

Genetically Modified Organisms Act

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Chapter One

GENERAL DISPOSITIONS

Article 1. (1) This Act regulates the social relations associated with:

1. the contained use of genetically modified organisms (GMOs);
2. the deliberate release of GMOs into the environment;
3. the placing on the market of a GMO or of a combination of GMOs as or in products;
4. the transfer of GMOs;
5. the import, export and transit of GMOs;
6. the control over the activities covered under Items 1 to 5.

(2) This Act shall have as its objective to protect human health and the environment when carrying out the activities covered under Paragraph (1) in accordance with the precautionary principle, which means priority protection of human health and the environment if any potential harmful effects are likely to be realized, regardless of the existing economic interests or the unavailability of sufficient scientific data.

Article 2. (1) This Act shall apply to GMOs yielded through use of the following techniques and methods of genetic modification:

1. recombinant DNA technology, involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced 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;
2. techniques involving the direct introduction into an organism of heritable genetic material prepared outside the organism, including micro-injection, macro-injection and micro-encapsulation;
3. cell fusion or hybridization 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.

(2) The provisions of this Act shall not apply in respect of:

1. any organisms yielded through methods of genetic modification which do not involve the use of recombinant DNA technology or which do not use GMOs produced by the following methods:

(a) mutagenesis;

(b) cell fusion of prokaryotic and eukaryotic organisms, including protoplast fusion and plant cell fusion, which can exchange genetic material through traditional breeding methods, as well as production of hybridomas;

2. any micro-organisms yielded through methods of genetic modification which do not involve the use of recombinant DNA technology or which do not use GMOs produced by the following methods:

(a) mutagenesis;

(b) cell fusion of prokaryotic and eukaryotic organisms, including protoplast fusion, which can exchange genetic material through traditional breeding methods;

(c) self-cloning;

3. the placing on the market of genetically modified food, feed, human medicinal drugs and medicinal products for veterinary use which consist of or contain a GMO or a combination of GMOs and which are regulated, respectively, by the Foodstuffs Act, the Human Medicinal Drugs and Pharmacies Act and the Veterinary Practices Act.

(3) The provisions of Chapter Three shall not apply in respect of contained use of any GMOs which are not included in a list by order of the Minister of Environment and Water. The Minister of Environment and Water shall include in the said list GMOs meeting the criteria of safety established in an ordinance on contained use of GMOs as adopted by the Council of Ministers.

(4) The carriage by rail, road, sea, air or inland waterway of GMOs which are not subject to contained use shall be governed by the respective provisions on carriage of dangerous goods contained in the international treaties whereto the Republic of Bulgaria is a party, in the Rail Transport Act, the Carriage by Road Act, the Civil Aviation Act, the Merchant Shipping Code, and the statutory instruments of subordinate legislation on the application thereof.

Chapter Two

COMPETENT AUTHORITIES

Article 3. The Minister of Environment and Water and the Minister of Agriculture and Forestry shall conduct the state policy in the sphere of GMOs and shall coordinate the activity of the control authorities related to the application of the Act.

Article 4. (1) The Minister of Environment and Water shall exercise the following powers:

1. grant, modify and withdraw authorizations for:
 - (a) contained use of GMOs in the cases specified under this Act;
 - (b) deliberate release of GMOs into the environment;
2. register premises for contained use of GMOs;
3. organize public consultation on deliberate release of GMOs into the environment in the cases provided for in this Act;
4. coordinate the control powers of the other executive authorities in respect of GMOs.

(2) The Ministry of Environment and Water shall establish and maintain a Biosafety Clearing-House information system for implementation of obligations under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and for exchange of scientific, technical, environmental and legal information regarding GMOs.

(3) The data in the system referred to in Paragraph (2) shall be accessible to the public.

Article 5. The Minister of Agriculture and Forestry shall exercise the following powers:

1. grant, modify and withdraw authorizations for placing on the market of a GMO or of a combination of GMOs as or in products;
2. organize public consultations on placing of GMOs on the market.

Article 6. (1) There shall be established a Consultative Commission on Genetically Modified Organisms with the Minister of Environment and Water, hereinafter referred to as "the Commission."

(2) The Commission shall perform the following functions:

1. give opinions to the Minister of Environment and Water regarding:
 - (a) the grant, modification and withdrawal of authorizations for contained use of GMOs and for deliberate release of GMOs into the environment;
 - (b) the registration of premises for contained use of GMOs;

2. give opinions to the Minister of Agriculture and Forestry regarding the grant, modification and withdrawal of authorizations for placing on the market of a GMO or of a combination of GMOs as or in products;

3. give opinions to the Minister of Environment and Water and to the Minister of Agriculture and Forestry on other matters within the competence thereof as may arise upon the application of this Act;

4. participate in the elaboration of drafts of statutory instruments related to biosafety.

(3) The Commission shall make decisions by consensus. The decisions of the Commission shall be accessible to the public and shall be part of the information system referred to in Article 4 (2) herein.

Article 7. (1) The Commission shall consist of 15 academic degree-holding scientists in the sphere of molecular genetics, molecular biology, ecology and environmental protection, modern biotechnology, agronomy, animal husbandry, biology and medicine and other spheres of science thereto related, representatives of the Bulgarian Academy of Sciences and other research organizations.

(2) The Minister of Education and Science, the Minister of Environment and Water and the Minister of Agriculture and Forestry shall each nominate four academic degree-holding scientists for membership of the Commission, and the Minister of Health shall nominate three academic degree-holding scientists.

(3) The members of the Commission shall be appointed by order of the Minister of Environment and Water for a term of office of four years.

(4) At the first meeting thereof, the Commission shall elect a Chairperson from amongst the members thereof.

(5) The following shall participate in the work of the Commission in a non-voting capacity:

1. one representative each of:

(a) the Ministry of Environment and Water;

(b) the Ministry of Agriculture and Forestry;

(c) the Ministry of Health;

(d) the Ministry of Economy;

(e) the Ministry of Transport and Communications;

(f) the Ministry of Education and Science;

(g) the Commission on Trade and Consumer Protection;

2. three representatives of the non-governmental ecologist organizations, nominated according to a procedure endorsed thereby.

(6) The representatives covered under Paragraph (5) shall be designated by order of the Minister of Environment and Water on a motion by the heads of the relevant central-government departments and organizations referred to in Paragraph (5).

(7) By decision of the members of the Commission, experts included in the list of experts under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity may participate in the work of the Commission.

Article 8. The Chairperson of the Commission shall perform the following functions:

1. organize and direct the operation of the Commission;

2. appoint and preside over the meetings of the Commission;

3. keep the public informed of the operation of the Commission through the mass communication media.

Article 9. (1) The following shall be ineligible for membership of the Commission:

1. any person who is interested in the placing of GMOs on the market, as well as in the import or export of GMOs;
2. any person connected, within the meaning given by the Commerce Act, with any of the persons referred to in Articles 16 and 42 herein.

(2) The members of the Commission shall submit a declaration on the circumstances covered under Paragraph (1).

Article 10. (1) The members of the Commission shall vacate office prior to the expiry of the term of office thereof:

1. upon their own request, addressed in writing to the Minister of Environment and Water;
2. upon termination of the civil-service relationships or employment relationships with the appointing authority or with the employer or, where a civil-law contract has been concluded, upon termination or non-renewal of the said contract after expiry of the term for which the said contract has been concluded;
3. upon entry into effect of a sentence for a premeditated offence at public law;
4. upon permanent actual inability to discharge the duties thereof in the course of more than six months;
5. upon gross or systematic violations of this Act;
6. upon death.

(2) Within one month after a member of the Commission vacates office prior to the expiry of the term of office thereof, the Minister of Environment and Water, acting according to the procedure established by Article 7 herein, shall appoint a replacement for the remainder of the relevant term of office.

Article 11. (1) For each participation in the meetings of the Commission, the members referred to in Article 7 (1) herein shall be paid one minimum wage as fixed for the relevant year by Council of Ministers decree.

(2) The representatives referred to in Article 7 (5) shall not be remunerated for participation in the meetings of the Commission.

Article 12. The activity of the Commission shall be serviced by a structural unit of the specialized administration of the Ministry of Environment and Water.

Article 13. (1) The Commission shall adopt Rules of Operation thereof, which shall be endorsed by the Minister of Environment and Water.

(2) In the performance of the activity thereof, the members of the Commission shall be independent and shall be guided solely by the advances of sciences and technology. The meetings of the Commission shall be public.

