THE CROATIAN PARLIAMENT

1372

Pursuant to Article 88 of the Constitution of the Republic of Croatia, I hereby pass the

DECISION

PROMULGATING THE ACT ON GENETICALLY MODIFIED ORGANISMS

I hereby promulgate the Act on Genetically Modified Organisms, adopted by the Croatian Parliament at its session on 20 May 2005.

No: 01-081-05-1990/2
Zagreb, 27 May 2005

The President of the Republic of Croatia
Stjepan Mesić, m.p.

ACT

ON GENETICALLY MODIFIED ORGANISMS

I GENERAL PROVISIONS

Article 1

This Act regulates the handling of genetically modified organisms (hereinafter: GMOs), products containing and/or consisting of, or originating from GMOs, contained use of GMOs, deliberate release of GMOs into the environment, placing on the market of GMOs and products containing and/or consisting of, or originating from GMOs, handling, transportation and packaging of GMOs, managing waste resulting from using GMOs, liability for damage caused by unauthorised use of GMOs, competent authorities for implementation of this Act, and performing administrative and inspection supervision over the implementation of this Act.

Article 2

The terms used for the purpose of this Act have the following meanings:

– biological diversity means the entirety of all living organisms that are constituent parts of ecosystems and includes the diversity within species, between species and of ecosystems,

– genetic material means a part of a plant, animal, fungus, microorganism or virus, which contains hereditary information,

– genetic modification means the intentional change in the hereditary genetic material of an organism in a manner that cannot be achieved by a natural recombination and induction of mutations, or introduction of foreign hereditary genetic material into the hereditary genetic material of an organism, or removal of a part of the hereditary genetic material of an organism; genetic modification occurs through application of the following methods:

– 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, while for in vitro fertilisation, natural processes such as conjugation, transduction, transformation, polyploidy induction it is believed they do not lead to genetic modification, on the condition that they do not involve the use of recombinant nucleic acids molecules or genetically modified organisms other than those produced by techniques/methods that this Act is not applicable to.

– genetic diversity means the entirety of genes of all living organisms and their diversity among specimens, populations, species and higher taxonomic categories,

– genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;

– user means any legal or physical person who imports, places on the market, uses or produces GMOs or products,

–living modified organism means any GMO capable of replication or of transferring genetic material, including sterile organisms capable for growth,

– competent authority means the state administration body determined pursuant to the provisions of this Act,

– deliberate release of GMOs into the environment means any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment,

– unintended release of GMOs into the environment means accidental release of living modified organisms into the environment due to unforeseen events, accidents, inappropriate handling or storing of living modified organisms and other activities,

– contained use of GMOs means any use in the course of which GMOs are cultured, reproduced, stored, transported, destroyed, or disposed of, or in any other way used in a closed system, or in space for which physical barriers, or a combination of physical barriers together with chemical and/or biological barriers are used to limit their contact with the environment or their impact on it,

– notifier who submits the notification for using, introducing and placing GMOs on the market means any physical or legal person who intends to, or performs, contained use of GMOs, intends to, or deliberately releases GMOs into the environment, or intends to, or places, these products on the market,

– monitoring means planned and systematic monitoring and supervision of GMOs and the receiving environment, contained use of GMOs, procedures for deliberate release of GMOs into the environment, and placing on the market GMOs and products containing and/or consisting of, or originating from GMOs, and possible adverse effects, pursuant to regulations,

– cross-border movement of GMOs means import or export of GMOs or products containing and/or consisting of, or originating from GMOs,

– notification means the application that contains the prescribed information, that the notifier submits to the competent authority in order to obtain consent or certificate,

– environmental risk assessment means determining and evaluating hazards to biological diversity, or to human health that may occur due to contained use of GMOs, deliberate release into the environment or placing on the market, for each specific case,

– GMO product means a preparation consisting of and/or containing one or more GMOs, regardless of the degree it was treated, which is intended for placing on the market,

– transit of living modified organisms means any transport of GMOs intended for a user in a another country, which passes across the territory of the Republic of Croatia,

– placing GMOs and products on the market means to make GMOs and products available to third parties, whether in return for payment, or free of charge,

– closed system means a laboratory or a production department, or other space isolated from the environment in which GMOs are handled.

Article 3

For the implementation of this Act, performing expert, administrative and inspection activities, in case of GMO and/or products containing and/or consisting of, or originating from GMOs:

– contained use in closed system: the competent authority is the central state administration body responsible for science,

– deliberate release into the environment: the competent authority is the central state administration body responsible for nature protection,

– placing on the market:

a) as food: the competent authority is the central state administration body responsible for health;

b) as food for animals: the competent authority is the central state administration body responsible for agriculture, fishery and veterinary medicine,

c) as reproductive material in agriculture, forestry and veterinary medicine: the competent authority is the central state administration body responsible for agriculture, forestry and veterinary medicine,

d) as medicine in veterinary medicine and substances for protection of plants: the competent authority is the central state administration body responsible for agriculture, forestry and veterinary medicine,

e) inspection supervision of the labelling of GMOs and/or products containing and/or consisting of, or originating from GMOs is under the competence of the State Inspector's Office.

In handling cases referred to in paragraph 1 subparagraphs 1, 2 and 3 items b, c and d of this Article, the competent authorities shall obtain prior approval from the central state administration body responsible for health.

For using GMOs and/or products containing and/or consisting of, or originating from GMOs in cosmetics, pharmacy and health services for people: the competent authority is the central state administration body for health.

Article 4

For deliberate release of GMOs and/or products containing and/or consisting of, or originating from GMOs into the environment, the competent authority referred to in Article 3 paragraph 1 subparagraph 2 of this Act, shall obtain approval from the central state administration body responsible for agriculture and forestry.

Provisions of the Food Act shall apply to placing food or animal food on the market that is a GMO and/or contains and/or consists of or originates from GMOs. If the food is a living GMO or contains living GMOs, the state administration body competent pursuant to the Food

Act shall obtain approval from the central state administration body responsible for nature protection.

Scientific and expert bodies established pursuant to this Act shall be in charge of providing expert support to the competent administrative bodies in the implementation of this Act, and the central and coordinating body for performing expert activities related to GMOs shall be the central state administration body responsible for health.

Article 5

The provisions of the Food Act shall apply to import, transit, placing on the market, use and production of food and animal food containing and/or consisting of, or originating from GMOs, which is not regulated by this Act,

Provisions of this Act shall apply to import, transit, placing on the market, use and production of medicine containing and/or consisting of, or originating from GMOs, only when it is explicitly prescribed.

Provisions of this Act shall not apply to mutagenesis and cell fusion (including protoplast fusion) of the plant cells of organisms that can exchange genetic material through traditional breeding methods, under the condition that these techniques/methods of genetic modification do not include the use of recombinant nucleic acid molecules or genetically modified organisms different from those produced with one or more techniques/methods.

In the cases referred to in paragraphs 1 and 2 of this Article it is obligatory to draw up the accompanying technical documentation with notifications, risk assessments, and plan for monitoring the effects on the environment pursuant to this Act.

Article 6

An appeal shall not be allowed against the administrative acts brought pursuant to this Act by the central bodies of state administration referred to in Article 3 of this Act, but an administrative procedure may be initiated.

II GENETICALLY MODIFIED ORGANISMS

Article 7

Cross-border movement, transit, contained use, deliberate release into the environment and placing on the market of GMOs and products containing and/or consisting of, or originating from GMOs (hereinafter: use of GMOs) shall be allowed under conditions and in the manner prescribed by this Act and special regulations.

