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# ACT

of January 22, 2004

**on the use of genetically modified organisms and genetic products**

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

## PART I

## INTRODUCTORY PROVISIONS

§ 1

### The object of the Act

(1) The Act in accordance with the Law of European Communities[1)] lays down the rights and obligations of persons and the competences of administrative bodies in 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 or the technique of a cell fusion or a fusion of protoplasts of the plant cells of organisms, for which the exchange of the genetic material can be achieved through the traditional breeding methods, unless these techniques at the same time involve the technical procedures referred to in point 1, Annex 1 to this Act, or the use of genetically modified organisms originated by 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, environmental components and biological diversity, laid down in Annex 2 to this Act,

c) contained use of genetically modified organisms concerning exclusively genetically modified micro-organisms originated from cell fusion or fusion of protoplasts of cells of the prokaryotic species that exchange genetic material via known physiological processes unless this fusion at the same time involves the technical procedures 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 fusion of protoplasts of the cells of the eukaryotic species including the creation of hybridomas, unless this fusion at the same time involves the technical procedures 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 genetic product is a medicinal product or a product for protection of plants that is subject to registration pursuant to the special legal regulation[2)], then it shall not be subject to the provisions of this Act concerning the administrative procedure for the registration into the List of genetically modified organisms and genetic products authorised for placing on the market (hereinafter the List for placing on the market) and on amendment thereof. The consent for placing on the market of such medicinal product or product for protection of plants according to the special legal regulation shall not be granted until the Ministry issues an opinion containing a specific environmental risk assessment of the medicinal product or the product for protection of plants. The Ministry shall be obliged to issue the opinion within 15 days after the receipt of a request from the relevant administrative body.

§ 2

**Basic definitions**

For the purposes of this Act:

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

b) heritable genetic material shall mean deoxyribonucleic or ribonucleic acid,

c) genetic modification shall mean 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 manner that cannot be achieved by natural recombination,

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

g) contained space shall mean a space 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 shall mean 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 the health of human beings and animals, the environmental components 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 space, unless the genetically modified organisms are registered in the List for placing on the market,

b) introduction of genetically modified organisms into the environment (hereinafter “introduction into the environment”) involving release thereof into the environment outside of a contained space, unless the genetically modified organisms are registered in the List for placing on the market,

c) placing of genetically modified organisms or genetic products on the market (hereinafter “placing on the market”) involving a transfer or an offer for a payment or free of charge to any other person, unless it is a transfer or an offer of genetically modified organisms or genetic products to an authorised person solely for the purpose of contained use or introduction 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, every individual in accordance with the precautionary principle shall be obliged to protect the health of human beings and animals, the environmental components and biological diversity (hereinafter “health and the environment”).

(4) Every individual using a genetically modified organism or genetic product shall be obliged to adhere to 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 use of genetically modified organisms and genetic products**

(1) The use of genetically modified organisms may proceed only based on 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.

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

(4) Authorisation for placing on the market shall arise from registration of the genetically modified organism or genetic product involved into the List for placing on the market. Detailed conditions for granting of such authorisation are laid down in § 23 and 24.

§ 5

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

(1) A request for granting consent for the contained use and for the introduction into the environment (hereinafter "consent") or for the registration into the List for placing on the market shall be submitted by the applicant to the Ministry in quadruplicate and simultaneously on a technical data medium or by e-mail. The request shall contain name or names, surname, business name, place of residence, place of business and tax identification number, if assigned, if the applicant is a natural person authorised to operate a business, name or business name, place of business and tax identification number if assigned, if the applicant is a legal person, and name or names, surname and place of residence of the professional consultant. Other requirements of a request necessary for the assessment of the use of the genetically modified organism or genetic product from the viewpoint of the protection of human health and the environment shall be laid down by the implementing legal regulation.

(2) The applicant in the application may refer to the data, information or results that are contained in requests submitted earlier by other applicants, if such data, information and results are not subject of protection pursuant to § 9, or if the persons concerned have given their written consent to do so.

(3) The Ministry within 5 days of receiving the request pursuant to paragraph 1 shall assess its completeness. If the request does not contain some of the requirements laid down pursuant to this Act, the Ministry shall within this time-period invite the applicant to complement the request. The Ministry in the invitation 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 invitation. If the applicant fails to complement the request within the set time-period, the Ministry shall suspend the administrative procedure.

(4) If the request meets all requirements pursuant to this Act, the Ministry within 5 days of expiration of the set time-period for assessment of request completeness or of the date of receiving the complemented request pursuant to paragraph 3 shall forward one copy thereof in

a written form and in electronic form as well to the Ministry of Agriculture and the Ministry of Health (hereinafter “the Ministries concerned”), and at the same time shall make available to the public the summary of the contents of the request in the manner pursuant to § 10 letter b), and information on commencement of the administrative procedure request in the manner pursuant to § 10 letters a) and c). The requirements of the summary of the contents of the request shall be laid down by the implementing legal regulation.

(5) The Ministries concerned may inform the Ministry in writing of their opinions regarding the request or raise claims for complementing information in the request within 30 days of receiving the request. If the Ministry concerned raises a claim for complementing information in the request, the Ministry shall invite the applicant to complement information within 5 working days of expiration of the set time-period referred to in the first clause. The Ministry in the invitation 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 invitation. If the applicant fails to complement the requested information within the set time-period, the Ministry shall suspend the administrative procedure. The Ministry shall forward the complemented request to the Ministries concerned that may consult their opinions within 15 working days of receiving the request. If the Ministry concerned does not consult its opinion within the time periods mentioned above, it shall be understood to have no comments on the request.

(6) Every individual may forward to the Ministry in writing his/her opinion within 30 days of making the summary of the contents of the request 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 in case of a request for granting consent for the introduction into the environment or for registration into the List for placing on the market, the Ministry pursuant to paragraph 6 receives negative opinion on introduction of the genetically modified organism or the genetic product into the environment or on the placing thereof on the market, in which environmental risk assessment results are doubted or an objection to insufficient protection of the health and the environment is made, the Ministry in the way pursuant to § 6 shall arrange for public consultation prior to making decision on the submitted request.

