NATIONAL ASSEMBLY
OF THE REPUBLIC OF SLOVENIA

Number 630-03/00-3/3
Ljubljana, 11 July 2002

AT A SESSION HELD ON 11.7.2002, THE NATIONAL ASSEMBLY OF THE REPUBLIC OF SLOVENIA ADOPTED THE MANAGEMENT OF GENETICALLY MODIFIED ORGANISMS ACT (ZRGSO) IN THE FOLLOWING TEXT

MANAGEMENT OF GENETICALLY MODIFIED ORGANISMS ACT (ZRGSO)

1. GENERAL PROVISIONS

Article 1
(Objective of the act)

(1) This act regulates management of genetically modified organisms (hereinafter: GMO) and determines measures for preventing and reducing possible adverse environmental effects, especially in relation to preserving biological diversity, and on human health, which could occur during contained use of GMOs, the deliberate release of GMOs into the environment or placing on the market GMOs or products containing GMOs or consisting of them or their combinations.
(2) This act also regulates the import and export of GMOs and products referred to in the previous paragraph.

Article 2
(Exclusive currency)

(1) The provisions of this Act relating to contained use shall not apply for the following procedures of modifying genetic material:
    1. mutagenesis,
    2. cell or protoplast fusion of cells of prokaryotic species if it is possible also to obtain the created organisms by traditional breeding methods,
    3. cell or protoplast fusion of cells of eukaryotic species, including obtaining hybridomas and plant cell fusions, and
    4. self-cloning, including the removal of nucleic acid (NA) sequences from a cell of an organism which may or may not be followed by the reinsertion of all or part of that NA, or a synthetic equivalent, with or without prior enzymatic or mechanical treatment, into cells of the same or phylogenetically related species. Such micro-organisms can replace genetic material by natural physiological processes but only if the resulting micro-organism does not cause disease to humans, animals or plants. Self-cloning may also include the use of recombinant vectors with

a verified safe use in the particular micro-organisms, provided that they do not use molecules of recombinant nucleic acids or other GMOs except those created with the use of these procedures.

(2) The provisions of this Act relating to the deliberate release of GMOs into the environment and placing on the market GMOs or products containing or consisting of GMOs or their combinations (hereinafter: placing products on the market), do not apply for the following procedures of modifying genetic material:
1. mutugenesis, and
2. cell or protoplast fusion of plant cells if it is possible to obtain the organisms thus created with ordinary culture techniques, provided that they do not include the use of molecules of recombinant nucleic acids or other GMOs except those created with the use of these procedures.

(3) The provisions of this Act shall not apply for the transport of GMOs by railway, road, waterways or air, except the provisions that refer to a risk assessment and the emergency plan and taking measures in the event of an accident during work with GMOs in a contained use.

(4) The provisions of this Act that refer to placing products on the market and to the import and export of GMOs and products, shall not apply for:

1. pharmaceuticals for use in human and veterinary medicine containing GMOs or consisting of them or their combinations, and
2. foodstuffs for use in human food containing GMOs or consisting of them or their combinations, the placing on the market and import and export of which shall be regulated by specific regulations.

Article 3
(Principles of the act)

(1) The state, within the framework of its competencies, in particular by the adoption of regulations, public finance policies, incentives and alleviation, in determining the conditions and contents of public education and information provision, and in stimulating research work and development, should ensure overall treatment of GMO management and measures for preventing possible adverse effects on the environment and human health (principle of integrity).
(2) Contained use, the intentional release of GMOs into the environment and placing products on the market shall only be permitted if, taking into account the state of science and technology, and the guarantee of safety measures, no direct or indirect, immediate or delayed or long-term cumulative adverse effects on the environment and human health can be expected (precautionary principle).
(3) In decisions connected with GMO management, and in management itself, it is necessary to take into account, in addition to human well-being also the well-being of all other living organisms and life associations and the integrity and

vulnerability of humanity, all other living organisms and the environment as a whole (bioethical principle).

(4) Permitting contained use, their deliberate release into the environment and placing products on the market shall take place in such a way that a case-by-case assessment is made in relation to possible adverse effects on the environment or human health (case-by-case principle).

(5) Introduction of a GMO into the environment may only take place in such a way that after contained use GMO is deliberately released into the environment or placed on the market step by step and only on condition that a high level of safety in relation to possible adverse effects at the previous stage enables transition to the next stage. In this context, it is necessary in the majority of cases, prior to placing a product on the market, to examine possible adverse effects with the deliberate release of the GMO into a restricted controlled area (step-by-step principle).

(6) At each stage of placing products on the market, their traceability should be guaranteed (traceability principle).

(7) A legal or natural person who performs work with GMOs in a contained use, deliberately releases GMOs into the environment or places products on the market, is criminally liable and liable for damages in compliance with the law in the event of damage resulting from their GMO management (liability principle).

(8) A legal or natural person who performs work with GMOs in contained use, deliberately releases a GMO into the environment or places a product on the market, shall cover the costs of measures required for guaranteeing safe management of the GMO, and the costs of measures required for reducing or preventing the consequences of adverse effects of their GMO management, in compliance with this Act (causer pays principle).

(9) The state should guarantee measures for reducing or preventing the consequences of adverse effects created by contained use, deliberate release of GMOs into the environment or placing products on the market, if the legal or natural person is not identifiable or if the consequences cannot otherwise be reduced or prevented, in compliance with this Act. If in a case referred to in the previous sentence the legal or natural person is subsequently identified, the state has the right and duty to claim from such a person reimbursement of the costs of reducing or preventing the consequences (principle of compulsory subsidiary measures).

(10) The public has the right to be informed about GMO management, and to be involved in the procedure of issuing permission in compliance with this Act (public principle).

Article 4
(Definitions)

The terms used in this Act shall have the following meanings:

1. An 'organism' is a single or multiple cell entity or a sub-cell biological entity capable of replication or of transferring genetic material.

2. A micro-organism is any cellular or non-cellular microbiological entity capable of replication or of transferring genetic material, including viruses, viroids, and artificially cultured animal and plant cells.
3. A genetically modified organism (GMO) is an organism, with the exception of human beings, or a micro-organism, in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination.
4. Procedures that modify genetic material other than occurs under natural conditions are:
    - recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation,
    - techniques involving the direct introduction into an organism of heritable material prepared outside the organism, including micro-injection, macro-injection and micro-encapsulation,
    - cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

    The following shall not be considered procedures which modify genetic material differently than under natural conditions:
    - in vitro fertilisation,
    - natural processes such as conjugation, transduction, transformation,
    - polyploidy induction,

    provided that they do not involve the use of recombinant nucleic acid molecules or other GMO except those formed by the use of one or more of these procedures.
5. Risk is the likelihood that GMO management will, indirectly or directly, immediately or delayed or long-term cumulatively effect the environment or human health, especially in relation to preserving biological diversity, preserving indigenous plant varieties and animal breeds, soil fertility, food chains or the health of human beings and animals.
6. Risk assessment is establishing and evaluating the risks that could occur because of work with GMOs in contained use, the deliberate release of a GMO into the environment or placing products on the market, on a case-by-case basis.
7. GMO management is work with GMOs in a contained use, the deliberate release of GMOs into the environment or placing products on the market.
8. A premise is a laboratory or production department or other confined space in which work with GMOs takes place.
9. Contained use is work in a premise by which an organism is genetically modified or cultured, stored, transported, destroyed, disposed of or in any other way used, and in which containment measures are carried out.
10. A containment measure is a physical enclosure or combination of physical enclosures with chemical or biological restrictions or other specific measures or

combination of measures, including the carrying out of good laboratory and production practice, which are used in contained use for limiting the contact of the GMO with the environment and general population or reducing the capacity of the GMO to replicate or transfer modified genetic material outside the contained use.

