Pursuant to Article 3, paragraph 2, and Article 4, paragraph 3 of the Law on Genetically Modified Organisms (Official Gazette of the Federal Republic of Yugoslavia no. 21/2001), the Federal Minister of Economy and Internal Trade has passed the following

REGULATIONS
ON CONTAINED USE
OF GENETICALLY MODIFIED ORGANISMS

I. General Provisions

Objective

Article 1

These Regulations set forth the criteria and norms for meeting the conditions for contained use of genetically modified organisms (hereinafter "GMO"), which must be met by the creator, user, or their authorised representative in the Federal Republic of Yugoslavia for foreign GMOs (hereinafter the "Applicant"), as well as an application form for contained use of a GMO.

The criteria and norms regulate every operation by which the organisms are genetically modified, or by which the GMOs are cultivated, stored, used, transported, destroyed, or put away, and by which physical barriers, or a combination of physical and chemical and/or biological barriers serve to limit their contact with any form of life and the environment.

Article 2

The provisions of these Regulations shall be applied to the GMOs which are created by the use of the techniques specified in Appendix 1, section A, which is enclosed herewith and makes an integral part of these Regulations, except for the techniques specified in Appendix 1, section B, which are not deemed to lead to the creation of GMOs.

The provisions of these Regulations shall not be applied to GMOs obtained by the techniques specified in Appendix 1, section C.

II. Standard Procedure of Handling the Application

Article 3

The Applicant shall, prior to a contained use of a GMO, submit an application to the competent federal organisation in charge of the matters of contained use, production, and distribution of GMOs and GMO products (hereinafter the "Competent Federal Organisation").
The application referred to in paragraph 1 of this Article shall contain:

1) **data on the laboratory or institute**, given in Appendix 4 which is enclosed herewith and makes an integral part of these Regulations;

2) **technical documentation** that contains the data necessary for risk assessment of the contained use of the GMO, as specified in Appendix 2 which is enclosed herewith and makes an integral part of these Regulations;

3) **brief contents of the application**;

4) **risk assessment** and conclusions set out in Appendix 3 which is enclosed herewith and makes an integral part of these Regulations, together with all bibliographical data (references) and indication of the methods used.

**Article 4**

The Competent Federal Organisation shall, in accordance with the scientific development of biotechnology, review the procedure in the part that pertains to possible risks from the GMO, i.e., will review the requirements that need to be fulfilled in order for the application to be taken into consideration.

The Applicant may refer to the information provided in the application previously filled in by other applicants, if those information, data, or results are not confidential, or, if those applicants have given their written consent, and may submit additional information that the Applicant considers relevant.

The Competent Federal Organisation shall acknowledge the date of receipt of the application, and reply to the Applicant in writing within 90 days from the date of receipt of the application, and shall:

1) notify that the application fulfils the requirements laid down by these Regulations, i.e. that the contained use is approved;

2) notify that the application fails to fulfill the requirements laid down by these Regulations, and that it is therefore rejected; or

3) request additional information.

In analysing the information provided in the application the Competent Federal Organisation shall consult the National Council for Biological Safety (hereinafter "NCBS") which is formed by the Federal Ministry of Economy and Internal Trade. The NCBS shall, within 60 days, give its expert opinion about the analysis of the information provided in the application for the contained use of the GMO.

If the Competent Federal Organisation requests additional information, it must state the reasons for so doing, and a deadline shall be set for providing additional information.

The Competent Federal Organisation may approve a contained use of a GMO for a set term at the same site or at other sites with the same purpose, based on the information provided in one application.
The Applicant may proceed with the contained use of a GMO only after obtaining approval from the Competent Federal Organisation.

Handling of Modifications and New Information

Article 5

In the event of any modification of, or unintended change to the GMO intended for contained use, which information may have consequences with regard to risks for human health and the environment, become available to the Applicant after the approval for the contained use of the GMO has been granted by the Competent Federal Organisation, or if new information on such risks become available during the process of considering the application by the Competent Federal Organisation, the Applicant shall:

1) take the measures necessary to protect human health and the environment;
2) inform the Competent Federal Organisation if an unintended change has become known, or if new information has become available to the Applicant;
3) revise the measures for the protection of human health and the environment, as set out in Appendix 2.

