DECREE

No. 209/2004 Coll.

of 15 April 2004

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

as amended by Decree No. 86/2006 Coll., No. 29/2010 Coll. and 372/2016 Coll.

The Ministry of the 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

The Decree in accordance with the law of the European Union[1)] lays down detailed conditions for the use of genetically modified organisms and genetic products as follows:

a) examples of notification of classes 3 or 4 of the contained use, notification of the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market, and notification for the registration into the List of genetically modified organisms and genetic products authorised to be placed on the market (hereinafter "the List for placing on the market"),

b) requirements for the summary content of notification for the deliberate release into the environment, and for the registration into the List of genetically modified organisms and genetic products authorised to be placed on the market,

c) requirements and procedures for risk assessment,

d) threshold minimum of traces,

e) requirements for work area and protective measures of contained use,

f) example of notification formats on the first and second class of the contained use,

g) example of risk assessment for the first and second class of the contained use pursuant to the § 16a paragraph 4 of the Act,

h) manner and scope of keeping records in the dossier,

i) example of Emergency Response Plan and the scope of information released by the Ministry

j) requirements for the Assessment report.

§ 2

Definitions

For the purposes of this Decree:

a) "Recipient" means an organism, into whose heritable genetic material a heterogeneous heritable material has been introduced by genetic modification,

b) donor means an organism, from whose heritable genetic material comes a heritable genetic material introduced into the genetic material of a recipient,

c) parental organism means an organism, from whose heritable genetic material a part of the heritable genetic material has been extracted by genetic modification,

d) target organism means an organism whose effect on a genetically modified organism should be influenced by genetic modification,

e) vector means a non-cellular entity containing a heritable genetic material and capable of insertion of this heritable genetic material together with the inserted heterogeneous heritable genetic material into the cells of a recipient,

f) therapeutic vector means a non-cellular entity, particularly a plasmid or a transposon, containing a heritable genetic material and capable of insertion this heritable genetic material into cells of treated organism, into which is applied for the purpose of gene therapy,

g) insert - heterogeneous heritable genetic material inserted into the heritable genetic material of a recipient,

h) construct - artificially modified molecule of nucleic acid,

i) signal gene - gene contained in the construct that determines an easily detectable trait of the cells or organism containing a functional construct,

j) selection gene - gene contained in the construct and determining the lack of sensitivity to a certain substance or to an influence preventing the multiplication of cells that do not contain this gene,

k) higher plant - gymnosperms (Gymnospermae) and angiosperms (Angiospermae).

§ 3

Examples of notifications, applications and other documents

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

1) Example

a) notification of the contained use is included in the Annex 1, part A to this Decree

1. in section 1 in case of the notifications of the first class of contained use

2. in section 3 in case of the notifications of the second class of contained use

3. in section 4 in case of the notifications of the second class of contained use submitted pursuant the § 16a paragraphs 5 of the Act

b) risk assessment for the first class of the contained use submitted pursuant to the § 16a paragraphs 4 of the Act is included in Annex 1, part A, section 2 to this Decree

c) notifications of the 3rd and 4th class of contained use are included in Annex 1, part B to this Decree,

d) risk assessment procedures of the contained use is included in Annex 1, part C to this Decree,

e) notification of deliberate release into the environment is included in Annex 2 to this Decree

1. in section 1, part A in case of the genetically modified organism other than higher plant

2. in section 2, part A in case of the genetically modified organism that is a higher plant

3. in part B in case of genetically modified organism deliberately released into the environment for the purpose of clinical assessment of medicinal preparations

f) notification of the registration into the List for placing on the market is included in Annex 3 to this Decree

1. in part A in case of the genetically modified organism other than higher plant or genetic product other than containing genetically modified higher plant,

2. in part B in case of genetically modified organism that is a higher plant or genetic product containing genetically modified higher plant.

2) Notifications and risk assessment shall be submitted in structuring as presented in Annexes 1, 2 and 3 to this Decree. In case of dossier submitted on a technical data porter or in electronic version text documents shall be saved in "Rich Text Format" (RTF format), graphic documents (plans, maps, scanned documents etc.) in JPG format; in both cases "Portable Document Format" (PDF format) may be used.

3) If the notification is submitted for more genetically modified organisms (§ 18 paragraph 3 of the Act), all required data must be included separately for every genetically modified organism.

§ 4

Requirements for the summary of notification made available to the public

(ad § 5 paragraph 4 of the Act)

Requirements for summary of the notification of deliberate release into the environment and notification of the registration into the List for placing on the market are included in Annexes 2 and 3 to this Decree.

§ 5

Risk assessment requirements and procedures

(ad § 7 paragraph 6 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

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

h) 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,

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

j) delayed – effects that need not to 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

k) 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 toxigenicity of organisms, or through the transfer of genes conferring resistance to antibiotics used in medicine or veterinary medicine,

c) phenotypic or genetic instability of the genetically modified organism,

d) interaction of the genetically modified organism with other organisms and/or

e) differences between the use of the 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) recipient,

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

c) vector,

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

e) insertion of a construct,

f) signal and selection genes,

g) insert,

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

i) final genetically modified organism,

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

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

l) potential interactions between the 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 use at the given workplace or site of release 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 first step in the risk assessment of the contained use is the identification of any possible harmful effects pursuant paragraph 3 letter a) – i)

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

b) 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).

6) The risk assessment of the contained use shall also take into consideration

a) characteristic of the environment that could be affected by the genetically modified organism in case its release from the contained area,

b) nature and scope of the contained use; and

c) any non-standard activities carried out during the course of the contained use (e.g. animals vaccination by genetically modified organisms or operation of facilities capable of aerosol formation).

These facts are also taken into consideration in assigning appropriate class of the contained use pursuant Annex 3 of the Act.

7) The risk assessment procedure shall contain

a) identification of all potential harmful effects pursuant to paragraphs 1 to 6 and an assessment of the seriousness thereof,

b) evaluation of the consequences of any harmful effect, if it occurs,

c) likelihood evaluation of harmful effect occurrence under 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 likelihood evaluation of this harmful effect occurrence and its seriousness, if it occurs,

e) comparison of the obtained information with the corresponding information on the donor organism, the recipient, and/or the parental organism under comparable conditions,

f) summarising of the results, in case of the contained use the assignment of the activity to a certain class of the contained use pursuant to Annex 3 to the Act.

8) All the steps in the procedure pursuant to paragraph 7 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. To obtain information necessary to conduct risk assessment, appropriate legal instructions of the European Union, international or domestic classification schemes incl. new scientific and technical knowledge shall be used. To classify the contained use with genetically modified organisms into categories as identified in Annex 3 to the Act the classification of biological entities into four classes as regards the level of risk of infection pursuant to the § 36 and the Annex No. 7 to the Government Regulation No. 361/2007 Coll. or classification schemes concerning plant and animal pathogens may be used [1a].

9) The risk assessment of the deliberate release into the environment of genetically modified organisms other than higher plants shall contain

a) likelihood that, under the conditions of the deliberate release 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 the deliberate release into the environment,

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

d) 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) 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) 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) potential immediate or delayed effects on animal health and consequences for food chains arising from the consumption of the genetically modified organism or genetic product, which is intended for feed,

h) 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 deliberate release of genetically modified organism into the environment, and

i) 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.

10) The risk assessment of the deliberate release 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 material2), as appropriate, must contain the following information

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

d) 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) 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) 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) potential immediate or delayed effects on the animal health and consequences for food chains resulting from consumption of a genetically modified higher plant or genetic product intended for feed,

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

11) Risk assessment conducted for the deliberate release into the environment for the purpose of clinical assessment of the medicinal preparations shall also contain

a) description of ways how the genetically modified organism or its part may spread out of a tested subject (human or animal) into the environment,

b) presentation of selection and rejection criteria for choosing the subjects of clinical assessment and the effect of such criteria on risk for the environment

c) identification and assessment of possible harmful effects in case of interaction genetically modified organism with a human who is not a subject of clinical assessment carried out pursuant paragraph 7.

12) 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 of unavoidable traces

(ad § 11 paragraph 4 of the Act)

Genetic products intended for direct processing that do not contain more than 0.9 % of traces of genetically modified organisms authorised for placing on the market under § 23 paragraph 1 of the Act, provided these traces are adventitious or technically unavoidable, shall be considered as genetic products that need not to be labelled according to § 11 paragraph 4 of the Act.

§ 7

Requirements on the contained area and protective measures for individual classes of contained uses

(ad § 15 paragraph 2 of the Act)

1) Requirements on the contained area and protective measures for the contained use are given in Annex No. 4 to this Decree according to the type of workplace and assigned class of the contained use (§ 15 paragraph 1 of the Act).

2) Observing the Code of Practice of the workplace, principles of work hygiene and labour protection, and further ensuring the training and retraining courses shall be parts 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 practice3) 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) copy of the notification for the contained use, consent for the deliberate release into the environment or for the registration into the List for the placing on the market or extension of its validity submitted under § 5 paragraph 1 of the Act, a copy of the notification submitted under § 16 paragraph 3 or § 16a paragraph 5 of the Act, or risk assessment submitted under § 16a paragraph 4 of the Act,

b) issued decisions on granted consent for the contained use, consent for the deliberate release into the environment (§ 5 of the Act) and for prolongation of validity (§ 16c paragraph 4 and § 18 paragraph 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 (§ 16b paragraph 1 of the Act), the decision pursuant to § 34 of the Act and also the decision on imposing a fine under § 35 or § 35a of the Act or officially verified copies of these decisions, as appropriate,

c) the 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) guidelines on activities connected with the use of genetically modified organisms if they are treated (e.g. standard operation procedures) and are not included in a 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 paragraph 5 of the Act),

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

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

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

l) reports on controls of genetically modified organisms occurrence outside of a contained area or plots, 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 availability is ensured if needed.

3) 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 any change compared to the description of the use occurs during the use of genetically modified organisms, 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 biosafety officer shall confirm the notification of the change in the documentation.

6) 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 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, 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 biosafety officer. The final report contains mainly

a) purpose of the use of the genetically modified organisms,

b) information given in the valid consent for the contained use or the deliberate release 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 classes of the contained use,

c) address of a workplace or the location and description of premises where the use proceeded, as appropriate,

d) date of beginning and termination of the use of the genetically modified organism,

e) information unambiguously specifying the genetically modified organisms which were used in the contained area or deliberately released into the environment,

f) isolated heritable genetic material, which was used or the techniques of genetic modification, if performed,

g) description of the use of genetically modified organisms, including the date, description and assessment of all 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 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 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 biosafety officer, his signature and date of the signature.

9) Special legal regulations4) on keeping documentation shall not be prejudiced.

§ 9

Example of the Emergency response plan and the scope of information on the Emergency response plan released by the Ministry

(ad § 20 paragraph 4 and 5 of the Act)

1) Example of the Emergency response plan is included in Annex No. 5 to this Decree

a) In Part A in case of the Emergency response plan for contained use

b) in Part B in case of the Emergency response plan for deliberate release into the environment

2) The Ministry shall release the information on the Emergency response plan in scope characterized in Annex No. 5 to this Decree.

§ 10

Requirements of the assessment report

(ad § 24b paragraph 7 of the Act)

The assessment report under § 24a paragraph 2 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 deliberate release of non-modified recipient into the environment or placing on the market,

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

c) evaluation whether the genetic modification is characterized properly in the notification for the purpose of risk assessment

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 the European Union concerning specific issues of the risk assessment, are necessary, as appropriate. The conclusion contains a clear statement to the proposed mode of the use, risk management and proposed plan of monitoring. In case the genetically modified organism or genetic product should not be placed on the market, the conclusion contains also reasons for such position.

§ 11

Repealing provisions

The following shall be repealed:

1) Decree No. 372/2000 Coll., laying down techniques that are considered to result in a genetically modified organism and techniques that do not result in a genetically modified organism.

2) Decree No. 373/2000 Coll., laying down the requirements on contained area and protective measures for the individual class of the contained uses 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.

[1)] 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
Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms

[1a)] § 7 – 30 of the Act No. 326/2004 Coll., on plant health as amended by Act No. 131/2006 Coll., Act No. 249/2008 Coll., and Act No. 291/2009 Coll.
Act No. 166/1999 on veterinary care and amending some related Acts (The Veterinary Act), as amended
Annexes No. 1 and 2 to the Decree No. 215/2008 on measures against the introduction of organisms harmful to plants and plant products and against their spread, as amended
Decree No 356/2004 Coll., on monitoring of zoonoses and zoonotic agents and amending Decree No 299/2003 Coll., on measures for prevention and eradication of epizooties and zoonoses,
Decree No. 474/2002 Coll., Implementing Act No. 281/2002 Coll., on Some Measures Related to Prohibition of Bacteriological (Biological) and Toxin Weapons and on Amendments to Trades Licensing Act

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

[3)] 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

[4)] 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.

Annex No. 1 to the Decree No. 209/2004 Coll.

Notification example of the first class of contained use, example of the risk assessment for the first class of contained use submitted pursuant § 16a paragraph 4 of the Act, notification example of the second class of contained use, notification example of the second class of contained use submitted pursuant § 16 paragraph 5 of the Act, notification example of the third or fourth class of contained use and the example of risk assessment procedure for contained use

Documents marked by (+) shall be elaborated (attached) as an individual Annex.

All the enclosed documents must include the name or the title (trading company) of a notifier.

PART A

NOTIFICATION EXAMPLE OF THE FIRST CLASS OF CONTAINED USE, EXAMPLE OF THE RISK ASSESSMENT FOR THE FIRST CLASS OF CONTAINED USE SUBMITTED PURSUANT § 16a PARAGRAPH 4 OF THE ACT , NOTIFICATION EXAMPLE OF THE SECOND CLASS OF CONTAINED USE, AND NOTIFICATION EXAMPLE OF THE SECOND CLASS OF CONTAINED USE SUBMITTED PURSUANT § 16 PARAGRAPH 5 OF THE ACT

Section 1

NOTIFICATION EXAMPLE OF THE FIRST CLASS OF CONTAINED USE

[Ad § 16 paragraph 6 letter a) of the Act]

Date of submission

1. Person submitting the notification (hereinafter "notifier")

1.1. Name or title or trade company, if the notifier is a natural person authorized to operate a business
1.2. Title or trade company and the legal form, if the notifier is a legal person
1.3. Nationality (in case of natural persons)
1.4. Place of business and place of residence (in case of natural persons)
1.5. Company registration number (if assigned)
1.6. Names 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. Biosafety officer

(+) 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[7)])

2.1. Name, academic degree
2.2. Occupation or employer and function, as appropriate
2.3. Education
2.4. Professional courses
2.5. Work history

2.6. Address of residence
2.7. Telephone
2.8. E-mail

3. Contact person at the workplace if it differs from the biosafety officer

3.1. Name, academic degree
3.2. Telephone
3.3. E-mail

4. Purpose of the contained use – character of activity carried out by the notifier (research, training, detection, production and others)

5. Workplace, where the contained use will be carried out

5.1. Workplace address
5.2. Character of the workplace:
5.2.1 Microbiology / molecular genetics laboratory
5.2.2 Pilot plant
5.3.3 Production facilities
5.2.4 Greenhouse / cultivation room
5.2.5 Animal facilities
5.2.6 Other (unambiguously specify the workplace, for example operational rooms, transport)

(+) Layout of rooms, floors premises
(+) Document on granting the accreditation and an experiment plan under the special legal regulation in case of animal units [8])

6. Genetically modified organisms in use

Recipient / parental organism; group of recipients / parental organisms as appropriate	Donor	Inserted gene / insert/ deleted gene, or their group as appropriate	Vector

In case of unambiguous classification of all items into the first class of contained use it is possible to present all individual items (recipient / parental organism, donor, inserted gene / insert, deleted gene, vector) as one group, which member has the identical risk assessment.
In case of recipients and donors it is possible to present microbial species (e.g. *Saccharomyces cerevisiae* strains) as one group; in case of inserted genes / inserts, their mutated and deleted versions their groups (e.g. "*Bacillus subtilis* genes" and their mutated and deletion variants, "human genes", "mouse genes", chromosome fragments "*Corynebacterium glutamicum*").