11. Deliberate release of a GMO into the environment is any intentional introduction into the environment of a GMO or combination of GMOs, except placing on the market, for which no special containment measures are used to limit the contact of the GMO with the environment and general population and to ensure a high level of safety.
12. Placing on the market is making available to third parties, whether in return for payment or free of charge.
    Making available a GMO to a third person in contained use or for deliberate release of the GMO into the environment in compliance with this act shall not be considered placing on the market.
13. Import is any introduction of a product into the customs territory of the Republic of Slovenia irrespective of the use or notification of the product that has been allowed in compliance with regulations, except transit.
14. A product is a GMO or combination of GMOs or preparations consisting of or containing a GMO or combination of GMOs and which is placed on the market.
15. An accident is any incident or series of incidents when during work with GMOs in contained use, an unintended release of a GMO into the environment occurs which could present an immediate or delayed hazard to human health or the environment.
16. Monitoring is monitoring and inspecting GMOs and monitoring the environment, processes and procedures in the deliberate release of GMOs into the environment or the placing of products on the market and possible adverse effects, in compliance with regulations.
17. A notification is a submission containing required data, which a notifier submits in order to obtain a required receipt or permit.
18. A notifier is a natural or legal person who intends to carry out or is carrying out work with GMOs in contained use, intends to deliberately release or deliberately releases a GMO into the environment or intends to place a product on the market or is placing a product on the market.
19. The state of science and technology are generally accepted findings in the sphere of science and technology.

Article 5
(Commission for GMO management)

The Government of the Republic of Slovenia (hereinafter: government) shall set up a commission for GMO management (hereinafter: commission) for monitoring conditions and developments in the area of GMO management.

Article 6
(Members of the commission)

(1) The commission shall consist of seventeen members, who shall be appointed by the government for a period of four years.
(2) The commission shall consist of:
    1. a representative of the Slovenian Academy of Sciences and Arts,
    2. two representatives of the social sciences,
    3. two representatives of the humanist sciences
    4. two representatives of the natural sciences,
    5. a representative of medical science,
    6. a representative of veterinary science,
    7. one representative from each of the scientific committees referred to in Article 8 of this Act,
    8. two representatives of non-governmental organisations from the sphere of environmental protection and one representative each from non-government organisations from the sphere of consumer protection and health safety,
    9. a representative of the Chamber of Commerce and Industry of Slovenia, and
    10. a representative of the Chamber of Agriculture and Forestry of Slovenia.

(3) The representatives of social, humanist, natural, medical and veterinary sciences referred to in the previous paragraph shall be proposed by the universities, representatives of the scientific committees referred to in Article 8 of this Act by the committees, representatives of non-governmental organisations by the ministry responsible for the environmental protection on the basis of a public call according to a procedure that shall be provided by the minister responsible for environmental protection (hereinafter: minister).
(4) The commission shall elect from among its members a president of the commission and his deputy, and adopt standing orders on its method of work, which shall be put in force when the government has given its consent to it.
(5) The commission shall be independent and sovereign in its work, and its work shall be public.
(6) The ministry responsible for environmental protection (hereinafter: ministry) shall ensure coverage of the material costs and the technical and administrative work of the commission.

Article 7
(Duties of the commission)

The duties of the commission shall be:
1. monitoring conditions and development in the field of the use of genetic technologies and GMO management,
2. adopting positions and providing opinions and initiatives in connection with the use of gene technologies and GMO management and in relation to social, ethical, technical and technological, scientific and other aspects of GMO management,
3. advising to the government in connection with use of gene technology and GMO management,

4. enlightening and informing the general public about conditions and developments in the field of the use of genetic technologies and GMO management, about their positions and opinions and about their work, and
5. exchange data and experiences with related institutions abroad and cooperation with them.

Article 8
(Scientific committees)

In order to provide professional assistance to ministries responsible for deciding on GMO management, the government shall found a scientific committee for work with GMOs in contained use (hereinafter: committee for contained use) and a scientific committee for the deliberate release of GMOs into the environment and placing products on the market (hereinafter: committee for releasing GMOs).

Article 9
(Members of the committees)

(1) The committee for contained use shall consist of seven members who shall be experts from the field of microbiology, genetics, medicine, biochemistry and molecular biology, pharmacy, biotechnology and safety at work.
(2) The committee for releasing GMOs shall consist of seven members who shall be experts from the field of genetics, biology, agriculture, veterinary science, biochemistry and molecular biology, microbiology and medicine.
(3) Members of the committees referred to in the previous paragraphs, taking into account the expert system of assessment in science, shall be proposed by the ministry responsible for science, and appointed by the government for a period of four years.
(4) On the proposal of the ministry referred to in the previous paragraph, the government shall also appoint a deputy for each of the members of the committees, who should be an expert from the same field as the member who s/he replaces.
(5) The committee referred to in the first and second paragraphs of this Article may, in relation to the nature of the notification about which it is giving an expert opinion, invite to the discussion other experts from fields relevant to the discussion of the notification and preparation of an expert opinion.
(6) The government shall provide the method of operation of the two committees, the manner and form of providing expert opinions in procedures according to this Act, the manner and form of reporting of the committees and procedures for ensuring the exclusion of interest and protection of data which are confidential in accordance with this Act, in the work of the committees.

Article 10
(Duties of the committees)

(1) The duties of the committees referred to in Article 8 of this Act shall be:

1. providing expert opinions on GMO management in administrative procedures under this Act,
2. providing opinions and proposals in the preparation of regulations on GMO management,
3. providing opinions and proposals in other matters in connection with GMO management requested by competent ministries, and
4. cooperation with related institutions abroad.

(2) The committees referred to in Article 8 of this Act shall issue annual reports on their work in the past year, which they shall send to the government, and publish these in such a manner that they are accessible to the general public.
(3) The ministry shall provide coverage of material costs and technical and administrative work for both committees.

Article 11
(Exclusion of interest and data protection)

(1) Members of the committees referred to in Article 8 of this Act and their deputies may not be related, or associated in business or financial connected with notifiers about whose notifications the committee adopts an expert opinion in compliance with this Act.
(2) Members and their deputies referred to in the previous paragraph are bound during their term of office on the committee and after its expiry, to protect data which are defined as confidential in compliance with this Act.
(3) External experts and professionals who are invited to co-operate in the committees or co-operate in procedures of issuing permits under this Act are also bound to protect confidential data referred to in the previous paragraph.

Article 12
(Information to the public)

(1) Data on contained use, the deliberate release of GMOs into the environment and placing products on the market, and data on procedures and activities of ministries responsible for GMO management under this Act, shall be public in compliance with regulations in the field of environmental protection.
(2) Irrespective of the provision of the previous paragraph, competent ministries may not reveal to third persons data that are protected as confidential in compliance with this Act.

Article 13
(Subsidiary obligation of the state)

(1) In a case in which, in accordance with this Act, the state is responsible for guaranteeing measures for reducing or remedying the consequences of adverse effects caused by contained use, the deliberate release of GMOs into the

environment or placing products on the market, the ministry shall guarantee preparation and implementation of such measures.

(2) The ministry should inform the general public about the consequences and measures referred to in the previous paragraph, and through the ministry responsible for foreign affairs, subject to conditions of reciprocity being fulfilled, also the competent bodies of neighbouring countries, if the adverse effects could have consequences for the environment or human health in these countries.

II CONTAINED USE

Article 14
(Classes)

(1) Contained use should be classified into one of four classes, namely:
- class 1, if it is work in which the risk is negligible,
- class 2, if it is work in which there is low risk,
- class 3, if it is work in which the risk is moderate, or
- class 4, if it is work in which the risk is high.

(2) Classified contained use of GMO shall be treated in compliance with required containment and other safety measures and required provisions.

(3) The criteria to classify each contained use of GMO into a specific class, containment and other safety measures, rules of management and other conditions for individual class shall be specified in a separate regulation.

Article 15
(Notifications of premise)

(1) Contained use may only be performed in a premise in which the required conditions for the class into which the intended work is classified are fulfilled.

(2) Before the premise is used for the first time for contained use the notifier should submit a notification to the ministry.

