

**DECREE**

of 15 April 2004

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

The Ministry of Environment, in agreement with The Ministry of Health and The Ministry of Agriculture, lays down, pursuant to § 38 of Act No. 78/2004 Coll. on the use of genetically modified organisms and genetic products (hereinafter "the Act") to implement § 5 paragraphs 1 and 4, § 7 paragraph 7, § 11 paragraph 3, § 15 paragraph 2, § 16 paragraphs 2 and 3, § 19 letter b), § 20 paragraph 4 and § 24 paragraph 17:

## § 1

**Subject of the Regulation**

The Decree in accordance with the Law of European Communities<sup>1)</sup> lays down detailed conditions for the use of genetically modified organisms and genetic products, and/or the requirements for granting the consent for the contained use of genetically modified organisms, the requirements for granting the consent for the introduction of genetically modified organisms into the environment, the requirements of the request for the registration into the List of genetically modified organisms and genetic products authorised to be placed on the market, the requirements for notification of the contained use of genetically modified organisms in the first and second risk category, the requirements for the summary of the contents of the request, the requirements and procedures of the risk assessment, threshold minimum of unavoidable traces, the requirements for contained space and protective measures for the individual risk categories during the contained use of genetically modified organisms, the manner and the scope of keeping records, the requirements for the Emergency Response Plan and the requirements for the assessment report.

## § 2

**Basic definitions**

For the purposes of this Decree:

- a) recipient shall mean an organism, into whose heritable genetic material a heterogeneous heritable material has been introduced by genetic modification,
- b) donor shall mean an organism, from whose heritable genetic material comes a heritable genetic material introduced into the genetic material of a recipient,
- c) parental organism shall mean an organism, from whose heritable genetic material a part of the heritable genetic material has been extracted by genetic modification,

- d) target organism shall mean an organism whose effect on a genetically modified organism should be influenced by genetic modification,
- e) vector shall mean a non-cellular entity containing a heritable genetic material and capable of introduction of this heritable genetic material together with the inserted heterogeneous heritable genetic material into the cells of a recipient,
- f) insert shall mean a heterogeneous heritable genetic material inserted into the heritable genetic material of a recipient,
- g) construct shall mean an artificially modified molecule of nucleic acid,
- h) signal gene shall mean a gene contained in the construct and rendering an easily determinable property of the cells or organism containing a functional construct,
- i) selection gene shall mean a gene contained in the 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,
- j) higher plant shall mean gymnosperms and angiosperms.

### § 3

**The requirements for granting the consent for the contained use of genetically modified organisms, the requirements for granting the consent for the introduction of genetically modified organisms into the environment, the requirements of the request for the registration into the List of genetically modified organisms and genetic products authorised to be placed on the market, and the requirements for the notification of the contained use in the first and second risk category**

(ad § 5 paragraph 1 and § 16 paragraphs 2 and 3 of the Act)

#### (1) Requirements

- a) notifications of contained use of genetically modified organisms (hereinafter the “contained use”) in the first and second risk category are included in the part A of the Annex 1 to this Decree,
- b) requests for granting the consent for the contained use are included in the part B of Annex 1 to this Decree,
- c) requests for granting the consent for the introduction of genetically modified organisms into the environment (hereinafter the “introduction into the environment”) are included in the Annex 2 to this Decree, or
- d) requests for the registration into the List of genetically modified organisms and genetic products authorised for placing on the market (hereinafter “the List for placing on the market”) are included in the Annex 3 to this Decree.

(2) The notification or the request pursuant to paragraph 1 must be submitted in Czech language, structured as laid down in Annexes 1 to 3 to this Decree and, in case of a request submitted on a technical data media or via electronic mail, namely text documents in the “Rich Text Format” (RTF extension), graphical documents (plans, map, scanned documents etc.) in the JPEG format (JPG extension); in both cases “Portable Document Format” (PDF extension) may be used.

(3) If the documents for the notification or the request required by this Decree are in other language than Czech, they shall be submitted as officially authenticated translation.

(4) If the request for granting the consent is submitted for more genetically modified organisms (§ 18 par. 3 of the Act), all required data must be included separately for every genetically modified organism.

#### § 4

### **Requirements for the summary of the contents of the request made available to the public**

(§ 5 par. 4 of the Act)

Requirements for summary of the contents of the request for the individual ways of the use of genetically modified organisms and genetic products are given in Annexes 1 to 3 to this Decree.

#### § 5

### **Risk assessment requirements and procedures**

( ad § 7 par. 7 of the Act)

(1) When assessing the risk all the potential harmful effects of the use of genetically modified organisms and genetic products must be taken into consideration, regardless of the likelihood of their occurrence, and must be compared with the harmful effects of use of the recipient or parental organism or related organism, as appropriate. The effects of the use of genetically modified organism or genetic product may be

a) direct – primary effects on human health, animals, plants or on the environment, that are directly connected with the genetically modified organism or genetic product,

b) indirect – effects on human health, animals, plants or on the environment, that occur through a causal chain of events, e.g. through interaction with other organisms, transfer of heritable genetic material or changes in the manner of use; indirect effects may appear with a delay,

c) immediate – effects that are observed during the use of genetically modified organism or genetic product; the immediate effects may be direct or indirect,

d) delayed – effects that need not be observed during the use of genetically modified organism or genetic product but can be determined as direct or indirect effects after the termination of the use of genetically modified organism or genetic product, or

e) cumulative and long-term effects – total effects of the use of genetically modified organisms or genetic products on human health, animals, plants and on the environment.

(2) Harmful effects on human health, animals, and plants or on the environment may occur through

a) settlement and spread of genetically modified organism in the environment, e.g. through its effect on population dynamics of species in the receiving environment, or on genetic diversity of some of them,

b) natural transfer of inserted heritable genetic material to other organisms that may result for example in reducing the possibilities of prophylactic and therapeutic treatment in the area of medicine, veterinary medicine or phytosanitary medicine, e.g. through the transfer of genes increasing the pathogenicity, virulence or toxogenicity of organisms, or through the transfer of genes conferring resistance to antibiotics used in medicine or veterinary medicine,

c) phenotypic or genetic instability of genetically modified organism,

d) interaction of genetically modified organism with other organisms or

e) differences between the use of genetically modified organism or genetic product and the use of the recipient or parental organism including eventual changes in agrotechnical procedures that may cause changes in biochemical processes in the soil, e.g. the decomposition of organic material and carbon and nitrogen cycles.

(3) In risk assessment, it is necessary to identify the occurrence of potential harmful effects in connection with

a) the recipient

b) the inserted heritable genetic material (derived from the donor organism),

c) the vector,

d) the donor organism (if a donor organism is used during genetic modification),

e) the insertion of a construct

f) the signal and selection genes,

g) the insert,

h) removal of a part of heritable genetic material (if used in the genetic modification),

i) the final genetically modified organism,

j) the location and scope of the use of genetically modified organism or genetic product,

k) the environment at the site of use of genetically modified organism or genetic product, and

1) potential interactions between genetically modified organism or genetic product and the environment at the site of use thereof.

(4) The risk assessment shall always contain an 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 that are supposed to or that could occur. The risk assessment must further take into consideration the characteristic of the activity and the possible dangers following therefrom.

(5) The risk assessment for contained use shall also take into consideration

a) the characteristic of the environment that could be affected by release of genetically modified organism from the contained space,

b) the nature and scale of the contained use,

c) any non-standard operations carried out during the contained use (e.g. the inoculation of animals with genetically modified micro-organisms or the operation of a facility that may generate aerosols).

These facts shall be also taken into consideration during assigning of the contained use to a certain risk category pursuant to Annex 3 to the Act.

(6) The procedure of risk assessment shall contain

a) identification of all potential harmful effects pursuant to paragraphs 1 to 5 and an assessment of the seriousness thereof,

b) evaluation of the consequences of each harmful effects, in case if occurs,

c) evaluation of the likelihood of occurrence of the harmful effect under the given conditions,

d) estimation of the risk for human health and the environment represented by each of the identified harmful effects on the basis of evaluation of the likelihood of occurrence of this 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) summarising the results, in the case of contained use the assignment of the activity to a certain risk category pursuant to Annex 3 to the Act.

(7) All the steps in the procedure pursuant to paragraph 6 must be documented in writing and, where possible, documented with references to the scientific literature, protocols from experimental studies and documentation on previous use of genetically modified organism as appropriate. This written analysis shall be a part of the documentation pursuant to § 19 letter b) of the Act.

(8) The risk assessment of the introduction into the environment of genetically modified organisms other than higher plants shall contain

a) the likelihood that, under the conditions of introduction into the environment, the 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 arising from the genetic modification and the likelihood that this advantage or disadvantage will show up under the conditions of introduction into the environment,

c) the possibility of transfer of the heritable genetic material to other species under the conditions of introduction into the environment, and every selective advantage or disadvantage that could be transferred this way,

d) the potential immediate or delayed effects on the environment caused by direct or indirect interactions between genetically modified organism and the target organism (if target organism exists),

e) the potential immediate or delayed effects on the environment caused by direct or indirect interactions between genetically modified organism and non-target organisms, including the effect on the population levels of competitors, preys, symbionts, predators, parasites and pathogens,

f) the potential immediate or delayed effects on human health arising from potential direct or indirect interactions between genetically modified organism and persons coming into contact with it.

g) the potential immediate or delayed effects on the health of animals and consequences for food chains arising from the consumption of the genetically modified organism or genetic product, which is intended for use as feedstuff,

h) the potential immediate or delayed effects on biogeochemical processes arising from potential direct or indirect interactions of the genetically modified organism and target and non-target organisms in the vicinity of the introduction of genetically modified organism into the environment, and

i) the potential immediate or delayed, direct or indirect effects on the environment resulting from the use of specific techniques for the use of genetically modified organisms if these techniques differ from those normally used for corresponding non-modified organisms.

(9) The risk assessment of the introduction of genetically modified higher plants into the environment, and of the placing on the market if the genetically modified higher plants are placed on the market as seeds or planting material<sup>2)</sup>, as appropriate, must contain the following 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 further selective advantage or disadvantage arising from the genetic modification, i.e. the selective advantage of genetically modified organism in comparison with the recipient or parental organism, as appropriate,

c) the possibility of transfer of heritable genetic material to the same or other species under the conditions of cultivation of genetically modified higher plants and every selective advantage or disadvantage that may be transferred in this way,

d) the potential immediate or delayed effects on the environment arising from direct or indirect interactions between genetically modified higher plant and the target organism (if the target organism exists),

e) the potential immediate or delayed effects on the environment arising from direct or indirect interactions between the genetically modified higher plant and non-target organisms including the effect on the population levels 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 genetically modified higher plant and persons coming into contact with it,

g) the potential immediate or delayed effects on the health of animals and consequences for food chains resulting from consumption of a genetically modified higher plant or genetic product intended to be used as a feedstuff,

h) the potential immediate or delayed effects on biogeochemical processes arising from potential direct or indirect interactions of genetically modified higher plant and target and non-target organisms in the vicinity of the place of cultivation of the genetically modified higher plant, and

i) the potential immediate or delayed, direct or indirect effects on the environment, in consequence of the use of specific growing, harvesting and processing techniques for genetically modified plants if these techniques differ from those commonly used for corresponding non-modified higher plants.

(10) The risk assessment of the genetic product containing several different genetically modified organisms must involve also the evaluation of relevant information for each of these organisms.

## § 6

### **Threshold minimum of unavoidable traces**

(ad § 11 paragraph 3 of the Act)

Genetic products that shall not have to be labelled according to § 11 paragraph 3 of the Act shall be apprehended as genetic products intended for direct processing that do not contain

more than 0.9 % of traces of genetically modified organisms authorised for the placing on the market under § 23 paragraph 1 or 2 of the Act if these traces are random or technically unavoidable.

## § 7

### **Requirements on the contained space and protective measures for the individual risk categories during the contained use**

(ad § 15 paragraph 2 of the Act)

- (1) Requirements on the contained space and protective measures for the contained use are given in Annex No. 4 to this Decree according to the type of workplace and risk category to which the contained use has been assigned (§ 15 paragraph 1 of the Act).
- (2) Observing the Code of Practice of the workplace, principles of work hygiene and occupational safety, and further ensuring the training and refresher courses shall be a part of the protective measures (§ 19 letters f) and g) of the Act.
- (3) Special legal regulations laying out the procedure of good work and laboratory practice<sup>3)</sup> shall not be prejudiced by provisions of paragraphs 1 and 2.

## § 8

### **The manner and the scope of keeping records**

(ad § 19 letter b) of the Act)

- (1) Records on the use of genetically modified organisms (hereinafter “the records”) pursuant to § 19 letter b) of the Act shall contain
  - a) a copy of the submitted request for granting the consent for the contained use, a consent for the introduction into the environment or for the registration into the List for the placing on the market submitted under § 5 par. 1 of the Act or a copy of the notification submitted under § 16 par. 2 or 3 of the Act, as appropriate,
  - b) issued decisions on granted consent for the contained use, consent for the introduction into the environment (§ 5 of the Act) and for prolongation of validity (§ 16, par. 10 and § 17 par. 7 of the Act), amendment and repeal (§ 12 of the Act) of these consents, decisions imposing on the notifier a modification of conditions of the use presented in the notification (§ 16, par. 5 of the Act), the decision pursuant to § 34 of the Act and also the decision on imposing a fine under § 35 of the Act or officially verified copies of these decisions, as appropriate,
  - c) a risk assessment of the use of genetically modified organisms (§ 7 of the Act),
  - d) Code of Practice of the workplace (§ 19 letter f) of the Act),
  - e) Emergency Response Plan (§ 20 of the Act),

f) methodologies of activities connected with the use of genetically modified organisms if they are treated (e.g. standard operation procedures) and are not included in a request or notification under letter a),

g) factory journals,

h) interim reports (e.g. reports containing information pursuant to § 19 letter c) of the Act and § 25 par. 5 of the Act),

i) reports on the reviews done pursuant to § 15 par. 3 of the Act and on the results thereof,

j) a final report pursuant to § 19 letter d) of the Act

k) reports on staff training, training in refresher courses and acquaintance with the Code of Practice of the workplace pursuant to § 19 letter g) of the Act, and

l) reports on the reviews of release of genetically modified organisms outside of a contained space or property, at which the use of genetically modified organism proceeds or has been proceeding, as appropriate, reports on the results of these reviews, and reports on reviews carried out by administrative bodies including the protocols on review findings.

(2) Documentation shall be filed, kept and stored in writing and electronic form so that its content is not lost, damaged or stolen, and its comprehensive arrangement and easy obtainability is ensured if needed.

(3) A factory journal, which is kept and updated during the use of genetically modified organisms, shall contain

a) description of the use of genetically modified organisms,

b) information on the course of use of the genetically modified organisms, particularly on each difference from the description presented in the letter a),

c) primary information obtained in the course of the use of genetically modified organisms,

d) reports on all performed reviews, controls and their results,

e) reports on all the emergencies and accidents,

f) date of every report, name and signature of person who has reported.

(4) In case of long term projects the use of genetically modified organisms may be divided into several stages, i.e. periods for obtaining sub-results, if reasonable. For each stage a separate factory journal may be kept in such case.

(5) If during the use of genetically modified organisms a change against the description of the use occurs, it is necessary to record in the factory journal the reason for such change and a date of the decision on the change or of an occurrence thereof. The professional consultant shall confirm the notification of the change in the documentation.

(6) The person who makes records must record immediately, accurately and in readable form all the data on the course of the use of genetically modified organisms. The records must contain the name or names, as appropriate, surname and signature of a person, who made the record, and the date of the record. Any changes in original data on results of observation, measurement and registration of variables, shall be written down in such a way so as the original report is readable. In such case there must be added reason for the change of data, name or names, as appropriate, surname and signature of a person who has decided on the change, and of a person who has done the change, and the date or time of performing the change, as appropriate.

(7) Data saved in electronic form shall be backed up. Changes and corrections of such data shall be recorded including the name or names, as appropriate, and the surname of a person who has done changes and corrections. Records on photosensitive paper or on other materials with limited durability must be transferred onto durable record.