If the information referred to in paragraph 1 of this article, which information may have significant consequences with regard to assessment of risk for human health and environment, become available to the Competent Federal Organisation, the Competent Federal Organisation shall evaluate those information, make them available to the public, and request of the Applicant to:

1) modify the conditions of the contained use of the GMO;
2) suspend the contained use of the GMO, or
3) discontinue the contained use of the GMO and GMO products.

Applicant's Report on the Contained use of a GMO

Article 6

During and after the termination of a contained use of the GMO, in intervals defined in the approval of the contained use of the GMO, the Applicant shall submit to the Competent Federal Organisation a report on the results of the contained use of the GMO, particularly in respect of the risk for human health and environment.

Confidentiality of Information

Article 7

The Competent Federal Organisation and the NCBS shall not disclose confidential information contained in the application referred to in Article 3, paragraph 2 hereof.
The Applicant must mark confidential data in the application referred to in Article 3, paragraph 2 of these Regulations, and must state the reasons for so doing.

Having consulted the Applicant, the Competent Federal Organisation shall decide which information will be kept confidential, and shall notify the Applicant accordingly.

The following information shall not be deemed confidential:
1) name and address of the Applicant, general description(s) of the GMO, the objective of the contained use, site (place) of the contained use;
2) methods and plans for monitoring of the contained use of the GMO and the response in case of an accidental situation;
3) risk assessment.

If the Applicant withdraws the application, the Competent Federal Organisation and the NCBS shall respect the confidentiality of the information provided in the application referred to in Article 3, paragraph 2 of these Regulations.

III. Non-standard Procedure of Handling the Application

Article 8

If there is experience of contained use of a specific GMO, and if the GMO meets the criteria set out in Appendix 5 which is enclosed herewith and makes an integral part of these Regulations, the Competent Federal Organisation may apply a non-standard procedure of handling the application.

The Applicant shall file with the Competent Federal Organisation a request for initiation of a non-standard application procedure.

The request referred to in paragraph 2 hereof shall contain the following information:
1) general information:
   - name and address of the Applicant (laboratory or institute);
   - name, qualifications, and experience of the responsible researcher;
   - title of the project;
2) information relating to the GMO:
   - Latin name;
   - taxonomic status;
   - other names (common name, name of strain, etc.)
   - phenotypic and genetic markers;
   - nature and source of vectors;
   - techniques used in genetic modification;
   - sequence, functional identity and location of the altered/inserted/deleted segments of the nucleic acid in question, with particular reference to any known harmful sequence;
   - description of the genetic trait or phenotypic characteristic and in particular any new trait and characteristic that may be expressed or no longer expressed.
Article 9

In considering the request referred to in Article 8, paragraph 2 of these Regulations, the Competent Federal Organisation shall consult the NCBS which shall, within 15 days from the date of filing of the request, give its expert opinion about the request filed, and define the minimum of the necessary information referred to in Article 3, paragraph 2 of these Regulations.

Prior to the contained use of the GMO, the Applicant shall file the application referred to in Article 8, paragraph 1 of these Regulations, with the Competent Federal Organisation.

The Applicant may refer to the information provided in the application previously filled in by other applicants, if those information, data, or results, are not confidential, or, if those applicants have given their written consent, and may submit additional information that the Applicant considers relevant.

The Competent Federal Organisation shall acknowledge the date of receipt of the application, and reply to the Applicant in writing within 45 days from the day of receipt of the application, and shall:
1) notify that the application fulfils the requirements laid down by these Regulations, i.e. that the implementation is approved;
2) notify that the application fails to fulfil the requirements laid down by these Regulations, and that it is therefore rejected; or
3) request additional information.

In analysing the application referred to in Article 8, paragraph 1 hereof, the Competent Federal Organisation shall consult the NCBS. The NCBS shall, within 30 days, give its expert opinion about the analysis of the information provided in the application.

