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ACT

of 10 May 2000

on the use of genetically modified organisms and products and amendment of some related Acts

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

PART ONE
THE USE OF GENETICALLY MODIFIED ORGANISMS AND PRODUCTS

CHAPTER I
INTRODUCTORY PROVISIONS

1
The Subject and the Scope of the Act

(1) The Act lays down the obligations of persons and the competence of the administrative authorities in the use of genetically modified organisms and products.

(2) If a genetically modified organism is a medicinal substance pursuant to the special legal regulation[1)], then it shall not be subject to the provisions of # 9 of this Act.

2
Basic Definitions

For the purposes of this Act:

a) **organism** shall mean a biological entity, cellular or non-cellular, capable of replication or of transferring heritable genetic material, including viruses, viroids, animal and plant cells in a culture,

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 in a manner that cannot be achieved by natural recombination, that is the

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[1)] Act No. 79/1997 Coll., on medicinal substances and supplementing some related Acts, as amended by Act No. .../2000 Coll.

introduction of foreign heritable genetic material into the heritable genetic material of the organism or removal of part of the heritable genetic material of the organism,

d) **genetically modified organism** shall mean an organism, with the exception of human beings, whose heritable genetic material has been altered through genetic modification; technical procedures, that may result in the creation of a genetically modified organism and technical procedures that are not considered to result in creation of genetically modified organism, shall be laid down in a Decree,

e) **product** shall mean a preparation containing one or more genetically modified organisms, that was produced or obtained in any other way, regardless of the degree of processing thereof, and that is intended for placing on the market,

f) **use of genetically modified organisms and products** shall mean any activity involving genetically modified organisms or products from the formation thereof by genetic modification up to the instant when they lose the ability to replicate or transfer heritable genetic material,

g) **user** shall mean a legal person or natural person authorized to operate a business, who is authorised to use genetically modified organisms or products which have not been placed on the market pursuant to # 9, or who applies for this authorization,

h) **contained space** shall mean a space bounded by physical barriers, or by a combination of physical barriers with chemical or biological barriers, which limit the contact of genetically modified organisms and products with human beings, animals and the environment[2)],

i) **contained use of genetically modified organisms** shall mean the use of genetically modified organisms in a contained space, in particular the formation thereof by genetic modification, and the culture, storage and disposal thereof,

j) **introduction of genetically modified organisms into the environment** shall mean intentional release thereof into the environment outside the contained space, for any other purpose than placing on the market,

k) **placing of genetically modified organisms and products on the market** shall mean provision or offer of provision thereof in return for payment or free of charge to any other person for the purpose of distribution or use; this shall not apply to the procedure referred to in # 9 par. 2.,

l) **risk assessment of the use of genetically modified organisms and products** shall mean a written analysis defining the risk represented by the assessed use of the genetically modified organism or product for the health of human beings and animals, the environment and biological diversity[3], carried out on the basis of verified scientific knowledge, experience and the principle of risk precaution,

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[2)] Act No. 17/1992 Coll., on the environment, as amended by Act No. 123/1998 Coll.

[3)] Communication of the Ministry of Foreign Affairs No. 134/1999 Coll. on negotiation of the Convention on Biological Diversity

m) **risk category** shall mean classification of the use of the genetically modified organism or product based on the risk assessment result of the activity, listed in Annex 1 to this Act,

n) **accident** shall mean any event during the use of genetically modified organisms or products involving a significant unintentional release of the genetically modified organisms, that can cause immediate or delayed hazard to the health of human beings and animals, the environment and biological diversity.

CHAPTER II
GENERAL PROVISIONS
 # 3

(1) In the use of genetically modified organisms and products, every individual shall be obliged to protect the health of human beings and animals, the environment and biological diversity.

(2) Genetically modified organisms may be used in the following ways:

a) contained use of genetically modified organisms (hereinafter “contained use”),
b) introduction of genetically modified organisms into the environment (hereinafter “introduction into the environment”),
c) placing of genetically modified organisms and products on the market (hereinafter “placing on the market”.

(3) Authorization for the use of genetically modified organisms and products pursuant to this Act shall arise through a decision on registration in the pertinent list and terminate by a removal therefrom, except when this Act lays down otherwise (# 7 par. 4). These lists shall be:

a) The List of persons authorized for a certain manner of use of genetically modified organisms and products (hereinafter the "List of Users"),
b) The List of genetically modified organisms registered for contained use (hereinafter the “List for Contained Use”),
c) The List of genetically modified organisms registered for introduction into the environment (hereinafter the “List for Introduction into the Environment”),
d) The List of genetically modified organisms and products registered for the placing on the market in the Czech Republic (hereinafter the “List for the placing on the market”).

(4) An application for registration into the Lists set forth in par. 3 shall be submitted by the user to the Ministry of the Environment (hereinafter the "Ministry") in the Czech language in quadruplicate and simultaneously in electronic form.

(5) Immediately after receiving an application for the registration in the Lists set forth in paragraph 3, the Ministry shall forward one copy thereof each to the Ministry of Health, the Ministry of Agriculture and the Czech Commission for Use of Genetically Modified Organisms and Products (hereinafter the "Commission"). These Ministries and the Commission shall inform the Ministry in writing on their standpoints within 45 days of receiving the application. Having considered these standpoints, the Ministry shall issue a decision within 90 days of receiving the application. If the application is not complete, the

Ministry shall request a complement thereof and shall suspend the administrative procedure[4)]. If the administrative procedure is suspended, the period for the issue of the decision shall not proceed. The Ministry shall send the decision also to the Ministry of Health, to the Ministry of Agriculture and to the Commission. The Ministry may limit the period of validity of the consent and, in justified cases and on the basis of a request from the user, it may prolong the period of validity thereof.

(6) In the decision, the Ministry shall lay down conditions for the use which shall also follow from the standpoints of the Ministries and the Commission pursuant to paragraph 5.

