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 PLACING GENETICALLY MODIFIED ORGANISMS AND PRODUCTS DERIVED FROM THE GENETICALLY MODIFIED ORGANISMS ON THE MARKET

I. General Provisions

Objective

Article 1

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

The criteria and norms for meeting the conditions for placing on the market of GMOs and GMO products regulate the procedure of placing on the market of GMOs and GMO products, by which the GMOs and GMO products are made available to third parties.

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.

Exemption

Article 3

The provisions of these Regulations shall not apply to the cases of carriage of GMOs and GMO products by rail, road, inland waterway, sea, and air across the territory of the Federal Republic of Yugoslavia.

The provisions of these Regulations shall not apply to the GMOs and GMO products intended for human or medical use.

II. Standard Procedure of Handling the Application

Article 4

The Applicant shall, prior to placing a GMO and GMO products on the market, submit an application to the competent federal organisation in charge of the matters of contained use, release, 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) **technical documentation** which contains the data necessary for risk assessment of placing the GMO and GMO products on the market, as specified in Appendix 2 which is enclosed herewith and makes an integral part of these Regulations;
2) **brief contents of the application**;
3) **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;
4) **a monitoring plan** in accordance with Appendix 5 which is enclosed herewith and makes an integral part of these Regulations.

Article 5

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 and GMO products, i.e., will review the requirements that need to be met 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 meets the requirements laid down by these Regulations, i.e. that the placing on the market is approved;
2) notify that the application fails to meet 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 release of the GMO and GMO products.

The 90 day deadline referred to in paragraph 3 of this article shall not include the time which the Competent Federal Organisation takes to consult and inform the public in accordance with paragraph 7 of these Regulations. The deadline set forth in paragraph 3 of this article may be extended by maximum 30 days.

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.

Article 6

The Applicant may proceed with placing the GMO and GMO products on the market only after obtaining the approval from the Competent Federal Organisation.

The approval referred to in paragraph 1 hereof shall define:

1) the objective of the placing on the market, including the identity of the GMO being placed on the market;
2) the period of validity of the approval;
3) the conditions for the placing on the market, including all specific conditions of use and handling, as well as the conditions for the protection of particular ecosystems/environments, and/or geographical areas;
4) the obligation of the Applicant to provide control samples, available to the Competent Federal Organisation on request;
5) the requirements for labelling which shall clearly state that a GMO is present. The words "This product contains a genetically modified organism" shall appear either on a label or in a document accompanying the GMO product or other products containing the GMO;
6) monitoring requirements in accordance with Appendix 5, including obligation to report to the Competent Federal Organisation, and the time period of the monitoring plan.

Consulting and Informing the Public

Article 7

The Competent Federal Organisation shall consult the public and certain expert groups on the proposed placing of the GMO and GMO products on the market. The Competent Federal Organisation shall complete consultations within the deadline set out in Article 5, paragraph 5 of these Regulations.

Renewal of Approval

Article 8

No later than nine months before the expiry of the approval referred to in Article 6, paragraph 1 of these Regulations, the Applicant shall submit an application for renewal of approval to the Competent Federal Organisation.

The application referred to in paragraph 1 of this Article shall contain:

1) a copy of the approval referred to in Article 6, paragraph 1 of these Regulations;
2) a report on the results of the monitoring referred to in Article 6, paragraph 2 of these Regulations;
3) any new information with regard to the assessment of risk to human health and the environment;
4) a proposal for amending or complementing the conditions of the approval referred to in Article 6, paragraph 1 of these Regulations.

By virtue of the application for renewal of the approval referred to in paragraph 1 hereof, the Applicant shall continue placing the GMO and GMO products on the market, until the issuance of the decision by the Competent Federal Organisation.

The Competent Federal Organisation shall acknowledge the date of receipt of the application for renewal of approval referred to in paragraph 1 hereof and reply in writing to the Applicant within 90 days from the date of receipt of the application, and shall:

1) notify that the application for renewal of approval meets the requirements laid down in paragraph 2 of this Article, i.e. that the placing on the market is approved;
2) notify that the application for renewal of approval does not meet the requirements laid down in paragraph 2 hereof, and is, therefore, rejected; or
3) request additional information.