If the Competent Federal Organisation requests additional information, it must state the reasons for so doing, and a deadline shall be set for providing the additional information.

The Applicant referred to in Article 8, paragraph 1 of these Regulations, may begin the contained use of the GMO only after obtaining the approval from the Competent Federal Organisation.

Article 10

The procedure of handling the application referred to in Article 8, paragraph 1 of these Regulations shall be governed by the provisions of Articles 5 through 7 hereof.
IV. Miscellaneous

Article 11

The Applicant who has been granted approval of the contained use of a GMO shall:

1) implement and apply technical measures and devices for protection of persons and buildings, including sites;
2) carry out tests on the presence of the GMOs in use beyond the site designated in the approval of the contained use.

Article 12

In the contained use of a GMO, it is necessary to apply the following preventive measures:

1) the packaging used for keeping and transportation must satisfy the following requirements:
   - that it is safe from uncontrolled GMO release (emission);
   - that all constituent parts of the packaging must comply with manipulation requirements, and that they cannot be damaged in transportation;
   - that the labelling provides the following data: name and address of the producer, or a representative of the foreign producer, including logo, contents of the packaging, genetic name, date of production, and expiry date, with a clearly visible label "genetically modified organism";
2) destroying of empty packaging used for holding a GMO shall be carried out by the end user, by known physical and chemical means;
3) the site of the contained use of a GMO must satisfy the following requirements:
   - "GMO handling" labels must be posted;
   - the conditions and criteria specified in the approval of the contained use must be met.

Access to the site of the contained use of the GMO may be available only to the staff of the laboratory or institute.

V. Final Provision

Article 13

These Regulations shall come into force on the eight day from the day of publication in the Official Gazette of the FR of Yugoslavia.

No. 1244/1
13th November 2002
Belgrade

Federal Minister of Economy and Internal Trade
Petar Trojanović (sgd.)
Appendix 1

A) The techniques **deemed to lead** to genetic modifications are:
1) techniques with recombinant nucleic acids, which include forming of new combinations of genetic material by inserting nucleic acid molecules, formed by any means outside an organism, into any virus, bacterial plasmid, or another vector system, and their introduction into a host organism in which they are not naturally found, but in which their continuous reproduction is enabled;
2) techniques which include direct introduction of hereditary material (prepared outside an organism) into an organism, including micro-injection, macro-injection, and micro-encapsulation;
3) cell fusion (including protoplast fusion), or hybridisation techniques in which live cells with a new combination, non-existent in nature, of hereditary genetic material are formed by the method of fusion of two or more cells.

B) The techniques **not deemed to lead** to genetic modification, provided they do not include the use of recombinant nucleic acid molecules or genetically modified organisms created by the techniques other than those exempted in Appendix 1, section C:
1) **in vitro** fertilisation;
2) natural processes such as: conjugation, transduction, transformation;
3) induction of polyploidy.

C) The techniques of genetic modification, which yield organisms that may be exempted from the provisions of these Regulations, provided they do not include the use of recombinant nucleic acid molecules or genetically modified organisms, except for those obtained by one or more of the following techniques, are:
1) mutagenesis;
2) plant cell fusion (including protoplast fusion) in organisms which can exchange genetic material by the classical crossing method.
Appendix 2

Information Required for the Application for Contained use of GMO

I. General Information:

1) name and address of the Applicant;
2) data on staff and their qualifications:
   - name of the person in charge of supervision, monitoring, and safety, as well as
     the name and qualification of the responsible scientist;
   - information on the experience and qualifications of the staff involved in the
     process of the contained use of GMO;
3) title of the project.