(7) The user shall be obliged

a) to appoint a professionally qualified and blameless natural person to carry out expert control over the use of genetically modified organisms and products (hereinafter "professional consultant"); the requirements for the qualification shall be a completed university education in a relevant branch and at least 5 years experience in the branch, 2 years of which shall be in work with genetically modified organisms; details of the qualification requirements shall be laid down in a Decree,
b) to keep records of the use of genetically modified organisms and products for each workplace and to store these documents for a period of at least 10 years following the date of termination of the use of the genetically modified organism or product; the manner and scope of keeping records shall be laid down in a Decree,
c) to submit to the Ministry in written and electronic form, a list of the genetically modified organisms and products which he or she uses, and information on the amount and manner of use thereof for the past calendar year, by February 15 of each calendar year,
d) to send to the Ministry within 60 days from the termination of the use of the genetically modified organism or product, a report on the results of this activity, particularly in relation to any risk of hazard to the health of human beings and animals, the environment or biological diversity,
e) to provide for the carrying out of an assessment of the risks posed by the use of the genetically modified organisms and products (hereinafter a "risk assessment") pursuant to # 4 and to prepare an emergency response plan pursuant to # 5,
f) to provide for the code of practice of the workplace where the genetically modified organisms or products are used, to contain also the information listed in Annex 2 to this Act,
g) to provide for training of his or her employees prior to commencing the use of genetically modified organisms or products and for refresher courses following every change of work process or at least once a year, and to demonstrably acquaint the employees with the code of practice of the workplace,
h) to notify the Ministry, Ministry of Health and Ministry of Agriculture immediately, and at the latest within 24 hours after discovery, of every accident, by telephone, in written form or by electronic mail, stating the genetically modified organisms or products involved, the amount thereof, the site where the accident occurred, the possible consequences of the accident, in particular the potential risks for the health of human beings and animals, the environment and biological diversity, and the means of elimination thereof,
i) to provide the Administrative authorities pursuant to # 14, # 17 to 19 with cooperation in inspection of the premises and facilities intended for the use of genetically modified

[4] # 29 of Act No. 71/1967 Coll., on administrative procedure (the Code of Administrative Procedure)

organisms and products, to enable inspection of documents and, where applicable, to allow samples to be taken free-of-charge for test purposes,

j) to notify the Ministry of any change in information listed in the application pursuant to paragraph 4. The Ministry, following consultations with the Ministry of Health and Ministry of Agriculture and within 60 days after the notification, shall decide whether it is necessary to submit a new application for registration in the Lists set forth in paragraph 3. A new application must be submitted by the user within 30 days after this decision comes into force.

(8) Activities related to the use of live vertebrates, especially activities that intervene in their physiological functions or modify their metabolic products, shall be considered to constitute experiments on animals pursuant to the special regulations[5)].

(9) An application submitted pursuant to paragraph 4 must include the opinion of the professional consultant.

(10) If the genetically modified organism or product is registered according to # 7 to 9 in any of the lists mentioned in paragraph 3 let. b) to d), it shall not be necessary to submit a new application for registration therein.

4
Risk Assessment

(1) The user shall be obliged to submit a risk assessment to the Ministry

a) as a part of the application for registration in the Lists set forth in # 3 par. 3,
b) regularly following the expiry of 5 years from the date of the last completed risk assessment,
c) within 20 days in cases set forth in # 6 par. 8.

Details and processes of the risk assessment shall be laid down in a Decree.

(2) The risk assessment must contain an evaluation of potential direct and indirect detrimental effects on the health of human beings and animals, the environment and biological diversity, both immediate and delayed, in particular an evaluation of

a) the adverse impact on human beings,
b) the adverse impact on fauna and flora,
c) compromising of the ability to treat a disease or to provide for effective prophylaxis resulting from resistance to antibiotics,
d) colonization and spreading of genetically modified organism in the environment,
e) natural transfer of inserted genetic material to other organisms.

(3) The user shall be obliged to provide for utilization in the risk assessment of

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 genetic material, if the genetic modification includes the use of such material,

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

d) verified experience with the genetic modification involved,
e) verified experience with the genetically modified organism or product involved,
f) qualified estimates in cases where verified scientific information is lacking; in these cases it shall be necessary to use the precautionary principle,
g) the opinion of the professional consultant.

(4) The user shall be obliged to provide for carrying out of a risk assessment for each genetically modified organism separately.

5
The Emergency Response Plan

(1) The emergency response plan shall be a document describing activities and measures carried out in case of an accident, that lead to mitigation of the consequences thereof for the health of human beings and animals, for the environment and for biological diversity.

(2) The user shall be obliged to submit an emergency response plan to the Ministry
a) as a part of the application for registration in the Lists set forth in # 3 par. 3,
b) regularly following the expiry of 5 years from the date of the last submission of an emergency response plan,
c) within 30 days of a change in facts that could seriously affect measures laid down for the case of an accident.

(3) Prior to commencement of the use of genetically modified organisms and within 15 days of every subsequent submission pursuant to paragraph 2 letters b) and c), the user shall be obliged to provide the emergency response plan also to the Ministry of Health, to the Ministry of Agriculture, to the affected municipalities accordingly to the place of use and, where appropriate, to persons that could be affected by any accident.

(4) The emergency response plan must state all the information related to a potential hazard to the health of human beings and animals and damage to the environment and biological diversity as a consequence of an accident. The emergency response plan must contain in particular
a) the first name, surname, place of residence, telephone number and, where applicable also fax number and e-mail address of the professional consultant,
b) an exact description of the premises and facilities where the use of the genetically modified organisms and products takes place, where they are stored and where an accident could occur, stating the location of these premises,
c) methods and procedures that can be used for detection and inactivation of the genetically modified organisms and products concerned in accordance with special legal regulations[6)],
d) methods and procedures for protection of health of human beings and animals, the environment and biological diversity,

[6)] E.g. Act No. 246/1992 Coll., on protection of animals against cruelty, as amended, Act No. 166/1999 Coll., on veterinary care and amending related Acts (the Veterinary Act), Act No. 125/1997 Coll., on waste, as amended by Act No. 167/1998 Coll.

e) the relevant administrative authorities mentioned in # 13 according to their competence and the means of notifying them, and the manner of warning the inhabitants, where appropriate,
f) opinion of the professional consultant.

The details of the emergency response plan shall be laid down in a Decree.

6
Registration of the User

(1) An application for registration in the List of Users, submitted by a user to the Ministry prior to commencement of the use of a genetically modified organism or product, must contain:

a) the name, surname, state citizenship, place of residence, business address, identification and birth certificate numbers for a natural person authorized to operate a business,
b) the business name, legal form, business address and identification number of a legal person,
c) the name, surname, place of residence of the professional consultant, documents on his or her blamelessness, qualification and experience,
d) the officially verified copy of the business license in case of a natural person authorized to operate a business,
e) an excerpt from the Business Index, which shall not be more than 3 months old, or the officially verified copy of a charter, in case of a legal person,
f) the manner of use of the genetically modified organism or product,
g) the purpose and duration of the use of the genetically modified organism or product,
h) the address and description of the workplaces or properties at which the use will take place,
i) information on the organism that is genetically modified including the origin thereof,
j) information on the genetic modification, including information for identification of the altered heritable genetic material,
k) information on the genetically modified organism or product,
l) information on whether the given genetically modified organism has already been approved in any other country and for what purposes,
m) risk assessment pursuant to # 4, including a classification of the use of genetically modified organism or product in the risk category,
n) the emergency response plan pursuant to # 5,
o) a description of the use of the genetically modified organism or product in accordance with the risk assessment, including measures for protecting of the health of human beings and animals, the environment and biological diversity,
p) information on the system of carrying out tests and the means of inactivation of the genetically modified organisms in accordance with the special legal regulations[6)],
q) the treatment of waste, including hazardous waste, waste water and waste gaseous products in accordance with the special legal regulations[7)].