(3) A notification of a premise should include in particular data on the notifier, the premise and the class of the intended contained use.

(4) The ministry shall verify the compliance of the notification with required provisions and after obtaining the prior expert opinion (hereinafter: opinion) of the committee for contained use shall enter the premise in the register of GMOs, and issue receipt of the entry to the notifier within 60 days of receiving the notification.

(5) The committee referred to in the previous paragraph should send a written opinion to the ministry within 30 days of the ministry sending a copy of the notification to them, otherwise the opinion shall be considered negative.

(6) Detailed contents of the notification referred to in the third paragraph of this Article shall be specified in a separate regulation.

Article 16
(Risk assessment)

(1) A notifier, prior to the commencement of contained use, should ensure an assessment of the risks of the intended work.
(2) In the risk assessment it is necessary on the basis of analysis of the characteristics of the GMO and the intended work with it and the environment which could be exposed to risk, to ascertain and evaluate in particular possible adverse effects, the level of risk and necessary containment and other safety measures. In particular, it is necessary to determine measures for waste management and effluent disposal from the premise.
(3) On the basis of the risk assessment, the notifier shall classify the contained use into one of the classes in compliance with Article 14 of this Act.
(4) If the notifier has doubts as to which class contained use should be classified it should be classified into the class with more stringent containment measures, and into the class with less stringent measures only with the agreement of the ministry.
(5) The notifier should retain the risk assessment until the completion of work with the GMO.
(6) During implementation of the contained use, the notifier should review the risk assessment at least once a year, and supplement it as necessary, especially from the point of view of the suitability of the containment and other measures in relation to the class and new scientific understandings, and inform the ministry of supplements if this concerns work with a GMO referred to in the second, third or fourth class.
(7) The elements and the extent of the risk assessment for contained use and the methodology for its production shall be specified in a separate regulation.

Article 17
(Emergency plan)

(1) A notifier, prior to the commencement of contained use should ensure an emergency plan in the event of an accident.
(2) The emergency plan should contain in particular:
    - an assessment of risk to the environment and human health and possible consequences in the event of an accident,
    - a statement of measures for removing the risk and immediate and delayed consequences of an accident,
    - a statement of persons and bodies who should be involved in implementing the anticipated measures, and
    - the manner and extent of providing information and warning competent bodies, services and the general population in the case of an accident.

(3) A notifier, prior to the start of contained use, is bound to acquaint with the emergency plan the ministry, the ministry responsible for civil protection and disaster relief, and competent services of the local community on the territory of which the contained use is being carried out, which should use the emergency

plan in the production of a risk assessment and plan of protection and rescue in compliance with the act on natural disasters.

(4) The notifier should verify the adequacy of the emergency plan at least once a year and supplement it as necessary, and inform the bodies and services referred to in the previous paragraph about supplements to the plan.

(5) Detailed contents and the extent of the emergency plan in relation to the class of the work, the methodology of its preparation, examining and supplementing and the manner and extent of informing and warning competent bodies, services and the general population in the event of an accident shall be specified in a separate regulation.

Article 18
(Confidentiality of data)

(1) A notifier may in a notification referred to in Articles 15, 21 or 22 of this Act specify data which are business and intellectual property rights which should be treated in the procedure as confidential, and the its verifiable justification should be given.

(2) A notifier may not in the notification determine as data referred to in the first paragraph of this Article:

1. the name and surname, business name, address and registered office of the notifier,
2. the site of contained use,
3. the general characteristics of the GMO.
4. the class of the contained use,
5. containment measures, and
6. data on possible adverse and other effects on the environment or human health.

(3) The ministry shall issue a decision within seven days after receiving a complete notification by which it decides which data from the notification will be protected as confidential in the procedure.

(4) If the ministry does not issue a decision referred to in the previous paragraph within the defined time limit, it shall be considered that it agrees with the specification of data referred to in the first paragraph of this Article.

(5) Data which are identified as confidential in compliance with the provisions of this Article shall remain protected as confidential even in a case in which the notifier withdraws his notification.

Article 19
(Consultation of and information to the public)

(1) In a procedure for issuing a permit for contained use referred to in the third or fourth class, the ministry should provide the general public with perusal of the notification and risk assessment referred to in the second paragraph of Article 22 of this Act and the opinion of the committee for contained use on the intended work, and a public hearing of the intended work.

(2) A public announcement containing a statement of the place and time for perusal and public hearing referred to in the previous paragraph and the manner of providing opinions and comments, shall be published in public media.
(3) The time limit in which the ministry shall guarantee perusal and the possibility of giving opinions and comments may be a minimum of 15 days and maximum of 30 days and shall not be counted in the time limit for the issue of a permit referred to in Article 22 of this Act.
(4) The ministry should also include in the reasoning of the decision on a permit a standpoint to the opinions and comments of the general public given within the framework of the public hearing and in the manner referred to in the second paragraph of this Article.
(5) The costs of the public hearing referred to in the first paragraph of this Article should be paid by the notifier.

Article 20
(Class 1 contained use)

(1) Class 1 contained use may be commenced without notification to the ministry if it is carried out in a premise for which receipt of compliance with Article 15 of this Act has been issued.
(2) A notifier should sent the risk assessment of the intended work referred to in the previous paragraph during implementation of the work, at the ministry's demand.

Article 21
(Class 2 contained use)

(1) Class 2 contained use which will take place in a premise for which a receipt has been issued in compliance with the provisions of Article 15 of this Act should be notified to the ministry.
(2) A notification of work referred to in the previous paragraph should include in particular data on the premise, the type and characteristics of the GMO, the duration and purpose of the work with them, envisaged containment and other safety measures, including measures of waste management and disposal of effluent, and measures in the event of an accident. Part of the notification should be a summary of the risk assessment for the intended work with the GMO.
(3) The notifier may commence work 45 days after submitting the notification, and previously at its request only with the permission of the ministry.
(4) The ministry may require within the time limit stated in the previous paragraph that the contained use does not begin and issue a decision on this.
(5) Without prejudice to the provisions of the third paragraph of this Article, the notifier may commence work immediately after submission of the notification if he has previously carried out work in the same premise with a GMO from the second or higher class and all the required conditions have been fulfilled. In such a case, the notifier may request that the ministry issue a permit for the intended work.

(6) The ministry should decide on a request referred to in the previous paragraph after obtaining the opinion of the committee for contained use not later than within 45 days after submission of the notification.
(7) The committee for contained use should communicate to the ministry a written opinion referred to in the fourth paragraph of this Article or the previous paragraph not later than in 21 days from the day on which a copy of the notification has been communicated to it, otherwise it shall be considered that the opinion is negative.
(8) Detailed contents of the notification for class 2 contained use shall be specified in a separate regulation.

Article 22
(Class 3 and 4 contained use)

(1) Class 3 and 4 contained use which will take place in a premise and for which a receipt has been issued in compliance with the provisions of Article 15 of this Act, a notifier should obtain a permit from the ministry.
(2) A notification for obtaining a permit referred to in the previous paragraph should include data determined in the second paragraph of the previous article, a description of the equipment of the premise and a summary of the notification. Part of the notification should be the risk assessment for the intended contained use and the emergency plan in the event of an accident.
(3) The ministry shall verify the compliance of the notification with the required provisions and after obtaining the opinion of the committee for contained use shall decide on the permit within 45 days after submission of the notification if class 3 or 4 contained use has already been carried out, for which a permit has been issued, and all the required conditions were fulfilled during the contained use.
(4) If it is not a case referred to in the previous paragraph, the ministry shall verify the compliance of the notification with required provisions and after obtaining the opinion of the committee for contained use shall decide on a permit within 90 days after submission of the notification.
(5) The committee for contained use should communicate to the ministry a written opinion in cases referred to in the third paragraph of this Article within 21 days, and in cases referred to in the previous article within 45 days from the day on which a copy of the notification has been submitted to it, otherwise it shall be considered that the opinion is negative.
(6) The ministry shall issue a permit referred to in the first paragraph of this Article for a maximum of the period for which the notifier has requested, and after the expiry of the validity of the permit the notifier may request its extension if all required conditions are fulfilled.
(7) Detailed contents of the notification for class 3 and 4 contained use shall be specified in a separate regulation.