Approval to use GMOs shall be issued by a decision of the competent authority referred to in Article 3 of this Act.

Detailed content and method of submitting the notification and method to protect confidentiality of information contained in the notification, and the procedure for issuing the approval pursuant to paragraph 2 of this Article shall be prescribed by ordinance by the head of the competent authority.

Article 8

Approval to use GMOs determines the work method and safety measures, allowed techniques and allowed genetic modifications.

In case of uncontrolled use or release into the environment of GMOs and products containing and/or consisting of, or originating from GMOs, the head of the competent authority shall issue an order to determine the appropriate safety and security measures.

Article 9

Use of GMOs shall be carried out in such a way that prevents or decreases to the lowest degree possible the hazard to biological diversity, while taking into account the hazards for human health and environment.

The appropriate protection measures for the purpose of safe use of GMOs shall be ensured and implemented, while taking into account the hazards for human health and environment, in order to prevent adverse effects on preserving and sustainably using biological diversity.

Article 10

Laboratory for examining, controlling and monitoring GMO and products containing and/or consisting of, or originating from GMOs is authorised by the central state administration body responsible for health, if it meets the requirements referred to in paragraph 2 of this Article.

The requirements that have to be met by the laboratory referred to in paragraph 1 of this Article shall be prescribed by ordinance by the head of the central state administration body responsible for health, subject to the approval of the head of the central state administration body responsible for nature protection, environmental protection, agriculture and forestry.

Article 11

Information on the use of GMOs and information on procedures under the governance of the competent authority pursuant to this Act, shall be public pursuant to this Act and other regulations.

Cross-boundary movement of genetically modified organisms

Article 12

Import of GMOs or products containing and/or consisting of, or originating from GMOs is allowed if prior to import of GMOs or products containing and/or consisting of, or originating from GMOs approval was issued by the competent authority for contained use of GMOs, or for deliberate release into the environment or placing on the market of GMOs or products containing and/or consisting of, or originating from GMOs, pursuant to the provisions of this Act and special regulations.

Import for the purpose of contained use of GMOs classified within the first or second level of hazard is allowed if prior to import a certificate on the registration of the closed system into the GMO register referred to in Article 15 paragraph 4 of this Act was obtained.

Article 13

The Government of the Republic of Croatia shall at the proposal of a competent authority temporarily or permanently limit or ban import and use of GMOs or products containing and/or consisting of, or originating from GMOs in case there is lack of scientific information and knowledge on the possible scope of adverse consequences on biological diversity, environment and/or human health, or if there are new or additional scientifically based information that shows the product may present a hazard for biological diversity, environment and/or human health.

Contained use of GMOs

Article 14

Contained use of GMOs shall be classified into one of the four groups according to the level of hazard:

- the first level of hazard relates to a contained use involving a negligible risk;

- the second level of hazard relates to a contained use involving a low degree of risk;

- the third level of hazard relates to a contained use involving considerable risks; and

- the fourth level of hazard relates to a contained use involving high risks.

The classification of the contained use of GMOs into a specific level of hazard shall be carried out taking into account compliance with the prescribed safety measures and prescribed requirements.

The competent authority shall prescribe the criteria for classification of the contained use into levels of hazard, standards for facilities in closed systems, prevention and other precautionary measures, the method of handling and other conditions for a specific level of hazard.

Article 15

Contained use of GMOs shall take place in a closed system that meets all the conditions prescribed for the level of hazard within which the intended use has been classified. The notifier shall notify the competent authority referred to in Article 3 of this Act about the closed system prior to the first contained use of a GMO.

A notification of the closed system shall contain all information on the notifier, on the closed system and on the level of hazard of actions planned within a closed system: name of the user, including those who are responsible for safety and security; information on level of education and qualifications of persons responsible for monitoring and safety; details on all expert bodies; address and general description of objects and facilities; nature of work that shall be performed; level of hazard of contained use of GMOs, and for the contained use of GMOs at the first level of hazard the summary of risk assessment for the intended use of GMOs and waste management, or its deactivation prior to release. Detailed content of the notification shall be prescribed by the head of the competent authority by ordinance.

If following the notification referred to in paragraph 2 of this Article, the notifier becomes aware of new information that may have significantly impact on biological diversity, environment or human health, or should be classified in another level of hazard, the notifier shall inform the competent authority thereof and submit a new notification.

The competent authority shall examine whether the closed system meets the prescribed criteria, and after obtaining an expert opinion from the Committee for Contained Use of GMOs, the closed system shall be entered into the closed system register. The competent authority shall issue a certificate to the notifier within sixty days upon receipt of the notification.

The Committee for Contained Use of GMOs shall deliver its opinion within thirty days upon receipt of the notification.

Standards of facilities for contained use of GMOs within a closed system with respect to the level of hazard shall be established in an ordinance issued by the head of the competent authority for science and technology subject to the approval of the head of the competent authority responsible for nature protection, environmental protection, health, agriculture and forestry.

Article 16

Prior to the commencement of contained use of GMOs the applicant shall prepare a risk assessment for the intended use.

On the basis of the analysis of GMO features and the intended use, including the environment likely to be exposed to risk, the risk assessment shall contain an evaluation of the possible adverse effect, level of hazard, necessary prevention and other safety measures. The assessment shall also lay down measures for the management of waste and wastewater resulting from the closed system.

On the basis of risk assessment the notifier shall classify the contained use of GMOs into one

of the levels of hazard as referred to in Article 14, paragraph 1 of this Act, subject to the approval of the competent authority.

In case of doubt as to the level of hazard to be applied to the contained use of GMOs, it shall be classified at the level involving stricter supervision measures.

The contents and scope of risk assessment for the contained use of GMOs and the methodology for its production shall be prescribed by ordinance by the head of the competent authority, subject to the approval of the head of the central state administration body responsible for environmental protection.

Article 17

Prior to the commencement of the contained use of GMOs, the notifier shall draw up a plan of emergency measures pursuant to this Act and special regulations. The notifier shall submit information on the plan of emergency measures to the central state administration body responsible for health, environmental protection, nature protection, agriculture and forestry, science, internal affairs, and competent administrative bodies of regional self-government and local self-government units.

Information about the emergency measures shall be available to the public.

Article 18

The notifier may mark in the notification information that is a business secret or that is protected pursuant to special regulations.

The competent authority shall decide which information in the procedure shall be treated as confidential, following consultations with the notifier.

The notifier may not mark the following information as confidential:

– first and last name, company, company headquarters,

– area of contained use of GMOs,

– description of GMO features,

– level of hazard of the contained use of GMOs,

– supervision measures,

– information on possible adverse and other effects on biological diversity, environment and human health.

Information marked as confidential, shall remain confidential in the case the notifier withdraws the notification.

Article 19

The competent authority shall, during the procedure of issuing approvals for the contained use of GMOs classified within the third and fourth level of hazard allow public insight into the content of the notification, risk assessment, and opinion of the Committee for Contained Use of GMOs.

A public statement containing the stated time and duration for insight into the acts referred to in paragraph 1 of this Article, and the method for providing opinions and remarks, shall be published in the public media.

The deadline, by which the competent authority shall make the acts referred in paragraph 1 of this Article available for insight and for providing opinions and remarks, should not be longer than thirty days. This deadline is not included in the timeframe for issuing approvals pursuant to Article 22 of this Act.