(2) Professional qualification shall be proven by a certificate of completed university education in a relevant branch and by a document certifying the required experience pursuant to # 3 par. 7 letter a); blamelessness shall be proven by an extract from the Criminal Register which shall not be more than 3 months old, certifying that the person has not been convicted

[7)] E.g. Act No. 125/1997 Coll., on waste, as amended

for premeditated criminal act. Further details of certain information contained in the application for each manner of use shall be laid down by a Decree.

(3) An applicant may submit a joint application for a particular manner of use in the same risk category with a combination of genetically modified organisms.

(4) The List of Users shall contain

a) identification information on the user mentioned in the application,
b) identification information on the professional consultant,
c) the address of the workplace where the use of the genetically modified organisms or product will take place,
d) specification of the genetically modified organism or product, or several organisms pursuant to paragraph 3,
e) the manner of use of the genetically modified organism or product,
f) the period of validity of the decision on registration, if stated.

(5) The user shall be removed from the List of Users on the basis of

a) expiry of the period of validity of the registration,
b) a decision of the Ministry on removal from the List of Users pursuant to paragraph 6 and 7,
c) the liquidation or extinguishment of a legal person or termination of the authorization to operate a business of a natural person,
d) the death of a natural person authorized to operate a business or the declaring dead thereof.

Removal from the List of Users shall not lead to termination of the obligations following from the decision on registration in the List of Users.

(6) If the user infringes against the provisions of this Act or fails to comply with the conditions laid down by the decision on registration in the List of Users, the Ministry shall make a decision on removal of such user from the List of Users. A new application for registration in the List of Users may be submitted at earliest five years from the date of a decision on removal from the List of Users.

(7) The Ministry may remove a user from the List of Users on the basis of a request thereby or if new facts occur that consequently change the conditions under which he/she was registered in the List of Users.

(8) If the Ministry obtains new information on possible hazards for the health of human beings and animals, the environment or biological diversity, resulting from the use of the genetically modified organism or product in question, either during the period of assessing of the application or after the user has been registered in the List of Users, it shall ask the user to, at the latest within 20 days of receiving the request,

a) carry out a new risk assessment pursuant to # 4,
b) review the measures set forth in the application pursuant to paragraph 1 letter o) and, if appropriate, change them so as to ensure protection of the health of human beings and animals, the environment and biological diversity.

(9) The obligation to apply for registration in the List of Users shall not apply to Administrative Authorities mentioned in # 13, if they use genetically modified organisms within the extent of their competence as set forth in # 14 to 19 and to a legal person with

whom the Ministry has concluded a contract on cooperation in execution of its competence pursuant to # 14.

7
Contained Use

(1) A user may use genetically modified organisms only in a contained space that complies with the requirements on containment and protective measures laid down for the pertinent or higher risk category. If the risk assessment carried out pursuant to # 4 has not resulted in the definite assignment of the use of the genetically modified organism to a certain risk category, it is necessary to assess the use in compliance with the requirements for the higher risk category. Requirements on contained space and protective measures for the individual risk categories shall be laid down in a Decree.

(2) An application for registration in the List of Users in the case of contained use must contain the information set forth in # 6 par. 1 and furthermore

a) a description of the location of the premises for contained use and technical description of its facilities,
b) an assessment of this premises and facilities and their location pursuant to the requirements on contained space and protective measures laid down for the individual risk categories,
c) the expected amount of genetically modified organisms that are to be used.

Further details of certain information contained in the application shall be laid down by a Decree.

(3) If contained use in the first risk category, exclusively for the purposes of teaching or scientific research and development, is involved, the user shall enter in the application for registration in the List of Users, the organism or a group of organisms and genetic modifications that are to be used.

(4) In case of contained use in the first and second risk categories, the user may commence activities 90 days after submitting the application if the Ministry does not decide otherwise by the end of this period of time. In case of contained use in the third and fourth risk categories, the user may commence activities only with the consent of the Ministry.

(5) In case of contained use in the first and second risk categories, the Ministry shall register the genetically modified organism mentioned in the application, or a group of organisms pursuant to paragraph 3, in the List for contained use, at the same time as it registers the user in the List of Users

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(6) In case of contained use in the third and fourth risk categories, the user shall be obliged, together with the application for registration in the List of Users, to submit an application for registration of the genetically modified organism in the List for contained use. The user may commence the contained use in the third and fourth risk categories only after the decision on registration of the genetically modified organism in the List for contained use has come into legal force.

(7) The application for registration of a genetically modified organism in the List for contained use must contain the information set forth in # 6 par. 1, paragraph 2 and also

a) information on the function of the genetic modification,
b) a description of the genetic modification and of the part of the altered deoxyribonucleic or ribonucleic acid permitting unambiguous identification of the genetically modified organism.

Further details of certain information contained in the application shall be laid down by a Decree.

(8) The List for contained use shall contain

a) specification of the genetically modified organism, or a group of organisms pursuant to paragraph 3,
b) specification of the genetic modification,
c) the risk category,
d) identification of the user who uses this genetically modified organism,
e) the purpose of such use,
f) the period of validity of the decision on registration, if laid down.

(9) If the Ministry obtains new information that could mean a risk caused by the contained use under the set conditions, it shall, within 60 days of the date of obtaining such information, lay down by a decision for the user, new conditions of the contained use or conditions for suspension or termination of the contained use, including inactivation of the genetically modified organisms. The Ministry, after consulting the Ministry of Health and the Ministry of Agriculture, may, on the basis of new information, make a decision on a change in the risk category for contained use of a genetically modified organism registered in the List for contained use. In such a case, the user shall be obliged, within the period of time laid down in the decision, to ensure the premises and facilities correspond to the changed risk category and carry out the appropriate measures. If the user fails to do so within the set time period he/she must not proceed with the contained use.

(10) The user shall be obliged during the contained use to review the contained space and the protective measures regularly according to the code of practice and shall do so immediately in the case mentioned in # 6 par. 8 or when the Ministry has made a decision on a change of assignment to a risk category pursuant to paragraph 9.

