Act No. 78/2004 Coll.,

on the use of genetically modified organisms and genetic products

As amended by Act No. 346/2005 Coll., Act No. 124/2008 Coll., Act No. 227/2009 Coll., Act No. 281/2009 Coll., Act No. 18/2012 Coll., Act 279/2013 Coll., 243/2016/Coll., 371/2016 Coll., 183/2017 Coll.

The Parliament has adopted the following Act of the Czech Republic:

PART I

INTRODUCTORY PROVISIONS

§ 1

Objective

(1) The Act implements relevant regulations of the European Union[1)], follows directly applicable regulations of the European Union[21)] and provides for rights and obligations of persons and the competences of competent authorities in the use of genetically modified organisms and genetic products.

(2) This Act shall not apply to

a) the use of organisms obtained through the technique of mutagenesis, cell fusion or a plant cells protoplasts fusion of organisms, for which the exchange of the genetic material can be achieved through the traditional breeding, unless these techniques at the same time involve the techniques referred to in point 1, Annex 1 to this Act, or the use of genetically modified organisms originated from these procedures,

b) contained use of genetically modified organisms concerning exclusively genetically modified micro-organisms that comply with the safety criteria for human health, animal health, the environment and biological diversity, laid down in Annex 2 to this Act,

c) contained use of genetically modified organisms concerning exclusively genetically modified micro-organisms obtained through cell fusion or protoplasts fusion of cells of prokaryotic species that exchange genetic material via known physiological processes unless this fusion at the same time involves the techniques referred to in point 1, Annex 1 to this Act, or the use of genetically modified organisms originated from these procedures,

d) contained use of genetically modified organisms concerning exclusively genetically modified micro-organisms originated from cell fusion or protoplasts fusion of cells of eukaryotic species including hybridomas formation unless this fusion at the same time

involves techniques referred to in point 1, Annex 1 to this Act, or the use of genetically modified organisms originated from these procedures.

(3) In doubts, whether it is an exemption to the scope of this Act pursuant to paragraph 2, the Ministry of the Environment (hereinafter the "Ministry") shall make the decision.

(4) If a genetically modified organism or a genetic product is a medicinal product subject to registration according to the directly applicable European Union legislation governing the procedures for the registration of human and veterinary medicinal products and the supervision of them[2)] or it is a plant protection product for which the authorisation for placing on the market shall be issued in accordance with the applicable European Union legislation directly governing the placing of plant protection products on the market[22)], it is not subject to § 11 and to provisions of part four of this Act.

§ 2

Definitions

For the purposes of this Act:

a) organism means a biological entity, including a microbiological entity, capable of replication or of transferring a heritable genetic material,

b) heritable genetic material means deoxyribonucleic or ribonucleic acid,

c) genetic modification means the intentional alteration of the heritable genetic material of an organism involving the introduction of foreign heritable genetic material into the heritable genetic material of the organism or removal of part of the heritable genetic material from the organism in a way that cannot be achieved by natural recombination,

d) genetically modified organism means an organism, with the exception of human beings, in which the genetic material has been altered by genetic modification through the use of some of the techniques listed in point 1, Annex 1 to this Act,

e) genetically modified micro-organism means a microbiological entity, capable of replication or of transferring heritable genetic material, including viruses, viroids, animal and plant cells in a culture, whose heritable genetic material has been altered by a genetic modification,

f) genetic product means any preparation containing one or more genetically modified organisms that was produced or obtained in any other way, regardless the degree of its processing, and which is intended for placing on market,

g) contained area means an area bounded by physical barriers, or by combination of physical barriers with chemical or biological barriers, which limit the contact of genetically modified organisms or genetic products with human beings, animals and the environment[3)],

h) monitoring means the identification of the presence of a genetic modification in an organism or a product and observation of the impacts of the genetically modified organism or genetic product on human health, animal health , the environment and biological diversity.

§ 3

The use of genetically modified organisms and genetic products

(1) For the purposes of this Act, the use of genetically modified organisms and genetic products shall mean:

a) contained use of genetically modified organisms (hereinafter "contained use") involving any activity in which organisms are genetically modified or in which genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used in any other way inside a contained area unless the genetically modified organisms are authorized for placing on the market pursuant to § 23 paragraph 1,

b) deliberate release of genetically modified organisms into the environment (hereinafter "release into the environment") involving release thereof into the environment outside of a contained area, unless the genetically modified organisms are authorized for placing on the market pursuant to § 23 paragraph 1,

c) placing of genetically modified organisms or genetic products on the market (hereinafter "placing on the market") involving a transfer for a payment or free of charge to any other person, unless it is a transfer of genetically modified organisms or genetic products to an authorised person solely for the purpose of contained use or release into the environment.

(2) The use of genetically modified organisms and genetic products shall not mean the use thereof from the instant they lose the ability to replicate or transfer heritable genetic material.

(3) In the use of genetically modified organisms and genetic products, any person in accordance with the precautionary principle shall be obliged to protect human and animal health, the environment and biological diversity (hereinafter "health and the environment").

(4) Any person handling a genetically modified organism or genetic product shall be obliged to meet the conditions indicated on the packaging or on the document accompanying the genetically modified organism or genetic product, and use it solely for the purpose stated thereon.

(5) Live vertebrates involved in use of genetically modified organisms and genetic products shall be considered to constitute experiments on animals pursuant to the special legal regulation[4)].

PART II

GENERAL PROVISIONS

§ 4

Authorisation for the use of genetically modified organisms and genetic products

(1) The use of genetically modified organisms may proceed only on the basis of an authorisation pursuant to this Act.

(2) Authorisation for the contained use shall arise from consent for the contained use or a notification thereof. Detailed conditions for granting such authorisation are laid down in § 16 t 16c.

(3) Authorisation for the release into the environment shall arise from the consent for the release into the environment. Detailed conditions for granting such authorisation are laid in § 17 and 18.

(4) The authorisation for placing on the market originates on the day of legal force of the decision on registration of genetically modified organism or genetic product in the list for placing on the market or by issuing a written consent with its placing on the market by the competent authority of another Member State of the European Union (hereinafter referred to as "Member State") or an authorisation pursuant to the directly applicable legislation of the European Union relating to genetically modified food and feed[23)]. More detailed conditions for this authorisation are provided by § 23 to 24c.

§ 5

Administrative procedure for granting consent for the contained use, for the deliberate release into the environment, and for the registration into the List for placing on the market

(1) The notifier submits the notification for the contained use, release into the environment or the registration in the list for placing on the market under this Act to the Ministry
a) via a data box,
(b) in electronic form signed by a recognized electronic signature or
(c) in paper form, if it is at the same time served on the technical data medium or sent in electronic form via a public data network.

(2) In the notification, the notifier may refer to the data, information or results which are included in previously submitted notifications. The data, information or results contained in notifications submitted by other notifiers can be referenced only if such data, information or results are not subject to protection under § 9 or if the notifier whose notification is referenced has granted his written consent.

(3) The Ministry shall, within 5 days of its receipt, examine whether the notification is complete according to the paragraph 1, and shall, if necessary, ask the notifier for additional information. The Ministry shall state in the written call what was incomplete in the submitted data, and at the same time shall lay down the time-period for complementing thereof. This time-period shall not be shorter than 30 days from the date of delivery of the written call. If the notifier fails to complement the notification within the set time-period, the Ministry stops the administrative procedure.

(4) If the notification is in accordance with this Act, the Ministry forwards it to the Ministry of Agriculture and the Ministry of Health (hereinafter “the Ministries concerned”) within 5

days after the expiration of the set time-period for assessment of the notification completeness or after the date of receipt of the complemented notification pursuant to para. 3. Ministry shall make available to the public information on commencement of the administrative procedure on granting consent for the release into the environment or the administrative procedure on the registration in the list for placing on the market in the manner pursuant § 10. Ministry shall make available to the public summary of the notification for the release into the environment or the summary of the notification for the registration in the list for placing on the market in the manner pursuant 10 § letter b.
The requirements of the summary of the notification shall be laid down by the implementing legal act.

(5) The Ministries concerned may inform the Ministry in writing of their opinions or ask for additional information regarding the notification within 30 days of its receipt. If the Ministry concerned asks for additional information, the Ministry shall, within 5 working days of expiration of the time-period referred to in the first clause, ask the notifier to complement the information. In the written call, the Ministry shall state what was incomplete in the submitted information, and at the same time shall lay down the time-period for complementing thereof. This time-period shall not be shorter than 30 days from the date of delivery of the written call. If the notifier fails to complement the requested information within the set time-period, the Ministry stops the administrative procedure. The Ministry shall forward the complemented notification to the Ministries concerned that may express their opinions within 15 working days of its receipt. If the Ministry concerned does not express its opinion within the time periods mentioned above, it is understood to have no comments on the notification.

(6) Every person may forward to the Ministry in writing his/her opinion within 30 days of making the summary of the notification available to the public. The Ministry shall not be obliged to take into account the opinions delivered after expiration of the set time-period.

(7) If the Ministry obtains a negative opinion on the deliberate release of the genetically modified organism into the environment or on the placing of the genetically modified organism or genetic product on the market pursuant to paragraph 6, in which environmental risk assessment results are doubted or an objection to insufficient protection of health and the environment is made, the Ministry shall arrange for a public consultation pursuant to § 6, prior to making a decision on the submitted notification.

(8) The Ministry shall take a decision on the notification within 90 days of the receipt thereof. For the purpose of calculating this time-period, any period for complementing the notification pursuant to paragraphs 3 and 5 and any period during which a public consultation proceeded pursuant to § 6 shall not be taken into account; however, the public consultation shall not prolong the period for the decision by more than 30 days.

(9) When making the decision, the Ministry shall consider also the opinions of the Ministries concerned and of the public. The decision on the submitted notification shall always contain the summary settlement of opinions submitted pursuant to paragraphs 5 and 6, and also results from the public consultation carried out pursuant to paragraph 7.

(10) If the Ministry pursuant to paragraph 8 decides on granting the consent or on registration into the List for placing on the market, the Ministry shall also lay down in this decision the conditions for the use of genetically modified organisms and genetic products.

(11) The Ministry shall also forward the decision pursuant to paragraph 8 to the Ministries concerned and make it available to the public pursuant to § 10.

(12) Pursuant the paragraphs 4, 5, 9 and 11, § 16c paragraph 4 and § 18 paragraph 7, the Regional Authority, in whose administrative district the contained use or the release into the environment is to be immediately carried out, has the same position as concerned Ministries.

§ 6

Public consultation

(1) In the cases pursuant to § 5 paragraph 7, the Ministry shall arrange for a public consultation at latest within 30 days of the expiration of the time-period for the opinion in writing pursuant to § 5 paragraph 6. The Ministry shall make available to the public the information on the public consultation including the place and date thereof pursuant to § 10 at least 5 days before the public consultation takes place.

(2) Besides the Ministry, the notifier applying for granting consent for the release into the environment or for registration into the List for placing on the market shall always take part in the public consultation. In the case of the notifier's absence, the Ministry may suspend the public consultation. In such case the Ministry shall lay down the place and date of a new public consultation at the expense of the notifier. New public consultation shall take place at least within 5 days of the date of suspension of the public consultation referred to in the second clause. The Ministry shall inform the notifier on the place and date of the new public consultation.

(3) The Ministry shall draw up a record of the public consultation containing particularly the information on participation and conclusions of the consultation as well as a complete audio record thereof. The Ministry shall forward this record to the notifier within 5 working days of termination of the public consultation and make it available to the public pursuant to § 10 letter b).

(4) The right to information pursuant to special legal regulations[5)] shall not be prejudiced by this Act.