(8) Documentation of the use of genetically modified organisms shall be ended by the final report (§ 19 letter d) of the Act) positively assessed by the professional consultant. The final report contains mainly

- a) the purpose of the use of genetically modified organisms,
- b) information given in the valid consent for the contained use or the introduction into the environment, the date and consent number or the date of submission of notification, as appropriate, in case of contained use in the first or the second risk category,
- c) the address of a workplace or the location and description of premises where the use proceeded, as appropriate,
- d) the date of beginning and termination of the use of genetically modified organism,
- e) information unambiguously identifying genetically modified organisms which were used in contained space or introduced into the environment,
- f) isolated heritable genetic material, which was used or the ways of genetic modification, if applicable,
- g) description of the use of genetically modified organisms, including the date, description and assessment of all the emergencies and accidents,
- h) description and date of liquidation of used genetically modified organisms and also a verification of the effectiveness of the liquidation, including the name or names, as appropriate, and surname (name or trading company) of the person that was carrying out the liquidation for the person authorised to use genetically modified organism or verifying its effectiveness, unless the authorised person was carrying out these activities by himself,
- i) results of the use of genetically modified organisms and their assessment including the results of running monitoring,

j) description of provision of monitoring sites and premises after termination of the use of genetically modified organisms and the name or names, as appropriate, and surname (name or trading company) of a person that carries out the monitoring for the person authorised to the use, unless the authorised person carries out the monitoring by himself,

k) statement of the professional consultant, his signature and date of the signature.

(9) Special legal regulations<sup>4)</sup> on keeping documentation shall not be prejudiced.

## § 9

### **Requirements for the Emergency Response Plan**

(ad § 20 par. 4 of the Act)

The Emergency Response Plan contains besides the information given in § 20 par. 4 of the Act the following requirements:

a) address of a workplace,

b) accurate identification of premises<sup>5)</sup>, sites and facilities, where genetically modified organisms are used, and the accurate identification of a place, where these premises, sites or facilities are situated,

c) plan of a workplace with identification of places that are important for the reduction of accident consequences (switch control of power and auxiliary media supplies, places of storage of genetically modified organisms, protective measures for the contained space, in case of the contained use etc.); description of measures for prevention of deliberate release of genetically modified organisms during the transport,

d) description of an accident that can occur in spaces or a place, where genetically modified organisms are used,

e) review on possible accident impacts on human health, animals, the environment and biological diversity including the methods for detection of such impacts and effective protection from them,

f) validated procedures for the detection of presence of genetically modified organisms,

g) validated methods and procedures available for liquidation of genetically modified organisms and for decontamination of an affected space,

h) methods of isolation of spaces and facilities affected by accident including methods of control of isolation effectiveness,

i) description and layout of decontamination agents available to liquidate genetically modified organisms and decontaminate an affected space,

j) procedures for protection of human health, animals, the environment and biological diversity in case of undesirable effects of an accident; or methods of disposal or remediation

of plants and animals that were in the respective area at the time of accident, as appropriate, pursuant to special legal regulations<sup>6)</sup>,

k) description of a procedure of subsequent monitoring of sites and premises after the termination of decontamination process,

l) municipalities or persons, to whom the Emergency Response Plan is submitted pursuant to § 20 par. 3 of the Act, as appropriate,

m) the manner of notification of an accident to administrative bodies mentioned in § 27 of the Act and also the manner of warning of inhabitants depending on the place of accident and on its possible consequences,

n) statement of the professional consultant, his signature and date of the signature.

## § 10

### **Requirements of the assessment report**

(ad § 24 par. 17 of the Act)

The assessment report under § 24 par. 5 of the Act shall always contain the following information:

a) identification of such properties of a recipient that are important for the assessment of particular use of genetically modified organisms or genetic products, and further the identification of any known risks for health and the environment arising from the introduction of non-modified recipient into the environment or on the market,

b) description of results of genetic modification in genetically modified organism,

c) evaluation of the sufficiency of characterising genetic modification in the request to assess risks

d) identification of risks for human health, animals, plants and the environment that may arise from the use of genetically modified organism or genetic product in comparison with the use of corresponding non-modified organism or product, based on the risk assessment conducted pursuant to § 7 of the Act,

e) conclusion whether particular genetically modified organism or genetic product can be placed on the market, and under which conditions, or whether particular genetically modified organism could not be placed on the market, or whether opinions of other administrative bodies, the European Commission or committees, mentioned in particular legal regulations of European Communities concerning specific issues of the risk assessment, are necessary, as appropriate. The conclusion contains a clear statement to the proposed manner of the use, risk management and proposed plan of monitoring. In the case, when particular genetically modified organism or genetic product should not be placed on the market, the conclusion contains also reasons for such approach.

## § 11

## **Repealing provisions**

The following shall be repealed:

1. Decree No. 372/2000 Coll., laying down technical methods that may be used to create a genetically modified organism and technical methods that do not lead to the formation of a genetically modified organism.
2. Decree No. 373/2000 Coll., laying down the requirements on contained space and protective measures for the individual risk categories in contained use of genetically modified organisms.
3. Decree No. 374/2000 Coll. on detailed conditions for the use of genetically modified organisms and genetic products

§ 12

### **Effective date**

This Decree becomes effective on the day of its declaration.

Minister:

**RNDr. Ambrozek** by own hand

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<sup>1)</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms. Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

<sup>2)</sup> Act No. 219/2003 Coll. on the marketing of seed and planting material of cultivated plants and amending some related Acts (Seed Act)

<sup>i3)</sup> for example the Government Order No. 178/2001 Coll. laying down conditions for occupational health as amended by the Government Order No. 523/2002 Coll., Decree No. 472/2000 Coll. laying down good clinical practice and detailed conditions of clinical evaluation of medicinal substances as amended by Decree No. 301/2003 Coll., Decree No. 504/2000 Coll. laying down good laboratory practice in the area of medicinal substances, Decree No. 311/1997 Coll. on the breeding and the use of experimental animals.

<sup>4)</sup> for example Decree No. 472/2000 Coll., as amended by Decree No. 301/2003 Coll., Decree No. 504/2000 Coll., Decree No. 311/1997 Coll.

<sup>5)</sup> § 5 par.1 of Act No. 344/1992 Coll. on Cadastre of Real Estates of the Czech Republic (Cadastral Law)

<sup>6)</sup> for example Act No. 353/1999 Coll. on prevention of major accidents caused by selected hazardous 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 last amended (Act on prevention of major accidents), as amended by Act No. 258/2000 Coll. and Act No. 320/2002 Coll., Act No. 246/1992 Coll. on protection of animals against cruelty, as amended by Act No. 162/1993 Col., Act No. 193/1994 Coll., Act No. 243/1997 Coll. and Act No. 30/1998 Coll., Act No. 166/1999 on veterinary care and amending some related Acts (The Veterinary Act), as amended by Act No. 29/200 Coll., Act No. 154/2000 Coll., Act No. 102/2001 Coll., Act No. 76/2002 Coll., Act No. 120/2002 Coll., Act No. 320/2002 Coll., Act No. 131/2003 Coll. and Act No. 309/2003 Coll., Act No. 185/2001 on waste and amending some related Acts, as amended by Act No. 477/2001 Coll., Act No. 76/2002 Coll., Act No. 275/2002 Coll., Act No. 320/2002 Col. and Act No. 356/2003 Coll., Act No. 147/1996 Coll. on phytosanitary care and amending some related Acts, as amended by Act No. 409/2000 Coll., Act No. 314/2001 Coll. and Act No. 320/2002 Coll.

**Requirements for the notification of the contained use in the first and second risk category and requirements for the request for granting the consent to the contained use**

Information marked by (+) must be supplemented with the original document or a certified copy thereof. All the enclosed documents must include the name or names, as appropriate, and the surname or the title (trading company) of an applicant.

Information regarding the summary of the contents of the request intended to be published shall be underlined.

**PART A  
REQUIREMENTS FOR THE NOTIFICATION OF THE CONTAINED USE IN THE  
FIRST AND SECOND RISK CATEGORY**

**SECTION 1**

**GENERAL REQUIREMENTS FOR THE NOTIFICATION**

**Date of submission**

**1. A person submitting notification (hereinafter “notifier”)**

(+) extract from the Trade Register (not older than 3 months), or a certified copy of the Trade Licence or the Foundation Charter, as appropriate

1.1 Name or names, as appropriate, and surname (trade company), if a notifier is the natural person authorised to operate a business

1.2 Title (trade company) and the legal form, if the notifier is legal person

1.3 Nationality (in case of natural persons)

1.4 Place of business (in case of legal persons) or place of business and place of residence (in case of natural persons)

1.5 Company registration number (if assigned)

1.6 Tax identification number (if assigned)

1.7 Subject of activity (according to the Foundation Charter or the record in Trade Register)

1.8 Name or names and surnames of persons, who represent a statutory body of the notifier, including the manner of acting on behalf of the notifier (in case of legal persons), as appropriate.

**2. Professional consultant**

(+) extract from the Criminal Register or the other relevant document pursuant to special legal regulation<sup>7)</sup>, as appropriate.

(+) certificate for achieved education and length of professional experience (if Member State citizen has obtained the professional experience in other Member State this certificate means a decision on the recognition of professional qualification pursuant to the special legal regulation<sup>1)</sup>).

2.1 Name or names, as appropriate, surname, academic degree

2.2 Occupation or employer and function, as appropriate

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<sup>1)</sup> § 20 of Act No. 18/2004 Coll. on recognition of professional and other qualifications of citizens of EU Member States and amending certain acts (Act on recognition of professional qualifications)

- 2.3 Education
- 2.4 Professional courses
- 2.5 Previous experience
- 2.6 Address of residence
- 2.7 Contact address
- 2.8 Telephone number
- 2.9 Fax number
- 2.10 E-mail

## Section 2

### OTHER REQUIREMENTS FOR THE NOTIFICATION IN CASE OF NOTIFICATION CONCERNING THE FIRST RISK CATEGORY

#### **1. Purpose and period of contained use**

- 1.1 Purpose of contained use – character of an activity that will be carried out by notifier (e.g. research, training, laboratory control, manufacture)
- 1.2 Total period of contained use and date of its expected starting-up

#### **2. Risk assessment**

(+) Summary risk assessment under § 7 of the Act for particular species of organism (species of organisms)

- 2.1 Risk assessment result

#### **3. Workplace, where the contained use will be carried out**

(+) Code of Practice of a workplace under the Annex No. 4 to the Act

(+) Emergency Response Plan under § 20 of the Act

(+) Document on granting the accreditation and an experiment plan under the special legal regulation in case of breeding facilities for animals<sup>2)</sup>

- 3.1 Address of workplace

- 3.2 Character of workplace

- microbiological laboratory
- pilot plant
- production facilities
- glasshouse / growth room
- animal breeding facility
- other (unambiguously identifying the description of workplace)

- 3.3 Description of location of the area for the contained use and description of their main facilities

(+) Layout of premises and of the location of main facilities

- 3.4 Evaluation of the area and the facilities of the workplace and its location pursuant to the requirements on a contained space and protective measures laid down for the first risk category in Annex No. 4 to this Decree.

#### **4. Species and amount of used organisms and the used genetic modifications including nominally mentioned validated methods for detection of occurrence of genetically modified organisms**

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<sup>2)</sup> § 15 par. 2 and § 23 par. 1 letter a) of Act No. 246/1992 Coll.

## **5. Data on waste management of particular workplaces (wastewater, waste gaseous harmful substances, other and hazardous waste)**

### Section 3

#### **OTHER REQUIREMENTS OF THE NOTIFICATION IN CASE OF THE NOTIFICATION CONCERNING THE SECOND RISK CATEGORY**

##### **1. Purpose and period of the contained use**

1.1 Purpose of contained use – character of an activity that will be carried out by notifier (e.g. research, training, laboratory control, manufacture)

1.2 Expected result of the contained use

1.3 Total period of contained use and date of its expected starting-up and particular periods and starting dates if the contained use is divided into individual stages

##### **2. Risk assessment**

(+) Risk assessment pursuant to § 7 worked up separately for each genetically modified organism

2.1 Result of the risk assessment

##### **3. Workplace where the contained use will be carried out**

(+) Code of Practice of a workplace under the Annex No. 4 to the Act

(+) Emergency Response Plan under § 20 of the Act

(+) Document on granting the accreditation and an experiment plan under the special legal regulation in case of breeding facilities for animals<sup>2)</sup>

3.1 Address of workplace

3.2 Character of workplace

- microbiological laboratory
- pilot plant
- production facilities
- glasshouse / growth room
- animal breeding facility
- other (unambiguously identifying the description of workplace)

3.3 Description of location of the area for the contained use and description of their main facilities

(+) Layout of premises and of the location of main facilities

3.4 Evaluation of the space and the facilities of the workplace and its location pursuant to the requirements on a contained space and protective measures laid down for the second risk category in Annex No. 4 to this Decree

(+) Comparison table of requirements for the second risk category laid down by Annex No. 4 to this Decree, and for the real equipping of the workplace.

##### **4. Genetically modified organism**

4.1 Information on the donor organism including its origin

4.2 Information on the recipient and parental organism including the origin thereof

4.3 Information on the vector including its origin

4.4 Information on the insert

4.5 Method of introduction of the insert

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<sup>2)</sup> § 15 par. 2 and § 23 par. 1 letter a) of Act No. 246/1992 Coll.

- 4.6 Information on the genetically modified organism
  - 4.6.1 Specification of resulting genetically modified organism
  - 4.6.2 Function of inserted or extracted genes, as appropriate
  - 4.6.3 Method for detection and control of occurrence of genetic modification including the validated methods for unambiguous identification of genetically modified organisms
- 4.7 The approximate amount of genetically modified organisms to be used (volume of the culture, number of plants or animals)
- 4.8 Information on whether the genetically modified organism has already been approved in some other country and for what purpose.

## **5. Description of the use of the genetically modified organism**

- 5.1 In case of import or export of the genetically modified organism intended for contained use
  - 5.1.1 The country of origin or destination, as appropriate
  - 5.1.2 Importer or exporter, as appropriate
  - 5.1.3 Maximum amount of the genetically modified organism to be imported or exported
  - 5.1.4 Means of transportation
  - 5.1.5 Means of packaging and labelling
- 5.2 Description of the use of the genetically modified organism according to the risk assessment
- 5.3 Measures to protect human health and animals, the environment and biological diversity
- 5.4 Frequency and the manner of carrying out control of the occurrence of genetically modified organism inside and outside of the contained space
- 5.5 The manner of liquidation of the genetically modified organism and control of its effectiveness
- 5.6 Description of waste management (wastewater, waste gaseous harmful substances, other and hazardous waste)

## **6. Supplementary information**

- 6.1 Place of storing the documentation on the use of genetically modified organisms kept under § 19 letter b) of the Act
- 6.2 Plan of training of employees prior to the commencement of the use of genetically modified organisms, and the plan of their refresher training
- 6.3 Validated methods for detection of occurrence of genetically modified organisms and determination of their amount in case of microorganisms

## **PART B**

### **REQUIREMENTS FOR GRANTING THE CONSENT FOR CONTAINED USE**

#### **Date of submission**

##### **1. Applicant**

(+) Extract from the Trade Register (not older than 3 months), or a certified copy of the Trade Licence or the Foundation Charter, as appropriate

1.1 Name or names, as appropriate, and surname (trade company), if an applicant is the natural person authorised to operate a business

1.2 Title (trade company) and the legal form, if the applicant is legal person

1.3 Nationality (in case of natural persons)

1.4 Place of business (in case of legal persons) or place of business and place of residence (in case of natural persons)

- 1.5 Company registration number (if assigned)  
1.6 Tax identification number (if assigned)  
1.7 Subject of activity (according to the Foundation Charter or the record in the Trade Register)  
1.8 Name or names and surnames of persons, who represent a statutory body of the applicant, including the manner of acting on behalf of applicant (in case of legal persons), as appropriate.

## **2. Professional consultant**

(+) extract from the Criminal Register or the other relevant document pursuant to special legal regulation<sup>7)</sup>, as appropriate.

(+) certificate for achieved education and length of professional experience (if Member State citizen has obtained the professional experience in the other Member State this certificate means a decision on the recognition of professional qualification pursuant to the special legal regulation<sup>1)</sup>).