Article 23
(Genetically modified vertebrates)

(1) Work for obtaining genetically modified vertebrates and work with them by means of interspecific hybridisation may only be carried out for research purposes.
(2) For work for obtaining genetically modified vertebrates and work with them in a contained use, the ministry shall issue a receipt referred to in Article 15 of this Act or a permit referred to in Articles 21 or 22 of this Act in agreement with the ministry responsible for veterinary sciences.
(3) Work referred to in the first paragraph of this Article should take place in compliance with regulations governing the protection of animals from torture.
(4) In terms of this Act, it shall be considered interspecific hybridisation if the identity of the species of the recipient organism is altered in relation to essential characteristics of its physical construction, its replication and its physiological functions and capacities.

Article 24
(Additional requirements)

(1) If the ministry, in the procedure of issuing a receipt referred to in Article 15 of this Act or a permit referred to in Articles 21 or 22 of this Act considers that for the decision additional data are required or for the sake of protection of the environment and human health it is necessary to alter the conditions of the intended work, or its classification in a class, the notifier may be required to supplement its notification within a specified time limit.
(2) If the notifier does not supplement its notification within the time limit referred to in the previous paragraph, the ministry shall by resolution terminate the procedure referred to in the previous paragraph.
(3) If the ministry on the basis of the class 2 contained use judges that for the sake of protection of the environment and human health it is necessary to change the conditions in which the contained use is carried out or the class assigned to the contained use, the notifier may be required by means of a decision that within a specified time limit the necessary changes are realised and that during this time the contained use is temporarily suspended until this is permitted on the basis of a new notification.
(4) If the ministry finds that for the sake of protection of the environment and human health it is necessary to change the conditions of class 1 contained use, it may by decision require of the notifier that it introduce the necessary changes within a specified time limit and that during that time it temporarily suspends work.
(5) The time limit for supplementing a notification referred to in the first paragraph of this Article shall not be counted within the time limit for the issue of a receipt referred to in Article 15 of this Act or a permit referred to in Articles 21 or 22 of this Act.

Article 25
(New information)

(1) If the notifier obtains new information about the contained use which he is performing, or modifies the contained use, and this could significantly effect the level of risk or classification of the contained use, he should submit a new notification to the ministry without delay if it concerns class 2 contained use, or request a permit if it concerns class 3 or 4 contained use.
(2) If the ministry itself obtains new information on contained use which is being carried out and could significantly effect the level of risk or classification of the contained use, it shall ex officio commence a procedure and require the notifier to alter the conditions of contained use in such a way that it takes place in compliance with new requirements.
(3) In cases referred to in the previous paragraphs, the ministry may require of the notifier the temporary suspension of contained use for the period until its decision on the compliance of the new notification with the requirements ordered.
(4) If on the basis of new information on contained use or about changes in the work, which could significantly effect the level of risk, the ministry finds that the contained use may no longer be carried out, it shall prohibit it.

Article 26
(Accident)

(1) A notifier should take measures in the event of an accident in accordance with the emergency plan and immediately notify the ministry about:
    1. the circumstances of the accident,
    2. the types and quantities of GMO which have entered the environment from the contained use,
    3. measures taken and required, and
    4. other data relevant to an assessment of the effects of the accident on the environment and human health.
(2) The ministry should notify the Information Centre of the Republic of Slovenia about the accident and, subject to the fulfilment of the condition of reciprocity, through the ministry responsible for foreign affairs also competent bodies of neighbouring countries if the accident could signify a risk to the environment or human health in these countries.
(3) The ministry should prepare a report on the accident and measures taken and their efficiency, not later than three months after the notification referred to in the first paragraph of this Article, which the government shall adopt and acquaint the public of it without delay.

III. DELIBERATE RELEASE OF GMOs INTO THE ENVIRONMENT

Article 27
(Deliberate release of a GMO)

(1) A notifier should obtain a permit from the ministry for the deliberate release of a GMO into the environment. The ministry shall issue such a permit with the agreement of the ministry responsible for agriculture, forestry and food.

(2) The deliberate release of a GMO into the environment should take place in compliance with regulations and conditions determined in the permit.
(3) Material obtained from a GMO which is the subject of deliberate release into the environment may be placed on the market only on the basis of a permit referred to in Article 38 of this Act.

Article 28
(Risk assessment)

(1) A notifier, prior to submitting a notification for obtaining a permit for the deliberate release of a GMO into the environment, should ensure an assessment of the risk that the intended deliberate release represents.
(2) In the risk assessment it is necessary on the basis of an analysis of the characteristics of the GMO and its intended deliberate release and of the associated environment and the environment which could be exposed to risk, ascertain and evaluate, in particular, possible adverse effects and their possible consequences, the level of risk and measures required for their control.
(3) The minister, in agreement with the minister responsible for agriculture, forestry and food, shall ensure the methodology, the elements, and extent of the assessment of risk of the deliberate release of the GMO into the environment.

Article 29
(Emergency plan in the event of unintended release)

(1) A notifier, prior to the commencement of the deliberate release of a GMO into the environment, should ensure an emergency plan in the event of an unanticipated spread of the GMO in the environment occurring.
(2) The emergency plan should contain in particular:
    1. the method of control of the GMO in the event of unintended release in the environment,
    2. assessment of possible consequences and threats to the environment and human health,
    3. measures required in the site of the deliberate release of the GMO, and
    4. measures required for the prevention of further spread and removal of the GMO and remediation of the unintended release to the exposed environment.
(3) A notifier should periodically verify the suitability of the plan referred to in the previous paragraph and, as necessary, supplement it, and notify the ministry about supplements to the plan.

Article 30
(Confidentiality of data on the deliberate release of a GMO)

(1) A notifier may in a notification referred to in Article 31 of this Act specify data which are business and intellectual property rights which shall be protected in the procedure as confidential, and the verifiable justification should be given.

(2) A notifier may not in the notification determine as data referred to in the previous paragraph:
1. the name and surname, business name, address and registered office of the notifier,
2. the general characteristics of the GMO,
3. the purpose of the deliberate release and intended use,
4. the place of the deliberate release of the GMO,
5. the programme of monitoring and emergency plan in the event of an unintended release of the GMO in the environment, and
6. data from the risk assessment for the intended work.

(3) The ministry shall issue a decision by which it decides which data from the notification shall be protected as confidential in the procedure, within seven days after receipt of the notification from the notifier.

(4) If the ministry does not issue a decision referred to in the previous paragraph within the defined time limit, it shall be considered that it agrees with the specification of data referred to in the first paragraph of this Article.

(5) Data specified as confidential in compliance with the provisions of this Article shall remain protected as confidential also in the event of the notifier withdrawing his notification.

Article 31
(Notification)

(1) The notification for obtaining a permit for the deliberate release of a GMO into the environment should contain:
1. technical documentation which shall consist in particular of:
   - data on the notifier, including data on the qualifications of personnel,
   - data on the GMO,
   - data on the conditions of the deliberate release and the receiving environment,
   - data on the interaction of the GMO and the environment,
   - programme of monitoring for ascertaining and monitoring the effects on the environment and human health,
   - data on the methods of control of the released GMO in the environment, waste management and emergency plan in the event of an unintended release of the GMO in the environment, and
   - a summary of the technical documentation;
2. the risk assessment of the deliberate release of the GMO, and
3. other data that the notifier believes are relevant.

(2) The notifier may refer in the notification also to data or results of the deliberate release of the GMO into the environment that another notifier has submitted to the ministry at any time previously in its notification, if such are not protected as confidential in compliance with this Act or if he has obtained the previous notifier's written consent for their use.