§ 7

Risk assessment of the use of genetically modified organisms and genetic products

(1) The risk assessment of the use of genetically modified organisms and genetic products is an analysis in writing based on comparison of the use of genetically modified organisms and genetic products with the use of genetically non-modified organisms and products under corresponding conditions, and including the definition and evaluation of possible direct or indirect, immediate or delayed adverse effects of such use, in particular

a) effects on human health,

b) effects on animals and plants,

c) colonisation and spreading of the genetically modified organism in the environment,

d) natural transfer of inserted genetic material to other organisms, in particular transfer of an antibiotics-resistance gene and other preparations used for human or animal treatment, provided that such gene or genes have been inserted into the genetically modified organism.

(2) The risk assessment shall be conducted by a biosafety officer (§ 14).

(3) The following persons shall be obliged to submit the risk assessment to the Ministry

a) the notifier, as a part of the notification for granting consent and for the registration into the List for placing on the market,

b) the person submitting notification pursuant to § 16 paragraph 3 or § 16a paragraph 5 as a part of this notification,

c) the person authorised pursuant to this Act for the first class of contained use in the cases pursuant to § 16 paragraph 4,

d) the person authorised pursuant to this Act for contained use or the release into the environment, and the person registered in the List for placing on the market in the cases referred to in § 8 paragraph 2 and 3.

(4) The following shall have to be considered in the risk assessment:

a) current scientific knowledge,

b) verified experience with the organism that is genetically modified and with related organisms,

c) verified experience with the donor organism if the genetic modification involves insertion of foreign heritable material,

d) verified experience with the genetic modification involved,

e) verified experience with the genetic modified organism or genetic product involved,

f) qualified estimation, if verified scientific knowledge is missing; it is necessary to use the precautionary principle in such cases

(5) The protection of staff against risks from the use of genetically modified organisms and genetic products during the employment follows special legal regulation[6)].

(6) The requirements and procedures of the risk assessment shall be laid down by the implementing legal regulation.

§ 8

New information

(1) If the person authorised under this Act for the contained use or the release into the environment, the person registered in the List for placing on the market or the person applying for such authorisation or registering into the List for placing on the market, obtains new information concerning the risks of genetically modified organisms or products to human health or the environment, then this person shall immediately

a) take measures necessary for protection of human health and the environment, and

b) provide new information in writing and notify the Ministry of the measures taken.

The Ministry shall communicate the information and notify the measures pursuant to letter b) to other competent authorities involved, referred to in § 27.

(2) Further, the person pursuant to paragraph 1 shall carry out a new risk assessment and submit it to the Ministry at latest within 30 days of the date of obtaining new information.

(3) If the Ministry obtains new information on the risks of the genetically modified organism or genetic product to human health or the environment in other way than pursuant to paragraph 1 letter b), the Ministry shall inform the involved persons referred to in paragraph 1, and require them to carry out the new risk assessment and submit it to the Ministry at latest within 30 days of receipt the call. At the same time the Ministry shall notify the new information to other involved competent authorities referred to in § 27.

(4) If new information pursuant to paragraph 1 or 3 concern genetically modified organism or genetic product for which the notification for registration into the List for placing on the market was submitted, the Ministry shall immediately provide such information to the European Commission (hereinafter "Commission") and to the competent authorities of the other Member States. If the registration has not yet been made, the Ministry may require the notifier to submit additional information. When the new information has become available after the registration of the genetically modified organism or genetic product involved into the List for placing on the market, the Ministry shall within 60 days of receiving such information forward to the Commission an assessment report indicating whether and/or how registration should be amended or repealed. If Member States or the Commission do not submit any reasoned objections within 60 days of the date of forwarding the assessment report by the Commission to Member States, or if the outstanding issues are resolved within 75 days of the date of forwarding the assessment report, the Ministry shall take decision on the amendment of registration. The Ministry shall inform Member States, Commission and the Ministries concerned of such decision within 30 days of issuing thereof.

(5) If the Ministry considers that genetically modified organism or genetic product which has received a written consent for placing on the market by a competent authority of a Member State, constitutes a risk to human health or the environment, on the basis of new information that may affect the risk assessment or reassessment of existing information in the light of new scientific knowledge, the Ministry may provisionally restrict or prohibit the use and/or sale of such genetically modified organism or product under corresponding conditions as stipulated in the similar situations for a genetically modified organism or genetic product registered into the List for placing on the market pursuant to this Act. The Ministry shall make this decision available to the public pursuant to § 10.

(6) The Ministry shall immediately send to the Commission and competent authorities of Member States a report on the measures taken to implement the provisions of paragraph 5. This report shall include

a) reasons for the measures,

b) new information on which the decision is based,

c) information indicating whether / how the conditions of the written consent should be amended, or the written consent should be terminated.

(7) The Ministry shall make the report referred to in paragraph 6 available to the public pursuant to § 10.

§ 9

Protection of some information

(1) The notifier pursuant to § 5 paragraph 1 or § 16 paragraph 3 and § 16 paragraph 5, resp. may indicate data in the notification, disclosure of which might harm his/her competitive position and which should therefore be treated as the trade secret[7)] *(i.e. confidential business information*). The person pursuant to the first clause shall be obliged to give verifiable justification that the information indicated by him/her are his/her trade secret.

(2) According to this Act the following information can not be indicated as the trade secret

a) the general description of the genetically modified organism or genetic product,

b) the name or business name, place of business and tax identification number (if assigned) of the person pursuant to paragraph 1, if such person is a legal person, or the, business name, place of business and tax identification number (if assigned) of the person pursuant to paragraph 1, if such person is a natural person authorised to operate a business,

c) the place and the class of the contained uses, the requirements for the contained area and the protective measures for class of the contained uses involved,

d) the place and purpose of the release into the environment or the purpose of placing on the market,

e) the risk assessment

f) the emergency response plan

(3) The information indicated as the trade secret shall only be accessible to

a) the competent authorities referred to in § 27,

b) the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products,

c) the legal persons with which the Ministry has concluded contracts pursuant to § 28 paragraph 1 letter f)

d) the relevant competent authorities of Member States,

e) the Commission

(4) Unless stipulated otherwise by this Act, gathering, maintaining, making available to the public and other ways of processing of personal information performed in connection with the use of genetically modified organisms and genetic products shall proceed pursuant to the special law[8)].

§ 10

Information to the public

The Ministry shall pursuant to this Act make the information available to the public

a) on the official board of the Ministry,

b) on the website of the Ministry,

c) at least in one another appropriate manner in the municipality or region, in the territory of which the contained use or release into the environment takes place, or such use with regard to all circumstances is expected.

§ 11

Labelling

(1) The person providing genetically modified organism exclusively for the purpose of contained use or the release into the environment is required to ensure that on a label or in a document accompanying the GMO the words "genetically modified organism" are clearly marked and that the labelling of genetically modified organism meets any additional requirements for the labelling thereof resulting from the authorisation for the contained use or authorisation for the release into the environment.

(2) The person who, in the course of its business, places the genetically modified organism or genetic product on the market shall ensure that on the label or in a document accompanying the GMO or the genetic product the words "this product contains genetically modified organisms" are stated. The designation of genetically modified organism or genetic product must also include

a) the trade name of the genetic product,

b) the name of a genetically modified organism,

c) the name and registered office address of the person established in the territory of a Member State who is responsible for the placing on the market,

d) the indication of where it is possible to obtain additional publicly available information about this genetic product.

(3) In addition, the designation of genetically modified organism or genetic product placed on the market shall conform to further requirements for its labelling resulting from the registration in the list for placing on the market or from the written authorisation issued for the placing on the market by the competent authority of another Member State of the European Union or from the authorisation issued pursuant to the directly applicable legislation of the European Union relating to genetically modified food and feed[23)].

(4) For products in which adventitious and technically unavoidable traces of genetically modified organisms authorized for placing on the market pursuant to § 23 paragraph 1 cannot be excluded, the Ministry shall establish a minimum threshold of such traces by an implementing legal act, in accordance with the law of the European Union[8a)]. If the traces in the product do not reach the threshold minimum, this product shall not have to be labelled according to paragraphs 2 and 3.

(5) The conditions for placing on the market and requirements on packaging and labelling of products that are laid down by special legal regulations[9)], shall be in no way prejudiced by this provision.

§ 12

Amendment and repeal of consent and registration into the List for placing on the market

(1) The Ministry may amend or repeal the valid consent or registration in the List for placing on the market, if

a) there has been a substantial change of the conditions under which the consent was granted or registration was done,

b) it has been proved that information submitted by the person, which had been granted the consent or by the person registered in the List for placing on the market in the administrative procedure for granting the consent or registration into the List for placing on the market or the change thereof were incorrect, or

c) obligations laid down by this Act or stipulated pursuant to the Act have been seriously or repeatedly breached by the person that had been granted a consent or by the person registered in the List for placing on the market.

(2) The Ministry shall repeal the valid consent or registration in the List for placing on the market, if the person authorised for the contained use or the release into the environment, or the person registered in the List for placing on the market, requests the Ministry to do so.

(3) If necessary, the Ministry in the decision pursuant to paragraphs 1 or 2, shall lay down also the conditions for termination of the use of genetically modified organisms and genetic products including potential disposal thereof.

§ 13

Termination of authorisation for the use of genetically modified organisms and genetic products

Authorisation for the use of genetically modified organisms and genetic products pursuant to this Act shall be terminated by

a) the expiry of the time period for which the consent has been granted or for which the registration into the List for placing on the market has been valid,

b) the termination of authorisation to operate a business provided that the authorised person is a natural person authorised to operate business,

c) the death of a natural person authorised to operate a business or termination of a legal person authorised to operate a business,

d) the date of legal effect of the decision on repeal of the consent or of registration in the List for placing on the market,

e) the expiry of time period for which the written authorization for placing on the market has been issued by the competent authority of the other Member State or for which the authorisation has been issued pursuant to the directly applicable legislation of the European Union relating to genetically modified food and feed, or by repeal of this authorization,

(f) if a person authorised to contained use will not submit a new notification in the cases pursuant § 16b para 2.

§ 14

Biosafety officer

(1) Only blameless and professionally qualified natural person may be appointed a biosafety officer pursuant to this Act.

(2) A person, who has not been lawfully sentenced for a negligent crime whose acts are connected with the use of genetically modified organisms and genetic products, or for an intentional crime, shall be considered blameless for the purpose of this law. The blamelessness shall be proved by a record from the Criminal Register not older than 3 months.

(3) Professional qualification pursuant to paragraph 1 shall be proven by a certificate of completed university education in an accredited study programme[10)] in a branch of medicine, veterinary medicine, biochemistry and microbiology for the use of genetically modified micro-organisms; in a branch of natural sciences, agriculture or forestry for the use of genetically modified plants; or in a branch of natural sciences, agriculture or veterinary medicine for the use of genetically modified animals and by at least 5 years of practice in a relevant branch, out of that at least 2 years of the use of genetically modified organisms. A

postgraduate or doctoral study of the relevant branch concerning the use of genetically modified organisms is also included into the required two-years practice.

PART III

CONTAINED USE AND DELIBERATE RELEASE INTO THE ENVIRONMENT

CHAPTER I

CONTAINED USE

§ 15

(1) In the case of contained use, risk assessment shall result in the final classification in one of four classes set out in Annex 3 to this Act. Where there is doubt as to which class is appropriate for the proposed contained use, it shall be necessary to assess such use under the requirements for the higher class.

(2) To conduct contained use is possible only in a contained area that complies with the requirements on containment and protective measures laid down for the pertinent or higher risk class of the contained use. Requirements on contained area and protective measures for the individual class risk of the contained use shall be laid down by the implementing legal act.

(3) A person authorised for the contained use pursuant to § 16 to 16c shall control the contained area and the protective measures regularly during the contained use according to the Code of Practice and also immediately after having obtained information pursuant to § 8, and keep records on the reviews done.

§ 16

(1) The authorisation for contained use may only be granted to a legal entity or a natural person authorised to operate business.

(2) The authorisation for the first and second class contained uses, which are classified on the basis of the result of the risk assessment pursuant to § 7, originates by its notification. The authorisation for class 3 and 4 contained uses, which are classified on the basis of the result of the risk assessment pursuant to § 7, originates on the day of legal force of authorisation for contained use.