(3) The members of the Commission shall present opinions in writing on each of the matters discussed.

(4) The Commission shall mandatorily take minutes of the proceedings at the meetings thereof.

(5) The documents on the meetings of the Commission shall be preserved for a period of 20 years.

Article 14. (1) The members of the Commission, the officials of the specialized administration referred to in Article 12 herein, the persons referred to in Article 7 (5) herein, the experts referred to

in Article 7 (7) herein and the officials who exercise control under this Act shall be obligated to respect the confidentiality of any information constituting a secret protected by the law, which has come to the knowledge thereof upon or in connection with the performance of the activity thereof. The said persons shall sign a declaration pledging non-disclosure of any such information.

(2) The members of the Commission shall be obligated to respect the confidentiality of the information referred to in Paragraph (1) within three years after termination or expiry of the term of office thereof.

Article 15. The amount of the fees collected under this Act shall be endorsed by a Rate Schedule of the Council of Ministers.

Chapter Three

CONTAINED USE OF GMOs

Section I

Assessment of the Risk to Human Health and the Environment Posed by the Contained Use of GMOs

Article 16. (1) Contained use of GMOs shall be carried out by natural and legal persons, research institutes and higher schools, which have been granted authorization according to the procedure established by this Chapter.

(2) Prior to commencement of a contained use of GMOs, the persons covered under Paragraph (1) shall be obligated to perform an assessment of the risk as regards:

1. the potential adverse effects of the GMOs on human health and the environment;
2. the nature of the contained use;
3. the likelihood or probability of the potential adverse effects occurring;
4. the impact of the potential adverse effects.

(3) The risk assessment shall be documented and kept by the persons covered under Paragraph (1) and shall be made available upon request to the Ministry of Environment and Water and to the control authorities.

Article 17. On the basis of the risk assessment, the persons covered under Article 16 (1) herein shall classify the contained use of GMOs as follows:

1. Class 1: activities of negligible risk, for which Level 1 containment is appropriate to protect human right and the environment;
2. Class 2: activities of low risk, for which Level 2 containment is appropriate to protect human right and the environment;
3. Class 3: activities of moderate risk, for which Level 3 containment is appropriate to protect human right and the environment;
4. Class 4: activities of high risk, for which Level 4 containment is appropriate to protect human right and the environment.

Article 18. (1) Contained use of genetically modified micro-organisms shall be classified as Class 1 where:

1. the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants;
2. the nature of the vector and the insert is such that the genetically modified micro-organism yielded is unlikely to cause disease to humans, animals or plants, or to cause deleterious effects in the environment in the event of an unintended release therein.

(2) Contained use of genetically modified micro-organisms shall be classified as Class 2 where:

1. the recipient or parental micro-organism may cause disease to humans, animals or plants which is unlikely to spread and for which appropriate prophylactic measures or therapies are available, and is unlikely to cause deleterious effects in the environment in the event of an unintended release therein;

2. the nature of the vector and the insert is such that the genetically modified micro-organism yielded is likely to cause disease to humans, animals or plants directly through horizontal gene transfer or through another mechanism, which disease is unlikely to spread but for which appropriate prophylactic measures or therapies are available, and is unlikely to cause deleterious effects in the environment in the event of an unintended release therein;

(3) Contained use of genetically modified micro-organisms shall be classified as Class 3 where:

1. the recipient or parental micro-organism may cause disease to humans, animals or plants which is likely to spread but for which appropriate prophylactic measures or therapies are available, and is unlikely to cause deleterious effects in the environment if an accident occurs;

2. the nature of the vector and the insert is such that the genetically modified micro-organism yielded is likely to cause disease to humans, animals or plants directly through horizontal gene transfer or through another mechanism, which disease is likely to spread but for which appropriate prophylactic measures or therapies are available, and is unlikely to cause deleterious effects in the environment in the event of an unintended release therein;

(4) Contained use of genetically modified micro-organisms shall be classified as Class 4 where:

1. the recipient or parental micro-organism may cause disease to humans, animals or plants directly, through horizontal gene transfer or through another mechanism, which disease is likely to spread and for which appropriate prophylactic measures or therapies are not available, or is likely to cause deleterious effects in the environment in the event of an unintended release therein;

2. the nature of the vector and the insert is such that the genetically modified micro-organism yielded is likely to cause disease to humans, animals or plants, which is likely to spread and for which appropriate prophylactic measures or therapies are not available, or is likely to cause deleterious effects in the environment in the event of an unintended release therein.

(5) The pathogenicity of the parental and recipient micro-organism shall be determined according to the classification under Ordinance No. 4 dated 14 October 2002 on Protection of Workers from Risks Related to Exposure to Biological Agents at Work ([promulgated in the] *State Gazette* No. 105 of 2002).

Article 19. (1) Contained use of genetically modified plants shall be classified in two classes.

(2) Contained use of genetically modified plants shall be classified as Class 1 where:

1. the genetically modified plants have a potential for transfer of genetic material to indigenous plant species which is limited by lack of sexually compatible species or by the nature of the transformation conditioning prevention or minimization of pollen dispersal;

2. the plant pathogens used in the transformation are of an unviable strain.

(3) Contained use of genetically modified plants shall be classified as Class 2 where:

1. the genetically modified plants have a potential for transfer of genetic material to indigenous plant species;

2. the genetically modified plants are potential pests;

3. the plant pathogens used in the transformation are of an unviable strain;

4. there is a possibility of a horizontal gene transfer from genetically modified plants to other species, resulting in occurrence of adverse effects.

Article 20. (1) Contained use of genetically modified animals shall be classified in two classes.

(2) Contained use of genetically modified animals shall be classified as Class 1 where one of the following conditions is fulfilled:

1. the genetically modified animals have no capacity to survive in the Bulgarian environment;
2. the genetically modified animals have a limited capability for transfer of genetic material to indigenous animal species;
3. the genetically modified animals are not infected with genetically modified micro-organisms or other pathogens and the genetic modification does not present a greater hazard to human health or the environment than the hazard presented by the non-modified parental organisms;
4. the genetically modified farm animals have traits of a distinct appearance as a result of the genetic modification.

(3) Contained use of genetically modified animals shall be classified as Class 2 where one of the following conditions is fulfilled:

1. the genetically modified animals have a capacity to survive in the Bulgarian environment;
2. the genetically modified animals can cause harm to humans or the environment if they leave the contained premise and have a capacity for transfer of genetic material to indigenous animal species;
3. the genetically modified animals are not infected with genetically modified micro-organisms or other pathogens, but the genetic modification presents a greater hazard to human health or the environment than the hazard presented by the non-modified parental organisms.

Article 21. The terms and procedure for conduct of an assessment of the risk posed by contained use of GMOs shall be established by the ordinance referred to in Article 2 (3) herein.

Article 22. The assessment of the risk posed by contained use of GMOs and the protective measures applied shall be reviewed and updated by the applicant once every two years or whenever:

1. the protective measures are no longer adequate to the risk class assigned;
2. the class assigned does not correspond to the degree of risk involved;
3. the risk assessment is no longer appropriate judged in the light of new scientific or technical knowledge.

Section II

Registration of Premises for Contained Use of GMOs

Article 23. (1) Contained use of GMOs shall be carried out in premises registered at the Ministry of Environment and Water.

(2) Premises shall be registered subject to the condition that the persons covered under Article 16 herein have ensured therein the preventive and protective measures determined by the ordinance referred to in Article 2 (3) herein for the relevant class of use of GMOs, for the purpose of ensuring health and safety at work for the persons working in the premises and preventing exposure of the environment to the impact of GMOs.

Article 24. (1) The persons covered under Article 16 herein, hereinafter referred to as "applicants," shall submit an application in writing to the Minister of Environment and Water for registration of the premise which will be used for the first time to carry out contained uses of GMOs.

(2) Any such application shall contain:

1. identification of the applicant: name, number of identity document and permanent address (applicable to natural persons), or designation, registered office and address of the place of management, BULSTAT registration (applicable to sole traders and legal persons);
2. location and description of the premise wherein contained uses of GMOs are to be carried out;
3. names and permanent addresses of the natural persons responsible for supervision and safety of the contained use of GMOs;
4. information on the training and qualifications of the persons referred to in Item 3;
5. details of any biosafety committees and groups established by the applicant which carry out the activities specified in the ordinance referred to in Article 2 (3) herein;
6. a description of the nature of the work which will be undertaken;
7. the class assigned under Article 17 herein;
8. a summary of the risk assessment and information on waste management.