- 2.1 Name or names, as appropriate, surname, academic degree  
2.2 Occupation or employer and function, as appropriate  
2.3 Education  
2.4 Professional courses  
2.5 Previous experience  
2.6 Address of residence  
2.7 Contact address  
2.8 Telephone number  
2.9 Fax number  
2.10 E-mail

## **3. Purpose and period of contained use**

3.1 Purpose of contained use – character of an activity that will be carried out by applicant (e.g. research, training, laboratory control, manufacture)

3.2 Expected result of contained use

3.3 Total period of contained use and date of its expected starting-up and particular periods and starting dates if the contained use is divided into individual stages.

## **4. Risk assessment**

(+) Risk assessment pursuant to § 7 worked up separately for each genetically modified organism

2.1 Result of the risk assessment

## **5. Workplace where the contained use will be carried out**

(+) Code of Practice of a workplace under the Annex No. 4 to the Act

(+) Emergency Response Plan under § 20 of the Act

(+) Document on granting the accreditation and an experiment plan under the special legal regulation in case of breeding facilities for animals<sup>8)</sup>

- 5.1 Address of workplace  
5.2 Character of workplace
- microbiological laboratory
  - pilot plant
-

- production facilities
- glasshouse / growth room
- animal breeding facility
- other (unambiguously identifying the description of workplace)

5.3 Description of location of the areas for the contained use and description of their main facilities

(+) Layout of premises and of the location of main facilities

3.4 Evaluation of the space and the facilities of the workplace and its location pursuant to the requirements on a contained space and protective measures laid down for the individual risk categories in Annex No. 4 to this Decree

(+) Comparison table of requirements for particular risk category laid down by Annex No. 4 to this Decree, and for the real equipping of the workplace.

## **6. Information on (A) donor organism, (B) recipient or (C) parental organism where applicable**

(A) Donor organism

(B) Recipient

(C) Parental organism

6.1 Organism means

- viroid
- RNA virus
- DNA virus
- Bacteria
- Fungus (mould, yeast)
- Higher plan
- Animal
- Other (specifying necessary)

6.2 Czech and Latin family and variety names of an organism including a precisely determining the cultivar (species, race, strain, line, form, hybrid, stock, pathovar)

6.3 Origin (collection, collection number, supplier)

6.4 Include if the organism is pathogenic or harmful in any other way (living or non-living including extracellular products). If yes, then include whether regarding to people, plants or otherwise. The harmfulness must be always unambiguously identified. Are pathogenic or harmful properties concerning the sequences used during genetic modification?

If yes, include unambiguously possible characteristics:

- pathogenicity: epidemicity, infectiousness, virulence
- allergenic effects
- toxic effects
- pathogen carrier,
- possible vectors, host area including non-target organism,
- potential activation of latent viruses (proviruses)
- potential ability to penetrate into other organisms or colonise them
- resistance to antibiotics and potential use of such antibiotics for prophylaxis and treatment human and animal diseases
- other (unambiguous characteristic)

6.5 Natural occurrence of an organism

6.6 Information on whether the heritable genetic material is naturally exchanged between donor organisms and recipient

## **7. Information on the genetic modification**

7.1 The type of genetic modification

- the introduction of foreign heritable genetic material
- removal of part of the heritable genetic material
- combination of removal and introduction of heritable genetic material
- cellular fusion
- other (necessary unambiguously identifying)

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 genetically modified organism

7.3.2 Type of the vector

- plasmid
- bacteriophage
- virus
- cosmid
- phasmid
- transposon
- other object (necessary unambiguously identifying)

7.3.3 Identity of the vector

7.3.4 Spectrum of the vector hosts

7.3.5 Presence of the sequence in the particular vector, which transfers the selectable or identifiable phenotype

- resistance to antibiotics (include the accurate name of the active substance)
- resistance to heavy metals
- resistance to pesticides (include the accurate name of the active substance)
- other resistance (necessary unambiguously identifying)

7.3.6 Methods of introduction of the vector into the recipient organism

- transformation
- electroporation
- macro-injection
- micro-injection
- biolistic transfer
- infection (agrobacterial, viral)
- other (necessary unambiguously identifying)

7.3.7 Fragments of the vector and their presence in the final genetically modified organism

7.4 The method of introduction of insert into the recipient organism, if a vector was not used in genetic modification

- transformation
- micro-injection
- micro-encapsulation
- macro-injection
- biolistic transfer

- other (necessary unambiguously identifying)

## **8. Information on the insert**

(Information from 8.1 to 8.3 could be summarized in a table and genetic map of the insert could be enclosed)

8.1 Composition of the insert

8.2 Source of each part of the insert

8.3 Intended function of each individual part of the insert in the final genetically modified organism

8.4 Location of the insert in the final genetically modified organism

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

8.5 Information on whether the insert contains any part whose product or function is not known

8.6 Information on whether the sequences contained in the insert cause in any way pathogenic or harmful effects of the donor organism or vector

## **9 Information on the final genetically modified organism**

9.1 Specification of the final genetically modified organism

9.2 Genetic properties and phenotypic characteristics of the recipient or parental organism, which have been altered as a result of the genetic modifications

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

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

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

9.3 The genetic stability of the genetically modified organism

9.4 Include whether the genetically modified organism (living or non-living including extracellular products) is pathogenic. If so, then include whether in relation to people, animals, plants or otherwise. The harmfulness must be always unambiguously identified.

9.5 Description of methods for identification and detection of the genetically modified organisms

9.5.1 Data for unambiguous identification of the altered section of the heritable genetic material

9.5.2 Methods for detection of the occurrence of genetically modified organism including validated methods of their unambiguous identification

## **10. Description of the contained use**

10.1 In case of import or export of genetically modified organism intended for the contained use

10.1.1 The country of origin or destination, as appropriate

10.1.2 Importer or exporter, as appropriate

10.1.3 Maximum amount of the genetically modified organism to be imported or exported

10.1.4 Means of transportation

10.1.5 Means of packaging and labelling

10.2 Description of the use of the genetically modified organism according to the risk assessment

10.3 Measures to protect human health and animals, the environment and biological diversity

10.4 Occupational health and safety according to special legal regulations<sup>3)</sup>

10.5 Information on the system of carrying out control of occurrence of genetically modified organisms

10.5.1 Frequency and the manner of carrying out control inside the contained space

10.5.2 Frequency and the manner of carrying out control outside of the contained space

10.6 The manner of inactivation of the genetically modified organism and control of its effectiveness

10.7 Description of waste management (wastewater, waste gaseous harmful substances, other and hazardous waste)

### **11. Supplementary information**

11.1 Place of storing the documentation on the use of genetically modified organisms having been kept under § 19 letter b) of the Act

11.2 Plan of training of employees prior to the commencement of the use of genetically modified organisms, and the plan of their refresher training

## **PART C**

### **COMMON REQUIREMENTS FOR NOTIFICATION AND REQUEST**

Statement, date and signature of the professional consultant

Date, signature and stamp of the applicant (notifier)

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<sup>3)</sup> For example the Government Order No. 178/2001 Coll., as amended by the Government Order No. 523/2002 Coll.

**Requirements of the request  
for granting the consent for introduction into the environment**

Information marked by (+) shall be necessary supplemented with the original document or a certified copy. All the enclosed documents must include the name or names, as appropriate, and the surname or the title (trading company) of an applicant.

Information regarding the summary of the contents of the request intended to be published shall be underlined.

PART A  
GENERAL REQUIREMENTS OF THE REQUEST

**Date of submission**

**1. Project name**

**2. Applicant**

(+) Extract from the Trade Register (not older than 3 months), or a certified copy of the Trade Licence or the Foundation Charter, as appropriate

2.1 Name or names, as appropriate, and surname (trade company), if an applicant is the natural person authorised to operate a business

2.2 Title (trade company) and the legal form, if the applicant is legal person

2.3 Nationality (in case of natural persons)

2.4 Place of business (in case of legal persons) or place of business and place of residence (in case of natural persons)

2.5 Company registration number (if assigned)

2.6 Tax identification number (if assigned)

2.7 Subject of activity (according to the Foundation Charter or the record in the Trade Register)

2.8 Name or names and surnames of persons, who represent a statutory body of the applicant, including the manner of acting on behalf of applicant (in case of legal persons), as appropriate.

**3. Professional consultant**

(+) extract from the Criminal Register or the other relevant document pursuant to special legal regulation<sup>7)</sup>, as appropriate.

(+) certificate for achieved education and length of professional experience (if Member State citizen has obtained the professional experience in the other Member State this certificate means a decision on the recognition of professional qualification pursuant to the special legal regulation<sup>1)</sup>).

3.1 Name or names, as appropriate, surname, academic degree

3.2 Occupation or employer and function, as appropriate

3.3 Education

3.4 Professional courses

- 3.5 Previous experience
- 3.6 Address of residence
- 3.7 Contact address
- 3.8 Telephone number
- 3.9 Fax number
- 3.10 E-mail

#### **4. Characteristic of the use of genetically modifies organism**

- 4.1 Purpose of introduction into the environment or name and marking of the project, project assigner, as appropriate  
(purpose of introduction including all the potential benefits for the environment)
- 4.2 Expected result of introduction into the environment

#### **5. Period of the introduction into the environment**

- 5.1 Total period of introduction into the environment of genetically modified organism and date of its expected starting-up
- 5.2 Binding schedule (description of the individual stages, date of expected starting-up and the duration thereof)

#### **6. Is the applicant planning the introduction of genetically modified organism into the environment in any Member State of European Communities or outside of its territory?**

If so, then include:

- the country of submission of the request
- date of submission and number or other marking of the request
- date and marking of a consent, if has been granted
- period for which the consent applies

#### **7. Has the applicant submitted a request for the introduction of the same genetically modified organism into the environment in any Member State of European Communities?**

If so, then include:

- the country of submission of the request
- date of submission and number or other marking of the request
- date and marking of a consent, if has been granted
- period for which the consent applies

#### **8. Has the applicant submitted a request for the introduction of the same genetically modified organism into the environment or on the market outside of the territory of European Communities?**

If so, then include:

- the country of submission of the request
- date of submission and number or other marking of the request
- date and marking of a consent, if has been granted
- period for which the consent applies

#### **9. The risk assessment of the introduction of genetically modified organism into the environment**

(+) The risk assessment pursuant to § 7 of the Act including the documentation of results of previous introductions into the environment, particularly from the point of view of the different range of activities and different recipient ecosystems

#### 9.1 Summary risk assessment

### PART B OTHER REQUIREMENTS OF THE REQUEST FOR GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS

#### **1. Characteristic of the genetically modified organism**

##### 1.1 Genetically modified organism means:

- viroid
- RNA virus
- DNA virus
- Bacteria
- Fungus (mould, yeast)
- Other microorganism
- Animal
  - Mammal
  - Insect
  - Fish
  - Other animal (include species)
- Other (specifying necessary)

##### 1.2 Czech and Latin family and variety names of the genetically modified organism including a precisely determining the race (strain, form, stock, cellular line, pathovar)

##### 1.3 Genetic stability

##### 1.3.1 Measures to ensure genetic stability, factors that influence this stability

##### 1.3.2 Methods of verification of the genetic stability

##### 1.3.3 Description of heritable genetic properties that should eliminate or reduce the spreading of genetic material

#### **2. Information on the recipient or parental organism, if applicable**

Characteristic of the recipient or parental organism, if applicable

##### 2.1 Organism means:

- viroid
- RNA virus
- DNA virus
- Bacteria
- Fungus (mould, yeast)
- Animal (include species)
- Other (specifying necessary)

##### 2.2 Czech and Latin family and variety names of the organism including a precisely determining the race (strain, form, stock, cellular line, pathovar)

##### 2.3 Origin (collection, number of collection, supplier)

##### 2.4 Plasmids (when concerning microorganisms)

##### 2.5 Bacteriophages (when concerning microorganisms)

##### 2.6 Phenotypic and genetic markers

##### 2.7 Degree of congeniality between donor organism and recipient

##### 2.8 Occurrence and living conditions

### 2.8.1 Geographical distribution

- origin or resident in the Czech Republic
- origin or resident in the states of European Communities

If the organism originates in the Czech Republic or in the states of European Communities, include the ecosystem where it occurs:

- Atlantic
- Mediterranean
- boreal
- Alpine
- continental
- other (unambiguously identifying)

### 2.8.2 Is the organism commonly used in the Czech Republic?

### 2.8.3 Is the organism commonly cultivated (grown) in the C Czech Republic?

### 2.8.4 Habitat (natural occurrence) of the organism

- aquatic environment
- soil, freely living
- soil in connection with the root system of plants
- in connection with the parts of plants above the soil
- in connection with animals
- other (unambiguously identifying)

Include a natural habitat or current ecosystem, if the organism is animal

## 2.9 Methods of identification and detection of the organism

### 2.9.1 Methods of detection including information on their sensibility, reliability and specificity

### 2.9.2 Methods of identification including information on their sensibility, reliability and specificity

2.10 Is the organism classified pursuant to the valid legal regulations of the Czech Republic<sup>9)</sup> or EC concerning the occupational and health safety? If so, include the classification and relevant legal regulation.

2.11 Include whether the organism is pathogenic or otherwise harmful (living or non-living including extracellular products). If so, then include whether regarding to people, animals, plants or otherwise. The harmfulness must be always unambiguously identified. Are pathogenic or harmful properties concerning the sequences used during genetic modification?

If so, then unambiguously identify possible characteristics:

- pathogenicity: epidemicity, infectiousness, virulence
- allergenic effects
- toxic effects
- pathogen carrier,
- possible vectors, host area including non-target organism,
- potential activation of latent viruses (proviruses)
- potential ability to penetrate into other organisms or colonise them
- resistance to antibiotics and potential use of such antibiotics for prophylaxis and treatment human and animal diseases
- other

### 2.12 Reproduction

#### 2.12.1 Generation time in the natural environment,

#### 2.12.2 Generation time in the ecosystem, into which the genetically modified organism should be introduced

#### 2.12.3 Means of reproduction (sexual, asexual)

2.12.4 Specific factors, which influence reproduction (if exist)

2.13 Survivability

2.13.1 Ability to form structures enhancing survival

- seeds
- endospores
- cysts
- sclerotia
- asexual spores (fungi)
- sexual spores (fungi)
- eggs
- pupae
- larvae
- other (unambiguously specifying)

2.14 Dissemination in the environment

2.14.1 Means and extent of dissemination

2.14.2 Specific factors, which influence dissemination (if exist)

2.15 Natural predators, preys, parasites and competitors, symbionts and hosts

2.16 Other potential interactions with other organisms

2.16.1 Other specific factors enhancing survival

2.16.2 Survivability in the individual weather seasons

2.17 Potential intercellular transfer of the genetic material between donor (parental organism) and other organisms

2.17.1 The manner of transfer (by plasmid, bacteriophage, otherwise)

2.17.2 Organisms with which the natural exchange of genetic material occurs

2.18 Verification of the genetic stability of the organism and factors affecting it

2.19 Involvement in environmental processes

- primary production
- nutrient turnover (consumer, predator)
- decomposition of organic matter
- other (unambiguously specifying)

2.20 Indigenous vectors of the organism

2.20.1 Sequences of the vector

2.20.2 Frequency of mobilisation of the vector

2.20.3 Specificity of the vector

2.20.4 Presence of genes conferring resistance

2.21 Previous genetic modifications of recipient or parental organism approved in the Czech Republic (including date and number of a consent]

### **3. Information on the genetic modification**

3.1 The type of genetic modification

- introduction of foreign heritable genetic material
- removal of part of the heritable genetic material
- combination of removal and introduction of the heritable genetic material
- cellular fusion

- other (unambiguously specifying)

### 3.2 Intended result of the genetic modification

### 3.3 Was the vector used in the genetic modification?

If no, continue at the point 3.4

#### 3.3.1 Is the vector partly or fully presented in the final genetically modified organism?

If the vector is not even partly presented, continue at the point 3.5.