Monitoring and Handling of New Information

Article 9

During the placing of the GMO and GMO products on the market, in time intervals defined in the approval of placing on the market referred to in Article 6, paragraph 1 of these Regulations, the Applicant shall submit to the Competent Federal Organisation a report on the results on placing on the market of the GMO and GMO products, particularly with regard to the risk to human health and the environment.

On the basis of the report referred to in paragraph 1 of this article the Competent Federal Organisation may review the request for the monitoring plant referred to in Article 4, paragraph 2 of these Regulations.

In the event of any modification of, or unintended change to the GMO and GMO products being placed on the market, which information may have consequences with regard to risks for human health and the environment, become available to the Applicant after the approval of placing the GMO and GMO products on the market 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 3 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 placing the GMO and GMO products on the market;
2) suspend placing the GMO and GMO products on the market, or
3) discontinue placing the GMO and GMO products on the market.

Confidentiality of Information

Article 10

The Competent Federal Organisation and the NCBS shall not disclose confidential information contained in the application referred to in Article 4, paragraph 2 hereof.

The Applicant must mark confidential information in the application referred to in Article 4, 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 and GMO products;
2) methods and plans for monitoring of placing the GMO and GMO products on the market, 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 4, paragraph 2 of these Regulations.

III. Non-standard Procedure of Handling the Application

Article 11

If there is experience of placing the GMO and GMO products on the market, and if the GMO and GMO products meet the criteria set out in Appendix 4 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;
   - name, qualifications, and experience of the responsible researcher;
   - title of the project;
   - name and address of the physical person or legal entity in the Federative Republic of Yugoslavia which is responsible for the placing on the market.
2) information relating to the GMO and GMO products which are being placed on the market:
   - 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 modified, or inserted, or deleted segments of the nucleic acid in question, with particular reference to any known harmful sequence;
   - description of the genetic property or phenotypic trait, and, particularly, any new trait and characteristic that may be expressed or ceases to be expressed.
   - commercial names of the product.

Article 12

In considering the request referred to in Article 11, 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 4, paragraph 2 of these Regulations.

Prior to placing the GMO and GMO products on the market, the Applicant shall file the **application** referred to in Article 11, 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 meets the requirements laid down by these Regulations, i.e. that the placing on the market is approved;
2) notify that the application fails to meet 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 11, 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.

The 45 day deadline referred to in paragraph 4 of this article shall not include the time which the Competent Federal Organisation takes to consult and inform the public in accordance with paragraph 7 of these Regulations. The deadline set forth in paragraph 4 of this article may be extended by maximum 30 days.

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 11, paragraph 1 of these Regulations may proceed with placing the GMO and GMO products on the market only after obtaining the approval from the Competent Federal Organisation.

Article 13

The procedure of handling the application referred to in Article 11, paragraph 1 of these Regulations shall be governed by the provisions of Articles 7 through 10 hereof.

V. Final Provision

Article 14

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. 1245/1
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 specified in Appendix 2, section A, shall be requested for placing on the market of all types of GMOs and GMO products other than higher plants. The information specified in Appendix 2, section B, shall be requested for placing on the market of genetically modified higher plants (hereinafter "GMHP"). "Higher plants" are plants which taxonomically belong to the group of Spermatophytes (*Gymnospermae* and *Angiospermae*).

A) Information Required in the Application for Placing on the Market GMOs and GMO products other than higher plants

I. General Information:

1) name and address of the Applicant;
2) names, qualifications and experience of the responsible research staff;
3) the title of the project.