7. Amount of genetically modified organisms

7.1. The approximate amount of genetically modified organisms to be used (volume of the culture, number of plants or animals)

(+) Plan of the experiment carried out pursuant other legal regulation in case of animal facilities[8)]

8. Risk assessment

8.1. Summary of the risk assessment pursuant § 7 of the Act and § 5 of this Decree for the use of genetically modified organisms set out in the point 5, elaborated by filling the tables in the Part C of this Annex.

8.2. Risk assessment result – classification in the risk classes

9. Evaluation of the area and facilities of the workplace pursuant to the requirements on a contained area and protective measures for the class of contained use laid down in Annex No. 4 to this Decree

(+) Comparison table of requirements for the workplace.

10. Information on waste management at the workplace

11. Code of Practice of the workplace

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

12. Statement of the biosafety officer

Section 2

EXAMPLE OF THE RISK ASSESSMENT FOR THE FIRST CLASS OF CONTAINED USE SUBMITTED PURSUANT § 16a PARAGRAPH 4 OF THE ACT

[Ad § 16a paragraph 4 of the Act]

Date of submission

1. Notification reference submitted pursuant § 16 paragraph 3 of the Act

1.1. Reference number

1.2. Date of submission

1.3. Class of risk

2. Genetically modified organisms recently used

Recipient / parental organism; group of recipients / parental organisms as appropriate	Donor	Inserted gene / insert/ deleted gene, or their group as appropriate	Vector

3. Risk assessment

3.1. Summary of the risk assessment for the contained use with recently used genetically modified organisms pursuant § 7 of the Act and § 5 of this Decree, elaborated by filling the tables in the Part C of this Annex
3.2. Risk assessment result – classification in the risk classes

4. Statement of the biosafety officer

Section 3

NOTIFICATION EXAMPLE OF THE SECOND CLASS OF CONTAINED USE

[Ad § 16 paragraph 6 letter b) of the Act]

Date of submission

1. Person submitting the notification (hereinafter "notifier")
1.1. Name or title or trade company, if the notifier is a natural person authorized to operate a business
1.2. Title or trade company and the legal form, if the notifier is a legal person
1.3. Nationality (in case of natural persons)
1.4. Place of business and place of residence (in case of natural persons)
1.5. Company registration number (if assigned)
1.6. Names 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. Biosafety officer
(+) 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[7)])

2.1. Name, academic degree
2.2. Occupation or employer and function, as appropriate
2.3. Education
2.4. Professional courses
2.5. Work history
2.6. Address of residence
2.7. Telephone
2.8. E-mail

3. Contact person at the workplace if it differs from the biosafety officer
3.1. Name, academic degree
3.2. Telephone
3.3. E-mail

4. Purpose of the contained use – character of activity carried out by the notifier (research, training, detection, production, and others)

5. Workplace, where the contained use will be carried out

5.1. Workplace address
5.2. Character of the workplace:
  5.2.1. Microbiology / molecular genetics laboratory
  5.2.2. Pilot plant
  5.2.3. Production facilities
  5.2.4. Greenhouse / cultivation room
  5.2.5. Animal facilities
  5.2.6. Other (unambiguously specify the workplace, for example operational rooms, transport)

(+) Layout of rooms, floors premises
(+) Document on granting the accreditation and an experiment plan under the special legal regulation in case of animal facilities [8])

6. Genetically modified organisms in use

6.1. Overview of genetically modified organisms in use

Recipient / parental organism	Donor	Gene / insert	Vector

6.2. Information on every genetically modified organism in use
  6.2.1. Information on the donor organism including its origin
  6.2.2. Information on the recipient and parental organism including the origin thereof
  6.2.3. Information on the vector including its origin
  6.2.4. Information on the insert
  6.2.5. Method of insertion of the insert
  6.2.6. Specification of the resulting genetically modified organism
  6.2.7. Function of the inserted or deleted genes, as appropriate
  6.2.8. Method for detection and control of occurrence of the genetic modification including the methods for identification of the genetically modified organisms
  6.2.9. The approximate amount of genetically modified organisms to be used (volume of the culture, number of plants or animals)
  6.2.10. Information on whether the genetically modified organism has already been authorized in some other country and for what purpose.

7. Risk assessment

(+) Summary of the risk assessment pursuant § 7 of the Act and § 5 of this Decree, elaborated by filling the tables in the Part C of this Annex individually for every genetically modified organism in use.

7.1. Risk assessment result – classification in the risk classes

8. Evaluation of the area and facilities of the workplace and its location pursuant to the requirements on a contained area and protective measures laid down for the second class of the contained use in Annex No. 4 to this Decree

(+) Comparison table of requirements for given workplace

9. Description of the use of the genetically modified organism

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

9.1.1. Country of origin or destination, as appropriate

9.1.2. Importer or exporter, as appropriate

9.1.3. Maximum amount of the genetically modified organisms to be imported or exported

9.1.4. Method of transportation

9.1.5. Method of packaging and labelling

9.2. Description of the use of the genetically modified organism according to the risk assessment

9.3. Measures to protect human and animal health, the environment and biological diversity

9.4. Frequency and the method of carrying out control of the occurrence of genetically modified organism inside and outside of the contained area

9.5. Method of liquidation of the genetically modified organism and control of its effectiveness

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

10. Code of Practice of the workplace

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

11. Emergency Response Plan

(+) Emergency Response Plan pursuant the Annex No. 5 to the Decree

12. Additional information

12.1. Place of storing the documentation on the use of genetically modified organisms kept under § 19 letter b) of the Act

12.2. Plan of training employees prior to the commencement of the use of genetically modified organisms, and the plan of their re-training

13. Statement of the biosafety officer

Section 4

NOTIFICATION EXAMPLE OF THE SECOND CLASS OF CONTAINED USE SUBMITTED PURSUANT § 16a PARAGRAPH 5 OF THE ACT

Date of submission

1. Reference to the previous notification on the second class of the contained use

1.1. Reference number

1.2. Date of submission

2. Genetically modified organisms recently used

2.1. Overview of genetically modified organisms in use

Recipient / parental organism	Donor	Gene / insert	Vector

2.2. **Information on every genetically modified organism in use**

2.2.1. Information on the donor organism including its origin
2.2.2. Information on the recipient and parental organism including the origin thereof
2.2.3. Information on the vector including its origin
2.2.4. Information on the insert
2.2.5. Method of insertion of the insert
2.2.6. Specification of the resulting genetically modified organism
2.2.7. Function of the inserted or deleted genes, as appropriate
2.2.8. Method for detection and control of occurrence of the genetic modification including the methods for identification of the genetically modified organisms
2.2.9. The approximate amount of genetically modified organisms to be used (volume of the culture, number of plants or animals)
2.2.10. Information on whether the genetically modified organism has already been authorized in some other country and for what purpose.

3. Risk assessment

(+) Summary of the risk assessment pursuant § 7 of the Act and § 5 of this Decree, elaborated by filling the tables in the Part C of this Annex individually for every recently used genetically modified organism

3.1. Risk assessment result – classification in the risk classes

4. Description of the use of the genetically modified organism

4.1. In case of import or export of the genetically modified organism intended for the contained use
4.1.1. Country of origin or destination, as appropriate
4.1.2. Importer or exporter, as appropriate
4.1.3. Maximum amount of the genetically modified organisms to be imported or exported
4.1.4. Method of transportation
4.1.5. Method of packaging and labelling (§ 11 paragraph 1)
4.2. Description of the use of the genetically modified organism according to the risk assessment
4.3. Measures to protect human and animal health, the environment and biological diversity
4.4. Frequency and the method of carrying out control of the occurrence of genetically modified organism inside and outside of the contained area
4.5. Method of liquidation of the genetically modified organism and control of its effectiveness
4.6. Description of waste management (wastewater, waste gaseous harmful substances, other and hazardous waste)

5. Code of Practice of the workplace

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

6. Emergency Response Plan

(+) Emergency Response Plan pursuant the Annex No. 5 to the Decree

7. Additional information

7.1. Place of storing the documentation on the use of genetically modified organisms kept under § 19 letter b) of the Act
7.2. Plan of training employees prior to the commencement of the use of genetically modified organisms, and the plan of their re-training

8. Statement of the biosafety officer

PART B

NOTIFICATION EXAMPLE OF THE THIRD OR FOURTH CLASS OF CONTAINED USE

[Ad § 16 paragraph 3 letter c) of the Act]

Date of submission

1. Notifier

1.1. Name or title or trade company, if the notifier is a natural person authorized to operate a business
1.2. Title or trade company and the legal form, if the notifier is a legal person
1.3. Nationality (in case of natural persons)
1.4. Place of business and place of residence (in case of natural persons)
1.5. Company registration number (if assigned)
1.6. Names 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. Biosafety officer

(+) 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[7)])

2.1. Name, academic degree
2.2. Occupation or employer and function, as appropriate
2.3. Education
2.4. Professional courses
2.5. Work history
2.6. Address of residence
2.7. Telephone
2.8. E-mail

3. Contact person at the workplace if it differs from the biosafety officer

3.1. Name, academic degree
3.2. Telephone
3.3. E-mail

4. Workplace, where the contained use will be carried out

4.1. Workplace address
4.2. Character of the workplace
4.2.1. Microbiology / molecular genetics laboratory

4.2.2. Pilot plant
4.2.3. Production facilities
4.2.4. Greenhouse / cultivation room
4.2.5. Animal facilities
4.2.6. Other (unambiguously specify the workplace, for example operational rooms, transport)

4.3. Description of location of the premises for contained use and description of their facilities

(+) Layout of rooms, floors and premises where places significant for the reduction of accident, if happen, are marked (main energy supply control, auxiliary medium supply control, places for storing of genetically modified organisms, safety elements of closing area, placing of device to avert an accident or its effect)

(+) Document on granting the accreditation and an experiment plan under the special legal regulation[8]) in case of animal facilities

5. Purpose and period of the contained use

5.1. Purpose of the contained use – specification of the activity that will be carried out by the notifier (e.g. research, training, detection, production)
5.2. Expected result of the contained use
5.3. Total period of the contained use and date of its expected starting-up and particular periods and starting dates if the contained use is divided into individual stages.

6. Information on (A) donor organism, (B) recipient or (C) parental organism where applicable (submit individually for A, B, C)

6.1. Organism is:
6.1.1. viroid
6.1.2. RNA virus
6.1.3. DNA virus
6.1.4. Bacteria
6.1.5. Fungus (fibrous micromycetes, yeast)
6.1.6. Higher plant
6.1.7. Animal
6.1.8. Other (specify)

6.2. Czech and Latin genus and species names of the organism including precise cultivar determination (variety, breed, strain, line, form, hybrid, stock, pathovar)
6.3. Origin (collection, collection number, supplier)
6.4. Specify whether the organism is pathogenic or harmful in any other way (living or non-living including extracellular products).

If yes, specify whether regarding to people, animals, plants or otherwise. The harmfulness shall be always unambiguously identified.

Do the sequences used in the genetic modification carry pathogenic or harmful properties?

If yes, indicate unambiguously possible characteristics:

6.4.1. pathogenicity: epidemicity, infectiousness, virulence
6.4.2. allergenic effects
6.4.3. toxic effects
6.4.4. pathogen carrier
6.4.5. possible vectors, host area including non-target organism
6.4.6. potential activation of latent viruses (proviruses)

6.4.7. potential ability to penetrate into other organisms or colonise them
6.4.8. resistance to antibiotics and potential use of such antibiotics for prophylaxis and treatment human and animal diseases
6.4.9. other (unambiguous characteristic)
6.5. Natural occurrence of the organism
6.6. Information on whether the heritable genetic material is naturally exchanged between the donor organisms and the recipient

7. Information on the genetic modification

7.1. The type of genetic modification
7.1.1. insertion of a foreign heritable genetic material
7.1.2. deletion of a part of the heritable genetic material
7.1.3. combination of deletion and insertion of heritable genetic material
7.1.4. cellular fusion
7.1.5. other (specify unambiguously)

7.2. Intended result of the genetic modification
7.3. Information on the vector used, if used in the genetic modification
(+) vector map
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
7.3.2.1. plasmid
7.3.2.2. bacteriophage
7.3.2.3. virus
7.3.2.4. cosmid
7.3.2.5. phasmid
7.3.2.6. transposon
7.3.2.7. other object (specify unambiguously)
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:
7.3.5.1. resistance to antibiotics (include the accurate name of the active substance)
7.3.5.2. resistance to heavy metals
7.3.5.3. resistance to pesticides (include the accurate name of the active substance)
7.3.5.4. other resistance (specify unambiguously)
7.3.5.5. other (specifiy unambiguously)
7.3.6. Methods of insertion of the vector into the recipient organism:
7.3.6.1. transformation
7.3.6.2. electroporation
7.3.6.3. macro-injection
7.3.6.4. micro-injection
7.3.6.5. biolistic transfer
7.3.6.6. infection (agrobacterial, viral)
7.3.6.7. other (specify unambiguously)
7.3.7. Fragments of the vector and their presence in the final genetically modified organism

7.4. The method of insertion of the insert into the recipient organism, if a vector was not used in the genetic modification:
  7.4.1. transformation
  7.4.2. micro-injection
  7.4.3. micro-encapsulation
  7.4.4. macro-injection
  7.4.5. biolistic transfer
  7.4.6. other (specify unambiguously)

8. **Information on the insert (information from 8.1 to 8.3 can be summarized in a table and the genetic map of the insert can 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:
    8.4.1. in a free plasmid
    8.4.2. integrated into a chromosome
    8.4.3. 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 means 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. Genetic stability of the genetically modified organism
  9.4. Specify whether the genetically modified organism is pathogenic or harmful in another way (living or non-living including extracellular products).
  If yes, specify 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 the genetically modified organisms including validated methods of their unambiguous identification

10. Risk assessment

(+) Summary of the risk assessment pursuant § 7 of the Act and § 5 of this Decree, elaborated by filling the tables in the Part C of this Annex individually for every genetically modified organism.