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

(9) The Ministry when making a decision shall consider also opinions of the Ministries concerned and of the public. A decision on the submitted request shall always contain a comprehensive settlement of the opinions submitted pursuant to paragraphs 5 and 6, and also results from the public consultation carried out pursuant to paragraphs 7.

(10) If the Ministry pursuant to paragraph 8 adopts the decision 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 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 in the manner pursuant to § 10.

§ 6

**Public consultation**

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

(2) Besides the Ministry, the applicant for granting the consent for introduction 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 applicant'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 applicant. 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 applicant 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 be obliged to forward to the applicant a record of the public consultation within 5 working days of its termination 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 a gene conditioning resistance to antibiotics and other preparations used for treatment of human beings or animals, provided that such gene or genes have been inserted into the genetically modified organism.

(2) The risk assessment shall be carried out by a professional consultant (§ 14).

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

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

b) the person submitting notification pursuant to § 16 par. 2 or 3 as a part of this notification,

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

d) the person authorised pursuant to this Act for contained use or introduction into the environment, and the person registered in the List for placing on the market every 5 years from the date of last submission.

(4) The following shall have to be utilized 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 organism that is the source of the heritable material used in the genetic modification, 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 estimates, if verified scientific knowledge is missing; it is necessary to use the precautionary principle in these cases

(5) The applicant or the person pursuant to paragraph 3 shall be obliged to keep records on the risk assessment for at least 10 years from the date of its submission, and provide it on request to the administrative bodies referred to in § 27.

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

(7) 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 introduction into the environment, the person registered in the List for placing on the market or the person requesting 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 be obliged immediately

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

b) to provide newly obtained 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 administrative bodies involved, referred to in § 27.

(2) The person pursuant to paragraph 1 shall be further obliged to carry out and submit to the Ministry the new risk assessment at latest within 30 days of the date of obtaining new information.

(3) If the Ministry obtains new information with regard to the risks of the genetically modified organism or genetic product to human health or the environment in other manner than pursuant to paragraph 1 letter b), the Ministry shall inform the persons involved referred to in paragraph 1, and invite them to carry out and submit to the Ministry the new risk assessment at latest within 30 days of the date of receiving the invitation. At the same time the Ministry shall notify new information to other administrative bodies involved referred to in § 27.

(4) If new information pursuant to paragraph 1 or 3 concern genetically modified organism or genetic product for which the request 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 of the European Communities (hereinafter “Member States”). If the registration has not yet been made, the Ministry may require additional information from the applicant. When the new information has been obtained 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 obtaining 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 obtains as a result of new information that may affect the risk assessment or reassessment of existing information on the basis of new scientific knowledge, detailed

grounds for considering that genetically modified organism or genetic product which has received a consent for placing on the market granted by competent authority of a Member State constitutes a risk to human health or the environment, 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 the 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 a Member State 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 respectively how the conditions of the consent or permission should be amended, or the granted consent or permission 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 applicant pursuant to § 5 par. 1 or the notifier pursuant to § 16 par. 2 or 3 may indicate data in the request, or, where applicable, in the notification, disclosure of which might harm his competitive position and which should therefore be treated as confidential. The person pursuant to the first clause shall be obliged to give verifiable justification that the disclosure of the information indicated as confidential would actually harm his or her competitive position, otherwise such information can not be indicated as confidential.

(2) The following information can not be indicated as confidential

a) 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 name or names, surname, 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 risk category of the contained use, the requirements for the contained space and the protective measures for the risk category of the contained use involved,

d) the place and purpose of the introduction 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 confidential shall only be accessible to

a) administrative bodies referred to in § 27,

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

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

d) the relevant authorities of Member States,

e) the Commission

(4) The information kept as confidential may only be made available with the consent of the person concerned.

(5) The obligation to protect information indicated as confidential shall continue even if the request is rejected or withdrawn.

(6) For the purpose of this Act, the provisions concerning business secrecy pursuant to the special legal regulation[7)] shall not apply to the information that pursuant to paragraphs 1 and 2 may not be indicated as confidential.

(7) 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

**Making information available 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) through the Internet,

c) at least in one another appropriate manner in the municipality or region, on territory of which the immediate contained use or introduction into the environment proceeds, or such handling with regard to all circumstances is expected.

§ 11

**Labelling**

(1) The person that places on the market the genetically modified organism or genetic product, and the person that provides the genetically modified organism exclusively for the purpose of contained use or introduction into the environment, shall ensure that the packaging of the genetically modified organism or genetic product has a visible label clearly stating “genetically modified organism” or “this product contains a genetically modified organism” or “this product contains a genetically modified organisms”; this text shall appear also in the accompanying documents and in all stages of the product processing. The Ministry in its decision on granting the permission may also lay down further requirements for the labelling.

(2) The person that places on the market the genetically modified organism or genetic product within his or her business activity, shall ensure that the packaging or if it is not possible the accompanying document, also contains the following information

a) the commercial name of the product,

b) the name of genetically modified organism,

c) the name or names, surname, business name, place of business and tax identification number (if assigned) of the person registered for this genetically modified organism or genetic product in the List for placing on the market, if he or she is a natural person authorised to operate a business, or the name or business name, place of business and tax identification number (if assigned), if such person is a legal person,

d) the conditions and purpose of the use of the genetically modified organism or genetic product registered in the List for placing on the market,

e) guidance on the manner of obtaining further information that are contained in the registration into the List for placing on the market, pursuant to this Act,

f) information on occupational safety and personal protective equipment in such cases when the use of genetically modified organisms or genetic products requires the equipment or measures beyond scope of those commonly used.

The Ministry in registration into the List for placing on the market may also lay down additional requirements on the labelling.

(3) For products where adventitious and technically unavoidable traces of genetically modified organisms registered in the List for placing on the market can not be excluded, the Ministry after discussing with the Ministries concerned shall establish by the implementing legal regulation the threshold minimum of such traces; if the values of the traces in the product are below the threshold minimum, this product shall not have to be labelled according to paragraphs 1 and 2.