#### 3.3.2 Type of the vector

- plasmid
- bacteriophage
- virus
- cosmid
- phasmid
- transposon
- other object (unambiguously specifying)

(+ genetic map of the vector)

#### 3.3.3 Identity of the vector (origin)

#### 3.3.4 Spectrum of hosts of the vector

#### 3.3.5 Presence of the sequence in particular vector, which transfers the selectable or identifiable phenotype

- resistance to antibiotics
- resistance to heavy metals
- resistance to pesticides (include accurate name of the active substance)
- other (unambiguously specifying)

#### 3.3.6 Fragments of the vector and their presence in the final genetically modified organism

#### 3.3.7 Methods of introduction of the vector into the recipient organism

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

#### 3.3.8 Information on the degree to which the vector is limited to the sequence of the nucleic acid required to perform the intended function, and if the vector contains sequences, which product or functions are not known

### 3.4 If a vector was not used in the genetic modification, the method of introduction of the insert into the recipient organism

- transformation
- micro-injection
- micro-encapsulation
- macro-injection
- other (unambiguously identifying)

### 3.5 Methods and criteria used for selection

## **4. Information on the insert**

### 4.1 Information on each part of the insert or each removed part of the heritable genetic material, as appropriate, with special emphasis on any known harmful sequences

#### 4.1.1 Size

#### 4.1.2 Sequence

#### 4.1.3 Origin

#### 4.1.4 Functional characteristics

#### 4.2 Location of the insert in the recipient organism

- on the free plasmid
- integrated into the chromosome
- other (unambiguously identifying)

#### 4.3 Does the insert contain parts, which products or functions are unknown?

If so, specify

4.4. Information on the degree to which the insert is limited to the sequence of the nucleic acid required to perform the intended function

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

4.6 Structure and size of each section of the nucleic acid derived from the vector or donor organism remaining in the final genetically modified organism including methods and information required for identification and detection of the introduced sequences.

4.7 In case of removal of part of the heritable genetic material (deletion), the size and function of the removed section of nucleic acid

4.8 The number of copies of the introduced heritable genetic material

4.9 Stability of the introduced heritable genetic material and stability of the location thereof

### **5. Information on the donor organism (organism, from which the insert is derived)**

#### 5.1 Donor organism means

- viroid
- RNA virus
- DNA virus
- bacteria
- fungus (mould, yeast)
- other microorganism
- animal
- other (specifying necessary)

5.2 Czech and Latin family and variety name of a donor organism including a precisely determining the cultivar (species, race, strain, line, form, hybrid, stock, pathovar)

5.3 Include if the donor organism is pathogenic or harmful in any other way (living or non-living including extracellular products). If yes, then include whether regarding to people, animals, plants or otherwise. The harmfulness must be always unambiguously identified.

Are pathogenic or harmful properties concerning the sequences used during genetic modification?

If yes, include unambiguously possible characteristics:

- pathogenicity: epidemicity, infectiousness, virulence
- allergenic effects
- toxic effects
- pathogen carrier,
- possible vectors, host area including non-target organism,
- potential activation of latent viruses (proviruses)
- potential ability to penetrate into other organisms or colonise them
- resistance to antibiotics and potential use of such antibiotics for prophylaxis and treatment human and animal diseases
- other

5.4 Is the donor organism classified pursuant to the valid legal regulations of the Czech Republic<sup>9)</sup> or EC concerning the occupational and health safety?

If so, include the classification and relevant legal regulation.

5.5 Do the recipient and donor organism exchange the genetic material in the natural way?

## **6. Information on the final genetically modified organism**

6.1 Description of heritable properties and phenotypic markers, which were altered as a result of the genetic modification

6.1.1 Does the genetically modified organism differ from the recipient in its survivability?

If so, then identify unambiguously

6.1.2 Does the genetically modified organism differ from the recipient in the manner or rate of reproduction?

If so, then identify unambiguously

6.1.3 Does the genetically modified organism differ from the recipient in its ability to disseminate?

If so, then identify unambiguously

6.1.4 Does the genetically modified organism differ from the recipient in its pathogenicity?

If so, then identify unambiguously

6.2 Genetic stability of genetically modified organism

6.3 Properties of genetically modified organism, which influence its survival, reproduction and dissemination in the environment

6.4 Known or predicted environmental conditions, which may affect survival, reproduction and dissemination in the environment (wind, water, soil, temperature, pH etc.)

6.5 Sensitivity to specific substances (agents)

6.6 Include whether the organism is pathogenic or harmful in any other way (living or non-living including extracellular products). If yes, then include whether regarding to people, animals, plants or otherwise. The harmfulness must be always unambiguously identified. Are pathogenic or harmful properties concerning the sequences used during genetic modification?

If yes, unambiguously include possible characteristics:

- pathogenicity: epidemicity, infectiousness, virulence
- allergenic effects
- toxic effects
- pathogen carrier,
- possible vectors, host area including non-target organism,
- potential activation of latent viruses (proviruses)
- potential ability to penetrate into other organisms or colonise them
- resistance to antibiotics and potential use of such antibiotics for prophylaxis and treatment human and animal diseases
- other (unambiguous characteristic)

6.7 Description of methods of identification and detection of genetically modified organism

6.7.1 Methods used for detection of genetically modified organisms including the verified detection methodology

6.7.2 Methods used to identify genetically modified organism in the environment including the verified methodology for identification and data on reliability and sensitivity of the methods

6.7.3 Data for unambiguous identification of the altered section of the heritable genetic material

6.8 Expression of the introduced heritable genetic material

6.8.1 Rate and level of expression of the heritable genetic material, dependence on the life cycle, organs where the expression occurs

- 6.8.2 Description of methods and sensitivity of measurement
- 6.8.3 Stability of the expression
- 6.9 Expressed proteins
  - 6.9.1 Activity of the expressed proteins
  - 6.9.2 Description of the methods of identification and detection of expressed proteins and the data on sensibility, reliability and specificity of these methods
- 6.10 Previous use of the genetically modified organism

**7. Information on introduction into the environment and premises where the introduction will occur**

7.1 Does the place of the introduction into the environment differ from the ecosystem where the recipient or parental organism obviously occur or are grown and/or cultivated?

If so, specify.

7.2 Workplace and premises where the introduction into the environment will occur

(+) Methodology of the experiments

(+) Emergency Response Plan under § 20 of the Act

(+) Code of Practice of a workplace under Annex No. 4 to the Act

(+) Copies of cadastral maps with designated premises at which the introduction into the environment will occur, and the comprehensive layout containing also the information on the use of surrounding premises including the species of plant grown

7.3 The owner of premises, if he is not a person submitting the request for the introduction of genetically modified organism into the environment, and the contractual relation between the owner and this person

7.4 Specification of the premises

7.4.1 Region

7.4.2 Municipality

7.4.3 Name of cadastral territory and cadastral number,

(+ location of the area of the cultivation of genetically modified organism at the premises, and marking its size in the layout in the appropriate scale)

7.4.4 Identification number of the soil block or the section of the soil block, as appropriate, if the premises is the subject of the agriculture land registration under the special legal regulation<sup>4)</sup>

7.5 Total area of the site, where the introduction into the environment shall occur (m<sup>2</sup>)

- actual area of the experiment
- the area of experiment premises (including isolation zone etc.)

7.6 The distance of the experimental premises from the specific territories (in metres or kilometres)

7.6.1 especially protected territories<sup>5)</sup>

7.6.2 housing, settlement

7.6.3 protective zones of water sources

7.6.4 water course, water reservoirs

7.6.5 territories managed in the ecological agriculture<sup>6)</sup>

<sup>4)</sup> Act No. 252/1997 Coll., on agriculture as amended by Act No. 62/2000 Coll., Act No. 307/2000 Coll. and Act No. 128/2003 Coll.

<sup>5)</sup> Act No. 114/1992 Coll. on protection of nature and the landscape as amended by Act No. 347/1992 Coll., Act No. 289/1992 Coll., the Finding of the Constitutional Court No. 3/1997 Coll., Act No. 16/1997 Coll., Act No. 123/1998 Coll., Act No. 161/1999 Coll., Act No. 238/1999 Coll., Act No. 132/2000 Coll., Act No. 76/2002 Coll. and Act No. 320/2002 Coll.

<sup>6)</sup> Act No. 242/2000 Coll. on ecological agriculture and on amendments to Act No. 368/1992 Coll. on administrative fees, as later amended, as amended by Act No. 320/2002 Coll.

#### 7.6.6 other

7.7 Use of the surrounding premises including the crops grown at the surrounding premises (mark in the layout)

7.8 Flora and fauna including the agricultural crops, domestic animals and migrating animals that could be affected by genetically modified organism

7.9 Methods of the introduction into the environment and amount of the used genetically modified organisms

7.9.1 Approximate amount of genetically modified organisms to be used

7.9.2 The manner of safeguarding the premises

- against unjustified persons
- against animals
- against water runoff

7.9.3 Extent and manner of the use of isolation zone around the site of cultivation of genetically modified organisms

7.9.4 Other methods of the elimination or minimisation of the dissemination of genetically modified organisms outside of the trial premises

7.9.5 Brief description of the usual weather conditions

7.9.6 Description of the ecosystem at the place of the introduction into the environment and the disruptive effects on the ecosystem

- type of soil
- water regime including irrigation
- climatic conditions

7.10 Relevant data on previous cases of the introduction the same genetic organism into the environment, if exist, particularly in relation to potential effects of such activity on human and animal health, the environment and biological diversity.

7.11 Description of the systems that could be affected

7.12 Comparison of the natural habitat of the recipient or parental organism, as appropriate, with the proposed place of the introduction into the environment

7.13 Any planned changes in the use of the premises in the vicinity of the place of the introduction into the environment that could affect the environmental impact of genetically modified organisms.

### **8. Description of the use of genetically modified organisms**

8.1 Use of the genetically modified organisms prior to its introduction into the environment (contained use, transportation)

8.2 Procedure through which the genetically modified organisms will be introduced into the environment

8.3 Approximate number of genetically modified organisms (per m<sup>2</sup> or m<sup>3</sup>, as appropriate)

8.4 Preparation and the manner of treatment of the premises prior to the introduction of genetically modified organisms

8.5 The manner of transportation of genetically modified organisms

8.6 The manner of the protection of occupational health during the use of genetically modified organisms pursuant to special legal regulations<sup>9)</sup>

8.7 The manner of the cultivation of genetically modified organisms

8.8 Description of further use of genetically modified organisms including its disposal

8.9 Date and manner of the evaluation of the introduction of genetically modified organisms into the environment

### **9. Information on interactions between genetically modified organisms and the environment, and on potential effect of the interactions on the environment**

- 9.1 Czech and Latin family and variety name of an target organism, if exist, including a precisely determining the cultivar (species, race, strain, line, form, hybrid, stock, pathovar)
- 9.2 Expected mechanism and result of the interaction between genetically modified organism introduced into the environment and the target organism
- 9.3 Expected mechanism and result of the interactions between other organisms in the environment that could be important
- 9.4 Is it likely that the selection occurs after the introduction into the environment, e.g. higher competitiveness or invasiveness of genetically modified organism?
- 9.5 Possibility of rapid growth of the population of genetically modified organism in the environment and conditions for this growth
- 9.6 The ways of biological dissemination the genetically modified organism, known or unknown ways of the interaction with the disseminating agents
- 9.7 Types of ecosystems where the genetically modified organism could be disseminated from the place of the introduction into the environment and where could settle
- 9.8 Name (Czech and Latin family and variety name of an non-target organism including a precisely determining the cultivar (species, race, strain, line, form, hybrid, stock, pathovar), which regarding to the character of the recipient environment could be affected by the introduction of genetically modified organism into the environment
- 9.9 Expected mechanism of determined undesirable interactions between genetically modified organisms and non-target organisms including competitors, preys, hosts, symbionts, predators, parasites and pathogens.
- 9.10 Ability to transfer the heritable genetic material in vivo
- 9.10.1 Possibility to transfer the heritable genetic material from the genetically modified organism into the other organism after the introduction of genetically modified organism into the environment and consequences of this transfer
- 9.10.2 Possibility to transfer the heritable genetic material from the naturally occurring organism on the genetically modified organism after the introduction the genetically modified organism into the environment and consequences of this transfer
- 9.11 Results of the studying the behaviour and properties of the genetically modified organism and their environmental effects carried out in the simulated natural environment
- 9.12 Known or expected involvement into biogeochemical processes
- 9.13 Other potential effects on the environment and biological diversity (unambiguously specify)

## **10. Monitoring the occurrence and effects of genetically modified organisms**

- 10.1 Methods of determining the presence of the genetically modified organisms
- 10.2 Specificity of the methods of identification of the genetically modified organisms and differentiating the genetically modified organism from the donor organism, recipient or parental organism, as appropriate, the sensitivity and reliability of these methods
- 10.3 Methods of monitoring the effects on the ecosystem
- 10.4 Techniques (methods) of detection of transfer of the introduced heritable genetic material to other organisms
- 10.5 The area where the monitoring shall be carried out (m<sup>2</sup>)
- 10.6 Period of the monitoring
- 10.7 Frequency of the monitoring

## **11. Information on measures after the termination of an experiment and on waste management**

- 11.1 Description of measures after the termination of the experiment

11.2 The manner of liquidation of genetically modified organisms and control of its effectiveness

11.3 Plan of controls and supervision

11.4 Types of waste generated and its expected amount

11.5 Potential risks resulting from the handling with wastes

11.6 Description of the disposal of wastes and methods of control of its effectiveness

## **12. Provision of samples of genetically modified organisms**

12.1 The amount and means of supply of samples provided under § 18 par. 2 of the Act

## **13. In case of import or export of genetically modified organism intended exclusively for the introduction into the environment (transfer to the third person that is not considered as placing on the market)**

13.1 The country of origin or destination, as appropriate

13.2 Importer or exporter, as appropriate

13.3 Maximum amount of the genetically modified organism to be imported or exported

13.4 Means of transportation

13.5 Means of packaging and labelling

## **14. The place of storing the documentation on the use of genetically modified organisms having been kept under § 19 letter b) of the Act**

## **15.**

### **Plan of training of employees prior to the commencement of the use of genetically modified organisms, and the plan of their refresher training**

## PART C

### OTHER REQUIREMENTS OF THE REQUEST FOR GENETICALLY MODIFIED HIGHER PLANTS

#### **1. Information on the recipient or parental organism where applicable**

1.1 Czech and Latin family and variety names of an organism including a precisely determining the cultivar (species, line, hybrid)

1.2 Origin (collection, number of the collection, supplier)

1.3 Reproduction

1.3.1 Means of reproduction

1.3.2 Specific factors that affect reproduction (if exist)

1.3.3 Generation time

1.3.4 Sexual compatibility with the other cultivated or uncultivated varieties and spreading of these compatible varieties in the Czech Republic

1.4 Survivability

1.4.1 Ability to form structures that enhance survival or dormance, and the time period of potential survival or dormance,

1.4.2 Other specific factors enhancing survival, if exist

1.5 Spreading the plant in the environment

1.5.1 The manner and extent of the spreading (decrease of the amount of pollen and seeds in relation to the distance from the source, power and direction of wind and other factors)

1.5.2 Specific factors affecting the spreading (if exist)

1.6 Geographic spreading of the plant

1.7 Description of the habit including the information on natural consumers, pathogens, parasites, competitors and symbionts, if the plant is not grown in the Czech Republic

1.8 Other potential relevant interactions of the plant with other organisms in the ecosystem where the plant is usually grown.

1.9 Effects on human and animal health and the environment

- toxicity
- allergenicity
- other (unambiguously identifying)

## **2. Information on genetic modification and genetically modified higher plant**

2.1 Czech and Latin family and variety names of the genetically modified higher plant including a precisely determining the cultivar (species, line, hybrid)

2.2 Description and characterisation of heritable genetic properties that were introduced or altered including signal and selective genes and previous modifications, and description its phenotype exhibitions

2.3 The type of genetic modification

- the introduction of foreign heritable genetic material
- removal of part of the heritable genetic material
- combination of removal and introduction of heritable genetic material
- cellular fusion
- other (necessary unambiguously identifying)

2.4 Properties and origin of used vector (if the vector was used)

(+ map of the vector)

2.5 Information on every part of the section of DNA, which was introduced into the organism of recipient (if genetic modification includes the introduction of the heritable genetic material)

2.5.1 Origin (Czech and Latin family and variety names of the donor organism including a precisely determining the cultivar (species, race, strain, line, form, hybrid, stock, pathovar)

2.5.2 Functional characteristics

2.5.3 Size

2.5.4 Location – if it was integrated

2.5.5 Sequence

2.6 a If it concerns removal of a part of heritable genetic material (deletion), size and function of removed section

2.7 Description of the method used for genetic modification

2.8 If the recipient or parental organism is forest tree species, specify methods of dissemination and specific factors affecting dissemination

2.9 Placing the heritable genetic material in the plant cell (introduced in chromosomes, chloroplasts or in non-integrated form)

2.10 Number of copies of the introduced heritable genetic material

2.11 Stability of the introduced heritable genetic material and stability of the placing

2.12 Methods of determination of particular information

2.13 Information on the expression of the introduced heritable genetic material

2.13.1 The place where the expression of the introduced genes occurs in the plant (e.g. roots, stem, leaves, pollen etc.)

