characteristics of genetically modified organism,

g) purpose of utilization of genetic technologies including the expected results,

h) data on planned amounts of cultures of organisms to be used,

i) description of protective measures to be used including data on waste management and handling of waste according to the separate Act, [[3]](#footnote-3)3)

j) total duration of operation and date of expected beginning,

k) documentation deposit site.

(2) Notification annexes are as follows:

a) risk assessment report,

b) statement of project head,

c) emergency plan.

**Art. 18**

If genetically modified organisms are intended for contained use that were imported from states out of the European Union **or non-party to the Agreement on the European Economic Area**, also the state of genetically modified organism origin and importer should be noticed in the notification

**Requisites of applications for permit**

**Art. 19**

(1) Application for permit for the first contained use, in addition to general requisites of application, includes [[4]](#footnote-4)4)

a) address and general description of the facility, especially information whether GMO facilities allow to meet the good microbiological practice principles, and to implement protective measures resulting from the classification of the planned utilization into risk category, as well as connection of the facility to public transportation and technical alignment of the territory,

b) information on waste management and waste handling according to a separate Act,[[5]](#footnote-5)4a)

c) data on number, structure and qualification specifications of personnel who is involved in contained use,

d) registration number of project heads,

e) puprose of contained use including expected results.

(2) Application annexes are as follows:

a) authorization for contained use according to separate regulations, [[6]](#footnote-6)5)

b) confirmation that the user is not filed a petition for bankruptcy,

c) copy from register where the user is recorded,[[7]](#footnote-7)5a)

d) authorised copy of founding charter or other confirmation of legal subject if the user is not an entrepreneur,

e) rent contract regarding the GMO facility if the user is not its owner,

f) plan of indoor construction-technical and operational layout of the GMO facility by the user, **showing the location of the GMO facility, where will be carried out the use of genetic technologies and genetically modified organisms, and its designation,**

g) different certificates and other documents confirming data in the application or information supporting competence of the facility for utilization of genetic technologies,

h) list of performed research projects of the facility that relate to the utilization of genetically modified organisms,

i) operation manual,

**j) risk assessment report, if the GMO facilities are used for activities assigned to risk class 1.**

**Art. 20**

(1) Application for issuance of permit for activities pursuant to Art. 13 par. 1 b) to e) of the Act, in addition to general requisites of the application, includes

a) date of application submission for the first contained use,

b) registration number of project head,

c) total duration of operation and date of expected beginning,

d) identification of recipient and parental organism to be used,

e) identification of used host - vector system,

f) data on source and intended purpose of genetic material involved into the genetic alteration,

g) data on identity and characteristics of genetically modified organism,

h) data on planned amounts of cultures of organisms to be used,

i) description of intended protective measures including data on waste management and waste handling according to separate Act, 3)

j) purpose of utilized genetic technologies including expected results,

k) data on accident prevention and emergency plan including data on dangers resulting from localisation of contained use,

l) description of preventive measures, especially safety equipment of the GMO facility, alarm system as well as control methods,

m) description of procedures and plans for verification of permanent effectiveness of protective measures,

n) documentation deposit site.

(2) Application has the following annexes:

a) risk assessment report according to Art. 7,

b) statement of the project head,

c) emergency plan.

**Art. 21**

(1) The application for issuing of the consent with introduction of genetically modified organisms, other than higher plants, into the environment shall include in addition to general proprieties of the submission 4)

1. title of the project, in framework of which the introduction is intended to occur,
2. registration number of the head of the project,
3. data related to the characteristics of the genetically modified organism,
4. data related to the characteristics of donor, recipient and, if appropriate, also the parental organism,
5. data related to the characteristics of the vector,
6. description of characteristics affecting the survival, reproduction and spread of genetically modified organisms,

g) information on items listed under Art. 24 a) in order to facilitate proposing of conclusions regarding possible impacts to the environment after release of genetically modified organisms or their placing on the market,

h) data related to the conditions of the introduction and receiving environment,

i) information on the monitoring plan and information on conducting of control of the introduction,

j) summary notification information form [[8]](#footnote-8)6).