(3) The notification of the contained uses must be submitted to the Ministry before the first contained use in a contained area under § 15 paragraph 2. The notification for the contained use may be submitted together for more contained areas provided they are located in one building.

(4) The notification for the first and second class contained uses and the request for granting consent for the third and fourth class contained uses shall, in addition to the general requirements under the administrative code, always contain

a) the identification, contact and other information about the biosafety officer and the contact person at the workplace,

b) the information about genetically modified organisms,

c) the purpose of the contained use,

d) the address and description of the workplace where the contained use will be carried out,

e) the assessment of space and equipment of the workplace where the contained use will be carried out, in terms of the fulfilment of requirements for contained area and protective measures laid down for the relevant risk category and

f) the statement of the biosafety officer

(5) The notification for the third and fourth class contained uses must also include

a) the description of contained use and

b) the information about the duration of contained use.

(6) The implementing legislation lays down, in the form of notification example its detailed content

a) notification for the class 1 contained use,

b) notification for the class 2 contained use,

c) request for granting of authorisation for the 3 or 4 class contained uses.

§ 16a

(1) The notifier submits the notification for the class 1 or 2 contained uses to the Ministry

a) via a data box,

b) in electronic form signed by a recognized electronic signature or

c) in paper form, if it is at the same time served on the technical data medium or sent in electronic form via a public data network.

(2) The notifier may refer the notification to the data, information or results which are the content of previously filed notifications. The data, information or results contained in notifications submitted by other notifiers can be referenced only if such data, information or results are not subject to protection under § 9 or if the notifier whose notification is referenced has granted his written consent.

(3) The class 1 contained use may be commenced immediately following the submission of notification. The class 2 contained use may be started after the expiration of 45 days from the date of notification submission unless within that period the Ministry will not issue any of the decisions referred to in § 16b, paragraph 1. With the consent of the Ministry the class 2

contained use can be commenced even before the expiry of that period; the second and third section of the administrative code shall not apply to the issue of consent by the Ministry.

(4) If the genetically modified organisms which have not been listed in the notification are to be subsequently used in the enclosed area notified pursuant to paragraph 1 and the result of the risk assessment of the contained uses of these organisms under § 7 is classified in the class 1, the notifier shall submit to the Ministry only the relevant risk assessment with reference to the previous notification submitted in accordance with paragraph 1. The contained use of these organisms can be commenced immediately upon the submission of risk assessment. The risk assessment for class 1 contained use must, in addition to the reference to the prior notification, contain information about newly used genetically modified organisms, and the statement of the biosafety officer. The risk assessment example of such case of class 1 contained use is defined by implementing legislation.

(5) If the genetically modified organisms which have not been listed in the notification are to be subsequently used in the enclosed area notified pursuant to paragraph 1 and the result of risk assessment of the contained uses of these organisms under § 7 is classified in the class 2, the notifier shall submit a new notification to the Ministry.

(6) The Ministry shall send the acknowledgement of receipt to the notifier pursuant to the paragraph 1 or 5, or the acknowledgement of the receipt of the risk assessment referred to in paragraph 4 within 5 working days from the date of the notification submission. The Ministry is authorised to request the notifier, within 30 days from the date of submission of the notification or the submission of risk assessment referred to in paragraph 4, to present more information or specification of information referred to in the notification or in the risk assessment.

§ 16b

(1) The Ministry may, based on the submitted notification, risk assessment, additional information or data specifications pursuant to § 16a paragraph 6 or new information according to § 8, require the notifier to amend conditions of the contained use as referred to in the notification, or to classify the contained use in a different class risk, or to suspend or terminate the contained use if it is necessary in terms of the health or environment protection. The appeal against the decision by which the notifier was obliged to make amendments of conditions for contained uses referred to in the notification, to classify the contained use in a different risk category, or to suspend or terminate the contained use, does not have suspensory effect.

(2) The person authorized for contained use must submit a new notification if such person

a) modifies the contained area or the contained use in a way which could have significant consequences for the risks associated with that use, or

b) gets new information which could have significant consequences for the risks associated with that use.
(3) The Ministry issues, upon the notifier´s request, the confirmation of issuance of the authorisation for contained use pursuant to § 16 paragraph 3 or 16a paragraph 4.

§ 16c

(1) The third and fourth class contained uses may be operated only within the extent and under the conditions laid down in the authorisation for contained use.

(2) The procedure for granting the authorisation for contained use is ruled by § 5.

(3) The authorisation for contained use contains

a) the name or title or business company, home address, office address and identification number of the entitled person, if assigned, if it is a natural person authorized to conduct business, or the business company, office address and identification number of the entitled person, if allocated, if it is a legal person,

b) the specification of genetically modified organism,

c) the specification of the genetic modification,

d) the conditions of contained use, taking into account the requirements for the health and environment protection,

e) the class risk for which it has been granted,

f) the purpose of contained use,

g) any additional requirements for labelling under § 11 paragraph 1,

h) the period of validity of the authorisation.

(4) The validity of authorisation for contained use must be limited in time. The Ministry may, on request of the entitled person submitted not later than 60 days before the date of expiry of the authorisation, and after the consultation with the concerned ministries, extend the period of validity of the authorisation. The entitled person may continue in the contained use within the scope and in accordance with the conditions laid down in the authorisation until the decision on the application for its renewal is issued.

(5) The authorisation for contained use may not be transferred to another person.

CHAPTER II

DELIBERATE RELEASE INTO THE ENVIRONMENT

§ 17

(1) Only a legal person or a natural person authorised to operate business, which has been granted consent for the release into the environment, should be authorised to release genetically modified organisms into the environment, as long as it is within the scope and conditions laid down therein.

(2) The notification for the release into the environment must, in addition to the general requirements for applications according to the administrative code, always contain

a) the title of project,

b) the identification, contact and other information on the biosafety officer and the contact person at the workplace,

c) the information on genetically modified organisms,

d) the information on the place where the release into the environment is to be carried out,

e) the purpose and duration of the release into the environment,

f) the description of the use of genetically modified organism,

g) the information on the monitoring,

h) the information on measures being taken after termination of the release into the environment and on waste management,

i) the information on the release of genetically modified organism into the environment in other states and

j) the statement of the biosafety officer.

(3) The implementing legislation lays down, in the form of notification example, the detailed content of notification for the release into the environment of a genetically modified organism, which is

a) a higher plant,

b) other organism than a higher plant,

c) deliberately released into the environment for the purposes of a clinical evaluation of medicinal products.

(4) The person pursuant to paragraph 1 shall ensure that no material derived from genetically modified organism which he/she releases into the environment, is placed on the market unless in accordance with the provision of § 23.

§ 18

(1) The administrative procedure for granting consent for the release into the environment shall proceed pursuant to § 5 unless stipulated otherwise.

(2) The notifier shall make available control samples of the genetically modified organism involved on request to the Ministry or to a legal person designated by the Ministry with which

the Ministry has concluded the contract for co-operation in the exercise of its responsibility pursuant to § 28 paragraph 1 letter f).

(3) In case of the release into the environment of the same genetically modified organism at different places or the combination of genetically modified organisms on the same site or different sites for the same purpose, the notifier may a joint notification.

(4) The Ministry shall within 30 days of receipt of the notification for the release into the environment forward the summary of the dossier referred to in § 5 paragraph 4 to the Commission. The Ministry shall forward a full copy of the notification to the competent authority of Member State and to the Commission on request.

(5) In the decision on the release into the environment, the opinions of competent authorities of Member States shall be taken into account if the opinions have been submitted within 60 days of forwarding the summary of the dossier to the Commission referred to in paragraph 4.

(6) The consent for the release into the environment shall contain

a) the name, name of business, home address, office address and tax identification number (if assigned) of the authorised person, if he/she is a natural person authorised to operate business, or name or name of business, office address and tax identification number (if assigned) of the authorised person, if the authorised person is a legal person,

b) the specification of genetically modified organism,

c) specification of the genetic modification,

d) the result of risk assessment carried out pursuant § 7

e) the conditions for the use taking into account the requirements on the protection of human health and the environment

f) the purpose of the use,

g) other requirements on the labelling, where applicable (§ 11 paragraph 1),

h) the place where the release into the environment will be performed, in case of field trials including unambiguous determination of the site,

i) the requirements on the monitoring and reporting the results thereof,

j) the validity of consent.

(7) The validity of consent for the release into the environment must be time-limited. The Ministry on the request of the authorised person submitted at the latest within 60 days before expiry of validity of the consent, and after consulting with the Ministries concerned, may prolong the time-period of validity of the consent. On the basis of the request submitted pursuant to the second clause, the authorised person may continue with the the release into the environment in accordance with the conditions laid down in the consent until the decision on prolongation thereof is issued. The Ministry shall notify the Commission regarding the

information on the issue of the decision on authorisation for the release into the environment or on extension of its validity.

(8) The consent for the release into the environment may not be transferred to other person.

(9) The person granted the consent for the release into the environment shall ensure that monitoring and reporting the results thereof are carried out in accordance with the requirements laid down in the consent.

CHAPTER III

COMMON PROVISIONS FOR CONTAINED USE AND DELIBERATE RELEASE INTO THE ENVIRONMENT

§ 19

Obligations of persons authorised for contained use and of persons authorised for deliberate release into the environment

The person authorised for contained use pursuant to this Act, and the person authorised for the release into the environment pursuant to this Act, shall

a) ensure that the expert control of the use of genetically modified organisms will be performed by a biosafety officer, if the authorised person itself fails to comply with the conditions under § 14,

b) keep records on the use of genetically modified organisms for each workplace incl. its Code of practice, which required details are set in the Annex 4 to this Act, and to store it for a period of at least 5 years from the termination of this use in the case of contained use and 10 years in the case of the release into the environment, and to provide it on request to the administrative authorities referred to in § 27,

c) to send to the Ministry, always as per 15th February of calendar year, the list of genetically modified organisms, information about their quantities, manner of the use thereof and the statement for the review of risk assessment for the past calendar year.

d) forward to the Ministry within 60 days from the termination of the use of genetically modified organisms a final report on the course and consequences of such use, particularly in relation to any risk of hazards to human health and the environment,

e) ensure that risk assessment of the use of genetically modified organisms shall be carried out pursuant to § 7,

f) ensure that the Code of Practice of the workplace, where the genetically modified organisms are used, shall contain the requirements laid down in Annex 4 to this Act,

g) ensure that the employees shall be trained before commencing the use of the genetically modified organisms, and re-trained after any change of working procedures or at least once a year, and demonstrably acquainted with the Code of Practice of the workplace,

h) provide the competent authorities pursuant to § 28 and § 31 to § 33 with co-operation in inspection of sites, premises and facilities intended for the use of genetically modified organisms, or sites, premises and facilities in which such use proceeds or may proceed, including provision of documents and allowing samples to be taken free-of-charge for control purposes.

§ 20

Emergency response plan

(1) The emergency response plan shall mean a document describing activities and measures carried out in the event of an accident (§ 21) that lead to mitigation or removal of the consequences thereof for human health and the environment, using all available measures.

(2) The following persons shall draw up an emergency response plan and submit it to the Ministry

a) notifier, as a part of the notification,

b) person submitting notification for the first or second class contained uses pursuant to § 16 paragraph 3 or § 16a paragraph 5 as a part of this notification,

c) person authorised pursuant to this Act for the second and higher class contained uses or a person authorised for the release into the environment every 5 years from the date of last submission,

d) person authorised pursuant to this Act for the second and higher class contained uses or a person authorised for the release into the environment, in case of change in facts that may seriously affect measures laid down for the event of an accident, within 30 days from the date when this person learned of such change.

(3) Persons referred to in paragraph 2 shall submit the emergency response plan prior to commencement of the use of genetically modified organisms, and in the cases referred to in paragraph 2 letters c) and d) also to the municipalities to which the places of the use belong, to the fire brigade and the Regional Authority and on request also to the persons that may be directly affected by an accident.