2.13.2 Changes in expression in dependence on the life cycle of the plant

2.13.3 Stability of the expression

2.13.4 Methods used for characterisation of the expression

2.14 Information for unambiguous identification of genetically modified higher plant

2.14.1 Description of the altered part of the DNA

2.14.2 Methods of detection and identification of genetically modified higher plant and the verified methodology thereof

2.15 Behaviour of the introduced genes

2.15.1 during hybridisation with the same species

2.15.2 during hybridisation with distant species

2.16 Unambiguous information on how the genetically modified higher plants differ from the recipient or parental organism

- manner and rate of reproduction
- spreading in the environment
- survivability
- effects on human and animal health and the environment
- other (specify)

2.17 Phenotypic stability of genetically modified higher plant

2.18 Any change in ability of genetically modified higher plant to transfer genetic material to other organisms in consequence of genetic modification.

2.19 Information on any potential harmful effects of genetically modified higher plant on human health arising from the genetic modification

2.20 Information on the safety of genetically modified higher plant for animal health, particularly in relation to any harmful effects arising from the genetic modification, if the genetically modified higher plant shall be used as feedstuff

2.21 Mechanism of interaction between the genetically modified higher plant and the target organism, a target organism exists

2.22 Potential changes in the interactions of the genetically modified higher plant with non-target organisms arising from the genetic modification

2.23 Potential interactions of the genetically modified higher plant with non-living components of the environment

### **3. Information on the amount of genetically modified higher plants that is to be used and on the total area of premises**

3.1 Approximate amount of genetically modified higher plants that is to be introduced into the environment

3.2 Total area of the site where the genetically modified higher plants are to be grown

### **4. Workplaces and premises where the introduction will occur**

(+) Emergency Response Plan under § 20 of the Act

(+) Code of Practice of a workplace under the Annex No. 4 to the Act

(+) Copies of cadastral maps with designated premises and the comprehensive layout containing the information on the crops grown in surrounding premises

4.1 The purpose of the introduction into the environment (including all the relevant information available in this phase), e.g. agronomic purposes, hybridisation tests, change in survivability or spreading, detection of the effects on the target or non-target organisms

4.2 Location of the premises

4.2.1 Region

4.2.2 Municipality

4.2.3 Name of cadastral territory and cadastral number.

4.2.4 Identification number of the soil block or the section of the soil block, as appropriate, if the premises is the subject of the agriculture land registration under the special legal regulation<sup>10)</sup>

4.3 Size of the premises

4.3.1 Location of the cultivation of genetically modified higher plant on the premises and its size (m<sup>2</sup>) (layout in the appropriate scale)

4.3.2 Size (m<sup>2</sup>) and the manner of use of the isolation zone around the area for cultivation of the genetically modified plant (mark in the layout)

4.4 The use of surrounding premises

4.5 The distance of the premises from specific territories (in metres or kilometres)

4.5.1 Specially protected territories<sup>11)</sup>

4.5.2 Protective zones of water sources

4.5.3 Water course, water reservoirs

4.5.4 Territories managed in the ecological agriculture<sup>12)</sup>

4.5.5 Other

4.6 The manner of safeguarding the premises

4.6.1 safeguarding the premises against unjustified persons

4.6.2 safeguarding the premises against animals

4.6.3 safeguarding the premises against water runoff

4.7 Description of the ecosystem at the place of premises

4.7.1 Type of soil

4.7.2 Water regime including irrigation

4.7.3 Climatic conditions

4.7.4 Flora including agricultural crops

4.7.5 Fauna including domestic and migrating animals

4.8 Presence of wild or cultivated sexually compatible plants in the premises and in its vicinity

4.9 Relevant information concerning the previous cases of the introduction into the environment of the same genetically modified higher plant, if exist, particularly relating to the potential effects on human and animal health, the environment and biological diversity

## **5. Description of the use of genetically modified higher plants**

5.1 Use of the genetically modified higher plants prior to its introduction into the environment (contained use, transportation)

5.2 Procedure through which the genetically modified higher plants will be introduced into the environment

5.3 Approximate number of genetically modified higher plants (per m<sup>2</sup>)

5.4 Preparation and the manner of treatment of the premises prior to the cultivation of genetically modified higher plants

5.5 The manner of transportation of genetically modified higher plants

5.6 The manner of the protection of occupational health during the use of genetically modified higher plants pursuant to special legal regulations<sup>9)</sup>

5.7 The manner of the cultivation of genetically modified higher plants on the premises

5.8 The manner of harvesting the genetically modified higher plants

5.9 Description of further use of genetically modified higher plants

5.10 Date and manner of the evaluation of the introduction of genetically modified higher plants into the environment

## **6. Measures to protect human and animal health, the environment and biological diversity and waste management**

6.1 The distance of the site of cultivation of genetically modified higher plants from wild or cultivated sexually compatible species of plants

6.2 Measures to decrease or prevent air-transport of pollen or seeds, if used

6.3 Description of the methods for treatment of the premises after termination of the experiment

- 6.4 Description of the methods for transport and processing of the genetically modified higher plants
- 6.5 Control and methods of monitoring the occurrence and effects of genetically modified higher plants
  - 6.5.1 Methods of detection of the presence of genetically modified higher plants and monitoring its effects on ecosystem
  - 6.5.2 Specificity of the methods for identification of genetically modified higher plants and differentiating the genetically modified plants from the donor organism, recipient or parental organism, as appropriate, sensitivity and reliability of these methods
  - 6.5.3 Techniques (methods) for detection of the transferring of introduced heritable genetic material to other organisms
  - 6.5.4 The site where the monitoring will be carried out
  - 6.5.5 The period of monitoring
- 6.6 Waste management including the disposal of genetically modified higher plants
- 6.7 Summary of protective measures

**7. Summary information on planned field trials carried out for the purpose of obtaining new information on the effects of the introduction of genetically modified higher plants into the environment on human and animal health and the environment**

PART D

COMMON REQUIREMENTS FOR ALL REQUESTS

Opinion, date and signature of a professional consultant .....

Date, signature and the stamp of an applicant .....

## Requirements of the request for registering into the List for the placing on the market

Information marked by (+) must be supplemented with the original document or a certified copy thereof. All the enclosed documents must include the name or names, as appropriate, and the surname or the title (trading company) of an applicant.

Information regarding the summary of the contents of the request intended to be published shall be underlined.

### PART A GENERAL REQUIREMENTS OF THE REQUEST

#### The date of submission

#### **1. Name of the genetic product (commercial name and other names)**

#### **2. Applicant**

(+) extract from the Trade Register (not older than 3 months), or a certified copy of the Trade Licence or the Foundation Charter, as appropriate

2.1 Name or names, as appropriate, and surname (trade company), if an applicant is the natural person authorised to operate a business

2.2 Title (trade company) and the legal form, if the applicant is legal person

2.3 Nationality (in case of natural persons)

2.4 Place of business (in case of legal persons) or place of business and place of residence (in case of natural persons)

2.5 Company registration number (if assigned)

2.6 Tax identification number (if assigned)

2.7 Subject of activity (according to the Foundation Charter or the record in Trade Register)

2.8 Name or names and surnames of persons, who represent a statutory body of the applicant, including the manner of acting on behalf of the applicant (in case of legal persons), as appropriate.

2.9 The applicant is

- inland producer
- importer
- other (specify)

2.10 In case of the import

- name or names, as appropriate, and surname (trade company) of the producer, if he is a natural person, or the title (trade company), if the applicant is legal person
- address of the producer

#### **3. Professional consultant**

(+) extract from the Criminal Register or the other relevant document pursuant to special legal regulation<sup>7)</sup>, as appropriate.

(+) certificate for achieved education and length of professional experience (if Member State citizen has obtained the professional experience in the other Member State this certificate means a decision on the recognition of professional qualification pursuant to the special legal regulation<sup>7)</sup>).

2.1 Name or names, as appropriate, surname, academic degree

2.2 Occupation or employer and function, as appropriate

- 2.3 Education
- 2.4 Professional courses
- 2.5 Previous experience
- 2.6 Address of residence
- 2.7 Contact address
- 2.8 Telephone number
- 2.9 Fax number
- 2.10 E-mail

#### **4. Characterisation of the genetically modified organism contained in the genetic product**

The name, origin and properties of each genetically modified organism contained in the genetic product

#### **5. Purpose and procedure of the placing of genetically modified organism or genetic product on the market**

5.1 The purpose of placing of the genetically modified organism or genetic product on the market

5.2 Date of expected commencement of the placing genetically modified organism or genetic product on the market and its binding schedule (details of the individual stages, the date of expected commencement thereof and the period of particular stages)

5.3 Expected amount of the genetically modified organism or genetic product that will be used in the individual stages including information on whether the production comes from the territory of the Czech Republic or European Communities, as appropriate, or whether it's imported.

#### **6. Risk assessment of the placing of genetically modified organism or genetic product on the market**

(+) Risk assessment under § 7 of the Act

### PART B

#### OTHER REQUIREMENTS OF THE REQUEST FOR GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANT OR FOR GENETIC PRODUCTS OTHER THAN CONTAINING GENETICALLY MODIFIED HIGHER PLANTS, AS APPROPRIATE

#### **1. Common description of the genetically modified organism or genetic product and the genetically modified organism, which is contained in genetic product**

1.1 Type of genetically modified organism or genetic product (expected use of genetically modified organism or genetic product)

1.2 Composition of genetic product

1.3 Specificity (difference) of genetic product (in comparison with the same type of the product that does not contain genetically modified organisms)

1.4 Target group of consumers (e.g. industry, agriculture, small consumers)

1.5 Conditions of the use, particularly differences between the use of genetically modified organism or genetic product and the use of similar non-modified organisms or products containing non-modified organisms

1.6 Unambiguous determination of geographical territory in the EU, as appropriate, where the placing of genetically modified organism or genetic product shall be limited to

1.7 Type of the environment where the use of genetically modified organism (genetic product) is undesirable

1.8 Estimated annual demand

- in the Czech Republic
- in the European Union
- on the export markets

1.9 Unambiguous identification code of genetically modified organism or genetically modified organisms contained in the genetic product

1.10 Has the same applicant submitted the request for the introduction into the environment for the same genetically modified organism or organisms contained in the genetic product?

If so, include the number or other marking of the request (date and assigning of the request) and the country of the submission

If no, include the risk assessment of genetically modified organism pursuant to the requirements of the request for granting the consent for the introduction into the environment (part A, point 9 of Annex No. 2 to this Decree)

1.11 Is the applicant at the same time submitting a request for the placing of the same genetically modified organism or genetic product on the market in any Member State of EU?

If so, include the number or other marking of the request and the country of submission

1.12 Was product with the same genetically modified organism (the same combination of genetically modified organisms) placed on the market in EU by another applicant?

If so, include the applicant, date and marking of the consent, the country of submission and the period for which the consent applies

1.13 Information on whether the request (notification) for the placing of the same genetically modified organism or genetic product on the market was submitted in other country outside of EU

If so, include the country where the request (notification) was submitted, number or other marking of the request (date and marking of the consent, if issued), applicant, purpose and period of placing on the market

1.14 Summary of data obtained from the previous or running cases of the introduction of the same genetically modified organism or the same combination of genetically modified organisms into the environment on different conditions representing different environments where the genetically modified organism may be used

1.15 Supposed guidance and recommendations concerning the use, transportation, storing and other use of genetically modified organism (genetic product) including possible limitations that are proposed as conditions of the requested consent

1.16 Proposed method of packaging of the genetically modified organism or genetic product

1.17 Proposed method of labelling above the scope of the Act

1.18 Measures to be taken in the case of an accident or illegal use of the genetically modified organisms or genetic products

1.19 The method of waste management including the disposal of wastes containing genetically modified organisms

## **2. Information on the recipient or parental organism, if applicable**

2.1 Czech and Latin family and variety names of a recipient or parental organism including a precise determination of the race (strain, form, stock, cellular line, pathovar)

2.2 Origin (collection, collection number, supplier)

2.3 Phenotypic and genetic markers

2.4 Particular plasmids, bacteriophages and other vectors (when concerning microorganisms)

2.4.1 Sequences of the vector

2.4.2 Frequency of mobilisation of the vector

- 2.4.3 Specificity of the vector
- 2.4.4 Presence of genes that cause resistance of the vector to antibiotics
- 2.5 Degree of congeniality between donor organism and recipient
- 2.6 Occurrence and living conditions
  - 2.6.1 Geographical dissemination
  - 2.6.2 Habitat (natural occurrence) of the organism
  - 2.6.3 Natural predators, preys, parasites and competitors, symbionts and hosts
  - 2.6.4 Other potential interactions between other organisms
- 2.7 Genetic stability and affecting factors
- 2.8 Potential intercellular transfer of the heritable genetic material between the donor (parental organism) and other organisms
  - 2.8.1 The manner of transfer (by means of plasmid, bacteriophage, otherwise)
  - 2.8.2 Organisms with which the natural exchange of heritable genetic material occurs
  - 2.8.3 Consequences of such transfer
- 2.9 Reproduction
  - 2.9.1 Means of reproduction
  - 2.9.2 Specific factors that affect reproduction (if exist)
  - 2.9.3 Generation time in the natural environment and generation time in the ecosystem where the genetically modified organism is to be introduced
- 2.10 Survivability
  - 2.10.1 Survivability in the individual weather seasons
  - 2.10.2 Ability to form persistent surviving forms (e.g. spores, sclerotia)
  - 2.10.3 Other specific factors enhancing the survival, if exist
- 2.11 Spreading in the environment
  - 2.11.1 The manner and extent of the spreading
  - 2.11.2 Specific factors affecting the spreading (if exist)
- 2.12 Spectrum of hosts including the non-target organisms
- 2.13 Interactions with the environment
- 2.14 Involvement into the environmental processes
  - primary production
  - nutrient turnover (consumer, predator)
  - decomposition of organic matter
  - other (unambiguously specifying)
- 2.15 Methods of detection
  - 2.15.1 Description of methods
  - 2.15.2 Sensitivity, reliability (quantitatively) and specificity of the methods
- 2.16 Methods of identification
  - 2.16.1 Description of methods
  - 2.16.2 Sensitivity, reliability (quantitatively) and specificity of the methods
- 2.17 Classification of the organism pursuant to special legal regulations of the Czech Republic<sup>9)</sup> and EC regulations concerning the protection of environment or human health
- 2.18 Include if the organism is pathogenic or otherwise harmful (living or non-living including extracellular products) related to human, animals, plants or otherwise. If so, then unambiguously identify potential characteristics:
  - pathogenicity: epidemicity, infectiousness, virulence
  - allergenic effects
  - toxic effects
  - pathogen carrier,
  - possible vectors, host area including non-target organism,
  - potential activation of latent viruses (proviruses)

- potential ability to penetrate into other organisms or colonise them
- resistance to antibiotics and potential use of such antibiotics for prophylaxis and treatment human and animal diseases
- other

2.19 Nature and description of known extrachromosomal genetic particles

2.20 Description of previous genetic modifications of the organism

### **3. Information on the genetic modification**

3.1 Type of genetic modification

- introduction of the foreign heritable genetic material
- removal of a part of the heritable genetic material
- combination of removal and introduction of heritable genetic material
- cellular fusion
- other (unambiguously identify)

3.2 Description of methods used for the genetic modification

3.3 Information on the vector, if it was used during the genetic modification

3.3.1 Type of the vector

3.3.2 Identity of the vector (origin)

3.3.3 Description of the construction of vector

(+ genetic map or restriction map of the vector, as appropriate)

3.3.4 Sequence of the vector

3.3.5 Information on the degree to which the vector is limited to the sequence of the nucleic acid required to perform the intended function, and if the vector contains sequences, which product or functions are not known

3.3.6 Ability of the vector to transfer heritable genetic material

3.3.7 Frequency of the mobilisation of vector

3.3.8 Information on whether the vector is fully or partly present in the final genetically modified organism

3.3.9 Spectrum of the hosts of vector

3.3.10 Presence of the sequence of particular vector, which transfers the selectable or identifiable phenotype

- resistance to the antibiotics (identify the precise name of the active substance)
- resistance to heavy metals
- resistance to pesticides (identify the precise name of the active substance)
- other (unambiguously identify)

3.3.11 Method of introduction of the vector into the organism of recipient

### **4. Information on the insert**

4.1 If the vector has not been used in the genetic modification, method of the introduction of the insert into the organism of recipient

4.2 Methods used for construction of the insert

4.3 Restriction places

4.4 Sequence of the insert

4.5 Information on each part of the insert or on each removed part of heritable genetic material, as appropriate, with special emphasis on any known harmful sequences

4.5.1 Origin

4.5.2 Functional characteristic

4.5.3 Size

4.5.4 Location

#### 4.5.5 Sequence

4.6 Information on the degree to which the insert is limited to the sequence of the nucleic acid required to perform the intended function

4.7 Information on whether the insert contains parts, whose products or functions are not known

If so, then unambiguously identify

4.8 Placing the insert into the final genetically modified organism

- on the free plasmid
- integrated into chromosomes
- other (unambiguously identify)

4.9 Number of copies of the introduced heritable genetic material

4.10 Stability of the introduced heritable genetic material and the stability of its placing

### **5. Information on the donor organism (donor organisms)**

5.1 Czech and Latin family and variety names of an organism including a precisely determining the cultivar (species, race, strain, line, form, hybrid, stock, pathovar)

5.2 Include if the donor organism is pathogenic or otherwise harmful (living or non-living including extracellular products).