(4) the conditions for placing on the market and requirements on packaging and labelling of the products that are laid down by the 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 a valid consent or registration in the List for placing on the market, if

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

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

c) obligations laid down by this Act or stipulated pursuant to the Act are seriously or repeatedly breached by the person that was 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 on the basis thereof authorised for contained use or introduction 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) expiry of the time period for which the consent was granted or for which the registration into the List for placing on the market was valid,

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

§ 14

**Professional consultant**

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

(2) A person, who was not finally and conclusively 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 an extract 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 at least 5 years of practice in a relevant branch, out of that at least 2 years of handling genetically modified organisms. The required two-years practice also includes a postgraduate or doctoral study in the relevant branch concerning the use of genetically modified organisms.

## PART III

## CONTAINED USE AND INTRODUCTION INTO THE ENVIRONMENT

### CHAPTER I

### CONTAINED USE

### § 15

(1) The result of the risk assessment in case of contained use shall be the assignment of such use to one of the risk categories referred to in Annex 3 to this Act. If the risk assessment has not resulted in the definite assignment of the contained use to a certain risk category, it shall be necessary to assess such use under the requirements for the higher risk category.

(2) A user may use genetically modified organisms or products only in a contained space that complies with the requirements on containment and protective measures laid down for the pertinent or higher risk category. Requirements on contained space and protective measures for the individual risk categories shall be laid down by the implementing legal regulation.

(3) A person authorised pursuant to § 16 for the contained use shall be obliged during the contained use to review the contained space and the protective measures regularly 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) Authorisation for the contained use may only arise for a legal person or a natural person authorised to operate a business.

(2) If the risk assessment pursuant to § 7 has resulted in assignment of the contained use to the first risk category, the person pursuant to paragraph 1 may commence such use provided that the person submits a notification thereof to the Ministry. A notification for the first risk category shall be submitted in writing and simultaneously on technical data carrier or in e-mail and shall contain the name or names, surname, business name, place of residence, place of business and tax identification number (if assigned), if a notifier is a natural person authorised to operate a business, and the name or business name, place of business and tax identification number (if assigned), if the notifier is a legal person, and the name or names, surname and place of residence of a professional consultant. Other requirements for the notification that are necessary for the assessment of the contained use from the viewpoint of the protection of human health and the environment shall be laid down by the implementing legal regulation.

(4) The Ministry shall be entitled to require from the notifier within 15 days of receiving the notification pursuant to paragraphs 2 or 3 additional information or precision of the data presented in the notification.

(5) The Ministry may, on the basis of the submitted notification, additional information or precision of the data pursuant to paragraph 4 or new information pursuant to § 8, may ask the notifier to modify the conditions of the use presented in the notification, if it is necessary from the viewpoint of protection of human health and the environment. In such case the contained use may not proceed before the Ministry gives its consent thereto. The Ministry shall give its consent as soon as the conditions of the contained use are modified in accordance with the Ministry's requirements. Appeals against the decision asking the notifier to modify the conditions of the use given in the notification shall not suspend the requirement to carry out the imposed measures.

(6) The Ministry shall issue on request of the authorised person the confirmation of the authorisation for the contained use pursuant to paragraphs 2 or 3.

(7) Contained use in the third or fourth risk categories may only be commenced on the basis of consent for the contained use, and only within the scope and under conditions laid down therein.

(8) The administrative procedure for granting the consent for contained use shall proceed pursuant to § 5.

(9) The consent for contained use shall contain

a) name or names, surname, name of business, place of residence, place of business 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, place of business and tax identification number (if assigned) of the authorised person, if the authorised person is a legal person.

b) specification of the genetically modified organism,

c) specification of the genetic modification,

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

e) the risk category, for which the consent was granted,

f) the purpose of the use,

g) additional requirements on the labelling, where applicable (§ 11 par. 1),

h) the period of validity of the consent.

(10) The validity of the consent for the contained use must be time-limited. The Ministry on the request of 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. The authorised person on the basis of the request submitted pursuant to the second clause, may continue the contained use in accordance with the conditions laid down in the consent until the decision on prolongation thereof is issued. The Ministry shall forward to the Ministries concerned the decision and make it available to the public pursuant to §10 of this Act.

(11) The consent for the contained use may not be transferred to other persons.

## CHAPTER II

## INTRODUCTION INTO THE ENVIRONMENT

### § 17

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

(2) The person pursuant to paragraph 1 shall be obliged to ensure that no material derived from genetically modified organism that is being introduced into the environment, is placed on the market unless it is in compliance with the provision of § 23.

### § 18

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

(2) The applicant shall be obliged to provide control samples of the genetically modified organism involved to the Ministry or to the 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 par. 1 letter f), together with the request or at the latest within 10 days of submitting thereof.

(3) In case of the introduction 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 applicant may submit a single joint request.

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

(5) In the decision on the submitted request for granting the consent for the introduction 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 introduction into the environment shall contain

a) name or names, surname, name of business, place of residence, place of business 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, place of business and tax identification number (if assigned) of the authorised person, if the authorised person is a legal person,

b) specification of the genetically modified organism,

c) specification of the genetic modification,

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

e) the purpose of the use,

f) other requirements on the labelling, where applicable (§ 11 par. 1),

g) the place at which the introduction into the environment will proceed, including unambiguous determination of the site,

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

i) the period of validity of the consent.

(7) The validity of the consent for the introduction into the environment must be time-limited. The Ministry on the request of 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. The authorised person on the basis of the request submitted pursuant to the second clause, may continue with the introduction into the environment in accordance with the conditions laid down in the consent until the decision on prolongation thereof is issued. The Ministry shall forward to the Ministries concerned the decision and make it available to the public pursuant to §10 of this Act.