(3) A certificate of current status of the Commercial Register record on the applicant and a documentary proof of payment of a fee for application for registration of premises for contained use of GMOs shall be attached to the application.

Article 25. (1) The applicant shall be notified of any deficiencies or inaccuracies ascertained within seven days after receipt of the application.

(2) The applicant shall be obligated to cure the deficiencies or inaccuracies as ascertained.

(3) The Commission shall examine the accuracy and completeness of the information given in the application as submitted, the correctness of the risk assessment as carried out and of the class of contained use as assigned, and the suitability of the protective measures.

(4) Within 30 days after submission of an application, the Commission shall prepare an opinion and shall submit the said opinion to the Minister of Environment and Water.

(5) Any period of time during which curing of the deficiencies and inaccuracies in the application is awaited shall not be taken into account for the purpose of calculating the time limit referred to in Paragraph (4).

Article 26. (1) The Minister of Environment and Water shall issue an order on entry of the premise into a register of premises for contained use of GMOs or shall issue a reasoned refusal of registration within 15 days after receiving the opinion of the Commission.

(2) The Minister of Environment and Water shall issue a certificate of registration of the premise to the applicant.

(3) The Minister of Environment and Water shall refuse registration of a premise which does not meet the conditions under Article 23 herein.

(4) The Ministry of Environment and Water shall notify the applicant of a refusal by the Minister of Environment and Water within seven days after issuance of the said refusal.

(5) A refusal of registration of a premise shall be appealable according to the procedure established by the Supreme Administrative Court Act.

Article 27. (1) A public register of the premises for contained use of GMOs shall be established and maintained in an electronic form at the Ministry of Environment and Water.

(2) The public register referred to in Paragraph (1) shall be part of the information system referred to in Article 4 (2) herein.

(3) The particulars and circumstances covered under Article 24 (2) herein shall be subject to entry into the register.

(4) Upon any change of the particulars and circumstances referred to in Paragraph (3), the persons who or which have received a certificate of registration shall be obligated to notify the Minister of Environment and Water within seven days. The new circumstances shall be entered into the register.

(5) The Minister of Environment and Water shall expunge premises in the register:

1. upon written request by the person who or which has received a certificate of registration of the premise;
2. where, as a result of control under Chapter Seven herein, it has been established that the premise does not meet the conditions covered under Article 23 herein.

Article 28. The Ministry of Environment and Water shall collect a fee for registration under this Section.

Section III

Terms and Procedure for Contained Use of GMOs

Article 29. (1) Contained used of GMOs shall be carried out by the persons covered under Article 16 herein, who or which have obtained an authorization from the Minister of Environment and Water, in premises which have been registered according to Section II of this Chapter.

(2) Authorizations shall be granted for each particular case of contained use of GMOs and for each particular class of use of GMOs, provided the Commission has given a favourable opinion.

(3) Any laboratories or operations using GMOs must be headed by persons with higher education and length of service of not less than five years in a similar laboratory or operation.

Article 30. (1) Any persons covered under Article 16 herein, who or which wish to carry out contained uses of GMOs, shall submit an application in writing to the Minister of Environment and Water.

(2) Any such application shall contain:

1. identification of the applicant: name, number of identity document and permanent address (applicable to natural persons), or designation, registered office and address of the place of management, BULSTAT registration (applicable to sole traders and legal persons);
2. the registration number of the premise for use;
3. the names of the natural persons responsible for supervision and safety of the contained use of GMOs;
4. information on the training and qualifications of the persons referred to in Item 3;
5. the recipient, donor and/or parental organism used, also indicating the host-vector system;
6. the source or sources and the intended functions of the genetic material involved in the modification;
7. identity and characteristics of the GMOs;
8. the purpose of the contained use, including the expected results;
9. approximate culture volumes to be used;
10. description of the contained use, including information about waste management regarding waste treatment, final form and destination;
11. time period for which the contained use of GMOs is to be carried out;
12. a summary of the risk assessment (applicable to Classes 1 and 2) or a copy of the risk assessment (applicable to Classes 3 and 4);

13. the information necessary for the Commission to evaluate the emergency response plan referred to in Article 31 (4) herein.

(3) Accident prevention and emergency response plans shall be attached to any application for contained use of GMOs of Classes 3 and 4, referred to in Paragraph (2), and the said plans shall contain information regarding:

1. any specific hazards arising from the location of the installation;
2. the preventive measures applied, such as safety equipment, alarm systems and containment methods;
3. procedures and plans for verifying the continuing effectiveness of the containment measures;
4. a description of information provided to persons working with GMOs in containment conditions.

(4) Any application shall be submitted in a Bulgarian language version and in an English language version. An application may be submitted electronically as well.

(5) A certificate of current status of the Commercial Register record on the applicant and a documentary proof of payment of a fee shall be attached to the application.

Article 31. (1) The applicant shall be notified of any deficiencies or inaccuracies ascertained within seven days after receipt of the application.

(2) The applicant shall be obligated to cure the deficiencies or inaccuracies as ascertained within 14 days after receipt of the notification under Paragraph (1).

(3) The Commission shall examine the accuracy and completeness of the information given in the application as submitted, the correctness of the risk assessment as carried out and of the class of contained use as assigned, the suitability of the protective measures, the waste management, and emergency response measures.

(4) The Commission shall:

1. examine the emergency response plan for contained use of GMOs as drawn up where failure of the containment measures could lead to serious danger to humans outside the premises and/or to the environment;
2. verify whether information on the plan referred to in Item 1 and the relevant safety measures to be applied is supplied to the persons liable to be affected by accidents.

(5) The information referred to in Item 2 of Paragraph (4) shall be made publicly available and shall be updated at appropriate intervals.

(6) After completion of the examinations covered under Paragraphs (1) to (4), the Minister of Environment and Water, acting on an opinion given by the Commission, may:

1. ask the applicant:

- (a) to provide further information;
- (b) to modify the conditions of the proposed contained use;
- (c) to amend the class assigned to the contained use;

2. limit the time for which the contained use should be permitted, or subject the said contained use to certain specific conditions.

(7) Within 30 days after submission of an application, the Commission shall prepare an opinion and shall submit the said opinion to the Minister of Environment and Water.

Article 32. (1) Acting on an opinion given by the Commission and after consultation with the Minister of Agriculture and Forestry, the Minister of Environment and Water shall grant an authorization for contained use of GMOs of all classes within the following time limits:

1. at the latest 45 days after submission of an application: applicable to Class 1 and Class 2;
2. at the latest 90 days after submission of an application: applicable to Class 3 and Class 3;
3. at the latest 45 days after submission of an application, where the premises for use have been used for Class 3 or a higher class of contained uses of GMOs and the uses carried out conformed to an authorization granted by the Minister of Environment and Water.

(2) The following periods of time shall not be taken into account for the purpose of calculating the time limit referred to in Paragraph (1):

1. any period of time during which curing of the deficiencies and inaccuracies in the application is awaited;
2. any period of time during which further information, referred to in Item 1 (a) of Article 31 (6) herein, is awaited from the applicant.

(3) The authorization shall lay down requirements for carrying out contained uses, including requirements for the transport thereof.

Article 33. (1) The Minister of Environment and Water shall refuse the grant of an authorization under Article 32 should the Commission give a negative opinion and where:

1. the risk assessment as carried out is inaccurate, the class of contained use has not been assigned correctly, the protective measures, the waste management, and emergency response measures are unsuitable for the relevant class of contained use;
2. the applicant has failed to cure the deficiencies and inaccuracies in the application thereof within the time limit referred to in Article 31 (2) herein.

(2) Any refusal under Paragraph (1) shall be appealable according to the procedure established by the Supreme Administrative Court Act.

Article 34. (1) An authorization referred to in Article 32 herein shall be granted for a period not exceeding five years.

(2) Within six months prior to the expiry of the period of validity of an authorization referred to under Paragraph (1), the persons may submit an application for an extension of the said period.

Article 35. The Minister of Environment and Water shall notify the applicant of the authorization referred to in Article 32 herein or of the refusal referred to in Article 33 herein within fourteen days after delivery of the decision.

Article 36. (1) A public register of the authorizations for contained use of GMOs as granted shall be established and maintained in an electronic form at the Ministry of Environment and Water.

(2) The public register referred to in Paragraph (1) shall be part of the information system referred to in Article 4 (2) herein.