(3) A notifier may in the notification request a uniform permit for the deliberate release of the same GMO or combination of GMOs in various places for the same purpose within a specified time.
(4) Detailed contents of the notification shall be specified in a separate regulation in agreement with the minister responsible for agriculture, forestry and food.

Article 32
(Issue of a permit)

(1) The ministry shall verify compliance of the notification with required provisions and after obtaining the opinion of the committee for releasing GMOs, with the agreement of the ministry responsible for agriculture, forestry and food, shall decide on a permit for the deliberate release of a GMO into the environment, within 90 days of receiving the notification.
(2) The committee for releasing GMOs should communicate a written opinion to the ministry within 45 days of the day on which a copy of the notification was sent to them, otherwise it shall be considered that the opinion is negative.
(3) The ministry shall issue a permit for a maximum of the period for which the notifier has requested, and after the expiry of validity of the permit, the notifier may request its extension, provided all the required conditions are met.

Article 33
(Additional requirements)

(1) If the bodies in the procedure for issuing a permit referred to in Article 32 of this Act consider that additional data for their decision is needed, the ministry may require from the notifier that within a specified time limit he supplements his notification. In the request the ministry should also state the reasons for the necessity of such data.
(2) If the notifier does not supplement his notification in the time limit referred to in the previous paragraph, the ministry shall by decision terminate the procedure for issuing a permit.
(3) The time limit referred to in the first paragraph of this Article shall not be counted in the time limit for the issue of a permit referred to in Article 32 of this Act.

Article 34
(Consultation of and information to the public)

(1) In a procedure for issuing a permit under Article 32 of this Act, the ministry should provide the general public perusal of the technical documentation and risk assessment referred to in the first paragraph of Article 31 of this Act and the opinion of the committee for the release of GMOs on the intended deliberate release and a public hearing of the intended release.
(2) The public announcement, with a statement of the place and time for perusal and the public hearing referred to in the previous paragraph and the manner of giving opinions and comments, shall be published in the public media.

(3) The time limit in which the ministry shall provide perusal and the possibility of giving opinions and comments may be at least 15 days and at most 30 days and shall not be counted in the time limit for the issue of the permit referred to in Article 32 of this Act.
(4) The ministry should in the reasoning of the decision on the permit also include a position in regard to the opinions and comments of the general public provided within the framework of the public hearing and in the manner referred to in the second paragraph of this Article.
(5) The costs of public hearing referred to in the first paragraph of this Article shall be paid by the notifier.

Article 35
(New data)

(1) If the notifier, after submitting the notification referred to in the first paragraph of Article 31 of this Act and prior to the issue of the permit, obtains new data in connection with the intended deliberate release of the GMO into the environment which are relevant for the level of risk, he should inform the ministry without delay and submit a new notification.
(2) If after the issue of a permit for the deliberate release of a GMO into the environment the notifier obtains new data referred to in the previous paragraph, or during the deliberate release which he is carrying out there are any planned or unexpected changes relevant for the level of risk, the notifier should without delay:
    1. carry out the necessary measures for protecting the environment and human health.
    2. inform the ministry about the planned or unexpected changes or new data, and
    3. submit a new notification.
(3) If the bodies referred to in the first paragraph of Article 27 of this Act, after the issue of the permit for the deliberate release of a GMO into the environment themselves obtain new data or information about changes referred to in the previous paragraph, the ministry shall ex officio commence a procedure and require the notifier to change the conditions of the deliberate release of the GMO into the environment in such a way that it takes place in compliance with the new requirements.
(4) In a case referred to in the second or third paragraph of this Article, the ministry, in agreement with the ministry responsible for agriculture, forestry and food, shall require of the notifier that the deliberate release of the GMO into the environment be temporarily suspended until a decision on the compliance of the new notification with the requirements.
(5) If in a case referred to in the second or third paragraphs of this Article the bodies referred to in the previous paragraph find that, because of the new data or changes which significantly effect the level of risk, the deliberate release of the GMO into the environment may no longer be carried out, the ministry, with the agreement of the ministry responsible for agriculture, forestry and food, shall prohibit it.

(6) The ministry should inform the general public about new data and changes that have occurred after the issue of a permit for the deliberate release of a GMO into the environment and about decisions in connection with it.

Article 36
(Reporting)

(1) A notifier, not later than 60 days after the expiry of the period for which the ministry has permitted the deliberate release of a GMO into the environment, or within a time limit determined in the permit referred to in Article 32 of this Act, should communicate to the ministry a report on the results of the deliberate release of the GMO into the environment.
(2) The notifier should also state in the report referred to in the previous paragraph data on whether he intends to place on the market as a product any other material obtained from the GMO which was the subject of the deliberate release into the environment referred to in the previous paragraph.
(3) The extent and content of the report referred to in the first paragraph of this Article shall be specified in a separate regulation in agreement with the minister responsible for agriculture, forestry and food.

Article 37
(Unintended release of a GMO)

(1) A notifier, in the event of the unintended release of a GMO into the environment, should take measures in compliance with the emergency plan referred to in Article 29 of this Act and immediately notify the ministry about:
    1. the extent of the consequences of the unintended release of the GMO and threat to the environment and human health,
    2. measures taken and still required for protecting the environment and human health,
    3. measures taken and still required for reducing or remedying the consequences, removal of the GMO and remediation of the unintended release of the exposed environment, and
    4. other data relevant to an assessment of the effects of the unintended release of the GMO on the environment and human health.
(2) On the basis of the notification referred to in the previous paragraph, the ministry, in cooperation with competent ministries, shall guarantee preparation of an overall programme for the remediation of the consequences of the uncontrolled spread of the GMO into the environment, which the government shall adopt.
(3) In the programme referred to in the previous paragraph, on the basis of the assessment of how demanding it is, shall be determined in particular responsible bodies, conditions and measures for reducing or rectifying the consequences and preventing further uncontrolled spread of the GMO, time limits for their preparation and implementation, the manner of covering the costs and necessary restrictions or prohibitions in connection with further deliberate release of the GMO, its import, trade or use.

(4) The ministry should prepare a report on an event referred to in the first paragraph of this Article and on preparation and implementation of the programme referred to in the second paragraph of this Article, which the government shall adopt, and acquaint the general public with it without delay.
(5) The ministry, subject to the fulfilment of the condition of reciprocity, should also inform through the ministry responsible for foreign affairs, competent bodies of neighbouring countries if the uncontrolled spread of the GMO could signify a risk to the environment or human health in these countries.

IV. PLACING A PRODUCT ON THE MARKET

Article 38
(Placing a product on the market)

A notifier should obtain a permit from the ministry for placing a product on the market if it is a product that is being placed on the market for the first time. The permit shall be issued in agreement with the ministry responsible for health, and the ministry responsible for agriculture, forestry and food.

Article 39
(Risk assessment)

(1) Prior to submitting a notification for a permit for placing a product on the market, the notifier should assure an assessment of the risk which the intended placing of the product on the market represents.
(2) In the risk assessment it is necessary, on the basis of an analysis of the characteristics of the GMO, the product and its use and the environment in which the product will be used, to ascertain and evaluate in particular possible adverse effects on the environment and human health, the possible consequences of these effects, the level of risk and necessary measures for its control.
(3) The minister, in agreement with the minister responsible for health, and the minister responsible for agriculture, forestry and food, shall provide the elements and the extent of the assessment of the risk of placing a product on the market and the methodology of its production.

Article 40
(Confidentiality of data)

(1) The notifier may in a notification referred to in Articles 41 or 44 of this Act specify data which are business and intellectual property rights which should be protected in the procedure as confidential, and the verifiable justification should be given.
(2) A notifier may not in the notification determine as data referred to in the previous paragraph:
    1. the name and surname, business name, address and registered office of the notifier,

2. the intended method of use of the product and site of placing the product on the market and its use,
3. general characteristics of the product and the GMO which is in it,
4. the programme of monitoring in connection with placing the product on the market and its use and measures in the event of unanticipated risks during the placing of the product on the market and its use, and
5. the risk assessment.