II. Information on the product being placed on the market

1. Information required in the application:

1) the proposed commercial names of the product and names of the GMO it contains, as well as any specific identification, name, or code used for identification of the GMO by the Applicant. Upon obtaining of the approval, any new commercial name shall be reported to the Competent Federal Organisation;
2) the name and full address of the physical person or legal entity in the FR of Yugoslavia responsible for the placing on the market - whether the producer, importer, or distributor;
3) the name and full address of the provider of control samples;
4) description of the intended use of the GMO and GMO product. It is necessary to emphasize the differences in the use or handling of the GMO in comparison with a similar genetically unmodified product;
5) description of geographical areas and environment types where the product is intended to be used, as well as the estimated scale of the use in each area;
6) categories of targeted consumers, e.g. - industry, agriculture and craft, public consumption;
7) information on the genetic modification, which may be used in detection and identification of specific GMO products in order to facilitate post-marketing control and inspection. This information should include: where the samples of the GMO or its genetic material can be stored in a competent way, as well as the details on the nucleotide sequence and other types of information necessary for identifying the GMO product and its progeny (e.g. - methods of detection and identification of the GMO product, including experimental data which show the specificity of the methods).

2. Required information on the product, if relevant:

1) measures intended to be taken in case of unintentional placing on the market;
2) specific instructions and recommendations for storing and handling;
3) particular instructions by the Competent Federal Organisation for monitoring and notifying the Applicant
4) suggested limits in the approved use of the GMO and GMO products, e.g. where and for what purpose the product may be used;
5) proposed packaging.

III. Information relating to the GMO

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

1) Latin name;
2) taxonomic status
3) other names (common name, name of sort, name of strain, 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, as well as organisms with a known genetic transfer potential under natural conditions;
10) verification of genetic stability and factors affecting that stability;
11) pathological, ecological and physiological traits, specifically:
    - generation time in natural ecosystems, sexual and asexual reproductive cycle;
    - data on survivability, including seasonal effects and the potential for forming structures for surviving under unfavourable conditions (spores or sclerotiae);
    - pathogenicity: infectiousness, toxicity, virility, allergenicity, pathogen carriers (vectors), possible host organism carriers, including those that are not susceptible to the pathogenic action of agents (non-target organisms). Potential for activating latent viruses (pro-viruses). Potential for colonisation of other organisms;
    - resistance to antibiotics and potential use of those antibiotics in protection and therapy in humans and domestic animals;
    - participation in ecological processes: in primary production, material exchange, organic matter degradation, respiration, etc.;
12) natural vector characteristics:
    - sequence
    - degree of genetic mobility
    - specificity
    - presence of genes conferring resistance;
13) history of previous genetic modifications.

2. Characteristics of the Vector:

1) the nature and source of the vector;
2) the sequences of the transposon, vector, and other non-coding genetic segments used in GMO construction in order to enable the inserted vector and the insert to function in the GMO;
3) the mobilisation frequency of the inserted vector and/or the potential for genetic transfer, including the methods for determination ;
4) information on the degree to which the vector is limited to the DNA required to perform the intended function.

3. Characteristics of the Modified Organism:

1) Information related to the genetic modification:

   - methods used for the modification;
   - methods used to construct and introduce the insert into the recipient or to delete a sequence;
   - description of the insert and vector construction;
   - 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;
   - methods and criteria used for selection;
   - sequence, functional identity, and location of the DNA segments that are modified/inserted/deleted, with particular reference to any known harmful sequence.

2) Information on the final GMO:

   - description of the genetic trait or phenotypic characteristics, and in particular any new traits and characteristics which may be expressed or no longer expressed;
   - structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;
   - stability of the organism in terms of genetic traits;
   - rate and level of expression of the new genetic material. Methods and sensitivity of measurement;
   - activity of the expressed protein;
   - description of identification and detection techniques including techniques for identification and detection of the inserted sequence and vector;
   - sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
   - history of previous releases or uses of the GMO;
   - considerations for human health and the environment:
     a) toxic and allergenic effects of the GMOs and/or their metabolic products;
     b) comparison of the modified organism to the donor, recipient, or parental organism regarding pathogenicity;
     c) capacity for colonisation;

d) if the organism is pathogenic to humans with a normal immune system, indicate:
   - diseases caused and mechanism of pathogenicity including invasiveness and virulence;
   - communicability;
   - infective dose;
   - host range, possibility of alteration;
   - possibility of survival outside of human host;
   - presence of vectors or means of dissemination;
   - biological stability;
   - antibiotic resistance patterns;
   - allergenicity;
   - availability of appropriate therapies.

e) other hazards from the GMO and GMO products.