(3) The circumstances and particulars contained in the authorization for contained use of GMOs shall be subject to entry into the register.

(4) Any changes in the particulars and circumstances referred to in Paragraph (3) shall likewise be subject to entry into the register.

Article 37. (1) In the event of an accident, the person who or which has been granted an authorization for contained use of GMOs shall be obligated to inform the Minister of Environment and Water within 24 hours after the accident of, providing the following information:

1. the circumstances whereunder the accident occurred;
2. the identity and quantities of the GMOs concerned;

3. any other information necessary to assess the effects of the accident on the health of the general population and the environment;
4. the emergency protective measures taken.

(2) In the cases referred to in Paragraph (1) the Commission:

1. shall propose to the Minister of Environment and Water to apply the relevant emergency measures;
2. shall collect the necessary information, analyze the causes for occurrence of the accidents, and make recommendations to avoid such accidents in the future and to limit the effects thereof.

Article 38. Before modifying the conditions of the contained use, which may alter the level of risk of the use as carried out, the person who or which has been granted an authorization shall be obligated to notify the Minister of Environment and Water and to submit a new application under Article 30 herein.

Article 39. (1) Should new scientific data concerning an increase in the risk to human health or the environment become available after the grant of an authorization for contained use of GMOs, the person who has been granted an authorization for such use shall be obligated to inform immediately the Minister of Environment and Water.

(2) In the cases referred to in Paragraph (1), the Minister of Environment and Water shall obligate the person who has been granted an authorization for contained use of GMOs to modify the conditions of use or to discontinue the said use.

(3) The provision of Paragraph (2) shall furthermore apply in the cases where the data referred to in Paragraph (1) are received at the Ministry of Environment and Water or members of the Commission become aware of any such data.

Article 40. The Minister of Environment and Water shall withdraw an authorization for contained use of GMOs if the conditions defined by the authorization as granted are breached resulting in the occurrence of adverse effects on human health and the environment.

Article 41. The Ministry of Environment and Water shall collect a fee for the grant of authorizations under this Section.

Chapter Four

PROCEDURE FOR DELIBERATE RELEASE OF GMOs INTO THE ENVIRONMENT AND PLACING ON THE MARKET OF A GMO OR OF A COMBINATION OF GMOs AS OR IN PRODUCTS

Section I

Assessment of the Risk to Human Health and the Environment Posed by the Deliberate Release of GMOs into the Environment and by the Placing on the Market of a GMO or of a Combination of GMOs as or in Products

Article 42. (1) Before undertaking a deliberate release of GMOs into the Environment or placing on the market of a GMO or of a combination of GMOs as or in products, each natural or legal person shall be obligated to carry out an assessment of the risk to human right and the environment.

(2) The risk assessment shall include results of observations carried out and a detailed monitoring plan to identify potential short-term and long-term effects on human health and the environment of the deliberate release of GMOs into the environment and the placing of GMOs on the market.

Article 43. (1) The risk assessment shall cover all potential adverse effects on human and animal health, the environment and biological diversity, which may occur directly or indirectly upon the deliberate release into the environment and/or the placing of GMOs on the market, including an

analysis of the potential cumulative long-term effects relevant to the deliberate release or placing of GMOs on the market.

(2) The risk assessment shall be carried out on the basis of the available scientific and technical data from national and international sources.

(3) The risk assessment shall be carried out in accordance with the principles and methodology outlined in Annex 1 hereto.

(4) On the basis of the risk assessment, the persons referred to in Article 42 herein shall determine the need for and methods of risk management.

(5) The risk assessment shall furthermore include a conclusion on the potential impact on human health and the environment from the deliberate release of GMOs into the environment or from the placing of GMOs on the market.

Article 44. (1) Should new scientific data concerning the GMO and the effects on human health or the environment of the deliberate release of the said GMO into the environment or the placing thereof on the market become available, the risk assessment shall be readdressed.

(2) The risk assessment shall determine whether the risk has changed and whether there is a need for amending the risk management.

Article 45. The terms and the procedure for carrying out an assessment of the risk posed by the deliberate release and the placing of GMOs on the market, as well as the information that must be included in the conclusion referred to in Article 43 (5) herein, shall be determined by an ordinance on deliberate release of GMOs into the environment and placing of GMOs on the market, adopted by the Council of Ministers.

Section II

Deliberate Release of GMOs into the Environment

Article 46. (1) A GMO or a combination of GMOs shall be deliberately released into the environment after obtaining an authorization granted by the Minister of Environment and Water, provided the Commission has given a favourable opinion.

(2) An authorization referred to in Paragraph (1) shall be granted for each particular case, acting on an application in writing from a person referred to in Article 42 herein.

Article 47. (1) Any application referred to in Article 46 (2) herein shall be submitted to the Minister of Environment and Water and shall consist of:

1. a technical dossier, supplying the information necessary for carrying out the environmental risk assessment of the deliberate release of a GMO or a combination of GMOs into the environment;
2. a risk assessment and a conclusion under Section I of this Chapter, including a description of the methods used and a reference to standardized or internationally recognized methods, and bibliographic reference.

(2) The technical dossier shall contain:

1. general information, including:

(a) identification of the applicant: name, number of identity document and permanent address (applicable to natural persons), or designation, registered office and address of the place of management, BULSTAT registration (applicable to sole traders and legal persons);

(b) names, qualifications and experience of the scientists and experts responsible for the project;

(c) title of the project;

2. information relating to the GMO, including marker genes contained therein;

3. information relating to the conditions of release and the receiving environment;
4. information on the interactions between the GMO(s) and the environment;
5. a plan for monitoring in order to identify effects of the GMO(s) on human health and/or the environment;
6. information on control, remediation methods, waste treatment and emergency response plans;
7. map of the farm whereon transgenic crops are to be grown under the application, the neighbours of the said farm, a list of owners of adjoining fields and agricultural practices (organic or conventional farming);
8. a summary of the dossier.

(3) The particulars which the information covered under Paragraph (2) must contain and the format of the application shall be established in the ordinance referred to in Article 45 herein.

(4) Any application shall be submitted in a Bulgarian language version and in an English language version. An application may be submitted electronically as well.

(5) A certificate of current status of the Commercial Register record on the applicant and a documentary proof of payment of a fee shall be attached to the application.

Article 48. (1) The applicant may refer to information, data or results from studies and analyses of applications previously submitted by other persons to the Minister of Environment and Water or to the relevant competent authorities of other States, provided that the said information, data or results are non-confidential or the previous applicants have given consent in writing for the use thereof.

(2) The applicant may submit additional information other than the information covered under Article 47 herein which the said applicant considers relevant.

Article 49. (1) The applicant shall be notified of any deficiencies or inaccuracies ascertained within seven days after receipt of the application.

(2) The applicant shall be obligated to cure the deficiencies or inaccuracies as ascertained within 14 days after receipt of a notification under Paragraph (1).

(3) The Commission shall examine the accuracy and completeness of the information given in the application as submitted, the correctness of the risk assessment as carried out, the suitability of the monitoring plan, of the control foreseen, of the remediation methods, of the manners of waste treatment, and of the emergency response plans.

(4) The Minister of Environment and Water, acting on an opinion given by the Commission, may request from the applicant to furnish additional information other than the information covered under Article 47 herein, stating in writing the reasons for any such request.

(5) Within 60 days after submission of an application, the Commission shall prepare an opinion and shall submit the said opinion to the Minister of Environment and Water.

Article 50. (1) After preparation of the opinion referred to in Article 49 (5) herein, the Ministry of Environment and Water shall organize a public consultation, which is to be held within 45 days.

(2) The summary of the technical dossier, the summary of the risk assessment referred to in Article 43 herein and the opinion of the Commission referred to in Article 49 (5) herein shall be presented in the public consultation.

(3) No information designated as confidential according to the procedure established by Chapter Six herein may be subject to consultation.

(4) Not later than 30 days prior to the day of the consultation, the subject of public consultation and the place where the necessary information is available to stakeholders shall be announced in one national daily newspaper, through the local mass communication media, through posting notices in

the relevant mayoralities in the area of the deliberate release of GMOs into the environment, as well as on the Internet site of the information system referred to in Article 4 (2) herein. Any such notice shall furthermore announce the date and venue of the public consultation.

(5) Any person may provide an opinion on the subject of the consultation, whether in writing or in an electronic form.

