

DECREE
of
the Ministry of the Environment

of October 6, 2000

on detailed conditions for the use of genetically modified organisms and products

Pursuant to § 24 letters b) to f) and h) to j) of Act No. 153/2000 Coll., on the use of genetically modified organisms and products and amending some related Acts (hereinafter the "Act"), the Ministry of the Environment, in agreement with the Ministry of Health and the Ministry of Agriculture hereby lays down the detailed conditions for:

§1

For the purposes of this Decree:

- a) a recipient means an organism into whose heritable material the foreign heritable material is inserted by genetic modification,
- b) the donor organism means the organism from whose heritable material is derived the heritable material inserted into the genetic material of the recipient,
- c) the parental organism means the organism from whose heritable material a part has been removed by genetic modification,
- d) a vector means a noncellular entity containing heritable material and capable of incorporating this heritable material together with the inserted foreign heritable material into the cells of the recipient,
- e) an insert means foreign heritable material inserted into the heritable material of the recipient,
- f) a construct means an artificially modified molecule of nucleic acid,
- g) a signal gene means a gene contained in the construct and rendering a easily determinable property of the cells or organism containing a functional construct,
- h) a selection gene means a gene contained in a construct and rendering the lack of sensitivity to a certain substance or to an influence preventing the multiplication of cells that do not contain this gene,
- i) a stage means the period of time during which an activity or a set of activities is carried out in the use of the genetically modified organism or product, directed towards a certain conclusion, obtaining of information or some other partial result,
- j) primary data means all the laboratory and work records and documents or authenticated copies thereof that are the result of original observations, measurements and registrations of parameters.

§ 2

Detailed Conditions of the Professional Qualification of the Professional Consultant

(ad § 3 par. 7 letter a) of the Act)

(1) A condition for designating a natural person as a professional consultant shall consist in properly completed university education¹⁾ in the field of

- a) medicine, veterinary medicine, biochemistry or microbiology, for the use of genetically modified microorganisms,
- b) the natural sciences, agriculture or forestry for the use of genetically modified plants, or
- c) the natural sciences, agriculture or veterinary medicine for the use of genetically modified animals.

(2) The period of postgraduate or doctoral studies in the appropriate field and in the field of the use of genetically modified organisms shall be included in the period of the required two years of experience in the use of genetically modified organisms²⁾.

(3) In supervision of an experiment using animals and other use of genetically modified animals, the professional consultant pursuant to paragraph 1 must also fulfill the conditions of qualification pursuant to the special legal regulations³⁾.

§3

Details of the Applications for Entry in the Lists

(Ad §6 par. 1, §7 par. 2 and 7, §8 par. 3, and §9 par. 3 of the Act)

(1) As part of an application for entry in the lists specified in §3 par. 3 of the Act, the user may also submit the requested information on the properties of a genetically modified organism prepared for some other legal person or natural person licensed to operate a business, provided that (s)he simultaneously submits an authenticated identical copy of the consent of such person to the use of the submitted information by the user.

(2) Documents for the application required by this Decree, that are translations from foreign languages, shall be submitted in the form of an officially authenticated translation and simultaneously in the original. With the application, the user may enclose further information material in English language, together with a brief summary thereof in Czech.

(3) A sample application for entry in the List of Users for contained use of genetically modified organisms (hereinafter "contained use") is given in Annex No. 1; a sample application for entry in the List of Users for introduction of genetically modified organisms into the environment (hereinafter "introduction into the environment") is given in Annex No. 2; a sample application for entry in the List of Users for placing genetically modified organisms and products on the market (hereinafter "placing on the market") is given in Annex No. 3.

(4) If the application for entry in the List of Users is submitted pursuant to § 6 par. 3 of the Act, all the information for each genetically modified organism must be entered separately in the application; this shall not apply to the case set forth in § 7 par. 3 of the Act.

¹⁾ Act No. 111/1998 Coll., on higher institutes of learning and amending and supplementing some other acts (the Act on higher institutes of learning).

²⁾ §3 par. 7 letter a) of Act No. 153/2000 Coll., on the use of genetically modified organisms and amending some related acts.

³⁾ §17 of Act No. 246/1992 Coll., on protection of animals against cruelty, as amended.

(5) A sample application for entry of a genetically modified organism in the List of genetically modified organisms registered for contained use is given in Annex No. 4.

(6) Samples of applications for entry of a genetically modified organism into the List of genetically modified organisms registered for introduction into the environment are given

- a) in Annex No. 5, when the genetically modified organism is a microorganism,
- b) in Annex No. 6, when the genetically modified organism is a higher plant, or
- c) in Annex No. 7, when the genetically modified organism is an animal.

(7) If an application for entry in the List of genetically modified organisms registered for introduction into the environment is submitted pursuant to § 8 par. 4 of the Act, it is necessary to state in the application all the information separately for each genetically modified organism.

(8) Samples of applications for entry of a genetically modified organism or product into the List of genetically modified organisms and products registered for placing on the market in the Czech Republic are given

- a) in Annex No. 8, when the genetically modified organism is an organism other than a higher plant, or
- b) in Annex No. 9, when the genetically modified organism is a higher plant.

§ 4

Risk Assessment

(Ad § 4 of the Act)

(1) The purpose of risk assessment carried out according to § 4 of the Act shall be to identify and evaluate potential adverse effects of the proposed use of the genetically modified organism or product on the health of humans and animals, the environment and biological diversity. Risk assessment must take into consideration all the potential harmful effects, regardless of the likelihood of their occurrence, and compare them with the harmful effects of use of the recipient or parental organism or related organisms, as appropriate.

(2) The effects of the use of a genetically modified organism or product may be

- a) direct, i.e. primary effects on the health of humans and animals, the environment and biological diversity, that are directly connected with the genetically modified organism or product,
- b) indirect, i.e. effects on the health of humans and animals, the environment and biological diversity, that occur through a causal chain of events, e.g. through interaction with other organisms, transfer of heritable material or changes in the manner of use; indirect effects may be manifested with a delay,
- c) immediate, i.e. effects that are observed during the use of the genetically modified organism or product; immediate effects may be direct or indirect,
- d) delayed, i.e. effects that need not be observed during the use of the genetically modified organism or product but can be determined as direct or indirect effects after the termination of the use of the genetically modified organism or product.

(3) Potential harmful effects include

- a) adverse effects on humans, including diseases, allergic and toxic effects,

- b) adverse effects on animals and plants, including diseases, toxic or allergic effects,
- c) influence on the population dynamics of species within the receiving environment and on the genetic diversity of each of these populations,
- d) compromising prophylactic and therapeutic treatments in the area of medicine, veterinary medicine or plant medicine, e.g. through transfer of genes increasing the pathogenicity, virulence or toxogenicity of organisms or genes conferring resistance to antibiotics used in medicine or veterinary medicine,
- e) effects on biogeochemical processes, particularly the carbon and nitrogen cycles, through changes in the decomposition of organic material in the soil.

(4) Harmful effects on the health of humans and animals, the environment and biological diversity may occur through

- a) settlement and spread of genetically modified organisms in the environment,
- b) natural transfer of inserted heritable material to other organisms,
- c) phenotypic and genetic instability,
- d) interactions with other organisms,
- e) changes in the management of organisms or products, including changes in agrotechnical procedures.

(5) In risk assessment, it is necessary to identify the occurrence of potential harmful effects of the use of the genetically modified organism or product in connection with

- a) the recipient,
- b) the inserted heritable material (originally from the donor organism),
- c) the vector,
- d) the donor organism (if a donor organism is used in carrying out the genetic modification),
- e) insertion of a construct,
- f) the signal and selection genes,
- g) the insert,
- h) removal of a part of the heritable material (if used in the genetic modification),
- i) the final genetically modified organism,
- j) the location and scope of the use of the genetically modified organism or product,
- k) the environment at the site of use,
- l) potential interaction between the genetically modified organism or product and the environment at the site of use.

(6) The risk assessment must contain evaluation of the seriousness of every potential harmful effect and the likelihood of occurrence of this harmful effect, in the evaluated manner of use at the given workplace or site of introduction into the environment and under the conditions under which they are to be used or that could occur. The risk assessment must further take into consideration the characteristics of the activity and the danger following therefrom.

(7) The procedure in risk assessment shall consist in

- a) identification of all potential harmful effects pursuant to paragraphs 2 to 5 and assessment of the seriousness thereof,
- b) evaluation of the consequences of each harmful effect, in case it occurs,
- c) evaluation of the likelihood of occurrence of the harmful effect under the given conditions,
- d) estimation of the risk for the health of humans and animals, the environment and biological diversity represented by each of the identified harmful effects on the basis of

evaluation of the likelihood of occurrence of the harmful effect and the seriousness of this effect if it occurs,

- e) comparison of the information obtained with the corresponding information for the donor organism, the recipient, and/or the parental organism under comparable conditions,
- f) classification of the activity in the appropriate risk category pursuant to Annex No. 1 to the Act on the basis of the results obtained.

(8) All the steps in the procedure pursuant to paragraph 7 must be documented in writing and, where possible, documented by reference to the scientific literature, protocols from experimental studies or documentation on previous use. This written analysis must be stored together with the other documentation pursuant to § 3 par. 7 letter b) of the Act.

(9) The risk assessment must promptly reviewed if there is a change in

- a) the scientific or technical knowledge related to the effects of use of the genetically modified organism or product pursuant to paragraphs 1 to 6, or
- b) the procedure of the use of the genetically modified organism or product.

(10) The risk assessment for contained use must take into consideration the facts pursuant to paragraphs 1 to 6 and also

- a) the characteristics of the environment that could be affected by dissemination of the genetically modified organism from the contained space,
- b) the nature and scale of the contained use,
- c) any nonstandard operations carried out during the contained use.

These facts may affect the classification of the use of the genetically modified organism in the pertinent risk category pursuant to paragraph 7) letter f).

(11) The risk assessment for introduction into the environment for genetically modified organisms other than higher plants must contain

- a) the likelihood that, under the conditions of introduction into the environment, the genetically modified organism will become more persistent or more invasive than the recipient or parental organism in its natural habitat,
- b) any selective advantage or disadvantage resulting from the genetic modification and the likelihood that this advantage or disadvantage will become realized under the conditions of introduction into the environment,
- c) the possibility of transfer of the heritable material to other species under the conditions of introduction into the environment and each selective advantage or disadvantage that could be thus transferred,
- d) the potential immediate or delayed effects on the environment caused by direct or indirect interactions between the genetically modified organism and the target organism (if a target organism exists),
- e) the potential immediate or delayed environmental impact caused by direct or indirect interactions between the genetically modified organism and nontarget organisms, including the effect on the population levels of competitors, prey, symbionts, predators, parasites and pathogens,
- f) the potential immediate or delayed effects on human health resulting from potential direct or indirect interactions between the genetically modified organism and persons coming into contact therewith,

- g) the potential immediate or delayed effects on the health of animals and consequences for food chains resulting from the consumption of the genetically modified organism or product, which is intended for use as a feedingstuff,
- h) the potential immediate or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the genetically modified organism and target and nontarget organisms in the vicinity of the release of the genetically modified organism into the environment, and
- i) the potential immediate or delayed, direct and indirect effects on the environment as a consequence of the use of specific techniques for the use of genetically modified organisms if these techniques differ from those normally used.

(12) The risk assessment for the release of genetically modified higher plants into the environment or for placing on the market, if the genetically modified higher plants are placed on the market as seeds or seedlings⁴⁾, as appropriate, must contain the following resultant information:

- a) the likelihood that, under the conditions of introduction into the environment, the genetically modified higher plants become more persistent than the recipient or parental organism in an agricultural environment or more invasive in the natural environment,
- b) any selective advantage or disadvantage resulting from the genetic modification,
- c) the potential of transfer of the heritable material to the same or a sexually compatible species under the conditions of cultivation of genetically modified higher plants and each selective advantage or disadvantage that can be thus transferred,
- d) the potential immediate or delayed environmental impact resulting from direct or indirect interactions between the genetically modified higher plant and the target organism (if a target organism exists),
- e) the potential immediate or delayed environmental impact resulting from direct or indirect interactions between the genetically modified higher plant and nontarget organisms, including the impact on the population level of competitors, herbivores, or symbionts, parasites and pathogens,
- f) the potential immediate or delayed effects on human health resulting from potential direct or indirect interactions between the genetically modified higher plant and persons coming into contact therewith,
- g) the potential immediate or delayed effects on the health of animals and the consequences for food chains resulting from consumption of a genetically modified higher plant or product, intended as a feedingstuff,
- h) the potential immediate or delayed effects on biogeochemical processes following from potential direct and indirect interactions of the genetically modified higher plant and target and nontarget organisms in the vicinity of the place of cultivation of the genetically modified higher plant, and
- i) the potential immediate or delayed direct and indirect environmental impacts as a consequence of the use of specific growing, harvesting and processing techniques for the genetically modified plants if these techniques differ from those in common use.

(13) The risk assessment for a product containing several different genetically modified organisms must contain evaluation of the relevant information for each of these organisms.