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

a) information on methods used in the genetic modification,

b) information on methods used for setting up and introduction of the inserted genetic material to the recipient or for deletion of a sequence,

c) description of the combination of the insert and vector,

d) information on the purity 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) description of methods and criteria used for the selection,

f) description of the sequence, functional identity and location of the altered, deleted nucleic acid segment, with particular reference to any known harmful sequence,

g) description of genetic attribute or phenotypic characteristics of the genetically modified organism, in particular any new attributes and characteristics, which may be expressed or no longer expressed,

h) data on the structure and amount of vector and nucleic acid donor in the final construction of the genetically modified organism,

i) data on the stability of the genetically modified organism in terms of genetic attributes,

j) data on rate and level of expression of the new genetic material and on methods and sensitivity of measurement,

k) description of the activity of the proteins,

l) description of identification and detection techniques used for the identification and detection of the inserted sequence and vector and quantitative expression of their sensitivity, reliability and specificity,

m) overview of previous introductions and other uses of genetically modified organisms,

n) description of significance of the genetically modified organism 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, if applicable, parental organism regarding pathogenicity,

3. description of colony forming capacity,

4. data on pathogenicity to humans who are immunocompetent, in particular data on diseases caused and mechanism of pathogenicity including invasiveness and virulence, infectivity, 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 potential hazards.

(3) Data according to paragraph 1 letter d) include

a) scientific name of the organism,

b) taxonomic classification of the organism,

c) other names of the organism, in particular usual name, family name,

d) phenotypic and genetic attributes of the organism,

e) assigning of the degree of relatedness between donor and recipient or between parental organisms,

f) description of identification and detection techniques and quantitative expression of their sensitivity, reliability and specificity,

g) description of the geographic distribution and of the natural biotopes of the organism, including information on natural predators, preys, competitors, symbionts and hosts,

h) assigning of organisms known that transfer of genetic material occurs under natural conditions,

i) results of verification of the genetic stability of the organisms and factors affecting it,

j) data on pathological, ecological and physiological attributes, i.e.

1. classification of hazard according to existing rules for the protection of human health and the environment,

2. generation life span in natural ecosystems, sexual and asexual reproductive cycle,

3. survival capacity including season specificity 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 organism, 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, nutrient cycle, decomposition of organic matter, and respiration,

k) data on nature of indigenous vectors, sequence, frequency of mobilisation, specificity and presence of genes which confer resistance,

l) overview of previous genetic modifications.

(4) The information according the paragraph 1 letter e) include data on

a) the nature and source of the vector,

b) the sequence of transposons, vectors and other non-coding genetic segments used to construct the genetically modified organism and to preparation of the introduced vector and insert function into the organism,

c) the frequency of mobilisation of inserted vector and genetic transfer capabilities and methods of determination,

d) the degree to which the vector is limited to deoxyribonucleic acid required to perform the intended function of the organism.

(5) Data according to paragraph 1 letter f) include

a) description of biological features which affect survival, reproduction and spread of the genetically modified organisms in the environment,

b) data on known or predicted environmental conditions which may affect survival, reproduction and dissemination of genetically modified organisms, in particular wind, water, soil, temperature, and pH,

c) data on sensitivity of genetically modified organisms to specific agents,

d) description of predicted site of the genetically modified organisms appearance,

e) study of the behaviour and characteristics of the genetically modified organisms and their ecological impact during the experiment carried out in simulated natural environments e.g. greenhouses, growth chamber,

f) data on post-release genetic material transfer capability

1. from genetically modified organism into organisms in affected ecosystems,

2. from indigenous organisms to the genetically modified organisms,

g) data on likelihood of post-release selection leading to the expression of unexpected and undesirable attributes in the genetically modified organism,

h) description of measures employed to ensure and to verify the genetic stability, description of genetic attributes which may prevent or reduce dissemination of genetic material, and of methods to verify genetic stability,

i) data on pathways of biological spread, known or potential modes of interaction with the dissemination agent, including inhalation, ingestion, surface infiltration, penetration to the organism,