IV. Information Relating to the Conditions of Release of the GMO and GMO products and Information on the Receiving Environment

1. Information on the release:

1) description of the proposed release, including the objective of the release and foreseen products;
2) foreseen dates of the release and time planning of the experiment, including frequency and duration of releases;
3) preparation of the site previous to the release;
4) size of the site;
5) methods to be used for the release;
6) quantities of GMOs to be released;
7) disturbance on the site (type and method of cultivation, mining, irrigation, or other activities);
8) worker protection measures taken during the release;
9) post-release treatment of the site;
10) techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment;
11) information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

2. Information on the Environment at the Site of the Release, 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) proximity to significant biotopes, protected areas, or drinking water supplies;
4) size of the local population;
5) economic activities of the local populations, which are based on utilisation of natural resources of the area;
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 target and non-target ecosystems likely to be affected;
10) a comparison of the natural habitat of the recipient organism with the proposed sites of release;
11) any known development plan or change of land use in the region which could influence the environmental impact of the GMO release.

V. Information Relating to the Interactions Between the GMOs 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) studies of the behaviour and characteristics of the GMOs and their ecological impact, carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses;
3) Genetic transfer capability:
    - postrelease transfer of genetic material from the GMO to other organisms in the ecosystem;
    - postrelease transfer of genetic material from indigenous organisms to the GMO;
4) likelihood of postrelease selection leading to the expression of unexpected and/or undesirable traits in the modified organism;
5) measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimise dispersal of genetic material. Methods to verify genetic stability;
6) routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, etc.;
7) description of ecosystems to which the GMO could be disseminated;
8) potential for excessive population increase in the environment;
9) competitive advantage of the GMO in relation to the unmodified recipient or parental organism;
10) identification and description of the target organisms;
11) anticipated mechanism and result of interaction between the released GMO and the target organism;
12) identification and description of non-target organisms which may be accidentally affected by the release of the GMO, and the anticipated mechanisms of any identified adverse interaction;
13) likelihood of postrelease shifts in biological interactions or in host range;
14) known or predicted interactions with non-target organisms in the environment, effect of competitors at the population level: prey, host, symbionts, predators, parasites, and pathogens;
15) known or predicted involvement in biogeochemical processes;
16) other potentially relevant interactions with the environment.

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

1. Methods of monitoring:

1) methods for tracing the GMO and for monitoring its effects;
2) specificity (to identify the GMO, and to easily distinguish it 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 release 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 release, or areas intended for their release;
2) methods and procedures to protect the site 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 uncontrolled spread;
2) methods for decontamination of the areas affected - eradication of the GMOs;
3) methods for disposal or sanitation of plants, animals, and soils that were exposed during or after the spread;
4) methods for isolating the areas affected by the spread;
5) plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

B) Information Required in the Application for Placing on the Market of GMHP and GMHP products (*Gymnospermae* and *Angiospermae*)

I. General information

1) Name and address of the Applicant;
2) name, qualifications and experience of the responsible researcher;
3) the title of the project.