II. Characteristics of the Donor, Recipient, or Parental Organism:

1) Latin name;
2) taxonomic status
3) other names (common name, name of strain, name of breeder etc.);
4) phenotypic and genetic markers;
5) degree of genetic relationship between the donor and recipient, or between parental
   organisms;
6) description of identification and detection techniques;
7) sensitivity, quantitative reliability, and specificities of the identification and
   detection techniques;
8) description of geographic distribution and natural habitat of the organism, including
   the data on natural predators, prey, parasites and competitors, symbionts and hosts;
9) potential of genetic transfer and potential of exchange with other organisms;
10) verification of genetic stability and factors affecting that stability;
11) pathogenic effects, ecological and physiological traits, specifically:
    - generation time in natural ecosystems, sexual and asexual reproductive cycle;
    - data on survivability, including survivability related to season;
    - participation in environmental processes: in primary production, in material
      exchange, in organic matter degradation, in transpiration, etc;
12) history of previous genetic modifications.

III. Characteristics of the Modified Organism:

1) methods used for the modification;
2) methods used to construct and introduce the insert into the recipient or to delete a
   sequence;
3) description of the insert and vector construction;
4) purity of the insert from any unknown sequence, and information on the degree to
   which the insert is limited to the sequence required to perform the intended function;
5) sequences, functional identity, and location of the DNA segment that is
   modified/inserted/deleted, with particular reference to any known harmful sequence.
IV. Information on the Contained use of the GMO and Information on the Environment

1. Information on the contained use of the GMO:

1) description of the contained use, including the purpose of the contained use and expected products;
2) anticipated dates of the contained use and the time plan of the experiment;
3) preparation of the site at which the contained use will be realised;
4) size of the site;
5) methods that will be used during the contained use;
6) quantity of the GMO that will be used;
7) safety precautions for workers during the use of the GMO;
8) anticipated techniques for inactivation or elimination of the GMO, at the end of the experiment.

2. Information on the Environment at the Site of the Contained use, and in the Wider Environment:

1) geographic location and grid reference of the site;
2) physical and biological proximity to humans settlements and other significant biotopes;
3) size of the local population;
4) economic activities of the local populations, which are based on utilisation of natural resources of the area;
5) distance from the nearest location of the protected drinking water source, or location that is environmentally protected for other reasons;
6) climatic characteristics of the region likely to be affected;
7) geographical, geological and pedological characteristics;
8) flora and fauna, including crops, livestock, and migratory species;
9) description of the ecosystems that are likely to be affected by the contained use, as well as those that are not likely to be affected;
10) comparison of the natural habitat of the recipient organism with the proposed site of the contained use of the GMO;
11) all known plans of cultivation or change of land use that could influence the environmental impact on the receiving environment.

V. Information on Interactions between the GMO and the Environment

1. Traits affecting survivability, reproduction, and dissemination:

1) biological traits which affect survivability, reproduction, and dissemination;
2) known or predicted environmental conditions which may affect survivability, reproduction, and dissemination (wind, water, soil, temperature, pH, etc.);
3) sensitivity to specific agents.
2. Interaction with the environment:

1) predicted habitat of the GMO;
2) research into GMO behaviour and characteristics, and their ecological impact on the environment, carried out in simulated natural environments such as microcosms, growth rooms, greenhouse;
3) Genetic transfer capability:
   - transfer of genetic material from the GMO to other organisms after its release into the ecosystem;
   - transfer of genetic material from indigenous species to the GMO upon its release;
   - routes of biological dispersal, known or likely modes of interaction with disseminating agents, including inhalation, ingestion, surface contact, etc;
   - description of ecosystems to which GMOs could be disseminated (spread).

3. Likely effects on the environment:

1) potential for excessive population increase in the given environment;
2) comparative advantages of the GMO in relation to the unmodified recipient or parental organisms;
3) identification and description of the target organisms;
4) anticipated mechanism and result of interaction between the released GMO and the target organism;
5) identification and description of non-target organisms that are not the target, which could be accidentally affected;
6) likelihood of biological interaction or change in the host range after the contained use of the GMO;
7) known or expected effects on non-target organisms in the environment, effect of competitors at the population level: prey, host, symbionts, predators, parasites, and pathogens;
8) known or expected participation in biogeochemical processes;
9) other potentially important interactions with the environment.