10.1. Risk assessment result – classification in the risk classes

11. Assessment of the workplaces premises and facilities and their placement according to the requirements for contained area and protective measures defined for resulting risk class pursuant Annex 4 to this Decree

(+) Comparative table of requirements for given risk class and real workplace equipment

12. Description of the contained use

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

12.1.1. The country of origin or destination, as appropriate

12.1.2. Importer or exporter, as appropriate

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

12.1.4. Means of transportation

12.1.5. Means of packaging and labelling (§ 11 paragraph 1 of the Act)

12.2. Description of the use of the genetically modified organism according to the risk assessment

12.3. Measures to protect human and animal health, the environment and biological diversity

12.4. Occupational health protection according to special legal regulations[9])

12.5. Information on the system of carrying out control of occurrence of the genetically

12.6. modified organisms

12.6.1.1. Frequency and the method of carrying out control inside the contained area

12.6.1.2. Frequency and the method of carrying out control outside of the contained area

12.7. The method of inactivation of the genetically modified organism and control of its effectiveness

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

13. **Code of Practice of the workplace**

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

14. Emergency Response Plan

(+) Emergency Response Plan pursuant the Annex No. 5 to the Decree

15. Additional information

15.1. Place of storing the documentation on the use of genetically modified organisms kept under § 19 letter b) of the Act

15.2. Plan of training employees prior to the commencement of the use of genetically modified organisms, and the plan of their re-training

16. **Statement of the biosafety officer**

PART C

EXAMPLES OF RISK ASSESSMENT PROCEDURE FOR CONTAINED USE

(Ad § 7 paragraph 6 of the Act)

Table 1. Characterisation of risks of contained use of assessed GMO– options

Source of risk	Risk substance	Potential harmful effect
Recipient	Pathogenic microorganism	Infection
	Presence of viral genes	Functional virus formation, tumour transformation
Parental organism	Pathogenic microorganism	Infection
Donor	Pathogenic microorganism, connection of cloned gene function with toxicity, pathogenicity or virulence	Infection, increased virulence
Inserted gene / insert	Cloned toxin gene	Toxin effect
	Cloned potential allergen gene	Allergic reaction
	Cloned gene, which function relates to pathogenicity or virulence	Pathogenic effect, increased virulence
Deleted gene	Gene deletion	Harmful product formation
Vector	Genes for resistance to antibiotic	Horizontal transfer of resistance gene
	Other genes included in vector	Horizontal transfer of genes
Intermediate product of contained use	Pseudovirus particle (when retroviral vector are used)	Transduction into human genome, tumour cells transformation
	Shotgun cloning from the genome of unknown organisms	Possibility of toxigenic and virulent strains formation
Resulting genetically modified organism	Formation of new pathogenic, virulent or toxigenic organism, new virus strain formation resistant to antibiotic	Pathogenic effect, increased virulence, toxigenicity, resistance to antibiotics or other medicines
Place and scope of the use	Biotechnological process	Horizontal gene transfer into other organisms

Table 2. Other procedure of risk assessment – options

<table>
<tr><th rowspan="2">Effects of use of GMO and their products</th><th colspan="3">Potential harmful effects</th><th rowspan="2">Risk estimation</th><th rowspan="2">Class classification</th></tr>
<tr><th>Identification</th><th>Consequence evaluation</th><th>Likelihood that harmful effect is to happen</th></tr>
<tr><td rowspan="4">Direct</td><td>Potential allergen</td><td>Allergic reaction</td><td>Low</td><td>Low</td><td>1</td></tr>
<tr><td>Infectious agent</td><td>Infection</td><td rowspan="2">Middle</td><td rowspan="2">Middle</td><td rowspan="3">2</td></tr>
<tr><td>Toxin</td><td>Harmful effect on animals and humans</td></tr>
<tr><td>Transduction by a pseudovirus particle, gene integration into a</td><td>Potential malignant transformation of somatic cell</td><td>Very low</td><td>It has not been described</td></tr>
</table>

	genome (retroviral vector)				
Indirect	Potential allergen	Allergic reaction	Middle	Low	2
	Toxin	Harmful effect on animals and humans			
	Resistance to antibiotics	Limited treatment options			
Immediate	Potential allergen	Allergic reaction	Low	Low	1
	Toxin	Harmful effect on animals and humans	Middle	Middle	2
Delayed or cumulative	Resistance to antibiotics	Limited treatment options	Low	Low	1
	Interference with natural microflora of human organism	Diarrhoea disease			
	Dissemination in the environment	Influencing diversity	Very low	Very low	1
	Transduction by a pseudovirus particle, transfection by adenoviral DNA, recombination with a latent adenovirus	Potential malignant transformation of somatic cell	Very low	It has not been described	2
Domiciliation in the environment	Domiciliation in water and soil	Influencing water quality, influencing diversity	Unlikely	Very low	1
Influence on population dynamics and genetic diversity	Interference with natural microflora of human organism	Diarrhoea disease	It has not been described	Very low	1
	Introduction and displacement of natural population	Influencing diversity			
	Influencing ecosystems	Influencing diversity			
Phenotypic and genetic instability	Plasmid loss and reconstruction	Influencing diversity	Middle	Low	1
	Deletion complementation	Wild strain formation			
Interaction with organisms	Transmission of plasmids and cloned inserts / genes	Influencing diversity	Low	Very low	1
	Toxin	Harmful effect on animals and humans			
Natural transmission	Transmission of plasmids and cloned inserts / genes	Influencing diversity	Low	Low	1

Annex No. 2 to the Decree No. 209/2004 Coll.

Examples of notifications of granting consent for deliberate release into the environment of genetically modified organisms

Information marked by (+) shall be necessary supported by the original document or a certified copy.

All the enclosed documents must include the name or the title (trading company) of a notifier.

Information forming the summary of the notification intended to be published shall be underlined.

PART A

EXAMPLES OF NOTIFICATIONS OF GRANTING CONSENT FOR DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS FOR PURPOSES OTHER THAN FOR CLINICAL ASSESSMENT OF MEDICINAL PREPARATIONS

Section 1

NOTIFICATION EXAMPLE OF GENETICALLY MODIFIED ORGANISM OTHER THAN A HIGHER PLANT

[Ad § 17 paragraph 3 letter b) of the Act]

Date of submission

1. **Project title**
2. **Notifier**
   - 2.1. Name or title or trade company, if the notifier is a natural person authorized to operate a business
   - 2.2. Title or trade company and the legal form, if the notifier is a legal person
   - 2.3. Nationality (in case of natural persons)
   - 2.4. Place of business and place of residence (in case of natural persons)
   - 2.5. Company registration number (if assigned)
   - 2.6. Names 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

3. **Biosafety officer**

(+) 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[7)])

- 3.1. Name, academic degree
- 3.2. Occupation or employer and function, as appropriate
- 3.3. Education
- 3.4. Professional courses
- 3.5. Work history
- 3.6. Address of residence
- 3.7. Telephone

3.8. E-mail

4. Contact person at the workplace if it differs from the biosafety officer

4.1. Name, academic degree
4.2. Telephone
4.3. E-mail

5. Purpose of the release into the environment

6. Period of the deliberate release into the environment

6.1. Total period of the deliberate release into the environment of the genetically modified organism and date of its expected starting-up
6.2. Binding schedule (description of the individual stages, date of expected starting-up and the duration thereof)

7. Is the notifier planning deliberate release of the genetically modified organism into the environment in any Member State of European Union or outside of its territory?

If so, then provide information on:
7.1. Country where the notifier plans the deliberate release into the environment,
7.2. Expected time and duration of the deliberate release into the environment.

8. Has the notifier submitted a notification for deliberate release into the environment of the same genetically modified organism in any Member State of European Union?

If so, then provide information on:
8.1. Country of the notification submission
8.2. Date of submission and number or other specification of the notification
8.3. Date and specification of a consent, if has been granted
8.4. Period of validity for which the consent applies

9. Has the notifier submitted a notification for the deliberate release into the environment or for placing on the market of the same genetically modified organism outside of the territory of European Union?

If so, then provide information on:
9.1. Country of the notification submission
9.2. Date of submission and number or other specification of the notification
9.3. Date and specification of a consent, if has been granted
9.4. Period of validity for which the consent applies¨

10. Risk assessment of the deliberate release into the environment of the genetically modified organism

(+) The risk assessment pursuant to § 7 of the Act and § 5 of the Decree, respectively, including the documentation on the results of previous deliberate releases into the environment, particularly from the point of view of the different range of activities and different recipient ecosystems

10.1. Summary of the risk assessment

11. Characteristic of the genetically modified organism

11.1. Genetically modified organism means:
- 11.1.1. Viroid
- 11.1.2. RNA virus
- 11.1.3. DNA virus
- 11.1.4. Bacteria
- 11.1.5. Fungus (mould, yeast)
- 11.1.6. Other microorganism
- 11.1.7. Mammal
- 11.1.8. Insect
- 11.1.9. Fish
- 11.1.10. Other animal (specify the class)
- 11.1.11. Other organism (specify)
- 11.1.12.

11.2. Czech and Latin genus and species names of the genetically modified organism including a precise determination of the breed (strain, form, stock, cellular line, pathovar)

11.3. Genetic stability
- 11.3.1. Measures to ensure genetic stability, factors that influence this stability
- 11.3.2. Methods of verification of the genetic stability
- 11.3.3. Description of heritable genetic properties that should eliminate or reduce the spreading of genetic material

12. Information on the recipient or parental organism, if applicable

12.1. Organism means:
- 12.1.1. Viroid
- 12.1.2. RNA virus
- 12.1.3. DNA virus
- 12.1.4. Bacteria
- 12.1.5. Fungus (fibrous micromycetes, yeast)
- 12.1.6. Animal (specify the class)
- 12.1.7. Other organism (specify)

12.2. Czech and Latin genus and species names of the organism including a precise determination of the breed (strain, form, stock, cellular line, pathovar)

12.3. Origin (collection, number of collection, supplier)

12.4. Plasmids (in case of microorganisms)

12.5. Bacteriophages (in case of microorganisms)

12.6. Phenotypic and genetic markers

12.7. Degree of congeniality between the donor organism and recipient

12.8. Occurrence and living conditions
- 12.8.1. Geographical distribution
  - 12.8.1.1. Indigenous or resident in the Czech Republic
  - 12.8.1.2. Indigenous or resident in the European Union
  - 12.8.1.3. If the organism originates in the Czech Republic or in the countries of the European Union, specify the ecosystem where it occurs:
    - 12.8.1.3.1. Atlantic
    - 12.8.1.3.2. Mediterranean
    - 12.8.1.3.3. Boreal
    - 12.8.1.3.4. Alpine
    - 12.8.1.3.5. Continental

12.8.1.3.6. Other (specify)

12.8.2. Is the organism commonly used in the Czech Republic?

12.8.3. Is the organism commonly cultivated (grown) in the Czech Republic?

12.8.4. Habitat (natural occurrence) of the organism:

12.8.4.1. Aquatic environment

12.8.4.2. Soil, freely living

12.8.4.3. Soil in connection with the root system of plants

12.8.4.4. in connection with the parts of plants above the soil

12.8.4.5. In connection with animals

12.8.4.6. Other (specify)

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

12.9. 2.9 Methods of identification and detection of the organism

12.9.1. Methods of detection including information on their sensibility, reliability and specificity

12.9.2. Methods of identification including information on their sensibility, reliability and specificity

12.10. Is the organism classified pursuant to the valid legal regulations of the Czech Republic[9)] or EC concerning the occupational and health safety? If so, specify the classification and relevant legal regulation.

12.11. Specify whether the organism is pathogenic or otherwise harmful (living or non-living including extracellular products).

If so, specify whether regarding to people, animals, plants or otherwise. The harmfulness must be always unambiguously identified.

Do pathogenic or harmful properties concern the sequences used during the genetic modification? If so, then specify unambiguously possible characteristics:

12.11.1. pathogenicity: epidemicity, infectiousness, virulence

12.11.2. allergenic effects

12.11.3. toxic effects

12.11.4. pathogen carrier

12.11.5. possible vectors, host area including non-target organism

12.11.6. potential activation of latent viruses (proviruses)

12.11.7. potential ability to penetrate into other organisms or colonise them

12.11.8. resistance to antibiotics and potential use of such antibiotics for prophylaxis and treatment human and animal diseases

12.11.9. other

12.12. Reproduction

12.12.1. Generation time in the natural environment

12.12.2. Generation time in the ecosystem, into which the genetically modified organism should be introduced

12.12.3. Means of reproduction (sexual, asexual)

12.12.4. Specific factors, which influence reproduction (if exist)

12.13. Survivability

12.13.1. Ability to form structures enhancing survival:

12.13.1.1. Seeds

12.13.1.2. Endospores
12.13.1.3. Cysts
12.13.1.4. Sclerotia
12.13.1.5. asexual spores (fungi)
12.13.1.6. sexual spores (fungi)
12.13.1.7. eggs
12.13.1.8. pupae
12.13.1.9. larvae
12.13.1.10. other (specify)

12.14. Dissemination in the environment
12.14.1. Means and extent of dissemination
12.14.2. Specific factors, which influence dissemination (if exist)
12.15. Natural predators, preys, parasites and competitors, symbionts and hosts
12.16. Other potential interactions with other organisms
12.16.1. Other specific factors enabling survival
12.16.2. Survivability in the individual weather seasons
12.17. Potential intercellular transfer of the genetic material between donor (parental organism) and other organisms
12.17.1. The means of transfer (by plasmid, bacteriophage, otherwise)
12.17.2. Organisms with which the natural exchange of genetic material occurs
12.18. Verification of the genetic stability of the organism and factors affecting it
12.19. Involvement in environmental processes:
12.19.1. primary production
12.19.2. nutrients conversion (consumer, predator)
12.19.3. decomposition of organic matter
12.19.4. other (specify)
12.20. Indigenous vectors of the organism
12.20.1. Sequences of the vector
12.20.2. Vector mobilisation frequency
12.20.3. Vector specificity
12.20.4. Presence of genes conferring vector resistance
12.21. Previous genetic modifications of the recipient or parental organism authorised in the Czech Republic (including the date and number of consent)

13. Information on the genetic modification

13.1. The type of the genetic modification:
13.1.1. Insertion of foreign heritable genetic material
13.1.2. Deletion of a part of the heritable genetic material
13.1.3. Combination of deletion and insertion of the heritable genetic material
13.1.4. Cellular fusion
13.1.5. Other (specify unambiguously)
13.2. Intended result of the genetic modification
13.3. Was the vector used in the genetic modification?
If no, continue at the point 3.4
13.3.1. 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.
13.3.2. Type of the vector
13.3.2.1. Plasmid

13.3.2.2. Bacteriophage
13.3.2.3. Virus
13.3.2.4. Cosmid
13.3.2.5. Phasmid
13.3.2.6. Transposon
13.3.2.7. Other object (specify unambiguously)
(+) The vector map
13.3.3. Identity of the vector (origin)
13.3.4. Spectrum of hosts of the vector
13.3.5. Presence of the sequence in the vector, which transfers a selectable or identifiable phenotype
13.3.5.1. Resistance to antibiotics (specify a medical substance)
13.3.5.2. Resistance to heavy metals
13.3.5.3. Resistance to pesticides (specify an active substance)
13.3.5.4. Other (unambiguously specify)
13.3.6. Fragments of the vector and their presence in the final genetically modified organism
13.3.7. Methods of insertion of the vector into the recipient organism:
13.3.7.1. Transformation
13.3.7.2. Electroporation
13.3.7.3. Macro-injection
13.3.7.4. Micro-injection
13.3.7.5. Infection
13.3.7.6. Other (specify)
13.3.8. Information on the extent to which the vector is limited to the sequences of a nucleic acid required to perform the intended function, and whether the vector contains sequences, product or functions of which are not known
13.4. If a vector has not been used in the genetic modification, the method of insertion of the insert into the recipient organism:
13.4.1. Transformation
13.4.2. Micro-injection
13.4.3. Micro-encapsulation
13.4.4. Macro-injection
13.4.5. Other (specify unambiguously)
13.5. Methods and criteria used for selection

14. Information on the insert

14.1. Information on each part of the insert or each deleted part of the heritable genetic material, as appropriate, with special emphasis on any known harmful sequences
14.1.1. Size
14.1.2. Sequence
14.1.3. Origin
14.1.4. Functional characteristics
14.2. Location of the insert in the recipient organism:
14.2.1. On the free plasmid
14.2.2. Insert integrated into the chromosome
14.2.3. Other (specify unambiguously)
14.3. Does the insert contain parts, which products or functions are unknown?
If so, specify.

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

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

14.6. 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 inserted sequences

14.7. In case of deletion of a part of the heritable genetic material, the size and function of the deleted section of nucleic acid

14.8. Number of copies of the inserted heritable genetic material

14.9. Stability of the inserted heritable genetic material and stability of the location thereof

15. Information on the donor organism (organism, from which the insert is derived)

15.1. Donor organism is:

15.1.1. Viroid

15.1.2. RNA virus

15.1.3. DNA virus

15.1.4. Bacteria

15.1.5. Fungus (fibrous micromycetes, yeast)

15.1.6. Other microorganism

15.1.7. Animal

15.1.8. Other (specify)

15.2. Czech and Latin genus and species name of the donor organism including a precise determination of the cultivar (species, breed, strain, line, form, hybrid, stock, pathovar)

15.3. Specify whether the donor organism is pathogenic or harmful in any other way (living or non-living, including extracellular products).

If so, then specify whether regarding to people, animals, plants or otherwise. The harmfulness must be always unambiguously identified.

Do the pathogenic or harmful properties concern sequences used during the genetic modification?

If so, unambiguously specify possible characteristics:

15.3.1. Pathogenicity: epidemicity, infectiousness, virulence

15.3.2. Allergenic effects

15.3.3. Toxic effects

15.3.4. Pathogen carrier,

15.3.5. Possible vectors, host area including non-target organism,

15.3.6. Potential activation of latent viruses (proviruses)

15.3.7. Ability to penetrate into other organisms or colonise them

15.3.8. Resistance to antibiotics and potential use of such antibiotics for prophylaxis and treatment of human and animal diseases

15.3.9. Other

15.4. Is the donor organism classified pursuant to the other legal regulation concerning the occupational and health safety[10)]?

If so, include the relevant classification.