8
Introduction into the Environment

(1) Only a user registered in the List of Users may introduce genetically modified organisms into the environment, within the scope of his/her registration therein.

(2) Only genetically modified organisms that are registered in the List for introduction into the environment may be introduced into the environment, while maintaining all the conditions set forth in the decision on registration in this List.

(3) An application for registration of a genetically modified organism in the List for introduction into the environment must contain the information set forth in # 6 par. 1 and also

a) information on the function of the genetic modification,
b) description of the genetic modification and of the part of the altered deoxyribonucleic or ribonucleic acid, permitting unambiguous identification of the genetically modified organism,
c) identification of the user or users who will carry out the introduction into the environment or participate therein, including documents or officially verified copies of the application for registration of such persons in the List of Users,
d) information on the sites at which the genetically modified organism will be introduced into the environment and the location thereof,
e) the amounts of genetically modified organisms that are to be used and the area over which the genetically modified organisms will be introduced into the environment,
f) measures that are intended to prevent the spreading of the genetically modified organisms during the introduction into the environment and the occurrence and spreading thereof at the given site after termination of the introduction into the environment,
g) information on possible interactions between the genetically modified organism and the environment.

Further details of certain information contained in the application shall be laid down by a Decree.

(4) If the introduction into the environment of several genetically modified organisms assigned to the first risk category is involved, that is carried out at the same time and for the same purpose, exclusively for the purposes of teaching or scientific research and development, the user may submit a single joint application.

(5) The List for introduction into the environment shall contain
a) specification of the genetically modified organism,
b) specification and the function of the genetic modification,
c) the result of the risk assessment,
d) identification of the user who shall use this genetically modified organism,
e) the purpose and site of introduction into the environment,
f) the period of validity of the decision on registration if laid down.

(6) If the Ministry obtains new information that could indicate a risk caused by introduction of the genetically modified organism into the environment under the set conditions, it shall, within 60 days of the date of obtaining such information, lay down by a decision for the user, new conditions for the introduction into the environment or the conditions for suspension or termination of the use.

(7) The Ministry after consulting the Ministry of Health and the Ministry of Agriculture may, on the basis of new information, decide to remove a genetically modified organism from the List for introduction into the environment. In the decision the Ministry shall lay down the conditions for the termination of the introduction of the genetically modified organism into the environment and the means of inactivation of the genetically modified organisms used. The Ministry shall publish the decision in the Bulletin of the Ministry and shall also send the decision to the Ministry of Health and Ministry of Agriculture.

 # 9

Placing on the Market

(1) Only genetically modified organisms and products registered in the List for placing on the market may be placed on the market, while maintaining all the conditions set forth in the decision on registration in this List. Decision-making on placing on the market thereof pursuant to the special legal regulations[8)] shall be in no way prejudiced by this provision.

(2) The provision of genetically modified organisms for scientific and testing purposes, for teaching and for collections shall not be considered to constitute placing on the market. Genetically modified organisms that are so provided must be clearly labelled "genetically modified organism" on the container.

(3) An application for registration of a genetically modified organism or product in the List for placing on the market must contain the information set forth in # 6 par. 1 and also

a) a document on registration of the user in the List of Users or an officially verified copy of an application for registration in this List,
b) information on the function of the genetic modification,
c) description of the genetic modification and of the part of the altered deoxyribonucleic or ribonucleic acid, permitting unambiguous identification of the genetically modified organism,
d) the means of laboratory testing for the presence of the genetic modification,
e) information on whether the particular genetically modified organism is registered in the List for introduction into the environment,
f) information on whether the particular genetically modified organism or product has been approved for placing on the market in other countries and under what conditions,
g) specification of the product and the usage thereof,
h) the means of packaging and labelling in compliance with the special legal regulations[8)], including the proposed instructions for consumers,
i) information on possible interactions between the genetically modified organism or product and the environment,
j) provision, manner and scope of keeping records on the use of the genetically modified organism or product after it has been placed on the market, or the monitoring of the effects of the genetically modified organism or product on the health of human beings and animals, the environment and biological diversity, when appropriate; the provision for, manner and frequency of informing the Ministry.

Further details of certain information contained in the application shall be laid down by a Decree.

(4) The List for placing on the market shall contain

a) specification and the usage of the genetically modified organism or product,
b) specification and function of the genetic modification,
c) the conclusions of the risk assessment,
d) the means of laboratory testing for the presence of the genetic modification,

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[8)] E.g. Act No. 110/1997 Coll., on foodstuffs and tobacco products and amending and supplementing some related Acts, Act No. 91/1996 Coll., on feedingstuffs, Act No. 92/1996 Coll., on varieties, seeds and seedlings of cultivated plants, as amended by Act No. 357/1999 Coll., Act No. 147/1996, on plant medicinal care and amending some related Acts, Act No. 166/1999 Coll., on veterinary care and amending some related Acts (the Veterinary Act), Act No. 79/1997 Coll., on medicinal substances and supplementing some related Acts, as amended by Act No. ..../2000 Coll.

e) identification of the user who applied for registration of the genetically modified organism or product in this List,
f) the conditions laid down in the decision on registration of the genetically modified organism or product in the List for placing on the market,
g) the period of validity of the decision on registration if laid down.

(5) Every person who places a genetically modified organism or product on the market shall be obliged to
a) comply with all the conditions laid down in the decision on registration of the genetically modified organism or product in the List for placing on the market,
b) ensure that the labelling on the packing of the genetically modified organism or product clearly states in a visible place: "genetically modified organism", or "this product contains a genetically modified organism"; such labelling must also appear in the accompanying documents.

The special legal regulations laying down requirements concerning packaging and labelling of products[8)] shall be in no way prejudiced by this provision.

(6) If the Ministry obtains new information that could mean a risk caused by placing of the genetically modified organism or product on the market under the set conditions, it shall, within 60 days of the date of obtaining such information, lay down by a decision new conditions for placing on the market. The Ministry shall publish the decision in the Bulletin of the Ministry and shall also send the decision to the Ministry of Health and Ministry of Agriculture.

(7) The Ministry after consulting the Ministry of Health and the Ministry of Agriculture may, on the basis of new information, decide to remove the genetically modified organism or product from the List for placing on the market. The Ministry shall publish the decision in the Bulletin of the Ministry and shall also send the decision to the Ministry of Health and Ministry of Agriculture.

(8) A legal or physical person who uses the genetically modified organism or product registered in the List for placing on the market shall not be considered to be a user.

10
Import, Export and Transit of Genetically Modified Organisms and Products

(1) Genetically modified organisms and products that have not been placed on the market in the Czech Republic may be imported, exported or placed in transit only by a user registered in the List of Users, in the manner and within the scope of use of genetically modified organisms and products as set forth in the registration in the List of Users.