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 genetically unmodified recipient or parental organism,

m) identification and description

1. target organisms if anticipated,

2. non-target organisms, which may be adversely affected by introduction to the environment, 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 shifts in biological interactions or in host range after introduction into the environment,

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 h) include:

a) description of the proposed introduction including the purpose and foreseen products,

b) information on the foreseen dates of the introduction and time planned for the experiment including frequency and duration of the individual introductions,

c) description of site preparation prior to the beginning of introduction into the environment,

d) information of size of the site for introduction into the environment,

e) description of the methods to be used for the introduction into the environment,

f) information on the quantity of genetically modified organisms to be introduced,

g) description of the possible disturbances on the site of the introduction into the environment, in particular the type and method of cultivation, mining, irrigation, or others,

h) description of employees protection measures taken during the introduction,

i) description of treatment of the site after introduction,

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 introductions or other uses of the genetically modified organisms, especially at different scales and in different ecosystems,

l) description of geographical location and grid reference of the site of introduction, 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 in relation to significant biotopes, and data on protected areas and drinking water supplies in the vicinity of the introduction site,

o) data on climatic characteristics of the region or area likely to be affected by introduced genetically modified organisms,

p) description of geographical, geological and soil characteristics of the introduction site,

r) data on fauna and flora, including crops, livestock and migratory species at the introduction site,

s) description of target and non-target ecosystems likely to be affected by introduction of the genetically modified organisms into the environment,

t) comparison of the natural habitat of the recipient organism with the proposed site of introduction,

u) data on any known planned changes in land use of the territory, which could influence the environmental effects of the introduction.

(7) Data according to paragraph 1 letter i) include

a) description of methods for searching the genetically modified organisms and for monitoring their effects,

b) data on the specificity of the genetically modified organisms identification and on 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 to reduce the spread of the genetically modified organisms beyond the site of introduction or the designated area for use,

2. to protect the site of introduction from intrusion of unauthorized individuals and to prevent other organisms from entering the site,

3. to control the genetically modified organisms in case of unexpected spread,

**f)** final assignment to a risk category and level of protection and result of re-evaluation of assignment, if appropriate.

(8) The application has the following annexes:

a) a report from the risk assessment according to Art. 8,

b) information on waste treatment,

c) emergency plan,

d) a dossier of documents concerning the data according to paragraphs 1 to 7,

e) copy of record from trade register where the user is listed, 5a)

f) verified copy of establishing document or another document of legal entity, when the user is not an entrepreneur,

g) rental contract to the ground where the genetically modified organisms are introduced into the environment by the state variety tests,

**h) snapshot of cadastral maps with drawing of the planned trial site.**

(9) The applicant may use in his application

a) data and results from previous notifications and proceedings for permit,

b) references to scientific literature including the authorities responsible for elaboration of studies,

c) a reference to the standardized or internationally recognized genetic methods and genetic techniques.

**Art. 22**

(1) The application for issuing of permit to introduce genetically modified higher plants into the environment shall include, in addition to general requisites of submission

a) title of the project in framework of which the release into the environment is intended to occur,

b) data concerning the genetically modified plant,

c) data concerning the higher plant donor and recipient and parental plants if appropriate, particularly

1. full 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 life of the plant,

3. data on survival capability of the plant, in particular on its ability to form structures for survival and dormancy period, and on specific factors affecting survival capability,

4. data on dissemination of the plant, in particular on the ways and extent of its natural dissemination, with estimation of pollen and seeds viability decline 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 related 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 source size and name (of donor plant) and intended function of each essential fragment intended for insertion,

e) information related to items listed under Art. 24 b) in order to facilitate the proposal of conclusions regarding the potential impacts to the environment after release of the genetically modified organisms, or after their placing on the market,

f) information related to the site of introduction, i.e.

1. description of location and extent of the introduction,

2. description of the introduction site ecosystem, including climate, flora and fauna,

3. information on presence of sexually compatible wild relatives or cultivated plant species,

4. information on proximity in relation to officially recognized biotopes or protected areas which could be affected by the released genetically modified plants,

g) information on the introduction, i.e.