(4) The emergency response plan shall be elaborated according to the example laid down by the implementing legal regulation

(5) The Ministry shall make the information on emergency response plan available to the public pursuant to § 10 letters b) and c). The scope of such information has been laid down by the implementing legal regulation.

(6) The Ministry shall forward the information on emergency response plan to the competent authority of a Member State that could be affected by an accident.

§ 21

Measures taken in case of an accident

(1) Accident for the purpose of this Act shall mean any incident involving an unintended release of genetically modified organisms or the immediate risk thereof in the course of their second or higher class contained uses or deliberate release into the environment which could present immediate or delayed hazard to human health or the environment.

(2) In case of an accident, the person authorised for the second or higher class contained uses or the release into the environment immediately after having learned of such accident shall carry out measures for mitigation or removal of its harmful effects in accordance with the emergency response plan.

(3) The person pursuant to paragraph 2 shall without delay notify to the Ministry by telephone and in written form or e-mail of any accident occurred, and to state

a) species and amount of the genetically modified organism involved,

b) circumstances of an accident,

c) place of an accident,

d) potential consequences of an accident, particularly risks of hazards to human health and the environment,

e) measures taken and further actions leading to removal or mitigation of the consequences of the accident.

(4) The person pursuant to paragraph 2 shall without delay also notify of the accident other competent authorities referred to in § 27, according to their competences.

(5) The Ministry after having obtained information on the accident shall without delay

a) inform competent authorities referred to in § 27,

b) make available information on an accident to the public in the manner pursuant to § 10 letters b) and c),

c) alert the relevant authority of any Member State which could be affected by the accident,

d) notify the Commission of the accident; the notification shall include information pursuant to paragraph 3.

(6) The Ministry shall further work up an analysis of the accident including the identification of the causes thereof and making recommendations to reduce accidents and prevent them in the future.

(7) The Ministry shall forward to the Commission the accident analysis pursuant to paragraph 6.

§ 22

The Register of authorized genetically modified organisms and the Register of users

(1) The Ministry shall keep the register of genetically modified organisms, for which the consent has been granted (hereinafter the "Register of authorized genetically modified organisms").

(2) The Register of authorized genetically modified organisms shall be kept separately for the contained use and for the release into the environment.

(3) Information on the contained in the consent pursuant to § 16c paragraph 3 and § 18 paragraph 6, except for information indicated as trade secret (§ 9), shall be recorded in the Register of the authorized genetically modified organisms.

(4) The Ministry shall further keep the register of persons that have been granted consent pursuant to this Act or that have been authorised for the contained use on the basis of notification pursuant to § 16 paragraph 3 or § 16a par 5 (hereinafter the "Register of users").

(5) The following shall be recorded in the Register of users

a) the name, name of business, office address and tax identification number (if assigned) of the person authorised for the contained use or the release into the environment, if it is a natural person authorised to operate business, or its name or business name, company address and tax identification number (if assigned), if it is a legal person,

b) genetically modified organism for which the consent has been granted to the notifier or the group of organisms stated in the notification or in the risk assessment submitted pursuant to § 16a paragraph 4,

c) the date of granting consent for the contained use or the release into the environment, and the time-period of consent validity.

(6) If the person pursuant to paragraph 5 is authorised to use genetically modified organisms on the basis of notification pursuant to § 16 paragraphs 3 or § 16a paragraphs 5 under the contained use regime, the purpose of the use and the class of the contained use shall be also recorded in the Register of users.

(7) The Ministry shall be obliged to record data pursuant to paragraphs 3, 5 and 6 in the Register of authorized genetically modified organisms and in the Register of users at the latest within 15 days from the date of legal effect of the granting or change of the consent, or, where applicable, from the date of granting the authorisation for contained use on the basis of

notification pursuant to § 16 paragraph 3 or § 16a paragraph 5 or on the basis of risk assessment submitted pursuant to § 16 paragraph 4.

(8) The Ministry shall be obliged to designate the date of termination of authorisation (§ 13) in the Register of authorized genetically modified organisms and in the Register of users at the latest within 15 days from the legal effect of the repeal of the consent or from the date the Ministry obtained the information of the termination of authorisation.

(9) The information recorded in the Register of authorized genetically modified organisms and in the Register of users shall be saved and made accessible to the public at least for the period of 5 years from the date of the termination of authorisation.

(10) The Register of authorized genetically modified organisms and the Register of users shall be made available to the public pursuant to § 10 letter b).

PART IV

PLACING ON THE MARKET

CHAPTER I

§ 23

(1) The genetically modified organism or genetic product can be placed on the market only if it has been registered in the list for placing on the market or if it has been placed on the market based on the written consent of the competent authority of another Member State, or if it has been authorised pursuant to the directly applicable legislation of the European Union relating to genetically modified food and feed[23)]. It is possible to use the genetically modified organism or genetic product authorised for placing on the market only within the scope of this text, consent or authorization, and under the conditions laid down herein.

(2) Anyone who cultivates genetically modified organisms authorised for the placing on the market referred to in paragraph 1 is obliged to provide to the Ministry a written information about the location of their cultivation, and this at the latest within 60 days from the start of their cultivation, in case that it has not been already done so according to the Act on Agriculture[20)]. The Ministry publishes the places of cultivation of genetically modified organisms on its website.

(3) The person registered in the list for placing on the market shall ensure to carry out monitoring and to report its results in accordance with the requirements set out in this registration. The Ministry is authorised, on the basis of these reports, after the first monitoring period, to specify the requirements for monitoring. The Ministry publishes the results of monitoring on its website.

(4) The Ministry shall submit reports on the results of monitoring pursuant to paragraph 3 to the Commission and to the competent authorities of Member States.

CHAPTER II

The procedure of registration into the List for placing on the market

§ 24

(1) The administrative procedure of registration in the List for placing on the market shall proceed pursuant to § 5 unless stipulated otherwise. The notification for registration may be only submitted by a legal person or a natural person authorised to operate business.

2) The notification for registration into the list for placing on the market shall, in addition to the general requirements for applications according to the administrative code, always contain

a) the title of genetic product,

b) the identification, contact and other information about the biosafety officer and the contact person at the workplace,

c) the information about a genetically modified organism contained in the genetic product,

d) the information about the genetic product,

e) the purpose and procedure of the placing on the market,

f) the information about previous release into the environment, where appropriate, also about previous placing on the market,

g) the cover design of genetic product and its designation, which meets requirements under § 11 paragraph 2,

h) the monitoring plan,

i) the details of making control samples available and

j) the statement of the biosafety officer.

(3) The implementing legislation lays down, in form of the notification example, the detailed content of notification for the registration into the list for placing on the market for a case of
a) genetically modified organism which is a higher plant, or the genetic product containing genetically modified higher plant,
b) genetically modified organism other than a higher plant, or the genetic product other than containing genetically modified higher plant,

(4) If, on the basis of results of the previous release into the environment or on the basis of relevant scientific knowledge, the notifier considers that the placing on the market and the use of a genetically modified organism or genetic product presents no risk to health and the environment, he can state some of the requirements for notification for registration into the list for placing on the market only to a limited extent. The notifier shall be obliged to justify such procedure in the notification.

(5) The notifier shall provide the Ministry or a legal entity with which the Ministry has concluded a cooperation agreement in the exercise of their jurisdiction, pursuant to § 28 paragraph 1 letter f), at the same time with the notification or at the latest within 10 days of its submission with a sample of the genetically modified organism or a genetic product for control purposes.

§ 24a

(1) The Ministry shall promptly, after the receipt of notification, submits the summary of content of the notification according to § 5 paragraph 4 to the Commission and to the competent authorities of the Member States. The Ministry shall provide the Commission, at the latest at the same time with the assessment report referred to in paragraph 2, with a copy of the complete notification.

(2) Taking into account the opinions of concerned ministries the Ministry shall elaborate within 90 days from the date of the receipt of notification the assessment report and shall send it to the notifier and to the concerned ministries within this period. The 90-day limit does not include the period during which the Ministry waits for information from the notifier pursuant to § 5 paragraph 3 or 5. The Ministry will publish the assessment report on its website. The assessment report must state that

a) the genetically modified organism or genetic product may be placed on the market and under which conditions, or

b) the genetically modified organism or genetic product may not be placed on the market.

(3) In the case referred to in paragraph 2 letter a) the Ministry shall submit the assessment report within 90 days of the receipt of notification also to the Commission. In case referred to in paragraph 2 letter (b) the Ministry shall submit the assessment report to the Commission no later than 105 days after the receipt of notification. For the purpose of period counting the provision of paragraph 2, second sentence, shall be applied.

(4) If the Commission or the competent authority of Member State within 60 days of the date on which the assessment report was circulated by the Commission requests additional information or submits comments or reasoned objections to the placing of the genetically modified organism or a genetic product on the market, the Ministry shall provide such information and discuss such comments or objections with the Commission or the competent authority of the Member State within 45 days from the expiry of that period.

(5) The Ministry shall, on the basis of request, comments or objections forwarded pursuant to paragraph 4, ask the notifier for additional information. In such case, any time-period during which the answer from the notifier is awaited shall not be taken into account for the purpose of calculating the 45 day period pursuant to paragraph 4.

(6) If, in the case referred to in paragraph 2 letter a), the Commission does not submit to the Ministry within 60 days pursuant to paragraph 4 any substantiated comments or reservations, or when the agreement has been reached within a period of 45 days pursuant to paragraph 4, the Ministry decides on registration into the list for placing on the market. The Ministry shall inform the Commission and the competent authorities of the Member States about this decision within 30 days from its issuance.

(7) If the agreement has not been reached within a period of 45 days pursuant to paragraph 4, the Ministry, in accordance with the outcome of procedure laid down for such cases by legislation of the European Union, shall within 30 days from the notification of its results decide on the registration into the list for placing on the market or on its rejection and shall inform the Commission and the competent authorities of Member States about this decision. The period of waiting time for a response from the notifier is not included in the period of 45 days referred to in paragraph 5.

§ 24b

(1) If the Ministry decides to perform the registration into the list for placing on the market, it shall make this registration within 15 days from the date of legal force of the decision. The Ministry shall define the contents of this registration in its decision on the registration to the list for placing on the market.

(2) In the case referred to in § 24a paragraph 2 letter b) the Ministry decides within 15 days from the submission of assessment report referred to in § 24a paragraph 3 about the rejection of notification.

(3) The registration into the list for placing on the market shall contain

a) the name or title or business company, home address, office address and identification number of the person, if assigned, of the person who submitted the notification provided it is a natural person authorized to operate business, or the title or business company, office address and identification number of the person, if allocated, that is a legal person,

b) the specification of genetically modified organism or genetic product,

c) the specification of genetic modification,

d) the results of risk assessment,

e) the conditions and the purpose of placing genetically modified organisms or genetic product on the market, including any specific condition for the use, handling and packaging, and furthermore conditions for the protection of particular ecosystems, environments or geographical areas,

f) any additional requirements for labelling under § 11 paragraph 3,

g) the method of laboratory control for the presence of genetic modification, including the description of modified part of deoxyribonucleic or ribonucleic acid allowing the unique identification of genetically modified organism, even under international rules,

h) the conditions for making control samples available to the competent administrative authority,

i) the requirements for monitoring and reporting of its results,

j) possible modification of the territorial scope by which the territory of Member State or a part thereof pursuant to § 24d is excluded from the cultivation of this genetically modified organism.

(4) The Ministry shall state, in the decision on registration into the list for placing on the market, the period of its validity which cannot be longer than 10 years.