If so, then include whether it is related to human, animals, plants or otherwise. Always unambiguously identify the harmfulness

Are pathogenic or harmful properties concerning the sequences used during genetic modification?

If so, identify unambiguously possible characteristics:

- pathogenicity: epidemicity, infectiousness, virulence
- allergenic effects
- toxic effects
- pathogen carrier,
- possible vectors, host area including non-target organism,
- potential activation of latent viruses (proviruses)
- potential ability to penetrate into other organisms or colonise them
- resistance to antibiotics and potential use of such antibiotics for prophylaxis and treatment human and animal diseases
- other

5.3 Classification of the donor organism pursuant to valid legal regulations of the Czech Republic<sup>9)</sup> and EC regulations concerning the protection of the environment or human health

5.4 Information on whether the natural exchange of heritable genetic material between the donor organism and recipient occurs or whether it is possible

### **6. Information on the final genetically modified organism (genetically modified organism contained in the genetic product)**

6.1 Description of heritable genetic properties and phenotypic markers, if they are different from the recipient or parental organism

6.2 Genetic stability of genetically modified organism, if it differs from the stability of the recipient or parental organism

6.3 Expression of the introduced heritable genetic material

6.3.1 Rate and level of expression of the heritable genetic material, dependence on the life cycle, organs where the expression occurs

6.3.2 Stability of the expression

6.3.3 Description of methods and sensitivity of measurement

## 6.9 Expressed proteins

### 6.4.1 Activity of the expressed proteins

6.4.2 Description of the methods of identification and detection of expressed proteins and the data on sensibility, reliability and specificity of these methods

6.5 Methods and criteria used for the selection of the final genetically modified organism

6.6 Methods of detection of genetically modified organism in the environment, if they differ from the detection of the recipient or parental organism

6.7 Methods of identification for the selection of genetically modified organism from the recipient or parental organism

6.7.1 Description of methods for the detection of the presence of genetic modification including the verified methods of sampling and preparations of samples

6.7.2 Information on the specificity, sensitivity and reliability (quantitatively) of these methods

6.7.3 Description of the part of altered nucleic acid enhancing the unambiguous identification of genetically modified organism

## 6.8 Effects on the health

6.8.1 Toxic or allergenic effects of genetically modified organism and the metabolic products thereof, if they differ from the effects of the recipient or parental organism

6.8.2 Risks of the genetic product

6.8.3 Comparison of the genetically modified organism with the donor organism, recipient or parental organism, as appropriate, as regarding to the pathogenicity

6.8.4 Ability to colonise, if it differs from the recipient or parental organism

6.8.5 If the genetically modified organism is more pathogenic for immunocompetent people, than the recipient or parental organism, then include

- diseases that could be caused by genetically modified organism and the mechanism of pathogenicity including invasivity and virulence,
- infectiousness,
- infectious dose,
- area of hosts, potential adaptations,
- survivability except of human host,
- presence of transferers or dissemination agents,
- degree of biological stability,
- characteristic of the resistance to antibiotics,
- allergenicity,
- availability of the appropriate therapies,

6.8.6 Information on possible harmful effects of the genetically modified organism or genetic product on human health resulting from the genetic modification. Identify always unambiguously possible harmful effects,

6.8.7 Information on the safety of the genetically modified organism or genetic product for human health, particularly with regards to any harmful effects resulting from genetic modification, if the genetically modified product is to be used as a part of feedstuff, veterinary medicine etc.

## 6.9 Interaction of genetically modified organism with the environment

6.10 Survivability and reproducibility of the genetically modified organism and its ability to disseminate, if this ability differs from the ability of recipient or parental organism

6.11 Effects of genetically modified organism on the environment, if they differ from the effects of the recipient or parental organism and the potential consequences thereof

6.12 Czech and Latin family and variety names of an target organism, if exist, including a precisely determining the cultivar (species, race, strain, line, form, hybrid, stock, pathovar)

6.13 Mechanism of the interaction between the genetically modified organism or genetic product and the target organism, if this organism exist

6.14 Potential changes in the interactions of genetically modified organism or genetic product with non-target organisms, resulting from the genetic modification

6.15 Potential changes in the interactions of genetically modified organism or genetic product with non-living components of the environment, resulting from the genetic modification

6.16 Stability of the genetically modified organism regarding to its heritable genetic properties

6.17 Information on how the genetically modified organism differs from the recipient or parental organism. Identify unambiguously the differences

- means and rate of the reproduction, generation time
- dissemination in the environment
- survivability
- effects on the health of human beings, animals and other organisms
- other

6.18 Ability of the genetically modified organism to transfer genetic material to other organisms, and the consequences of such transfer

## **7. Expected behaviour of the genetic product, if it differs from the behaviour of the recipient or parental organism**

## **8. Information on previous introduction into the environment in the Czech Republic (if applicable)**

8.1 Authorised person

8.2 Date and number of the consent

8.3 Place of the introduction into the environment

8.4 Purpose of the introduction into the environment

8.5 Period of the introduction into the environment, date of its commencement and termination

8.6 Orientation and period of monitoring

8.7 Conclusions of monitoring

8.8 Results of the introduction into the environment with regard to any risks for the health of human beings and animals, the environment and biological diversity

## **9. Information on previous introduction into the environment or on the market in other countries**

9.1 Authorised person

9.2 Date and marking of the consent

9.3 Country

9.4 Responsible administrative body

9.5 Place, date of the commencement and termination of the introduction into the environment

9.6 Period, date of the commencement and termination of monitoring

9.7 Orientation of monitoring

9.8 Conclusions of monitoring

9.9 Results of the introduction into the environment or on the market, as appropriate, regarding to any risks for the health of human beings, animals, the environment and biological diversity

## **10. Information on previous use (research, development, utilisation) , which is important for risk assessment**

## **11. Monitoring plan**

11.1 Identified markers, properties and ambiguities related to the genetically modified organism or genetic product or their interactions with the environment, to which the plan of monitoring should be orientated

11.2 Provision, extent and manner of the monitoring the effects of genetically modified organism or genetic product on the health of human beings, animals, the environment and biological diversity (monitoring of the genetically modified organism or genetic product)

11.3 Provision, manner and frequency of the sampling and analysing the samples after the genetically modified organism or genetic product is placed on the market

## **12. Information on providing the reference samples of genetically modified organism or genetic product and storing them at the administrative body or at the legal person assigned by this body**

12.1 Specification and amount of the sample provided together with the request under § 24 par. 3 of the Act

12.2 Frequency and the manner of the transfer of samples after granting the consent for placing on the market

### PART C

#### OTHER REQUIREMENTS OF THE REQUEST FOR GENETICALLY MODIFIED HIGHER PLANTS OR GENETIC PRODUCTS CONTAINING THE GENETICALLY MODIFIED HIGHER PLANTS, AS APPROPRIATE

### **1. General description of genetically modified higher plant or genetic product and genetically modified higher plant contained in the genetic product**

1.1 Czech and Latin family and variety names of an organism including a precisely determining the cultivar (species, line, hybrid)

1.2 Inappropriate forms for placing of genetically modified organisms on the market (seeds, cutting flowers, vegetative parts etc), as the proposed condition for placing on the market

1.3 Intended use of genetically modified higher plant or genetic product and the target group of consumers

1.4 Conditions for the use, particularly differences between the use of genetically modified higher plant or genetic product and the use of similar non-modified organisms or products containing non-modified organisms including binding restrictions proposed as the conditions for the placing on the market

1.5 Unambiguous determination of the geographic area in the European Union, as appropriate, where the placing of genetically modified organism or genetic product shall be delimited

1.6 Type of the environment where the use of genetically modified organism (genetic product) is undesirable

1.7 Proposed manner of packaging of genetically modified higher plant or genetic product

1.8 Proposed method of labelling out of scope of the Act

1.9 Estimated annual demand

- in the Czech Republic
- in the European Union
- on the export markets

1.10 Unambiguous identification code of genetically modified higher plant

1.11 Has a request for the introduction of the same genetically modified higher plant or genetically modified higher plant contained in the genetic product into the environment in any Member State of EU been submitted?

If so, include the applicant, the number or other marking of the request (date and assigning of the consent, if was granted) and the country of the submission

If no, include the risk assessment of genetically modified higher plant pursuant to the requirements of the request for granting the consent for the introduction into the environment (part A, point 9 of Annex No. 2 to this Decree)

1.12 Is the applicant at the same time submitting a request for the placing of the same genetically modified higher plant or genetic product on the market in another Member State of EU?

If so, include the number or other marking of the request and the country of submission

If no, include the risk assessment of genetically modified higher plant pursuant to the requirements of the request for granting the consent for the introduction into the environment (part A, point 9 of Annex No. 2 to this Decree)

1.13 Information on whether the request (notification) for the placing of the same genetically modified higher plant or genetic product on the market was or is submitted in other country outside of EU

If so, include the applicant, number or other marking of the request (date and marking of the consent, if it was granted), the country of submission and the period for which the request applies (the period for which the consent was granted)

1.14 Was already previously the request for the placing of the same genetically modified higher plant or the same genetic product on the market in EU submitted?

If so, include the number or other marking of the request and the country where the request was submitted

1.15 Measures to be taken in the case of an accident or illegal use of the genetically modified higher plants or genetic products

1.16 The manner of waste management including the disposal of wastes containing the genetically modified organisms

1.17 Summary of data obtained from previous or running cases of the introduction of the same genetic modified organism or the same combination of genetic modified organisms into the environment in the different conditions representing different environments where the genetic organism can be used

## **2. Information on the recipient or parental organism, as appropriate**

2.1 Czech and Latin family and variety names of an organism including a precisely determining the cultivar (species, line, hybrid)

2.2 Origin (collection, number of the collection, supplier)

2.3 Reproduction

2.3.1 Means of reproduction

2.3.2 Specific factors that affect reproduction (if exist)

2.3.3 Generation time

2.3.4 Sexual compatibility with the other cultivated or uncultivated varieties and spreading of these compatible varieties in the Czech Republic

2.4 Survivability

2.4.1 Ability to form structures that enhance survival or dormance, and the time period of potential survival or dormance,

2.4.2 Other specific factors enhancing survival, if exist

2.5 Spreading in the environment

2.5.1 The manner and extent of the spreading (decrease of the amount of pollen and seeds in relation to the distance from the source, power and direction of wind and other factors)

2.5.2 Specific factors affecting the spreading (if exist)

2.6 Geographic spreading

2.7 If the higher plant is not cultivated in the Czech Republic, description of the habit including the information on natural consumers, pathogens, parasites, competitors and symbionts,

2.8 Further potential relevant interactions of the higher plant with the other organisms in the ecosystem where the higher plant is usually cultivated,

2.9 Include if the organism is pathogenic or otherwise harmful (living or non-living including extracellular products) related to human beings, animals, plants or otherwise.

If so, then unambiguously identify possible characteristics

- pathogenicity: epidemicity, infectiousness, virulence
- allergenic effects
- toxic effects
- pathogen carrier,
- possible vectors, host area including non-target organism,
- potential activation of latent viruses (proviruses)
- potential ability to penetrate into other organisms or colonise them
- resistance to antibiotics and potential use of such antibiotics for prophylaxis and treatment human and animal diseases
- other

2.10 Significant phenotypic and genetic markers

### **3. Information on the genetic modification**

3.1 Type of the genetic modification

- the introduction of foreign heritable genetic material
- removal of part of the heritable genetic material
- combination of removal and introduction of heritable genetic material
- cellular fusion
- other (necessary unambiguously identifying)

3.2 Description of methods used for the genetic modification

3.3 Properties and origin of the used vector (if a vector was used in the genetic modification)

(+ genetic map of the vector)

3.4 Information on each part of the DNA section, which is to be introduced into the organism of the recipient (if the introduction of heritable genetic material is included in genetic modification)

3.4.1 Size

3.4.2 Location

3.4.3 Sequence

3.4.4 Origin (Czech and Latin family and variety names of a donor organism including a precisely determining the cultivar (species, race, strain, line, form, hybrid, stock, pathovar)

3.4.5 Functional characteristic

### **4. Information on the genetically modified higher plant**

4.1 Description and characteristic of heritable genetic properties that are introduced or altered including the signal and selection genes and previous modifications and description of their phenotypic effects

4.2 Information on the DNA section, which was introduced or removed

- 4.2.1 Structure and size of the introduced section including the information on each section of the vector, which was introduced into the genetically modified higher plant, or on any carrier or foreign DNA that remained in the genetically modified higher plant
- 4.2.2 In the case of the removal of the part of heritable genetic material (deletion), the size and function of each part of removed section of nucleic acid
- 4.2.3 Placing of the introduced heritable genetic material in the plant cell (introduced into chromosomes, chloroplasts or in non-integrated form) and methods of determination of these data
- 4.2.4 Number of copies of the introduced heritable genetic material
- 4.2.5 Stability of the introduced heritable genetic material and stability of the placing thereof
- 4.2.6 In the case of other genetic modification than introduction or removal of a part of the heritable genetic material, describe the function of heritable genetic material prior and after the performance of modification and further describe direct changes in the expression of genes resulting from the modification
- 4.3 Information on the expression of introduced heritable genetic material
  - 4.3.1 Expression of introduced heritable genetic material and methods used for the characterisation thereof
  - 4.3.2 Place where the expression of introduced genes in the plant occurs (e.g. roots, stem, leaves, pollen etc.)
  - 4.3.3 Changes in the expression related to the life cycle of the plant
  - 4.3.4 Stability of the expression
- 4.4 Information on how genetically modified higher plants differ from the recipient or parental organism (identify always unambiguously the differences)
  - 4.4.1 Means and rate of reproduction
  - 4.4.2 Spreading in the environment
  - 4.4.3 Survivability
  - 4.4.4 Effects on the health of human beings, animals and other organisms
  - 4.4.5 Effect on non-target organisms
  - 4.4.6 Other
- 4.5 Ability of the genetically modified higher plant to transfer genetic material to other organisms and consequences of this transfer
- 4.6 Information on potential harmful effects of the genetically modified higher plant on human health resulting from the genetic modification. Potential harmful effects identify always unambiguously
- 4.7 Information on the safety of genetically modified higher plant for animal health, when the genetically modified higher plant is to be used as the feedstuff, if the safety of genetically modified higher plant differs from the recipient or parental organism
- 4.8 Mechanism of the interaction between the genetically modified higher plant and target organism (if a target organism exist), if the mechanism of interaction of the genetically modified higher plant differs from the recipient or parental organism
- 4.9 Potential changes in interactions of the genetically modified organism or genetic product with the non-target organisms, resulting from the genetic modification
- 4.10 Information for unambiguous identification of the genetically modified higher plant
  - 4.10.1 Description of a part of the altered DNA
  - 4.10.2 Methods of detection and identification of genetically modified higher plant, verified methodology of the sampling and processing of samples
- 4.11 Behaviour of the introduced genes
  - 4.11.1 during hybridisation with the same species
  - 4.11.2 during hybridisation with the distant species
- 4.12 Phenotypic stability of the genetically modified higher plant