⁴⁾ Act No. 92/1996 Coll., on varieties, seeds and seedlings of cultivated plants, as amended.

§ 5
Emergency Response Plan
(ad § 5 letter of the Act)

An emergency response plan shall contain

- a) the name, surname, place of residence, state citizenship, place of business, birth certificate number or date of birth, as appropriate, and also the identification number of the user pursuant to § 2 letter g) of the Act, in case of a natural person licensed to operate a business,
- b) the name (business name), legal form, registered office and identification of the user pursuant to § 2 letter g) of the Act, and the name, surname and place of residence of the statutory body of the user, in case of a legal person,
- c) the name, surname, place of residence, telephone number and fax number, as appropriate, and e-mail address of the professional consultant,
- d) persons responsible for liquidation of accidents, the means of communication therewith and the organizational provisions for the case of occurrence of an accident,
- e) an exact description of the property⁵⁾, or premises and facilities where the use of the genetically modified organisms or products takes place, where they are stored and where an accident may occur, stating the place (address) where these properties or space are located; for export, import or transit, a description of the route,
- f) a plan of the workplace, denoting places important for controlling the consequences of an accident (the main control of the power source and sources of auxiliary media, sites of storage of the genetically modified organisms or products, safety features of the containment, for contained use, etc.); for export, import or transit, a description of preventing the dissemination of the genetically modified organisms or products,
- g) a description of an accident that could occur in the facility or at the site where the genetically modified organisms and products are used,
- h) a survey of potential consequences of an accident on the health of humans, animals and the environment and biological diversity, including the manner of determining these consequences and effective protection against them,
- i) procedures for detection of the presence of the genetically modified organisms or products,
- j) methods and procedures that can be used for inactivation of the genetically modified organisms or products involved and for decontamination of the areas affected,
- k) methods for isolation of areas and equipment affected by the accident, including methods for controlling the effectiveness of the isolation,
- l) description and depiction of the location of decontamination aids that can be used for inactivation of the genetically modified organisms or products involved and decontamination of the area affected,
- m) procedures for protection of the health of humans and animals and protection of the environment in case of the occurrence of an undesirable effect caused by an accident; as appropriate, methods of disposal or sanitation of plants or animals located in the area during the accident, in accord with the special regulations⁶⁾,

⁵⁾ § 5 par. 1 of Act No. 344/1992 Coll., on the Land Register of the Czech Republic (the Cadastral Act), as amended.

⁶⁾ E.g., Act No. 353/1999 Coll., on prevention of serious accidents caused by selected dangerous chemical substances and chemical preparations and amending Act No. 425/1990 Coll., on District Authorities, outlining of their jurisdiction and some other related measures, as amended (the Act on prevention of serious accidents), Act

- n) municipalities or persons, as appropriate, to whom the emergency response plan is submitted pursuant to § 5 par. 3 of the Act, and
- o) the administrative authorities set forth in § 13 of the Act and the means of informing them in case of an accident, and the means of informing the inhabitants, as appropriate, in relation to the site of the accident and the potential consequences thereof.

§ 6

Keeping of the Documentation

(Ad § 3 par. 7 letter b) of the Act)

(1) Documentation on the use of genetically modified organisms and products (hereinafter "documentation") pursuant to § 3 par. 7 letter b) of the Act shall be

- a) a copy of the application submitted pursuant to § 3 par. 4 of the Act,
- b) the decision pursuant to § 3 par. 5 of the Act or an officially authenticated copy thereof,
- c) assessment of the risk of the use of the genetically modified organism or product pursuant to § 4 of the Act,
- d) evaluation of the space and the facilities pursuant to § 7 par. 2 letter b) of the Act for contained use of genetically modified organisms,
- e) the code of practice of the workplace,
- f) the emergency response plan prepared pursuant to §5 of the Act,
- g) the operations day-books for the individual stages,
- h) the final reports for the individual stages,
- i) records of the controls carried out pursuant to § 7 par. 10 of the Act, for contained use of genetically modified organisms and
- j) the final report pursuant to § 3 par. 7 letter d) of the Act.

(2) Documentation shall be drawn up, kept and stored in written and electronic form so that documents cannot be lost, damaged or stolen and so as to ensure that they are well-arranged and readily accessible if required. Access to the documentation must be limited only to persons appointed by the user or by the administrative authorities pursuant to § 3 par. 7 letter i) of the Act, as appropriate.

(3) Before commencing a stage, a plan of the stage shall be prepared, which shall contain

- a) the purpose of the use of the genetically modified organism or product,
- b) information on the genetically modified organism,
- c) designation of the stage and its target,
- d) the name, surname and address of the leader of the stage,
- e) the name, surname and address of the professional consultant,
- f) the address of the workplace and/or the position and a description of the property, as appropriate, where the stage will take place,
- g) the date of commencing and the expected completion of the stage,
- h) a list of the organisms to be used during the stage,
- i) a list of the isolated heritable material to be used during the stage,

- j) potential risks in the stage, including risks in case of an accident,
- k) the category of risk of use of the genetically modified organism during the stage,
- l) the procedure for use of the genetically modified organisms and products during the stage, including binding operational procedures to be used during the stage,
- m) the monitoring system, in particular the methods of identification and monitoring of the genetically modified organism or product and its potential effects on the health of humans and animals, the environment and biological diversity,
- n) the kind and amount of wastes formed during the stage and the management thereof in accord with the special regulations⁷⁾,
- o) the manner of further use of the genetically modified organism or product after completion of the stage in connection with the next stage, or the manner of disposal of the genetically modified organism or product and subsequent control of the effectiveness of the disposal, and
- p) the statement of the professional consultant on the plan for the stage.

(4) The operations day-book, to be kept during the stage, shall contain

- a) the plan of the stage,
- b) a description of the progress of the stage, in particular every deviation of the progress of the stage from the plan for the stage,
- c) primary data obtained during the stage,
- d) records of all completed inspections and controls, and
- e) records of all extraordinary events and accidents.

(5) If a change occurs during the stage in the information specified in paragraph 3, it shall be necessary to state the reasons for the change and the date when a decision was made on the change or when it occurred. The professional consultant shall confirm in the documentation that (s)he was notified of the change. In case of an intentional change, the professional consultant shall also confirm favorable evaluation of this change in the documentation,

(6) The person who records the data must do the recording promptly, exactly and legibly. In the record, (s)he must state his(her) name, surname and the date of the entry. Any change in the primary data shall be entered so that the original entry is legible. If necessary, the reason for the change must be affixed, along with the name and surname of the person who made the change, and the date and time of making the change, as appropriate.

(7) Information stored in electronic form shall be backed up. Changes and corrections to this information shall be stored separately. Records on photo-sensitive paper or other materials with limited lifetime must be transferred to a permanent record.

(8) The documentation for a stage shall be completed by a final report that is favorably evaluated by the professional consultant. The final report shall contain in particular

- a) the purpose of the use of the genetically modified organism or product,
- b) designation of the stage and its target,
- c) the name, surname and address of the leader of the stage,
- d) the name, surname and address of the professional consultant,

⁷⁾ E.g., Act No. 125/1997 Coll., on wastes, as appropriate.

- e) the address of the workplace and/or the position and a description of the property, as appropriate, where the stage occurred,
- f) the date of commencing and completing the stage,
- g) information on the genetically modified organism used during the stage,
- h) the isolated heritable material used during the stage, and the means of genetic modification, as appropriate, if carried out during the stage,
- i) a description of the use of the genetically modified organism or product during the stage, including extraordinary events and accidents,
- j) results obtained during the stage and evaluation thereof.

(9) For the time period laid down in § 3 par. 7 letter b) of the Act, the following shall also be kept:

- a) records of training of employees, the instructions thereof and acquaintance with the code of practice of the workplace pursuant to § 3 par. 7 letter g) of the Act, and
- b) records of controls of the occurrence of genetically modified organisms outside of the contained space or property on which use of the genetically modified organisms or products takes or took place.

(10) The keeping of documentation pursuant to this Decree shall not apply on medicinal preparations specified in § 1 par. 2 of the Act.

(11) The special legal regulations⁸⁾ on keeping documentation shall be in no way prejudiced hereby.

§ 7 Legal Force

This Decree shall come into effect on January 1, 2001.

⁸⁾ E.g., Decree No. 230/1999 Coll., laying down proper clinical practice and detailed conditions of clinical evaluation of medicinal substances, Decree No. 74/1998 Coll., laying down proper laboratory practice in the area of medicinal substances, Decree No. 311/1997 Coll., on the breeding and use of experimental animals.

Sample application for entry in the List of Users for contained use of genetically modified organisms

(Information denoted (+) must be accompanied by an original document or an officially authenticated copy)

All enclosed documents shall be denoted with the name of the user

Date of submission

Summary information for the records

Application for entry in the List of Users for contained use	
User	
Professional consultant	
Workplace	
Genetically modified organism or group of organisms	
Purpose of use	
Period of use	
Risk category	

1. The user

(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment or association

- 1.1. Name and surname / trade name / designation
- 1.2. State citizenship (for natural persons)
- 1.3. Legal form
- 1.4. Permanent address / registered office
- 1.5. Business Id. No.
- 1.6. Birth certificate number (for natural persons)
- 1.7. Tax Id. No. (if assigned)
- 1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
- 1.9. Statutory body of the user (for legal persons)
 - 1.9.1. Name, surname, title
 - 1.9.2. Position

2. The professional consultant

(+) Excerpt from the Criminal Records not more than 3 months old

(+) Document of completed education and length of professional experience

- 2.1. Name, surname, title
- 2.2. Profession, and employer and position, as appropriate
- 2.3. Education
- 2.4. Professional courses

- 2.5. Experience to date
- 2.6. Permanent address
- 2.7. Contact address
- 2.8. Telephone
- 2.9. Fax
- 2.10. E-mail

3. Purpose and duration of the use of the genetically modified organism

- 3.1. Purpose of the use of the genetically modified organism
- 3.2. Expected result
- 3.3. Individual stages in the use and the duration thereof
- 3.4. Overall time of use

4. Result of risk assessment - classification in a risk category

- (+) Risk assessment pursuant to § 4 of the Act

5. Workplace at which the use will take place

(+) The code of practice of the workplace supplemented pursuant to § 3 par. 7 letter f) and Annex No. 2 to the Act

(+) The emergency response plan pursuant to § 5 of the Act

(+) Document of granting of certification pursuant to § 15 par. 2 of Act No. 246/1992 Coll., on protection of animals against cruelty, and the experiment plan § 23 par. 1 letter a) of Act No. 246/1992 Coll. for facilities for animals

5.1. Address

5.2 Character of the workplace

microbiological laboratory

microbiological activity¹

pilot plant

production unit

glasshouse / growing-room

facility for animals

other (specify)

5.3. Description of location of the space for contained use and technical description of the facilities thereof

(+) plans of the space and the location of the most important facilities

5.4. Assessment of the space and the facilities of the workplace and its location pursuant to the requirements on a contained space and protective measures as laid down for the individual risk categories by Decree No. 373/2000 Coll.

(+) Comparison table of requirements for the given category as laid down by the Decree and the actual equipping of the workplace

5.5 The contact person for the given workplace

5.5.1. Name, surname, title

5.5.2. Contact

6. The organism or group of organisms, as appropriate, pursuant to § 7 par. 3 of the Act

6.1. Information on the donor organism, including its origin

6.2. Information on the recipient or parental organism, including the origin thereof

6.3. Information on the vector, including the origin thereof

6.4. Information on the insert

- 6.5. Method of incorporating the insert
 - 6.6. Information on the genetically modified organism
 - 6.6.1. Function of the inserted or deleted genes, as appropriate
 - 6.6.2. Information permitting unambiguous identification of the altered heritable material
 - 6.6.3. The procedure of detection of the presence of the genetic modification, including the technique of molecular biology
 - 6.7. The approximate amount of genetically modified organisms to be used (volume of the culture, number of plants or animals)
 - 6.8. Information on whether the genetically modified organism involved has already been registered/approved in some other country and for what purpose.
- (Not all the information required in Part 6 of this Annex need to be known for cases subject to § 7 par. 3 of the Act).

7. Description of the use of the genetically modified organism

- 7.1. In case of import or export of the genetically modified organism
 - 7.1.1. The country of origin or destination, as appropriate
 - 7.1.2. Importer or exporter, as appropriate
 - 7.1.3. Maximum imported or exported volume
 - 7.1.4. Means of transportation
- 7.2. Description of the use of the genetically modified organism in accord with the risk assessment
- 7.3. Measures to protect the health of humans and animals, the environment and biological diversity
- 7.4. Information on the system of carrying out control of the occurrence of genetically modified organisms
 - 7.4.1. inside the contained space
 - 7.4.2. outside the contained space
- 7.5. The manner of inactivation of the genetically modified organism and control of the effectiveness of inactivation thereof
- 7.6. Description of management of wastes, including hazardous wastes, waste waters and waste gaseous products.