1. purpose of the introduction,

2. foreseen date of the introduction and its planned duration,

3. description of methods by which the genetically modified plants will be introduced into the environment,

4. description of methods for preparing the introduction site, prior to, during and after its termination, including soil cultivation practices and harvesting methods,

5. information on approximate number of plants or plant density per m2,

h) information on plans for control of introduction, monitoring and post-introduction status, i.e.

1. data on adopted preliminary measures to prevent or reduce the possibility of dispersal of reproductive material, in particular the pollen, seeds and tubers, and for sufficient distance from sexually compatible wild plant species or crops,

2. description of methods for treatment of the site after the introduction into the environment,

3. description of treatment methods for the genetically modified plants after their introduction,

4. description of monitoring plans and techniques,

**5.** description of methods and procedures to protect the introduction site,

i) summary notification information form.

(2) Data according to paragraph 1 letter b) include

a) description of the attributes 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 characterization including information on any parts of the vector introduced into the genetically modified plant, or on vector and foreign deoxyribonucleic acid remaining in the genetically modified plant,

2. data on size and function of the deleted region,

3. information on number of inserted copies,

4. description of location of the insert in the plant cell and methods for its determination,

c) information on the expression of the insert in the development during the lifecycle of the plant, on methods used for its characterization and on part of the plant where the insert is expressed, for example in roots, stem and pollen,

d) information on how the genetically modified plant differs from the donor plant in type and rate of reproduction, dissemination and survival capability,

e) information on genetic stability of the insert and phenotypic stability of the genetically modified plant,

f) information on changed ability of the genetically modified plant to transfer genetic material to other organisms,

g) information on toxic, allergenic or other harmful effects affecting 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 of the plant, if the genetically modified plant is intended to be used in animal feeds,

i) description of the mechanism of interaction between the genetically modified plants 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 deliberate releases of the genetically modified plant, if applicable.

(3) Application has the following annexes:

a) risk assessment report according to Art. 8,

b) information on waste treatment,

c) emergency plan,

d) dossier of documents concerning the data according to paragraphs 1 and 2.

e) copy from register where the user is listed, 5a)

f) certified copy of establishing document or another document on legal subject, if the user is not an entrepreneur,

g) rent contract to the ground where the genetically modified organisms are introduced into the environment if the user is not its owner, except introduction into the environment as state variety tests,

**h) snapshot of cadastral maps with drawing of the planned trial site.**

(4) The applicant may use in the application

a) data and results from previous notifications and proceedings for permit,

b) references to scientific literature including the authorities responsible for elaboration of studies,

c) reference to the standardized or internationally recognized genetic methods and genetic techniques.

**Art. 22a**

(1) An application for issuing of the permit to import genetically modified organisms intended to be introduced into the environment according to Art. 17 par. 1 c) of the Act includes, in addition to the general requisites of the submission

a) data on import, i.e. state from which the genetically modified organism will be imported, border crossing site and foreseen date of import,

b) identification of the genetically modified organism which is to be imported, its amount or volume,

c) description of genetic modification,

d) plan of measures which are appropriate to the risk level associated with the genetically modified organism including the method of control of genetic modification presence for the case of accident.

(2) If the importer of genetically modified organisms intended to be introduced into the environment is not at the same time user who will introduce these genetically modified organisms into the environment, the application pursuant to par. 1 shall contain also identification of the user, i.e. its title or trade name, identification number, address or domicile, as well as identification of statutory representative or another contact person.

**Art. 23**

(1) An application for issuing of the permit to placing of the product made of genetically modified organisms on the market shall include the requisites according to Article 21 and 22, depending on the fact, whether the product concerns genetically modified higher plant or genetically modified organisms other than higher plants. Moreover, the application shall include in addition to general requisites of submission

a) data and information on results of introductions into the environment arising from the permits issued on the basis of applications according to Articles 21 and 22,

b) conditions for the placing on the market of the product including specific requirements for its use and handling,

c) proposed period for the permit validity, which should not exceed ten years,

d) a proposal for the validity period of monitoring plan,

e) a proposal for labeling of the product and its packaging,

f) summary notification information form [[9]](#footnote-9)7).