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

16. Information on the final genetically modified organism

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

16.1.1. Does the genetically modified organism differ from the recipient in its survivability?
If so, then identify unambiguously.

16.1.2. Does the genetically modified organism differ from the recipient in the mode or rate of reproduction?
If so, then unambiguously identify the difference.

16.1.3. Does the genetically modified organism differ from the recipient in its ability to disseminate?
If so, then unambiguously identify the difference.

16.1.4. Does the genetically modified organism differ from the recipient in its pathogenicity?
If so, then unambiguously identify the difference.

16.2. Genetic stability of the genetically modified organism

16.3. Properties of the genetically modified organism that influence its survival, reproduction and dissemination in the environment

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

16.5. Sensitivity to specific substances (agents)

16.6. Specify whether the organism is pathogenic or harmful in any other way (living or non-living, including extracellular products). If so, specify whether regarding to people, animals, plants or otherwise.
The harmfulness must be always unambiguously identified.
Do the pathogenic or harmful properties concern sequences used during the genetic modification?
If so, unambiguously specify possible characteristics:

16.6.1. Pathogenicity: epidemicity, infectiousness, virulence

16.6.2. Allergenic effects

16.6.3. Toxic effects

16.6.4. Pathogen carrier

16.6.5. Possible vectors, host area including non-target organism,

16.6.6. Potential activation of latent viruses (proviruses)

16.6.7. Potential ability to penetrate into other organisms or colonise them

16.6.8. Resistance to antibiotics and potential use of such antibiotics for prophylaxis and treatment human and animal diseases

16.6.9. Other (unambiguous characteristic)

16.7. Description of methods of identification and detection of the genetically modified organism

16.7.1. Methods used for the detection of the genetically modified organism, including the verified detection methodology

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

16.7.3. Data for unique identification of the altered section of the heritable genetic material

16.8. Expression of the inserted heritable genetic material

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

16.8.2. Description of methods and sensitivity of measurement

16.8.3. Stability of the expression

16.9. Expressed proteins

16.9.1. Activity of the expressed proteins

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

16.10. Relevant information on previous cases of the release of the same genetically modified organism into the environment, if exist, particularly on possible effects of this release on human and animal health, the environment and biological diversity

17. Information on the place of the deliberate release into the environment

17.1. Does the place of the deliberate release into the environment differ from the ecosystem where the recipient or parental organism usually occur or are grown and/or cultivated?
If so, specify.

17.2. Workplace and plots where the deliberate release into the environment will be conducted

(+) Copies of cadastral maps with designated plots where the deliberate release into the environment will be conducted, and the comprehensive layout containing also the information on the use of surrounding plots including the species of plant grown

17.3. The owner of plots, if he is not the notifier, and the contractual relation between the owner and the notifier

17.4. Specification of the plot

17.4.1. 7.4.1 Region

17.4.2. 7.4.2 Municipality

17.4.3. Name of cadastral territory and cadastral number

17.4.4. Identification number of the land block or the section of the land block, as appropriate, if the plot is subject of the agriculture land registration under the special legal regulation[11)]

17.5. Total area of the site, where the deliberate release into the environment shall be carried out (m^2)

17.5.1. Actual area of the experiment

17.5.2. Area of the experimental plot (including isolation zone etc.)

17.6. The distance of the experimental plots from the specific territories (in metres or kilometres)

17.6.1. Especially protected territories[12)]

17.6.2. Residence, settlement

17.6.3. Water sources protective zones

17.6.4. Water course, water reservoirs

17.6.5. Territories managed in the organic agriculture[13)]

17.6.6. Other

17.7. Use of the surrounding plots including the crops grown at the surrounding plots (mark in the layout)

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

17.9. The method of safeguarding the plots:

17.9.1. Against non-authorized persons

17.9.2. Against animals

17.9.3. Against water runoff

17.10. Extent and method of the use of isolation zone around the site of cultivation of genetically modified organisms

17.11. Other methods of elimination or minimisation of the dissemination of genetically modified organisms outside of the trial plots

17.12. Brief description of the usual weather conditions

17.13. Description of the ecosystem at the place of the deliberate release into the environment and the disruptive effects on the ecosystem:

17.13.1. Type of soil

17.13.2. Water regime including irrigation

17.13.3. Climatic conditions

17.14. Description of the systems that could be affected

17.15. Any planned changes in the use of the plots in the vicinity of the place of the deliberate release into the environment that could affect the environmental impact of genetically modified organisms.

18. Description of the use of the genetically modified organism

(+) Methodology of the experiments

(+) Emergency Response Plan under Annex No. 5 to the Decree

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

18.1. Use of the genetically modified organisms prior to its deliberate release into the environment (contained use, transportation)

18.2. Procedure of the deliberate release of the genetically modified organisms into the environment

18.3. Approximate amount of genetically modified organisms to be used

18.4. Density of the genetically modified organisms (per m^2 or m^3, as appropriate)

18.5. Preparation and the method of treatment of the plots prior to the deliberate release of the genetically modified organisms

18.6. The method of transportation of the genetically modified organisms

18.7. The method of the protection of occupational health during the use of the genetically modified organisms pursuant to special legal regulations[9)]

18.8. The method of the cultivation of the genetically modified organisms

18.9. Description of further use of the genetically modified organisms including disposal thereof

18.10. Date and method of the evaluation of the deliberate release of the genetically modified organisms into the environment

19. Information on potential interactions between the genetically modified organisms and the environment, and on potential effect of the interactions on the environment

19.1. Czech and Latin genus and species name of an target organism, if it exists, including a precise determination of the cultivar (variety, breed, strain, line, form, hybrid, stock, pathovar)

19.2. Expected mechanism and result of the interaction between the genetically modified organism deliberately released into the environment and the target organism

19.3. Expected mechanism and result of interactions with other organisms in the environment that could be important

19.4. Is it likely that selection will occur after the deliberate release into the environment, e.g. higher competitiveness or invasiveness of the genetically modified organism?

19.5. Possibility of rapid growth of the genetically modified organism population in the environment and conditions for such growth to occur

19.6. Ways of biological dissemination of the genetically modified organism, known or possible ways of interactions with the disseminating agents

19.7. Types of ecosystems where the genetically modified organism could be disseminated from the place of the deliberate release into the environment and where it could settle

19.8. Name (Czech and Latin genus and species name including a precise determination of the cultivar (breed, strain, line, form, hybrid, stock, pathovar) of a non-target organism, which could be affected by the deliberate release of genetically modified organism into the environment, with regard to the character of the recipient environment

19.9. Expected mechanism of the identified undesirable interactions between the genetically modified organisms and non-target organisms including competitors, preys, hosts, symbionts, predators, parasites and pathogens

19.10. Ability to transfer the heritable genetic material in vivo

19.10.1. Possibility to transfer the heritable genetic material from the genetically modified organism into other organism after the deliberate release of genetically modified organism into the environment and consequences of this transfer

19.10.2. Possibility to transfer the heritable genetic material from a naturally occurring organism to the genetically modified organism after the deliberate release of the genetically modified organism into the environment and consequences of this transfer

19.11. Results of the studies on the behaviour and properties of the genetically modified organism and their environmental effects carried out in the simulated natural environment

19.12. Known or expected involvement in biogeochemical processes

19.13. Other potential effects on the environment and biological diversity (unambiguously specify)

20. Information on monitoring

20.1. Methods of detection of the presence of the genetically modified organisms

20.2. Specificity of the methods of identification of the genetically modified organisms and determining the genetically modified organism from the donor organism, recipient or parental organism, as appropriate, the sensitivity and reliability of these methods

20.3. Methods of monitoring the effects on the ecosystem

20.4. Detection techniques (methods) of transfer of the introduced heritable genetic material to other organisms

20.5. Area where the monitoring shall be carried out (m^2)

20.6. Period of the monitoring

20.7. Frequency of the monitoring

21. Information on measures after the termination of the experiment and on waste management

21.1. Description of measures after the experiment termination

21.2. The method of elimination of genetically modified organisms and control of its effectiveness

21.3. Plan of controls and supervision

21.4. Types of waste generated and its expected amount

21.5. Potential risks resulting from handling of the wastes

21.6. Description of the disposal of the wastes and methods of control of its effectiveness

22. In case of import or export of the genetically modified organism intended exclusively for the deliberate release into the environment (§ 25 paragraph 4 of the Act)

22.1. The country of origin or destination, as appropriate
22.2. Importer or exporter, as appropriate
22.3. Maximum amount of the genetically modified organism to be imported or exported
22.4. Means of transportation
22.5. Means of packaging and labelling

23. Place of storing the documentation on the use of genetically modified organisms kept under § 19 letter b) of the Act

24. Plan of training of employees prior to the commencement of the use of genetically modified organisms, and the plan of their re-training

25. Statement of the biosafety officer

Section 2

NOTIFICATION EXAMPLE OF GENETICALLY MODIFIED ORGANISM THAT IS A HIGHER PLANT

[Ad § 17 paragraph 3 letter a) of the Act]

Date of submission

1. Project title
2. Notifier
2.1. Name or title or trade company, if the notifier is a natural person authorized to operate a business
2.2. Title or trade company and the legal form, if the notifier is a legal person
2.3. Nationality (in case of natural persons)
2.4. Place of business and place of residence (in case of natural persons)
2.5. Company registration number (if assigned)
2.6. Names 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

3. Biosafety officer
(+) 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[7)])

3.1. Name, academic degree
3.2. Occupation or employer and function, as appropriate
3.3. Education
3.4. Professional courses
3.5. Work history

3.6. Address of residence
3.7. Telephone
3.8. E-mail

4. Contact person at the workplace if it differs from the biosafety officer
4.1. Name, academic degree
4.2. Telephone
4.3. E-mail

5. Characterisation of the use of genetically modified organism
5.1. The purpose of the deliberate release into the environment, particularly agronomic purposes, hybridisation tests, change in survivability or spreading, detection of the effects on the target or non-target organisms

6. Period of the deliberate release into the environment
6.1. Total period of the deliberate release into the environment of the genetically modified organism and date of its expected starting-up
6.2. Binding schedule (description of the individual stages, date of expected starting-up and the duration thereof)

7. Is the notifier planning deliberate release of the genetically modified organism into the environment in any Member State of European Union or outside of its territory?
If so, then provide information on:
7.1. Country where the notifier plans the deliberate release into the environment,
7.2. Expected time and duration of the deliberate release into the environment.

8. Has the notifier submitted a notification for deliberate release into the environment of the same genetically modified organism in any Member State of European Union?
If so, then provide information on:
8.1. Country of the notification submission
8.2. Date of submission and number or other specification of the notification
8.3. Date and specification of a consent, if has been granted
8.4. Period of validity for which the consent applies

9. Has the notifier submitted a notification for the deliberate release into the environment or for placing on the market of the same genetically modified organism outside of the territory of European Union?
If so, then provide information on:
9.1. Country of the notification submission
9.2. Date of submission and number or other specification of the notification
9.3. Date and specification of a consent, if has been granted
9.4. Period of validity for which the consent applies¨

10. Risk assessment of the deliberate release into the environment of the genetically modified organism

(+) The risk assessment pursuant to § 7 of the Act and § 5 of the Decree, respectively, including the documentation on the results of previous deliberate releases into the environment, particularly from the point of view of the different range of activities and different recipient ecosystems

10.1. Summary of the risk assessment

11. Information on the recipient or parental organism, if applicable

11.1. Czech and Latin genus and species names of the organism including a precise determination of the cultivar (variety, line, hybrid)

11.2. Origin (collection, number of collection, supplier)

11.3. Reproduction

11.3.1. Mode of reproduction

11.3.2. Specific factors that affect reproduction (if exist)

11.3.3. Generation time

11.3.4. Sexual compatibility with other cultivated or uncultivated species and distribution of these compatible species in the Czech Republic

11.4. Survivability

11.4.1. Ability to form structures that enhance survival or dormancy, and the time period of potential survival or dormancy,

11.4.2. Other specific factors enhancing survival, if exist

11.5. Dissemination of the plant in the environment

11.5.1. The method and extent of dissemination (decrease of the amount of pollen and seeds in relation to the distance from the source, power and direction of wind and other factors)

11.5.2. Specific factors affecting dissemination (if exist)

11.6. Geographic distribution of the plant

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

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

11.9. Effects on human and animal health and the environment

11.9.1. Toxicity

11.9.2. Allergenicity

11.9.3. Other (specify unambiguously)

12. Information on the genetic modification and genetically modified higher plant

12.1. Czech and Latin genus and species names of the genetically modified higher plant including a precise determination of the cultivar (variety, line, hybrid)

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

12.3. The type of genetic modification

12.3.1. Insertion of foreign heritable genetic material

12.3.2. Deletion of a part of the heritable genetic material

12.3.3. Combination of deletion and insertion of heritable genetic material

12.3.4. Cellular fusion

12.3.5. Other (specify unambiguously)

12.4. Properties and origin of the used vector (if the vector was used)

(+the vector map)

12.5. Information on every part of the DNA section, which was inserted into the organism of the recipient (if genetic modification includes the insertion of the heritable genetic material)

12.5.1. Origin (Czech and Latin genus and species names of the donor organism including a precise determination of the cultivar (variety, breed, strain, line, form, hybrid, stock, pathovar)

12.5.2. Functional characteristics

12.5.3. Size

12.5.4. Location – if it has been integrated

12.5.5. Sequence

12.6. In case of deletion of a part of the heritable genetic material, size and function of the deleted section

12.7. Description of the method used for genetic modification

12.8. Location of the heritable genetic material in a plant cell (inserted in chromosomes, chloroplasts or in non-integrated form)

12.9. Number of copies of the inserted heritable genetic material

12.10. Stability of the inserted heritable genetic material and stability of the location

12.11. Methods of determination of the above provided data information

12.12. Information on the expression of the inserted heritable genetic material

12.12.1. The location of the inserted genes expression in the plant (e.g. roots, stem, leaves, pollen etc.)

12.12.2. Changes in the expression depending on the plant life cycle

12.12.3. Stability of the expression

12.12.4. Methods used for characterisation of the expression

12.13. Information enabling unique identification of genetically modified higher plant

12.13.1. Description of the altered part of DNA

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

12.14. Behaviour of the inserted genes

12.14.1. During hybridisation with the same species

12.14.2. During hybridisation with distant species

12.15. Unambiguous information on how the genetically modified higher plants differ from the recipient or parental organism:

12.15.1. Mode and rate of reproduction

12.15.2. Dissemination in the environment

12.15.3. Survivability

12.15.4. Effects on human and animal health and the environment

12.15.5. Other (specify)

12.16. Phenotypic stability of the genetically modified higher plant

12.17. Any change in ability of the genetically modified higher plant to transfer genetic material to other organisms as a result of the genetic modification

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

12.19. Information on the safety of the 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 feed

12.20. Mechanism of interaction between the genetically modified higher plant and the target organism, if it exists

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

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

13. Workplace and plots where the deliberate release into the environment will be conducted

(+) Emergency Response Plan under Annex No. 5 to the Decree

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

(+) Copies of cadastral maps with designated plots where the deliberate release into the environment will be conducted; and the comprehensive layout in a suitable scale with marking of the trial and containing the information on species of plant grown at the surrounding plots.