(2) Every person that imports, exports or places in transit a genetically modified organism or product, registered in the List for placing on the market pursuant to # 9, shall be obliged to provide for compliance with all the conditions laid down in the decision on the registration of the genetically modified organism or product in the List for placing on the market, and in particular its packaging and labelling.

(3) Imported and exported genetically modified organisms and products and genetically modified organisms and products in transit must have on the packing a visible label clearly stating "genetically modified organism" or "this product contains a genetically modified organism"; this text in the Czech language and in the language of the country of destination must also appear in the accompanying documents.

(4) The accompanying documents of imported or exported genetically modified organisms and products or genetically modified organisms and products in transit must, in case of a genetically modified organism or product that has not yet been registered for placing on the market in the Czech Republic, contain a copy of the decision on registration of the user in the List of Users and a copy of the decision on registration of the genetically modified organism in the List mentioned in # 3 paragraph 3 let. b) or c), an emergency response plan pursuant to # 5 and the result of risk assessment pursuant to # 4. If a genetically modified organism or product registered for placing on the market in the Czech Republic is involved, the accompanying documents must contain all the information mentioned in the registration in the List for placing on the market pursuant to # 9 par. 4.

(5) The special legal regulations laying down the conditions for import, export and transit[9)] shall be in no way prejudiced by the provisions of paragraphs 1 to 4.

11
Business Secrecy *(Confidentiality)*

(1) In his/her applications, a user may indicate information, the disclosure of which could damage his/her competitive position, as being the subject of business secrecy pursuant to the special legal regulations[10)]. Justification of this request must be verifiably demonstrated.

(2) The following must not be indicated as being the subject of business secrecy

a) specification of the genetically modified organism or product and the function of the genetic modification,
b) description of the genetic modification and of the part of the altered deoxyribonucleic or ribonucleic acid, permitting unambiguous identification of the genetically modified organism,
c) the business name and business address or name and place of residence of the user,
d) the site and reason for introduction into the environment or the purpose of placing on the market,
e) the risk assessment and measures to protect the health of human beings and animals, the environment and biological diversity,
f) methods and programs for monitoring the genetically modified organism or product following its introduction into the environment or placing on the market,
g) the emergency response plan,

[9)] E.g. Act No. 21/1997 Coll., on control of the export and import of goods and technology subject to international control regimes, Act No. 42/1980 Coll., on economic contacts with foreign countries, as amended, Act No. 13/1993 Coll., the Customs Act, as amended, Act No. 166/1999 Coll., on veterinary care and amending some related Acts (the Veterinary Act) and Act No. 147/1996 Coll., on plant medicinal care and amending some related Acts.

[10)] E.g., Act No. 513/1991 Coll., the Commercial Code, as amended.

h) evaluation of predictable undesirable effects and the means of protection against such effects.

(3) The obligation to maintain secrecy about facts indicated by the user as being the subject of business secrecy shall apply to all persons who assess the applications or carry out tests of the genetically modified organisms in accordance with # 6 par. 9. The obligation to maintain secrecy shall continue even if the application is rejected or withdrawn, for a period of 5 years from submission of the application.

12
Informing the Public

(1) The Ministry shall enable every person to peruse the Lists mentioned in # 3 par. 3, to make excerpts, written extracts or copies thereof.

(2) Once a year the Ministry shall publish the up-dated Lists mentioned in # 3 par. 3 in the Bulletin of the Ministry as of December 31 of the previous calendar year.

(3) The right to information pursuant to the special legal regulations[11)] shall be in no way prejudiced by this Act.

(4) A civic association, whose purpose according to the Articles is protection of the environment or protection of the rights or interests of consumers, shall have the right to participate in an administrative procedure[12)] conducted pursuant to # 6 to 9 of this Act, provided it has requested the Ministry for participation therein.

(5) A request pursuant to paragraph 4 shall be valid for a period of one year from the date of submission thereof to the Ministry.

(6) The Ministry shall notify the civic association pursuant to paragraphs 4 and 5 of the commencing of a procedure at the same time as it notifies the participants in the procedure.

CHAPTER III
STATE ADMINISTRATION

13
Administrative Authorities in the Sector of the Use of Genetically Modified Organisms and Products

The competent administrative authorities for the sector of the use of genetically modified organisms and products shall be:
a) the Ministry of the Environment,
b) the Ministry of Health,

[11)] Act No. 123/1998 Coll., on the right to information on the environment.
Act No. 106/1999 Coll., on the free access to information.
[12)] Act No. 71/1967 Coll., on administrative procedure (the Code of Administrative Procedure), as amended by Act No. 29/2000 Coll.

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 Agricultural Control and Testing Institute,
h) the State Institute for Control of Pharmaceuticals,
i) the Institute for State Control of Veterinary Biopreparations and Pharmaceuticals,
j) the State Phytosanitary Administration,
k) the Czech Agricultural and Foodstuff Inspection.

 # 14
The Ministry

(1) The Ministry shall

a) be the central administrative authority in the area of assessing the impact of genetically modified organisms and products on the environment and biological diversity,
b) execute supreme state supervision in the area of the use of genetically modified organisms and products from the standpoint of protection of the environment and biological diversity,
c) lay down procedures for risk assessment in the use of genetically modified organisms and products pursuant to # 4 from the standpoint of protection of the environment,
d) establish the Commission as its administrative part,
e) make decisions pursuant to # 3 par. 5 on registration in the Lists mentioned in # 3 par. 3 and on removal from the Lists pursuant to # 6 par. 5 to 7, # 8 par. 7 and # 9 par. 7,
f) keep the Lists mentioned in # 3 par. 3,
g) make information available to the public pursuant to # 12,
h) execute the function of the competent administrative authority for international exchange of information in the area of genetically modified organisms,
i) be the appeal body against decisions of the Inspection.

(2) The Ministry shall authorize the Commission to

a) follow scientific and technical developments in the area of the use of genetically modified organisms and products and, when necessary, inform the Ministry and recommend appropriate measures,
b) control the information set forth in applications pursuant to # 3, # 6 to 9 and issue standpoints on these applications pursuant to # 3 par. 5,
c) carry out professional inspections of the workplaces of users and sites of introduction into the environment in cooperation with administrative authorities mentioned in # 17 and 19,
d) carry out professional inspections of documents kept by the users pursuant to # 3 par. 7 let. b) in cooperation with administrative authorities mentioned in # 17 and 19,
e) discuss the reports prepared by users pursuant to # 3 par. 7 let. d),
f) propose methods for testing of genetically modified organisms and propose equipment of workplaces for carrying out such tests.