## **5. Information on potential effects on the environment resulting from the use of genetically modified higher plants (identify always unambiguously potential effects)**

5.1 Potential effect on the environment resulting from the placing of genetically modified higher plant on the market

5.2 Potential effect on the environment resulting from the interaction between genetically modified higher plant and target organism (if exist), if it differs from the interaction of the recipient or parental organism, as appropriate

5.3 Potential effect on the environment resulting from the interaction between genetically modified higher plant and non-target organisms, if it differs from the interaction of the recipient or parental organism, as appropriate

5.3.1 Effects on the biological diversity in the place of cultivation

5.3.2 Effects on the biological diversity in the other environments

5.3.3 Effects on pollinators

5.3.4 Effects on endangered species

5.3.5 Potential interactions with the non-living components of the environment

## **6. Information on previous cases of the introduction of genetically modified higher plant into the environment**

6.1 Previous introduction into the environment carried out by the applicant in the Czech Republic

6.1.1 Date and number of the consent

6.1.2 Monitoring conclusions

6.1.3 Results of the introduction into the environment or market, as appropriate, with regard to any risks for the health of human beings and animals, the environment and biological diversity

6.2 Previous cases of the introduction into the environment or on the market carried out by the applicant in other countries

6.2.1 Country

6.2.2 Responsible administrative body

6.2.3 Date and marking of the consent

6.2.4 Place of the introduction into the environment

6.2.5 Purpose of the introduction into the environment

6.2.6 Period of the introduction into the environment

6.2.7 Period of monitoring

6.2.8 Orientation of monitoring

6.2.9 Monitoring conclusions

6.2.10 Results of the introduction into the environment or on the market, as appropriate, with regard to any risks for the health of human beings and animals, the environment and biological diversity

## **7. Monitoring plan**

7.1.1 Identified markers, properties and ambiguities related to the genetically modified higher plant or genetic product or their interactions with the environment, to which the plan of monitoring should be orientated

7.1.2 Provision, extent and manner of monitoring of the effects of genetically modified higher plant or genetic product on the health of human beings, animals, the environment and biological diversity (monitoring of the genetically modified organism or genetic product)

7.1.3 Provision, manner and frequency of sampling and analysing of the samples after the genetically modified higher plants or genetic product are placed on the market

**If the product contains more genetically modified organisms, the part B shall be necessary to elaborate or C for each genetically modified organism separately, as appropriate**

PART D

COMMON REQUIREMENTS FOR ALL THE REQUESTS

Opinion, date and signature of the professional consultant .....

Date, signature and stamp of the applicant .....

**Part A: Requirements for the contained space and protective measures for microbiological laboratories**

Hygienic airlock means the entry to the laboratory through separated spaces, whose so called clean side must be separated from the laboratory by safety doors, cloakroom for changing clothes and shower.

Standard operation procedure means the procedure enabling the safe transfer of material to the sterilisation equipment outside the laboratory and providing the same level of protection as the laboratory.

Protective clothes mean for example work cotton cover, PVC protective apron, rubber-textile protective apron, special PE overalls, high pressure protective clothing, work coat with cold protective lining, work cold protective coat with cape, protective raincoat, work cotton trousers, boiler suit, grating for head, protective hat.

Protective footwear means for example gum boots, golosh, closed work boots - type of ankle boots, closed toes sandals, medical sandals.

Personal protective work aids mean for example cotton gloves, latex gloves, PE disposable gloves, nitrilic gloves or requirement for the sterility of gloves – disposable vinyl gloves, protective goggles, goggles for dust protection, face shield, filtering mask to protect against particles (mouthpiece assembly), filtering half masks to protect against solid particles (with or without expiratory valve), filtering half mask or quarter mask, face filtering mask (necessary specify the subject of filtration), isolation non-autonomous breathing apparatus (hose), autonomous breathing apparatus.

		<b>For the risk category</b>			
		<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
	<b>Contained space</b>				
1	Isolation inside the building or placed in a separated building	Not required	Isolation inside the building	Isolation inside the building	Required to be placed in a separated building
2	Sealable for fumigation	Not required	Not required	Required	Required
	<b>Equipment</b>				
3	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required for work area, floor and walls	Required for work area, floor and walls	Required for work area, floor and walls	Required for work area, floor, walls and ceiling
4	Entry to work area via airlock	Not required	Required only if resulting from the risk assessment	Required	Required
5	Negative pressure relative to the pressure of the immediate	Not required	Not required	Required	Required

	environment				
6	Extract and input air from the laboratory should be HEPA-filtered	Not required	Not required	Required for extract air	Required: when working with viruses, special measures must be taken against spreading of viruses
7	Sterile box – separated room	Not required	Required only if resulting from the risk assessment	Required	Required
8	Autoclave	In the building	In the building and in compliance with the standard operation procedure (see above)	In the contained space	In the laboratory, double ended (inserted between clean and dirty department)
	<b>System of work</b>				
9	Restricted access	Not required	Not required	Required	Required
10	Biohazard <sup>7)</sup> sign on the door	Not required	Required	Required	Required
11	Specific measures to control aerosol dissemination	Not required	Required: minimise spreading	Required: prevent spreading	Required: prevent spreading
12	Shower	Not required	In the building	Required	Required
13	Protective clothing and footwear	Suitable protective clothing (particular type and frequency of change depends on the risk assessment)	Suitable protective clothing (particular type and frequency of change depends on the risk assessment), protective footwear required if resulting from the risk assessment	Suitable protective clothing and footwear (particular type and frequency of change depends on the risk assessment)	Complete change of clothing and footwear before entry and exit (particular types and manner of handling with clothing, underwear and footwear during collection depends on

<sup>7)</sup> Government Order No. 11/2002 Coll., laying down visual aspect and placing of safety marks and introduction of signals

					the risk assessment)
14	Personal protective work aids	Required if resulting from the risk assessment	Required (particular type and frequency of change depends on the risk assessment)	Required protective gloves and other personal protective work aids under risk assessment (frequency of change depends on the risk assessment)	Required protective gloves, protective goggles and other personal protective work aids under risk assessment (frequency of change depends on the risk assessment)
15	Efficient vector control and elimination thereof (e.g. for insects and rodents)	Required	Required	Required	Required
	<b>Waste</b>				
16	Inactivation of genetically modified organisms in effluent from hand-washing sinks or drains and showers and similar effluents	Required if resulting from the risk assessment	Required	Required	Required
17	Inactivation of genetically modified organisms in used material and waste pursuant to special legal regulations <sup>8)</sup>	Required	Required including disinfection of protective clothing	Required including disinfection of protective clothing, footwear and other personal protective work aids	Required including disinfection of protective clothing, footwear and other personal protective work aids
	<b>Other measures</b>				
18	Laboratory to contain its own equipment	Required	Required	Required	Required
19	An observation window or alternative is to be present so that occupants can be seen	Required only if resulting from the risk assessment	Required only if resulting from the risk assessment	Required	Required

<sup>8)</sup> For example Act No. 185/2001 Coll. as later amended

20	Recuperation room outside of work area	Not required	Required only if resulting from the risk assessment	Required	Required
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**Part B: Containment requirements and protective measures for glasshouses and growth-rooms**

Glasshouse and growth-room mean a contained structure with walls, floor and roof (ceiling) designed and used principally for growing plants. If other genetically modified organisms than plants are also used in the glasshouse, the glasshouse must comply with conditions set up for the particular workplace (e.g. in part A of this Annex, in the case of genetically modified micro-organisms or in part C of this Annex, in the case of genetically modified animals).

Airlock means an entry to the glasshouse or growth-room through isolated chambers, whose clean side is separated from the laboratory by safety doors, cloakroom for change of clothing and shower.

Standard operation procedure means a procedure enabling the safe transfer of material into the sterilisation facility outside the glasshouse or growth-room, and ensuring the same level of protection as these structures.

Protective clothing means for example work cotton cover, PVC protective apron, rubber-textile protective apron, special PE overalls, high pressure protective clothing, work coat with cold protective lining, work cold protective coat with cape, protective raincoat, work cotton trousers, boiler suit, grating for head, protective hat.

Protective footwear means for example gum boots, golosh, closed work boots - type of ankle boots, closed toes sandals, medical sandals.

Personal protective work aids mean for example cotton gloves, latex gloves, PE disposable gloves, nitrilic gloves or requirement for the sterility of gloves – disposable vinyl gloves, protective goggles, goggles for dust protection, face shield, filtering mask to protect against particles (mouthpiece assembly), filtering half masks to protect against solid particles (with or without expiratory valve), filtering half mask or quarter mask, face filtering mask (necessary to specify the subject of filtration), isolation non-autonomous breathing apparatus (hose), autonomous breathing apparatus.

		<b>For the risk category</b>			
		<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
	<b>Contained space</b>				
1	Glasshouse or growth-room are resistant against regional weather extremes	Not required	Required	Required	Required
2	Isolation inside the building or location in the special building	Not required	Required only if resulting from the risk assessment	Required only if resulting from the risk assessment	Required placing in the special building
3	Sealable for fumigation	Not required	Not required	Required	Required
4	Entry into work structure via	Not required	Required	Required entry via	Required entry via

	separated room with two interlocking doors			airlock	airlock
5	Negative pressure relative to the pressure of the immediate environment	Not required	Not required	Required	Required
6	Extract and input air from the laboratory should be HEPA-filtered by aerosol	Not required	Not required	Required for extract	Required
7	Autoclave	In the facility	In the building	In the building in compliance with the standard operation procedure (see above)	In containment and inserted between clean and dirty part
	<b>System of work</b>				
8	Restricted access	Not required	Required	Required	Required
9	Biohazard sign <sup>13)</sup> on the door	Not required	Required	Required	Required
10	Shower	Not required	In the building	Required	Required
11	Protective clothing and footwear	Suitable protective clothing (particular type and frequency of change depends on the risk assessment)	Suitable protective clothing (particular type and frequency of change depends on the risk assessment), protective footwear required only if resulting from the risk assessment	Suitable protective clothing and footwear (particular type and frequency of change depends on the risk assessment)	Complete change of clothing and footwear before entry and exit (particular types and manner of handling with clothing, underwear and footwear during collection depends on the risk assessment)
12	Personnel protective work aids	Required if resulting from the risk assessment	Required (particular type and frequency of change depends on	Required protective gloves and other personal protective work aids	Required protective gloves and other personal protective work aids

			the risk assessment)	under risk assessment (frequency of change depends on the risk assessment)	under risk assessment (frequency of change depends on the risk assessment)
	<b>Waste</b>				
13	Inactivation of genetically modified organisms in effluent from hand-washing, sinks or drains and showers and similar effluents pursuant to special legal regulations <sup>14)</sup>	Required only if resulting from the risk assessment	Required	Required	Required
14	Inactivation of genetically modified organisms in the used material and solid waste pursuant to special legal regulations <sup>14)</sup>	Required	Required including disinfection of protective clothing	Required including disinfection of protective clothing, footwear and other personnel work aids	Required including disinfection of protective clothing, footwear and other personnel work aids
	<b>Other measures</b>				
15	Restriction of occurrence of undesirable animals, insects, rodents etc by means of regular efficient treatment of facilities and equipment	Required	Required	Required preventing the occurrence	Required preventing the occurrence
16	Glasshouse or growth-room has its own equipment	Required	Required	Required	Required
17	Discharge only into sink where is inactivated under point 13	Required only if resulting from the risk assessment	Required restriction of discharges outside sinks to minimum	Required prevention of discharges outside sink	Required prevention of discharges outside sink
18	Treatment of waste soil in the autoclave or hot-air sterilisers	Not required	Required only if resulting from the risk assessment	Required	Required
19	The manner of transferring organisms into other	Required restriction of dissemination	Required prevention of dissemination	Required prevention of dissemination	Required prevention of dissemination

	facilities must enable to control dissemination of genetically modified organisms	to minimum outside the structures in which the organism is transferred	outside the structures in which the organism is transferred	outside the structures in which the organism is transferred	outside the structures in which the organism is transferred
20	Recuperation room	Not required	Required only if resulting from the risk assessment	Required	Required

### **Part C: Requirements for the containment and protective measures for animal use facilities**

If other genetically modified animals are also used in animal use facilities, the glasshouse must also comply with the requirements set up for the particular workplace (e.g. in part A of this Annex in the case of genetically modified micro-organisms, or in part B of this Annex in the case of genetically modified plants).

In the case of clinical assessment of human or veterinary medicaments containing genetically modified organisms, the requirements for containment and protective measures pursuant to special legal regulations<sup>9)</sup> shall be applied.

Animal unit means a separate building or separate area within a building containing facilities for animals and other areas (e.g. stores for feedstuff, beddings and aids), including equipment for stuff (e.g. changing rooms, showers, sterilisers, spaces for food storage etc).

Animal facility means a facility and equipment specialised depending on the type of animals for their breeding and carrying out experimental manipulations.

Isolator means a transparent box where small animals are contained; for large animals, isolated rooms are more appropriate.

Protective clothing means for example work cotton cover, PVC protective apron, rubber-textile protective apron, special PE overalls, high pressure protective clothing, work coat with cold protective lining, work cold protective coat with cape, protective raincoat, work cotton trousers, boiler suit, grating for head, protective hat.

Protective footwear means for example gum boots, golosh, closed work boots - type of ankle boots, closed toes sandals, medical sandals.

Personal protective work aids mean for example cotton gloves, latex gloves, PE disposable gloves, nitrilic gloves or requirement for the sterility of gloves – disposable vinyl gloves, protective goggles, goggles for dust protection, face shield, filtering mask to protect against particles (mouthpiece assembly), filtering half masks to protect against solid particles (with or without expiratory valve), filtering half mask or quarter mask, face filtering mask (necessary specify the subject of filtration), isolation non-autonomous breathing apparatus (hose), autonomous breathing apparatus.

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<sup>9)</sup> for example Act No. 79/1997 Coll. on medicinal substances and amending and supplementing some related Acts as amended by Act No. 149/2000 Coll., Act No. 153/2000 Coll., Act No. 258/2000 Coll., Act No. 102/2001 Coll., Act No. 138/2002 Coll., Act No. 309/2002 Coll., Act No. 320/2002 Coll., Act No. 129/2003 Coll. and Act No. 274/2003 Coll., Decree No. 472/2000 Coll. as amended by Decree No. 301/2003 Coll.