II. Information on the product being placed on the market

1. Information required in the application:

1) the proposed commercial names of the product and names of the GMO it contains, as well as any specific identification, name, or code used for identification of the GMO by the Applicant. Upon obtaining of the approval, any new commercial name shall be reported to the Competent Federal Organisation;
2) the name and full address of the physical person or legal entity in the FR of Yugoslavia responsible for the placing on the market;
3) the name and full address of the provider of control samples;
4) description of the intended use of the GMHP and GMHP product. It is necessary to emphasize the differences in the use or handling of the GMHP in comparison with a similar genetically unmodified product;
5) description of geographical areas and environment types where the product is intended to be used, as well as the estimated scale of the use in each area;
6) categories of targeted consumers, e.g. - industry, agriculture and craft, public consumption;
7) information on the genetic modification, which may be used in detection and identification of specific GMHP products in order to facilitate post-marketing control and inspection. This information should include: where the samples of the GMO or its genetic material can be stored in a competent way, as well as the details on the nucleotide sequence and other types of information necessary for identifying the GMHP product and its progeny (e.g. - methods of detection and identification of the GMHP product, including experimental data which show the specificity of the methods).

2. Required information on the product, if relevant:

1) measures intended to be taken in case of unintentional placing on the market;
2) specific instructions and recommendations for storing and handling;
3) particular instructions by the Competent Federal Organisation for monitoring and notifying the Applicant;
4) suggested limits in the approved use of the GMHP and GMHP products, e.g. where and for what purpose the product may be used;
5) proposed packaging.

III. Information relating to the recipients and parental plant

1. Complete name:
   1) family name;
   2) genus
   3) species;
   4) subspecies
   5) cultivar/breeding line/hybrid/genotype;
   6) common name.

2. Information relating to reproduction:
    1) modes of reproduction;
    2) specific factors affecting reproduction;
    3) generation time;
    4) sexual compatibility with other cultivated or wild plant species, including the distribution of the compatible species in Europe.
3. Survivability:
    1) ability to form structures for survival or dormancy;
    2) specific factors affecting survivability.
4. Dissemination:
    1) ways and extent (e.g. - an estimation of how pollen and/or seeds viability declines with distance);
    2) specific factors affecting dissemination.
5. Geographical distribution of the plant.
6. In case of plant species not normally grown in Yugoslavia, description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.
7. Other potential interactions of the plant, relevant to the GMHP, with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

IV. Information Relating to the Genetic Modification

1. Description of the methods used for the genetic modification.
2. Nature and source of the vector used.
3. Size, source (name) of donor organism and intended function of each constituent fragment of the region intended for insertion.

V. Information Relating to the GMHP

1. Description of the traits and characteristics which have been introduced or modified.
2. Information on the sequences actually inserted/deleted:
    1) size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced in the GMHP or any carrier of foreign DNA remaining in the GMHP;
    2) in case of deletion, size and function of the deleted region;
    3) number of copies of the insert;
    4) location of the insert in the plant cell (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination.
3. Information on the expression of the insert:
    1) information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterisation;
    2) information on the effect of the insert on the recipient plant genome expression;
    3) parts of the plant where the insert is expressed (e.g. roots, stem, pollen).

4. Information on how the genetically modified plant differs from the recipient plant in:
   1) modes and/or rate of reproduction;
   2) dissemination;
   3) survivability.
5. Genetic stability of the insert and phenotypic stability of the GMHP.
6. Any change to the ability of the GMHP to transfer genetic material to other organisms.
7. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.
8. Information on the safety of the GMHP to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the GMHP is intended to be used in animal feedstuffs.
9. Mechanism of interaction between the GMHP and target organisms.
10. Potential changes in the interactions of the GMHP with non-target organisms arising from the genetic modification.
11. Potential interactions with the abiotic environment.
12. Description of detection and identification techniques for the GMHP.
13. Information about previous releases of the GMHP.

VI. Information Relating to the Site of Release of the GMHP

1. Location and size of the release site.
2. Description of the release site ecosystem, including climate, flora and fauna.
3. Presence of sexually compatible wild relatives or cultivated plant species.
4. Proximity to officially recognised biotopes or protected areas which may be affected.

VII. Information Relating to the Release of the GMHP

1. Purpose of the release.
2. Foreseen dates and duration of the release.
3. Methods by which the GMHP will be released.
4. Methods for preparing and managing the release site, prior to, during, and after the release, including cultivation practices and harvesting methods.
5. Approximate number of plants (plants per m^2).