VI. Information on Monitoring, Control, Waste Treatment, and Emergency Response Plans

1. Methods of monitoring:

1) methods for tracing the GMOs and for monitoring their effects;
2) specificity (to identify the GMOs, and to easily distinguish them from the donor, recipient, or parental organism), sensitivity and reliability of the monitoring techniques;
3) techniques for detecting transfer of donor's genetic material to other organisms;
4) duration and frequency of the monitoring.
2. Control of the contained use of the GMO:

1) methods and procedures to avoid, or minimise, the spread of the GMOs beyond the boundaries of the site designated for their contained use, or areas intended for their use;
2) methods and procedures to protect the site of contained use from unauthorised access;
3) methods and procedures to prevent other organisms from entering the site.

3. Waste treatment

1) type of waste generated;
2) expected amount of waste;
3) possible risks;
4) description of the waste treatment envisaged.

4. Emergency response plans:

1) methods and procedures for controlling the GMOs in cases of unexpected spread;
2) methods for decontamination of the areas affected, or eradication of the GMOs;
3) methods for isolation of the areas affected;
4) plans for protecting human health and the environment in case of the occurrence of an undesirable effect.
Appendix 3

Risk Assessment Principles

Some expressions used in this Appendix have the following meanings:

- **direct effects** are primary effects on human health and the environment which are a result of the GMOs themselves, and which do not occur through a causal chain of events;

- **indirect effects** are effects on human health and the environment occurring through a causal chain of events, e.g. through mechanisms such as interaction with other organisms, transfer of genetic material, or changes in use or management;

- **immediate effects** are effects on human health and the environment which are observed during the contained use of the GMO. Immediate effects may be direct or indirect;

- **delayed effects** are effects on human health and the environment which may not be observed during the period of the contained use of the GMO, but become apparent as direct or indirect effects, either at the end or after the termination of the contained use of the GMO;

- **cumulative long-term effects** are accumulated effects on human health and the environment, including, among others, flora and fauna, soil fertility, soil organic material degradation, feed/food chains, biological diversity, animal health, and problems of resistance to antibiotics.

A) Objective

The objective of risk assessment is, on a case-by-case basis, to identify and evaluate potential adverse effects of the GMO on human health and the environment, whether direct or indirect, immediate or delayed, which may result from the contained use of the GMO. Risk assessment must establish whether risk management is needed, and, if so, the most appropriate method shall be determined.

B) General Principles

In accordance with the precautionary principle, the following general principles shall be followed when performing the risk assessment:

1) identified characteristics and use of the GMO, which may cause adverse effects, should be compared with the corresponding trait, or use, under corresponding conditions, of an unmodified organism which is the origin of the modified organism;

2) risk assessment shall be carried out in a scientifically sound and transparent manner, based on available scientific and technical data;

3) risk assessment shall be carried out on a case-by-case basis, meaning that the required information may vary depending on the type of the GMO, interest, intended use, and the potential environment;
4) if new information on the GMO and its effects on human health and the environment becomes available, the risk assessment may need to be readdressed in order to determine whether the risk has changed and whether the risk related procedure should be amended.

C) Methodology

1. Characteristics of the GMO and of the GMO release into the environment

Risk assessment must take into account relevant technical and scientific details on the following characteristics of:

1) the recipient or parental organism;
2) the genetic modifications - whether they include insertion or deletion of genetic material, and relevant information on the vector and the donor;
3) the GMO;
4) the intended contained use of the GMO and its scale;
5) the potential receiving environment;
6) the interactions between the GMO and the environment.

The ecological risk assessment may include information on the contained use and release of similar organisms and the organisms with similar traits, as well as data on their interaction with a similar environment.

2. Risk assessment measures

The following shall be considered in risk assessment:

1) identification of characteristics which may cause adverse effects.

Any GMO characteristic associated with the genetic modification, which may result in an adverse effect on human health and the environment, should be identified. Comparison of the GMO characteristics with those of unmodified organisms under corresponding conditions of release and use will help identify the exact adverse effects that result from the genetic modification. It is important not to minimise any potential adverse effect on the basis that it is unlikely to occur.