(2) The proposal according to paragraph 1 letter e) 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) trade name and address of the user who is responsible for the placing on the market, e.g. the manufacturer, the distributor, the importer,

c) trade name and address of each supplier of control samples,

d) description of how the product is to be used, with particular emphasis to the differences in use or handling of the genetically modified organism compared to similar non-genetically modified products,

e) description of the geographical area and types of environment where the product is intended to be used, including estimated scale of possible use in each area,

f) description of intended categories of users of the product e.g. industry, agriculture,

g) information on the genetic modification for the purposes of determination of identifiers, which can be used for the detection and identification of genetically modified organism in the product for control and inspection, including the storage of samples or genetic material, as well as data on nucleotide sequences and on results of experiments in confidential part of the register,

h) proposed description on label or in an accompanying document with the information on commercial name of the product and the information how to gather information in the publicly accessible part of the register,

i) description of measures to be taken for case of unintended release or misuse of the genetically modified organism,

j) specific instructions and recommendations for storage and handling of the product,

k) instructions for carrying out monitoring and reporting to the user on any adverse effect,

l) instructions on use patterns of the product and its purposes, as well as proposed limitations of product use in the framework of permitted usage,

m) proposed packaging,

n) estimated production volume in the Community or import volume,

o) proposed supplementary labeling of the product.

(3) The application has the following annexes:

a) copy from register where the user is listed, 5a)

b) certified copy of establishing document or another document on legal subject, if the user is not an entrepreneur.

**Art. 24**

On the basis of risk assessment performed in compliance with Art. 8 par. 1 to 4, the application for permit to deliberate release shall include

a) if genetically modified organisms are concerned except of higher plants, the following information:

1. probability that the genetically modified organism will become permanent and invasive in the natural biotopes under conditions of proposed release,

2. any selective advantage or disadvantage which is beard by the genetically modified organism, as well as probability of its occurrence under the proposed release conditions,

3. potential of transfer of gene into another species under proposed conditions of genetically modified organisms release, as well as selective advantage or disadvantage beard by those species,

4. potential immediate or delayed impact to the environment arising from direct or indirect correlation between genetically modified organism and target organisms , if applicable,

5. potential immediate or delayed impact to the environment arising from direct or indirect correlation between genetically modified organism and non-target organisms, including effects to population level of competitors, prey, hosts, symbionts, predators, parasites and pathogens,

6. potential immediate or delayed impacts to human health arising from direct or indirect correlation between genetically modified organisms and persons who work with them, or who are in contact with them or who are in vicinity of release(s) of genetically modified organisms,

7. potential immediate or delayed impacts to animal health and consequences for food chain arising from consumption of genetically modified organisms and any products derived from them, if they are intended to be used as animal feeds,

8. potential immediate or delayed impacts to biogeochemical processes arising from possible direct or indirect interactions between ľs and target as well as non-target organisms in vicinity of genetically modified organisms release,

9. potential immediate or delayed, direct or indirect impacts to the environment of the specific techniques used for control of genetically modified organisms, if such techniques differ from those used for organisms not genetically modified,

b) if genetically modified higher plants are concerned, the following information:

1. probability that genetically modified higher plant will become more resistant than receiving or parental plants in agricultural biotopes, and more invasive in natural biotopes,

2. any selective advantage or disadvantage that is beard by genetically modified higher plant,

3. potential gene transfer into identical or other sexually compatible plant species under conditions of planting of genetically modified higher plants, and any selective advantage or disadvantage that is transferred into such plant species,

4. potential immediate or delayed impact to the environment arising from direct or indirect correlation between genetically modified higher plants and target organisms, as predators, parasites and pathogens, if applicable,

5. potential immediate or delayed impact to the environment arising from direct or indirect correlation between genetically modified higher plants and non-target organisms, taking into consideration organisms that correlate with target organisms including competitors, herbivores, symbionts, and if applicable predators, parasites and pathogens,

6. potential immediate or delayed impact to the environment arising from direct or indirect correlation between genetically modified higher plants and persons who work with them, who are in contact with them or who are in vicinity to the genetically modified higher plants release,

7. potential immediate or delayed impact to biogeochemical processes arising from

possible direct or indirect correlation between genetically modified organisms and target as well as non-target organisms in vicinity to release(s) of genetically modified organisms,

8. potential immediate or delayed, direct or indirect impact to the environment of specific cultivation, growing and harvesting techniques utilized in relation with genetically modified higher plants, if such techniques differ from those used for higher plants that are not genetically modified,

9. potential immediate or delayed impact to animal health and consequences to the food chain arising from consumption of genetically modified organisms and any products derived from them if they are intended for use as animal feeds.