8. Supplementary information

- 8.1. Manner of keeping documentation on the use of the genetically modified organism and product and the site of depositing thereof
- 8.2. Plan of training of employees prior to commencing the use of the genetically modified organism or product and the subsequent instruction thereof.

Footnote:

¹ All workplaces where genetically modified microorganisms are used, without regard to the final modified organism, are considered to constitute microbiological activities. Microbiological activities may consist of a laboratory, greenhouse or breeding facility where work is carried out with genetically modified microorganisms.

Sample application for entry in the List of Users for introduction of genetically modified organisms into the environment

(Information denoted (+) must be accompanied by the original document or an officially authenticated copy)

All enclosed documents shall be denoted with the name of the user

Date of submission

Summary information for the records

Application for entry in the List of Users for introduction into the environment	
User	
Professional consultant	
Workplace or properties	
Genetically modified organism	
Purpose of use	
Period of use	

1. The user

(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment or association

- 1.1. Name and surname / trade name / designation
- 1.2. State citizenship (for natural persons)
- 1.3. Legal form
- 1.4. Permanent address / registered office
- 1.5. Business Id. No.
- 1.6. Birth certificate number (for natural persons)
- 1.7. Tax Id. No. (if assigned)
- 1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
- 1.9. Statutory body of the user (for legal persons)
 - 1.9.1. Name, surname, title
 - 1.9.2. Position

2. The professional consultant

(+) Excerpt from the Criminal Records not more than 3 months old

(+) Document of completed education and length of professional experience

- 2.1. Name, surname, title
- 2.2. Profession, and employer and position, as appropriate
- 2.3. Education
- 2.4. Professional courses
- 2.5. Experience to date

- 2.6. Permanent address
- 2.7. Contact address
- 2.8. Telephone
- 2.9. Fax
- 2.10. E-mail

3. Purpose and duration of the use of the genetically modified organism

- 3.1. Purpose of the use of the genetically modified organism
- 3.2. Expected result
- 3.3. Individual stages in the use and the duration thereof
- 3.4. Overall time of use

4. Result of risk assessment - classification in a risk category

- (+) Risk assessment pursuant to § 4 of the Act

5. Workplace or properties at which the use will occur

- (+) The code of practice of the workplace supplemented pursuant to § 3 par. 7 letter f) and Annex No. 2 to the Act

- (+) The emergency response plan pursuant to § 5 of the Act

- 5.1. The address of the workplace or the position of the properties, as appropriate
 - (+) copy of the map with designation of the property
- 5.2. Description of the properties on which the GMOs will be introduced into the environment
- 5.3. Size of the area on which the GMOs will be introduced into the environment
- 5.4. Character of the locality (use of surrounding properties, flora, fauna, distance from water courses, protected territories, etc.)
- 5.5. Measures for the protection of the health of humans and animals, the environment and biological diversity (e.g. safeguarding of properties against trespassing by unauthorized persons, animals, measures preventing the spread of the genetically modified organisms outside of the property)
- 5.6. The contact person for the given workplace
 - 5.5.1. Name, surname, title
 - 5.5.2. Contact information

6. The organism

- 6.1. Information on the donor organism, including the origin thereof
- 6.2. Information on the recipient or parental organism, as appropriate, including the origin thereof
- 6.3. Information on the vector, including its origin
- 6.4. Information on the insert
- 6.5. Method of incorporating the insert
- 6.6. Information on the genetically modified organism
 - 6.6.1. Function of the inserted or deleted genes
 - 6.6.2. Information permitting unambiguous identification of the altered genetic material
 - 6.6.3. The manner of detection of the presence of the genetic modification
- 6.7. The approximate amount of genetically modified organisms to be used
- 6.8. Information on whether the genetically modified organism involved has already been registered/approved in some other country and for what purpose.

7. Description of the use of the genetically modified organism

- 7.1. In case of import or export of the genetically modified organism
 - 7.1.1. The country of origin or destination, as appropriate
 - 7.1.2. The importer or exporter, as appropriate
 - 7.1.3. The maximum imported or exported volume
 - 7.1.4. The means of transportation
- 7.2. Description of the use of the genetically modified organism during its introduction into the environment and after completion thereof in accord with the risk assessment
- 7.3. Information on the system of carrying out control of the occurrence of genetically modified organisms on the property and in its vicinity
 - 7.4.1. during the introduction into the environment
 - 7.4.2. after terminating of the introduction into the environment
- 7.4. The manner of inactivation of the genetically modified organism and control of the effectiveness of inactivation
- 7.5. Description of management of wastes

8. Supplementary information

- 8.1. Means of keeping documentation on the use of the genetically modified organism and product and the site of deposition thereof
- 8.2. Plan of training of employees prior to commencing the use of the genetically modified organism or product and the subsequent instruction thereof.

Sample application for entry in the List of Users for placing of genetically modified organisms and products on the market

(Information denoted (+) must be accompanied by an original document or an officially authenticated copy)

All enclosed documents shall be denoted with the name of the user

Date of submission

Summary information for the records

Application for entry in the List of Users for placing on the market	
User	
Professional consultant	
Genetically modified organism	
Product	
Duration of placing on the market	

1. The user

(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment of association

- 1.1. Name and surname / trade name / designation
- 1.2. State citizenship (for natural persons)
- 1.3. Legal form
- 1.4. Permanent address / registered office
- 1.5. Business Id. No.
- 1.6. Birth certificate number (for natural persons)
- 1.7. Tax Id. No. (if assigned)
- 1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
- 1.9. Statutory body of the user (for legal persons)
 - 1.9.1. Name, surname, title
 - 1.9.2. Position

2. The professional consultant

(+) Excerpt from the Criminal Records not more than 3 months old

(+) Document of completed education and length of professional experience

- 2.1. Name, surname, title
- 2.2. Profession, and employer and position, as appropriate
- 2.3. Education
- 2.4. Professional courses
- 2.5. Experience to date
- 2.6. Permanent address

- 2.7. Contact address
- 2.8. Telephone
- 2.9. Fax
- 2.10. E-mail

3. Purpose and duration of the use of the genetically modified organism or product

- 3.1. Purpose of placing the genetically modified organism or product on the market
- 3.2. Individual stages in the use and the duration thereof
- 3.3. Overall time of placing on the market

4. Result of risk assessment - classification in a risk category

(+) Risk assessment pursuant to § 4 of the Act

5. The organism

- 5.1. Information on the donor organism, including the origin thereof
- 5.2. Information on the recipient or parental organism, including the origin thereof
- 5.3. Information on the vector, including its origin
- 5.4. Information on the insert
- 5.5. Method of incorporating the insert
- 5.6. Information on the genetically modified organism
 - 5.6.1. Function of the inserted or deleted genes, as appropriate
 - 5.6.2. Information permitting unambiguous identification of the altered heritable material
 - 5.6.3. The manner of control of the presence of the genetic modification, including techniques of molecular biology
- 5.7. The approximate amount of genetically modified organisms to be used
- 5.8. Information on whether the genetically modified organism or product involved has already been registered/approved in some other country and for what purpose
- 5.9. If the genetically modified organism of interest has been entered in the List of genetically modified organisms registered for introduction into the environment, the date and number of the decision on entry

6. The product

- 6.1. Specification of the product
- 6.2. The manner of use
- 6.3. Information permitting unambiguous identification of the altered genetic material
- 6.4. The manner of control of the presence of the genetic modification, including techniques of molecular biology
- 6.5. Approval of the product in another country and for what purposes
- 6.6. Packaging
- 6.7. Labelling
- 6.8. Information for the consumer
- 6.9. Further information pursuant to the special regulations (e.g. Act No. 110/1997 Coll., on food and tobacco products, Act No. 91/1996 Coll., on feeds, Act No. 92/1996 Coll., on varieties, seeds and seedlings of cultivated plants, Act No. 79/1997 Coll., on medicinal substances and supplementing some related Acts)

7. The use of the genetically modified organism or product

- 7.1. In case of import or export of the genetically modified organism

- 7.1.1. The country of origin or destination, as appropriate
- 7.1.2. The importer or exporter, as appropriate
- 7.1.3. The estimated imported or exported amount
- 7.1.4. The means of transportation
- 7.2. Measures for protection of the health of humans and animals, the environment and biological diversity (including measures to prevent dissemination of the genetically modified organism and the means of eliminating the genetically modified organism in case of dissemination thereof in the environment)
- 7.3. The manner of inactivation of the genetically modified organism or product
- 7.4. Description of management of wastes
- 7.5. Information on potential interactions of the genetically modified organism or product with the environment

8. Supplementary information

- 8.1. The means of keeping documentation on the use of the genetically modified organism and product and the site of deposition thereof
- 8.2. The manner and frequency of taking and analyzing samples after placing on the market
- 8.3. Monitoring of the effects of the genetically modified organism or product after placing on the market, on the health of humans and animals, the environment and biological diversity (monitoring), if this will be carried out
- 8.4. The means and frequency of informing the Ministry thereof.

Sample application for entry in the List of genetically modified organisms registered for contained use

(Information denoted (+) must be accompanied by an original document or an officially authenticated copy)

All enclosed documents shall be denoted with the name of the user and the designation of the genetically modified organism

Date of submission

Summary information for the records

Application for entry in the List of genetically modified organisms registered for contained use	
Genetically modified organism	
Genetic modification	
Risk category	
User	
Purpose of use	
Period of use	

1. The user

(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment or association

- 1.1. Name and surname / trade name / designation
- 1.2. State citizenship (for natural persons)
- 1.3. Legal form
- 1.4. Permanent address / registered office
- 1.5. Business Id. No.
- 1.6. Birth certificate number (for natural persons)
- 1.7. Tax Id. No. (if assigned)
- 1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
- 1.9. Statutory body of the user (for legal persons)
 - 1.9.1. Name, surname, title
 - 1.9.2. Position

2. The professional consultant

(+) Excerpt from the Criminal Records not more than 3 months old

(+) Document of completed education and length of professional experience

- 2.1. Name, surname, title
- 2.2. Profession, and employer and position, as appropriate
- 2.3. Education

- 2.4. Professional courses
- 2.5. Experience to date
- 2.6. Permanent address
- 2.7. Contact address
- 2.8. Telephone
- 2.9. Fax
- 2.10. E-mail

3. Purpose of the use of the genetically modified organism or product

- 3.1. Purpose of the contained use of the genetically modified organism
- 3.2. Expected result

4. Duration of the contained use of the GMO

Binding schedule (description of the individual stages and the duration thereof)

5. Information on (A) the donor organism, (B) the recipient and (where appropriate) (C) the parental organism

(state separately for A, B and C, as appropriate)

- 5.1. The organism is a
 - viroid
 - RNA virus
 - DNA virus
 - bacteria
 - fungus (mould, yeast)
 - higher plant
 - animal
 - other (specify)
- 5.2. Name (unless a higher plant is involved /Gymnospermae and Angiospermae/)
 - 5.2.1. The order or higher taxon
 - 5.2.2. The genus
 - 5.2.3. The species
 - 5.2.4. The subspecies
 - 5.2.5. The strain (for microorganisms)
 - 5.2.6. The common name (Czech, Latin)
- 5.3. Name (where a higher plant is involved /Gymnospermae and Angiospermae/)
 - 5.3.1. The family name
 - 5.3.2. The genus
 - 5.3.3. The species
 - 5.3.4. The subspecies
 - 5.3.5. The variety / breeding line
 - 5.3.6. The common name (Czech, Latin)
- 5.4. The origin (collection, collection number, supplier)
- 5.5. The geographic distribution of the organism
 - 5.5.1. Natural occurrence in CR
 - 5.5.2. Natural occurrence in Europe including the ecological system
(arctic, Atlantic, Mediterranean, continental)
 - 5.5.3. Natural habitat of the organism
 - Microorganisms

- aquatic environment
- soil,
- soil in connection with the root system of plants
- in connection with the parts of plants above the soil
- in connection with animals
- other

Plants

- natural habitat
- agro-ecosystem

Animals

- natural habitat
- agro-ecosystem

5.5.4. Used or cultivated in CR

5.5.5. Used or cultivated in Europe

5.6. If the organism is pathogenic or otherwise harmful (living or nonliving, including extracellular products), state whether in relation to

- humans
- animals
- plants

5.7. Information on whether there is natural exchange of heritable material between the donor organism and the recipient

6. Information on the genetic modification

6.1. The type of genetic modification

- incorporation of foreign heritable material
- deletion of part of the heritable material
- combination of deletion and incorporation of heritable material
- cell fusion
- other (specify)

6.2. Intended result of the genetic modification

6.3. Information on the vector used, if used in the genetic modification

(+ genetic map of the vector)

6.3.1. Information on whether the vector is fully or partly present in the final GMO

6.3.2. Type of vector

- plasmid
- bacteriophage
- virus
- cosmid
- phasmid
- transposon
- other object (specify)

6.3.3. Identity of the vector

6.3.4. Spectrum of the vector hosts

6.3.5. Presence of the sequence in the affected vector, which transfers the selectable or identifiable phenotype

- resistance to antibiotics
- resistance to heavy metals
- resistance to pesticides (specify)
- other resistance (specify)