The competent authority shall add its statement on the public remarks and opinions, together with a justification of the decision on the approval.

Article 20

Contained use of GMOs classified within the first level of hazard may begin without submitting the notification to the competent authority, in case it is performed within the closed system for which a certificate was issued pursuant to the provisions of Article 15 of this Act, but the user shall submit a written report to the competent authority.

The user shall submit the risk assessment for the intended use referred to in paragraph 1 of this Article, only at the request of the competent authority.

Article 21

The user shall report to the competent authority on the contained use of GMOs classified within the second level of hazard that shall be performed within the closed system for which a certificate was issued pursuant to Article 15 of this Act.

Detailed content of the notification referred to in paragraph 1 of this Article shall be prescribed by the head of the central state administration body responsible for science.

The notifier may begin using the GMO forty five days following the submission of the notification or prior to that deadline, only with the approval of the competent authority. Approval shall be issued by a decision.

The competent authority may within the deadline referred to in paragraph 3 of this Article, after it has obtained an opinion from the Committee for Contained Use of GMOs, prohibit the contained use and issue a decision thereof. The notifier may immediately after submitting the notification begin using GMOs referred to in paragraph 1 of this Article if the notifier had previously used GMOs from the second or higher level of hazard within the same closed system, and if the prescribed conditions were met.

In the case referred to in paragraph 5 of this Article, the notifier shall request from the competent authority to issue the approval for intended contained use.

The competent authority shall decide on the notification referred to in paragraph 6 of this Article, after obtaining the opinion from the Committee for Contained Use of GMOs, within forty five days from the day of receiving the notification.

The Committee for Contained Use of GMOs shall submit to the competent authority its written opinion referred to in paragraphs 4 and 7 of this Article, within twenty one day from the day a copy of the notification was delivered to it.

Article 22

For each contained use of GMOs classified within the third or fourth level of hazard that will be performed within the closed system for which the certificate was obtained pursuant to Article 15 of this Act, it shall be necessary to obtain the approval from the competent authority.

Detailed content of the notification referred to in paragraph 1 of this Article shall be prescribed by the head of the central state administration body responsible for science.

Competent authority shall check if the notification meets the prescribed requirements, and after it has obtained the opinion from the Committee for Contained Use of GMOs within forty five days from submitting the notification, shall issue the approval in case the activities will be performed within closed systems for which the certificate was already obtained for contained use within the third and fourth level of hazard, and all the prescribed supervision measures were met.

Outside of the cases referred to in paragraph 3 of this Article, the competent authority shall check if the notification meets the prescribed requirements, and after obtaining the opinion from the Committee for Contained Use of GMOs, it shall issue the approval within ninety days from the day notification was submitted.

The Committee for Contained Use of GMOs shall provide its written opinion within twenty one days, or within forty five days for the cases referred to in paragraph 4 of this Article, counting from the day of receiving a copy of the notification.

The competent authority shall issue the approval referred to in paragraph 1 of this Article at the longest for the period the notifier has stated in the notification.

Article 23

The competent authority may, following the receipt of the notification referred to in Articles 15, 21 and 22 of this Act for the purpose of protecting biological diversity, environment and/or human health, request from the notifier or the user to submit new information on the closed system or on the contained use of GMOs within a certain timeframe, or to change the conditions for the contained use of GMOs stated in the notification.

In the cases referred to in paragraph 1 of this Article, the competent authority may request from the notifier or the user not to start with the use, to interrupt or temporarily stop the use, until the competent authority allows the use on the basis of additional information or requested changes.

In the cases referred to in paragraph 1 of this Article, for the registration of a closed system into the GMO register or for contained use of GMOs classified within the second, third or fourth level of hazard, the time period referred to in paragraph 1 of this Article shall not be included in the time period for issuing certificates referred in Article 15 of this Act, or in the deadline for issuing approvals pursuant to Articles 21 and 22 of this Act.

Article 24

If the notifier, or the user becomes aware of new information on the contained use of GMOs, or a change occurs in the work with GMOs in the closed system in a way that it would significantly impact biological diversity, environment, human health or classification of use within a level of hazard, they shall inform the competent authority thereof and submit a new notification if it is the case of contained use of GMOs from the second, third or fourth level of hazard.

If new information becomes available to the competent authority on the contained use of GMOs that may significantly effect the risks to biological diversity, environment or human health, or the classification of use within a level of hazard, the competent authority may change the conditions of the contained use of GMOs, or request the notifier or the user to stop or permanently terminate the contained use of GMOs.

Article 25

In case of accident, the user shall act according to the plan of emergency measures, and to inform the competent authority thereof without any delay, particularly on:

- circumstances of the accident,

- type and amount of GMOs that was unintentionally released into the environment from the closed system,

- performed and needed actions and safety measures,

- other information that is needed in order to assess the effect of the accident on the biological diversity, environment and human health.

Deliberate release of GMOs into the environment

Article 26

The notifier shall obtain the approval for the deliberate release of GMOs into the environment from the competent authority, pursuant to Article 3 of this Act.

Deliberate release of GMO into the environment shall be performed on the basis of the approval referred to in paragraph 1 of this Article.

Article 27

It is permitted to release genetically modified reproductive plant material into the environment only on surfaces that will be determined by a regulation by the Government of the Republic of Croatia subject to the proposal of the central state administration body responsible for agriculture and forestry, with the approval of the central state administration body responsible for nature protection.

Releasing GMOs into the environment shall not be permitted in protected areas and in areas of ecological network, areas intended for ecological production of agricultural products and ecological forms of tourism, and areas representing protected zones of impact.

Protected zones of impact referred to in paragraph 2 of this Article shall encompass the areas that prevent spreading of GMOs in areas in which the deliberate release of GMOs into the environment is not permitted, which are determined pursuant to nature protection requirements, which are a constitutive part of the approval on the deliberate release of GMO into the environment.

Article 28

The notifier shall produce through an authorised legal person the risk assessment study for deliberate release prior to submitting the notification for obtaining the approval for deliberate release of GMOs into the environment.

The assessment shall establish an estimate of possible negative effects and their possible consequences, level of hazard and needed supervision measures, while taking into account the effect on human health, based on the analysis of GMO's characteristics and its intended release into the environment and ecological system in which the GMO would be released, and biological diversity that could be exposed to risks.

The notifier may submit a risk assessment study produced by another notifier for the same deliberate release of the same GMO into the environment, if he has obtained written consent from that notifier.

The content and scope of risk assessment for deliberate release of GMO into the environment and methodology for producing the assessment, and the conditions that need to be met by the legal person producing the risk assessment, shall all be prescribed by ordinance by the head of the central state administration body responsible for nature protection, subject to the approval of the head of the central state administration body responsible for agriculture, forestry and water management, and head of the central state administration body responsible for health.

Article 29

The notifier shall develop a plan of measures to be applied in case of uncontrolled spreading of GMOs into the environment, prior to initiating the deliberate release into the environment.

The plan of measures to be applied in case of uncontrolled spreading of GMO into the environment shall be approved by the competent authority by issuing an approval.

The plan of measures for removing the uncontrolled spreading of GMO in the environment

(hereinafter: the plan of measures), is a document that describes the actions and measures to be applied in case of accident, which would decrease possible negative consequences to biological diversity, environment and human health.