**Art. 25**

**Content of the assessment report**

(1) The assessment report includes

a) identification of the characteristics of the recipient non-modified organism which is relevant to the assessment of any known risks resulting from the genetically modified organism to human health and the environment at the introduction into the environment,

b) description of the result of the genetic modification in the genetically modified organism,

c) evaluation 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 result from the introduction 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, or whether it should not be placed on the market,

2. the genetically modified organism should be withdrawn from the market in or as a product, or whether it should stay on the market and under which conditions, or

3. the views of other authorities should be sought in case of specific aspects be identified in risk assessment.

(2) The conclusion of assessment report addresses also the proposed use of the genetically modified organism, the monitoring plan and risk management.

(3) If the conclusion of the assessment report states that the genetically modified organisms should not be placed on the market, the conclusion shall be justified.

**Art. 26**

**Monitoring plan**

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

(2) The Monitoring shall take place after the issuing of permit to 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 in order to observe, whether they are result of deliberate release or of another environmental factors, which are not related to the deliberate release of the genetically modified organisms.

(3) The monitoring plan shall

a) be sufficiently detailed, elaborated 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 their possible use and the relevant environmental conditions where the genetically modified organisms may be released,

c) incorporate rules for general surveillance of unanticipated adverse effects and, if necessary, also 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 indirect effects, using already established routine surveillance practices such as the monitoring of agricultural cultivars, plant protection, or effects of medical and veterinary products,

d) facilitate the observation, in a systematic manner, of the introduction of a genetically modified organism in the receiving environment and the interpretation of these observations with respect to the 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) consider the mechanisms for identifying and confirming of 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 permit to implement the measures necessary to protect human health and the environment.

**Final provisions**

**Art. 27**

This Regulation transposes legal binding acts of the European Union listed in the Annex **6**.

**Art. 28**

Regulation No. 252/2002 Coll. of the Ministry of Environment of the Slovak Republic that regulates the Act on utilization of genetic technologies and genetically modified organisms is derogated.

**Art. 29**

Regulation **No. 399/2005 Coll.** enters into force on 1 October, 2005.

*László Miklós himself*

Regulation **No. 312/2008 Coll.** enters into force on 15 August, 2008.

*Jaroslav Izák himself*

**Annexes to the Decree No. 399/2005 Coll. as amended by Decree No. 312/2008 Coll.**

**Annex 1**

# 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 |
| 10 | Biohazard sign on the door | Not required | Required | Required | Required |
| 11 | 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 | Suitable protective clothing and (optional) footwear | 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 nsects) | Optional | Required | Required | Required |

## Waste

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 17 | Inactivation of genetically modified micro-organisms **and genetically modified 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 **and genetically modified organisms** in contamined material and waste | Optional | Required | Required | Required |

## 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**

### 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[[10]](#footnote-10)1) | Not required | Required | Required | Required |

**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 ([[11]](#footnote-11)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 of genetically modified micro-organisms **and genetically modified organisms** | Minimise dissemination | Minimise dissemination | Prevent dissemination | Prevent dissemination |

**Annex 3**

**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[[12]](#footnote-12)1) | Optional | Required | Required | Required |
| 2 | Animal facilities[[13]](#footnote-13)2) 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 facilitiessuch as cages, pens or tanks | Optional | Optional | Optional | Optional |
| 6 | Filters on isolators or isolated room[[14]](#footnote-14)3) | Not required | Optional | Required | Required |