6.3.6. Methods of incorporation of the vector into the recipient organism

- transformation
- electroporation¹
- macro-injection
- micro-injection
- infection
- other (specify)

6.3.7. Fragments of the vector and their presence in the final GMO

6.4. If a vector was not used in the genetic modification, the method of incorporating the insert into the recipient organism

- transformation
- micro-injection
- micro-encapsulation
- macro-injection
- other (specify)

7. Information on the insert

(Summarize information ad 7.1 to 7.3 in a table, + genetic map of the insert)

7.1. Composition of the insert

7.2. Source of each part of the insert

7.3. Intended function of each individual part of the insert in the final GMO

7.4. Location of the insert in the final GMO

- on the free plasmid
- integrated into the chromosome
- other (specify)

7.5. Information on whether the insert contains any part whose products or functions are not known

7.6. Information on whether the sequences contained in the insert participate in any way in pathogenic or harmful properties of the donor organism or vector

8. Information on the resultant genetically modified organism

8.1. Genetic properties and phenotypic characteristics of the recipient or parental organism, that were altered as a result of the genetic modification

8.1.1. Information on whether the genetically modified organism differs from the recipient or parental organism in its survivability

8.1.2. Information on whether the genetically modified organism differs from the recipient or parental organism in the manner or rate of reproduction

8.1.3. Information on whether the genetically modified organism differs from the recipient or parental organism in its ability to disseminate in the environment

8.2. The genetic stability of the genetically modified organism

8.3. Information on whether the genetically modified organism (living or nonliving, including its extracellular products) is pathogenic or otherwise harmful

if so, in relation to

- humans
- animals
- plants

8.4. Description of methods for identification and detection of the GMO

8.4.1. Methods used to detect the GMO

8.4.2. Methods used to detect the GMO in the environment

8.4.3. Methods permitting unambiguous identification of the altered section of the heritable material.

9. The results of risk assessment of contained use of the GMO - classification in a risk category

(+) Risk assessment pursuant to § 4 of the Act

10. Workplace at which the contained use will occur

(+) The emergency response plan pursuant to § 5 of the Act

(+) The code of practice of the installation pursuant to § 3 par. 7 letter f) and Annex No. 2 of the Act

10.1. The address

10.2. The character of the workplace

microbiological workplace

microbiological activities²

pilot plant

production unit

glasshouse / growth room

experimental facility for animals (information on granting of certification and the plan of experiments pursuant to Act No. 246/1992 Coll., on protection of animals against cruelty)

other (specify)

10.3. Description of location of the premises for contained use and a technical description of the facilities thereof

(+) plans of the location of the space and the location of selected facilities

10.4. Assessment of the space and the facilities of the workplace and its location pursuant to the requirements on a contained space and protective measures as laid down for the individual risk categories by Decree No. 373/2000 Coll.

(+) Comparison table of requirements for the given category as laid down by the Decree and the actual equipping of the workplace

11. Description of the use of the genetically modified organism in accord with the risk assessment

12. Measures for the protection of the health of humans and animals, the environment and biological diversity, including the manner of inactivation of the genetically modified organism and control of the effectiveness of the inactivation

13. System of carrying out control of the occurrence of genetically modified organisms during the use of the GMOs and after completion thereof

13.1. The manner and frequency of carrying out controls inside the contained space

13.2. The manner and frequency of carrying out controls outside the contained space

14. Description of waste management

14.1. Solid wastes

14.2. Liquid wastes

14.3. Gaseous wastes

Footnote:

¹ Electroporation means the method of incorporating foreign DNA or chromosomes into cells through the effect of a short voltage pulse, which temporarily increases the permeability of the membrane and thus allows the cells to absorb DNA or chromosomes from the surrounding solution.

² All workplaces where genetically modified microorganisms are used, without regard to the final modified organism, are considered to constitute microbiological activities. Microbiological activities may consist in a laboratory, glasshouse or animal facility where work is carried out on genetically modified microorganisms.

Sample application for entry in the List of genetically modified organisms registered for introduction into the environment for genetically modified microorganisms (GMM)

(Information denoted (+) must be accompanied by an original document or an officially authenticated copy)

All enclosed documents shall be denoted with the name of the user and the designation of the genetically modified organism

Date of submission

Summary information for the records

Application for entry in the List of genetically modified organisms registered for introduction into the environment	
Genetically modified organism	
Genetic modification	
Result of risk assessment	
User	
Purpose of introduction into the environment	
Place of introduction into the environment	
Duration of use	

1. The user submitting the application

(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment or association

- 1.1. Name and surname / trade name / designation
- 1.2. State citizenship (for natural persons)
- 1.3. Legal form
- 1.4. Permanent address / registered office
- 1.5. Business Id. No.
- 1.6. Birth certificate number (for natural persons)
- 1.7. Tax Id. No. (if assigned)
- 1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
- 1.9. Statutory body of the user (for legal persons)
 - 1.9.1. Name, surname, title
 - 1.9.2. Position

2. The professional consultant

(+) Excerpt from the Criminal Records not more than 3 months old

(+) Document of completed education and length of professional experience

- 2.1. Name, surname, title

- 2.2. Profession, and employer and position, as appropriate
- 2.3. Education
- 2.4. Professional courses
- 2.5. Experience to date
- 2.6. Permanent address
- 2.7. Contact address
- 2.8. Telephone
- 2.9. Fax
- 2.10. E-mail

3. Purpose of the use of the genetically modified organism or product

- 3.1. Purpose of releasing the GMM into the environment
- 3.2. Expected result of releasing the GMM into the environment

4. Duration of the release of the GMM into the environment

Binding schedule (description of the individual stages and the duration thereof)

5. Identification information on other users who will carry out release of the GMM into the environment or will participate therein

(+)Officially authenticated copies of the decision on entry of these persons into the List of Users or applications of these persons for entry into the List of Users

- 5.1. The user
- 5.2. The work that (s)he will carry out

6. Information on (A) the donor organism, (B) the recipient and (where appropriate) (C) the parental organism

(state separately for A, B and C, as appropriate)

- 6.1. Name
 - 6.1.1. The order
 - 6.1.2. The genus
 - 6.1.3. The species
 - 6.1.4. The subspecies
 - 6.1.5. The strain
 - 6.1.6. The common name (Czech, Latin)
- 6.2. The origin (collection, collection number, supplier)
- 6.3. Plasmids
- 6.4. Bacteriophages
- 6.5. Phenotypic and genetic signal markers
- 6.6. Degree of relatedness between the donor organism and the recipient
- 6.7. Methods of identification and detection
 - 6.7.1. Description of the methods
 - 6.7.2. Sensitivity, reliability (in quantitative terms) and specificity of identification and detection methods
- 6.8. Occurrence and living conditions
 - 6.8.1. Geographic distribution
 - 6.8.2. The natural habitat of the organism
 - aquatic environment
 - soil,
 - soil in connection with the root system of plants

- in connection with the parts of plants above the soil
 - in connection with animals
 - other
- 6.8.3. Natural predators, preys, parasites and competitors, symbionts and hosts
- 6.8.4. Other potential interactions with other organisms
- 6.9. Potential intercellular transfer of genetic material
 - 6.9.1. Means of transfer (plasmid, bacteriophage, other)
 - 6.9.2. Organisms with which natural exchange of genetic material occurs
- 6.10. Verification of the genetic stability of the organism and the factors that affect this stability
- 6.11. Reproduction
 - 6.11.1. Means of reproduction
 - 6.11.2. Specific factors affecting reproduction (if any)
 - 6.11.3. Generation time in the natural environment
- 6.12. Survivability
 - 6.12.1. Survivability in the individual seasons
 - 6.12.2. Ability to form survival structures, such as seeds, spores, sclerotia
 - 6.12.3. Other specific factors enabling survival
- 6.13. Dissemination in the environment
 - 6.13.1. Means and extent of dissemination
 - 6.13.2. Specific factors affecting dissemination
- 6.14. Effects of a living or nonliving organism (including extracellular products) on the health of humans, animals and other organisms
 - pathogenicity: contagiousness, infectivity, virulence
 - allergic effects
 - toxic effects
 - carrier of pathogen
 - possible activation of latent viruses (proviruses)
 - ability to penetrate into other organisms or colonize other organisms
 - antibiotic resistance and potential use of these antibiotics for prophylaxis and treatment of diseases of humans and animals
 - other (specify)
- 6.15. Involvement in environmental processes
 - primary production
 - nutrient turnover
 - decomposition of organic matter
 - other (specify)
- 6.16. Indigenous vectors of the organism
 - 6.16.1. sequence
 - 6.16.2. frequency of mobilization
 - 6.16.3. specificity
 - 6.16.4. presence of genes conferring resistance
- 6.17. Previous genetic modifications

7. Information on the genetic modification

- 7.1. The type of genetic modification
 - insertion of foreign heritable material
 - deletion of part of the heritable material
 - combination of deletion and incorporation of heritable material

- cell fusion
- other (specify)
- 7.2. Intended result of the genetic modification
- 7.3. Information on the vector used, if used in the genetic modification
 - (+ genetic map of the vector)
 - 7.3.1. Information on whether the vector is fully or partly present in the final GMM
 - 7.3.2. Type of vector
 - plasmid
 - bacteriophage
 - virus
 - cosmid
 - phasmid
 - transposon
 - other object (specify)
 - 7.3.3. Identity of the vector (origin)
 - 7.3.4. Spectrum of the vector hosts
 - 7.3.5. Presence of the sequence in the vector in question, which transfers the selectable or identifiable phenotype
 - resistance to antibiotics
 - resistance to heavy metals
 - resistance to pesticides (specify)
 - other resistance (specify)
 - 7.3.6. Methods of incorporation of the vector into the recipient organism
 - transformation
 - electroporation¹
 - macro-injection
 - micro-injection
 - infection
 - other (specify)
 - 7.3.7. Information on the degree to which the vector is limited to the sequence of the nucleic acid required to perform the intended function.
 - 7.3.8. Fragments of the vector and their presence in the final GMM
- 7.4. If a vector was not used in the genetic modification, the method of incorporating the insert into the recipient organism
 - transformation
 - micro-injection
 - micro-encapsulation
 - macro-injection
 - other (specify)
- 7.5. Methods and criteria used for selection

8. Information on the insert

- 8.1. Information on each part of the insert or each eliminated part of the heritable material with special emphasis on any known harmful sequences
 - 8.1.1. size
 - 8.1.2. position
 - 8.1.3. sequence
 - 8.1.4. origin
 - 8.1.5. functional characteristics

- 8.2. Purity of the insert
 - 8.2.1. Information on whether the insert contains a part whose products or functions are not known
 - 8.2.2. Information on the degree to which the insert is limited to the sequence of the nucleic acid required to perform the intended function
- 8.3. Information on whether the sequences contained in the insert participate in any way in pathogenic or harmful properties of the donor organism or vector.

9. Information on the resultant genetically modified organism

- 9.1. Description of the heritable properties and phenotypic traits, that were altered as a result of the genetic modification
- 9.2. Information on the altered section of the nucleic acid
 - 9.2.1. Structure and size of each section of the nucleic acid derived from the vector and/or donor organism remaining in the final GMM, including methods and information required for identification and detection of the inserted sequence
 - 9.2.2. In case of deletion of part of the heritable material, the size and function of the deleted nucleic acid segment
 - 9.2.3. The location of the inserted genetic material in the cell
 - 9.2.4. The number of copies of the inserted genetic material
 - 9.2.5. The stability of the location thereof
- 9.3. The genetic stability of the GMM according to the heritable properties
- 9.4. Expression of the inserted heritable material
 - 9.4.1. Rate and degree of expression of the new heritable material
 - 9.4.2. Description of the methods of measurement, giving its sensitivity
 - 9.4.3. The stability of the expression
- 9.5. Expressed proteins
 - 9.5.1. Activity of the expressed proteins
 - 9.5.2. Description of identification and detection methods, giving their sensitivity, reliability and specificity
- 9.6. Health factors
 - 9.6.1. Toxic or allergic effects of the genetically modified organism or its metabolic products
 - 9.6.2. Comparison of the modified organism with the donor organism, recipient or (where appropriate) parental organism, regarding pathogenicity
 - 9.6.3. Ability to colonize / penetrate into other organisms
 - 9.6.4. If the organism is pathogenic to human individuals who are immunocompetent:
 - 9.6.4.1. diseases caused and mechanism of pathogenicity including invasiveness and virulence
 - 9.6.4.2. communicability / infectiousness
 - 9.6.4.3. infective dose
 - 9.6.4.4. host range, possibility of alteration
 - 9.6.4.5. possibility of survival outside the human host
 - 9.6.4.6. presence of vectors or means of dissemination
 - 9.6.4.7. biological stability
 - 9.6.4.8. antibiotic-resistance patterns
 - 9.6.4.9. allergic effects
 - 9.6.4.10. availability of appropriate therapy
 - 9.6.4.11. other risks
- 9.7. Information on the way in which the GMM differs from the parental microorganism

means and rate of multiplication
dissemination in the environment
survivability
effects on the health of humans, animals and other organisms
other (specify)