(3) The Minister of Environment shall name and recall the chair and members of the Commission, after consulting the Ministers of Health and Agriculture, from amongst professionals nominated by the administrative authorities mentioned in # 13, by the Academy of Sciences of the Czech Republic and by civic associations. In carrying out of the activities

mentioned in paragraph 2, the Commission shall be subject to the statute and the rules of procedure, which shall be issued by the Ministry.

15
The Ministry of Health

The Ministry of Health shall

a) propose to the Ministry procedures for assessment of health risks connected with the use of genetically modified organisms and products,
b) issue standpoints from the aspect of protection of human health to the applications pursuant to # 3 par. 5.

16
The Ministry of Agriculture

The Ministry of Agriculture shall

a) propose to the Ministry procedures for assessment of risks connected with the use of genetically modified organisms and products from the standpoint of agriculture,
b) issue standpoints to the applications pursuant to # 3 par. 5.

17
The Inspection

(1) The Inspection shall

a) control how legal persons and natural persons comply with the provisions of the legal regulations and with the conditions laid down by the decisions of the Ministry related to the use of genetically modified organisms and products, from the standpoint of the environment, and cooperate with the customs authorities;
b) impose on legal persons and natural persons remedial measures and penalties for infringement against obligations pursuant to this Act,
c) carry out inspections on its own or in cooperation with the administrative authorities mentioned in # 14, # 18 and 19.

(2) Inspectors of the inspection shall be entitled to enter the properties and premises to the absolutely necessary extent, to carry out inspection pursuant to paragraph 1. In this, they must provide authorization to carry out the inspection. The state shall be liable for any damage caused by the inspection; it may not relieve itself of this liability.

18
The Customs Authorities

The customs authorities shall

a) control consignments that are declared as genetically modified organisms or products at border crossing points, to ensure that they are accompanied by the appropriate documents pursuant to # 10 of this Act and the special legal regulations for transit[13)], export and import[9)],
b) impound the goods, in case of discovery of any infringement against this Act or in case of suspicion thereof, inform the Inspection and the Ministry thereof and, in case of doubt, ask the Inspection for professional assistance,
c) keep records of all consignments of genetically modified organisms and products allowed to cross the border and enable the employees of the Ministry and Inspection to peruse such records, make excerpts therefrom, copy information or make copies thereof, including providing this evidence in electronic form or by e-mail.

19
Other Administrative Bodies

(1) The bodies of the veterinary administration, the State Phytosanitary Administration, the Czech Agricultural and Foodstuff Inspection, the Central Agricultural Control and Testing Institute, the State Institute for Control of Pharmaceuticals and the Institute for State Control of Veterinary Biopreparations and Pharmaceuticals
a) shall carry out state professional control of the use of genetically modified organisms and products, and control and tests of genetically modified organisms and products within the framework of their jurisdictions and pursuant to special legal regulations[14)],
b) in cases of discovery of infringement against this Act, shall submit to the Inspection a proposal for commencement of an administrative procedure and shall immediately inform the Ministry thereof.

(2) The special legal regulations[14)] shall be in no way prejudiced by the provisions of paragraph 1.

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

20
Remedial Measures

(1) The Inspection may require that persons, who use genetically modified organisms or products without authorization or contrary to this Act, carry out, at their own cost, remedial measures consisting, for example, in preventing the release of the genetically modified

[13)] Decree of the Ministry of Foreign Affairs No. 64/1987 Coll., on the European Agreement on international highway transport of dangerous goods (ADR) as amended by Communication of the Ministry of Foreign Affairs No. 159/1997 Coll. and Communication of the Ministry of Foreign Affairs No. 54/1999 Coll., Act No. 111/1994 Coll., on highway transport, as amended by Act No. 38/1995 Coll. and Act No. 304/1997 Coll.
[14)] E.g. Act No. 166/1999 Coll., on veterinary care and amending some related Acts (the Veterinary Act), Act No. 147/1996 Coll., on plant medicinal care and amending some related Acts, Act No. 92/1996 Coll., on varieties, seeds and seedlings of cultivated plants.
[15)] Act No. 20/1966 Coll., on the health of the population, as amended.

organism from the contained space, in preventing the occurrence or spread of the genetically modified organism or product in the environment or in the immediate inactivation of the genetically modified organism or product.

(2) If the person causing the impediments pursuant to paragraph 1 is not found or there could be a hazard following from delay, the above measures may also be imposed by the Inspection on the owner of the property on which or in which the use of the genetically modified organisms or products occurs or, as appropriate, the Inspection may carry out these measures itself. If the Inspection carried out the remedial measure itself for reasons of hazards associated with delay, the costs connected with the remedial measure shall be paid by the person causing the impediment or by the owner of the property.

21
Penalties

(1) The Inspection shall impose a penalty of 100 000 to 1 000 000 CZK on a person who

a) fails to comply with the general conditions for the use of genetically modified organisms and products pursuant to # 3,
b) fails to comply with obligations related to risk assessment pursuant to # 4,
c) does not have or does not comply with the emergency response plan pursuant to # 5,
d) states untrue information when keeping records pursuant to # 3 par. 7 let. b),
e) fails to comply with the requirements for placing genetically modified organisms or products on the market pursuant to # 9,
f) fails to comply with the conditions related to import, export and transit pursuant to # 10.
g) fails to comply with remedial measures pursuant to # 20,
h) fails to comply with obligations laid down in # 11.

(2) The Inspection shall impose a penalty of 700 000 to 1 500 000 CZK on a user who

a) fails to comply with the conditions in the decision on the use of genetically modified organisms or products, laid down pursuant to # 3,
b) uses genetically modified organisms or products contrary to the information set forth in the List of Users pursuant to # 6,
c) fails to comply with the conditions for contained use pursuant to # 7,
d) fails to comply with the conditions for introduction into the environment pursuant to # 8.

(3) In making a decision on the amount of a penalty, the Inspection shall take into consideration particularly the seriousness of the infringement against obligations, the duration of the illegal state and the detrimental consequences of the illegal acts that have occurred or of which there is a hazard.

(4) If repeated infringement against the obligations, for which a fine was imposed pursuant to paragraphs 1 and 2, occurs within a period of 1 year of the date of legal force of the decision on imposing of the fine, and the user has not complied with the measures for a remedy laid down by the Inspection within the set period of time, the Inspection shall impose a fine on such person up to an amount of twice the sum laid down in paragraphs 1 and 2.

(5) An administrative procedure on imposing a penalty may be commenced within 2 years of the date when the Inspection discovered the infringement against obligations and at the latest 5 years from the date when the infringement against obligations occurred.