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

(9) The person that was granted the consent for the introduction 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 INTRODUCTION INTO THE ENVIRONMENT

### § 19

### Obligations of persons authorised for contained use and of persons authorised for introduction into the environment

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

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

b) to keep records on the use of genetically modified organisms for each workplace and to store it for a period of at least 10 years from the termination of this use; the manner and the scope of keeping records shall be stipulated by the implementing legal regulation,

c) to submit to the Ministry in written and electronic form a list of genetically modified organisms, information on the amount and manner of the use thereof for the past calendar year, by February 15 of each calendar year,

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

f) to ensure that 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) to ensure that the employees shall be trained before the commencing the use of the genetically modified organisms, and trained in refresher courses following every change of working procedures or at least once a year, and demonstrably acquainted with the Code of Practice of the workplace,

h) to provide the administrative bodies pursuant to § 28 and § 31 to § 33 with co-operation in inspection of the sites, premises and facilities intended for the use of genetically modified organisms, or the 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

**The 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 be obliged to draw up an emergency response plan and submit it to the Ministry

a) the applicant, as part of the request for granting the consent,

b) the person submitting notification pursuant to § 16 par. 2 or 3 as a part of this notification,

c) the person authorised pursuant to this Act for contained use or introduction into the environment every 5 years from the date of last submission,

d) the person pursuant to this Act authorised for contained use or for introduction into the environment, in the 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) The applicant and the persons referred to in paragraph 2 shall be obliged to 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 contain the name or names, surname, name of business, place of residence, place of business, tax identification number (if assigned), telephone number, and, where applicable, also fax number and e-mail address of the person pursuant to paragraph 2, if he/she is a natural person, or the name or business name, place of business and identification number (if assigned), and telephone number, and, where applicable, also fax number and e-mail address of the statutory body, if the person involved is a legal person. The emergency response plan shall also contain the name or names, surname, place of residence, telephone number, and, where applicable, also fax number and e-mail address of the professional consultant and of the person responsible for liquidation of an accident. The further requirements for the emergency response plan shall be laid down by the implementing legal regulation.

(5) The Ministry shall make the emergency response plan available to the public pursuant to § 10 letters b) and c).

(6) The Ministry shall forward the 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 undesirable release of genetically modified micro-organisms or the immediate risk thereof in the course of their contained use or introduction into the environment which could present an immediate or delayed hazard to human health or the environment.

(2) In case of an accident, the person authorised for contained use or introduction into the environment immediately after having learned of such accident shall be obliged in accordance with the emergency response plan to carry out measures for mitigation or removal of its harmful effects.

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

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

b) the circumstances of an accident,

c) the place of an accident,

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

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

(4) The person pursuant to paragraph 2 shall be also obliged to notify without delay to the other administrative bodies referred to in § 27 according to their competences of an accident occurred.

(5) The Ministry after having learned of the accident shall be obliged without delay

a) to inform administrative bodies referred to in § 27,

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

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

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

(6) The Ministry shall be further obliged to work up an analysis of the accident occurred including the identification of the causes thereof and making recommendations to reduce accidents and avoid such accidents in the future.

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

§ 22

**The Register of permitted genetically modified organisms and the Register of users**

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

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

(3) Information contained in the consent pursuant to § 16 par. 9 and § 18 par. 6, except for information considered confidential (§ 9), shall be recorded in the Register of the permitted genetically modified organisms.

(4) The Ministry shall further keep a register of persons that have been granted the consent pursuant to this Act or that have been authorised for the contained use on the basis of notification pursuant to § 16 par. 2 or 3 (hereinafter the "Register of users").

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

a) name or names, surname, name of business, place of business and tax identification number (if assigned) of the person authorised for the contained use or the introduction into the environment, if it is a natural person authorised to operate a business, or its name or business name, place of business and tax identification number (if assigned), if it is a legal person,

b) genetically modified organisms for which the user was granted consent, and, where applicable, the species of organisms listed in the notification,

c) date of granting of the authorisation for the contained use or the introduction into the environment, and the time-period of consent validity, if the authorisation was granted on the basis of a consent.

(6) If the person pursuant to paragraph 5 in case of the contained use is authorised to use genetically modified organisms on the basis of notification pursuant to § 16 paragraphs 2 or 3, the purpose of the use and the risk category 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 the permitted 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 the notification pursuant to § 16 par. 2 or 3.

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

(9) The information recorded in the Register of permitted genetically modified organisms and in the Register of users shall be stored 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 permitted genetically modified organisms and the Register of users shall be made available to the public pursuant to § 10 letter b).

## PART IV

## THE PLACING ON THE MARKET

§ 23

(1) Only genetically modified organisms or genetic products registered in the List for placing on the market may be placed on the market. Taking decisions on placing on the market pursuant to special legal regulation[11)] shall not be prejudiced by this provision.

(2) The genetically modified organism or genetic product may only be placed on the market if it is registered in the List for placing on the market or if the consent or permission thereof was granted by the competent authority of a Member State, and if it complies with the requirements of the legislation of the European Communities.

(3) Anyone who grows genetically modified organisms permitted to be placed on the market pursuant to paragraph 1 or 2 shall be obliged to submit to the Ministry in writing information on the place of growing thereof for the past calendar year, by February 15 of each calendar year. The Ministry shall make available to the public such information on the basis of proved reasonable interest.

(4) The person registered in the List for placing on the market shall be obliged to ensure carrying out of monitoring and reporting its results in compliance with the requirements laid down in the registration. The Ministry shall be entitled on the basis of these reports to precise the requirements on the monitoring after the first monitoring period. The Ministry shall make available to the public the results of the monitoring pursuant to § 10 letter b).

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

§ 24

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

2) If on the basis of the results of any previous introduction into the environment or on the basis of substantive scientific knowledge, the applicant considers that the placing on the market and use of genetically modified organism or genetic product do not pose a risk to human health or the environment, he/she may before submitting the request propose to the Ministry not to require some of the information. In such case, the Ministry shall, within 30 days of receiving the proposal and after consulting it with the Ministries concerned, forward its opinion to the applicant. The Code of Administrative Procedure shall not apply to the procedure pursuant to this paragraph.

(3) The applicant shall forward control samples of the genetically modified organism or genetic product to the Ministry or to a legal person with which the Ministry has concluded the contract for co-operation in the exercise of its responsibility pursuant to § 28 par. 1 letter f), together with the request or at the latest within 10 days of submitting thereof.