Adverse effects may appear directly or indirectly through:

- dissemination of the GMO in the environment;
- transfer of the introduced genetic material to other organisms, or the same organism, whether genetically modified or not;
- instability of phenotypes and genotypes;
- interaction with other organisms;
- change of the usual agricultural practice.

Potential adverse effects of the GMO will vary from case to case, and they include:

- disease to humans, including allergic and toxic effects;
- diseases to animals and plants, including toxic ones, and where appropriate, allergenic effects;
- effects on the dynamics of populations of the species in the receiving environment, and on the genetic diversity of each of these populations;
- altered susceptibility to pathogens facilitating the dissemination of infectious diseases, or creating new reservoirs or vectors;
- compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine;
- effects on biogeochemistry (biogeochemical cycles), particularly on carbon and nitrogen recycling changes in soil decomposition of organic material.

2) evaluation of the potential consequences of each adverse effect - the extent of consequences should be evaluated for each adverse effect. The evaluation assumes that such an adverse effect will occur. The extent of the consequences depends on the receiving environment, as well as on the method of release;

3) evaluation of the likelihood of the occurrence of each identified potential adverse effect - the major factor in evaluating the likelihood or probability of adverse effect occurring are the characteristics of the receiving environment, and the method of the intended release;

4) assessment of risk posed by each identified GMO characteristic - assessment of risk for human health and the environment posed by each identified GMO characteristic should be made, taking into account the probability of the adverse effect occurrence, as well as the extent and consequences if it occurs;

5) implementation of the risk management strategy in the contained use of the GMO - risk assessment may identify the risks that require management. Risk management strategy should be defined;

6) determination of the overall risk from the GMO - an overall risk assessment from the GMO should be made, taking into account the proposed risk management strategy, as well.

D) Conclusions on the potential environmental impact associated with the contained use of the GMO - based on risk assessment, in order to assist in drawing conclusions on the potential effects of the contained use of the GMO on the environment, the following information shall be included in the application:

1) in the case of GMOs other than higher plants:
   - likelihood of the GMO to become persistent and invasive in natural habitats under the conditions of the intended contained use;
   - any selective advantage or disadvantage of the GMO, and the likelihood of its expression under the conditions of the intended contained use;
   - potential for gene transfer to other species under the conditions of the intended contained use of the GMO, and any selective advantage or disadvantage conferred to those species;
potential immediate and/or delayed environmental impact of the direct or indirect interactions of the GMO with target organisms;
- potential immediate and/or delayed environmental impact of the direct or indirect interactions of the GMO with non-target organisms, including impact on population levels of competitors, prey, hosts, symbionts, predators, parasites, and pathogens;
- possible immediate and/or delayed effects on human health resulting from potential direct or indirect interactions of the GMO with the persons working with the GMO, coming into contact with the GMO, or being in the vicinity of the intended contained use of the GMO;
- possible immediate and/or delayed effects on the health of animals and effects on the food chain resulting from consumption of the GMO and any product derived from it, if intended to be used as animal feed;
- possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO with target and non-target organisms in the vicinity of the contained use of the GMO;
- possible immediate and/or delayed direct or indirect environmental impacts of the specific techniques applied in the management of the GMO, where different from the conventional techniques.

2) in cases of genetically modified higher plants (hereinafter "GMHP")