13.1. Location of the plot

13.1.1. Region

13.1.2. Municipality

13.1.3. Name of cadastral territory and cadastral number

13.1.4. Identification number of the land block or the section of the landblock, as appropriate, if the plot is subject of the agriculture land registration under the special legal regulation[11])

13.2. Owner of plot, if he is not the person submitting the notification for the deliberate release of genetically modified organism into the environment, and the contractual relation between the owner and the notifier

13.3. Size and use of the plot

13.3.1. Total area of the plot

13.3.2. Area and situation of the site, where the deliberate release into the environment shall occur (m^2)

13.3.3. Size (m^2) and the use of isolation zone surrounding the area of genetically modified higher plant cultivation (mark in the layout)

13.4. Use of the surrounding plots

13.5. Distance of the experimental plot from the specific territories (in metres or kilometres)

13.5.1. Especially protected territories[12])

13.5.2. Water sources protective zones

13.5.3. Water course, water reservoirs

13.5.4. Territories managed in the organic agriculture[13])

13.5.5. Other

13.6. Method of safeguarding the plot

13.6.1. Safeguarding the plot against non-authorized persons

13.6.2. Safeguarding the plot against animals

13.6.3. Safeguarding the plot against water runoff

13.7. Description of the ecosystem at the place of the deliberate release into the environment

13.7.1. Type of soil

13.7.2. Water regime including irrigation

13.7.3. Climatic conditions

13.7.4. Flora including the agricultural crops

13.7.5. Fauna including domestic animals and migrating animals

13.8. Presence of wild or cultivated sexually compatible plants on the plot and its vicinity

13.9. Relevant information concerning the previous cases of the deliberate release 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

14. Description of the use of the genetically modified higher plants

14.1. Use of the genetically modified higher plants prior to its deliberate release into the environment (contained use, transportation)

14.2. Preparation and method of treatment of the plot prior to the cultivation of the genetically modified higher plants

14.3. The method of transportation of the genetically modified higher plants

14.4. Approximate amount of genetically modified higher plants to be deliberately released into the environment

14.5. Approximate number of the genetically modified higher plants (per m^2)

14.6. Method of cultivation of the genetically modified higher plants on the plot

14.7. Method of harvesting the genetically modified higher plants

14.8. Description of further use of the genetically modified higher plants, including the samples taken

14.9. Date and method of evaluation of the deliberate release of the genetically modified higher plants into the environment

14.10. Method of protection of occupational health during the use of genetically modified higher plants pursuant to special legal regulations[9)]

15. Measures to protect human and animal health, the environment and biological diversity and waste management

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

15.2. Measures to decrease or prevent pollen or seeds flow, if used

15.3. Description of the methods for treatment of the plot after termination of the trial

15.4. Monitoring

15.4.1. Methods of detection of the presence of the genetically modified higher plants and monitoring their effects on ecosystem

15.4.2. Specificity of the methods for identification of the genetically modified higher plants and determining the genetically modified plants from the donor organism, recipient or parental organism, as appropriate, sensitivity and reliability of these methods

15.4.3. Techniques (methods) for detection of the transferring of introduced heritable genetic material to other organisms

15.4.4. The site where the monitoring will be carried out

15.4.5. The period of monitoring

15.4.6. Frequency of monitoring

15.4.7. Waste management including the disposal of the genetically modified higher plants

15.4.8. Summary of the protective measures

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

17. Statement of the biosafety officer

PART B

NOTIFICATION EXAMPLE OF GRANTING CONSENT FOR DELIBERATE RELEASE FOR PURPOSE OF CLINICAL ASSESSMENT OF MEDICINAL PREPARATIONS

[Ad § 17 paragraph 3 letter c) of the Act]

Date of submission

1. Project title

2. Notifier

2.1. Name or title or trade company, if the notifier is a natural person authorized to operate a business
2.2. Title or trade company and the legal form, if the notifier is a legal person
2.3. Nationality (in case of natural persons)
2.4. Place of business and place of residence (in case of natural persons)
2.5. Company registration number (if assigned)
2.6. Names 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

3. Biosafety officer

(+) 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[7])

3.1. Name, academic degree
3.2. Occupation or employer and function, as appropriate
3.3. Education
3.4. Professional courses
3.5. Work history
3.6. Address of residence
3.7. Telephone
3.8. E-mail

4. Contact person at the workplace if it differs from the biosafety officer

4.1. Name, academic degree
4.2. Telephone
4.3. E-mail

5. Information on a medicinal product and medicinal procedure

5.1. Medicinal product contains
  5.1.1. Genetically modified organism
  5.1.2. Therapeutic vector
5.2. Medicinal procedure is:
  5.2.1. Gene therapy (in vivo or ex-vivo)
  5.2.2. Somatic cell therapy
  5.2.3. Other (Specify)

6. Characteristic of genetically modified organism or therapeutic vector in a medicinal product

6.1. Genetically modified organism in the medicinal product is:

6.1.1. Pseudovirus particle
6.1.2. Plasmid
6.1.3. Cell Line
6.1.4. Other (specify)

6.2. Therapeutic vector in the medicinal product is:

6.2.1. Pseudovirus particle
6.2.2. Bacteria
6.2.3. Cell line
6.2.4. DNA/RNA fragment
6.2.5. Interfering RNA
6.2.6. Other (specify)

Fill in the points from 7 to 19 only in case the medicinal product is a genetically modified organism

7. Characteristic of the use of genetically modified organism

7.1. Purpose of the deliberate release into the environment

8. Period of the deliberate release into the environment

8.1. Total period of the deliberate release into the environment of the genetically modified organism and date of its expected starting-up

8.2. Binding schedule (description of the individual stages, date of expected starting-up and the duration thereof)

9. Is the notifier planning deliberate release of the genetically modified organism into the environment in any Member State of European Union or outside of its territory?

If so, then provide information on:

9.1. Country of planned deliberate release into the environment

9.2. Expected starting-up and duration of the deliberate release into the environment

10. Has the notifier submitted a notification for deliberate release into the environment of the same genetically modified organism in any Member State of European Union?

If so, then provide information on:

10.1. Country of the notification submission
10.2. Date of submission and number or other specification of the notification
10.3. Date and specification of a consent, if has been granted
10.4. Period of validity for which the consent applies

11. Has the notifier submitted a notification for the deliberate release into the environment or for placing on the market of the same genetically modified organism outside of the territory of European Union?

If so, then provide information on:

11.1. Country of the notification submission
11.2. Date of submission and number or other specification of the notification
11.3. Date and specification of a consent, if has been granted

11.4. Period of validity for which the consent applies

12. Risk assessment of the deliberate release of the genetically modified organism into the environment

(+) The risk assessment pursuant to § 7 of the Act and § 5 of the Decree, respectively

12.1. Summary of the risk assessment

13. Information on the recipient or parental organism, if applicable

13.1. Organism means

13.1.1. Virus

13.1.2. Bacteria

13.1.3. Cell line

13.1.4. Other (specifying necessary)

13.2. Czech and Latin genus and species names of the organism including a precise determination of the breed (strain, form, stock, cellular line, pathovar)

13.3. Origin (collection, number of collection, supplier)

13.4. Phenotypic and genetic markers

13.5. Degree of congeniality between the donor organism and recipient

13.6. Occurrence and living conditions

13.6.1. Geographical distribution, natural occurrence of the organism

13.6.2. Is the organism commonly used in the Czech Republic / European Union?

13.7. Methods of identification and detection of the organism

13.7.1. Methods of detection including information on their sensibility, reliability and specificity

13.7.2. Methods of identification including information on their sensibility, reliability and specificity

13.8. Is the organism classified pursuant to the valid legal regulations concerning the occupational and health safety[10)]?

If so, specify the classification

13.9. Specify whether the organism is pathogenic or otherwise harmful (living or non-living including extracellular products).

If so, specify whether regarding to people, animals, plants or otherwise.

Do pathogenic or harmful properties concern the sequences used during the genetic modification?

If so, then specify unambiguously possible characteristics:

13.9.1. Pathogenicity: epidemicity, infectiousness, virulence

13.9.2. Allergenic effects

13.9.3. Toxic effects

13.9.4. Pathogen carrier

13.9.5. Possible vectors, host area including non-target organism

13.9.6. Potential activation of latent viruses (proviruses)

13.9.7. Potential ability to penetrate into other organisms or colonise them

13.9.8. Resistance to antibiotics and potential use of such antibiotics for prophylaxis and treatment human and animal diseases

13.9.9. Other

13.10. Reproduction

13.10.1. Generation time in the natural environment,
13.10.2. Means of reproduction (sexual, asexual)
13.10.3. Specific factors, which influence reproduction (if exist)
13.10.4. Survivability
13.10.5. Ability to form structures enhancing survival:
13.10.5.1. Endospores
13.10.5.2. Cysts
13.10.5.3. Other (specify unambiguously)
13.11. Dissemination in the environment
13.11.1. Means and extent of dissemination
13.11.2. Specific factors, which influence dissemination (if exist)
13.12. Natural predators, preys, parasites and competitors, symbionts and hosts
13.13. Other potential interactions with other organisms
13.13.1. Other specific factors enhancing survival
13.14. Potential intercellular transfer of the genetic material between donor (parental organism) and other organisms
13.14.1. Means of transfer (by plasmid, bacteriophage, otherwise)
13.14.2. Organisms with which the natural exchange of genetic material occurs
13.15. Verification of the genetic stability of the organism and factors affecting it
13.16. Indigenous vectors of the organism
13.16.1. Sequences of the vector
13.16.2. Vector mobilisation frequency
13.16.3. Vector specificity
13.16.4. Presence of genes conferring vector resistance
13.17. Previous genetic modifications of the recipient or parental organism authorised in the Czech Republic (including the date and number of consent)

14. Information on the genetic modification

14.1. The type of the genetic modification:
14.1.1. Insertion of foreign heritable genetic material
14.1.2. Deletion of a part of the heritable genetic material
14.1.3. Combination of deletion and insertion of the heritable genetic material
14.1.4. Cellular fusion
14.1.5. Other (specify unambiguously)
14.2. Intended result of the genetic modification
14.3. Was the vector used in the genetic modification?
(+) vector map
If no, continue at the point 14.4
14.3.1. 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 14.5.
14.3.2. Type of the vector:
14.3.2.1. Plasmid
14.3.2.2. Bacteriophage
14.3.2.3. Virus
14.3.2.4. Cosmid
14.3.2.5. Phasmid
14.3.2.6. Transposon
14.3.2.7. Other vector (specify unambiguously)

14.3.3. Identity of the vector (origin, full scientific name, trivial name)
14.3.4. Spectrum of hosts of the vector (natural hosts, reservoirs)
14.3.5. Presence of the sequence in the vector, which transfers a selectable or identifiable phenotype
14.3.5.1. Resistance to antibiotics (specify a medical substance)
14.3.5.2. Other (unambiguously specify)
14.3.6. Fragments of the vector and their presence in the final genetically modified organism
14.3.7. Methods of insertion of the vector into the recipient organism:
14.3.7.1. Transformation
14.3.7.2. Electroporation
14.3.7.3. Macro-injection
14.3.7.4. Micro-injection
14.3.7.5. Infection
14.3.7.6. Other (specify)
14.3.8. Information on the extent to which the vector is limited to the sequences of a nucleic acid required to perform the intended function, and whether the vector contains sequences, product or functions of which are not known

14.4. If a vector has not been used in the genetic modification, the method of insertion of the insert into the recipient organism:
14.4.1. Transformation
14.4.2. Micro-injection
14.4.3. Micro-encapsulation
14.4.4. Macro-injection
14.4.5. Other (specify unambiguously)

14.5. Methods and criteria used for selection

15. Information on the insert

15.1. Information on each part of the insert or each deleted part of the heritable genetic material, as appropriate, with special emphasis on any known harmful sequences
15.1.1. Size
15.1.2. Sequence
15.1.3. Origin
15.1.4. Functional characteristics

15.2. Location of the insert in the recipient organism:
15.2.1. On the free plasmid
15.2.2. Insert integrated into the chromosome
15.2.3. Other (specify unambiguously)

15.3. Does the insert contain parts, which products or functions are unknown?
If so, specify.

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

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

15.6. 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 inserted sequences.

15.7. In case of deletion of a part of the heritable genetic material, the size and function of the deleted section of nucleic acid

15.8. The number of copies of the inserted heritable genetic material

15.9. Stability of the inserted heritable genetic material and stability of the location thereof

16. Information on the donor organism (organism, from which the insert is derived)

16.1. Donor organism is:

16.1.1. Viroid

16.1.2. RNA virus

16.1.3. DNA virus

16.1.4. Bacteria

16.1.5. Fungus (mould, yeast)

16.1.6. Other microorganism

16.1.7. Animal (specify class)

16.1.8. Other (specify)

16.2. Czech and Latin genus and species name of the donor organism including a precise determination of the cultivar (variety, breed, strain, line, form, hybrid, stock, pathovar)

16.3. Specify whether the donor organism is pathogenic or harmful in any other way (living or non-living, including extracellular products).

If so, then specify whether regarding to people, animals, plants or otherwise. The harmfulness must be always unambiguously identified.

Do the pathogenic or harmful properties concern sequences used during the genetic modification?

If so, unambiguously specify possible characteristics:

16.3.1. Pathogenicity: epidemicity, infectiousness, virulence

16.3.2. Allergenic effects

16.3.3. Toxic effects

16.3.4. Pathogen carrier,

16.3.5. Possible vectors, host area including non-target organism,

16.3.6. Potential activation of latent viruses (proviruses)

16.3.7. Potential ability to penetrate into other organisms or colonise them

16.3.8. Resistance to antibiotics and potential use of such antibiotics for prophylaxis and treatment of human and animal diseases

16.3.9. Other

16.4. Is the donor organism classified pursuant to the valid legal regulations concerning the occupational and health safety [8)]?

If so, include the classification.

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

17. Information on the final genetically modified organism

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

17.1.1. Does the genetically modified organism differ from the recipient in its survivability?
If so, identify unambiguously.

17.1.2. Does the genetically modified organism differ from the recipient in the mode or rate of reproduction?
If so, unambiguously identify.

17.1.3. Does the genetically modified organism differ from the recipient in its ability to disseminate?
If so, unambiguously identify.

17.1.4. Does the genetically modified organism differ from the recipient in its pathogenicity?
If so, unambiguously identify.

17.2. Genetic stability of the genetically modified organism

17.2.1. Measures ensuring genetic stability, factors influencing the stability

17.2.2. Methods verifying genetic stability

17.3. Properties of the genetically modified organism that influence its survival, reproduction and dissemination in the environment

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

17.5. Sensitivity to specific substances (agents)

17.6. Specify whether the organism is pathogenic or harmful in any other way (living or non-living, including extracellular products).
If so, specify whether regarding to people, animals, plants or otherwise.
Harmfulness must be always unambiguously identified.
Do the pathogenic or harmful properties concern sequences used during the genetic modification?
If so, unambiguously specify possible characteristics:

17.6.1. Pathogenicity: epidemicity, infectiousness, virulence

17.6.2. Allergenic effects

17.6.3. Toxic effects

17.6.4. Pathogen carrier

17.6.5. Possible vectors, host area including non-target organism

17.6.6. Potential activation of latent viruses (proviruses)

17.6.7. Potential ability to penetrate into other organisms or colonise them

17.6.8. Resistance to antibiotics and potential use of such antibiotics for prophylaxis and treatment human and animal diseases

17.6.9. Other (unambiguous characteristic)

17.7. Description of methods of identification and detection of the genetically modified organism

17.7.1. Methods used for the detection of the genetically modified organism, including the verified detection methodology

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

17.7.3. Data for unique identification of the altered section of the heritable genetic material

17.8. Expression of the inserted heritable genetic material

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

17.8.2. Stability of the expression

17.8.3. Description of methods and sensitivity of measurement

17.9. Expressed proteins

17.9.1. Activity of the expressed proteins

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

17.10. Relevant information on previous cases of the release of the same genetically modified organism into the environment, if exist, particularly on possible effects of this release on human and animal health, the environment and biological diversity

18. Information on the deliberate release into the environment and plots where the release will be conducted

18.1. Workplace and plots where the deliberate release into the environment will be conducted

18.2. Workplace address

(+) Methodology of the experiments

(+) Emergency Response Plan under Annex No. 5 to the Decree

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

(+) Layout of the workplace where the deliberate release into the environment will be conducted

19. Description of the use of medicinal product containing the genetically modified organism

19.1. Use of the genetically modified organism prior to its deliberate release into the environment (contained use, transportation)

19.2. Procedure of the deliberate release of the genetically modified organisms into the environment

19.2.1. Preparation method of the medicinal product

19.2.2. Method of storage of the medicinal product

19.2.3. System of the transportation of the medicinal product

19.2.4. Application method of the medicinal product

19.2.5. Observation Plan of subjects under the clinical assessment

19.2.6. Measures concerning subjects of clinical assessment

19.2.7. System of sampling, processing and storage of samples

19.2.8. Method of harvesting and disposal of the contaminated material

19.3. Approximate amount of genetically modified organisms to be used, the amount of subjects and doses

19.4. The method of the protection of occupational health during either the use of medicinal product or the contact with subjects under the clinical assessment