**Annex 4**

**Containment and other protective measures for other activities**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Specifications** | | **Containment levels** | | | |
| **1** | **2** | **3** | **4** |
| 1 | Viable 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 of bulk culture fluids before removal from the closed system | Optional | Required, by validated means | Required, by validated means | Required, by 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 |

**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 measures to adequately ventilate the controlled area in order to minimise air contamination | Optional | Optional | Optional | Required |
| 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 shower before leaving the controlled area | Not required | Not required | Optional | Required |
| 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 **and genetically modified organisms** in effluent from handwashing sinks and showers or similar effluents | Not required | Not required | Optional | Required |
| 19 | Inactivation of genetically modified micro-organisms **and genetically modified 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 |

**Annex 5**

**The dossier on the safety of genetically modified microorganisms excluded from the scope of contained use provisions**

(1) The dossier on verification of the strain of genetically modified organism contains

a) authentication of the strain’s identity,

b) characteristics of the vector and insert for its structure and function as it occurs in the final GMM,

c) a detailed strain history for his safety evaluation, including the genetic modifications,

d) the taxonomic relationship to closely related, known, harmful microorganisms,

e) relevant literature search for history, safety records, taxonomic detail, phenotypic and genetic markers,

f) results of any tests carried out to confirm identity of the GMM, in the case of a novel isolate or a strain that has not been extensively studied,

g) data to prove the successful removal of harmful or potentially harmful traits of genetically modified organism, if the genetic modification was designed to remove a harmful or pathogenic trait from the recipient or parental strain.

(2) The dossier on the stability of microorganism’s genetic modification contains data to prove that

a) microorganism’s genetic stability compared with the unmodified microorganism in the environment shall not be increased, or

b) the instability or stability increased by the genetic modification shall not feature a risk for safety, or

c) genetically modified microorganism shall be stabile, if a disabling mutation has been introduced into the GMM to attenuate harmful properties.

(3) The dossier on the non-pathogenic genetically modified organism contains

a) data of genetically modified microorganism capability to cause disease or harm to healthy humans, plants or animals under any normal conditions or as the result of a reasonably foreseeable incident,

b) the possible effects of exposure immunocompromised individuals, if there is an increased probability of such exposure,

c) literature search on previous handling of the species and closely related strains, on human, animal and plant pathogens, or if eukaryotic viral vectors should be excluded from the scope of contained use provisions, on effects to human health and environment, on their origin as well as the mechanism of their attenuation and the stability of the relevant features,

d) verified data on non-virulent strains of acknowledged pathogenic species, such as live human and animal vaccines, which confirm that

1. the strain has no adverse effects on human, animal or plant health, or

2. the strain is stably deficient in genetic material that determines virulence, or

3. the strain has stable mutations known to sufficiently reduce virulence and for which good evidence of safety exists,

e) data on constructs that use DNA or RNA vectors derived from viruses in cultured cells as hosts where no infective virus is involved or can be produced,

f) data on tests with genetically modified microorganism or with the recipient or parental strain, if there is a lack of pathogenicity information from a literature,

g) data on a pathogenicity determinant capable of substituting for a disabling mutation present in the parental organism and that the inserted genetic material does not encode a pathogenicity determinant.

h) data on vector and insert as they occur in the final GMM, if their genes could code an active protein or transcript at a level and in a form which endow the GMM with a phenotype likely to cause disease to humans, animals and plants or to cause adverse effects in the environment.

(4) Dossier for non-toxic genetically modified organism shall include the toxicity data of recipient, donor and parental strain and the data that genetically modified organisms should not produce unexpected toxins nor increased toxigenicity as a result of the genetic modification.

(5) Dossier for non-allergic genetically modified organism shall include description of biological activities of the genetically modified organism that includes expressed vector and insert, which could lead to significant allergens.

(6) Dossier for absence of known adventitious agents, which could be harmful intra or besides genetically modified organism, contains data about

a) used recipient or parental strain,

b) animal cell cultures context with potentially harmful adventitious organisms.