- likelihood of the GMHP becoming more persistent than recipient or parental plants in agricultural habitats, or more invasive in natural habitats;
- any selective advantage or disadvantage characteristic to the GMHP;
- potential for gene transfer to the same or other sexually compatible plant species under the GMHP planting conditions, and any selective advantage or disadvantage conferred to those plant species;
- possible immediate and/or delayed, direct or indirect, effect on the environment, resulting from direct or indirect interactions of the GMHP with target organisms, such as predators, parasites, and pathogens (if applicable);
- possible immediate and/or delayed, direct or indirect, effect on the environment, resulting from direct or indirect interaction of the GMHP with non-target organisms (also take into account the organisms which interact with target organisms), including impact on population levels of competitors, plant eaters, symbionts (where applicable), parasites, and pathogens;
- possible immediate and/or delayed effects on human health resulting from potential direct or indirect interactions of the GMHP with the persons working with the GMHP, coming into contact with the GMHP, or being in the vicinity of GMHP release;
- possible immediate and/or delayed effects on animal health, and consequences on the food chain resulting from consumption of the GMHP and any derived product from it, if intended for use as animal feed;
- possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMHP with target and non-target organisms in the vicinity of the GMHP release;
- possible immediate and/or delayed, direct and indirect, environmental impacts of specific techniques used for managing the GMHP where different from the conventional techniques.
Appendix 4

Questionnaire on the State of the Laboratory/Institute

I. General Information

Name of the institute/laboratory ________________________________________________
_________________________________________________________________________
Address ___________________________________________________________________
_________________________________________________________________________
City ______________________________________________________________________
__________________________________________________________________________
Telephone _________________________________________________________________
Fax ______________________________________________________________________
E-mail ____________________________________________________________________
Head of the laboratory/institute ______________________________________________
When was the laboratory/institute founded? ____________________________________

II. Structure of the staff involved in the work with GMO

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III. Basic Activity of the Laboratory/Institute
(mark the appropriate activity)

- Research
- Research/Education
- Research/Technology transfer
- Commercial production with applied research
- Commercial production
- Other (specify) ____________________________

IV. RESEARCH

1. Systems that are research subjects
(specify on which species/strains you work on, in case of human material specify the kind of tissue/cells you work on)

- Human material ____________________________
- Animals ____________________________
- Plants ____________________________
- Bacteria ____________________________
- Viruses ____________________________

2. Needs for training of research and laboratory staff in respect of GMO handling - would you like a person authorized by the Competent Federal Organisation to provide a course on safe handling of GMOs?

- Yes
- No

3. GMO projects

- Total number of projects in the last two years ____________________________
- Number of fundamental projects ____________________________
Number of applied projects ____________________________________________________________

Number of interdisciplinary projects ______________________________________________________

Number of joint projects with other laboratories in this country __________________________________

Number of joint projects with other laboratories abroad ______________________________________

(in the space below specify the names of all projects and/or subprojects in the past two years)

1. ________________________________________________________________________________

2. ________________________________________________________________________________

3. ________________________________________________________________________________

4. ________________________________________________________________________________

4. Novel GMO genotypes

Total number of novel genotypes __________________________________________________________

- animals __________________________________________________________
- plants ________________________________________________________________
- microorganisms _______________________________________________________
Appendix 5

Criteria for applying a non-standard procedure of handling an application are as follows:

1) taxonomic status and biology of the unmodified recipient organism should be known (for example, way of reproduction and pollination, ability of crossing with related species, pathogenicity);
2) existence of knowledge on the safety for human health and the environment of the parental and recipient organisms in the environment of the GMO release;
3) availability of data on any interaction of interest to risk assessment, including parental, recipient and other organisms in the environment of the GMO release;
4) availability of data on the genetic material inserted, as well as data on the construction of any vector system or sequence of the genetic material used with DNA carrier, should be available. In cases where the genetic modification includes deletion of genetic material, the extent of deletion should be known. Data on the genetic modification should be available in such a way as to enable identification of the GMO and its progeny;
5) GMO should not pose an additional or increased risk for human health and the environment under the conditions of experimental release, relative to the risk shown at release of the corresponding parental and recipient organisms. Any ability of dissemination in the environment and occupying of other distinct ecosystems and the ability of genetic material transfer to other organisms should have no harmful effects.

This is a certified translation of the original document in the Serbian language.

Svetlana J. Janković
Sworn-in Court Translator for English and Spanish
appointed by the Decision of the Republican Ministry of Justice and Administration No. 74-150/89-03 dtd. Apr. 3, 1990

Belgrade, May 21, 2003
No. 80/2003