9.8. Previous use of the GMM

9.9. Description of methods of identification and detection of the GMM

9.9.1. Methods used to detect the GMM

9.9.2. Methods used to identify the GMM in the environment

9.9.3. Information permitting unambiguous identification of the altered section of the heritable material

10. Result of risk assessment of contained use of the GMM - classification in a risk category

(+) Risk assessment pursuant to § 4 of the Act

11. Information on release of the GMM into the environment in other countries

11.1. Information on whether the GMM has already been registered/approved for introduction into the environment (where possible, state the number or designation of the registration)

11.1.1. Country

11.1.2. User / applicant / notifier (pursuant to the EC Directive)

11.1.3. Purpose of introduction into the environment

11.1.4. Period in time

11.2. Information on whether release of the GMM into the environment is planned in another country

11.2.1. Country

11.2.2 User / applicant / notifier (pursuant to the EC Directive)

11.2.3. Purpose

11.2.4. Date

12. Information on the amount of GMM to be used and on the total area of the properties

12.1. Approximate amount of GMM to be used

12.2. Total extent of the area over which the release of the GMM into the environment is to occur

13. Workplace and properties at which the introduction into the environment will occur

(+) The emergency response plan pursuant to § 5 of the Act

(+) The code of practice of the workplace pursuant to § 3 par. 7 letter f) and Annex No. 2 of the Act

(+) Copies of the maps

13.1. The user who will carry out release of the GMM on the given property, and the owner of the property

13.2. Address (location)

13.3. Contact person for the given property

13.3.1. Name, surname, title

13.3.2. Contact

13.4. Specification of the property

- 13.4.1 Municipality
- 13.4.2. District
- 13.4.3. Position of the area for cultivation of the GMM on the property and the size thereof
 - (+ plan on a suitable scale)
- 13.4.4. Size and use of the isolation zone around the area for cultivation of the GMM
 - (+ denote on the plan)
- 13.4.5. Use of the surrounding properties
- 13.5. Distance from specific territories
 - 13.5.1. Specially protected territories (Act No. 114/1992 Coll., on protection of nature and the landscape, as amended)
 - 13.5.2. Protective zones of water sources
 - 13.5.3. Water courses, water reservoirs
 - 13.5.4. Other
- 13.6. Safeguarding the property
 - 13.6.1. Safeguarding against unauthorized persons
 - 13.6.2. Safeguarding against animals
 - 13.6.3. Safeguarding against water runoff
- 13.7. Description of the ecosystem at the site of the property
 - 13.7.1. Type of soil
 - 13.7.2. Water regime including irrigation
 - 13.7.3. Climatic conditions
 - 13.7.4. Flora including agricultural crops
 - 13.7.5. Fauna including domestic and migrating animals
- 13.8. Description of target and nontarget ecological systems likely to be affected
- 13.9. Comparison of the natural habitat of the recipient or parental organism, as appropriate, with the proposed site of release of the GMM into the environment
- 13.10. Any known planned changes in the use of the properties in the vicinity of the site of release of the GMM into the environment that are likely to affect the environmental impact of the GMM

14. Description of the use of the GMM

- 14.1. Use of the GMM prior to its introduction into the environment (contained use, transportation)
- 14.2. Procedure through which the GMM will be released into the environment
- 14.3. Approximate number of GMM (per m² or m³)
- 14.4. Preparation and treatment of the property prior to application of the GMM
- 14.5. Cultivation of the GMM on the property
- 14.6. Elimination of the GMM from the environment
- 14.7. Further use of the GMM including inactivation thereof
- 14.8. Date and manner of evaluation of the release of the GMM into the environment

15. Measures to protect the health of humans and animals, the environment and biological diversity, including the manner of disposal of the genetically modified organism and control of the effectiveness of the disposal and waste management

- 15.1. Monitoring of the occurrence and effects of the GMM
 - 15.1.1. Methods of determining the presence of GMM and monitoring of their effects

- 15.1.2. Specificity of methods of identification of GMM and differentiation of GMM from the donor organisms, recipients, or parental organisms, as appropriate, sensitivity and reliability of these methods
- 15.1.3. Techniques (methods) of detection of transfer of the inserted heritable material to other organisms
- 15.2. Measures adopted to prevent spread of the GMM to the environment during introduction into the environment
 - 15.2.1. Technical measures
 - 15.2.2. Plan of controls and supervision
- 15.3. Measures adopted to minimize the occurrence of the GMM on the property and in its vicinity after termination of the release of the GMM into the environment
 - 15.3.1. Description of methods for treating the property after terminating the experiment
 - 15.3.2. Plan of controls and supervision
 - 15.3.3. Means of inactivation of the GMM and control of the efficiency thereof
- 15.4. Manner of transport of the GMM
- 15.5. Protection of the health of employees during use of the GMM
- 15.6. Waste management
 - 15.6.1. Kinds of wastes formed and the expected amounts thereof
 - 15.6.2. Potential risks from waste management
 - 15.6.3. Description of waste disposal and methods of controlling the effectiveness of the disposal thereof

16. Information on interactions between the GMM and the environment

- 16.1. Survival, multiplication and dispersal
 - 16.1.1. Properties of the GMM that affect survival, multiplication and dispersal of the GMM in the environment
 - 16.1.2. Known or predicted environmental conditions that could affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.)
 - 16.1.3. Sensitivity to specific substances (agents)
- 16.2. Predicted habitat of the GMM
- 16.3. Results of studies of the behaviour and properties of the GMM and their environmental impacts carried out in a simulated natural environment
- 16.4. Genetic transfer capability
 - 16.4.1. Possibility of post-release transfer of heritable materials from GMMs into other organisms
 - 16.4.2. Possibility of post-release transfer of heritable material from indigenous organisms to the GMM
- 16.5. Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the GMM
- 16.6. Genetic stability of GMM in the environment
 - 16.6.1. Measures to ensure genetic stability
 - 16.6.2. Description of genetic traits which are supposed to prevent or limit dispersal of the genetic material
 - 16.6.3. Methods of verifying the genetic stability
- 16.7. Routes of biological dispersal of the GMM, known or potential modes of interaction with the disseminating agents (inhalation, ingestion, surface contact, etc.)
- 16.8. Ecosystems into which the GMMs could be disseminated
- 16.9. Potential for excessive increase in the population of GMM in the environment

- 16.10. Competitive advantage of the GMMs in relation to the recipient or parental organism, as appropriate
- 16.11. Identification and description of the target organisms, if any
- 16.12. Anticipated mechanism and result of interaction between the GMMs and the target organism, if a target organism exists
- 16.13. Identification and description of nontarget organisms which could be detrimentally affected by release of the GMM into the environment and the expected mechanism of determined undesirable impacts
- 16.14. Likelihood of post-release shifts in biological interactions or in the host range
- 16.15. Known or predicted interactions with nontarget organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens
- 16.16. Known or predicted involvement in biogeochemical processes
- 16.17. Likelihood that the GMMs will become more resistant or more invasive than the recipient in the environment
- 16.18. Other potential impacts on the environment and biological diversity.

17. Provision of samples and necessary information for detection of the altered heritable material

(Specification of the samples provided to the workplace carrying out the detection, the amount, frequency and means of supply thereof)

- 17.1. Prior to commencement of the use
- 17.2. During the use

¹ Electroporation means the method of incorporating foreign DNA or chromosomes into cells through the effect of a short voltage pulse, which temporarily increases the permeability of the membrane and thus allows the cells to absorb DNA or chromosomes from the surrounding solution.

Sample application for entry in the List of genetically modified organisms registered for introduction into the environment for genetically modified higher plants (GMHP)

(Information denoted (+) must be accompanied by an original document or an officially authenticated copy)

All enclosed documents shall be denoted with the name of the user and the designation of the genetically modified organism

Date of submission

Summary information for the records

Application for entry in the List of genetically modified organisms registered for introduction into the environment	
Genetically modified organism	
Genetic modification	
Result of risk assessment	
User	
Purpose of introduction into the environment	
Place of introduction into the environment	
Duration of use	

1. The User submitting the application

(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment or association

- 1.1. Name and surname / trade name / designation
- 1.2. State citizenship (for natural persons)
- 1.3. Legal form
- 1.4. Permanent address / registered office
- 1.5. Business Id. No.
- 1.6. Birth certificate number (for natural persons)
- 1.7. Tax Id. No. (if assigned)
- 1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
- 1.9. Statutory body of the user (for legal persons)
 - 1.9.1. Name, surname, title
 - 1.9.2. Position

2. The professional consultant

(+) Excerpt from the Criminal Records not more than 3 months old

(+) Document of completed education and length of professional experience

- 2.1. Name, surname, title

- 2.2. Profession, and employer and position, as appropriate
- 2.3. Education
- 2.4. Professional courses
- 2.5. Experience to date
- 2.6. Permanent address
- 2.7. Contact address
- 2.8. Telephone
- 2.9. Fax
- 2.10. e-mail

3. Purpose of the use of the genetically modified organism or product

- 3.1. Purpose of releasing the GMHP into the environment
- 3.2. Expected result of releasing the GMHP into the environment

4. Duration of the release of the GMHP into the environment

Binding schedule (description of the individual stages and the duration thereof)

5. Identification information on other users who will carry out release of the GMHP into the environment or will participate therein

(+)Officially authenticated copies of the decisions on entry of these persons into the List of Users or of applications of these persons for entry into the List of Users

- 5.1. The user
- 5.2. The work that (s)he will carry out

6. Information on (A) the recipient and (where appropriate) (B) the parental plant

(state separately for A and B, as appropriate)

- 6.1. Name
 - 6.1.1. The order
 - 6.1.2. The genus
 - 6.1.3. The species
 - 6.1.4. The subspecies
 - 6.1.5. The variety, breeding line
 - 6.1.6. The Czech name, Latin name
- 6.2. The origin (collection, collection number, supplier)
- 6.3. Reproduction
 - 6.3.1. Modes of reproduction
 - 6.3.2. Specific factors affecting reproduction (if any)
 - 6.3.3. Generation time
 - 6.3.4. Sexual compatibility with other cultivated or wild species and distribution of these compatible species in CR
- 6.4. Survivability
 - 6.4.1. Ability to form structures enabling survival or dormancy and the length of potential survival or dormancy
 - 6.4.2. Further specific factors enabling survivability, if any
- 6.5. Dissemination of the plant in the environment
 - 6.5.1. Ways and extent of spreading (decrease in the amount of pollen and seeds in dependence on distance from the source)
 - 6.5.2. Specific factors affecting spreading (if any)
- 6.6. Geographical distribution of the plant

- 6.7. If the plant is not cultivated in CR, a description of the natural habitat, including information on natural enemies (predators), parasites, competitors and symbionts
- 6.8. Other potentially significant interactions of the plant with other organisms in the ecosystem where it is usually cultivated, and elsewhere
- 6.9. Effects on the health of humans, animals and other organisms
 - toxicity
 - allergenicity
 - other (specify)

7. Information on the genetic modification

- 7.1. The type of genetic modification
 - incorporation of foreign heritable material
 - deletion of part of the heritable material
 - combination of deletion and incorporation of heritable material
 - other (specify)
- 7.2. Description of the methods used in the genetic modification
- 7.3. Properties and origin of the vector used (if a vector was used in the genetic modification)
 - (+ map of the vector)
- 7.4. Information on each part of the section of the DNA that was inserted into the organism of the recipient (if the genetic modification includes insertion of heritable material)
 - 7.4.1. Size
 - 7.4.2. Position - if integrated
 - 7.4.3. Sequence
 - 7.4.4. Origin (name of the donor organism)
 - 7.4.5. Functional characteristics

8. Information on the genetically modified higher plant

- 8.1. Description and characteristics of the heritable properties and phenotypic traits, that were altered as a result of the genetic modification
- 8.2. Information on the DNA section that was inserted or deleted
 - 8.2.1. Structure and size of the DNA insert, including information on each vector section inserted into the GMHP, or on any carrier or foreign DNA remaining in the GMHP,
 - 8.2.2. In case of deletion of part of the heritable material, the size and function of the part of the deleted nucleic acid segment
 - 8.2.3. The location of the inserted heritable material in the plant cell (integrated in the chromosome, chloroplast, mitochondria or in a non-integrated form)
 - 8.2.4. The number of copies of the inserted heritable material
 - 8.2.5. The stability of the inserted heritable material and the stability of its location
 - 8.2.6. Methods of determining the data set forth in points 8.2.1 to 8.2.5.
- 8.3. Information on expression of the inserted heritable material
 - 8.3.1. Methods used for characterization of the expression
 - 8.3.2. Parts of the plant where the insert is expressed (e.g., roots, stem, leaves, pollen, etc.)
 - 8.3.3. Changes in expression in dependence on the life cycle of the plant
 - 8.3.4. Stability of the expression
- 8.4. Information permitting unambiguous identification of the GMHP
 - 8.4.1. Description of the altered part of the DNA