(3) The ministry shall issue a decision within seven days after receipt of a complete notification from the notifier, by which it shall decide which data from the notification will be protected as confidential in the procedure.

(4) If the ministry does not issue the decision referred to in the previous paragraph within the required time limit, it shall be considered that it agrees with the specification of data referred to in the first paragraph of this Article.

(5) Data which are specified as confidential in compliance with the provisions of this Article shall remain protected even in the event of the notifier withdrawing his notification.

Article 41
(Notification)

(1) A notification for obtaining a permit for placing a product on the market should contain:

1. technical documentation, which shall consist of data specified in point 1 of the first paragraph of Article 31 of this Act, and data in particular on:
   - the proposed trade name of the product,
   - the manufacturer, importer or distributor who, in accordance with regulations is responsible for placing the product on the market,
   - persons who will provide control of samples and their dispatch to the competent body,
   - the intended use of the product,
2. the assessment of risk of the intended placing of the product on the market,
3. data on the conditions of placing the product on the market, including specific conditions of use of the product and handling with them,
4. the programme of monitoring the effects of the product and its use on the environment and human health, including the proposed period of its implementation,
5. proposal of the period for which the permit should be issued,
6. proposal for labelling the product in relation to the GMO content,
7. proposal for packaging the product, and
8. a summary of the content of the notification.

(2) If the notifier, on the basis of the results of a deliberate release of a GMO into the environment which has been carried out at any time previously in compliance with this Act, or on the basis of other well-founded scientific understandings, considers that placing a product on the market and its use does not represent any

risk, he may propose to the ministry that it specify a lesser extent of notification than that referred to in the previous paragraph, and the ministry shall issue a decision on this.

(3) A notifier may also include in the notification data on the results of the deliberate release of the same GMO or combination of GMOs as is in the product, into the environment, which has been or is notified and has been or is being carried out.

(4) A notifier may also refer in the notification to data or results which another notifier has at any time previously submitted to the ministry in its notification, provided such are not protected as confidential in compliance with this Act, or provided that he has obtained their written consent for their use.

(5) A notifier should submit a new notification for obtaining a permit for placing a product on the market for each intended use of a product which is different from the permitted use.

(6) The contents of the notification for placing a product on the market and data which shall not be part of the notification in a case referred to in the second paragraph of this Article shall be specified in a separate regulation in agreement with the minister responsible for agriculture, forestry and food.

Article 42
(Assessment report of a product)

(1) The ministry shall verify compliance of the notification with required provisions and, after obtaining the opinion of the committee for releasing GMOs, in cooperation with the ministries referred to in Article 43 of this Act shall prepare an assessment report of the product for placing on the market and its use (hereinafter: assessment report) from which it should be evident that the product is:
- suitable for placing on the market,
- suitable for placing on the market under specified additional conditions, or
- unsuitable for placing on the market.

(2) The committee for releasing GMOs should communicate the written opinion referred to in the previous paragraph not later than 45 days from the day on which a copy of the notification has been communicated to them, otherwise it shall be considered that the opinion is negative.

(3) The ministry shall send the assessment report to the notifier not later than 60 days after receipt of the notification.

(4) The notifier may within seven days of receipt of the assessment report withdraw its notification for obtaining a permit for placing a product on the market or inform the ministry in writing that it intends to supplement its notification if it follows from the report that the product is suitable for placing on the market under specified additional conditions.

(5) If the notifier does not inform the ministry in writing of the intention to supplement its notification when it follows from the report that the product is suitable for placing on the market under specified additional conditions, its shall be considered that the notification has been withdrawn.

(6) If the notifier withdraws the notification within the time limit referred to in the fourth paragraph of this Article or behaves in accordance with the provisions of the previous paragraph, the ministry shall terminate the procedure by resolution.
(7) There shall be no appeal against a resolution referred to in the previous paragraph.
(8) If the notifier within the time limit referred to in the fourth paragraph of this Article informs the ministry in writing that he intends to supplement his notification, the ministry shall determine a time limit in which the supplement should be communicated. The time limit for supplementing shall not be counted in the time limit for issuing a permit referred to in Article 43 of this Act.
(9) The extent and elements of the assessment report shall be specified in a separate regulation.

Article 43
(Permit for placing a product on the market)

(1) Provided it does not concern a case referred to in the sixth paragraph of the previous article, the ministry, in agreement with the ministry responsible for health and the ministry responsible for agriculture, forestry and food, shall decide on the permit for placing a product on the market within 105 days after receiving the notification.
(2) The notifier may only place the product on the market in the way and under the conditions that are required and specified in the permit.
(3) The permit for placing a product on the market may be issued for a maximum of 10 years, with the possibility of extension in accordance with the provisions of this Act.
(4) If the products are materials for replication in forestry activities or seed, the permit referred to in the first paragraph of this Act shall be issued for a maximum of 10 years from the day of entry in the national sort register in compliance with regulations.

Article 44
(Extending a permit)

(1) A notifier who intends to request an extension of a permit for placing a product on the market should, not later than nine months before the expiry of its validity, submit a notification to the ministry for extending the permit, which shall contain in particular:
    1. a copy of the permit for placing a product on the market which he wishes to extend,
    2. the report on monitoring referred to in Article 49 of this Act,
    3. new information on risks that the product and its use may represent, if such is available to him, and
    4. a proposal for amendments and supplements to conditions specified in connection with placing the product on the market in the original permit, in particular in relation to implementing monitoring and time limitations on the validity of the permit, if these are relevant.

(2) The provisions of Article 42 of this Act shall be used for the procedure of issuing a decision on extending a permit for placing a product on the market.
(3) If it does not concern a case referred to in the sixth paragraph of Article 42 of this Act, the ministry, in agreement with the ministries referred to in the previous article, shall decide on the extension of the permit for placing a product on the market within 90 days of receipt of the notification.
(4) A permit may be extended one or more times if all the conditions for this are fulfilled, each time for a maximum of ten years.

Article 45
(Content of a permit)

(1) The following shall be specified in a permit for placing a product on the market:
1. the purpose and extent for which the permit has been issued, including data and marks for identification of the product and GMOs in it and on their properties,
2. the period of validity of the permit,
3. conditions for placing the product on the market, including specific conditions for use of the product, handling with it and its packaging and conditions for protecting specific ecosystems, parts of the environment or geographic areas,
4. the obligation of the notifier to send to the competent ministry at its request control samples of the product,
5. requirements for labelling the product in relation to GMO content,
6. requirements for implementing monitoring, including specification of the period of their implementation and obligations of the notifier to report to competent ministries on the results of monitoring, and
7. possible other obligations of persons who sell or use the product.

(2) Permits, except for data that are protected as confidential in compliance with this Act, and the risk assessment referred to in Article 39 of this Act should be available to the general public in accordance with regulations in the area of environmental protection.

Article 46
(Consultation to the public)

(1) Whenever it is evident from the assessment report that the product is suitable for placing on the market, the ministry should in the procedure of issuing the permit for placing a product on the market or its extension, guarantee the general public perusal of the notification, the opinion of the committee for releasing GMOs and the assessment report.
(2) The public announcement, with a statement of the time and place for perusal referred to in the previous paragraph and on the way of providing opinions and comments, shall be published in the public media.
(3) The time limit in which the ministry shall provide perusal and the opportunity to provide opinions and comments may be at least 15 days and at most 30 days and

shall not be counted within the time limit for issuing a permit referred to in Article 43 of this Act or extending a permit under Article 44 of this Act.

(4) The ministry should also include a standpoint to opinions and comments given by the general public in the reasoning of its decision referred to in the previous paragraph.

Article 47
(Informing the public)

(1) The ministry should immediately inform the general public through the ministry responsible for consumer protection about the issue of a permit for placing a product on the market or its extension, or that the issue or extension of a permit has been refused.
(2) In the information about the issuing or extension of a permit referred to in the previous paragraph should be stated which GMOs or their combination the product contains or from which it is composed and for what use the product is intended.