(5) In the case of genetically modified organism for which only the marketing of their seeds is expected, the period of the first consent shall end at the latest ten years after the date of the first inclusion of the first plant variety containing GMO on the official national catalogue of plant varieties in accordance with the law on circulation of seeds and plants[24)]. In the case of forest reproductive material, validity of the decision on the registration pursuant to paragraph 4 shall end ten years after the date of registration of a recognised source of forest reproductive material in the Register of approved reproductive material sources maintained pursuant to the act on trade in forest reproductive material of tree species[25)].

(6) The Ministry shall make available to the public the List for placing on the market on its website.

(7) The implementation legislation defines the requirements of assessment report referred to in § 24a paragraph 2.

CHAPTER III

Renewal of the consent

§ 24c

(1) The consent for registration into the list for placing on the market may be, on request of the person registered in the list for placing on the market, renewed, even repeatedly. At the latest 9 months before the expiry of consent, the notifier shall submit a notification for renewal. The procedure of the renewal of consent is set out in § 5, 24 to 24b accordingly unless it is stipulated otherwise.

(2) Notification for the renewal of consent shall contain:

a) the report on monitoring results,

b) any new information which has become available with regard to the risks of genetically modified organism or its product to human health and/or the environment

c) as appropriate, a proposal for amending or complementing the conditions for the use stated in the original consent

(3) The Ministry shall without delay draw up the assessment report, in which it must be indicated that

a) the genetically modified organism or genetic product may remain on the market and under which conditions; or

b) the genetically modified organism or genetic product should not remain on the market anymore.

(4) The Ministry shall send to the Commission the notification for the renewal of consent and its assessment report to the Commission. The competent authority of the Member State or the Commission shall discuss any comments or objections within 75 days from the date of circulation of the assessment report by the Commission.

(5) In the decision the Ministry shall specify the period of validity of the renewal of the consent. The period of validity of the decision on registration into the list for placing on the market can be extended for no more than 10 years. The Ministry may, in the decision on the consent of renewal, limit or extend its period of validity and adapt conditions for the registration in the list for placing on the market as referred to in § 24b paragraph 3.

CHAPTER IV

Restriction or ban on cultivation of the genetically modified organism

§ 24 d

(1) Provided the competent authority of Member State, in the course of the authorisation procedure for registration in the list for placing on the market or in the course of proceedings concerning the renewal of consent, demands the adjustment of the geographical scope to that effect that all or part of the territory of that Member State is to be excluded from cultivation of a genetically modified organism, and provided the notifier has adapted, on the basis of this requirement, his notification for registration in the list for placing on the market within 30 days from the date of its submission by the Commission, the Ministry shall decide on the registration in the list for placing on the market on the basis of such modified notification and shall adapt its geographical scope in the registration in the list for placing on the market so that the territory of that Member State or the particular part thereof is excluded from the cultivation of relevant genetically modified organism.

(2) The Ministry shall adjust, in the registration in the list for placing on the market, its geographical scope so that all or the part of territory of the Member State is excluded from the cultivation of genetically modified organism also in the case where the competent authority of this Member state has demanded for such adjustment during the procedure for registration in the list for placing on the market or during the procedure concerning the renewal of the consent and where the notifier has not confirmed his original notification for registration in the list for placing on the market within 30 days from the date at which the Commission has presented this demand.

(3) Provided the competent authority of the Member State has asked for adjustment of the geographical scope by which all or the part of territory of that Member State is excluded from the cultivation of a genetically modified organism after the date of circulation of the assessment report by the Commission, the period for issuance of the decision on registration in the list for placing on the market is extended by 15 days; the period for the issuance of the decision on the registration to the list for placing on the market is extended only once regardless of the number of Member States of which the competent authority has applied a demand after the date of circulation of the assessment report by the Commission.

(4) The Ministry cancels the adjustment of the geographical scope of registration in the List tor placing on the market by which the territory of that Member State or a certain part of it is excluded from the cultivation of a genetically modified organism, provided the Member State wishes to be reintegrated into the geographical scope of the registration in the list for placing on the market.

(5) The Ministry shall immediately inform the Commission, other Member States and the authorisation holder about the cancellation of adjustment of geographical scope of the registration in the list for placing on the market by which the territory of that Member State or its certain part is excluded from the cultivation of relevant genetically modified organisms.

§ 24e

(1) The Ministry, following the agreement with the Ministry of agriculture, may, not later than 45 days from the date of receipt of the assessment report, submit a demand to the Commission regarding the amendment of the geographical scope of the written consent issued for the placing of genetically modified organism on the market by the competent authority of the Member State by which the territory of the Czech Republic or its particular part is excluded from the cultivation of the relevant genetically modified organism.

(2) The Ministry of agriculture, following the agreement with the Ministry, may, not later than 45 days from the date of receipt of the opinion of the European food safety authority regarding the notification for authorizations granted for the placing of the genetically modified organism on the market, in accordance with the directly applicable European Union legislation governing the genetically modified food and feed[23)], submit a demand to the Commission regarding the amendment of the geographical scope of this consent by which the territory of the Czech Republic or its particular part is excluded from the cultivation of the genetically modified organism.

(3) If the request has not been submitted in accordance with paragraph 1 or if the notifier has confirmed the geographical scope of his original notification within 30 days from the date of submission of demand of the Ministry by the Commission and the competent authority of the Member State has been issued its written consent for the placing of relevant genetically modified organism on the market, the Government can restrict or prohibit the cultivation of relevant genetically modified organism or of a group of genetically modified organisms as defined on the basis of specific crop or character (hereinafter referred to as "the Group of genetically modified organisms") at the territory of the Czech Republic or its part.

(4) If the request has not been submitted in accordance with paragraph 2 or if the notifier has confirmed the geographical scope of his original notification within 30 days from the date of submission of demand of the Ministry by the Commission and the consent for the placing of relevant genetically modified organism on the market has been issued pursuant to the directly applicable legislation of the European Union governing the genetically modified food and feed[23)], the Government can limit or prohibit the cultivation of relevant genetically modified organism or of a group of genetically modified organisms at the territory of the Czech Republic or its part.

(5) The Ministry, following the agreement with the Ministry of agriculture, may submit to the competent authority of the Member State that issued the written consent for the placing of the genetically modified organism on the market a demand for cancellation of the adjustment of

its geographical scope by which the territory of the Czech Republic or its particular part is excluded from the cultivation of the relevant genetically modified organism.

(6) The Ministry of agriculture, following the agreement with the Ministry, may submit to the Commission a demand for cancellation of the adjustment of geographical scope of the consent issued for the placing of the genetically modified organism on the market, in accordance with the directly applicable European Union legislation governing the genetically modified food and feed[23)], by which the territory of the Czech Republic or its particular part is excluded from the cultivation of the genetically modified organism.

§ 24f

(1) The Government may restrict or prohibit the cultivation of genetically modified organism or group of genetically modified organisms for which the written consent for the placing on the market has been issued by the competent authority of the Member State or for which the placing on the market was authorised in accordance with the directly applicable European Union legislation governing genetically modified food and feed[23)], in case that their cultivation can

a) be in contradiction with the national environmental policy,

b) be in contradiction with objectives and tasks of spatial planning,

c) be in contradiction with the national agricultural policy,

d) be in contradiction with the principles of protection of agricultural land,

e) cause unacceptable social or economic impacts,

f) despite the measures taken pursuant to the Act on Agriculture[20)], cause the presence of genetically modified organism in other products, or

g) be in contradiction with public order provided one of the conditions referred to in points a) to (f) has been fulfilled.

(2) The restriction or the ban of the cultivation of genetically modified organism or group of genetically modified organisms is determined by the Government through a measure of general nature.

(3) The measure of general nature defines the genetically modified organism or the group of genetically modified organisms, of which the cultivation is restricted or prohibited; the territory to which the restriction or the prohibition relates and, in the case of restriction of cultivation the scope of this restriction.

(4). Provided the reasons of restriction or prohibition of the cultivation of genetically modified organism or the group of genetically modified organisms pass away, the Government cancels the measure of general nature.

§ 24g

(1) § 172 of the Administrative code does not apply to the measure of general nature under this Act.

(2) The Ministry sends the draft of the measure of general nature to the Commission; in the case of genetically modified organism or group of genetically modified organisms, for which the authorisation for placing on the market was granted under the directly applicable European Union legislation governing genetically modified food and feed[23)], the draft of the measure of general nature is sent to the Commission by the Ministry of agriculture. The measure of general nature may be issued at the earliest after expiration of 75 days from the date of its draft sending to the Commission.

(3) The Ministry or the Ministry of agriculture makes available the information on sending of the measure of general nature draft to the Commission on its official board to the public. The Ministry or the Ministry of agriculture publishes, together with such information, the draft of measure of general nature, including its justification on its official board.

(4) For the period of 75 days from the date of publication of the information pursuant to paragraph 3 the cultivation of genetically modified organism or group of genetically modified organisms as defined in this draft may not be commenced in the territory of the Czech Republic or its part as defined in the draft of the measure of general nature.

(5) The measure of general nature is published through the public decree of the Ministry; in the case of genetically modified organism or group of genetically modified organisms, for which the authorisation for placing on the market was granted under the directly applicable European Union legislation governing genetically modified food and feed[23)], the measure of general nature is published through the public decree of the Ministry of agriculture.

(6) The Ministry or the Ministry of agriculture immediately informs the Commission and other Member States about the issuance of the measure of general nature under this Act. The Ministry immediately informs the person registered in the List for placing on the market or the person to whom the competent authority of another Member State issued the written authorisation for placing of genetically modified organism on the market about the issuance of the measure of general nature. The Ministry of agriculture immediately informs the authorisation holder issued under the directly applicable European Union legislation governing genetically modified food and feed[23)] about the issuance of the measure of general nature.

PART V

IMPORT, EXPORT AND TRANSIT OF GENETICALLY MODIFIED ORGANISMS AND GENETIC PRODUCTS

§ 25

Import and export of genetically modified organisms and genetic products

(1) Only genetically modified organisms or genetic products registered in the List for placing on the market, or authorized for placing on the market by the competent authority of another Member State, or for which the authorisation was granted under the directly applicable European Union legislation governing genetically modified food and feed[23)] may be imported

or exported[12)]. This provision shall not apply to the import and export of genetically modified organisms in accordance with paragraphs 3 and 4.

(3) The person authorised for contained use pursuant § 16 to 16c shall be authorised to import or to export genetically modified organisms to which this authorisation applies, provided that they are exclusively intended for contained use.

(4) The person, who has been granted consent for the release into the environment (§ 18), shall be authorised to import or to export genetically modified organisms to which the consent applies, provided that they are exclusively intended for the release into the environment.

(5) The person that intends to import or to export genetically modified organisms pursuant to paragraph 3 or 4, shall, at the latest 5 days before realizing the import or export, inform the Ministry about the species and amount of genetically modified organisms to be imported or exported, and about the supposed place of entry to or exit from the territory of the Czech Republic.

(6) Importer or exporter of genetically modified organism or genetic product shall immediately notify of the arrival of such goods at the place of entry to the relevant customs authority, in the case of foodstuffs and raw materials for food processing purposes also the Czech Agricultural and Foodstuff Inspection, in the case of feed, seeds and plant protection products also the Central Institute for Supervising and Testing in Agriculture (hereinafter "the Institute"), and in the case of human medicinal preparations also the State Institute for Drug Control, and in the case of veterinary medicinal preparations also the Institute for State Control of Veterinary Biopreparations and Drugs, to allow an inspection to be carried out, and to provide the authorities carrying out inspection with necessary cooperation.

(7) The importer or exporter of the genetically modified organism or genetic product shall submit to the customs authority the accompanying documents containing

a) the specification of genetically modified organism or genetic product,

b) the information on the transported amount,

c) the name, business name, office address and tax identification number (if assigned) of the importer or exporter, if he is a natural person authorised to operate business, or the name or business name and tax identification number (if assigned) of the importer or exporter, if such person is a legal person,

d) the name, business name, office address and tax identification number (if assigned) of the person, the carrier as well as of the person responsible for the shipment, if he is a natural person authorised to operate business, or the name or business name and tax identification number (if assigned) of the person, the carrier as well as of the person responsible for the shipment, if such person is a legal person.