The notifier shall submit the plan of measures, except in cases prescribed in paragraph 1 of this Article, and in the following cases:

- following the expiry of a five–year period from the date the last plan of measures was submitted,

- within thirty days from the day the conditions and situation were changed which could seriously impact the measures prescribed in case of accident.

The plan of measures contains:

- method of supervising GMOs in case of uncontrolled spread in the environment,

- estimate of possible consequences and hazard to biological diversity, environment and human health,

- needed protection measures,

- measures needed for preventing further spread and for removing the GMO, and remediation of the environment that could be exposed to the uncontrolled spread of GMOs.

Detailed content of the plan of measures and method of its implementation shall be prescribed by the head of the competent authority referred in Article 3 of this Act, subject to the approval of the head of the central state administration body responsible for environmental protection.

Article 30

Notification for obtaining approval for the deliberate release of GMOs into the environment shall contain:

1 technical documentation with the prescribed constituent parts,

2 risk assessment of the intended release of GMOs into the environment,

3 plan of measures in case of uncontrolled spread of GMOs into the environment,

4 monitoring plan of GMO effects on the environment, biodiversity and human health,

5 information on waste management: type of waste generated, expected amount of waste, description of planned treatment method,

6 techniques planned for removal or for deactivating GMOs at the end of experiment,

7 other information the notifier deems important.

The notifier may refer to information or results of deliberate release submitted to the competent authority by another notifier, if that information is not marked as classified, and if the notifier has obtained written consent from that notifier.

The notifier may be allowed, by the issuing of one approval, a deliberate release of a GMO into the environment or a combination of GMOs in the same area or in different areas, but for the same purpose and within a certain time period.

The detailed content of the notification and the method for submitting the notification shall be prescribed by ordinance by the head of the central state administration body responsible for nature protection subject to the approval of the central state administration bodies responsible for health and agriculture and forestry and environmental protection.

Article 31

A summary of the notification referred to in Article 30 of this Act shall be submitted to the European Commission within 30 days from when it was received by the competent authority, with the purpose of forwarding it to the competent authorities of Member States of the European Union which can disclose an opinion in regards to the notification. The entire notification shall be delivered by the competent authority to the competent authority of a Member State of the European Union at its request.

Remarks submitted by the competent authorities of Member States of the European Union shall be taken into account by the competent authority while deciding on the notification for issuing approval for deliberate release of GMOs into the environment.

The competent authority informs the European Commission on the issued approvals for the deliberate release of GMOs into the environment, on the reasons for declining to issue an approval, and on the results of the deliberate release of GMOs into the environment.

Article 32

The competent authority referred to in Article 3 of this Act shall issue an approval for the deliberate release of GMOs into the environment on the basis of the opinion which was previously obtained from the Committee for Release of GMOs into the Environment, within ninety days from the day the notification was received, if all the requirements were met.

If the competent authority deems necessary, it shall request in writing additional information from the notifier, and shall set the deadline for submitting the information. The time period within which the notifier shall be obligated to submit the information requested at a later stage will not be taken into account when calculating the deadline for issuing the approval referred to in paragraph 1 of this Article.

If the notifier does not submit additional information to the competent authority within the time period referred to in paragraph 2 of this Article, the competent authority shall reject the notification.

The competent authority shall forward copies of the notification referred to in Articles 30 and 33 of this Act, without any delay to the Committee for Release of GMOs into the Environment.

If the Committee finds that it cannot be clearly determined what will be the effects of the deliberate release on human health, environment, and biological diversity, from the information provided in the notification, it may request from the competent authority to request additional information from the notifier regarding the effects of the intended deliberate release of GMO into the environment.

The Committee for Release of GMOs into the Environment shall deliver its opinion within forty five days from the days the notification was received.

Article 33

Approval for deliberate release of GMOs into the environment may be issued within a shorter procedure if there is enough information and experience on the intended release of a specific GMO into certain ecological system and if the GMO meets the prescribed requirements, particularly in regards to removing hazard.

An application needs to be submitted for obtaining the approval for deliberate release of GMOs into the environment within a shorter procedure.

The competent authority referred to in Article 3 of this Act shall decide on the notification within 30 days from receiving the notification, and shall issue an approval if the prescribed requirements are met, according to the previously obtained opinion from the Committee for Release of GMOs into the Environment.

The competent authority may request from the notifier additional information and shall set a deadline by which the information needs to be submitted. The time period for submitting additional information will not be taken into account when calculating the deadline prescribed for issuing an approval.

The Committee for Release of GMOs into the Environment shall deliver a written opinion to the competent authority within fifteen days from receiving a copy of the notification.

Detailed content of the notification and method for submitting the notification shall be prescribed by the ordinance referred to in Article 40 paragraph 4 of this Act.

Article 34

The shorter procedure referred to in Article 33 of this Act may apply if the European Commission has brought a decision on applying such a procedure for a certain GMO, pursuant to this decision.

The competent authority shall previously inform the European Commission on applying the shorter procedure for deliberate release of GMOs into the environment.

If it is estimated that all the prescribed requirements are met, the competent authority may propose to the European Commission to allow the application of the shorter procedure for the deliberate release of certain GMO into the environment.

Article 35

The competent authority shall allow the public to have insight in the content of the notification, content of technical documentation, risk assessment and opinion of the Committee for Release of GMOs into the Environment, in the course of procedure for issuing approval for deliberate release of GMOs.

Public invitation, which shall state the time and place for insight referred to in paragraph 1 of this Article, and the manner in which the opinion was issued, shall be published through the public media.

The time period during which the competent authority will allow insight and giving opinions and remarks may not be longer than thirty days, and will not be included into the time period for issuing the approval.

The competent authority shall be obliged to disclose on the public opinion and stated remarks within the justification of the decision on issuing the approval.

Article 36

If after submitting the notification or after issuing the approval for the deliberate release of GMOs into the environment any modifications or unplanned changes occur in the deliberate release into the environment, which could have an adverse effect to biological diversity, environment or human health, or if there is new information, the notifier or the user shall without any delay:

- undertake measures to protect biological diversity and human health,

- inform the competent authority on modifications or unplanned changes and new information,

- adapt the conditions of release into the environment that were suggested in the notification according to the occurred changes.

In the case referred to in paragraph 1 of this Article the competent authority may request from the notifier or the user to change the conditions of the deliberate release of GMOs into the environment, or to temporarily or permanently prohibit the deliberate release of GMOs into

the environment.

In case of any modifications or unplanned changes in the deliberate release into the environment pursuant to paragraph 1 of this Article, the competent authority shall inform the public after the risk assessment has been performed.

Article 37

The user shall submit to the competent authority a report on the results of the intended release of GMO into the environment, within sixty days from the day the deadline expired for which the competent authority has issued the approval for deliberate release of GMOs into the environment, or within the time period determined in the approval referred to in Articles 32 and 33 of this Act.

If the notifier or the user intends to place on the market as a product any material obtained from GMOs that was the subject of deliberate release into the environment, he or she shall include information thereof in the report referred to in paragraph 1 of this Article.

Article 38

The notifier or the user shall in case of unplanned spread of GMOs into the environment act in accordance with the plan of measures referred to in Article 29 of this Act and inform the competent authority and State Institute for Nature Protection on:

- the scope of consequences of the unplanned spread of GMO into the environment and degree of hazard for biological diversity, environment and human health,

-implemented and needed measures for protection of biological diversity, environment or human health,

- implemented and needed measures for decreasing or removing consequences, removing GMOs and remediation of the environment exposed to the unplanned spread,

- other information needed for assessing the impact of the unplanned spread of GMO on the biological diversity, environment or human health.