(7) Dossier for transmissible genetic material inserted to genetically modified organism shall include

a) details about elimination the transfer, and also potential, if it could cause a harmful phenotype in a recipient microorganism,

b) information about vectors or recipients gene non-mobilization, if they could transfer any resistance markers, what could compromise therapeutic treatment,

c) details about vectors non-lysogenic, that is virus, cosmid or any type of virus-derived vector, when used as a cloning vector,

d) details about mechanisms that may facilitate chromosome or or transposition to other replicons that may be present in the host, if they were integrated into the host chromosome.

(8) Dossier that confirms that the genetically modified organism in the event of an escape from containment is unlikely to have an adverse effect on environment shall include

a) exact details of deliberate releases or accidental escape in the past and any associated impact on the environment, if they available are.

b) the different environmental conditions, where necessary, extreme case scenarios should be considered,

c) assessment of the ability to survive in the environment, as

1. influence of biological characteristics the genetically modified organism for a change able to survive in the environment,

2. the method of dispersal and the likelihood of survival during dispersal,

3. the size of the viable population, the size of the niche and the frequency of suitable niches for the specific species of genetically modified organism,

4. resistance or sensitivity to biotic or abiotic stresses,

5. ability to adapt to environmental conditions or to initiate a competitive growth in consequence to genetic modification,

d) the likelihood of interaction with the environment, especially the possible fate of GMMs that escape from containment into food webs, and likelihood of genetic material transfer.

**Annex 6**

# list of implemented legal Binding acts of the european union

1. **Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms. (Recast) (O. J. EU, L 125, 21st May 2009)**

2. Directive 2001/18/ES of the European Parliament and the Council Rady of March 12, 2001 on Deliberate Release of Genetically Modified Organisms into the Environment, and on repealing of the Council Directive 90/220/EHS (special edition of the O.J. EU 15/6) as amended.

1. 1)  Art. 2 par. 14 of the Act No. 395/2002 Coll. on Archives and Registration and on amendment of certain acts, as amended. [↑](#footnote-ref-1)
2. 2) Commission Decision No. 701/2003/ES of September 29th 2003, that sets out template for submission of results of higher plants deliberate release for other purposes than placement on the market according to the European Parliament and Council 2001/18/ES (special issue of O.J. EU chapter 15/07). [↑](#footnote-ref-2)
3. 3) Art. 7 par. 1 g) of the Act No. 223/2001 Coll. on Waste, amending and supplementing certain acts. [↑](#footnote-ref-3)
4. 4) Art. 19 par. 2 of the Act No. 71/1967 Coll. on administrative procedures (administrative order). [↑](#footnote-ref-4)
5. 4a) Art. 6 of the Act No. 223/2001 Coll. [↑](#footnote-ref-5)
6. 5) Art. 13 par. 4 a) and h) of the Act No. 355/2007 Coll. on protection, support and development of public health and on amendment of certain acts. Art. 13 par. 4 h) of the Act No. 355/2007 Coll.. Art. 39 par. 1 of the Act No. 39/2007 Coll. on veterinary care. [↑](#footnote-ref-6)
7. 5a)  e.g. Art. 2 par. 2 of Trade Act, Art. 19 par. 2 of the Civil Act as amended by Act No. 509/1991 Coll. [↑](#footnote-ref-7)
8. 6) Council Decision 2002/813/ES of October 3rd, 2002, setting out summary notification information form for notification regarding deliberate release of the genetically modified organisms for other purposes than placing on the market, according to the European Parliament and Council Directive 2001/18/ES (O.J. ES L 280 2002, pp. 62 – 83). [↑](#footnote-ref-8)
9. 7) Council Decision 2002/812/ES of October 3rd, 2002, setting out summary notification information form for notification regarding deliberate release of the genetically modified organisms for other purposes than placing on the market, according to the European Parliament and Council Directive 2001/18/ES (O.J. ES L 280 2002, pp. 37 – 61). [↑](#footnote-ref-9)
10. 1) 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. [↑](#footnote-ref-10)
11. 2) Where transmission can occur through the ground. [↑](#footnote-ref-11)
12. 1) 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. [↑](#footnote-ref-12)
13. 2) 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. [↑](#footnote-ref-13)
14. 3) Isolators: transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate. [↑](#footnote-ref-14)