(8) In the case of the import or export of the genetically modified organism or genetic product intended exclusively for contained use or the release into the environment, the importer or exporter shall further forward to the customs authority

a) the verified copy of the consent for contained use or the release into the environment, or, where applicable, the confirmation pursuant to § 16b paragraph 3,

b) the copy of emergency response plan if it is not the case of the first class contained use.

(9) The persons that import, export or transit genetically modified organisms or genetic products shall declare to the customs authorities in submitting the customs declaration the substantial information referred to in paragraphs 1 to 8.

(10) After carrying out the inspection, the customs authority

a) shall release the imported or exported genetically modified organism or genetic product into the proposed customs regime, provided that the conditions for release of goods laid down by this Act and special legal regulations are met, or

b) shall not release the imported or exported genetically modified organism or genetic product into the proposed customs regime, after prior informing the Ministry and the Czech Environmental Inspection, and, where applicable, after prior consulting with them, if the conditions for release of the goods laid down by this Act and by special legal regulations are not met.

(11) The imported or exported genetically modified organism or genetic product may not be released into the proposed customs regime, if

a) any of the requirements laid down in paragraphs 1 to 6 are not met,

b) the shipment containing the genetically modified organism or genetic product does not contain the accompanying documents pursuant to paragraphs 7 and 8,

c) the accompanying documentation pursuant to paragraphs 7 and 8 is incomplete, or

d) there are justified doubts about the origin or identity of the genetically modified organism or genetic product.

§ 26

Transit of genetically modified organisms and genetic products

(1) Transit[12)] of genetically modified organisms or genetic products through the territory of the Czech Republic from the place of entry to the place of exit may only take place in the transport means safeguarded against an unintended release of genetically modified organisms or genetic products into the environment, or against their loss or theft with regard to potential risk to human health and the environment.

(2) The genetically modified organism or genetic product may not be released into the transit customs regime, if the requirement pursuant to paragraph 1 is not met.

PART VI

PERFORMANCE OF STATE ADMINISTRATION

§ 27

Competent authorities

The competent authorities in the area of the use of genetically modified organisms and genetic products shall be pursuant to this Act

a) the Ministry of the Environment,

b) the Ministry of Health,

c) the Ministry of Agriculture,

d) the Czech Environmental Inspection (hereinafter the “Inspection”)

e) the customs authorities,

f) the bodies of the veterinary administration,

g) the Central Institute for Supervising and Testing in Agriculture,

h) the State Institute for Drug Control,

i) the Institute for State Control of Veterinary Biopreparations and Drugs,

j) the Czech Agriculture and Food Inspection Authority,

k) the bodies of public health protection

l) Regional Authority

§ 27a

(1) The Ministry of the Interior or the Police of the Czech Republic shall provide to the competent authorities for the use of genetically modified organisms and its products:

a) the referential data from the basic Register of inhabitants

b) the data from the information system of Register of citizens

c) the data from the information system of foreigners

(2) Provided data pursuant the paragraph 1 letter a) shall be

a) the name or names as appropriate, surname

b) th edate, place and district of birth, in the case of a foreign-born person date, place and the state of birth

c) the date and place of death, in the case of a person outside of the territory of the Czech Republic the date of death, place and state in which territory the decease has occurred; in case the court decision on declaration of death has been issued, the day that is stated in the decision as the day of death or the day that person pronounced dead has not survived, and the date of coming into force of the decision,

d) the place of residence,

e) the nationality or more nationalities as appropriate

(3) Provided data pursuant the paragraph 1 letter b) shall be

a) the name or names as appropriate, surname

b) the date, place and district of birth, in the case of a foreign-born person date, place and the state of birth

c) the birth identification number

d) the place of residence

e) the nationality or more nationalities as appropriate

(4) Provided data pursuant the paragraph 1 letter c) shall be

a) the name or names as appropriate, surname

b) the date, place and district of birth, in the case of a foreign-born person date, place and the state of birth

c) the nationality or more nationalities as appropriate

d) the type and address of the place of residence

e) the date of commencement and termination of residence, as appropriate

(5) Information kept as referential data in the basic Register of inhabitants shall be used from the Information system of Register of citizens or from the Information system of foreigners only if they are in the form preceding the current status.

(6) Only information that is necessary to fulfil given task in the given situation can be utilised from the provided data.

§ 28

The Ministry

(1) The Ministry shall

a) be the central administrative authority for the assessment of the impact of genetically modified organisms and genetic products on the environmental components and biological diversity,

b) carry out supreme state supervision on the use of genetically modified organisms and genetic products concerning the protection of the environment and biological diversity,

c) establish the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products as its consultative body,

d) execute the function of the administrative body for international exchange of information in the area of genetically modified organisms and genetic products,

e) take a decision on appeals against decisions of the Inspection,

f) conclude in the exercise of its responsibility the contracts of cooperation concerning the laboratory determination of the presence of genetically modified organisms with the laboratories that have established the system of quality according to the Czech Standard ČSN EN ISO/IEC 17 025, assessed by the accrediting person authorised pursuant to the special legal regulation[13)],

g) keep the List for placing on the market,

h) serve as a focal point and competent administrative body pursuant to the directly applied legal regulation of the European Union on transboundary movement of the genetically modified organisms[13a)],

inform without delay the Commission, the competent authorities of the Member States and the public in the manner pursuant to §10 letter b) and c) about cases of unauthorized use of genetically modified organisms or genetic products.

(2) The Minister of the Environment shall designate the chair and members of the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products, with their approval, from amongst experts nominated by the competent authorities referred to in § 27, by the Academy of Sciences of the Czech Republic, by Universities and specialized research institutes, and recall them after consulting with the Ministers of Health and Agriculture. The Czech Commission for the Use of Genetically Modified Organisms and Genetic Products shall be during the exercise of its activities subject to the rules of procedure, issued by the Ministry.

§ 29

The Ministry of Health

The Ministry of Health shall

a) propose to the Ministry procedures for the assessment of risks to human health originating from the use of genetically modified organisms and genetic products,

b) from the viewpoint of its responsibility, issue opinions on the notifications pursuant to § 5.

§ 30

The Ministry of Agriculture

The Ministry of Agriculture shall

a) propose to the Ministry procedures of the assessment of risks originating from the use of genetically modified organisms and genetic products from the viewpoint of agriculture and forestry,

b) from the viewpoint of its responsibility, issue opinions on the notifications pursuant to § 5.

c) be the central administrative authority in the area of genetically modified food and feed according to the directly applicable European Union legislation governing genetically modified food or feed[23)],

d) governs the conditions of cultivation of genetically modified plant varieties according to the Act on agriculture[20)].

§ 31

The Inspection

(1) The Inspection shall

a) control individually or in cooperation with the competent authorities referred to in § 27, with regard to the protection of the environment, how legal persons and natural persons comply with the provisions of the legal regulations and with the conditions laid down by the Ministry's decisions concerning the use of genetically modified organisms or genetic products,

b) impose on legal persons and natural persons remedial measures provided there is an imminent risk of harm to health or to the environment; it arranges without delay for the necessary remedial measures and imposes to the person who, with the use or other handling with the genetically modified organism or genetic product, infringed the obligation imposed by this Act or the decisions issued on its basis or by directly applicable provisions of the European Union[26)] to pay costs related to the implementation of the measures,

c) may prohibit further use or other handling with genetically modified organism or genetic product, if it is found during the inspection of use or other handling with genetically modified organisms or genetic products that the obligations imposed by this Act or the decisions issued on the basis of it or by directly applicable European Union legislation[27)] are infringed, and the imposition of remedial measures is not sufficient for the elimination of the unlawful situation,

d) immediately informs the Ministry about the cases of unauthorized use of genetically modified organisms or genetic products and about the fact that the decision on the imposition of remedial measures was issued or the use or other handling with the genetically modified organism or genetic product was prohibited.

(2) Inspectors shall present their warrants during the control activity as a proof of their control authorization.

§ 32

The customs authorities

The customs authorities shall

a) control whether imported, exported or transited shipments that are declared as genetically modified organisms or genetic products in release into the customs regime contain the relevant accompanying documents pursuant to § 25 and special legal regulations or international agreements for transport, export, import and transit,

b) impound the goods, in case of discovery of any infringement of this Act or in case of suspicion thereof, and immediately inform the Ministry, the Inspection, and in the case of plant protection products also the State Phytosanitary Administration, and in the case of foodstuffs and raw materials for foodstuff purposes also the Czech Agriculture and Food Inspection Authority; before taking a decision pursuant to § 25 paragraph 10 the customs authorities may ask the Ministry or the Inspection, in case of plant protection products also the State Phytosanitary Administration, and in case of foodstuffs and raw materials for foodstuff purposes also the Czech Agriculture and Food Inspection Authority for professional assistance,

c) keep records of all imported, exported and transited shipments of genetically modified organisms and genetic products, including the shipments allowed to cross the state border. The customs authorities shall enable employees of the Ministry, the Inspection, in case of plant protection products also the employees of the State Phytosanitary Administration, and in case of foodstuffs and raw materials for foodstuff purposes also the employees of the Czech Agriculture and Food Inspection Authority, to look into such records, make excerpts thereof, copy information or, where applicable, make copies thereof, including providing this evidence on a technical data medium or, where applicable, by e-mail.

§ 33

Other administrative bodies

(1) The bodies of the veterinary administration, the State Phytosanitary Administration, the Czech Agriculture and Food Inspection Authority, the Central Institute for Supervising and Testing in Agriculture, the State Institute for Drug Control and the Institute for State Control of Veterinary Biopreparations and Drugs

a) shall carry out expert control of the use of the genetically modified organisms and genetic products, control and tests of genetically modified organisms and genetic products within the scope of their responsibility and pursuant to special legal regulations[14)],

b) shall in case of discovery of any infringement of this Act, submit to the Inspection a proposal for commencement of an administrative procedure and shall inform the Ministry thereof.

(2) The authorised employees of the administrative bodies referred to in paragraph 1 shall be entitled to the absolutely necessary extent to enter the plots, premises and facilities intended for the use of genetically modified organisms or genetic products, or the plots, premises and facilities in which such use may proceed, for control purposes pursuant to paragraph 1 letter a). When doing so, they must present their warrants. The state shall be liable for any damage caused by the inspection; it may not be relieved from this liability.

(3) Supervision of employees health protection of at workplaces where the genetically modified organisms and genetic products are used, carried out by the bodies of public health protection, shall be subject to the special legal regulations[15)].

(4) State Office for Nuclear Safety shall execute state administration over compliance with the ban of bacteriological and toxin weapons pursuant to the special legal regulation[16)].

(5) The competencies of the determined Regional Authority pursuant to this Act are the exercise of delegated competencies.

PART VII

REMEDIAL MEASURES AND PENALTIES

Chapter 1

§ 34

Remedial measures

(1) Provided the Inspection discovers during the control of use or other handling with genetically modified organisms or genetic products that the obligations imposed by this Act or by the decisions issued pursuant this Act or by directly applicable European Union regulations[27)] are infringed, it imposes to the person who violates these obligations the appropriate remedial measures.

(2) The inspections may in particular:

a) suspend the use or other handling with the genetically modified organism or genetic product until the conditions for such use or another handling will be brought into accordance with this Act or the decisions issued on its basis or directly applicable European Union legislation[27)],

b) order the removal of the consequences of such use or other handling with the genetically modified organism or genetic product,

c) order the disposal of genetically modified organism or genetic product provided there is a risk of damage to the health or to the environment, or

d) order the adoption of other measures that are necessary to protect the health or the environment.

(3) The Inspection shall define in its decision on the imposition of remedial action also the period for its implementation.

(4) The appeal against the decision on the imposition of remedial action does not have suspensory effect.