(4) The Ministry without unnecessary delay after receipt of the request shall forward the summary of the dossier referred to in § 5 par. 4 to the Commission and to the relevant authorities of Member States. The Ministry shall forward a full copy of the request to the Commission at the latest together with the assessment report pursuant to paragraph 5.

(5) The Ministry, taking into account the opinions of the Ministries concerned, shall, within 90 days of receipt of the request work up an assessment report and send it within this time-period to the applicant and the Ministries concerned. For the purpose of calculating this time-period of 90 days, any period of time during which the Ministry is awaiting information from the applicant pursuant to § 5 par. 3 or 5, shall not be taken into account. The Ministry shall make available to the public an assessment report in the manner pursuant to § 10 letter b). In the assessment report it must be stated that

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

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

(6) In the case pursuant to paragraph 5 letter a), the Ministry shall send the assessment report also to the Commission within 90 days of receipt of the request. In the case pursuant to paragraph 5 letter b), the Ministry shall send the assessment report to the Commission at the latest within 105 days of receipt of the request. For the purpose of calculating the time-period the provision of the second clause in paragraph 5 shall be applied.

(7) If the Commission or the competent body of a Member State, within the time-period of 90 days of the date of sending to the Commission the assessment report pursuant to paragraph 5 letter a), asks for additional information or forwards comments or reasoned objections to placing on the market of the genetically modified organism or genetic product involved, the Ministry shall provide such information and discuss comments and objections with the Commission or the competent body of a Member State within 45 days following expiry of this time-period.

(8) The Ministry, on the basis of the request, comments or objections forwarded pursuant to paragraph 7, shall be entitled to ask the applicant for additional information. In such a case, any time-period during which the answer from the applicant is awaited shall not be taken into account for the purpose of calculating the 45 day period pursuant to paragraph 7.

(9) If in the case pursuant to paragraph 5 letter a), the Commission has not submitted to the Ministry within time-period of 90 days pursuant to paragraph 7 any reasoned comments or objections or an agreement has been reached within the time-period of 45 days pursuant to paragraph 7, the Ministry shall take a decision on registration in the List for placing on the market. The Ministry shall inform the Commission and the competent authorities of Member States on this decision within 30 days of issuing thereof.

(10) If no agreement has been reached within the period of 45 days pursuant to paragraph 7, the Ministry shall, in accordance with the result of the procedure laid down by the legislation of the European Communities for such cases, within 30 days of notifying the results thereof, take a decision on registration in the List for placing on the market or on rejection of the request and shall inform the Commission and the competent authorities of Member States thereof.

(11) If the Ministry takes a decision on making registration in the List for placing on the market, it shall make it at the latest within 15 days of the date of legal effect of the decision.

(12) In the case pursuant to paragraph 5 letter b), the Ministry shall, within 15 days of sending the assessment report pursuant to paragraph 6, take a decision on rejection of the request.

(13) Registration in the List for placing on the market shall contain

a) the name or names, surname, name of business, place of residence, place of business and tax identification number (if assigned) of the person who submitted the request for registration if he is a natural person authorised to operate business, or the name or business name, place of business and tax identification number (if assigned) of the person who submitted the request for registration if such person is a legal person,

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

c) specification of the genetic modification,

d) the results of the risk assessment,

e) the conditions and the purpose of placing on the market of the genetically modified organism or genetic product, including any specific conditions of utilization, use and packaging, and further conditions for the protection of particular ecosystems, environments or geographic areas,

f) other possible labelling requirements

g) the manner of laboratory testing for the presence of the genetic modification, including description of the part of the altered deoxyribonucleic or ribonucleic acid, allowing unambiguous identification of the genetically modified organism, and, where applicable, also according to international regulations,

h) the conditions of provision of control samples to the relevant administrative authority,

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

j) the time-period of validity of registration.

(14) The time-period of validity of registration in the List for placing on the market may be at maximum laid down as 10 years from the date of registration. The period of validity of registration may not be prolonged.

(15) In the case of a genetically modified organism intended only for the marketing of its seeds under the relevant legislation of the European Communities, the period of validity of registration pursuant to paragraph 14 shall end at the latest ten years after the date of the first inclusion of the first plant variety containing the genetically modified organism on the Czech National Variety List in accordance with the relevant legal regulation of the European Communities.

(16) The List for placing on the market shall be made available to the public in the manner pursuant to § 10 letter b).

(17) Requirements of the assessment report pursuant to paragraph 5 shall be laid down by the implementing legal regulation.

## 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 may be imported or exported[12)].

(2) Only genetically modified organisms or genetic products registered in the List for placing on the market, or for which the consent or permission for placing on the market was granted by the relevant authority of a Member State, may be imported or exported[12)].

(3) The person authorised for contained use (§ 16) 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 introduction 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 introduction 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 effecting the import or export, be obliged to inform the Ministry of the species and amount of genetically modified organisms that will be imported or exported, and of 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 be obliged to 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 preparations for the protection of plants also the State Phytosanitary Administration, and in the case of medicinal preparations also the State Institute for Drug Control, to allow 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 be obliged to submit to the customs authority the accompanying documents containing

a) specification of genetically modified organism or genetic product,

b) information on the transported amount,

c) the name or names, surname, business name, place of business and tax identification number (if assigned) of the importer or exporter, if he is a natural person authorised to operate a 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 or names, surname, business name, place of business and tax identification number (if assigned) of the forwarder as well as of the person responsible for the shipment, if he is a natural person authorised to operate a business, or the name or business name and tax identification number (if assigned) of the forwarder 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 introduction into the environment, the importer or exporter shall further be obliged to forward to the customs authority

a) the verified copy of the consent for contained use or of the consent for introduction into the environment, or, where applicable, the confirmation pursuant to § 16 par. 6,

b) the copy of the emergency response plan.