- 8.4.2. Methods of detection and identification of the GMHP, including methods of molecular biology
- 8.5. Behaviour of the inserted genes
 - 8.5.1. during hybridization with the same species
 - 8.5.2. during hybridization with distant species
- 8.6. Information on how the GMHP differs from the recipient or parental organism
 - mode and rate of reproduction
 - spreading in the environment
 - survivability
 - effects on the health of humans, animals and other organisms
 - other (specify)
- 8.7. Phenotypical stability of the GMHP
- 8.8. Ability of the GMHP to transfer genetic material to other organisms
- 8.9. Information on any potential harmful effects of the GMHP on human health arising from the genetic modification
- 8.10. Information on the safety of the GMHP for animal health, particularly in relation to any harmful effects arising from the genetic modification, if the GMHP is to be used as feedingstuff
- 8.11. Mechanism of interaction between the genetically modified plant and the target organism, if a target organism exists
- 8.12. Potential changes in the interactions of the GMHP with nontarget organisms arising from the genetic modification
- 8.13. Potential interaction with nonliving components of the environment.
- 8.14. Results of previous releases of the GMHP into the environment

9. Result of risk assessment of release of the GMHP into the environment - classification in a risk category

(+) Risk assessment pursuant to § 4 of the Act

10. Information on release of the GMHP into the environment in other countries

- 10.1. Information on whether the GMHP has already been registered/approved for introduction into the environment (where possible, state the number or designation of the registration)
 - 10.1.1. Country
 - 10.1.2. User / applicant / notifier (pursuant to the EC Directive)
 - 10.1.3. Purpose of introduction into the environment
 - 10.1.4. Period in time
- 10.2. Information on whether release of the GMHP into the environment is planned in another country
 - 10.2.1. Country
 - 10.2.2 User / applicant / notifier (pursuant to the EC Directive)
 - 10.2.3. Purpose
 - 10.2.4. Date

11. Information on the amount of GMHP to be used and on the total area of the properties

- 11.1. Approximate amount of GMHP to be released into the environment
- 11.2. Total extent of the area over which the release of the GMHP into the environment is to occur

12. Workplace and properties at which the introduction into the environment will occur

(+) The emergency response plan pursuant to § 5 of the Act

(+) The code of practice of the workplace pursuant to § 3 par. 7 letter f) and Annex No. 2 of the Act

(+) Copies of the maps

If all the information required in point 12 cannot be stated in the application for the entire period of release of the GMHP into the environment, the absent information must always be submitted to the Ministry at the latest 30 days before commencement of release of the GMHP into the environment

12.1. The user who will carry out release of the GMHP on the given property, and the owner of the property

12.2. Address (location)

12.3. Contact person for the given property

12.3.1. Name, surname, title

12.3.2. Contact information (telephone, fax, e-mail)

12.4. Specification of the property

12.4.1 Municipality

12.4.2. District

12.4.3. Name / designation / cadastral number

12.4.4. Position of the cultivation of the GMHP on the property and the size thereof

(+ plan on a suitable scale)

12.4.5. Size and use of the isolation zone around the area for cultivation of the GMHP

(+ denote on the plan)

12.4.6. Use of the surrounding properties

12.5. Distance from specific territories

12.5.1. Specially protected territories (Act No. 114/1992 Coll., on protection of nature and the landscape, as amended)

12.5.2. Protective zones of water sources

12.5.3. Water courses, water reservoirs

12.5.4. Other

12.6. Safeguarding the property

12.6.1. against unauthorized persons

12.6.2. against animals

12.6.3. against water runoff

12.7. Description of the ecosystem at the site of the property

12.7.1. Type of soil

12.7.2. Water regime including irrigation

12.7.3. Climatic conditions

12.7.4. Flora including agricultural crops

12.7.5. Fauna including domestic and migrating animals

12.8. Presence of wild or cultivated sexually compatible plants on the property and in its vicinity

13. Description of the use of the GMHP

13.1. Use of the GMHP prior to its introduction into the environment (contained use, transportation)

13.2. Procedure through which the GMHP will be released into the environment

13.3. Approximate number of plants per m²

- 13.4. Preparation and treatment of the property prior to cultivation of the GMHP
- 13.5. Cultivation of the GMHP on the property
- 13.6. Harvesting of the GMHP
- 13.7. Further use of the GMHP
- 13.8. Date and manner of evaluation of the release of the GMHP into the environment

14. Measures to protect the health of humans and animals, the environment and biological diversity and waste management

- 14.1. Distance of the area for cultivation of the GMHP from wild or cultivated sexually compatible species of plants
- 14.2. Measures to decrease or prevent air-transport of pollen or seeds, if used
- 14.3. Description of the methods for treatment of the property after the end of the experiment
- 14.4. Description of the methods for transport and processing of the GMHP
- 14.5. Description of the plan of control and methods of supervision during release of the GMHP into the environment and after completion thereof
- 14.6. Waste management including disposal of the GMHP

15. Provision of samples and necessary information for detection of the altered heritable material

(Specification of the samples provided to the workplace carrying out the detection, the amount, frequency and means of supply thereof)

- 15.1. Prior to commencement of use
- 15.2. During use

Sample application for entry in the List of genetically modified organisms registered for introduction into the environment for genetically modified animals (GMA)

(Information denoted (+) must be accompanied by an original document or an officially authenticated copy)

All enclosed documents shall be denoted with the name of the user and the designation of the genetically modified organism

Date of submission

Summary information for the records

Application for entry in the List of genetically modified organisms registered for introduction into the environment	
Genetically modified organism	
Genetic modification	
Result of risk assessment	
User	
Purpose of introduction into the environment	
Place of introduction into the environment	
Duration of use	

1. The user submitting the application

(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment or association

- 1.1. Name and surname / trade name / designation
- 1.2. State citizenship (for natural persons)
- 1.3. Legal form
- 1.4. Permanent address / registered office
- 1.5. Business Id. No.
- 1.6. Birth certificate number (for natural persons)
- 1.7. Tax Id. No. (if assigned)
- 1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
- 1.9. Statutory body of the user (for legal persons)
 - 1.9.1. Name, surname, title
 - 1.9.2. Position

2. The professional consultant

(+) Excerpt from the Criminal Records not more than 3 months old

(+) Document of completed education and length of professional experience

- 2.1. Name, surname, title

- 2.2. Profession, and employer and position, as appropriate
- 2.3. Education
- 2.4. Professional courses
- 2.5. Experience to date
- 2.6. Permanent address
- 2.7. Contact address
- 2.8. Telephone
- 2.9. Fax
- 2.10. E-mail

3. Purpose of the use of the genetically modified organism or product

- 3.1. Purpose of releasing the GMA into the environment
- 3.2. Expected result of releasing the GMA into the environment

4. Duration of the release of the GMA into the environment

Binding schedule (description of the individual stages and the duration thereof)

5. Identification information on other users who will carry out release of the GMA into the environment or will participate therein

(+) Officially authenticated copies of the decisions on entry of these persons into the List of Users or of applications of these persons for entry into the List of Users

- 5.1. The user
- 5.2. The work that (s)he will carry out

6. Information on (A) the donor organism, (B) the recipient and (where appropriate) (C) the parental organism

(state separately for A, B and C, as appropriate)

- 6.1. Name
 - 6.1.1. The order
 - 6.1.2. The genus
 - 6.1.3. The species
 - 6.1.4. The subspecies
 - 6.1.5. The variety
 - 6.1.6. The Czech name, Latin name
- 6.2. The origin (collection, collection number, supplier)
- 6.3. Phenotypic and genetic markers
- 6.4. Degree of relatedness between the donor organism and the recipient
- 6.5. Occurrence and living conditions
 - 6.5.1. Geographical distribution
 - 6.5.2. Habitat (natural occurrence) of the organisms
 - 6.5.3. Natural predators, preys, parasites and competitors, symbionts and hosts
 - 6.5.4. Further potential interactions with other organisms
- 6.6. Verification of the genetic stability of the organisms and the factors that affect this stability
- 6.7. Reproduction
 - 6.7.1. Means of reproduction
 - 6.7.2. Specific factors affecting reproduction (if any)
 - 6.7.3. Generation time in the natural environment
- 6.8. Survivability

- 6.8.1. Survivability in the individual seasons
- 6.8.2. Ability to form resistant survival structures
- 6.8.3. Other specific factors enabling survival, if any
- 6.9. Dissemination in the environment
 - 6.9.1. Means and extent of spreading
 - 6.9.2. Specific factors affecting spreading (if any)
- 6.10. Effects of a living or nonliving organism (including metabolic products) on the health of humans, animals and other organisms
 - pathogenicity/ infectivity
 - toxic effects
 - allergic effects
 - carrier of pathogen
 - other (specify)
- 6.11. Spectrum of hosts, including nontarget organisms
- 6.12. Involvement in environmental processes
 - primary production
 - nutrient turnover
 - decomposition of organic matter
 - other (specify)
- 6.13. Description of previous genetic modifications

7. Information on the genetic modification

- 7.1. The type of genetic modification
 - insertion of foreign heritable material
 - deletion of part of the heritable material
 - combination of deletion and incorporation of heritable material
 - other (specify)
- 7.2. Description of the methods used for the genetic modification
- 7.3. Information on the properties and origin of the vector used (if a vector was used in the genetic modification)
 - (+ map of the vector)
- 7.4. Information on each part of the DNA sector inserted into the organism of the recipient (if the genetic modification includes insertion of heritable material)
 - 7.4.1. Size
 - 7.4.2. Position - if integrated
 - 7.4.3. Sequence
 - 7.4.4. Origin (name of the donor organism)
 - 7.4.5. Functional characteristics

8. Information on the genetically modified animal

- 8.1. Description and characteristics of the heritable properties and phenotypic traits, that were altered as a result of the genetic modification
- 8.2. Information on the DNA segment that was inserted or deleted
 - 8.2.1. Structure and size of the inserted DNA, including information on each vector segment that was inserted into the GMA, or on any carrier or foreign DNA remaining in the GMA
 - 8.2.2. In case of deletion of part of the heritable material, the size and function of the each deleted nucleic acid segment
 - 8.2.3. The location of the inserted genetic material in the cell

- 8.2.4. The number of copies of the inserted genetic material
- 8.2.5. The stability of the inserted genetic material and the stability of the location thereof
- 8.2.6. Methods of determining the information specified in points 8.2.1. to 8.2.5.
- 8.3. Information on expression of the inserted heritable material
 - 8.3.1. Methods used for characterizing the expression
 - 8.3.2. Organs where the inserted genes are expressed
 - 8.3.3. Rate and degree of expression, changes in expression in dependence on the life cycle
 - 8.3.4. The stability of the expression
- 8.4. Expressed proteins
 - 8.4.1. Activity of the expressed proteins
 - 8.4.2. Description of identification and detection methods, giving their sensitivity, reliability and specificity
- 8.5. Information enabling unambiguous identification of the GMA
 - 8.5.1. Description of the part of the altered DNA
 - 8.5.2. Methods of detection and identification of the GMA, including methods of molecular biology
- 8.6. Stability of the GMA according to its heritable properties
- 8.7. Information on the way in which the GMA differs from the parental microorganism
 - means and rate of reproduction
 - dispersal in the environment
 - survivability
 - effects on the health of humans, animals and other organisms
 - other (specify)
- 8.8. Ability of the GMA to transfer genetic material to other organisms
- 8.9. Information on every potential harmful effect of the GMA, including its metabolic products, on the health of humans and animals caused by the genetic modification
 - pathogenicity/ infectivity
 - toxic or allergic effects
 - ability to colonize other organisms
 - other (specify)
- 8.10. Mechanism of interaction between the GMA and the target organism, if a target organism exists
- 8.11. Potential changes in the interactions of the GMA with nontarget organisms, following from the genetic modification
- 8.12. Potential interactions with nonliving components of the environment
- 8.13. The results of previous use of the GMA

9. Result of risk assessment of contained use of the GMA - classification in a risk category

(+) Risk assessment pursuant to § 4 of the Act

10. Information on release of the GMA into the environment in other countries

- 10.1. Information on whether the GMA has already been registered/approved for introduction into the environment (where possible, state the number of designation of the registration)
 - 10.1.1. Country
 - 10.1.2. User / applicant / notifier (pursuant to the EC Directive)

- 10.1.3. Purpose of introduction into the environment
- 10.1.4. Period in time
- 10.2. Information on whether release of the GMA into the environment is planned in another country
 - 10.2.1. Country
 - 10.2.2 User / applicant / notifier (pursuant to the EC Directive)
 - 10.2.3. Purpose
 - 10.2.4. Date

11. Information on the amount of GMA to be used and on the total area of the properties

- 11.1. Approximate amount of GMA to be released into the environment
- 11.2. Total extent of the area over which the release of the GMA into the environment is to occur

12. Workplace and properties at which the introduction into the environment will occur

- (+) The emergency response plan pursuant to § 5 of the Act
- (+) The code of practice of the workplace pursuant to § 3 par. 7 letter f) and Annex No. 2 of the Act
- (+) Copies of the cadastral maps