(5) The Inspection can, in connection with the implementation of remedial action, impose to the owner of the property the obligation to tolerate restriction of its common use to the necessary extent and for the necessary duration. The compensation for such incurred damages are paid to the owner by the state who has the title for damages compensation against the person based on which unlawful action the remedial action has been imposed.

Administrative offences

§ 35

Offences

(1) The natural person has committed the offence so that

a) in contradiction with § 3 paragraph 4 he does not follow conditions for the use of genetically modified organisms or genetic products as marked on the product packaging or in the accompanying document or he uses it for any other purpose than indicated herein,

b) in contradiction with the § 23 paragraph 1 he places on the market genetically modified organism or genetic product that has not been registered in the List for placing on the market, the written consent for its placing on the market has not been issued by the competent authority of another Member State or the authorisation pursuant to the directly applicable legislation of the European Union relating to genetically modified food and feed[23)] has not been issued, or he does not observe the scope and conditions of this registration, written consent or authorisation,

c) he does not provide the Ministry within the given time limit the written information about the cultivation location of genetically modified organisms approved for placing on the market pursuant to § 23 paragraph 2,

d) he cultivates the genetically modified organism in contradiction with the ban or restriction determined by the measure of general nature issued pursuant to § 24e paragraph 3 or 4,

e) he starts the cultivation of the genetically modified organism in contradiction with § 24g paragraph 4, or

f) he imports or exports genetically modified organisms or genetic products in contradiction with § 25 paragraph 2.

(2) It is possible to impose a fine for the offence at the amount of

a) CZK 500 000,- provided the offence pursuant to paragraph 1 letter a), b), d) or f) is concerned,

b) CZK 50 000,- provided the offence pursuant to paragraph 1 letter c) or e) is concerned.

§ 35a

Administrative offences committed by legal persons and natural persons operating business

(1) The legal entity or the natural person operating business commits an administrative offence so that

a) in contradiction with § 3 paragraph 4 he does not follow conditions for the use of genetically modified organisms or genetic products as marked on the product packaging or in the accompanying document or he uses it for any other purpose than indicated herein,

b) he uses the genetically modified organism in contained area without relevant authorisation pursuant to § 16 paragraph 2,

c) he releases the genetically modified organism into the environment without the authorisation according to § 17 paragraph 1,

d) in contradiction with § 23 paragraph 1 he places on the market the genetically modified organism or genetic product that has not been registered in the List for placing on the market, for which the written consent for its placing on the market has not been issued by the competent authority of another Member State or the authorisation pursuant to the directly applicable legislation of the European Union relating to genetically modified food and feed[23)] has not been issued, or he does not observe the scope and conditions of this registration, written consent or authorisation,

e) he does not provide the Ministry within the given time limit the written information about the cultivation location of genetically modified organisms approved for the placing on the market pursuant to § 23 paragraph 2,

f) he cultivates the genetically modified organism in contradiction with the ban or restriction determined by the measure of general nature issued pursuant to § 24e paragraph 3 or 4,

g) he starts the cultivation of the genetically modified organism in contradiction with § 24g paragraph 4, or

h) he imports or exports genetically modified organisms or genetic products in contradiction with § 25 paragraph 2.

(3) The legal entity or the natural person operating business who provides the genetically modified organism exclusively for the purpose of contained use or the release into the environment commits the administrative offence so that he, in contradiction with § 11 paragraph 1, does not ensure that the words "genetically modified organism" are clearly

marked on the label or in the accompanying document or that the genetically modified organism does not conform to additional requirements for its labelling pursuant to the authorisation for contained use or to the authorisation for release into the environment.

(4) The legal entity or the natural person operating business who places the genetically modified organism or genetic product on the market in the course of his business commits the administrative offence so that

a) he does not ensure that the genetically modified organism or the genetic product is labelled according to the directly applicable European Union legislation governing the traceability and labelling of genetically modified organisms[28)] or pursuant to § 11 paragraph 2 and 3, or

b) he fails to comply with any of the requirements on traceability of genetic products pursuant to the directly applicable European Union legislation relating to the traceability and labelling of genetically modified organisms[29)].

(5) The legal entity or the natural person operating business authorised for the contained use commits an administrative offence so that

a) in contradiction with § 15 paragraph 2 he uses the genetically modified organisms in premises that do not meet the requirements for the containment and the protective measures set out for the appropriate or higher class risk,

b) in contradiction with § 15 paragraph 3 he does not check the containment and the protective measures or he does not keep records about the performed controls,

c) he fails to submit a new notification pursuant to the 16b paragraph 2, or

d) he fails to comply with the scope or conditions for the use provided for in the authorisation for contained use under § 16 c paragraph 1.

(6) The legal entity or the natural person operating business authorised for the release into the environment commits an administrative offence so that

a) he fails to comply with the scope or conditions for the use provided for in the authorisation for the release into the environment under § 17 paragraph 1,

b) he fails to ensure that no material derived from the genetically modified organism that he releases into the environment is placed on the market pursuant to § 17 paragraph 4, or

c) he fails to ensure the implementation of monitoring or reporting on its results in accordance with the requirements laid down in the authorisation for the release into the environment according to § 18 paragraph 9.

(7) The legal entity or natural person authorised for the contained use or the release into the environment commits an administrative offence so that

a) he fails to ensure the performance of professional supervision over the use of genetically modified organisms by the biosafety officer pursuant to § 19 letter a),

b) in contradiction with § 19 letter b) he fails to keep or archive the documentation on the use of genetically modified organisms,

c) in contradiction with § 19 letter c) he fails to send within the given period to the Ministry the overview of genetically modified organisms, information about their quantities, about their management or the statement for the review of risk assessment for the previous calendar year,

d) he fails to send within given period to the Ministry the final report about the course and consequences of the use of genetically modified organisms under § 19 letter d),

e) he provides false information in the documentation on the use of genetically modified organisms or in the final report about the course and consequences of the use of genetically modified organisms,

f) he fails to ensure that the Code of practice of the workplace in which the genetically modified organisms are used contains all essentials listed in annex No. 4 hereof pursuant to § 19 letter f),

g) in the contradiction with § 19 letter g) he fails to ensure the training to his employees or demonstrably fails to acquaint them with the Code of practice of the workplace,

h) he fails to cooperate with the relevant administrative authorities during the supervision according to § 19 letter h), or

i) he fails to provide the Ministry within the given period with the information about the type and the quantity of genetically modified organisms or about the expected entry or exit point in accordance with § 25 paragraph 5.

(8) The legal entity or the natural person authorised for the second and higher class risk of contained use or for the release into the environment commits an administrative offence so that

a) he fails to submit to the Ministry the emergency plan for the second and higher class contained uses under § 20 paragraph 2 letter c),

b) he fails to submit to the Ministry within given time the emergency plan in case of a change of facts that may have a significant effect on the measures laid down for the case of an accident pursuant to § 20 paragraph 2 letter d),

c) in contradiction with § 20 paragraph 3 he fails to process or submit the emergency plant to the relevant municipalities, competent firefighting department of the region or to the Regional Authority,

d) in case of accident he fails to perform measures to eliminate or alleviate its harmful consequences pursuant to § 21 paragraph 2,

e) he fails to immediately notify by phone and in written or by the electronic mail the occurred accident to the Ministry pursuant to § 21 paragraph 3, or

f) he fails to immediately notify the occurred accident to other administrative authorities pursuant to § 21 paragraph 4.

(9) The legal entity or the natural person authorised to operate business registered in the list for placing on the market commits an administrative offence by failing to ensure the implementation of monitoring or reporting on its results in accordance with § 23 paragraph 3.

(10) The legal entity or the natural person authorised to operate business who is the importer or exporter of genetically modified organism or genetic product commits an administrative offence so that

a) in contradiction with § 25 paragraph 6 he fails to immediately inform the competent Customs office or other administrative authorities on the arrival of goods to the entry point;

b) he fails to submit the necessary accompanying documents to the Customs office in accordance with § 25 paragraph 7, or

c) he fails to submit the certified copy of the authorisation for the contained use or the release into the environment or a copy of the emergency plan to the Customs office in accordance with § 25 paragraph 8.

(11) The legal entity or the natural person authorised to operate business who is the exporter of genetically modified organism or genetic product commits an administrative offence so that he fails to meet any of the obligations of exporter imposed by the directly applicable EU regulation governing the cross-border movement of genetically modified organisms[30)].

(12) The penalty applicable to administrative offences is determined

a) 5,000,000 CZK in the case of the administrative offence pursuant paragraph 1 letter b), c) or f),

b) 1,500,000 CZK in the case of the administrative offence pursuant paragraph 5 letter a) or d),

c) 1,000,000 CZK in the case of the administrative offence pursuant paragraph 2, 3, paragraph 4 letter a) or b), paragraph 5 letter b) or c), paragraph 6, paragraph 7 letter h), paragraph 8 letter d) to f) or paragraph 9,

d) 500,000 CZK in the case of the administrative offence pursuant paragraph 1 letter a), d), g) or h), paragraph 7 letter a) to e) or paragraph 8 letter a) to c), paragraph 10 or 11,

e) 50,000 CZK in the case of the administrative offence pursuant paragraph 1 letter e) or paragraph 7 letter f) or g).

(13) If, within the period of one year from the legal force date of the decision on imposing the fine, the similar administrative offence for which the fine was imposed is committed again, the upper limit of the fine amount referred to in paragraph 1 to 5 shall be doubled.

§ 36

Common provisions of administrative offences

(1) The legal entity is not liable for an administrative offence if it proves that it has exerted every effort that it would be possible to require to prevent the breach of legal obligation.

(2) In determining the amount of the fine for a legal entity the seriousness of the administrative offence shall be taken into account, namely the way of its commitment and its consequences and circumstances under which it was committed.

(3) The liability of legal person for the administrative offence shall cease, if the administrative authority does not commence proceedings with him within 2 years from the date on which it has been informed on the offence, but not later than within 5 years from the date on which it was committed; the liability of legal person for the administrative offence under § 35a paragraph 1 letter e) or § 35a paragraph 7 letter f) or g) shall expire no later than 3 years from the date on which it was committed.

(4) The liability for acts carried out during doing business by a natural person or in direct connection with it shall be subject to the provisions of this Act on the liability and sanctions of legal entities.

(5) The administrative offences under this Act shall be negotiated by the Inspection.

(6) The fines are collected by the Inspection. The income from fines belongs to the income of the State Environmental Fund of the Czech Republic. The fine is payable within 30 days of the effective date of the decision through which it was imposed.

PART EIGHT

TRANSITIONAL AND CONCLUDING PROVISIONS

§ 37

(1) Decisions on registration to the List of users, List for the contained use, List for the release into the environment and List for placing on the market issued pursuant to the Act No. 153/2000 Coll., on the use of genetically modified organisms and genetic products and amendments to some related acts, shall expire at the latest on 17th October, 2006.

(2) After 31st December 2004, genetically modified organisms containing genes for resistance to antibiotics used in treatment of infections of humans or animals, provided that such genes have been inserted by genetic modification, shall not be placed on market.

(3) After 31st December 2004, genetically modified organisms containing genes for resistance to antibiotics used in treatment of infections of humans or animals, provided that such genes have been inserted by genetic modification, shall not be released into the environment.

(4) Administrative procedures initiated before legal force of this Act shall be completed pursuant to the current legal regulations[18)].

(5) When imposing an increased penalty, the penalties imposed pursuant to current legal regulations[18)] shall be considered as penalties imposed pursuant to this Act.