Article 48
(New information)

(1) If the notifier, after submitting the notification referred to in Articles 41 or 44 of this Act and prior to the issue of the permit, obtains new information in connection with the risk that placing the product on the market or its use represents, he should inform the ministry of this without delay and submit a new notification.
(2) If the notifier obtains new information referred to in the previous paragraph from users or in another way after obtaining a permit for placing the product on the market, he should without delay:
    - take the necessary measures for protecting the environment and human health,
    - inform the ministry about the new information and changed conditions, and
    - submit a new notification.
(3) If the ministry obtains new information in connection with risk that placing a product on the market or its use represents prior to the issue of a permit for placing the product on the market, it should take this into account in deciding on the permit.
(4) If the ministry obtains new information referred to in the previous paragraph after the issue of a permit for placing a product on the market, it may ex officio commence a procedure and require the notifier to change the conditions of placing the product on the market in such a way that it takes place in accordance with new requirements.
(5) The ministry, in agreement with the ministries referred to in Article 43 of this Act shall issue a new permit for placing a product on the market within 90 days of obtaining the notification on changed conditions in accordance with new

requirements, by which it supplements the existing, or shall annul the valid permit if it finds that because of the changed conditions the product may no longer be placed on the market.

(6) For the procedure of issuing a permit or its annulment referred to in the previous paragraph, the provisions of Articles 42, 46 and 47 of this Act shall be used.

Article 49
(Monitoring)

(1) A notifier who places a product on the market should ensure implementation of monitoring of the effects of the product and its use on the environment and human health in accordance with its programme and regularly report to the ministry on the results of monitoring, in compliance with the permit referred to in Article 45 of this Act.
(2) The ministry may on the basis of data referred to in the first report on the results of monitoring, require of the notifier that the programme of monitoring specified in the permit be altered or supplemented.
(3) Data from the report on the results of monitoring shall be public in accordance with regulations on environmental protection.
(4) The contents and extent of the programme of monitoring and the manner and extent of reporting referred to in the first paragraph of this Article shall be specified in a separate regulation in agreement with the minister responsible for health and the minister responsible for agriculture, forestry and food.

Article 50
(Labelling products)

(1) A notifier may only place on the market a product that states on the packaging or in the declaration data that it contains or consists of a GMO, and other required data in connection with the product and its use.
(2) The labelling on packaging or in the declaration should also contain in a visible place the words: »This product contains a genetically modified organism«.
(3) The extent of data on the packaging or in the declaration of the product and requirements for packaging the product shall be specified in a separate regulation in agreement with the minister responsible for health and the minister responsible for agriculture, forestry and food.

Article 51
(Labelling GMOs)

GMOs that are made available to third persons for contained use or for deliberate release into the environment should also be labelled in the manner specified in the previous article, but making available in such a way shall not be considered placing on the market in accordance with point 12 of Article 4 of this Act.

V. IMPORT AND EXPORT OF GMOs AND PRODUCTS

Article 52
(Import of GMOs)

(1) Import of GMOs or products shall only be permitted if, prior to the import, a permit for contained use, for deliberate release into the environment or placing a product on the market has been issued for the GMOs or products that are the subject of import, in compliance with this Act.
(2) Irrespective of the provision of the previous paragraph, the import of a GMO for contained use, classified in the class 1 or 2 shall be permitted if, prior to the import, a receipt has been obtained of entry of the premise in the GMO register referred to in Article 15 of this Act.
(3) Compulsory management and other conditions in connection with the import of GMOs or products shall be specified in a separate regulation.

Article 53
(Export of GMOs and products)

Compulsory management and other conditions in connection with the export of GMOs or products shall be specified in a separate regulation.

VI. GMO REGISTER

Article 54
(GMO register)

(1) The GMO register shall consist of records of premise, contained use, deliberate releases of GMOs into the environment and placings of products on the market.
(2) Records referred to in the previous paragraph shall contain in particular data on:
    1. business names and registered offices or addresses of notifiers for:
        - contained use,
        - deliberate release of GMOs into the environment, or
        - placing a product on the market,
    2. addresses and properties of the premise
    3. contained use and its classification,
    4. deliberate releases of GMOs into the environment, including an exact description of the location of release, and
    5. products and their placement on the market, including a description of the site in which the product is placed on the market.
(3) An integral part of the register shall be receipts and permits issued for premises, contained use, deliberate release into the environment and for placing products on the market.
(4) The GMO register shall be kept by the ministry as a public document.
(5) Anyone shall have the right to peruse the data from the GMO register and request and obtain an extract from the GMO register against payment of the costs, which may not exceed the material costs of communicating the data.

(6) Data which in compliance with this Act are protected as confidential may not be entered in the records referred to in the first paragraph of this Article.
(7) The form and manner of keeping the register and the manner of determining the material costs of communicating data shall be specified in a separate regulation.

VII. SUPERVISION

Article 55
(Inspection supervision)

(1) Inspection supervision of the implementation of the provisions of this Act and regulations issued on its basis shall be performed by the Inspectorate of the Republic of Slovenia for the Environment and Spatial Planning, the Health Inspectorate of the Republic of Slovenia, the Inspectorate of the Republic of Slovenia for Agriculture, Forestry, Hunting and Fishing, the Inspectorate of the Republic of Slovenia for Quality Control of Agricultural Products and Foodstuffs, the Office for Inspection Supervision within the Veterinary Administration of the Republic of Slovenia, the Inspectorate of the Republic of Slovenia for Safety at Work and the Market Inspectorate of the Republic of Slovenia, each in accordance with its competencies.
(2) Supervision referred to in the previous paragraph shall cover in particular:
    1. supervision of the implementation of contained use,
    2. supervision of the implementation of deliberate releases of GMOs into the environment,
    3. supervision of placing products on the market,
    4. supervision of the implementation of regulations or measures ordered for preventing possible adverse effects and prohibitions ordered in this connection.
(3) If an inspector during the performance of his work or on the basis of a notification establishes that because of unfulfilled required conditions and requirements, the environment or human health are at risk because of possible adverse effects, he may order the following measures:
    1. prohibit contained use, deliberate release of a GMO into the environment or placing a product on the market,
    2. order the temporary suspension of contained use, the deliberate release of GMOs into the environment or placing a product on the market,
    3. order the rectifying of established irregularities within a time limit that he specifies, and
    4. order remediation and other measures for rectifying or reducing the consequences of adverse effect that have occurred because of GMO management.

VIII. PENALTY PROVISIONS

Article 56
(Violations)

(1) A legal person shall be fined from 300,000 to 30,000,000 tolars for a violation, if:

1. during contained use, it does not ensure the required containment and other safety measures and does not behave in compliance with required provisions in relation to the classification (second paragraph of Article 14),
2. it operates a premise without a receipt from the ministry on entry of the premise in the GMO register (fourth paragraph of Article 15).
3. it does dot retain the risk assessment until the conclusion of work with a GMO or does not inform the ministry of a supplementary assessment if it concerns work in the class 2, 3 or 4 (fifth and sixth paragraphs of Article 16)
4. it does not ensure production of a emergency plan in the event of an accident or does not acquaint the competent ministries and competent services of local communities with it or its supplements (Article 17),
5. it performs work with a GMO from the contained use class 1 without receipt on entry of the premise in the GMO register (first paragraph of Article 20),
6. it does not communicate the risk assessment for contained use to the ministry at its request (second paragraph of Article 20),
7. it performs work with GMOs classified in the class 2 without notification or starts to implement it prior to the expiry of the legally specified time limit or without permission of the ministry or in conflict with a decision on a prohibition of work (first, third and fourth paragraphs of Article 21),
8. it performs work with a GMO classified in the class 3 or 4 without a permit or in conflict with a permit (first paragraph of Article 22),
9. it performs work for obtaining genetically modified vertebrates or work with them without a permit or in conflict with a permit (first paragraph of Article 23),
10. it acts in conflict with the provisions of Article 24,
11. it acts in conflict with the provisions of Article 25,
12. in the event of an accident it does not take measures in accordance with the emergency plan or does not immediately inform the ministry about an accident (Article 26),
13. it deliberately releases a GMO into the environment without a permit or in conflict with a permit (first and third paragraphs of Article 27),
14. it does not ensure the production of an emergency plan in the event of unintended release of a GMO (Article 29),
15. it acts in conflict with the provisions of Article 35 of this Act,
16. it does not communicate to the ministry the report on results of the deliberate release of a GMO into the environment within the required or specified time limits (first paragraph of Article 36),
17. in the event of unintended release of a GMO in the environment it does not take measures in accordance with the emergency plan and does not immediately inform the ministry about the event (first paragraph of Article 37),