(6) The applicant or representatives thereof and the members of the Commission shall likewise be invited to participate in the public consultation.

(7) Minutes shall be taken at the public consultation and shall be attached to the documents on grant of the authorization.

Article 51. (1) Acting on the opinion given by the Commission and the results of the public consultation and after consultation with the Minister of Agriculture and Forestry, the Minister of Environment and Water shall grant or shall refuse to grant an authorization for the deliberate release of a GMO or a combination of GMOs into the environment within 90 days after receipt of an application.

(2) The following periods of time shall not be taken into account for the purpose of calculating the time limit referred to in Paragraph (1):

1. any period of time during which curing of the deficiencies and inaccuracies in the application is awaited;

2. any period of time during which further information, referred to in Article 49 (4) herein, is awaited from the applicant;

3. the shorter of the duration of holding a public consultation under Article 50 herein and 30 days after expiry of the time limit referred to in Paragraph (1).

(3) GMOs shall be deliberately released into the environment by stages, conforming to the conditions provided for in the authorization, and a memorandum shall be drawn up on implementation of each stage. A succeeding stage shall be proceeded with solely provided no adverse effects on the environment or human and animal health and biological diversity have been ascertained at the preceding stage.

(4) The authorization referred to in Paragraph (1) shall lay down the time period and the conditions whereunder GMOs are to be deliberately released into the environment, including the isolation distances according to Annex 2 hereto.

Article 52. (1) The Minister of Environment and Water shall refuse to grant an authorization for the deliberate release of GMOs into the environment, where the applicant has failed to cure the deficiencies and inaccuracies in the application thereof within the time limit referred to in Article 49 (2) herein and should the opinion of the Commission be that the said release poses risks to human health or the environment and that the protective measures taken are insufficient or ineffective.

(2) The Minister of Environment and Water shall refuse to grant an authorization for the deliberate release of GMOs into the environment if organic farming is practised on an adjoining field.

(3) Any refusal under Paragraphs (1) and (2) shall be appealable according to the procedure established by the Supreme Administrative Court Act.

Article 53. The Ministry of Environment and Water shall notify the applicant of the decision referred to in Article 51 herein or of the refusal referred to in Article 52 herein within 14 days after delivery of the said decision or refusal.

Article 54. (1) In the event of occurrence, after the grant of an authorization for deliberate release, of any changes upon the deliberate release of a GMO or a combination of GMOs which may increase the risk to human health or the environment, the applicant shall be obligated immediately:

1. to take the necessary measures for protection of human health and the environment;
2. to inform the Minister of Environment and Water of the changes or of the new circumstances;
3. to review the protective measures applied and, if necessary, to modify the said measures.

(2) Where the data referred to in Paragraph (1) are received at the Ministry of Environment and Water or members of the Commission become aware of any such data, the said information shall be subject to evaluation by the Commission. The information referred to in Paragraph (1) and the evaluation of the Commission shall be made available to the public.

(3) The requirement under Paragraph (1) shall furthermore apply should new scientific data concerning an increase in the risk to human health or the environment become available both while consideration of an application is in progress and after grant of an authorization for deliberate release.

(4) In the cases covered under Paragraphs (1) to (3), the Minister of Environment and Water, acting on an opinion given by the Commission, shall modify the conditions or shall suspend or terminate the deliberate release of the GMOs into the environment, stating the reasons for so doing and notifying the public thereof.

Article 55. (1) After a deliberate release of GMOs into the environment, the person who or which has been granted an authorization for such release shall be obligated, within the time limits established in the said authorization, to inform the Minister of the Environment and Water of the results of the release in respect of any risk to human health and the environment.

(2) The information referred to in Paragraph (1) shall be furnished in a manner established by the ordinance referred to in Article 45 herein.

Article 56. The Minister of Environment and Water shall withdraw an authorization for the deliberate release of GMOs into the environment if the conditions defined by the authorization as granted are breached.

Article 57. (1) The following public registers shall be established and maintained in an electronic form at the Ministry of Environment and Water:

1. a public register of the authorizations for deliberate release of GMOs into the environment as granted;
2. a public register of the areas wherein the deliberate release of GMOs is authorized.

(2) The registers referred to in Paragraph (1) shall be part of the information system referred to in Article 4 (2) herein.

(3) The circumstances and particulars which are specified in the ordinance referred to in Article 45 herein shall be entered into the registers.

(4) Any changes in the particulars and circumstances referred to in Paragraph (3) shall likewise be entered into the registers.

Article 58. The Ministry of Environment and Water shall collect a fee for the grant of authorizations under this Section.

Section III

Placing on the Market of a GMO or of a Combination of GMOs as or in Products

Article 59. (1) No GMO or a combination of GMOs as or in products, which are not foodstuffs or ingredients of a foodstuff within the meaning given by the Foodstuffs Act, shall be placed on the market before obtaining an authorization from the Minister of Agriculture and Forestry.

(2) The Minister of Agriculture and Forestry shall grant an authorization acting on an application in writing by a person referred to in Article 42, who or which wishes to place any GMO or a

combination of GMOs as or in products, and on a favourable written opinion given by the Commission.

Article 60. (1) Any application referred to in Article 59 (2) herein shall be submitted to the Minister of Agriculture and Forestry and shall contain:

1. identification of the applicant:

(a) name and number of identity document and permanent address: applicable to natural persons;

(b) designation, registered office and address of the place of management and BULSTAT registration: applicable to sole traders and legal persons;

2. information relating to the GMO(s);

3. information relating to the conditions and manners of release of the GMO and the receiving environment;

4. information on the interactions between the GMO(s) and the environment;

5. information on monitoring, control, waste treatment and emergency response plans;

6. a risk assessment and a conclusion under Section I of this Chapter;

7. the conditions for the placing on the market of the product, if there are any such conditions, including any specific conditions of use;

8. a proposed period of validity of the authorization for placing on the market, which may not exceed five years;

9. a monitoring plan and a proposal for the time-period of the said monitoring plan;

10. a proposal for the manner of labelling of the product;

11. a proposal for packaging of the product;

12. a summary of the full dossier;

13. additional information.

(2) Any application shall be submitted in a Bulgarian language version and in an English language version. An application may be submitted electronically as well.

(3) A certificate of current status of the Commercial Register record on the applicant and a documentary proof of payment of a fee shall be attached to the application.

(4) The information covered under Items 2 to 5 of Paragraph (1), the requirements for the monitoring plan referred to in Item 9 of Paragraph (1), the additional information referred to in Item 13 of Paragraph (1) and the format of the application shall be established in the ordinance referred to in Article 45 herein.

(5) The information covered under Items 2 to 5 and Item 13 of Paragraph (1) shall take into account the diversity of sites of use of the GMO as or in products and shall include information on data and results obtained from research and developmental releases of the GMO concerning the impact of the release on human health and the environment.

Article 61. A separate application for placing on the market shall be required where a GMO or a combination of GMOs, in respect of which an application has already been submitted, are to be used for purposes different from the purposes specified in the original application.

Article 62. (1) The applicant shall include in the application information on data or results from deliberate releases of the same GMOs or the same combination of GMOs in respect of which the said applicant has submitted applications or which releases the said applicant has carried out either inside or outside Bulgaria.

(2) The applicant may refer to data or results from applications previously submitted by other applicants or submit additional information as the applicant considers relevant, provided that the information and results are non-confidential or the other applicants have given their consent in writing.

Article 63. (1) The applicant shall be notified of any deficiencies or inaccuracies ascertained within seven days after receipt of the application.

(2) The applicant shall be obligated to cure the deficiencies or inaccuracies as ascertained within 14 days after receipt of the notification under Paragraph (1).

(3) The Commission shall examine the accuracy and completeness of the information given in the application as submitted, the correctness of the risk assessment as carried out, the suitability of the monitoring plan, the manners of waste treatment and the emergency response plans, as well as the proposal for the manner of labelling and packaging of the product.

(4) After completion of the examinations, the Minister of Agriculture and Forestry, acting on an opinion given by the Commission, may ask the applicant to provide further information, stating in writing the reasons for any such request.

(5) Within 60 days after submission of an application, the Commission shall prepare an opinion and shall submit the said opinion to the Minister of Agriculture and Forestry.

Article 64. (1) After preparation of the opinion referred to in Article 63 (5) herein, the Ministry of Agriculture and Forestry shall hold a public consultation, whereof the duration may not exceed 45 days.