VIII. Information on Control, Monitoring, Post-Marketing procedures, and Waste Treatment Plans

1. Precautions taken:
   1) determining distances from sexually compatible plant species, both wild relatives and crops;
   2) minimising/preventing dispersal of any reproductive organ of the GMHP (e.g. pollen, seeds, tuber).
2. Description of methods for postrelease treatment of the site surfaces.
3. Description of treatment methods for the genetically modified plant genetic material, including wastes.
4. Description of monitoring plans and methods.
5. Description of emergency plans.
6. Methods and procedures to protect the site.

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 release 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 release of the GMO, but become apparent as direct or indirect effects, either at the end or after the termination of the release 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 release 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 effect on human health and the environment becomes available, the risk assessment may 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 release of the GMO and GMO products 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 release or use of the GMO and their scale;
5) the potential receiving environment;
6) the interactions between the GMO and GMO products with the environment.

The ecological risk assessment may include information on the 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;

- disease 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 placing the GMO and GMO products on the market - 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 release of the GMO - based on risk assessment, in order to assist in drawing conclusions on the potential effects of the release 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 release;
- any selective advantage or disadvantage of the GMO, and the likelihood of its expression under the conditions of the intended release;
- potential for gene transfer to other species under the conditions of the intended release 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 release of the GMO;
- possible immediate and/or delayed effects on the health of animals and effects on the food/feed 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 release 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 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 and 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 the 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 and 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/feed 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

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.

Appendix 5

Monitoring Plan

A) Objective

The objective of a monitoring plan is to:
- confirm any assumptions regarding the occurrence and impact of potential adverse effects of the GMO and GMO products on human health and the environment;
- identify the occurrence of adverse effects of the GMO and GMO products on human health and the environment if not anticipated in risk assessment.

B) General principles

The interpretation of the data collected by monitoring should be considered in the light of other existing environmental conditions and activities. Where changes in the environment are observed, further assessment should establish whether they are a consequence of the GMOs and their use, as such changes may be the result of environmental factors other than the placing of the GMO on the market.

Experience and data collected through the monitoring of the contained use of the GMO and during release of the GMO and GMO products into the environment, may assist in designing the post-marketing monitoring regime.

C) Design of the monitoring plan

The design of the monitoring plan should:

1. be detailed on a case-by-case basis, taking into account the risk assessment;
2. take into account the characteristics of the GMO, the characteristics and scale of its intended use, and the range of relevant environmental conditions where the GMO is expected to be released;
3. incorporate general surveillance for unanticipated adverse effects of the GMOs and GMO products on human health and the environment and, if necessary, (case-) specific monitoring of adverse effects identified in the risk assessment:
   - whereas case-specific monitoring should be carried out for a sufficient time period to detect immediate and direct as well as, where appropriate, delayed or indirect effects which have been identified in risk assessment;
   - whereas surveillance should make use of already established routine surveillance practices such as the monitoring of agricultural cultivars, plant protection, or veterinary and medical products. An explanation as to how the relevant information collected through established routine surveillance practices will be made available to the Applicant should be provided;

4. facilitate the observation, in a systematic manner, of the release of a GMO in the receiving environment and the interpretation of these observations with respect to safety for human health and the environment;
5. identify who (Applicant, users) will carry out various tasks the monitoring plan requires, and who is responsible for ensuring that the monitoring plan is made and implemented appropriately, and ensure that there is a route by which the Applicant and the Competent Federal Organisation will be informed on any adverse effects of the GMOs and GMO products on human health and the environment (monitoring timetable and schedule of reports on results of monitoring shall be indicated);
6. give consideration to the mechanisms for identifying and confirming any observed adverse effects of the GMOs and GMO products on human health and the environment, and enable the Applicant or the Competent Federal Organisation to take the measures necessary to protect human health and the environment.

----------*End of Translation* ----------

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. 82/2003