19.5. Measures taken preventing the genetically modified organism from dissemination into the environment

19.6. Description of further use of the medicinal product and waste, including disposal thereof

19.6.1. Description of measures taken after the clinical assessment has been terminated

19.6.2. Method of elimination of genetically modified organisms and the control of its effectiveness

19.6.3. Plan of controls and supervision

19.6.4. Types of waste generated and its expected amount

19.6.5. Potential risks resulting from handling waste

19.6.6. Description of the disposal of the wastes and methods of control of its effectiveness

19.7. Description of subsequent care for tested subjects

19.8. Term and method of assessment of deliberate release of genetically modified organisms into the environment

20. Information on potential interactions between the genetically modified organisms and the environment, and on potential effect of the interactions on the environment

20.1. Expected mechanism and result of the interaction with other organisms in the environment that can be significant

20.2. Possibility that selection will occur after the release into the environment

20.3. Possibility of rapid growth of the genetically modified organism population in the environment and conditions for such growth to occur

20.4. Ways of biological dissemination of the genetically modified organism, known or possible ways of interactions with the disseminating agents

20.5. Types of ecosystems where the genetically modified organism could be disseminated from the place of the deliberate release into the environment and where it could settle

20.6. Expected mechanism of the identified undesirable interactions between the genetically modified organisms and non-target organisms including competitors, preys, hosts, symbionts, predators, parasites and pathogens

20.7. Ability to transfer the heritable genetic material in vivo

20.8. Possibility to transfer the heritable genetic material from the genetically modified organism into other organism after the deliberate release of genetically modified organism into the environment and consequences of this transfer

20.9. Possibility to transfer the heritable genetic material from a naturally occurring organism to the genetically modified organism after the deliberate release of the genetically modified organism into the environment and consequences of this transfer

20.10. Results of the studies on the behaviour and properties of the genetically modified organism and their environmental effects carried out in the simulated natural environment

20.11. Other potential effects on the environment and biological diversity (unambiguously specify)

21. Information on monitoring

21.1. Methods of detection of the presence of the genetically modified organisms

21.2. Specificity of the methods of identification of the genetically modified organisms and determining the genetically modified organism from the donor organism, recipient or parental organism, as appropriate, the sensitivity and reliability of these methods

21.3. Detection techniques (methods) of transfer of the introduced heritable genetic material to other organisms

21.4. Methods of monitoring the effects of genetically modified organism on non-target organisms

21.5. Locations where the monitoring shall be carried out

21.6. Period of the monitoring

21.7. Frequency of the monitoring

22. In case of import or export of the genetically modified organism intended exclusively for the deliberate release into the environment (handover to the third person, which is not considered the placing on the market)

22.1. The country of origin or destination, as appropriate

22.2. Importer or exporter, as appropriate

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

22.4. Means of transportation

22.5. Means of packaging and labelling

23. **Place of storing the documentation on the use of genetically modified organisms kept under § 19 letter b) of the Act**

24. **Plan of training of employees prior to the commencement of the use of genetically modified organisms and therapeutic vectors, and the plan of their re-training**

25. **Statement of the biosafety officer**

Annex No. 3 to the Decree No. 209/2004 Coll.

Examples of notifications on registering into the List for the placing on the market

Information marked by (+) shall be necessary supported by the original document or a certified copy.

All the enclosed documents must include the name or the title (trading company) of a notifier.

Information forming the summary of the notification intended to be published shall be underlined.

PART A

EXAMPLE OF NOTIFICATION ON THE GENETICALLY MODIFIED ORGANISM OTHER THAN A HIGHER PLANT OR A GENETIC PRODUCT OTHER THAN CONTAINING GENETICALLY MODIFIED HIGHER PLANT

[Ad § 24 paragraph 3 letter b) of the Act]

Date of submission

1. Name of the genetic product (trade name and other names)

2. Person submitting the notification (hereinafter "notifier")

2.1. Name or title or trade company, if the notifier is a natural person authorized to operate a business
2.2. Title or trade company and the legal form, if the notifier is a legal person
2.3. Nationality (in case of natural persons)
2.4. Place of business and place of residence (in case of natural persons)
2.5. Company registration number (if assigned)
2.6. Names 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
2.7. Notifier is:
  2.7.1. Domestic producer
  2.7.2. Importer
  2.7.3. Other (specify)
2.8. In case of import:
  2.8.1. Name or title or trade company of a producer, if he is a natural person authorized to operate a business or the title or trade company in case of legal persons

3. Biosafety officer

(+) 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[7j])

3.1. Name, academic degree
3.2. Occupation or employer and function, as appropriate
3.3. Education
3.4. Professional courses

3.5. Work history
3.6. Address of residence
3.7. Telephone
3.8. E-mail

4. Contact person at the workplace if it differs from the biosafety officer
4.1. Name, academic degree
4.2. Telephone
4.3. E-mail

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

6. Purpose and procedure of the placing of genetically modified organism or genetic product on the market
6.1. Purpose of placing of the genetically modified organism or genetic product on the market
6.2. Date of expected commencement of the placing of the genetically modified organism or genetic product on the market and its schedule (details of the individual stages, the date of expected commencement thereof and the period of particular stages)
6.3. 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 Union, as appropriate, or whether it is to be imported.

7. Risk assessment of the placing of genetically modified organism or genetic product on the market
(+) Risk assessment under § 7 of the Act

If the product contains more genetically modified organisms, the point from 8 to 13 must be filled in for each genetically modified organism separately.

8. General description of the genetically modified organism or genetic product and the genetically modified organism, as or in product
8.1. Type of genetically modified organism or genetic product (expected use of the genetically modified organism or genetic product)
8.2. Composition of the genetic product
8.3. Specificity (difference) of the genetic product (in comparison with the same type of a product that does not contain genetically modified organisms)
8.4. Target group of consumers (e.g. industry, agriculture, small consumers)
8.5. Conditions of the use, particularly differences between the use of the genetically modified organism or genetic product and the use of similar non-modified organisms or products containing non-modified organisms
8.6. Unambiguous determination of a geographical territory in the EU, where the placing on the market of the genetically modified organism or genetic product shall be limited to, as appropriate

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

8.8. Estimated annual demand:

8.8.1. in the Czech Republic

8.8.2. in the European Union

8.8.3. on the export markets

8.9. Unique identifier of the genetically modified organism as or in product

8.10. Has the same notifier submitted a notification for the deliberate release into the environment for the same genetically modified organism as or in the product?

If so, provide the number or other identification of the notification (date and notification identification) and the country of the submission

If no, provide the risk assessment of the genetically modified organism pursuant to the requirements of the notification for granting the consent for the deliberate release into the environment (part A, section 1, point 10 of Annex No. 2 to this Decree)

8.11. Is the notifier at the same time submitting a notification for the placing of the same genetically modified organism or genetic product on the market in any other Member State of the European Union?

If so, provide the number or other identification of the notification and the country of submission

8.12. Has a product containing the same genetically modified organism (the same combination of genetically modified organisms) been placed on the market in EU by another notifier?

If so, specify the notifier, date and identification of the consent, the country of submission and the consent validity

8.13. Information on whether a notification for placing of the same genetically modified organism or genetic product on the market has been submitted in other country outside of the European Union.

If so, specify the country where the notification has been submitted, number or other notification identification (date and specification of the consent, if issued), the notifier, purpose and period of placing on the market

8.14. Summary of data obtained from the previous or ongoing cases of deliberate release of the same genetically modified organism or the same combination of genetically modified organisms into the environment in various conditions representing different environments where the genetically modified organism may be used

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

8.16. Proposed form of packaging of the genetically modified organism or genetic product

8.17. Proposed form of labelling beyond the scope of regulations applicable to the European Union[14)]

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

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

9. Information on the recipient or parental organism, if applicable

9.1. Czech and Latin genus and species names of the recipient or parental organism including a precise determination of the breed (strain, form, stock, cellular line, pathovar)
9.2. Origin (collection, collection number, supplier)
9.3. Phenotypic and genetic markers
9.4. Own plasmids, bacteriophages and other vectors (when concerning microorganisms)
  9.4.1. Sequences of the vector
  9.4.2. Frequency of mobilisation of the vector
  9.4.3. Specificity of the vector
  9.4.4. Presence of genes for resistance of the vector to antibiotics
9.5. Degree of congeniality between donor organism and recipient
9.6. Occurrence and living conditions
  9.6.1. Geographical distribution
  9.6.2. Habitat (natural occurrence) of the organism
  9.6.3. Natural predators, preys, parasites and competitors, symbionts and hosts
  9.6.4. Other potential interactions with other organisms
9.7. Genetic stability and affecting factors
9.8. Potential intercellular transfer of the heritable genetic material between the donor (parental organism) and other organisms
  9.8.1. The way of transfer (by means of plasmid, bacteriophage, otherwise)
  9.8.2. Organisms with which the natural exchange of heritable genetic material occurs
  9.8.3. Consequences of such transfer
9.9. Reproduction
  9.9.1. Mode of reproduction
  9.9.2. Specific factors that affect reproduction (if exist)
  9.9.3. Generation time in the natural environment and generation time in the ecosystem where the genetically modified organism is to be released
9.10. Survivability
  9.10.1. Survivability in the individual weather seasons
  9.10.2. Ability to form persistent surviving forms (e.g. spores, sclerotia)
  9.10.3. Other specific factors enhancing the survival, if exist
9.11. Dissemination in the environment
  9.11.1. Ways and extent of dissemination
  9.11.2. Specific factors affecting dissemination (if exist)
9.12. Spectrum of hosts including non-target organisms
9.13. Interactions with the environment
9.14. Involvement in environmental processes:
  - Primary production
  - Nutrients turnover (consumer, predator)
  - Decomposition of organic matter
  - Other (unambiguously specify)
9.15. Methods of detection
  9.15.1. Description of the methods
  9.15.2. Sensitivity, reliability (quantitatively) and specificity of the methods
9.16. Methods of identification
  9.16.1. Description of the methods
  9.16.2. Sensitivity, reliability (quantitatively) and specificity of the methods
9.17. Classification of the organism pursuant to special legal regulations of the Czech Republic concerning the protection of environment or human health

9.18. Specify whether the organism is pathogenic or otherwise harmful (living or non-living including extracellular products) relating to humans, animals, plants or otherwise.
If so, specify unambiguously potential characteristics:
- 9.18.1. Pathogenicity: epidemicity, infectiousness, virulence
- 9.18.2. Allergenic effects
- 9.18.3. Toxic effects
- 9.18.4. Pathogen carrier,
- 9.18.5. Possible vectors, host area including non-target organism,
- 9.18.6. Potential activation of latent viruses (proviruses)
- 9.18.7. Potential ability to penetrate into other organisms or colonise them
- 9.18.8. Resistance to antibiotics and potential use of such antibiotics for prophylaxis and treatment human and animal diseases
- 9.18.9. Other

9.19. Nature and description of known extrachromosomal genetic particles

9.20. Description of previous genetic modifications of the organism

10. Information on the genetic modification

10.1. Type of genetic modification:
- 10.1.1. Insertion of the foreign heritable genetic material
- 10.1.2. Deletion of a part of the heritable genetic material
- 10.1.3. Combination of deletion and insertion of heritable genetic material
- 10.1.4. Cellular fusion
- 10.1.5. Other (specify unambiguously)

10.2. Description of methods used for the genetic modification

10.3. Information on the vector, if it was used during the genetic modification
- 10.3.1. Type of the vector
- 10.3.2. Identity of the vector (origin)
- 10.3.3. Description of the vector construction

(+) Genetic map or restriction map of the vector, as appropriate
- 10.3.4. Sequence of the vector
- 10.3.5. 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
- 10.3.6. Ability of the vector to transfer heritable genetic material
- 10.3.7. Frequency of the mobilisation of the vector
- 10.3.8. Information on whether the vector is fully or partly present in the final genetically modified organism
- 10.3.9. Spectrum of the hosts of the vector
- 10.3.10. Presence of a sequence of the vector, which transfers a selectable or identifiable phenotype:
  - 10.3.10.1. Resistance to the antibiotics (identify the precise name of the active substance)
  - 10.3.10.2. Resistance to heavy metals
  - 10.3.10.3. Resistance to pesticides (identify the precise name of the active substance)
  - 10.3.10.4. Other (specify unambiguously)
- 10.3.11. Method of insertion of the vector into the recipient organism

11. Information on the insert

11.1. If the vector has not been used in the genetic modification, method of the insertion of the insert into the organism of the recipient

11.2. Methods used for construction of the insert

11.3. Restriction sites

11.4. Sequence of the insert

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

11.5.1. Origin

11.5.2. Functional characteristic

11.5.3. Size

11.5.4. Location

11.5.5. Sequence

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

11.7. Information on whether the insert contains parts, products or functions of which are not known

If so, specify unambiguously

11.8. Location of the insert in the final genetically modified organism:

11.8.1. On a free plasmid

11.8.2. Integrated into chromosomes

11.8.3. Other (specify unambiguously)

11.9. Number of copies of the inserted heritable genetic material

11.10. Stability of the inserted heritable genetic material and the stability of its location

12. Information on the donor organism (donor organisms)

12.1. Czech and Latin genus and species names of the organism including a precise determination of the cultivar (variety, breed, strain, line, form, hybrid, stock, pathovar)

12.2. Specify whether the donor organism is pathogenic or otherwise harmful (living or non-living, including extracellular products)

If so, then specify whether it is related to humans, animals, and plants or otherwise.

Always specify unambiguously the harmfulness.

Do pathogenic or harmful properties concern the sequences used during genetic modification?

If so, identify unambiguously possible characteristics:

12.2.1. Pathogenicity: epidemicity, infectiousness, virulence

12.2.2. Allergenic effects

12.2.3. Toxic effects

12.2.4. Pathogen carrier

12.2.5. Possible vectors, host area including non-target organism

12.2.6. Potential activation of latent viruses (proviruses)

12.2.7. Potential ability to penetrate into other organisms or colonise them

12.2.8. Resistance to antibiotics and potential use of such antibiotics for prophylaxis and treatment human and animal diseases

12.2.9. Other

12.3. Classification of the donor organism pursuant to other valid legal regulations concerning the protection of the environment or human health

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

13. Information on the final genetically modified organism (genetically modified organism contained in the genetic product)

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

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

13.3. Expression of the introduced heritable genetic material

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

13.3.2. Expression stability

13.3.3. Description of measurement methods and their sensitivity

13.4. Expressed proteins

13.4.1. Activity of the expressed proteins

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

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

13.6. Detection methods of the genetically modified organism in the environment, if they differ from the detection of the recipient or parental organism

13.7. Identification methods for the distinction of genetically modified organism from the recipient or parental organism

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

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

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

13.8. Effects on health

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

13.8.2. Risks of the genetic product

13.8.3. Comparison of the genetically modified organism with the donor organism, recipient or parental organism, as appropriate, as regard to pathogenicity

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

13.8.5. If the genetically modified organism is more pathogenic for immunocompetent people, than the recipient or parental organism, then specify:

13.8.5.1. Diseases that could be caused by the genetically modified organism and the mechanism of pathogenicity including invasivity and virulence

13.8.5.2. infectiousness

13.8.5.3. Infectious dose

13.8.5.4. Hosts area, potential adaptations

13.8.5.5. Survivability outside of human host

13.8.5.6. Presence of vectors or dissemination agents

13.8.5.7. Degree of biological stability

13.8.5.8. Characteristic of the resistance to antibiotics

13.8.5.9. Allergenicity

13.8.5.10. Availability of appropriate therapies

13.8.6. Information on possible harmful effects of the genetically modified organism or genetic product on human health resulting from the genetic modification.
Always specify unambiguously possible harmful effects

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

13.9. Interaction of the genetically modified organism with the environment

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

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

13.12. Czech and Latin genus and species names of an target organism, if it exists, including a precise determination of the cultivar (variety, breed, strain, line, form, hybrid, stock, pathovar)

13.13. Mechanism of the interaction between the genetically modified organism or genetic product and the target organism, if this organism exists

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

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

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

13.17. Information on how the genetically modified organism differs from the recipient or parental organism.
Specify unambiguously the differences:

13.17.1. Means and rate of the reproduction, generation time

13.17.2. Dissemination in the environment

13.17.3. Survivability

13.17.4. Effects on health of human beings, animals and other organisms

13.17.5. Other

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

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

14.1. Effects of the product on the environment

14.2. Effects of the product on the health of human beings

15. Information on previous deliberate release into the environment in the Czech Republic (if applicable)

15.1. Authorised person

15.2. Date and number of the consent

15.3. Place of the deliberate release into the environment

15.4. Purpose of the deliberate release into the environment

15.5. Period of the deliberate release into the environment, date of its commencement and

15.6. termination

15.7. Specificity and period of monitoring
15.8. Conclusions of monitoring
15.9. Results of the deliberate release into the environment with regard to any risks for human and animal health, the environment and biological diversity

16. Information on previous deliberate release into the environment or placing on the market in other countries

16.1. Authorised person
16.2. Date and specification of the consent
16.3. Country
16.4. Competent authority
16.5. Place, date of the commencement and termination of the deliberate release into the environment
16.6. Period, date of the commencement and termination of monitoring
16.7. Scope of monitoring
16.8. Conclusions of monitoring
16.9. Results of the deliberate release into the environment or placing on the market, as appropriate, regarding to any risks for human and animal health, the environment and biologically diversity

17. Information on previous use (research, development, utilisation) important for risk assessment

18. Monitoring plan

18.1. Identified markers, properties and unclarities related to the genetically modified organism or genetic product or their interactions with the environment, on which the monitoring plan should be focused
18.2. Provision, extent and method of monitoring the effects of genetically modified organism or genetic product on human and animal health, the environment and biological diversity (monitoring of the genetically modified organism or genetic product)
18.3. Provision, method and frequency of sampling and analysing the samples after the genetically modified organism or genetic product is placed on the market

19. Information on providing reference samples of the genetically modified organism or genetic product and storing them with the competent authority or a legal person assigned by this authority

19.1. Specification and volume of a sample provided together with the notification under § 24 paragraph 5 of the Act
19.2. Frequency and the method of the transfer of samples after granting the consent for placing on the market

20. Statement of the biosafety officer

PART B

EXAMPLE OF NOTIFICATION OF THE GENETICALLY MODIFIED ORGANISM THAT IS A HIGHER PLANT OR A GENETIC PRODUCT CONTAINING GENETICALLY MODIFIED HIGHER PLANT

[Ad § 24 paragraph 3 letter a) of the Act]

Date of submission

1. Name of the genetic product (trade name and other names)

2. Person submitting the notification (hereinafter "notifier")

2.1. Name or title or trade company, if the notifier is a natural person authorized to operate a business
2.2. Title or trade company and the legal form, if the notifier is a legal person
2.3. Nationality (in case of natural persons)
2.4. Place of business (in case of legal persons) and place of residence (in case of natural persons)
2.5. Company registration number (if assigned)
2.6. Names 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
2.7. Notifier is:
  2.7.1. Domestic producer
  2.7.2. Importer
  2.7.3. Other (specify)
2.8. In case of import:
  2.8.1. Name or title or trade company of a producer, if he is a natural person authorized to operate a business or the title or trade company in case of legal persons
  2.8.2. Place of business and place of residence (in case of natural persons)

3. Biosafety officer

(+) 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[7)])

3.1. Name, academic degree
3.2. Occupation or employer and function, as appropriate
3.3. Education
3.4. Professional courses
3.5. Work history
3.6. Address of residence
3.7. Telephone
3.8. E-mail

4. Contact person at the workplace if it differs from the biosafety officer

4.1. Name, academic degree
4.2. Telephone
4.3. E-mail

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

5.1. Purpose of placing of the genetically modified organism or genetic product on the market
5.2. Date of expected commencement of the placing of the genetically modified organism or genetic product on the market and its 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 Union, as appropriate, or whether it is to be imported.

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

(+) Risk assessment under § 7 of the Act

If the product contains more genetically modified higher plants, it shall be necessary to elaborate points from 7 to 10 separately for each genetically modified organism, as appropriate.

7. General description of the genetically modified higher plant or genetic product and genetically modified higher plant contained in the genetic product

7.1. Czech and Latin genus and species names of the recipient or the parental plant including a precise determination of the cultivar (variety, line, hybrid)

7.2. Functions of the genetically modification

7.3. Forms that are inappropriate for placing of the genetically modified organism or the genetic product on the market (seeds, cutting flowers, vegetative parts etc.), as a proposed condition for the placing on the market

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

7.5. Conditions for the use, particularly differences between the use of the 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 conditions for the placing on the market

7.6. Unambiguous determination of a geographic area in the European Union, to which the placing of the genetically modified organism or genetic product shall be limited, as appropriate

7.7. The environment where the use of the genetically modified organism (genetic product) is undesirable

7.8. Proposed form of packaging of genetically modified higher plant or genetic product

7.9. Proposed form of labelling beyond required scope of the relevant regulations of the European Union[14)]

7.10. Estimated annual demand:

7.10.1. in the Czech Republic

7.10.2. in the European Union

7.10.3. on the export markets

7.11. Unique identifier of the genetically modified higher plant

7.12. Has a notification for the deliberate release of the same genetically modified higher plant or genetically modified higher plant contained in the genetic product into the environment been submitted in any Member State of EU?

If so, specify the notifier, the number or other identification of the notification (date and assigning of the consent, if was granted) and the country of submission

If no, provide the risk assessment of the genetically modified higher plant pursuant to the notification requirements for granting a consent for the deliberate release into the environment (part A, point 10 of Annex No. 2 to this Decree)

7.13. Is the notifier at the same time submitting a notification for the placing of the same genetically modified higher plant or genetic product on the market in another Member State of EU?

If so, provide the number or other identification of the notification and the country of submission.

If no, provide the risk assessment of the genetically modified higher plant pursuant to the requirements of the notification for granting a consent for the deliberate release into the environment (part A, point 10 of Annex No. 2 to this Decree).

7.14. Information on whether the notification for the placing of the same genetically modified higher plant or genetic product on the market has been or is submitted in other country outside the EU

If so, specify the notifier, number or other identification of the notification (date and identification of the consent, if it was granted), the country of submission and the period validity (the period for which the consent has been granted).

7.15. Has the notification for placing of the same genetically modified higher plant or the same genetic product on the market in EU already been previously submitted?

If so, specify the number or other identification of the notification and the country where the notification has been submitted.

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

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

7.18. Summary of data obtained from previous or ongoing cases of the deliberate release of the same genetically modified higher plant or the same combination of genetic modified higher plants into the environment under various conditions representing different environments where the genetically modified higher plant can be used

8. Information on the recipient or parental organism, as appropriate

8.1. Czech and Latin genus and species names of the plant including a precise determination of the cultivar (variety, line, hybrid)

8.2. Origin (collection, number of the collection, supplier)

8.3. Reproduction

8.3.1. Mode of reproduction

8.3.2. Specific factors that affect reproduction (if exist)

8.3.3. Generation time

8.3.4. Sexual compatibility with other cultivated or wild species and distribution of these compatible species in the Czech Republic

8.4. Survivability

8.4.1. Ability to form structures that enhance survival or dormancy, and the time period of potential survival or dormancy

8.4.2. Other specific factors enhancing survival, if exist

8.5. Dissemination in the environment

8.5.1. The way and extent of dissemination (decrease of pollen and seeds amount in relation to the distance from the source, power and direction of wind and other factors)

8.5.2. Specific factors affecting dissemination (if exist)

8.6. Geographic distribution

8.7. If the higher plant is not cultivated in the Czech Republic, description of the habitat including the information on natural consumers, pathogens, parasites, competitors and symbionts
8.8. Further potential relevant interactions of the higher plant with other organisms in the ecosystem where the higher plant is usually cultivated
8.9. Specify whether there are any effects of plant on human beings, animals or other organisms
8.9.1. Allergenic effects
8.9.2. Toxic effects
8.9.3. Other harmful effects,
8.10. Significant phenotypic and genetic markers

9. Information on the genetic modification

9.1. Type of the genetic modification:
9.1.1. Insertion of foreign heritable genetic material
9.1.2. Deletion of a part of the heritable genetic material
9.1.3. Combination of deletion and insertion of heritable genetic material
9.1.4. Cellular fusion
9.1.5. Other (necessary specify unambiguously)
9.2. Description of methods used for the genetic modification
9.3. Properties and origin of the used vector (if a vector has been used in the genetic modification) (+) Vector map
9.4. Information on each part of the DNA section, which is to be inserted into the organism of the recipient (if the insertion of heritable genetic material is included in the genetic modification)
9.4.1. 3.4.1 Size
9.4.2. 3.4.2 Location
9.4.3. 3.4.3 Sequence
9.4.4. 3.4.4 Origin (Czech and Latin genus and species names of the donor organism including precise determination of the cultivar - variety, breed, strain, line, form, hybrid, stock, pathovar)
9.4.5. Functional characteristic

10. Information on the genetically modified higher plant

10.1. Description and characteristic of the heritable genetic properties that are introduced or altered including the signal and selection genes and previous modifications and description of their phenotypic effects
10.2. Information on the DNA section, which has been inserted or deleted
10.2.1. Structure and size of the inserted section including the information on each section of the vector, which was inserted into the genetically modified higher plant, or on any carrier or foreign DNA that remained in the genetically modified higher plant
10.2.2. In case of the deletion of a part of the heritable genetic material, the size and function of each part of the deleted section of nucleic acid
10.2.3. Location of the inserted heritable genetic material in the plant cell (integrated into chromosomes, chloroplasts or in non-integrated form) and methods of determination of these data
10.2.4. Stability of the inserted heritable genetic material and stability of the location thereof
10.2.5. In the case of genetic modification other than insertion or removal of a part of the heritable genetic material, describe the function of the heritable genetic material prior and after the performance of modification and further describe direct changes in the expression of genes resulting from the modification

10.3. Information on the expression of the inserted heritable genetic material
- 10.3.1. Expression of the inserted heritable genetic material and methods used for the characterisation thereof
- 10.3.2. Place where the expression of introduced genes in the plant occurs (e.g. roots, stem, leaves, pollen etc.)
- 10.3.3. Changes in the expression related to the plant life cycle
- 10.3.4. Expression stability

10.4. Information on how the genetically modified higher plants differ from the recipient or parental organism (specify always unambiguously the differences)
- 10.4.1. Mode and rate of reproduction
- 10.4.2. Dissemination in the environment
- 10.4.3. Survivability
- 10.4.4. Effects on human and animal health, and other organisms
- 10.4.5. Effect on non-target organisms
- 10.4.6. Other

10.5. Ability of the genetically modified higher plant to transfer genetic material to other organisms and consequences of this transfer

10.6. Information on potential harmful effects of the genetically modified higher plant on human health resulting from the genetic modification. Potential harmful effects always unambiguously.

10.7. Information on the safety of the genetically modified higher plant for animal health, when the genetically modified higher plant is to be used as feed, if the safety of genetically modified higher plant differs from the recipient or parental organism

10.8. 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

10.9. Potential changes in interactions of the genetically modified organism or genetic product with non-target organisms, resulting from the genetic modification
- 10.9.1. Description of the part of altered DNA
- 10.9.2. Methods of detection and identification of the genetically modified higher plant, verified sampling methodology and processing of samples

10.10. Behaviour of the inserted genes
- 10.10.1. During hybridisation with the same species
- 10.10.2. During hybridisation with distant species

10.11. Phenotypic stability of the genetically modified higher plant

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

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

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

11.3. Potential effect on the environment resulting from the interaction between the genetically modified higher plant and non-target organisms, if it differs from the interaction of the recipient or parental organism, as appropriate
- 11.3.1. Effects on the biological diversity at the place of cultivation
- 11.3.2. Effects on the biological diversity in other environments

11.3.3. Effects on pollinators
11.3.4. Effects on endangered species
11.3.5. Potential interactions with non-living components of the environment

12. Information on previous cases of the deliberate release of genetically modified higher plant into the environment

12.1. Previous deliberate release into the environment carried out by the notifier in the Czech Republic
12.1.1. Date and number of the consent
12.1.2. Conclusions of the monitoring
12.1.3. Results of the deliberate release into the environment or placing market, as appropriate, with regard to any risks for human and animal health, the environment and biological diversity

12.2. Previous cases of the deliberate release into the environment or placing on the market carried out by the notifier in other countries
12.2.1. Country
12.2.2. Competent authority
12.2.3. Date and specification of the consent
12.2.4. Place of the deliberate release into the environment
12.2.5. Purpose of the deliberate release into the environment
12.2.6. Period of the deliberate release into the environment
12.2.7. Period of monitoring
12.2.8. Scope of the monitoring
12.2.9. Conclusions of the monitoring
12.2.10. Results of the deliberate release into the environment or placing on the market, as appropriate, with regard to any risks for human and animal health, the environment and biological diversity

13. Monitoring plan

13.1. Identified markers, properties and unclarities related to the genetically modified higher plant or genetic product or their interactions with the environment, on which the plan of monitoring should be focused

13.2. Provision, extent and method of monitoring of effects of the genetically modified higher plant or genetic product on humans and animal health, the environment and biological diversity (monitoring of the genetically modified organism or genetic product)

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

14. Statement of the biosafety officer

Annex No. 4 to the Decree No. 209/2004 Coll.

Requirements for the contained area and protective measures for the contained use

PART A

REQUIREMENTS FOR THE CONTAINED AREA AND PROTECTIVE MEASURES FOR MICROBIOLOGICAL LABORATORIES

For the purposes of this part of the Annex the following definitions shall apply:

1. Hygienic airlock means an entry to a laboratory via separated areas, so called clean side of which must be separated from the laboratory by safety doors, cloakroom for changing clothes and shower;
2. standard operation procedure means a procedure enabling safe transfer of material to a sterilisation equipment outside the laboratory and providing the same level of protection as the laboratory;
3. protective clothes mean for example cotton work cover, protective PVC apron, protective rubber-textile apron, special PE overalls, high pressure protective clothing, work coat with cold protective lining, cold protective work coat with cape, protective waterproof coat, cotton work trousers, boiler suit, net cape, protective hat;
4. protective footwear means particularly rubber boots, rubber galoshes, closed work boots - type of ankle boots, closed toes sandals, medical sandals;
5. Personal protective work aids mean for example cotton gloves, latex gloves, PE disposable gloves, nitrilic gloves or requirement for sterility of the 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.

		Class of the contained use			
		I.	**II.**	**III.**	**IV.**
	Contained area				
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
	Equipment				
3.	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination	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 and walls, ceiling

	agents and easy to clean				
4.	Entry to work area via hygienic airlock	Not required	Required only if resulting from the risk assessment	Required	Required
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	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	Required in the building	Required in the building and in compliance with the standard operation procedure (see above)	Required in the contained area	Required in the laboratory, (inserted between „clean“ and „dirty“ department)
	System of work				
9.	Restricted access	Not required	Required	Required	Required
10.	„Biohazard“[15)] sign on the door	Not required	Required	Required	Required
11.	Specific measures to control aerosol dissemination	Not required	Required to minimise spreading	Required to minimise spreading	Required to minimise spreading
12.	Shower	Not required	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)	Protective clothing and footwear (particular type depends on the risk assessment), complete change of clothing and footwear before entry and exit (method of handling with clothing and footwear during collection depends on 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 in compliance with risk assessment (frequency of change depends on the risk assessment)
15.	Efficient control and elimination of GMO vectors (e.g. for insects and rodents)	Required	Required	Required	Required
	Waste				
16	Inactivation of genetically modified organisms in effluent from hand-washing	Required if resulting from the risk assessment	Required	Required	Required

	sinks or drains and showers and similar effluents				
17.	Inactivation of genetically modified organisms in used material and waste pursuant to special legal regulations[16)]	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
	Other measures				
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
20.	Recuperation room outside of the work area	Not required	Required only if resulting from the risk assessment	Required	Required

PART B

CONTAINMENT REQUIREMENTS AND PROTECTIVE MEASURES FOR GLASSHOUSES AND GROWTH-ROOMS

For the purposes of this part of the Annex the following definitions shall apply:

1. 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).
2. Airlock means an entry to the glasshouse or growth-room through isolated chambers, clean side of which is separated from the laboratory by safety doors, cloakroom for change of clothing and shower.
3. 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.