(2) The summary of the technical dossier, the summary of the risk assessment referred to in Article 43 herein and the opinion of the Commission referred to in Article 63 (5) herein shall be made available at the public consultation.

(3) No information designated as confidential according to the procedure established by Chapter Six herein may be subject to consultation.

(4) Not later than 30 days prior to the day of the consultation, the subject of public consultation and the place where the necessary information is available to stakeholders shall be announced in one national daily newspaper, through the local mass communication media, as well as on the Internet site of the information system referred to in Article 4 (2) herein. Any such notice shall furthermore announce the date and venue of the public consultation.

(5) Any person may provide an opinion on the subject of the consultation, whether in writing or in an electronic form.

(6) The applicant or representatives thereof and the members of the Commission shall likewise be invited to participate in the public consultation.

(7) Minutes shall be taken at the public consultation and shall be attached to the documents on grant of the authorization.

Article 65. Should new scientific data concerning an increase in the risk to human health or the environment become available before the grant of an authorization for placing on the market, the applicant shall be obligated immediately:

1. to propose the necessary measures for protection of human health and the environment;
2. to inform the Minister of Agriculture and Forestry of the new data and the proposed measures under Item 1;
3. to review the available information and to propose modifications in the conditions for placing on the market.

Article 66. (1) Acting on a favourable opinion given by the Commission and the results of the public consultation and after consultation with the Minister of Environment and Water, the Minister of Agriculture and Forestry shall grant an authorization for placing of GMOs on the market or shall refuse to grant an authorization within 90 days after receipt of the application.

(2) The following periods of time shall not be taken into account for the purpose of calculating the time limit referred to in Paragraph (1):

1. any period of time during which curing of the deficiencies and inaccuracies in the application is awaited;
2. any period of time during which further information, referred to in Article 63 (4) herein, is awaited from the applicant;
3. the shorter of the duration of holding a public consultation under Article 64 herein and 30 days after expiry of the time limit referred to in Paragraph (1).

(3) The authorization shall be dispatched to the applicant within 14 days after delivery of the decision.

Article 67. (1) An authorization for placing of GMOs on the market shall contain:

1. the identity of the GMO(s) to be placed on the market as or in products, and the unique identifier of the said GMO(s);
2. the period for which the authorization is granted;
3. the conditions for the placing of GMO(s) on the market, including any specific condition of use, handling and packaging of the said GMO(s), and conditions for the protection of particular ecosystems or geographical areas;
4. an obligation of the applicant to keep control samples which are to be made available to the control authorities on request;
5. the labelling requirements;
6. the requirements for the monitoring plan and the time period thereof, as well as, where appropriate, any obligations of any person selling the product or any user thereof, in the case of GMOs grown.

(2) The rules for composition of the unique identifier referred to in Item 1 of Paragraph (1) shall be regulated by the ordinance referred to in Article 45 herein.

(3) An authorization shall be granted for a period not exceeding five years.

(4) In respect of any GMOs intended for production and marketing as seeds and planting stock, the period referred to in Paragraph (3) shall begin to run as from the day of inclusion of the plant variety on the official national catalogue of plant varieties according to the Seed Stock and Planting Stock Act.

(5) In respect of forest reproductive material, the period referred to in Paragraph (3) shall begin to run as from the day of inclusion of the basic material containing the GMO on the National Register of Basic Forest Reproductive Material.

Article 68. (1) The Minister of Agriculture and Forestry shall refuse to grant an authorization for placing on the market, stating the reasons for any such refusal, should the opinion of the Commission be that the said placing poses risks to human health or the environment and that the protective measures taken are insufficient or ineffective, and where the applicant has failed to cure the deficiencies and inaccuracies in the application thereof within the time limit referred to in Article 63 (2) herein.

(2) Any refusal under Paragraph (1) shall be appealable according to the procedure established by the Supreme Administrative Court Act.

Article 69. (1) A public register of the authorizations for placing of GMOs on the market shall be established and maintained in an electronic form at the Ministry of Agriculture and Forestry.

(2) The electronic register referred to in Paragraph (1) shall be part of the information system referred to in Article 4 (2) herein.

(3) The circumstances and particulars, contained in the authorization for placing of GMOs on the market, shall be subject to entry into the register.

(4) Any changes in the particulars and circumstances referred to in Paragraph (3) shall likewise be entered into the register.

Article 70. (1) The person who or which has been granted an authorization shall carry out monitoring in several steps under the plan referred to in Item 6 of Article 67 (1) herein, as approved by the authorization, and shall prepare reports on the results of the said monitoring on the placing on the market of GMOs as or in products, which shall be submitted to the Minister of Agriculture and Forestry.

(2) After expiry of the first monitoring under the monitoring plan and on the basis of the reports referred to in Paragraph (1), the Minister of Agriculture and Forestry may obligate the person who or which has been granted the authorization to amend or complement the monitoring plan in accordance with the authorization as granted and within the monitoring plan as approved. The Minister of Agriculture and Forestry shall take any such decision on the basis of an opinion given by the Commission.

(3) The results under the monitoring plan shall be made accessible to the public.

Article 71. (1) A public register of the areas planted with genetically modified crops authorized for placing on the market shall be established and maintained in an electronic form at the Ministry of Agriculture and Forestry so as to ensure monitoring of the impact of these genetically modified plants on human health and the environment according to Article 70 herein.

(2) The register referred to in Paragraph (1) shall be part of the information system referred to in Article 4 (2) herein.

(3) Any persons, who or which grow genetically modified plants under the terms established by Paragraph (1), shall be obligated to observe mandatory isolation distances from the areas planted with genetically modified crops to the adjoining areas planted with non-modified crops of the same species according to Annex 2 hereto.

(4) Any persons, who or which grow genetically modified plants under the terms established by Paragraph (1), shall be obligated to inform the Ministry of Agriculture and Forestry of the location and size of the areas planted.

(5) The Ministry of Agriculture and Forestry shall notify the Ministry of Environment and Water of the location and size of the areas.

Article 72. (1) Should new scientific data concerning an increase in the risk to human health or the environment from the placing of GMOs on the market become available after the grant of an authorization for placing on the market, the person who or which has been granted the said authorization shall be obligated immediately:

1. to take the necessary measures for protection of human health and the environment;
2. to inform the Minister of Agriculture and Forestry of the new data and the measures taken under Item 1;
3. to review the conditions for placing on the market.

(2) Where the data referred to in Paragraph (1) are received at the Ministry of Agriculture and Forestry or members of the Commission become aware of any such data, the said data shall be subject to evaluation.

(3) In the cases referred to in Paragraphs (1) and (2), the Minister of Agriculture and Forestry, acting on an opinion given by the Commission, shall modify the conditions for placing in the market of GMOs as or in products or shall suspend or terminate the placing on the market, stating the reasons for so doing and notifying the public thereof.

Article 73. (1) The Minister of Agriculture and Forestry may extend the period of an authorization, acting on a new application submitted not later than nine months prior to the expiry of the period of the previous authorization.

(2) Any application referred to in Paragraph (1) shall contain:

1. identification of the applicant:

(a) name and number of identity document and permanent address: applicable to natural persons;

(b) designation, registered office and address of the place of management and BULSTAT registration: applicable to sole traders and legal persons;

2. any new information which has become available with regard to the risks of the product to human health and/or the environment;

3. a proposal for amending or complementing the conditions of the original authorization, should this be necessary with a view to avoiding the risk to human health and the environment.

(3) A copy of the authorization for placing of GMOs on the market and a report on the results of the monitoring referred to in Article 70 herein shall be attached to any such application.

(4) The Minister of Agriculture and Forestry shall take a decision on extension of the period of an authorization within the time limit referred to in Paragraph (1), acting on an opinion given by the Commission. The period of the authorization may be extended by not more than five years.

(5) The Ministry of Agriculture and Forestry shall notify the applicant of the decision referred to in Paragraph (4) within 14 days after delivery of the said decision.

(6) The applicant may continue to place the GMOs on the market under the conditions specified in the original authorization until a final decision has been taken by the Minister of Agriculture and Forestry.

Article 74. (1) At all stages of the placing on the market of GMOs as or in products, the labelling and packaging thereof must conform to the requirements in the authorization as granted by the Minister of Agriculture and Forestry.

(2) The following information, as a minimum, must appear on the label of the product:

1. commercial name of the product;

2. the words: "This product contains genetically modified organisms";

3. the name of the GMO;

4. name or, respectively, designation and address or, respectively, registered office of the person who or which is responsible for the placing of the GMO on the market, whether it be the manufacturer, the importer or the distributor;

5. indication on how to access the register referred to in Article 69 herein.