The competent authority in cooperation with other competent authorities shall bring and implement the programme for removing the consequences of the uncontrolled spread of GMO into the environment.

The programme referred to in paragraph 2 of this Article, on the basis of the assessed hazard, will determine the responsible person, conditions and measures for decreasing or removing consequences and for preventing further uncontrolled spread of GMOs, method of covering the expenses and special limitations or bans in regard to further release of GMOs into the environment, through traffic or use.

The competent authority shall report to the Government of the Republic of Croatia and to the public on the event referred to in paragraph 1 of this Article, and on the preparation and implementation of the programme referred to in paragraph 2 of this Article.

In case of unplanned spread of GMOs into the environment which can have significant negative consequences on biological diversity, environment and human health, the competent authority shall inform the states under risk or under potential risk, and when necessary, appropriate international organisations, and make available to them all the information needed for determining appropriate measures.

Placing GMOs and products containing and/or consisting of GMOs on the market

Article 39

The notifier shall obtain approval for each GMO or product containing and/or consisting of,

or originating from GMOs that the notifier intends to place on the market for the first time.

The notifier shall prior to submitting the notification for issuing the approval for placing on the market the GMO or products containing and/or consisting of, or originating from GMOs, to draw up the assessment of risks that may occur as a result of the intended placing on the market.

The assessment determines, on the basis of the analysis of characteristics of GMOs and products containing and/or consisting of, or originating from GMOs, and its use, the evaluation of the possible adverse effects and consequences to biological diversity, environment and human health, level of hazard, as well as needed supervision measures.

The content and scope of the risk assessment for placing the GMO or products containing and/or consisting of, or originating from GMOs on the market , the methodology of assessment and requirements that need to be met by the legal person for drawing up the risk assessment, shall be prescribed by ordinance by the head of the central state administration body responsible for health, subject to the approval of the heads of central state administration bodies responsible for agriculture, forestry and veterinary medicine.

Risk assessment shall be produced by the legal persons authorised by the head of the central state administration body responsible for health, subject to the approval of heads of the central state administration bodies responsible for agriculture, forestry and veterinary sciences.

Article 40

The competent authority shall confirm the receipt of the notification referred to in Article 39 of this Act, and shall without any delay submit the summary of the notification dossier to the European Commission and to the authorised bodies of Member States of the European Union.

Article 41

The notifier may in the notification mark the information that is confidential or that is protected pursuant to special regulation. Information that is deemed as confidential in the procedure must be verifiably sound.

The competent authority shall, following a consultation with the notifier, decide which information in the procedure shall be considered as confidential.

The notifier may not mark as confidential the following information:

- first and last name, company and company headquarters,

- intended method of use of GMOs and products containing and/or consisting of, or originating from GMOs, conditions for placing the product on the market, and conditions of its use,

- characteristics of the GMO and products, or GMOs that it contains,

- monitoring plan in regards to placing on the market of GMO and products containing and/or consisting of, or originating from GMOs, its use and measures in case of unforeseen risks related to its placing on the market or use,

- risk assessment.

In case the notifier withdraws the notification information shall remain confidential.

Article 42

Notification for obtaining the approval for placing on the market of GMOs or products containing and/or consisting of, or originating from GMOs, must contain:

1 technical documentation with prescribed constituent parts,

2 risk assessment for the environment pursuant to provisions of Article 28 of this Act,

3 information on the conditions of placing on the market, including the special requirement for using and handling the product,

4 plan for monitoring the effect of the product and its use on the biological diversity, environment and human health, including the period during which the monitoring plan shall be implemented

5 proposal of the period for which the approval is requested,

6 proposal for labelling the product,

7 proposal for packaging the product,

8 summary of technical documentation.

The notifier may include in the notification the information on the results of the deliberate release into the environment of the same GMO or combination of GMOs that the product contains, which was the subject of the notifier's earlier notification, or if such deliberate release is still being implemented.

The notifier may refer to information or results relating to products that were proposed to the competent authority by another notifier, in case that information is not confidential and the notifier has obtained the other notifier's written consent.

The notifier shall for every intended use of GMOs or products containing and/or consisting of, or originating from GMOs, which is different than the permitted one, submit to the competent authority new notification for obtaining the approval for placing on the market.

The content of the notification and technical documentation for placing on the market of GMOs or products containing and/or consisting of, or originating from GMOs, requirements for monitoring, labelling and packaging of the product, shall be prescribed pursuant to the authorities determined in Article 39 paragraph 4 of this Act.

Article 43

The competent authority shall examine and determine the compliance of the notification referred to in Article 42 of this Act with the provision of this Act and other regulations, and following the obtained opinion from the Committee for Release of GMOs into the Environment and/or Croatian Food Agency and held public discussion, produce a report on the assessed suitability of placing on the market the GMO and products containing and/or consisting of, or originating from GMOs, in which it is stated that a certain GMO or product containing and/or consisting of, or originating from GMOs is:

- suitable for placing on the market,

- suitable for placing on the market according to specified additional conditions, or

- not suitable for placing on the market.

The Committee for Release of GMOs into the Environment or Croatian Food Agency shall submit to the competent authority a written opinion referred to in paragraph 1 of this Article within forty five days from the day it receives a copy of the notification. If the Committee for Release of GMOs and/or Croatian Food Agency does not submit the opinion within the mentioned period, it shall be deemed that the opinion was negative.

The competent authority shall deliver the report referred to in paragraph 1 of this Article to the notifier within sixty days from receiving the notification.

The notifier may, within seven days from receiving the report referred to in paragraph 1 of this Article, withdraw the notification or inform the competent authority in writing that the

notifier intends to amend the notification, if the report states that a certain GMO or product containing and/or consisting of, or originating from GMOs is suitable for placing on the market under additional conditions.

If the notifier referred to in paragraph 4 of this Article informs in writing the competent authority that the notifier intends to amend the notification, a deadline will be set by which the amended notification must be submitted. The time period for amending the notification shall not be included into the time period prescribed for issuing the approval referred to in Article 46 paragraph 1 of this Act.

If the notifier referred to in paragraph 4 of this Article does not inform the competent authority within the prescribed time period on the intention to amend the notification in the case when the report states that the certain GMO or product containing and/or consisting of, or originating from GMOs is suitable for placing on the market under additional conditions, it shall be deemed that the notification has been withdrawn.

The competent authority shall terminate the procedure for issuing the approval if the notifier has withdrawn the notification within the time period referred to in paragraph 4 of this Article or has not amended the notification within the time period referred to in paragraph 5 of this Article, or has failed to notify the competent authority within the prescribed time period of his intention to amend the notification in accordance with paragraph 6 of this Article.

The competent authority shall prescribe the scope and content of the report referred to in paragraph 1 of this Article.

Article 44

The competent authority shall submit the report referred to in Article 43 paragraph 1 items 1 and 2 of this Act to the European Commission within ninety days from receiving the notification with all the established information.

The competent authority shall submit the report referred to in Article 43 paragraph 1 item 3 of this Act to the European Commission within fifteen days from the day it was delivered to the notifier and by the latest within one hundred and five days from the day the notification was received.

The European Commission and competent authorities of the Member States of the European Union may submit to the competent authority a disclosure and justified remarks in regards to placing on the market of a certain GMO or products containing and/or consisting of, or originating from GMOs, within sixty days from the day the report referred to in Article 43 of this Act was delivered.