4. Protective clothes mean for example cotton work cover, protective PVC apron, protective rubber-textile apron, special PE overalls, high pressure protective clothing, work coat with cold protective lining, cold protective work coat with cape, protective waterproof coat, cotton work trousers, boiler suit, net cape, protective hat.
5. Protective footwear means for example rubber boots, rubber galoshes, closed work boots - type of ankle boots, closed toes sandals, medical sandals.
6. Personal protective work aids mean for example cotton gloves, latex gloves, PE disposable gloves, nitrilic 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.

		Class of the contained use			
		I.	**II.**	**III.**	**IV.**
	Contained space				
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
	Equipment				
4.	Entry into work structure via separated room with two interlocking doors	Not required	Required	Required entry via airlock	Required entry via 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 HEPAfiltered by aerosol	Not required	Not required	Required for extract air	Required
7.	Autoclave	Required in the facility	Required in the building	Required in the building, in compliance with the standard	Required in containment and it must be inserted between clean

				operation procedure (see above)	and dirty part
	System of work				
8.	Restricted access	Not required	Required	Required	Required
9.	Biohazard sign[15)] on the door	Not required	Required	Required	Required
10.	Shower	Not required	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)	Suitable protective clothing and footwear (particular type depends on the risk assessment) Complete change of clothing and footwear before entry and exit (method of handling with clothing and footwear during collection depends on the risk assessment)
12.	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 personal protective work aids in compliance with the risk assessment (frequency of change depends on the risk	Required protective gloves and other personal protective work aids in compliance with the risk assessment (frequency of change depends on the risk assessment)

				assessment)	
	Waste				
13.	Inactivation of genetically modified organisms in effluent from hand-washing, sinks or drains and showers and similar effluents pursuant to special legal regulations[14)]	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[14)]	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
	Other measures				
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.	Water outflow only into sink where inactivation is carried out in compliance with point 13	Required only if resulting from the risk assessment	Required outflow restriction outside sinks to minimum	Required prevention of outflow outside sink	Required prevention of outflow 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 method of transferring organisms into other facilities must enable to control	Required restriction of dissemination to minimum	Required prevention of dissemination outside the	Required prevention of dissemination outside the	Required prevention of disseminationv outside the

	dissemination of genetically modified organisms	outside the structures in which the organism is transferred	structures in which the organism is transferred	structures in which the organism is transferred	structures in which the organism is transferred
20.	Recuperation room outside of the work area	Not required	Required only if resulting from the risk assessment	Required	Required

PART C:

REQUIREMENTS FOR THE CONTAINMENT AND PROTECTIVE MEASURES FOR ANIMAL FACILITIES

1. If other genetically modified organisms are also used in animal facilities, the facility must also comply with the requirements set up for the particular workplace (e.g. in part A of this Annex in case of genetically modified micro-organisms, or in part B of this Annex in case of genetically modified plants).
2. In case of the clinical assessment of human or veterinary medicinal products containing genetically modified organisms, the requirements for containment and protective measures pursuant to special legal regulations[17)] shall be applied.
3. For the purposes of this part of the Annex the following definitions shall apply:
    a. Animal unit means a separate building or separate area within a building containing facilities for animals and other areas (e.g. feed storage areas, beddings and aids), including equipment for staff (e.g. changing rooms, showers, sterilisers, spaces for food storage etc.)
    b. Animal facility means a facility and equipment specialised depending on the type of animals for their breeding and carrying out experimental manipulations
    c. Isolator means a transparent box where small animals are contained; for large animals isolated rooms are more appropriate.
    d. Protective clothes mean for example cotton work cover, protective PVC apron, protective rubber-textile apron, special PE overalls, high pressure protective clothing, work coat with cold protective lining, cold protective work coat with cape, protective waterproof coat, cotton work trousers, boiler suit, net cape, protective hat
    e. Protective footwear means for example rubber boots, rubber galoshes, closed work boots -type of ankle boots, closed toes sandals, medical sandals
    f. Personal protective work aids mean for example cotton gloves, latex gloves, PE disposable gloves, nitrilic gloves or requirement for sterility of the 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

4. Besides requirements set up by special legal regulations[18)] the animal facilities must comply with the provisions as follows:

		Class of the contained use			
		I.	**II.**	**III.**	**IV.**
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	Required in the building	Required	Required
9.	Protective clothing and footwear	Suitable protective clothing (particular type and frequency of	Suitable protective clothing (particular type and frequency of	Suitable protective clothing and footwear (particular type and	Suitable protective clothing and footwear (particular type depends

		change depends on the risk assessment)	change depends on the risk assessment), protective footwear required if resulting from the risk assessment	frequency of change depends on the risk assessment)	on the risk assessment) Complete change of clothing and footwear before entry and exit (method of handling with clothing and footwear during collection depends on the risk assessment)
10.	Personal 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 personal protective work aids in compliance with risk assessment (frequency of change depends on the risk assessment)	Required protective gloves and other personal protective work aids in compliance with 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
In case of facilities for water animals					
12.	Inactivation of animals in wastewater	Required	Required	Required	Required
13.	Construction of the room such that in case of leakage, rupture or overflow of the tank for animals it prevents 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

(FOR EXAMPLE PRODUCTION PLANTS, PILOT PLANTS)

For the purposes of this part of the Annex the following definitions shall apply:

1. A contained system means an installation permanently located in a contained area intended for the storage and cultivation of genetically modified organisms, usually in large volumes.
2. An airlock means an entrance to the contained area via separated areas. Their "clean" side shall be separated from the contained area by safety doors, a changing room for changing clothing and a shower.
3. Protective clothes mean for example cotton work cover, protective PVC apron, protective rubber-textile apron, special PE overalls, high pressure protective clothing, work coat with cold protective lining, cold protective work coat with cape, protective waterproof coat, cotton work trousers, boiler suit, net cape, protective hat.
4. Protective footwear means for example rubber boots, rubber galoshes, closed work boots - type of ankle boots, closed toes sandals, medical sandals.
5. Personal protective work aids mean for example cotton gloves, latex gloves, PE disposable gloves, nitrilic gloves or requirement for sterility of the 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.

		Class of the contained use			
		I.	**II.**	**III.**	**IV.**
	Contained system				
1.	Viable organisms should be kept in a contained system which separates them from the environment	Required only if resulting from the risk assessment	Required	Required	Required
2.	Control of dissemination of aerosols escaping from the contained 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 contained system or transfer of material to another contained 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 culture medium before removal from the	Necessary inactivation by means of	Necessary inactivation by means of	Necessary inactivation by means of	Necessary inactivation by means of

	contained system	chemical or physical method	chemical or physical method	chemical or physical method with proven 100 % efficiency	chemical or physical 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
	Other requirements for the contained area				
6.	Capture tank must contain the entire contents of the contained system in case of leakage	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
	System of work				
13.	The entire contained	Not required	Required only	Required	Required

	system should be located within a contained area		if resulting from the risk assessment		
14.	Restricted access	Required	Required	Required	Required
15.	Biohazard signs "Biological Hazard"[15)] should be posted	Not required	Required	Required	Required
16.	Personnel should shower before leaving the controlled area	Not required	Not required	Required	Required
17.	Protective clothing and protective footwear	Required suitable protective clothing (particular type and frequency of change depends on the risk assessment)	Required 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)	Required protective clothing and footwear (particular type depends on the risk assessment) with complete change of clothing and footwear before entry and exit (the method 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 depends on the risk assessment)	Required protective gloves and other personnel protective work aids under risk assessment (frequency of change depends on the risk assessment
	Wastes				
19.	Inactivation of genetically modified	Required only if resulting	Required	Required	Required

	organisms in effluent from hand washing sinks and showers or similar effluents	from the risk assessment			
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[16)]	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
	Other measures				
22.	Recuperation room	Not required	Required only if resulting from the risk assessment	Required	Required

Annex No. 5 to the Decree No. 209/2004 Coll.

Examples of Emergency response plan

Information marked by (+) shall be necessary supported by the original document or a certified copy.

All the enclosed documents must include the name or the title (trading company) of a notifier.

Information on the emergency response plan pursuant § 20 paragraph 5 of the Act intended to be published shall be underlined.

PART A

EXAMPLE OF THE EMERGENCY RESPONSE PLAN FOR THE CONTAINED USE

1. **Notifier (person authorized to use GMO)**
   - 1.1. Name or title or trade company, if the notifier is a natural person authorized to operate a business
   - 1.2. Title or trade company and the legal form, if the notifier is a legal person
   - 1.3. Place of residence
   - 1.4. Company registration number (if assigned)

   In case of natural persons:
   - 1.5. Address of residence
   - 1.6. Telephone
   - 1.7. E-mail

2. **Members of the statutory body (in case of legal persons)**
   - 2.1. Name, academic degree, position
   - 2.2. Address of residence
   - 2.3. Contact address
   - 2.4. Telephone
   - 2.5. E-mail

3. **Biosafety officer**
   - 3.1. Name, academic degree
   - 3.2. Address of residence
   - 3.3. Contact address
   - 3.4. Telephone
   - 3.5. E-mail

4. **Person responsible for the liquidation of accident**
   - 4.1. Name, academic degree
   - 4.2. Address of residence
   - 4.3. Contact address
   - 4.4. Telephone
   - 4.5. E-mail

5. Workplace

5.1. Address of workplace

5.2. Precise designation of premises and facilities

(+) Workplace layout where places significant for the reduction of accident, if happen, are marked (main energy supply control, auxiliary medium supply control, and places for storing of genetically modified organisms, safety elements of closing area or placing of decontamination device for a liquidation an accident)

6. Transportation of genetically modified organisms (if the use of genetically modified organisms includes their transportation outside of the mentioned workplace)

6.1. Method of transportation, description of protection against the leakage of genetically modified organisms

7. Description of an accident that may happen in premises where the use of genetically modified organisms takes place

8. Overview of potential effects of accident on human beings, animals, the environment and biodiversity, incl. methods of detection of these effects and efficient protection against them

9. Methods of detection of genetically modified organisms

10. Procedure in case of an accident

10.1. Decontamination means usable for the liquidation of genetically modified organisms and decontamination of affected space and the place of their storage

10.2. Decontamination means usable for the liquidation of genetically modified organisms and decontamination of affected space

10.3. Methods of isolation of premises and facilities affected by the accident, incl. the methods of isolation efficiency control

10.4. Procedures of protection of human and animals health, the environment, and biological diversity in case of undesirable influencing by the accident; and the methods for elimination or recovery of plants and animals that were present in the area during the accident, pursuant other legal regulation [19)], as appropriate

10.5. Ensuring of subsequent monitoring of premises and plots after the decontamination has been finished

11. Municipalities or persons, as appropriate, to which the emergency response plan is delivered pursuant § 20 paragraph 3 of the Act

12. Manner of notice to authorities stated in § 27 of the Act in case of accident, or manner of warning to citizens, as appropriate

15. Statement of the biosafety officer

PART B

EXAMPLE OF THE EMERGENCY RESPONSE PLAN FOR THE DELIBERATE RELEASE INTO THE ENVIRONMENT

1. **Notifier (person authorized to use GMO)**
   - 1.1. Name or title or trade company, if the notifier is a natural person authorized to operate a business
   - 1.2. Title or trade company and the legal form, if the notifier is a legal person
   - 1.3. Place of residence
   - 1.4. Company registration number (if assigned)

   In case of natural persons:
   - 1.5. Address of residence
   - 1.6. Telephone
   - 1.7. E-mail

2. **Members of the statutory body (in case of legal persons)**
   - 2.1. Name, academic degree, position
   - 2.2. Address of residence
   - 2.3. Contact address
   - 2.4. Telephone
   - 2.5. E-mail

3. **Biosafety officer**
   - 3.1. Name, academic degree
   - 3.2. Address of residence
   - 3.3. Contact address
   - 3.4. Telephone
   - 3.5. E-mail

4. **Person responsible for the liquidation of accident**
   - 4.1. Name, academic degree
   - 4.2. Address of residence
   - 4.3. Contact address
   - 4.4. Telephone
   - 4.5. E-mail

5. **Workplace and plots**
   - 5.1. Address of the workplace
   - 5.2. Precise designation of the plots[20)] or premises and facilities used for storage, as appropriate

   (+) Map with designated plots where the deliberate release into the environment will be conducted; and the comprehensive layout in a suitable scale with marking of the trial and containing the information on species of plant grown at the surrounding plots.

6. **Transportation of genetically modified organisms (if the use of genetically modified organisms includes their transportation outside of the mentioned workplace)**
   - 6.1. Method of transportation, description of protection against the leakage of genetically modified organisms

7. Description of an accident that may happen

8. Overview of potential effects of accident on human beings, animals, the environment and biodiversity, incl. methods of detection of these effects and efficient protection against them

9. Methods of detection of genetically modified organisms

10. Procedure in case of an accident

10.1. Decontamination means usable for the liquidation of genetically modified organisms and decontamination of affected space and the place of their storage

10.2. Decontamination means usable for the liquidation of genetically modified organisms and decontamination of affected plots

10.3. Methods of isolation of premises and facilities affected by the accident, incl. the methods of isolation efficiency control

10.4. Procedures of protection of human and animals health, the environment, and biological diversity in case of undesirable influencing by the accident; and the methods for elimination or recovery of plants and animals that were present in the area during the accident, pursuant other legal regulation [19)], as appropriate

10.5. Ensuring of subsequent monitoring of premises and plots after the decontamination has been finished

11. Municipalities or persons, as appropriate, to which the emergency response plan is delivered pursuant § 20 paragraph 3 of the Act

12. Manner of notice to authorities stated in § 27 of the Act in case of accident, or manner of warning to citizens, as appropriate

13. Statement of the biosafety officer

[7)] Act No 18/2004 Coll., on the recognition of professional qualifications and other competencies of nationals of Member States of the European Union and on the amendment of some Acts (Act on recognition of professional qualifications), as amended

[8)] Act No. 246/1992 Coll., on the protection of animals against cruelty, as amended

[9)] Act No. 258/2000 Coll., on the protection of public health and on changes to certain related laws, as amended
Act No. 309/2006 Coll., on stipulating further requirements for health and safety at work in labour relations and concerning occupational health and safety protection in activities or services provided outside labour relations (Act on Further Requirements on Occupational Health and Safety), as amended

[10)] Government Regulation No. 361/2007 determining conditions of occupational health protection), as amended

[11)] Act No. 252/1997 Coll., on agriculture, as amended

[12)] Act No. 114/1992 Coll., on the conservation of nature and landscape

[13)] Act No. 242/2000 Coll., on organic farming and on the amendment of the Act No. 368/1992 of the Col., on the administrative fees, as last amended.

[14)] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed
Regulation (EC) No 1830/2003 of the European Parliament and of the Council 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

[15)] Government Regulation No. 11/2002 Coll., establishing the appearance and placement of safety signs and introduction of signals, as amended

[16)] for example Act No. 185/2001 Coll., on waste and amendment of certain other acts

[17)] for example Act No. 378/2007 Coll., on pharmaceuticals and on amendments to some related acts; Decree No. 226/2008 Coll., on good clinical practice and detailed conditions of clinical trials on medicinal products, as amended

[18)] for example Act. No. 246/1992 Coll., as amended; Decree No. 419/2012 Coll., on the protection of experimental animals, as amended by Decree No. 299/2014 Coll.; Act No. 166/1999 Coll., on veterinary care and on a change of some related laws (veterinary act), as amended; Act. No. 258/2000 Coll.; Government Decree No. 27/2002 Coll., laying down the methods of organization of work and work procedures that the employer is obliged to ensure for work related to animal breeding.

[19)] for example Act No. 246/1992 Coll., as amended; Act. No. 166/1999 Coll., as amended; Act No. 185/2001 Coll., as amended; Act No. 147/1996 Coll., on plant medicinal care and changes some related laws, as amended.

[20)] § 8 letter a) and b) of the Act No. 256/2013 Coll. on Land Register (Cadastral Law), as amended.