18. it places a product on the market without a permit or in conflict with a permit (Article 38 and second paragraph of Article 43)
19. it does not submit a notification for the extension of a permit for placing a product on the market within the required time limit (first paragraph of Article 44),
20. it acts in conflict with the provisions of Article 48 of this Act,
21. it does not carry out monitoring of the effects of a product and its use on the environment and human health or does not report to the ministry on the results of monitoring (first paragraph of Article 49).
22. it places on the market a product which is not labelled or packaged in the required manner (Article 50),
23. it provides a GMO to a third person for contained use or for deliberate release in conflict with Article 51 of this Act, and
24. it imports a GMO or product in conflict with the provisions of the first and second paragraphs of Article 52 of this Act.

(2) An individual who commits an act referred to in the previous paragraph in connection with the independent performance of activities shall be fined from 75,000 to 15,000,000 tolars for a violation.

(3) The responsible person of a legal person which commits an act referred to in the first paragraph of this Article shall be fined from 30,000 to 1,500,000 tolars for a violation.

(4) A natural person who, as member of a scientific committee does not protect data which are specified as confidential in compliance with this Act shall be fined from 3,000 to 450,000 tolars (second paragraph of Article 11).

IX. TRANSITIONAL AND FINAL PROVISIONS

Article 57
(Government regulations)

(1) The government shall, within nine months of this Act entering into force, provide:

1. the manner of operation of the committees, the manner and form of providing professional opinions, the manner and form of reporting of the committees and the procedure for ensuring the exclusion of interest and protection of data (sixth paragraph of Article 9),
2. standards for classifying contained use into classes, containment and other safety measures, rules of management and other conditions for individual classes (third paragraph of Article 14),
3. the extent and elements of the assessment report (ninth paragraph of Article 42),
4. compulsory management and other conditions in connection with the import of GMOs or products (third paragraph of Article 52), and
5. compulsory management and other conditions in connection with exports of GMOs or products (Article 53).

(2) Within three months after this Act enters into force, the government shall ensure the founding of the commission for GMO management(Article 5) referred to in point 1 of the first paragraph of Article 58 of this Act.
(3) Within three months after this Act enters into force, the government shall found the committee for contained use and the committee for release of GMOs (Article 8) referred to in point 1 of the first paragraph of this Article.

Article 58
(Ministerial regulations)

(1) Not later than nine months after this Act enters into force, the minister shall provide:
    1. the procedure for determining the proposal of representatives of non-government organisations as members of the commission (third paragraph of Article 6),
    2. the elements and extent of the risk assessment for contained use and the methodology for its production (seventh paragraph of Article 16),
    3. more detailed content and extent of the emergency plan in the event of accident, the methodology of its production, examining and supplementing and the manner and extent of provided information in the event of accident (fifth paragraph of Article 17),
    4. more detailed contents of the notification:
        – for a premise (sixth paragraph of Article 15),
        – for the class 2 contained use (eighth paragraph of Article 21),
        – for obtaining a permit for class 3 and 4 contained use (seventh paragraph of Article 22),
    5. more detailed form and manner of keeping the GMO register and the manner of defining material costs for communicating data (seventh paragraph of Article 54).
(2) The minister, in agreement with competent ministers and in the time limit referred to in the previous paragraph shall provide:
    1. the elements and extent of the risk assessment for deliberate release of a GMO into the environment and for placing a product on the market and the methodology of their production (third paragraph of Article 28 and third paragraph of Article 39),
    2. more detailed content of the notification:
        - for obtaining a permit for the deliberate release of a GMO into the environment (fourth paragraph of Article 31),
        - for obtaining a permit for placing a product on the market (sixth paragraph of Article 41),
    3. the extent and more detailed content of the report on the results of the deliberate release of a GMO into the environment (third paragraph of Article 36),
    4. the content and extent of the programme of monitoring and the manner and extent of reporting (fourth paragraph of Article 49), and

5. the more detailed extent of data on packaging and in the declaration of a product and requirements for packaging a product (third paragraph of Article 50).

Article 59
(Commission)

Until the appointment of the commission referred to in Article 5 of this Act, its duties will be performed by the Inter-ministerial Sub-commission for Biotechnology, which was founded by resolution of the government of 5.8.1997.

Article 60
(Prohibition)

GMOs which are placed on the market after 31 December 2004 may no longer contain marker genes for resistance to antibiotics used in human and veterinary medicine, and GMOs that are deliberately released into the environment may no longer contain them after 31 December 2008.

Article 61
(Foodstuffs)

(1) Irrespective of the provisions of the fourth paragraph of Article 2 of this Act, until regulations on specific requirements that new foodstuffs should fulfil before being placed on the market enter into force, the provisions of this Act relating to placing products on the market and to import and export of GMOs and products shall also be used for foodstuffs, which are GMOs or their combinations or consist of or contain them.
(2) In cases referred to in the previous paragraph, the ministry responsible for health in agreement with the ministry and the ministry responsible for agriculture, forestry and food shall decide on a permit referred to in Article 43 and 44 of this Act.

Article 62
(Products from EU territories)

(1) The ministry may, in agreement with the ministries specified in Article 43 of this Act, in a procedure for the issue of a permit for placing a product on the market may by decision recognise for a notifier the validity of documents by which he has obtained a permit for placing a product on the market in the area of the European Union, if these documents are such in their specified conditions in relation to use of the product and the characteristics of the environment that they also correspond to conditions in Slovenia.
(2) The decision referred to in the previous paragraph shall replace the permit for placing a product on the market under this Act.

(3) In the decision referred to in the previous paragraph shall also be specified the conditions for implementing the programme of monitoring and reporting in accordance with Article 49 of this Act.
(4) Irrespective of the provisions of the first paragraph of this Article, the ministry may, in agreement with the ministries specified in Article 43 of this Act, temporarily restrict or prohibit placing a product referred to in the first paragraph of this Article on the market if, on the basis of information about new or additional scientifically based data, it finds that the product or its use may signify a risk which was not taken into account in the issue of the permit referred to in the first paragraph of this Article.
(5) In a case referred to in the previous paragraph, the competent body shall inform the competent body of the European Union about its decision.

Article 63
(Harmonising obligations in the import of GMOs)

The provisions of this Act relating to the import of GMOs or products shall commence to be used within the time limit defined in the regulations referred to in the third paragraph of Article 52 of this Act.

Article 64
(Adapting activities)

(1) A legal and natural person who on the day that this Act enters into force is working with a GMO in a premise should submit a notification of GMO management in compliance with this Act within six months of the regulations referred to in Articles 57 and 58 of this Act relating to contained use, entering into force.
(2) A legal or natural person who on the day that this Act enters into force is deliberately releasing a GMO into the environment should submit a notification for GMO management in compliance with this Act within six months of the regulations referred to in the first and second points of the second paragraph of Article 58 of this Act relating to the deliberate release of a GMO into the environment, entering into force.
(3) A legal or natural person who on the day that this Act enters into force is placing a product on the market should submit a notification for GMO management in compliance with this Act within six months of the regulations referred to in Articles 57 and 58 of this Act relating to placing products on the market, entering into force.

Article 65
(Commencement of validity)

This act shall enter into force fifteen days after promulgation in the Official gazette of the Republic of Slovenia.