(9) The persons that import, export or transit genetically modified organisms or genetic products shall be obliged to declare to the customs authorities in submitting the customs declaration the substantially 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 is 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 undesirable leakage 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

**Administrative bodies in the area of the use of genetically modified organisms and genetic products**

The administrative bodies 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 State Phytosanitary Administration,

k) the Czech Agriculture and Food Inspection Authority,

l) the bodies of public health protection

§ 28

**The Ministry**

(1) The Ministry shall

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

b) carry out supreme state supervision in the area of 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.

(2) The Minister of the Environment shall designate and recall the chair and members of the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products, with their approval, after consulting with the Ministers of Health and Agriculture, from amongst professionals nominated by the administrative bodies referred to in § 27, by the Academy of Sciences of the Czech Republic, by Universities and special research institutes. 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, which shall be 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 from the use of genetically modified organisms and genetic products,

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

§ 30

**The Ministry of Agriculture**

The Ministry of Agriculture shall

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

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

§ 31

**The Inspection**

(1) The Inspection shall

a) individually or in cooperation with the administrative bodies referred to in § 27, control 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 (§ 34) and penalties for infringement of the obligations pursuant to this Act (§ 35).

(2) Inspectors of the Inspection shall be entitled, to the absolutely necessary extent, to enter the sites, premises and facilities intended for the use of genetically modified organisms or

genetic products, or the sites, premises and facilities in which such use proceeds or may proceed, as well as take samples, for control purposes pursuant to paragraph 1 letter a). In this, 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.

§ 32

**The customs authorities**

The customs authorities shall

a) control whether imported, exported or transited shipments that in release into the customs regime are declared as genetically modified organisms or genetic products, 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 preparations for the protection of plants 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 the case of preparations for the protection of plants also the State Phytosanitary Administration, and in the case of food stuffs 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 the case of preparations for the protection of plants also the employees of the State Phytosanitary Administration, and in the 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 professional 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) in case of discovery of any infringement of this Act, shall 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 sites, premises and facilities intended for the use of genetically modified organisms or genetic products, or the sites, premises and facilities in which such use may proceed, for control purposes pursuant to paragraph 1 letter a). When doing this 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 the protection of health of employees 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) The state administration over compliance with the ban of bacteriological and toxin weapons pursuant to the special legal regulation[16)] shall appertain to the State Office for Nuclear Safety.

## PART VII

## REMEDIAL MEASURES AND PENALTIES

### § 34

### Remedial measures

(1) If the Inspection discovers that the use of genetically modified organisms and genetic products occurred or occurs in contrary with this Act or in contrary with the decisions issued pursuant to this Act, it may, depending on the seriousness of the infringed obligation, suspend or even prohibit the further use thereof. Appeal against the decision pursuant to the first clause shall have no suspensory effect.

(2) If the person uses or used the genetically modified organisms or genetic products in contrary with this Act or in contrary with the decisions issued pursuant to this Act, the Inspection, as appropriate, may impose on such person the obligation to carry out the appropriate remedial measures within the set time-period and at its expense. If such person remains inactive, the Inspection shall carry out the remedial measures at such person’s expense.

(3) If the person pursuant to paragraph 2 is not known or cannot be found and there is a risk of hazard to human health or the environment, the Inspection shall carry out the remedial measures itself.

(4) The Inspection may decide to impose the obligation to carry out remedial measure also on other legal person or natural person that is authorised to operate a business and professionally and technically competent to carry out the remedial measure. In such case only this person shall be the participant in the administrative procedure. The person referred to in the first

clause shall be entitled to receive adequate financial compensation for carrying out the remedial measure.

(5) The Inspection, in connection with the measure pursuant to paragraph 2, may impose on the owner of the property the obligation to allow, to the necessary extent and for the necessary time-period, restriction of the usual use thereof. Compensation of eventual damage thereby arisen shall be paid to the property owner by the person, in consequence of whose illegal activity the measure for a remedy was imposed. If this person is not identified, compensation of damage shall be paid by the state. If the person is identified after the state has paid the compensation, the state may claim compensation from this person.

(6) The Inspection shall immediately inform the Ministry of the decision pursuant to paragraph 1, or, if applicable, of the measures imposed for a remedy.

(7) The Ministry, immediately after having learned of the use of genetically modified organisms or genetic products without authorisation, shall inform of this fact the Commission, the relevant bodies of Member States and further the public pursuant to § 10 letters b) and c).

§35

**Penalties**

(1) The inspection may impose a penalty of up to 50,000 CZK on a person that

a) does not keep risk assessment for a period of at least 10 years from its submission or that fails to provide it on request to legal authorities laid down in § 27 although the person is obliged to do so pursuant to § 7 par. 5.,

b) as a person pursuant to this Act authorised for contained use or introduction into the environment, fails to ensure that Code of Practice of the workplace, where genetically modified organisms are used, contains all the requirements laid down in Annex 4 to this Act [§ 19 lett. f)],

c) as a person pursuant to this Act authorised for contained use or introduction into environment, fails to provide for employee training prior to the commencement of use of genetically modified organisms or fails to provide for employee refresher training following every change of work process or at least once a year, or that fails to demonstrably acquaint employees with the Code of Practice of the workplace [§ 19 lett. g)],

(2) The inspection may impose a penalty of up to 500,000 CZK on a person that

a) when using a genetically modified organisms or a genetic product fails to comply with the conditions indicated on packaging or accompanying documents or that uses it for any other purpose than stated thereon (§ 3 par. 4),

b) fails to submit to the Ministry new risk assessment containing requirements pursuant to this Act at the latest within 5 years from submission of the last risk assessment, although the person is obliged to do so pursuant to § 7 par. 3 lett d).,

c) as a person pursuant to this Act authorised for contained use or introduction into the environment, fails to provide for execution of a professional review over use of genetically modified organisms by a professional consultant if the person does not meet by itself the conditions pursuant to § 14 [§ 19 lett. a)],

d) as a person pursuant to this Act authorised for contained use or introduction into the environment, presents untrue information in the documentation § 19 lett. b) or in the final report pursuant to § 19 lett. d),

e) as a person pursuant to this Act authorised for contained use or introduction into the environment, fails to submit to the Ministry the list of genetically modified organisms, information on amount and manner of use thereof for past calendar year,

f) as a person pursuant to this Act authorised for contained use or introduction into the environment, fails to send to the Ministry the final report on the course and consequences of these activities [§ 19 lett. d)],

g) fails to elaborate or submit to the Ministry the emergency response plan containing the requirements pursuant to this Act, although the person is obliged to do so pursuant to § 20 par. 2 lett. c),

h) grows genetically modified organisms registered in the List for placing on the market and fails to submit to the Ministry written information on place of cultivation thereof for the past calendar year [§ 23 par. 3].