(3) The provisions of Paragraphs (1) and (2) shall not apply to any products:

1. wherein adventitious or technically unavoidable traces of GMOs authorized for placing on the market are present below a minimum threshold established by the ordinance referred to in Article 45 herein;

2. intended for direct processing, wherein adventitious or technically unavoidable traces of GMOs authorized for placing on the market are present in a proportion no higher than 0.5 per cent or a lower threshold established by the ordinance referred to in Article 45 herein.

(4) The following additional information may appear on the label in a summarized form:

1. description of how the product is intended to be used, including a description of the differences in use compared to similar non-modified products;

2. description of the geographical area or areas and types of environment where the product is intended to be used and, where possible, estimated scale of use in each area;

3. measures to take in case of misuse or unintended release;

4. specific instructions for handling and storage;

5. specific instructions for carrying out monitoring and reporting to the applicant under Article 59 (2) herein and, if required, the control authorities, upon occurrence of any adverse effects on human health and the environment;

6. restrictions on authorized use of GMOs.

(5) The information covered under Paragraph (4) shall be provided subject to the condition that the said information has been stated in the application referred to in Article 60 herein and has been approved by the Minister of Agriculture and Forestry in the authorization granted thereby.

Article 75. (1) The Minister of Agriculture and Forestry, after consultation with the Minister of Environment and Water, may provisionally restrict or prohibit the use and/or sale of a GMO as or in a product which has been authorized for placing on the market, where there are grounds for considering that the said GMO constitutes a risk to human health or the environment on the basis of information made available since the grant of the authorization affecting the risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge.

(2) In the cases referred to in Paragraph (1), the Ministry of Agriculture and Forestry shall inform the public of the measures taken and the reasons for the said measures.

(3) On the basis of the information referred to in Paragraph (1), the person who has been granted authorization for placing of the GMO on the market under Paragraph (1) shall reassess the risk and shall submit the reassessment to the Ministry of Agriculture and Forestry.

(4) The Minister of Agriculture and Forestry, acting on an opinion given by the Commission, may request from the person referred to in Paragraph (3) to furnish additional information, stating in writing the reasons for any such request.

(5) Within 60 days after submission of the risk reassessment, the Minister of Agriculture and Forestry:

1. shall revoke the authorization as granted, or

2. shall grant a new authorization specifying the new conditions for placing on the market, or

3. shall lift the restriction or prohibition on use or sale of the relevant GMO.

Article 76. The Minister of Agriculture and Forestry shall withdraw an authorization for placing of GMOs on the market if the conditions defined therein are breached.

Article 77. Any persons, who or which place on the market GMOs as or in products, shall be obligated to comply with the rules for traceability of the products as laid down by the ordinance referred to in Article 45 herein.

Article 78. The Ministry of Agriculture and Forestry shall collect a fee for the grant of authorizations under this Section.

Section IV Prohibitions

Article 79. (1) The deliberate release into the environment and the placing on the market of the following GMOs is hereby prohibited: tobacco, vine, cotton, damask rose, wheat, and all vegetable and orchard crops.

(2) The Minister of Agriculture and Forestry, in consultation with the Minister of Environment and Water, shall add GMOs to the list under Paragraph (1) by an order which shall be promulgated in the *State Gazette*.

Article 80. The a deliberate release of any GMOs into the areas included in the National Ecological Network within the meaning given by the Biological Diversity Act, as well as into the adjoining areas within a zone of 30 kilometres around any such areas, is hereby prohibited.

Article 81. The deliberate release into the environment and the placing on the market of any GMOs containing antibiotic resistance marker genes is hereby prohibited.

Article 82. The deliberate release into the environment and the placing on the market of any GMOs as or in products, which have been refused consent in the Member States of the European Union, is hereby prohibited.

Chapter Five

IMPORT, EXPORT, TRANSIT AND UNINTENTIONAL TRANSBOUNDARY MOVEMENT OF GMOs

Section I

Import

Article 83. Any GMOs and GMOs as or in products shall be imported after obtaining an authorization from the Minister of Environment and Water or from the Minister of Agriculture and Forestry according to the procedure established by Chapter Three or Four, depending on the intended use of the GMOs.

Article 84. Upon import, information regarding the presence of GMOs shall mandatorily be entered into the veterinary or phytosanitary certificate.

Section III (*sic*)

Export. Common Provisions

Article 85. The Advance Informed Agreement Procedure, as provided for in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, hereinafter referred to as "the Protocol," shall be applied upon export of GMOs.

Article 86. (1) Exporters shall state in the documents accompanying the GMO that the goods contain or consist of GMOs and the unique identifier, if such as been assigned to the relevant GMO.

(2) The information referred to in Paragraph (1) shall furthermore be provided to the person whereto the GMOs are consigned.

(3) Upon export of any GMOs intended for direct use as food or feed, or for processing, the information referred to in Paragraph (1) shall be supplemented by a declaration by the exporter:

1. stating that the GMOs are intended for direct use as food or feed, or for processing, and that the said GMOs are not intended for deliberate release into the environment;
2. giving the name, address and telephone number of a contact point for further information.

(4) The provision of Item 2 of Paragraph (3) shall not apply to any products consisting of or containing mixtures of GMOs to be used only and directly as food or feed, or for processing. The provisions of Articles 74 and 77 herein shall apply to any such products.

(5) Upon export of any GMOs intended for contained use, the information referred to in Paragraph (1) shall be supplemented by a declaration by the exporter which shall specify:

1. any requirements for the safe use, storage and transport of the said GMOs;
2. the name, address and telephone number of a contact point for further information, including the name, address and telephone number of the person whereto the GMOs are consigned.

(6) Upon export of any GMOs intended for deliberate release into the environment, the information referred to in Paragraph (1) shall be supplemented by a declaration by the exporter which shall set out:

1. the identity and relevant traits and characteristics of the GMOs;
2. any requirements for the safe use, storage and transport of these GMOs;
3. the name, address and telephone number of a contact point for further information and, as appropriate, the name, address and telephone number of the person whereto the GMOs are consigned;
4. a declaration that the export is in conformity with the requirements of the Protocol.

Article 87. The Minister of Environment and Water or the Minister of Agriculture and Forestry shall issue a certificate in writing to the exporter of GMOs who or which has obtained consent to import from the Party of import.

Article 88. The Ministry of Environment and Water and the Ministry of Agriculture and Forestry shall notify the National Customs Agency of each decision of the Party of import.

Article 89. Export of GMOs shall not be allowed to proceed unless the procedures laid down in Sections II, III and IV of this Chapter have been followed.

Section III

Export of GMOs Intended for Deliberate Release into the Environment

Article 90. Any GMOs intended for deliberate release into the environment shall be exported only after obtaining a prior written consent from the Party of import, given in accordance with the procedure laid down in Articles 9 and 10 of the Protocol.

Article 91. (1) Exporters of GMOs intended for deliberate release into the environment shall submit an application in writing to the Ministry of Environment and Water.

(2) Any application referred to in Paragraph (1) shall contain, as a minimum, the following information:

1. name, telephone number and address as contact details of the exporter of the GMOs;
2. name, telephone number and address as contact details of the person whereto the GMOs are consigned;
3. name and identity of the GMO;
4. intended date of the export, if known;
5. taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety;
6. centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organism and a description of the habitats where the organisms may persist or proliferate;

7. taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety;
8. description of the nucleic acid or the modification introduced, the techniques used, and the resulting characteristics of the GMO;
9. intended use of the GMO or products thereof, namely, processed materials that are of GMO origin, containing detectable novel combinations of replicable genetic material obtained through techniques listed in Article 2 (1) herein;
10. quantity or volume of the GMO subject to the export;
11. previous and existing risk assessments carried out in accordance with Section I of Chapter Four herein;
12. suggested methods for safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures;
13. reference brief on the regulatory framework and status of the GMO exported: whether the said GMO is prohibited and for what reasons, whether the said GMO is subject to any other restrictions;
14. information regarding the results and purposes of all other notifications by the exporter to other countries regarding the said GMO;
15. a declaration that the circumstances stated in Items 1 to 14 are factually correct.

(3) The Ministry of Environment and Water shall forward the application to the competent authority of the Party of import and shall inform the Parties to the Protocol of the application as submitted through the Biosafety Clearing-House.