The competent authority shall consider in cooperation with the European Commission and competent authorities from the Member States of the European Union, conflicting issues in order to reach an agreement within forty five days, which does not include the days during which the notifier was expected to submit information, and by the latest within one hundred and five days from the day the report was delivered.

The competent authority may issue the approval for placing on the market of a specific GMO or products containing and/or consisting of, or originating from GMOs if within the deadline referred in paragraph 3 of this Article the justified remarks from the European Commission and competent authorities from Member States of the European Union were not submitted, or if all conflicting issues were resolved within the deadline referred to in paragraph 4 of this Article.

The competent authority shall inform the European Commission and the competent authorities from the Member States of European Union on issuing the approval for placing on the market GMOs or products containing and/or consisting of, or originating from GMOs

within thirty days from issuing the approval.

Article 45

If placing on the market of GMOs or products containing and/or consisting of, or originating from GMOs, also includes deliberate release or possibility of unintended release into the environment, the competent authority shall request an opinion from the Committee for Release of GMOs into the Environment.

The committee referred to in paragraph 1 of this Article shall submit to the competent authority within forty five days a written opinion on releasing into the environment or on deliberate placing on the market of GMO and products containing and/or consisting of, or originating from GMOs. The opinion shall be given on the basis of comprehensive analysis of product safety and its impact on biological diversity, environment and human health.

If the competent Committee does not deliver the opinion within the mentioned time period, it shall be deemed that the opinion was negative.

Article 46

The competent authority shall decide on the approval for placing on the market the GMO or products containing and/or consisting of, or originating from GMOs, following performed examination in regards to the notification meeting the prescribed requirements, and following the opinion obtained from the Committee for Release of GMOs into the Environment and/or Croatian Food Agency, and following a public discussion and production of the report on the assessment of suitability of placing on the market the GMO and products containing and/or consisting of, or originating from GMOs, within one hundred and five days from receiving the notification.

Approval for placing on the market shall be issued for a five-year period, at the longest, with a possibility of extending the period pursuant to the provisions of this Act.

The implementing regulations by which the procedures for issuing approvals will be prescribed will be passed by the head of the competent authority pursuant to the competences determined in Article 39 paragraph 4 of this Act.

The provisions of this Act and special regulations shall apply to the production, health safety, declaring and labelling food and animal food, and to placing on the market of food and animal feed that contains or originates from GMO.

Article 47

Approval for placing on the market of GMOs and products containing and/or consisting of, or originating from GMOs shall contain:

– information on the GMO and/or product containing and/or consisting of, or originating from GMOs,

- use and scope for which the approval is being issued, including the identification of products with statement on its characteristics,

- the validity period of the approval

- conditions for placing on the market, including special requirements for use, handling, packaging, and conditions for environmental protection or specific ecological system or geographical area,

- obligation to control samples and deliver results to the competent authority following its request,

- instructions for labelling,

- instructions for monitoring, including the obligation to report to the competent authority on the monitoring results,

- other conditions that the person who is placing the product on the market, or is using the product, is obligated to meet.

The approval shall be made available to the public pursuant to this Act and other regulations except for the information prescribed and marked as confidential and assessment of risks to biological diversity, environment and human health referred to in Article 39 of this Act.

Article 48

The competent authority may in the process of issuing the approval for placing on the market of a certain GMO and products containing and/or consisting of, or originating from GMOs, following the opinion obtained from the Committee for Release of GMO into the Environment and/or Croatian Food Agency, accept by a decision the validity of a document on the basis of which the notifier has received the approval for placing a GMO and products containing and/or consisting of, or originating from GMOs on the market of the European Union, in case the document contains such conditions that also meet the conditions of the Republic of Croatia.

The decision referred to in paragraph 1 of this Article shall replace the approval for placing on the market of GMOs and products containing and/or consisting of, or originating from GMOs pursuant to this Act.

The decision referred to in paragraph 2 of this Article shall determine the instructions for monitoring and reporting obligations to the competent authority on the monitoring results.

Regardless of the provisions referred to in paragraph 1 of this Article, the competent authority may, following the opinion obtained from the Committee for Release of GMOs into the Environment and/or Croatian Food Agency, temporarily limit or prohibit placing on the market of certain GMOs or products containing and/or consisting of, or originating from GMOs, if on the basis of sound information it is determined that the GMO or a product containing and/or consisting of, or originating from GMOs may present a risk that was not taken into account when issuing the approval. In this case the competent authority shall inform about its decision the competent authority of the European Union.

Article 49

The notifier or the user who intends to request the extension of the approval for placing on the market of GMOs or products containing and/or consisting of, or originating from GMOs, must at least nine months before the expiry of the validity of the approval submit to the competent authority a notification that contains:

- copy of the approval for placing on the market that the notifier wishes to extend,

- report on the monitoring results, produced in accordance with the prescribed methodology,

- new information on the product's hazard to biological diversity, environment and human health, if such information is available,

- proposal for changing or amending the conditions for placing on the market from the first approval, particularly those that refer to monitoring and time limit on the validity of the approval, if that is necessary.

Provisions of Articles 42, 43 and 44 of this Act shall apply to the procedure regarding the notification for extension of the approval.

Validity of the approval may be extended for up to five years.

The notifier or the user who is requesting from the competent authority the extension of the

approval for placing on the market of GMOs or products containing and/or consisting of, or originating from GMOs, pursuant to paragraph 1 of this Article, may continue to place the product on the market under the conditions determined in the first or previous approval until receiving the decision pursuant to paragraph 2 of this Article.

Article 50

If the notifier or the user after obtaining the approval finds out new information regarding the hazard of the GMO or products containing and/or consisting of, or originating from GMOs to biological diversity, environment or human health, they shall report it to the competent authority which issued the approval.

In the event referred to in paragraph 1 of this Article the notifier or the user shall submit to the competent authority a new notification on the basis of the changed conditions.

Every user of GMOs or products containing and/or consisting of, or originating from GMOs shall report to the competent authority and/or to the notifier on the new information regarding the hazard to biological diversity, environment and human health.

If new information regarding the hazard of a GMO or products containing and/or consisting of, or originating from GMOs or its use, becomes available to the competent authority before or during the procedure for issuing the approval, this information must be taken into account for bringing the decision on placing on the market of the products containing and/or consisting of, or originating from GMOs.

If new information becomes available to the competent authority after the approval becomes legally effective, the competent authority shall report it to and request the opinion of the competent Committee, and on the basis of the obtained opinion issue a decision by which it changes and/or amends the valid approval if the notifier or the user agrees with this, or to revoke the approval.

Article 51

The notifier or the user shall, when placing on the market, mark with a visible label on the packaging and on the accompanying documentation that this product is a GMO or containing and/or consisting of, or originating from GMOs, as well as all other information relating to the product or its use.

The label must clearly state „genetically modified organism“ or have a sentence „this product contains genetically modified organisms“ or „this product originates from genetically modified organisms“.

For products where accidental or technologically unavoidable traces of permitted GMOs cannot be excluded, the Government of the Republic of Croatia shall, at the proposal of the competent body, determine by regulation the level bellow which these products do not have to be labelled.

The person who places the GMO or products containing and/or consisting of, or originating from GMOs on the market shall have to prove to the competent authority that all the measures were taken for avoiding accidental or technologically inevitable contamination with the permitted GMO.