(3) The inspection may impose a penalty of up to 1,000,000 CZK on a person that

a) fails to submit to the Ministry new risk assessment containing the requirements pursuant to this Act, although the person is obliged to do so pursuant to § 8 par. 2 or was charged to do so pursuant to § 8 par. 3,

b) as a person pursuant to this Act authorised for contained use, fails to control contained space and safety measures in compliance with the requirements of § 15 par. 3 or fails to keep records of carried out controls,

c) as a person pursuant to this Act authorised for introduction into the environment, fails to ensure that no material from a genetically modified organism that is introduced into the environment may be placed on market if it does not comply with provision § 23 [§ 17 par. 2],

d) as a person pursuant to this Act authorised for contained use or introduction into the environment, fails to keep records on use of genetically modified organisms pursuant to § 19 lett. b), or fails to keep the records thereof for at least 10 years from termination of use,

e) in the event of change of facts that may have significant impact on the measures laid down for a case of an accident, fails to perform or submit to the Ministry an emergency response plan containing the requirements pursuant to this Act, although the person is obliged to do so pursuant to § 20 par. 2 lett. d),

f) as a person registered in the List for placing on the market, fails to perform monitoring or to report its results in compliance with the requirements laid down in the registration into the List for placing on the market (§ 23 par. 4), or fails to comply with the conditions for placing on the market or with the conditions for providing test samples laid down in the registration into the List for placing into the market,

g) fails to provide for labelling of a genetically modified organism or a genetic product in compliance with the requirements of § 11 par. 1 and 2,although the person is obliged to do so pursuant to § 11 par. 1 and 2,

h) as a person pursuant to this Act authorised for contained use or introduction into the environment or as a person registered in the List for putting into the market, obtains new information regarding risks of genetically modified organisms or genetic products to health or the environment and does not provide them such information to the Ministry, or fails to take measures necessary for protection of health and the environment (§ 8 par. 1),

i) as a person pursuant to this Act authorised for contained use or introduction into the environment, fails to provide the administrative authorities with cooperation in control of estates, premises and equipment intended for use of genetically modified organisms, or of estates, premises and equipment where such use proceeds or may proceed [§ 19 lett. h],

j) as a person pursuant to this Act authorised for contained use, fails to comply with the conditions for use laid down in the consent for contained use,

k) as a person pursuant to this Act authorised for introduction into the environment, fails to provide for monitoring and reporting results thereof in compliance with the requirements laid down in the consent for introduction into the environment, or fails to comply with the conditions of use laid down in the consent for introduction into the environment,

l) as a person pursuant to this Act authorised for contained use or introduction into the environment, in case of an accident, immediately after being informed, fails to take the measures to eliminate or mitigate harmful consequences thereof (§ 21 par. 2),

m) as a person pursuant to this Act authorised for contained use or introduction into the environment, fails to immediately notify the Ministry of an accident that occurred (§ 21 par. 3).

(4) Inspection may impose a penalty of up to 1,500,000 CZK on a legal person or a natural person authorised for contained use pursuant to this Act, that performs the contained use in a space, which fails to comply with the requirements on containment and protective measures laid down for the pertinent risk category (§ 15 par. 2).

(5) Inspection may impose a penalty of up to 5,000,000 CZK on a person that uses genetically modified organisms or genetic products without appropriate authorisation, or that fails to terminate the use in compliance with conditions laid down in the decision pursuant to § 12 par. 3.

(6) In consideration of whether and to what extent to impose a penalty, the commission shall take into account mainly the seriousness of the infringement of obligations, the duration of

this illegal state and the detrimental consequences from this illegal behaviour that has occurred or threatened to occur.

(7) If repeated infringement of the same obligation, for which a penalty had been previously imposed, occurs within one year from the date of legal force of the decision on imposing of the penalty, or the remedy measures laid down by the Inspection has not been carried out within the set period of time, then the upper limit of the penalty pursuant to paragraphs 1 to 5 shall increase up to twice.

(8) Administrative procedure on imposing of a penalty may be initiated within 5 years from the data of infringement of obligations. A penalty may be imposed at the latest 6 years after the date of infringement of obligations.

(9) A penalty is due within 30 days from the date of legal force of the decision on imposing thereof.

(10) Penalties shall be collected and enforced by the Inspection; the Inspection proceeds pursuant to the special legal regulation.[17)] A penalty shall be an income of the State Environmental Fund of the Czech Republic.

(11) The Inspection shall keep records of persons on which a penalty has been imposed pursuant to paragraphs 1 to 5. The record shall be erased from the evidence one year after the date of legal force of the decision on imposing thereof, if the penalty has been paid.

(12) Records of persons under paragraph 11 may not be used for purposes other than evaluating of responsibility pursuant to paragraph 6 or enforcing of current penalties.

§ 36

**Relation to the Code of Administrative Procedure**

Decision-making pursuant to this Act shall be subject to the Code of Administrative Procedure unless stated otherwise in this Act.

## PART EIGHT

## TRANSITIONAL AND CONCLUDING PROVISIONS

§ 37

(1) Decisions on registration to the List of users, List for contained use, List for introduction into the environment and List for placing on the market issued pursuant to the Act No. 153/2003 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 conditioning resistance to antibiotics used in treatment of infections of humans or animals, provided that such genes have been inserted by genetic modification, may not be placed on market.