Besides the requirements set up by special legal regulations<sup>10)</sup> the use facilities for animals must comply with the provisions as follows:

		<b>For the risk category</b>			
		<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
1	Animal unit is an isolated unit	Required only if resulting from the risk assessment	Required	Required	Required
2	Animal facilities separated by lockable doors	Required only if resulting from the risk assessment	Required	Required	Required
3	Animal facilities and auxiliary areas done to be easily cleanable and decontaminable (materials waterproof, easily washable and disinfectable)	Required	Required	Required	Required
4	Floor and/or walls in the rooms easily washable	Required only if resulting from the risk assessment	Required for floor	Required for floor and walls	Required for floor and walls
5	Animals kept in appropriate containment facilities such as cages, pens or tanks	Required	Required	Required	Required
6	Filters on isolators or isolated room	Not required	Required only if resulting from the risk assessment	Required	Required
7	If products derived from animals are used, the requirements for control (e.g. veterinary hygienic control) must be met	Required	Required	Required	Required
8	Shower	Not required	In the	Required	Required

<sup>10)</sup> for example Act No. 246/1992 Coll. as last amended, Decree No. 311/1997 Coll., Act No. 166/1999 Coll. as last amended, Act No. 20/1966 Coll. on human health care as amended by Act No. 210/1990 Coll., Act No. 425/1990 Coll., Act No. 548/1991 Coll., Act No. 550/1991 Coll., Act No. 590/1992 Coll., Act No. 15/1993 Coll., Act No. 161/1993 Coll., Act No. 307/1993 Coll., Act No. 60/1995 Coll., Act No. 206/1996, Act No.14/1997 Coll., Act No. 79/1997 Coll., Act No. 110/1997, Act No. 83/1998 Coll., 167/1998 Coll., Act No. 71/2000 Coll., Act No. 123/2000 Coll., Act No. 132/2000 Coll., Act No. 149/2000 Coll., Act No. 258/2000 Coll., Act No. 164/2001, Act No. 260/1991 Coll., Act No. 285/2002 Coll., Act No. 290/2002 Coll., Act No. 320/2002 Coll., Act No. 130/2003 Coll., Act No. 274/2003 Coll. and Act No. 356/2003 Coll.

			building		
9	Protective clothing and footwear	Suitable protective clothing (particular type and frequency of change depends on the risk assessment)	Suitable protective clothing (particular type and frequency of change depends on the risk assessment), protective footwear required if resulting from the risk assessment	Suitable protective clothing and footwear (particular type and frequency of change depends on the risk assessment)	Complete change of clothing and footwear before entry and exit (particular types and manner of handling with clothing, underwear and footwear during collection depends on the risk assessment)
10	Personal protective work aids	Required if resulting from the risk assessment	Required (particular type and frequency of change depends on the risk assessment)	Required protective gloves and other personal protective work aids under risk assessment (frequency of change depends on the risk assessment)	Required protective gloves and other personal protective work aids under risk assessment (frequency of change depends on the risk assessment)
11	Recuperation room	Not required	Required only if resulting from the risk assessment	Required	Required
<b>In the case of use facilities for water animals</b>					
12	Inactivation of animals in wastewater	Required	Required	Require	Required
13	Construction of the room so that prevent in the case of rupture, leakage or overflow of the tank for animals any release to the sewerage, surface or ground water	Required in case of potential release of organisms	Required in case of potential release of organisms	Required in case of potential leakage of water	Required in case of potential leakage of water

**Part D: Requirements for containment and other protective measures for other activities (e.g. production plants, pilot plants)**

A contained system means an installation permanently located in a contained space intended for the storage and cultivation of genetically modified organisms, usually in large volumes.

An airlock means entrance to the contained space through separated spaces. Their "clean" side shall be separated from the contained space by safety doors, a changing room for changing clothing and a shower.

Protective clothes means for example work cotton cover, PVC protective apron, rubber-textile protective apron, special PE overalls, high pressure protective clothing, work coat with cold protective lining, work cold protective coat with cape, protective raincoat, work cotton trousers, boiler suit, grating for head, protective hat.

Protective footwear means for example gum boots, golosh, closed work boots - type of ankle boots, closed toes sandals, medical sandals.

Personal protective work aids mean for example cotton gloves, latex gloves, PE disposable gloves, nitrilic gloves or requirement for the sterility of gloves – disposable vinyl gloves, protective goggles, goggles for dust protection, face shield, filtering mask to protect against particles (mouthpiece assembly), filtering half masks to protect against solid particles (with or without expiratory valve), filtering half mask or quarter mask, face filtering mask (necessary specify the subject of filtration), isolation non-autonomous breathing apparatus (hose), autonomous breathing apparatus.

		<b>For the risk category</b>			
		<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
	<b>Contained space</b>				
1	Viable organisms should be contained in closed system which separates the process from the environment	Required only if resulting from the risk assessment	Required	Required	Required
2	Control of dissemination of aerosols escaping from the closed system	Not required	Required limitation of dissemination to minimum	Required prevention of dissemination	Required prevention of dissemination
3	Control of aerosols during sample collection, addition of materials to a closed system or transfer of material to another closed system	Required only if resulting from the risk assessment	Required limitation of dissemination to minimum	Required prevention of dissemination	Required prevention of dissemination
4	Inactivation of bulk culture fluids before removal from the closed system	Necessary inactivation by means of chemical or physical	Necessary inactivation by means of chemical or physical	Necessary inactivation by means of chemical or physical	Necessary inactivation by means of chemical or physical

		method	method	method with proven 100 % efficiency	method with proven 100 % efficiency
5	Seals should be designed to prevent dissemination of organisms from the closed system	Required limitation of dissemination to minimum	Required prevention of dissemination	Required prevention of dissemination	Required prevention of dissemination
<b>Other requirements for the contained space</b>					
6	The controlled area should be designed (capture tank) to contain spillage of the entire contents of the closed system	Required only if resulting from the risk assessment	Required	Required	Required
7	The controlled area should be sealable to permit fumigation	Not required	Required only if resulting from the risk assessment	Required only if resulting from the risk assessment	Required
8	Entry via airlock	Not required	Not required	Required only if resulting from the risk assessment	Required
9	Surfaces easily cleanable, resistant to water, acids, alkalis, solvents enabling effective disinfection and decontamination	Required for work place, floor and walls	Required for work place, floor and walls	Required for work place, floor and walls	Required
10	Specific measures to adequately ventilate the controlled area in order to minimise air contamination	Required only if resulting from the risk assessment	Required only if resulting from the risk assessment	Required	Required
11	The controlled area should be maintained at an air pressure negative to the immediate surroundings	Not required	Not required	Required	Required
12	Extract and input air from the controlled area should be HEPA filtered	Not required	Not required	Required for the extract and input air only if resulting from the risk assessment	Required for the extract and input air
<b>System of work</b>					
13	The entire closed system should be	Not required	Required only if resulting	Required	Required

	located within a contained space		from the risk assessment		
14	Access should be restricted to nominated personnel only	Required	Required	Required	Required
15	Biohazard signs “Biological Hazard” <sup>13)</sup> should be posted	Not required	Required	Required	Required
16	Personnel should shower before leaving the controlled area	Not required	Not required	Required	Required
17	Personnel should wear protective clothing and/or footwear	Suitable protective clothing (particular type and frequency of change depends on the risk assessment)	Suitable protective clothing (particular type and frequency of change depends on the risk assessment), protective footwear required if resulting from the risk assessment	Suitable protective clothing and footwear (particular type and frequency of change depends on the risk assessment)	Required protective clothing and footwear (particular type depends on the risk assessment) with complete change of clothing and footwear before entry and exit (the manner of handling with clothing, underwear and footwear during collection depends on the risk assessment)
18	Personnel protective work aids	Required only if resulting from the risk assessment	Required (particular type and frequency of change depends on the risk assessment)	Required protective gloves and other personnel protective work aids under risk assessment (frequency of change)	Required protective gloves and other personnel protective work aids under risk assessment (frequency of change)

				depends on the risk assessment)	depends on the risk assessment)
<b>Wastes</b>					
19	Inactivation of genetically modified organisms in effluent from hand washing sinks and showers or similar effluents	Required only if resulting from the risk assessment	Required	Required	Required
20	Disinfection of work clothing and footwear and individual protective aids after use	Required only if resulting from the risk assessment	Required	Required	Required
21	Inactivation of genetically modified organisms in used contaminated material and in liquid and solid wastes during the process pursuant to special legal regulations <sup>14)</sup>	Necessary inactivation by means of physical or chemical method	Necessary inactivation by means of physical or chemical method	Necessary inactivation by means of chemical or physical method with proven 100 % efficiency	Necessary inactivation by means of chemical or physical method with proven 100 % efficiency
<b>Other measures</b>					
22	Recuperation room	Not required	Required only if resulting from the risk assessment	Required	Required

## JUSTIFICATION

### I. COMMON PART

#### **a) Explanation of the necessity of proposed legal regulation**

The draft decree is an implementing legal regulation to Act No. 78/2004 Coll. on the use of genetically modified organisms and genetic products (hereinafter the “Act”).

Provision of § 38 in the Act empowers the Ministry of the Environment to issue the decree stipulating requirements of the requests for granting consents for contained use and introduction into the environment, the requirements for summary of the contents of the request, the requirements of the notification the contained use in the first and second risk category, the requirements and procedures of the risk assessment, threshold minimum of unavoidable traces, the requirements for contained space and protective measures, the manner and the scope of keeping records, the requirements for the Emergency Response Plan and for the assessment report. In particular, the Decree aims to implement § 5 paragraphs 1 and 4, § 7 par. 7, § 11 par. 3, § 16 paragraphs 2 and 3, § 19 letter b), § 20 par. 4 and § 24 par. 17.

The Act that shall be implemented by means of this Decree was gradually amended during preparing and approval. The original objective to work up only an amendment to previous valid Act No. 153/2000 Coll. on the use of genetically modified organisms and products and amending some related Acts, as later amended, proved to be insufficient. To comply with the requirement for full compatibility of new law with the law of European Communities a whole new Act was prepared and approved. The preparing process obviously reflected these changes. Submitted version of the Decree reflects not only the new wording of the Act but also the newest scientific knowledge from the area of the use of genetically modified organisms.

Submitted Decree includes four annexes, three of which are conceived as standard samples of submission. The purpose of these annexes is to facilitate communication between particular administrative authority and applicant, since the use of standard sample may facilitate the position of an applicant and prevent useless returning of unsatisfactory requests.

#### **b) Contents of the proposed legal regulation**

The submitted decree lays down in details:

- Requirements on the requests for the use of genetically modified organisms and genetic products and the requirements on the notifications the contained use of genetically modified organisms as well,
- Requirements on summary the contents of requests, which is issued
- Requirements and procedures of the risk assessment,
- Requirements on the containment and protective measures for microbiological laboratories, glasshouses and growth rooms, use facilities for animals and for other activities,
- The manner and scope of keeping documentation on the use of genetically modified organisms,
- The requirements on the Emergency Response Plan
- The requirements of an assessment report

Standard requests shall be based on:

COUNCIL DECISION (2002/813/EC), establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notification concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market

COUNCIL DECISION (2002/812/EC), establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary information format relating to the placing on the market of genetically modified organisms as or in products

#### **c) The evaluation of the compliance of proposed legal regulation with legal regulations of the Czech Republic**

The proposed Decree is based on the authorisation laid down in § 38 of the Act. The draft Decree is fully complied with the system of law of the Czech Republic.

#### **d) The evaluation of the compliance with the international treaties and with the legal acts of European Communities**

Draft Decree complies with the law of European Communities. The Decree is fully consistent with Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms, as amended by Commission Directive 94/51/EC, Council Directive 98/81/EC and Council Decision 2001/204/EC, and with Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

Requirements for the requests given in the Draft Decree correspond with the requirements set up by Council Decision (2002/813/EC) establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market, and by Council Decision (2002/812/EC) establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products.

Requirements and procedures of the risk assessment correspond with Commission Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, and with Commission Decision (2000/608/EC) concerning the guidance notes for risk assessment outlined in Annex III of Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

#### **e) Effect of the proposed law on the State Budget and on the budgets of autonomous territorial entities**

State Budget requirements have been stipulated according to law. In the case of the proposed Decree the financial expenses relating to its implementation may be included in the costs intended for current administration of the state administrative bodies.

In the area of private sector, costs for elaborating the risk assessment and the entire documentation on the use of genetically modified organisms are involved. Thus based on the

submitted proposal of the implementing Decree there shall be no additional expenses of a significant amount.

## **2. SPECIAL PART**

### **Ad § 1**

The scope of the Act regarding to the legal regulations of European Communities shall be specified.

### **Ad § 2**

The basic terms further used in the text shall be defined.

### **Ad § 3**

The Act stipulates in § 5 par. 1 the basic requirements on the request for granting the consent for contained use of genetically modified organisms, on the consent for the introduction of genetically modified organisms into the environment, and on the registration of genetically modified organisms into the List for placing on the market, then in § 16 paragraphs 1 and 2 the basic requirements on the notification the contained use for the first and second risk category. These requirements should be stipulated directly by the Act regarding to the requirements on the protection of personal data that have been laid down by special legal regulation. The submitted detailed implementing legal regulation stipulates other requirements on the request necessary for the evaluation of the use of genetically modified organism or genetic product regarding to the protection of health and the environment.

### **Ad § 4**

Provision is connected to § 5 par. 4 of the Act stipulating that the Ministry shall publish the summary contents of request on the Internet provided that the request for granting authorisation to use genetically modified organisms and genetic products complies with the all prescribed requirements.

### **Ad § 5**

The risk assessment shall be one of the basic documents for making decision on granting an authorisation to use genetically modified organisms and genetic products and therefore it is an obligatory requirement on the request for granting the authorisation to use of genetically modified organisms and on the notification the contained use in the first and second risk category as well (§ 7 of the Act). The provision complements the Act by specifying potential effects of the use of genetically modified organism or genetic product and laying down the detailed procedure and criteria of the assessment of risk arising from the use.

### **Ad § 6**

A set threshold minimum shall arise from the value given in Article 21 par. 3 of the Directive 2001/18/EC of the European Parliament and the Council amended by Regulation 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

### **Ad § 7**

The contained use of genetically modified organisms shall be carried out only in such closed space, which complies with the requirements on the containment and protective measures laid down for particular or higher risk category ((§ 15 par. 2 of the Act). These requirements are laid down here by referencing the Annex No. 4 of the Decree.

### **Ad § 8**

Every person authorised to contained use or to introduction into the environment shall be obliged to keep documents on such use (§ 19 letter b) of the Act). All parts of this documentation shall be strictly determined in par. 1. Other paragraphs of this provision specify the handling with documentation whether it considers the filing, keeping and storing (par. 2), keeping a factory journal (paragraphs 3, 4 and 5), the manner and requirements on making record (par. 6) or the handling with data stored in electronic form (par. 7).

Documentation on the use of genetically modified organisms shall be concluded by the final report including prescribed requirements, which shall be evaluated by professional consultant.

### **Ad § 9**

The requirement for elaborating the Emergency Response Plan shall be based on the precautionary principle. The Act stipulates the basic requirements of the Emergency Response Plan in § 20, while all other requirements are stipulated in this provision.

### **Ad § 10**

This provision stipulates some most important requirements on the assessment report to be elaborated by the Ministry of the Environment as a one of basic documents for the proceedings concerning the submitted request for the placing genetically modified organism or genetic product on the market at the level of European Community (§ 24 of the Act).

### **Ad § 11**

The regulations up to now valid shall be cancelled and replaced by the submitted law.

### **Ad § 12**

The effectiveness of the Decree shall be proposed with regard to the date of effectiveness of the Act to the day of its declaration in the Collection of Law.

### **Ad Annex No. 1 to the Draft Decree**

Authorisation to contained use as concerning this Annex shall arise on the base of two quite different institutions – notification and consent, thus in direct connection with the degree of risk for human an animal health, for the components of the environment or biological diversity that obviously results from the contained use and therefore in the connection with the risk category (§ 15 of the Act). While in the case of the contained use in the first or second risk category (contained use in a risk type of lowest degree) the authorisation arises directly based on single legal act of a notifier (although in the different way in both cases), in the case of contained use in the third or fourth risk category the natural person authorised to operate business or legal person are authorised to start contained use only after granting the consent by means of general procedure under § 5 of the Act, and subsidiary pursuant to the Code of Administrative Procedure ((§ 36 of the Act). This provision shall arise from the requirements of Council Directive 98/81/EC.

Annex is divided into two parts. Part A stipulates requirements on the notification the contained use in the first and second risk category. This part is subsequently divided to section1 that contains general requirements of the request commonly for both risk categories, section 2 that stipulates other requirements of the notification for the first risk category and section 3 that contains other requirements of the notification for the second risk category. The different degree of risk of individual methods of contained use is connected with the different level of requirements laid down for the notifier.

The second part of the Annex stipulates requirements on the request for granting consent to contained use.

Requirements on the requests in this Annex and also in the other Annexes shall comply with the Council decision and they are included in the common part of the justification.

**Ad Annex No. 2 to the Draft Decree**

Requirements on the request for granting the consent for introduction of genetically modified organisms into the environment are included.

**Ad Annex No. 3 to the Draft Decree**

Prescribed requirements on the request for registration into the List of genetically modified organisms and genetic products approved to be placed on the market are included.

**Ad Annex No. 4 to the Draft Decree**

Requirements on the contained space and protective measures for microbiological laboratories, glasshouses and growth rooms, use facilities for animals and requirements on the containment and other protective measures for other activities, e.g. production and pilot plants, are stipulated.

Prague on the day .....

Minister by own hand .....