(6) The imposing of a penalty pursuant to paragraphs 1 and 2 shall in no way prejudice liability pursuant to the special legal regulations[16)].

(7) Penalties shall be collected and levied by the Inspection, which shall proceed pursuant to the special legal regulation[17)].

(8) A penalty shall be due within 30 days of the date of legal force of the decision by which the penalty was imposed and shall be an income for the State Environmental Fund.

 # 22
Relation to the Code of Administrative Procedure

(1) Decision-making pursuant to this Act shall be subject to the Code of Administrative Procedure[12)] unless stated otherwise in this Act.

(2) Appeals against a decision on imposing remedial measures pursuant to # 20 shall not have dilatory effect.

CHAPTER IV
TEMPORARY AND CONCLUDING PROVISIONS

 # 23

(1) Persons using genetically modified organisms prior to the date when this Act comes into effect shall be obliged to submit an application for registration in the List of Users pursuant to # 6 at the latest within 120 days of the date when this Act comes into effect.

(2) Persons carrying out contained use of genetically modified organisms in the third and fourth risk categories, according to the conclusion of the risk assessment submitted with the application pursuant to paragraph 1, shall be obliged to submit an application for registration of the genetically modified organisms that they use in the List for contained use pursuant to # 7 par. 5, at the latest 120 days from the date when this Act comes into effect.

(3) Persons who introduce genetically modified organisms into the environment on the basis of a consent issued by the Ministry prior to the date when this Act comes into effect, shall be obliged to submit an application for registration of these genetically modified organisms in the List of genetically modified organisms approved for introduction into the environment pursuant to # 8 at the latest six months from the date when this Act comes into effect.

[16)] Act No. 40/1964 Coll., the Civil Code, as amended.
[17)] Act No. 337/1992 Coll., on administration of taxes and fees, as amended.

 # 24

The Ministry, in agreement with the Ministry of Health and the Ministry of Agriculture, shall lay down by a Decree

a) technical procedures, that may result in the creation of a genetically modified organism and technical procedures that are not considered to result in creation of genetically modified organism (# 2 let. d)),
b) details of the qualification requirements for the professional consultant (# 3 par. 7 let. a)),
c) manner and scope of keeping records (# 3 par. 7 let. b)),
d) details and procedures for the risk assessment (# 4),
e) details of the emergency response plan (# 5),
f) further details of certain information contained in the application for registration into the List of Users for each manner of use (# 6 par. 1, # 7 par. 2),
g) requirements on contained space and protective measures for the individual risk categories in contained use (# 7 par. 1),
h) further details of certain information contained in the application for registration into the List for contained use (# 7 par. 5),
i) further details of certain information contained in the application for registration into the List for introduction in the environment (# 8 par. 3),
j) further details of certain information contained in the application for registration into the List for placing on the market (# 9 par. 3).

PART TWO
AMENDMENT OF THE ACT ON ADMINISTRATIVE CHARGES

 # 25

In Act No. 368/1992 Coll., on administrative charges, in the wording of Act No. 10/1993 Coll., Act No. 72/1994 Coll., Act No. 85/1994 Coll., Act No. 273/1994 Coll., Act No. 36/1995 Coll., Act No. 118/1995 Coll., Act No. 160/1995 Coll., Act No. 301/1995 Coll., Act No. 151/1997 Coll. and Act No. 305/1997 Coll., Act No. 149/1998 Coll., Act No. 157/1998 Coll., Act No. 167/1998 Coll., Act No. 63/1999 Coll., Act No. 166/1999 Coll., Act No. 223/1999 Coll., shall be amended as follows:

In the rate lists of administrative charges, following item 131b, a new item 131c shall be inserted, that shall read:

"**Item 131c**

a) for issuing of a decision on registration in the List of persons authorized for a certain manner of use of genetically modified organisms and products 10 000 CZK
b) for issuing of a decision on registration in the List of genetically modified organisms approved for contained use 2 000 CZK
c) for issuing of a decision on registration in the List of genetically modified organisms approved for introduction into the environment 20 000 CZK
d) for issuing of a decision on registration in the List of genetically modified organisms and products approved for placing on the market in the Czech Republic 30 000 CZK

PART THREE
AMENDMENT OF THE ACT ON VARIETIES, SEEDS AND SEEDLINGS OF CULTIVATED PLANTS

26

Act No. 92/1996 Coll., on varieties, seeds and seedlings of cultivated plants, shall be amended as follows:

1. In # 2, letter c) shall read:

"c) a genetically modified plant shall mean a plant that is a genetically modified organism[1a)],".

Footnote No. 1a shall read:

"[1a)] # 2 of Act No. ...../2000 Coll., on the use of genetically modified organisms and products and amending some related Acts.".

2. In # 2 a new letter d) shall be inserted after letter c) that shall read

"d) genetically modified variety shall mean a variety that includes genetically modified plants,"

The existing letters d) to m) shall be designated as letters e) to m).

3. In # 6 par 3, letter b) shall read:

"b) if a genetically modified variety is involved, prove that the genetically modified plants are registered in the List of genetically modified organisms and products approved for placing on the market in the Czech Republic pursuant to the special legal regulation[4a)],".

Footnote No. 4a) shall read:

"[4a)] # 3 par. 3 letter d) of Act No. ...../2000 Coll., on the use of genetically modified organisms and products and amending some related Acts.".

4. In # 7 at the end of let. f) the period shall be replaced by a comma and new letter g) shall be added, that shall read:

"g) if it includes genetically modified plants, these shall be registered in the List of genetically modified organisms and products approved for placing on the market in the Czech Republic pursuant to the special legal regulation[4a)].".

5. In # 12 at the end of par. 1, the period shall be replaced by a comma and new letter i) shall be added, that shall read:

"i) information on the function of the genetic modification[4b)].".

Footnote No. 4b shall read:

"[4b)] # 2 letter c) of Act No. ...../2000 Coll., on the use of genetically modified organisms and products and amending some related Acts.".

6. In # 16 at the end of par. 1, the period shall be replaced by a comma and new letter i) shall be added, that shall read:

"h) if a variety includes genetically modified plants that were removed from the List of genetically modified organisms and products approved for placing on the market in the Czech Republic pursuant to the special legal regulation[4c)].".

Footnote No. 4c) shall read:

"[4c)] # 9 par 9 of Act No. ...../2000 Coll., on the use of genetically modified organisms and products and amending some related Acts.".