If all the information required in point 12 cannot be stated in the application for the entire period of release of the GMA into the environment, the absent information must be submitted to the Ministry at the latest 30 days before commencement of release of the GMA into the environment

- 12.1. The user who will carry out release of the GMA on the given property, and the owner of the property
- 12.2. Address (location)
- 12.3. Contact person for the given property
 - 12.3.1. Name, surname, title
 - 12.3.2. Contact information (telephone, fax, e-mail)
- 12.4. Specification of the property
 - 12.4.1. Municipality
 - 12.4.2. District
 - 12.4.3. Name / designation / cadastral number
 - 12.4.4. Use of the surrounding properties
- 12.5. Distance from specific territories
 - 12.5.1. Specially protected territories (Act No. 114/1992 Coll., on protection of nature and the landscape, as amended)
 - 12.5.2. Protective zones of water sources
 - 12.5.3. Water courses, water reservoirs
 - 12.5.4. Other
- 12.6. Safeguarding the property
 - 12.6.1. Safeguarding against unauthorized persons
 - 12.6.2. Safeguarding against animals
 - 12.6.3. Safeguarding against runoff
- 12.7. Description of the ecosystem at the site of the property
 - 12.7.1. Type of soil
 - 12.7.2. Water regime including irrigation
 - 12.7.3. Climatic conditions

- 12.7.4. Flora including agricultural crops
- 12.7.5. Fauna including domestic and migrating animals
- 12.8. Description of target and nontarget ecosystems that could be affected
- 12.9. Comparison of the natural habitat of the recipient or parental organism, as appropriate, with the proposed site of release of the GMA into the environment
- 12.10. Any known planned changes in the use of the properties in the vicinity of the site of release of the GMA into the environment that could affect the environmental impact of the GMA

13. Description of the use of the GMA

- 13.1. Use of the GMA prior to its introduction into the environment (contained use, transportation)
- 13.2. Procedure through which the GMA will be released into the environment
- 13.3. Approximate number of GMA per m²
- 13.4. Preparation and treatment of the experimental areas prior to use of the GMA
- 13.5. Use of the GMA on the property
- 13.6. Elimination of the GMA from the environment
- 13.7. Further use of the GMA, including its disposal
- 13.8. Date and manner of evaluation of the release of the GMA into the environment

14. Measures to protect the health of humans and animals, the environment and biological diversity and waste management

- 14.1. Monitoring of the occurrence and effects of the GMA
 - 14.1.1. Methods of determining the presence of the GMAs and monitoring of their effects
 - 14.1.2. Specificity of the methods of identification of the GMA and differentiating the GMA from the recipient or parental organism, as appropriate, the sensitivity and reliability of these methods
 - 14.1.3. Techniques (methods) of detection of transfer of the inserted heritable material to other organisms
- 14.2. Measures adopted to decrease the dissemination of the GMA into the environment during the introduction into the environment
 - 14.2.1. Technical measures
 - 14.2.2. Plan of controls and supervision
- 14.3. Measures adopted to limit the occurrence of the GMA on the property after the end of the introduction into the environment
 - 14.3.1. Description of the method of treatment of the property after the end of the experiment
 - 14.3.2. Plan of controls and supervision
 - 14.3.3. Means of disposal of the GMA and control of the effectiveness of the disposal
- 14.4. The method for transport of the GMA
- 14.5. Protection of the health of workers during use of the GMA
- 14.6. Waste management
 - 14.6.1. Kinds of waste formed and the expected amounts thereof
 - 14.6.2. Potential risks from waste management
 - 14.6.3. Description of waste disposal and methods of controlling the efficiency of this disposal

15. Provision of samples and necessary information for detection of the altered heritable material

(Specification of samples provided to the workplace carrying out the detection, the amount, frequency and means of supply thereof)

15.1. Prior to commencement of use

15.2. During use

Sample application for entry in the List of genetically modified organisms and products registered for placing on the market in the Czech Republic for a genetically modified organism (GMO) other than a higher plant, or for a product containing a GMO other than a higher plant

(Information denoted (+) must be accompanied by an original document or an officially authenticated copy)

All enclosed documents shall be denoted with the name of the user and the name (designation) of the genetically modified organism

Date of submission

Summary information for the records

Application for entry in the List of genetically modified organisms registered for placing on the market in the Czech Republic	
Genetically modified organism	
Product	
Genetic modification	
Use of the GMO or product	
Conclusions of the risk assessment	
Means of laboratory control of the presence of the genetic modification	
The user who applied for entry of the GMO or product	
Time of use	

1. The user submitting the application

(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment or association

- 1.1. Name and surname / trade name / designation
- 1.2. State citizenship (for natural persons)
- 1.3. Legal form
- 1.4. Permanent address / registered office
- 1.5. Business Id. No.
- 1.6. Birth certificate number (for natural persons)
- 1.7. Tax Id. No. (if assigned)
- 1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
- 1.9. Statutory body of the user (for legal persons)
 - 1.9.1. Name, surname, title
 - 1.9.2. Position

2. The professional consultant

(+) Excerpt from the Criminal Records not more than 3 months old

(+) Document of completed education and length of professional experience

- 2.1. Name, surname, title
- 2.2. Profession, and employer and position, as appropriate
- 2.3. Education
- 2.4. Professional courses
- 2.5. Experience to date
- 2.6. Permanent address
- 2.7. Contact address
- 2.8. Telephone
- 2.9. Fax
- 2.10. e-mail

3. Person responsible for supplying control samples after placing the GMO or product on the market - the producer, distributor or importer, as appropriate

- 3.1. Identification information
- 3.2. Contact information

4. Commercial name of the GMO or product, any other specifications of the GMO or product, as appropriate

5. Placing the GMO or product on the market

- 5.1. Use of the GMO or product
- 5.2. Legal regulations governing the placing of the given GMO or product on the market for the use specified in point 5.1.
- 5.3. Description of the individual stages in the placing on the market and the duration thereof, including the binding schedule for placing on the market
- 5.4. Expected amount of GMO or product used in the individual stages, including statement of whether production inside CR or import will be involved.

6. Information on (A) the donor organism, (B) the recipient, and (where appropriate) (C) the parental organism

(state separately for A, B and C, as appropriate)

- 6.1. Name
 - 6.1.1. The order
 - 6.1.2. The genus
 - 6.1.3. The species
 - 6.1.4. The subspecies
 - 6.1.5. The variety
 - 6.1.6. The Czech name, Latin name
- 6.2. The origin (collection, collection number, supplier)
- 6.4. Phenotypic and genetic markers
 - 6.4. For microorganisms, the inherent plasmids, bacteriophages and other
 - 6.4.1. The sequence
 - 6.4.2. The frequency of mobilization
 - 6.4.3. The specificity
 - 6.4.4. The presence of genes causing resistance

- 6.5. The degree of relatedness between the donor organism and the recipient
- 6.6. Methods of identification and detection
 - 6.6.1. Description of the methods
 - 6.6.2. Sensitivity, reliability (quantitative) and specificity of the methods
- 6.7. Occurrence and living conditions
 - 6.7.1. Geographic distribution
 - 6.7.2. The habitat (natural area of occurrence) of the organism
 - 6.7.3. Natural predators, preys, parasites and competitors, symbionts and hosts
 - 6.7.4. Other potential interactions with other organisms
- 6.8. Potential intercellular transfer of genetic material
 - 6.8.1. Means of transfer (plasmid, bacteriophage, other)
 - 6.8.2. Organisms with which natural exchange of genetic material occurs
- 6.9. Verification of the genetic stability of the organisms and the factors that affect this stability
- 6.10. Reproduction
 - 6.10.1. Means of reproduction
 - 6.10.2. Specific factors affecting reproduction (if any)
 - 6.10.3. Generation time in the natural environment
- 6.11. Survivability
 - 6.11.1. Survivability in the individual seasons
 - 6.11.2. Ability to form resistant structures (e.g. seeds, spores, sclerotia)
 - 6.11.3. Other specific factors enabling survival, if any
- 6.12. Dissemination in the environment
 - 6.12.1. Means and extent of spreading
 - 6.12.2. Specific factors affecting spreading (if any)
- 6.13. Effects of a living or nonliving organism (including extracellular products) on the health of humans, animals and other organisms
 - pathogenicity, infectivity, virulence
 - allergic effects
 - toxic effects
 - carrier of pathogen
 - possible activation of latent viruses (proviruses)
 - ability to penetrate into other organisms or colonize other organisms
 - antibiotic resistance and potential use of these antibiotics in humans and animals for prophylaxis and therapy
 - other (specify)
- 6.14. Spectrum of hosts including nontarget organisms
- 6.15. Involvement in environmental processes
 - primary production
 - nutrient turnover
 - decomposition of organic matter
 - other (specify)
- 6.16. Description of previous genetic modifications

7. Information on the genetic modification

- 7.1. The type of genetic modification
 - insertion of foreign heritable material
 - deletion of part of the heritable material
 - combination of deletion and incorporation of heritable material

- other (specify)
- 7.2. Description of the methods used for the genetic modification
- 7.3. Information on the vector, if used in the genetic modification
 - (+ genetic map of the vector)
 - 7.3.1. Information on whether the vector is fully or partly present in the final GMO
 - 7.3.2. Type of vector
 - 7.3.3. Identity of the vector (origin)
 - 7.3.4. Presence of the sequence in the vector in question, which transfers the selectable or identifiable phenotype
 - 7.3.5. Information on the degree to which the given vector is limited to the sequence of the nucleic acid required to perform the intended function.
 - 7.3.6. Methods and criteria used for the selection
- 7.4. Information on each part of the insert or each deleted part of the heritable material with special emphasis on any known harmful sequences
 - 7.4.1. Size
 - 7.4.2. Position
 - 7.4.3. Sequence
 - 7.4.4. Origin
 - 7.4.5. Functional characteristics
- 7.5. Purity of the insert
 - 7.5.1. Information on whether the insert contains an insert part whose products or functions are not known
 - 7.5.2. Information on the degree to which the insert is limited to the sequence of the nucleic acid required to perform the intended function
- 7.6. Information on whether the sequences contained in the insert participate in any way in pathogenic or harmful properties of the donor organism or vector.

8. Information on the genetically modified organism

- 8.1. Description and characteristics of the heritable properties and phenotypic traits, that were altered as a result of the genetic modification
- 8.2. Information on the DNA section that was inserted or deleted
 - 8.2.1. Structure and size of the DNA insert, including information on each vector section inserted into the GMO, or on any carrier or foreign DNA remaining in the GMO,
 - 8.2.2. In case of deletion of part of the heritable material, the size and function of each deleted nucleic acid segment
 - 8.2.3. The location of the inserted heritable material in the cell
 - 8.2.4. The copy number of the inserted heritable material
 - 8.2.5. The stability of the inserted heritable material and the stability of its location
 - 8.2.6. Methods of determining the data set forth in points 8.2.1 to 8.2.5.
- 8.3. Information on expression of the inserted heritable material
 - 8.3.1. Methods used for characterization of the expression
 - 8.3.2. Organs where the inserted genes are expressed
 - 8.3.3. Rate and extent of expression, changes in expression in dependence on the life cycle
 - 8.3.4. Stability of the expression
- 8.4. Expressed proteins
 - 8.4.1. Activity of the expressed proteins

- 8.4.2. Description of identification and detection methods, giving their sensitivity, reliability and specificity
- 8.5. Information enabling unambiguous identification of the GMO
 - 8.5.1. Description of the part of the altered DNA
 - 8.5.2. Methods of detection and identification of the GMO, including methods of molecular biology
- 8.6. Stability of the GMO according to its heritable properties
- 8.7. Information on the way in which the GMO differs from the parental microorganism
 - means and rate of reproduction
 - dispersal in the environment
 - survivability
 - effects on the health of humans, animals and other organisms
 - other (specify)
- 8.8. Ability of the GMO to transfer genetic material to other organisms
- 8.9. Information on every potential harmful effect of the GMO, including its metabolic products, on the health of humans and animals caused by the genetic modification
 - pathogenicity/ infectivity
 - toxic or allergic effects
 - ability to colonize other organisms
 - other (specify)
- 8.10. Mechanism of interaction between the GMO and the target organism, if a target organism exists
- 8.11. Potential changes in the interactions of the GMO with nontarget organisms, following from the genetic modification
- 8.12. Potential interactions with nonliving components of the environment
- 8.13. The results of previous use of the GMO
 - 8.13.1. Information on whether the GMO has been entered in the List for contained use pursuant to § 7 of the Act (if yes, state the date and number of the decision)
 - 8.13.2. Information on whether the GMO has been entered in the List for introduction into the environment pursuant to § 8 of the Act (if yes, state the date and number of the decision)
 - 8.13.3. Other information (e.g. registration / approval abroad, etc.)