Article 52

The user or the person who places on the market GMOs or products containing and/or consisting of, or originating from GMOs shall ensure that the person who accepts the product receives the documentation from which it is clear that:

- it is a GMO or product containing and/or consisting of, or originating from GMOs, and

- appropriate unique code (numerical and alphabetical) assigned to this GMO.

While placing GMOs or products containing and/or consisting of, or originating from GMOs on the market, the seller shall provide the user with the documentation with information referred to in paragraph 1 of this Article.

The person referred to in paragraph 1 who places GMOs or products containing and/or consisting of, or originating from GMOs on the market shall maintain a database and ensure a procedure that would allow identification, for a period of five years for each placing on the market, of the person from whom the GMO or products containing and/or consisting of, or originating from GMOs were obtained and persons to whom these products were made available, with the exception of the final users.

Handling, transport and packaging of GMO

Article 53

During each handling, transport and packaging of a GMO the accompanying documentation shall clearly label the GMO that is:

- intended for direct use for food or for cattle feed or for processing and marked that it is not intended for deliberate release into the environment, and state the place for obtaining further information,

- intended for contained use, and mark all the conditions and requirements for safe handling, storing, transport and use, place to obtain further information, including name and address of the individual or institution to whom the GMO was entrusted to,

- intended for deliberate release into the environment, and mark the identity and appropriate characteristics and/or traits, all conditions for safe handling, storing, transport and use, as well as the place for obtaining further information.

The head of the competent authority shall prescribe by ordinance the conditions for handling and packaging, and for road, railway, air and river transport of the GMO, while taking into account all international regulations and practices.

Conditions regarding the labelling of GMOs shall be brought by competent authorities, each within its scope of competence.

The provisions of special regulations that regulate transport, transit and handling of hazardous substances, shall apply for road, railway, air and river transport and transit, and handling of living modified organisms that are not hazardous for the environment, unless otherwise stipulated by this Act or regulations passed on the basis of this Act.

Conditions for handling, packaging, labelling and transport of GMO in sea transport shall be prescribed by means of special regulation by the head of the central state administration body responsible for maritime affairs. Handling waste generated from the use of GMOs

Article 54

The notifier or the person using the GMO shall in the prescribed manner dispose of and permanently destroy in a non-hazardous manner the waste containing and/or consisting of, or originating from GMOs in the way that the GMO will no longer be capable of reproduction or transfer of genetic material, and that this genetic material cannot be transferred to other organisms.

III LIABILITY FOR DAMAGES CAUSED BY THE USE OF GMOs

Article 55

The user who imports GMOs, places them on the market, uses or produces GMOs or products

containing and/or consisting of, or originating from GMOs, shall provide compensation for damages caused by cross-border movement, transit, use, release into the environment, or placing on the market of GMOs or products containing and/or consisting of, or originating from GMOs, pursuant to special regulations.

IV SCIENTIFIC AND EXPERT BODIES FOR IMPLEMENTATION OF THE ACT

Article 56

The Government of the Republic of Croatia shall establish by decision the Council for Genetically Modified Organisms (hereinafter: the Council), for the purpose of monitoring and developing the area of GMO handling, and for providing expert support to competent authorities in the implementation of this Act.

The Council shall have seventeen members appointed by the Government of the Republic of Croatia, for a four-year period, at the proposal of competent bodies for nature protection, environmental protection, science, health and social welfare, agriculture and forestry, labour and economy.

The Council shall elect among its members the president and president's deputy. The Council shall be autonomous and independent, and its work shall be public.

The Council shall bring a rulebook establishing its method of operation.

Resources necessary for the operation of the Council and for performing expert and administrative activities shall be ensured from the state budget.

Article 57

The Council shall perform the following activities:

– monitor the state and development in the area of use of genetic technology and use of GMOs,

- monitor expert and scientific achievements and provide opinions and stimulations in regards to use of genetic technology and use of GMOs,

- provide opinions in regards to social, ethical, technical and technological, scientific and other conditions for using GMOs,

- advise competent authorities on issues regarding use of GMOs and genetic technology,

- report to the public on the state and development in the area of use of genetic technology and use of GMOs, and on its positions and opinions.

Article 58

The Council shall, at the proposal of the competent bodies in charge of the implementation of this Act, appoint for a four-year period a:

- Committee for Contained Use of GMOs,

- Committee for Release of GMOs into the Environment.

Article 59

The Committee for Contained Use of GMOs shall have eleven members, scientists and experts in the area of microbiology, genetics, medicine, biochemistry and molecular biology, pharmacy, biotechnology, agriculture, forestry and veterinary medicine, work safety, nature protection and environmental protection.

The Committee for Release of GMOs into the Environment shall have nine members, scientists and experts in the area of genetics, ecology, environmental protection, nature

protection, agriculture, forestry, veterinary medicine, biochemistry and molecular biology, microbiology and medicine.

Article 60

Committees referred to in Article 59 of this Act shall:

- provide opinions on the use of GMOs in administrative procedures and other procedures pursuant to this Act,

- provide opinions and proposals during the preparation of regulations regarding the use of GMOs,

- provide opinions and proposals to the competent state administration authorities on the issues of GMO usage,

- perform other expert activities prescribed by this Act and by regulations passed on the basis of this Act.

Committees shall submit annual reports on their work to the Council, and they shall be published in a manner that is accessible to the public.

Resources for the work of the committees and for performing expert and administrative activities shall be ensured by the central state administration body responsible for health.

Article 61

Members of the Council and of the committees shall keep information labelled as confidential for the entire course of their mandate and following the termination of their mandate, pursuant to the provisions of this Act.

All external experts participating in the work of the Council and of the committees, or those participating in the process of issuing approvals shall also protect the confidentiality of data, pursuant to the provisions of this Act.

V REGISTER OF GMOs

Article 62

A unique register of GMOs shall be kept by the central state administration body responsible for health, and special registers shall be kept by authorised bodies in accordance with their competences.

The Register of GMOs shall contain records on closed systems, issued certificates and approvals for contained use of GMOs, the deliberate release of GMOs into the environment and placing on the market of GMOs or products containing and/or consisting of or originating from GMOs.

The records shall contain information included in the notification, in particular:

1. company and headquarters of the notifier of:

- a closed system;

- a contained use of GMOs;

- a deliberate release of GMOs into the environment;

- placing on the market of GMOs and products containing and/or consisting of, or originating from GMOs;

2. name, level of hazard and description of the closed system;

3. information relating to the contained use and information relating to classification into a

group according to the level of hazard;

4. information relating to the deliberate release of GMOs into the environment, including the specific site of the GMO release;

5. information relating to the placing on the market of GMOs and products containing and/or consisting of, or originating from GMOs.

Certificates and approvals granted for the contained use, the deliberate release into the environment or placing on the market of GMOs and products containing GMOs shall form a constituent part of the register pursuant to paragraph 1 of this Article.

Anyone shall have the right to access the information from the GMO register, and to request and obtain print-outs from the GMO register, whilst paying for real costs of issuing print-outs.

Information marked as confidential pursuant to this Act, or the information protected pursuant to special regulation shall not be entered into the GMO register.

The form and method of keeping the register of GMOs and the method of determining the cost of print-outs shall be prescribed by ordinance by the head of the central state administration body responsible for health, subject to the approval of the heads of other competent bodies.

VI SUPERVISION

Administrative supervision

Article 63

Administrative supervision over the implementation of this Act and regulations passed on the basis of this Act shall be carried out by the competent authority, each within their scope of competence.