(3) After 31st December 2004, genetically modified organisms containing genes conditioning resistance to antibiotics used in treatment of infections of humans or animals, provided that such genes have been inserted by genetic modification, may not be introduced 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 in agreement with the Ministries concerned shall lay down by the implementing legal regulation

a) details of the application for granting permissions and details of the application for registration into the List for placing into the market (§ 5 par. 1),

b) details of summary of the contents of the applications (§ 5 par. 4),

c) details and procedures of risk assessment (§ 7 par. 7),

d) threshold level for presence of traces (§ 11 par. 3),

e) requirements on the contained space and on the safety measures in case of contained use (§ 15 par. 2),

f) details of the notification for contained use and the second category of risk (§ 16 par. 2 and 3),

g) the manner and scope of keeping records (§ 19 lett. b),

h) details of the emergency response plan (§ 20 par. 4),

i) details of the assessment report (§ 24 par. 17),

§ 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 par. 4 to 7, § 9 par. 3 lett. d) and e), § 18 par. 4 and 5, § 20 par. 6, § 21 par. 5 lett. c) and d), § 21 par. 7, § 23 par. 2 and 5, § 24 par. 4 to 10, § 24 par. 12, 15 and 17, § 25 par. 2 and § 34 par. 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 § 11 par. 3, § 23 par. 1 and § 25 par. 1 shall be repealed on the day of coming into force of the Treaty of Accession of the Czech Republic to the European Union.

**Zaorálek** by own hand

**Klaus** by own hand

**Špidla** by own hand

## Technical procedures, as a result of which a genetically modified organism may arise, and technical procedures, which do not lead to the arising of a genetically modified organism

1. genetically modified organisms may arise through the use of

a) recombinant nucleic acid technique forming a new combination of a heritable genetic material by insertion of a section of nucleic acid prepared by whatever means outside of an organism into any kind of virus, bacterial plasmid or other vector system and its subsequent incorporation into the organism of a recipient, in which it does not occur naturally but is in which it is capable of a continued reproduction.

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 a fusion of two or more cells results in formation of live cells with a new combination of heritable genetic material, by means or methods not occurring naturally.

2. The following technical procedures cannot lead to formation of genetically modified organisms without concurrent use of recombinant heritable genetic material as described in section 1 of this Annex or without the use of genetically modified organisms formed through as a result of 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 for genetically modified organisms

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

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

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

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

d) a 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.**

## Risk categories for contained use

The result of evaluation of the risks associated with contained use of particular genetically modified organism is splitting of this activity into the following risk categories:

1. The first category includes activities with 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 category by this Act is sufficient to protect health of human beings, animals, environment or biological diversity.

2. The second category includes activities with 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 category by this Act is sufficient to protect health of human beings, animals, environment or biological diversity.

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

4. The fourth category of risk 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 category by this Act is necessary to protect health of human beings, animals, environment or biological diversity.

**Annex 4 to Act No. 78/2004 Coll.**

## Requirements of the Code of Practice for a workplace where genetically modified organisms are used

Code of Practice of a workplace where genetically modified organisms are used must contain the following information:

a) name or names, surname, business name, place of business and tax identification number of the authorised person, if assigned, if he or she is a physical person authorised to operate a business,

b) name or business name, place of business and tax identification of the authorised person, if assigned, if he or she is a legal person, as well as name or names, surname and place of the statutory body of the authorised person,

c) name or names, surname and place of residence of the owner of the premises or property, in case the owner is the same as the authorised person and is a physical person, or his name or business name, place of business and tax identification number (if assigned), as well as name or names, surname and place of residence of the statutory body if the owner is a legal person,

d) name or names, surname, place of residence, telephone number, and ,where applicable, also fax number and e-mail address of the professional consultant,

e) the risk category for use of genetically modified organisms that may be carried out at the workplace in case of contained use,

f) name or names, surname, place of residence, telephone number, and ,where applicable, also fax numbed and e-mail address of the person responsible for operation of the workplace,

g) characterisation, purpose and description of the technical installations ensuring containment of the space in case of contained use,

h) list and description of the binding operating procedures used at the workplace,

i) list of personnel trained for work at the workplace,

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

k) organisational and technological provisions of the workplace,

l) measures for case of accident and fire, including the emergency response plan pursuant to § 20,

m) duties of personnel at work (adherence to standard operational principles, procedure of sanitation of space and equipment at the end of work, procedures for decontamination of instruments, personal protective aids and clothing),

n) system and frequency of reviewing the space, equipment and protective measures,

o) duties of personnel during maintenance of the equipment,

p) principles of hygiene and occupational safety in compliance with the provisions of the special legal regulations,

q) manner of handling of waste and contaminated material and equipment, particularly the procedures for disposal of a genetically modified organism and the means of testing of their effectiveness,

r) list of personal protective aids and of other means laid down by the employer in compliance with the special legal regulation,[19)] stating the activities for which these have to be used,

s) activities prohibited at the workplace,

t) principles of keeping records on the operation of the equipment, on sanitation carried out and on the reviews of protective installations,

u) measures to prevent access of unauthorised persons,

v) in case of introduction of genetically modified organisms into the environment further:

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

2. place and manner of storage of genetically modified organisms prior to introduction into the environment and after its completion, including the information on packaging and labelling,

w) information on eventual period of validity of the Code of Practice.

The Code of Practice must include certified information about number of pages; it is prohibited to remove or damage individual pages. The Code of Practice must be kept pursuant to § 19 lett. b).

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[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. Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms. Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

[2)] For example Act No. 79/1997 Coll. on medicinal substances and amending and supplementing some related acts, as last amended, Act No. 147/1996 Coll. on phytosanitary care and amending some related acts, as last amended.

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

[4)] Act No. 249/1992 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)] The Commercial Code

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

[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.

[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 Col., as last amended, Act No. 91/1996 Coll., as last amended, Act No. 147/1996, as last amended, Act No. 199/1999 Coll., as last amended, and Act No. 79/1997 Coll., as last amended.

[12] Act No. 13/1993 Coll. (The Customs Act), as last amended.

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

[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.

[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.

[17] Act No. 337/1992 Coll., on administration of taxes and fees, as amended

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

[19] Government Order No. 495/2001 Coll., laying down the extent and detailed conditions of the provision of personal protective means, washing and cleaning agents and disinfectants