§ 38

The Ministry determines in the implementing Decree

a) the details of the summary of notification content pursuant to § 5 paragraph 4,

b) the details and procedures of risk assessment pursuant to § 7 paragraph 6,

c) the threshold level for presence of traces pursuant to § 11 paragraph 4,

d) the requirements for the containment and safety measures in the case of contained use under § 15 paragraph 2,

e) the examples of notification for the first and second class of contained uses and of the notification for the third or fourth class contained uses that are subjects of written consent by the competent authority, according to § 16 paragraph 6,

f) the example of risk assessment for the first class of contained use under § 16a paragraph 4,

g) the example of notification for the release into the environment pursuant to § 17 paragraph 3,

h) the manner and the scope of documentation keeping according to § 19 letter b),

i) the example of emergency plan under § 20 paragraph 4 and the scope of information published by the Ministry regarding the emergency plan pursuant to § 20 paragraph 5,

j) the example of notification for registration in the list for placing on the market pursuant to § 24 paragraph 3,

k) the details of assessment report pursuant to § 24b paragraph 7.

§ 39

The Act No. 153/2000 Coll., on the use of genetically modified organisms and products and on amendment of some related acts is thereby repealed.

§ 40

Entry into force

(1) This Act becomes effective on the day of its declaration, except for the provisions of § 8 paragraph 4 to 7, § 9 paragraph 3 lett. d) and e), § 18 paragraph 4 and 5, § 20 paragraph 6, §

21 paragraph 5 lett. c) and d), § 21 paragraph 7, § 23 paragraph 2 and 5, § 24 paragraph 4 to 10, § 24 paragraph 12, 15 and 17, § 25 paragraph 2 and § 34 paragraph 7, which come into effect on the day of coming into force of the Treaty of Accession of the Czech Republic to the European Union.

(2) The provisions of § 23 paragraph 1 and § 25 paragraph 1 shall be repealed on the day of coming into force of the Treaty of Accession of the Czech Republic to the European Union.

(3) The provisions of § 24 paragraph 18 shall be repealed on April 18, 2007.

Annex 1 to Act No. 78/2004 Coll.

Technical procedures which are considered to result in a genetically modified organism and technical procedures that are not considered to result in a genetically modified organism

1. genetically modified organisms may occur inter alia through the use of the techniques

a) recombinant nucleic acid technique forming a new combination of a heritable genetic material by insertion of a nucleic acid molecules produced by whatever means outside of an organism into any virus, bacterial plasmid or other vector system and its subsequent incorporation into the organism of a recipient, in which do not naturally occur but in which they are capable of a continued propagation.

b) technique involving direct introduction of a heritable genetic material prepared by whatever means into the organism of a recipient, including micro-injection, macro-injection, biolistic methods, micro-encapsulation and artificial chromosomes, or

c) technique of cell fusion, including the protoplast fusion or cell hybridisation, where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

2. The following technical procedures are not considered to result in genetically modified organisms on condition that they do not involve the use of recombinant heritable genetic material as described in § 1 of this Annex or genetically modified organisms made by these techniques.

a) in vitro fertilisation,

b) bacterial conjugation, transformation, transduction and similar natural processes,

c) polyploidy and haploidy induction

Annex 2 to Act No. 78/2004 Coll.

Safety criteria forgenetically modified organisms

In order to comply with the requirements on safety for human health and the environment pursuant to §1 paragraph 2 letter b), contained use of genetically modified micro-organisms shall meet the following criteria:

a) the genetically modified organism has to be strictly defined, the strain identity has to be determined and verified, modifications have to be known and verified,

b) the evidence regarding safety of the organism has to be provided, accompanied by the necessary documentation,

c) the genetic stability has to be proven in case instability could adversely affect safety,

d) the genetically modified organism must not be capable of causing disease or detriment to a healthy human, plant or animal; since pathogenicity includes both toxinogenicity as well as allergenicity; a genetically modified micro-organism must not:

1. cause increased toxinogenicity as a result of the genetic modification and it must not have any known toxigenic characteristics,

2. cause increased allergenicity as a result of the genetic modification, it must not be a known allergen.

e) it must not contain accidentally acquired harmful elements, such as micro-organisms, active or latent, which exist outside or inside of the genetically modified organism, and which might have detrimental effect on health of human beings, animals, environmental components or biological diversity,

f) if its altered genetic material is transferred, it must not cause damage and it must not be auto-infectious or transferable with a frequency higher than other genes of the recipient or parent micro-organism,

g) it must not have immediate nor delayed adverse effects on the environment or biological diversity in the case of leakage of the genetically modified organism into the environment.

Annex 3 to Act No. 78/2004 Coll.

Classes of the contained use

Assessment of the contained use as regards the risks of particular genetically modified organism shall result in the classification of the contained use in the following classes:

1. The first class includes activities of no or negligible risk of adverse effect on health and environment; i.e. activities for which the level of containment and protective measures laid down for the first class by this Act is appropriate to protect human and animal health, environment or biological diversity.

2. The second class includes activities of low risk of adverse effect on health and environment that can easily be eliminated using generally known procedures; i.e. activities for which the level of containment and protective measures laid down for the second class by this Act is appropriate to protect human and animal health, environment or biological diversity.

3. The third class includes activities with a risk of such adverse effects on health and environment that can only be eliminated by demanding measures; i.e. activities for which the level of containment and protective measures laid down for the third class by this Act is appropriate to protect human and animal health, environment or biological diversity.

4. The fourth class includes activities with high risk of adverse effects on health and environment, for which the level of containment and protective measures laid down for the fourth class by this Act is necessary to protect human and animal health, environment or biological diversity.

Annex 4 to Act No. 78/2004 Coll.

Requirements of the Code of Practice for a workplace at which genetically modified organisms are used

The Code of Practice of the workplace at which the genetically modified organisms are used shall contain at least the following information:

a) the name or the title or the business name, official address and identification number, if assigned, of the entitled person provided it is a natural person authorized to operate business,

b) the name or the business name, official address and identification number, if assigned, of the entitled person provided it is a legal person, as well as the name and address of the place of residence of the statutory body of the entitled person,

c) the name and the domicile address of the owner of the building, in the case of contained use, or of the land in the case of the release into the environment, provided it is a natural person, or the name or the business name, official address and identification number of the person, if assigned, as well as the name and the domicile address of the statutory body, provided the owner is a legal entity, and provided the owner is not identical to the entitled person,

d) the name, the domicile address, telephone number and electronic mail address of the biosafety officer,

d) the name, the domicile address, telephone number and electronic mail address of the person responsible for the workplace,

f) the class of contained use of genetically modified organisms that may be carried out at the workplace,

g) the list and the approximate amount of genetically modified organisms that will be used at the workplace,

h) the list of personnel trained to work at the workplace,

i) the obligations of personnel at work, in particular the observance of working procedures, the procedure of the area and equipment sanitation after the end of work, the decontamination procedure of tools, personal protective equipment and clothing,

j) the list and the description of binding workflows used at the workplace,

k) prohibited activities at the workplace,

l) the principles of hygiene and safety at work, in accordance with the provisions of special legal regulation[6)],

m) the list of personal protective equipment and other tools determined by the employer in accordance with the special legal regulation[19)], indicating the activities for which it must be used,

n) the organizational and technological security of the workplace,

o) the obligations of personnel for the maintenance of equipment,

p) the character, purpose and description of technical elements that ensure the containment in the case of contained use,

q) the measures to prevent access of unauthorised persons,

r) the system and the frequency of checks of the work area, equipment and protective measures,

s) the measures for accidents and fire, including the emergency plan pursuant § 20,

t) the method of waste management and contaminated materials and objects disposal, in particular the procedures for the disposal of genetically modified organisms and the way of their effectiveness verification,

u) the principles of records keeping regarding the operation of the equipment, the performed sanitation and the inspection of security elements,

v) in the case of release of genetically modified organisms into the environment

1. the manner of transport to the plot including the safety measures

2. the place and manner of storage of genetically modified organisms prior their release into the environment and after its termination, including the information on packaging and labelling,

w) the information on possible time limitation of the Code of Practice.

[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.
Directive 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.

[2)] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

[3)] Act No. 17/1992 Coll., on the environment, as last amended

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

[5)] Act No. 123/1998 Coll., on the right to information on the environment, as amended by Act No. 132/2000 Coll.
Act No. 106/1999 Coll. on free access to information, as last amended.

[6)] For example Act No. 258/2000 Coll., on protection of public health and amending some related acts, as last amended.

[7)] Commercial Code.

[8)] Act No. 101/2000 Coll., on the protection of personal data and amending some acts, as last amended.

[8a)] Article 21 paragraph 2 of the Directive No. 2001/18/EC of the European Parliament and of the Council as amended by the 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.

[9)] For example, Act No. 110/1997 Coll., on foodstuffs and tobacco products and amending and supplementing some related acts, as last amended; Act No. 91/1996 Coll., on feeding stuffs, as last amended; Act No. 219/2003 Coll., on the marketing of seed and planting material of cultivated plants and amending some related acts (Seed Act); Act No. 147/1996 Coll. on plant medical care, as last amended; Act No. 166/1999 Coll., on veterinary care and amending some related acts (The Veterinary Act), as last amended, and Act No. 79/1997 on medicinal substances, as last amended.

[9a)] Act No. 269/1994 Sb., on the Registry of Criminal Records, as last amended.

[10)] § 44 of Act No. 111/1998, on universities and amending and supplementing some other acts (Act on universities).

[11)] For example, Act No. 110/1997 Coll., on foodstuffs and tobacco products and amending and supplementing some related acts, as last amended; Act No. 91/1996 Coll., on feeding stuffs, as last amended; Act No. 147/1996 Coll., on plant medicinal care and changes some related laws; Act No. 166/1999 Coll., on veterinary care and changes some related laws; Act No. 79/1997 Coll., on Pharmaceuticals, as last amended.

[11a)] Article 47 of the Regulation (EC) No. 1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed.
Article 12a of the 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 and amending the Regulation (EC) No 1829/2003.

[13)] § 15 of the Act No. 22/1997 Coll., on technical requirements on the products and amending some acts, as last amended.

[13a)] Article 17 of the Regulation (EC) No. 1946/2003 of the European Parliament and the Council of 15 July 2003 on transboundary movements of genetically modified organisms.

[14)] For example the Act No. 219/2003 Coll.; Act No. 147/1996 Coll., as last amended; Act No. 166/1999 Coll., as last amended; Act No. 146/2002 Col., On Czech Agricultural and Foodstuff Inspection and amendment of some related acts, as last amended.

[15)] Act No. 20/1966 Coll., on the health of the population, as last amended; Act No. 258/2000 Coll., as last amended.
Act No. 258/2000 Coll., as last amended.

[16)] Act No. 281/2002 Coll., on some measures related to the ban on bacteriological (biological) and toxin weapons and amending the Trade Licensing Act.

[16a)] Regulation (EC) No. 1946/2003 of the European Parliament and the Council of 15 July 2003 on transboundary movements of genetically modified organisms.

[16b)] 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.

[16c)] Article 4 paragraph 1 to 4 of the Regulation (EC) No. 1830/2003 of the European Parliament and the Council of 22 September 2003.

[17)] Act No. 337/1992 Coll., on Administration of Taxes, as last amended.

[18)] Act No. 153/2000 Coll., on the use of genetically modified organisms and products and amendment of some related acts.

[19)] Government Regulation No. 495/2001 Coll., establishing the scope and detailed conditions for the provision of personal protective equipment, washing, cleaning and disinfection.

[20)] Act No. 252/1997 Coll., on Agriculture, as last amended.

[21)] Regulation (EC) No 1829/2003 of the European Parliament and 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.
Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms.

[22)] Regulation (EC) No 1107/2009 of the. European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

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

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

[25)] Act No. 149/2003 Coll., on setting afloat reproductive material of forestry-important tree species and hybrids of trees, intended for forest reproduction and for forestation, and on a change of some related laws (an act about trade in reproductive material of forest-tree species).

[26)] Regulation (EC) No 1829/2003 of the European Parliament and 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.

[27)] 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.
Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms.

[28)] Article 4 paragraph 6 of the 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.

[29)] Article par 1 to 4 of the 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.
[30)] Regulation (EC) No 1946/2003 of the European Parliament and the Council of 15 July 2003 on transboundary movements of genetically modified organisms.