7. In # 16 par. 2 the words "letter e)" shall be replaced by the words "let. e) and h)".

8. In # 28, par. 2 shall read:

"(2) Information on the packaging of propagation material placed on the market and required by this Act must be

a) readily legible and indelible,
b) if propagation material of a genetically modified variety is involved, it must contain labelling pursuant to the special legal regulation[7a)].".

Footnote No. 7a shall read:

"[7a)] # 9 par. 5 of Act No. ...../2000 Coll., on the use of genetically modified organisms and products and amending some related Acts.".

9. In # 26 new paragraphs 3 and 4 shall be added that, including footnotes No. 11) and 12), shall read:

"(3) The administrative procedure on registration of a variety pursuant to # 5 ff., commenced before the legal force of the special regulation[11)], concerning the registration of a variety including genetically modified plants, shall be suspended until it is proven that these genetically modified plants have been registered in the List of genetically modified organisms and products registered for placing on the market in the Czech Republic pursuant to the special regulation[12)].

(4) An applicant who, prior to the legal force of the special regulation[11)], has proven in an administrative procedure on the registration of a variety, that the Ministry of the Environment consents pursuant to # 6 par. 3 let. b) to the field growing of a variety that includes genetically modified plants, shall be obliged, within 30 days of the legal force of the special regulation[11)], to apply for the registration of these plants in the List of genetically modified organisms and products registered for placing on the market in the Czech Republic pursuant to the special regulation[12)]. If the Ministry of Environment decides that it will not register such a plant in the List of genetically modified organisms and products registered for placing on the market in the Czech Republic pursuant to the special regulation[12)], the administrative procedure shall be terminated.

[11)] Act No. ...../2000 Coll., on the use of genetically modified organisms and products and amending some related Acts.

[12)] # 9 par. 5 of Act No. ...../2000 Coll., on the use of genetically modified organisms and products and amending some related Acts.".

PART FOUR
AMENDMENT OF THE ACT ON MEDICINAL SUBSTANCES

27

Act No. 79/1997 Coll., on medicinal substances and amending and supplementing some related Acts shall be amended as follows:

1. In # 25 new paragraph 9 shall be added that shall read:

"(9) If a medicinal preparation containing a genetically modified organism is involved, the State Institute for Control of Pharmaceuticals for a human medicinal substance or the Institute for State Control of Veterinary Biopreparations and Pharmaceuticals for a veterinary medicinal substance shall request the standpoint of the Ministry of the Environment on assessment of the risk for the environment pursuant to the special legal regulation*). The Ministry of the Environment shall issue this standpoint within a period of 90 days. It may decide not to issue this standpoint in cases where this standpoint was submitted together with the application or the application was submitted together with a report on environmental impact assessment carried out by a competent authority in the European Union.".

Footnote No. 17a shall read:
"[17a)] Act No. ...../2000 Coll., on use of genetically modified organisms and products and amending some related Acts.".

2. In # 35 par. 1 letter a) at the end of the text, the following words shall be added:
"and if a human medicinal substance is involved, that contains genetically modified organisms that have not been contained yet in any human medicinal preparation that is already registered, such a permit may be issued only if the genetically modified organism is registered in the List of genetically modified organisms and products registered for placing on the market in the Czech Republic pursuant to the special legal regulation [19a)].".

Footnote No. 19a shall read
"[19a)] # 9 of Act No. ...../2000 Coll., on use of genetically modified organisms and products and amending some related Acts.".

3. In # 39 paragraph 1 at the end of letter a), the following words shall be added:
" if a veterinary medicinal substance is involved, that contains genetically modified organisms that have not been yet contained in any veterinary medicinal preparation that is already registered, such a permit may be issued only if the genetically modified organism is registered in the List of genetically modified organisms and products approved for placing on the market in the Czech Republic pursuant to the special legal regulation [19a)].".

PART FIVE
EFFECT

 # 28

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

Annex No. 1 to Act No. 153/2000 Coll.

Risk Categories

The result of assessment of the risk resulting from the use of a certain genetically modified organism or product shall be an assignment of this activity to one of the following risk categories:

A) The first category shall include activities with no or minimal risk of detrimental impact on the health of human beings and animals, the environment or biological diversity.

B) The second category shall include activities with a risk of such detrimental impact on the health of human beings and animals, the environment or biological diversity that can be easily eliminated by generally known measures.

C) The third category shall include activities with a risk of such detrimental impact on the health of human beings and animals, the environment or biological diversity that can be eliminated only by especially demanding interventions.

D) The fourth category shall include activities with a risk of such detrimental impact on the health of human beings and animals, the environment or biological diversity that has a permanent impact and cannot be completely eliminated even by especially demanding interventions.

Annex No. 2 to Act No. 153/2000 Coll.

The details of the Code of Practice of the workplace where the genetically modified organisms or products are used

The Code of Practice of the workplace where the genetically modified organisms or products are used must contain:

a) identification information on the user pursuant to # 6 par. 1 let. a) and b) of the Act,
b) identification information on the owner of the premises or property, if the owner is not identical with the user,
c) the first name, surname, place of residence, telephone number and, where applicable, also fax number and e-mail address of the professional consultant,
d) the risk category of the use of the genetically modified organism, that may be carried out at the workplace,
e) the person or persons responsible for the operation of the workplace,
f) characterization, the use and description of the technical installations providing for the containment, if contained use is involved,
g) a list and description of the standard operating procedures used at the workplace,
h) a list of personnel trained for work at the workplace,
i) a list of genetically modified organisms or products that shall be used at the workplace and the approximate amounts thereof,
j) organizational and technical provisions for the workplace,
k) measures for the case of fire or accident, including the emergency response plan pursuant to # 5,
l) the duties of personnel at work (adherence to standard operational principles, the procedures of sanitation of the facilities after the end of work, the procedures of decontamination of the instruments, personal protective aids and clothing),
m) the system and frequency of reviewing the premises, installations and protective measures,
n) duties of the personnel in maintenance of the equipment,
o) principles of safety and hygiene at work pursuant to the requirements of the special legal regulations[15],
p) management of waste and contaminated materials and equipment, especially the processes of inactivation of genetically modified organisms and testing for the effectiveness thereof,
q) a list of obligatory equipment and personal safety means, stating the activities where these means must be employed,
r) activities prohibited at the workplace,
s) principles of keeping records on the operation of the facilities, on sanitation carried out and reviews of protective installations,
t) means to restrict access of unauthorised persons,
u) the date and issue number of the registration in the List of Users,
v) information on the limit of validity of the Code of Practice, if applicable.

The Code of Practice must contain an officially verified number of pages; it shall be prohibited to remove or damage the individual pages thereof. The Code of Practice must be kept pursuant to # 3 par. 7 let. b).