Inspection supervision

Article 64

Inspection supervision over the implementation of this Act and regulations passed on the basis of this Act shall be carried out by the inspections of the competent authorities as referred to in Article 3 of this Act, in accordance with their scope of competence.

Article 65

In the implementation of inspection supervision, the inspector referred to in Article 64 of this Act shall have the right and obligation to issue a decision prohibiting persons under supervision who do not have the approval of the competent authority and other certificates, from carrying out cross-border movement, transit, contained use, deliberate release into the environment, and placing on the market of GMOs and products containing and/or consisting of, or originating from GMOs.

The inspector may order emergency measures to protect human and animal lives, and to reduce damages resulting from performing unauthorised activities, actions, or operations.

Article 66

If there is suspicion that a GMO or product containing and/or consisting of, or originating from GMOs is being imported, released into the environment, placed on the market, being recovered or deposited into the environment in violation of the provisions of this Act or of special regulations, the inspector from the competent authority (hereinafter: the inspector) shall request from the importer or the user a reliable document, and shall set a deadline before which the document needs to be submitted.

If the importer or user does not submit the reliable document, the inspector shall temporarily prohibit import, contained use, release into the environment, placing on the market, or depositing in the environment, and the sample shall be delivered for an analysis to an authorised laboratory.

In case the analysis finds that it is not an allowed GMO or product containing and/or consisting of, or originating from GMOs, the inspector shall prohibit the import, contained use, release into the environment, placing on the market, or depositing in the environment, and the taken samples and/or confiscated genetically modified organisms and products shall be destroyed in a permanent and non-hazardous manner.

In case the analysis determines it is a case of non-allowed import, contained use, placing on the market or depositing in the environment, the costs of analysis and destruction, as well as of temporary storage and keeping shall be covered by the importer or user of GMOs or product containing and/or consisting of, or originating from GMOs.

VII PENAL PROVISIONS

Article 67

A legal or natural person shall be fined for misdemeanour in the amount ranging from HRK 500,000.00 to 1,000,000.00 if he:

– without approval or in violation of the determined conditions releases GMOs into the environment (Article 26),

– releases genetically modified reproduction material into the environment outside of consented areas (Article 27),

– releases GMOs in protected areas and in areas of the ecologic network, areas intended for ecologic production of agricultural product and ecological forms of tourism, and areas that represent protected zones (Article 27).

The responsible person within the legal person shall be fined for the misdemeanours referred to in paragraph 1 of this Article in the amount ranging from HRK 20,000.00 to 70,000.00.

Article 68

Legal or natural person shall be fined for misdemeanours in the amount ranging from HRK 100,000.00 to 500,000.00 if:

– performs activities of an authorised laboratory without the approval of the competent authority or in violation of the permitted work method (Article 10),

– imports GMOs without approval or in a manner that is not permitted (Article 12),

– implements contained use of GMOs in violation of prescribed control and other safety measures and in violation of prescribed criteria regarding the level of hazard (Article 14),

– uses closed system without notifying the competent authority and without registering in the register of GMOs (Article 15),

– does not introduce the contained use of GMOs within the appropriate level of hazard (Article 16),

– does not produce the plan of measures in case of accident (Article 17 paragraph 1),

– does not submit the data on the plan of measures to the competent authority and other competent authorities, and does not make the data available to the public (Article 17 paragraphs 2 and 3),

– uses GMOs from the 1st level of hazard without a certificate of entry into the register of

GMOs (Article 20 paragraph 1),

– does not submit the risk assessment to the competent authority at its request (Article 20 paragraph 2),

– implements contained use of GMOs from the 2nd level of hazard without notifying the competent authority and in violation of the prescribed conditions (Article 21),

– implements contained use of GMOs from the 3rd and 4th level of hazard without the approval of the competent authority or in violation of the conditions set out in the approval (Article 22),

– does not behave in accordance with the requirements of the competent authority (Articles 23 and 24),

– in case of accident does not act in accordance with the plan of measures for case of accident, or does not notify the competent authority about the accident (Article 25),

– does not perform risk assessment, or hazard assessment and plan of measures in case of uncontrolled release of GMOs (Articles 28 and 29),

– does not notify the competent authority on the changes, and does not behave in accordance with the competent authority's request to change the conditions of GMO release into the environment (Article 36),

– does not submit to the competent authority a report on the results of deliberate release of GMOs into the environment by the prescribed deadline (Article 37 paragraph 1),

– in case of unplanned release of GMOs into the environment does not act in accordance with the plan of measures, and does not notify the competent authority on the event (Article 38 paragraph 1),

– places GMOs on the market without approval or in violation of the approval (Articles 39 and 46 paragraph 2),

– does not notify the competent authorities on the hazards of GMO products and does not submit a new notification (Article 50),

– places on the market a product made from GMOs without necessary documentation, or which has not been labelled in the prescribed manner (Articles 51 and 52),

– does not apply regulation on transport of hazardous substances while handling, packaging, transporting and transiting GMOs (Article 53),

– does not dispose of, and destroys in the non-hazardous manner the waste containing and/or consisting of, or originating from GMOs in a prescribed manner (Article 54)

– does not compensate for damages caused by unauthorised cross-border movement, transit, usage, deliberate release into the environment and placing on the market of GMOs or products containing and/or consisting of, or originating from GMOs (Article 55).

The responsible person within the legal person shall be fined for the misdemeanour referred to in paragraph 1 of this Article in the amount ranging from HRK 15,000.00 to 50,000.00.

VIII TRANSITIONAL AND FINAL PROVISIONS

Article 69

Procedures initiated pursuant to the Nature Protection Act (OG 162/03), and which refer to GMOs and products containing and/or consisting of, or originating from GMOs, shall be continued by the competent authorities pursuant to the provisions of this Act.

Users are obliged to submit notifications for the contained use of GMOs pursuant to this Act

within three months from the day the secondary legislation referred to in Articles 15 and 21 of this Act is brought.

The competent authorities referred to in Article 3 of this Act shall take over the cases referred to in paragraph 1 of this Article within 15 days from the day this Act enters into force.

Misdemeanour procedures referring to GMOs and products containing and/or consisting of, or originating from GMOs, which were initiated prior to the day this Act enters into force, shall be continued before the competent court pursuant to the provisions of the Nature Protection Act.

Article 70

Expert bodies that will be established pursuant to this Act, shall be established and begin their work within sixty days from the day this Act enters into force.

Article 71

The Government of the Republic of Croatia and heads of competent authorities shall within one year from the day this Act enters into force, pass the legislation for which they are authorised by this Act.

Until the entry into force of the implementing regulations determined in this Act, the regulations regarding GMO passed on the basis of the Nature Protection Act (OG 162/03) shall remain in effect in the part in which their provisions are not contrary to the provisions of this Act.

Article 72

Articles 31, 33, 34, 40, 44 and 48 of this Act shall apply as of the day the Republic of Croatia gains full membership of the European Union.

Article 73

On the day this Act enters into force, Articles 89-141 of the Nature Protection Act (OG 162/03), and the provisions of Article 7 of the same Act referring to GMOs and products containing and/or consisting of, or originating from GMOs, shall cease to be valid.

Article 74

This Act shall enter into force on the eighth day from its publication in the Official Gazette.

Class: 310-26/04-01/02
Zagreb, 20 May 2005

THE CROATIAN PARLIAMENT

The President of the Croatian Parliament
Vladimir Šeks, m.p.