9. Result of risk assessment of placing the GMO on the market - classification in a risk category

(+) Risk assessment pursuant to § 4 of the Act

10. Information on placing the GMO on the market in other countries

- 10.1. Information on whether the GMO has been registered/approved for placing on the market in (where possible, state the number of designation of the registration)
 - 10.1.1. Country
 - 10.1.2. User / applicant / notifier (pursuant to the EC Directive)
 - 10.1.3. Purpose of placing on the market
 - 10.1.4. Period in time
- 10.2. Information on whether placing of the GMO on the market is planned in another country
 - 10.2.1. Country
 - 10.2.2. User / applicant / notifier (pursuant to the EC Directive)
 - 10.2.3. Purpose

10.2.4. Date

11. Information related to the expected use of the GMO or product

- 11.1. Expected use of the GMO or product
- 11.2. Composition of the product
- 11.3. Target group of consumers (e.g. industry, agriculture, consumers in the public)
- 11.4. Differences between use of the GMO or product and use of similar modified organisms or products containing unmodified organisms
- 11.5. Description of ecosystems and agricultural areas in which the GMOs or products will be used, including estimation of the extent of use in the given area or in the given ecosystem
- 11.6. Information on each potential harmful effect of the GMO or product on human health caused by the genetic modification
- 11.7. Information on the safety of the GMO or product for the health of animals, especially in relation to any harmful effects caused by the genetic modification, if the GMO or product is to be used as part of feedingsuffs, veterinary medicinal substances, etc.
- 11.8. The mechanism of interaction between the GMO or product and the target organism, if a target organism exists
- 11.9. Potential changes in interactions of the GMO or product with nontarget organisms, following from the genetic modification
- 11.10. Potential interactions of the GMO or product with nonliving components of the environment
- 11.11. Information enabling unambiguous identification of the GMO or product
 - 11.11.1. Description of the methods for determining the presence of the genetic modification, including the methods of taking and preparing samples
 - 11.11.2. Information on the specificity and reliability of these methods
 - 11.11.3. Description of the part of the altered nucleic acid permitting unambiguous identification of the GMO
- 11.12. Management of wastes that could contain the GMO or product
- 11.13. Proposed instructions for the consumer related to the use, transport and storage of the GMO or product, including waste management and any limitations on use
- 11.14. Safety instructions for the consumer
- 11.15. Proposed method of packaging and labelling the GMO and product
- 11.16. Estimate of the annual consumption / production / export / import after placing the GMO or product on the market in CR
- 11.17. Provision for, extent and manner of keeping records on use of the GMO or product after placing on the market
- 11.18. Provision for, extent and manner or monitoring the effects of the GMO or product on the health of humans and animals, the environment and biological diversity (monitoring the GMO or product), if monitoring is to be carried out
- 11.19. Provision for, means of and frequency of taking and analyzing samples after placing the GMO or product on the market
- 11.20. Provision for, means of and frequency of informing the Ministry of the Environment of the use of the GMO or product afterplacing on the market, and on the results of monitoring, if required.

Sample application for entry in the List of genetically modified organisms and products registered for placing on the market in the Czech Republic for a genetically modified higher plants (GMHP), or for a product containing a GMHP

(Information denoted (+) must be accompanied by an original document or an officially authenticated copy)

All enclosed documents shall be denoted with the name of the user and the name (designation) of the genetically modified organism

Date of submission

Summary information for the records

Application for entry in the List of genetically modified organisms registered for placing on the market in the Czech Republic	
Genetically modified organism	
Product	
Genetic modification	
Use of the GMHP or product	
Conclusions of the risk assessment	
Means of laboratory control of the presence of the genetic modification	
The user who applied for entry of the GMHP or product	
Duration of use	

1. The user submitting the application

(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment or association

- 1.1. Name and surname / trade name / designation
- 1.2. State citizenship (for natural persons)
- 1.3. Legal form
- 1.4. Permanent address / registered office
- 1.5. Business Id. No.
- 1.6. Birth certificate number (for natural persons)
- 1.7. Tax Id. No. (if assigned)
- 1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
- 1.9. Statutory body of the user (for legal persons)
 - 1.9.1. Name, surname, title

1.9.2. Position

2. The professional consultant

(+) Excerpt from the Criminal Records not more than 3 months old

(+) Document of completed education and length of professional experience

2.1. Name, surname, title

2.2. Profession, and employer and position, as appropriate

2.3. Education

2.4. Professional courses

2.5. Experience to date

2.6. Permanent address

2.7. Contact address

2.8. Telephone

2.9. Fax

2.10. e-mail

3. Person responsible for supplying control samples after placing the GMHP or product on the market - the producer, distributor or importer, as appropriate

3.1. Identification information

3.2. Contact information

4. Commercial name of the GMHP or product, any other specifications of the GMHP or product, as appropriate

5. Placing the GMHP or product on the market

5.1. Use of the GMHP or product

5.2. Legal regulations governing the placing of the given GMHP or product on the market for the use specified in point 5.1.

5.3. Description of the individual stages in the placing on the market and the duration thereof, including the binding timetable for placing on the market

5.4. Expected amount of GMHP or product used in the individual stages, including specification of whether production in the territory of CR or import will be involved.

6. Information on (A) the recipient and (where appropriate) (B) the parental plant

(state separately for A and B, as appropriate)

6.1. Name

6.1.1. The order

6.1.2. The genus

6.1.3. The species

6.1.4. The subspecies

6.1.5. The variety / breeding line

6.1.6. The Czech name, Latin name

6.2. The origin (collection, collection number, supplier)

6.3. Reproduction

6.3.1. Modes of reproduction

6.3.2. Specific factor, affecting reproduction (if any)

6.3.3. Generation time

6.3.4. Sexual compatibility with other cultivated or wild species and distribution of these compatible species in CR

- 6.4. Survivability
 - 6.4.1. Ability to form structures that enable survival or dormancy and the length of potential survival or dormancy
 - 6.4.2. Specific factors enabling survivability, if any
- 6.5. Dissemination of the plants in the environment
 - 6.5.1. Ways and extent of dissemination (decrease in the amount of pollen and seeds in dependence on distance from the source)
 - 6.5.2. Specific factors affecting dissemination (if any)
- 6.6. Geographical distribution of the plant
- 6.7. If the plant is not cultivated in CR, a description of the natural habitat, including information on natural predators, parasites, competitors and symbionts
- 6.8. Other potentially significant interactions of the plant with other organisms in the ecosystem where it is usually cultivated, and elsewhere.
- 6.9. Effects on the health of humans, animals and other organisms
 - toxicity
 - allergenicity
 - other (specify)

7. Information on the genetic modification

- 7.1. The type of genetic modification
 - incorporation of foreign heritable material
 - deletion of part of the heritable material
 - combination of deletion and incorporation of heritable material
 - other (specify)
- 7.2. Description of the methods used in the genetic modification
- 7.3. Properties and origin of the vector used (if a vector was used in the genetic modification)
 - (+ genetic map of the vector)
- 7.4. Information on each part of the section of the DNA that is to be inserted into the organism of the recipient (if the genetic modification includes insertion of heritable material)
 - 7.4.1. Size
 - 7.4.2. Position
 - 7.4.3. Sequence
 - 7.4.4. Origin (name of the donor organism)
 - 7.4.5. Functional characteristics

8. Information on the genetically modified higher plant

- 8.1. Description and characteristics of the heritable properties and phenotypic traits, that were altered as a result of the genetic modification
- 8.2. Information on the DNA section that was inserted or deleted
 - 8.2.1. Structure and size of the DNA insert, including information on each vector section inserted into the GMHP, or on any carrier or foreign DNA remaining in the GMHP,
 - 8.2.2. In case of deletion of part of the heritable material, the size and function of the deleted nucleic acid segment
 - 8.2.3. The location of the inserted heritable material in the plant cell (integrated in the chromosome, chloroplasts, mitochondria or in a non-integrated form)
 - 8.2.4. The number of copies of the inserted heritable material

- 8.2.5. The stability of the inserted heritable material and the stability of its location
- 8.2.6. Methods of determining the data set forth in points 8.2.1 to 8.2.5.
- 8.3. Information on expression of the inserted heritable material
 - 8.3.1. Methods used for characterization of the expression
 - 8.3.2. Place where the inserted genes are expressed (e.g., roots, stem, leaves, pollen, etc.)
 - 8.3.3. Changes in expression in dependence on the life cycle of the plant
 - 8.3.4. Stability of the expression
- 8.4. Information permitting unambiguous identification of the GMHP
 - 8.4.1. Description of the altered part of the DNA
 - 8.4.2. Methods of detection and identification of the GMHP, including methods of molecular biology
- 8.5. Behaviour of the inserted genes
 - 8.5.1. during hybridization with the same species
 - 8.5.2. during hybridization with distant species
- 8.6. Information on how the GMHP differs from the recipient or parental organism
 - mode and rate of reproduction
 - dissemination in the environment
 - survivability
 - effects on the health of humans, animals and other organisms
 - effects on nontarget organisms
 - other (specify)
- 8.7. Phenotypical stability of the GMHP
- 8.8 Ability of the GMHP to transfer genetic material to other organisms
- 8.9. Information on any potential harmful effect of the GMHP on human health arising from the genetic modification
- 8.10. Information on the safety of the GMHP for animal health, particularly in relation to any harmful effects arising from the genetic modification, if the GMHP is to be used as feedingstuff
- 8.11. Mechanism of interaction between the genetically modified plant and the target organism, if a target organism exists
- 8.12. Potential changes in the interactions of the GMHP with nontarget organisms arising from the genetic modification
- 8.13. Potential interaction with nonliving components of the environment.
- 8.14. Information about release of the GMHP into the environment, during previous use of the GMHP, if appropriate
 - 8.14.1. Information on whether the GMHP has entered in the List for introduction into the environment pursuant to § 8 of the Act (if yes, state the date and number of the decision)
 - 8.14.2. Information on whether the GMO has released into the environment in other countries
 - 8.14.3. Results of the release of the GMHP into the environment, especially in connection with the effects of the GMHP on the health of humans and animals, the environment and biological diversity
 - 8.14.4. Other previous use of the GMHP (approval / registration in other countries, etc.)

9. Result of risk assessment of release of the GMHP into the environment - classification in a risk category

(+) Risk assessment pursuant to § 4 of the Act

10. Information on placing the GMHP on the market in other countries

- 10.1. Information on whether the GMHP has been registered/approved for placing on the market in (where possible, state the number of designation of the registration)
 - 10.1.1. Country
 - 10.1.2. User / applicant / notifier (pursuant to the EC Directive)
 - 10.1.3. Purpose of placing on the market
 - 10.1.4. Period in time
- 10.2. Information on whether placing of the GMHP on the market is planned in another country
 - 10.2.1. Country
 - 10.2.2. User / applicant / notifier (pursuant to the EC Directive)
 - 10.2.3. Purpose
 - 10.2.4. Date

11. Information related to the expected use of the GMHP or product

- 11.1. Expected use of the GMHP or product
- 11.2. Composition of the product
- 11.3. Target group of consumers (e.g. industry, agriculture, consumers in the public)
- 11.4. Difference between use of the GMHP or product and use of similar unmodified organisms or products containing unmodified plants
- 11.5. Description of ecosystems and agricultural areas in which the GMHPs or products will be cultivated or used, including estimation of the extent of cultivation or use in the given area or in the given ecosystem
- 11.6. Information on any potential harmful effect of the GMHP or product on human health caused by the genetic modification
- 11.7. Information on the safety of the GMHP or product for the health of animals, especially in relation to any harmful effects caused by the genetic modification, if the GMHP or product is to be used as feedingstuff
- 11.8. The mechanism of interaction between the GMHP or product and the target organism, if a target organism exists
- 11.9. Potential changes in interactions of the GMHP or product with nontarget organisms, following from the genetic modification
- 11.10. Potential interactions of the GMHP or product with nonliving components of the environment.
- 11.11. Information enabling unambiguous identification of the GMHP or product
 - 11.11.1. Description of the methods for determining the presence of the genetic modification, including the methods of taking and preparing samples
 - 11.11.2. Information on the specificity and reliability of these methods
 - 11.11.3. Description of the part of the altered nucleic acid permitting unambiguous identification of the GMHP
- 11.12. Management of wastes that could contain the GMHP or product
- 11.13. Proposed instructions for the consumer related to the use, transport and storage of the GMHP or product, including waste management and any limitations on use
- 11.14. Safety instructions for the consumer
- 11.15. Proposed method of packaging and labelling the GMHP and product
- 11.16. Estimate of the annual consumption / production / export / import after placing the GMHP or product on the market in CR

- 11.17. Provision for, extent and manner of keeping records on use of the GMHP or product after placing it on the market
- 11.18. Provision for, extent and manner or monitoring the effects of the GMHP or product on the health of humans and animals, the environment and biological diversity (monitoring the GMHP or product), if monitoring is to be carried out
- 11.19. Provision for, means of and frequency of taking and analyzing samples after placing the GMHP or product on the market
- 11.20. Provision for, means of and frequency of informing the Ministry of the Environment of the use of the GMHP or product after placing it on the market, and on the results of monitoring, if required.