Article 92. (1) In the cases where the competent authority of the Party of import does not communicate the decision thereof in response to an application as submitted within 270 days after the date of receipt of any such application, the Ministry of Environment and Water shall send a written reminder with a copy to the Secretariat to the Protocol, allowing a deadline for response of 60 days from receipt of the said reminder.

(2) Any period of time during which additional relevant information is awaited shall not be taken into account for the purpose of calculating the time limit referred to in Paragraph (1).

(3) A failure of the Party of import to take a decision within the time limit specified in Paragraph (1) shall not imply consent to proceed with the export.

Article 93. A copy of the application referred to in Article 91 (1) herein, the acknowledgement of receipt of the application, as well as the decision of the Party of import, shall be preserved at the Ministry of Environment and Water for a period which may not be shorter than five years.

Article 94. (1) The exporter may propose to the Ministry of Environment and Water to ask the Party of import to review the decision thereof upon a change in circumstances that, as the exporter considers, may influence the outcome of the risk assessment whereupon the said decision was based, or if new additional scientific or technical information has become available.

(2) Where the Party of import does not respond to such a request within 90 days, the Ministry of Environment and Water shall send a written reminder, with a copy to the Secretariat, requesting a response within a set period following receipt of the reminder.

Article 95. The provisions of Article 90 to 94 herein shall not apply to export of any GMOs:

1. intended for contained use, where the export is undertaken in accordance with the legislation of the Party of import;
2. in respect of which the Party of import has specified in advance to the Biosafety Clearing-House that imports of such GMOs are to be exempted from the Advance Informed Agreement Procedure

and that adequate measures are applied to ensure the safe intentional transboundary movement of the said GMOs in accordance with the objective of the Protocol.

Section IV

Export of GMOs Intended for Direct Use as Food or Feed, or for Processing

Article 96. Any GMOs intended for direct use as food or feed, or for processing, shall be exported only after obtaining a prior written consent from the Party of import.

Article 97. (1) The Ministry of Agriculture and Forestry shall inform the Parties concerned through the Biosafety Clearing-House of any decision taken regarding the placing on the market of GMOs intended for direct use as food or feed, or for processing, that may be subject to export.

(2) The information shall contain as a minimum:

1. name, telephone number and address as contact details of the applicant;
2. telephone numbers and addresses as contact details of the responsible officials of the Ministry of Agriculture and Forestry;
3. name and identity of the GMO;
4. description of the gene modification, the techniques used, and the resulting characteristics of the GMO;
5. the unique identifier, if such as been assigned;
6. taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety;
7. centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organism and a description of the habitats where the organisms may persist or proliferate;
8. taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety;
9. approved uses of the GMO;
10. environmental risk assessment under Section I of Chapter Four herein;
11. suggested methods for safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures.

(3) The information covered under Paragraph (2) shall be dispatched within 15 days after delivery of the decision referred to in Paragraph (1).

(4) The Ministry of Agriculture and Forestry shall process each request submitted thereto by any other Parties for additional information regarding the decision referred to in Paragraph (1).

(5) A copy of the information referred to in Paragraphs (1) to (4) shall be sent in writing to the focal point in each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House.

Article 98. The exporter shall be obligated to respect any decision on the import of GMOs intended for direct use as food or feed, or for processing, taken by a Party in accordance with Article 11 (4) of the Protocol.

Section V

Transit

Article 99. (1) The persons who or which are to transit GMOs through the territory of the Republic of Bulgaria shall notify the Ministry of Environment and Water thereof in writing.

(2) Any notification referred to in Paragraph (1) shall be submitted not later than 14 days before the transit of the GMOs and shall contain:

1. name, telephone number and address as contact details of the transiter of the GMOs;
2. name, telephone number and address as contact details of the person whereto the GMOs are consigned;
3. name and identity of the GMOs;
4. intended date of the transit;
5. taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety;
6. centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organism and a description of the habitats where the organisms may persist or proliferate;
7. taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety;
8. description of the nucleic acid or the modification introduced, the techniques used, and the resulting characteristics of the GMO;
9. intended use of the GMO or products thereof, namely, processed materials that are of GMO origin, containing detectable novel combinations of replicable genetic material obtained through techniques listed in Article 2 (1) herein;
10. quantity or volume of the GMO subject to the transit;
11. measures taken for safe transport and use, including packaging, labelling, documentation, disposal and contingency procedures;
12. a declaration that the circumstances stated in Items 1 to 11 are factually correct.

Article 100. The Minister of Environment and Water shall issue a certificate in writing to the transiter of GMOs through the territory of the Republic of Bulgaria not later than three days before the transit.

Article 101. The Ministry of Environment and Water shall notify the National Customs Agency and the Ministry of Agriculture and Forestry of each certificate of transit of GMOs through Bulgarian territory as issued.

Article 102. Transit of GMOs through Bulgarian territory shall not be allowed to proceed unless the procedures laid down in this Section have been followed.

Section VI

Unintentional Transboundary Movement of GMOs

Article 103. (1) The Advance Informed Agreement Procedure, as provided for in the Protocol, shall be applied upon detection of unintentional transboundary movement of GMOs.

(2) As soon as the Ministry of Environment and Water becomes aware of a release of a GMO into the environment that may lead to an unintentional transboundary movement, the said Ministry shall:

1. inform the public, the affected or potentially affected States, the Parties to the Protocol and the Secretariat, as well as, where appropriate, relevant international organizations, through the Biosafety Clearing-House;
2. consult the affected or potentially affected States to enable them to determine appropriate responses and plan necessary action.

(3) Any notification referred to in Paragraph (1) shall include the entire information available regarding:

1. the estimated quantities and relevant characteristics or traits of the GMO;
2. the circumstances and estimated date of the release of the GMO;
3. the manner of use of the GMO;
4. the possible adverse effects on the conservation and sustainable use of biological diversity and on human health;
5. the risk management measures.

(4) The notification referred to in Paragraph (2) shall furthermore state any other relevant information related to the unintentional transboundary movement, as well as telephone numbers and address of a contact point at the Ministry of Environment and Water for further information.

Chapter Six

CONFIDENTIAL INFORMATION

Article 104. (1) Any applicant referred to in Chapters Three and Fourth herein and any exporter referred to in Chapter Five herein may submit a reasoned request to the Ministry of Environment and Water and to the Ministry of Agriculture and Forestry, respectively, to the effect that specific information of the application submitted thereby be kept confidential with a view to protecting the commercial interests of the said applicant.

(2) The Minister of Environment and Water or the Minister of Agriculture and Forestry shall decide by an order which of the information subject to the request under Paragraph (1) will be kept confidential. Should the relevant Minister determine that part or all of the said information will not be kept confidential, the said Minister shall give his or her reasons for so doing.

(3) Any information specified by the applicant or by the exporter, as the case may be, and decided by the authority referred to in Paragraph (2), whereof the divulgence to third party is likely to injure the commercial interests and cause harm to the competitive position of the said applicant or exporter, as well as any information subject to protection by a patent or other intellectual property rights, shall be kept confidential.

Article 105. The following information may not be kept confidential:

1. applicable to contained use of GMOs:
 - (a) the characteristics of the GMOs, including the marker genes;
 - (b) name and address of the applicant;
 - (c) location of the use of the GMOs;
 - (d) the class assigned and the protective measures applied;
 - (e) estimation of the potential harmful effects on human rights and the environment;
2. applicable to deliberate release of GMOs into the environment and upon placing on the market of GMOs as or in products:
 - (a) description of the GMOs;
 - (b) name and address of the applicant;
 - (c) purpose and location of the release site;
 - (d) methods and plans for monitoring of the GMO or GMOs and for emergency response;
 - (e) storage site;
 - (f) methods for transport;
 - (g) use of the GMOs;

(h) risk assessment;

3. applicable to import and export of GMOs:

(a) name and address of the exporter and importer;

(b) description of the GMOs;

(c) summary of the risk assessment of the effects on human health, as well as on the conservation and sustainable use of biological diversity;

(d) methods and plans for monitoring of the GMO or GMOs and for emergency response.

Article 106. The authorities referred to in Articles 4, 5 and 6 herein may not be denied access to information regarding the vectors, DNA sequences and marker genes used.

Article 107. Where any GMOs are protected by a patent or other intellectual property rights, the provisions of the special legislation in this fields shall furthermore apply.

Chapter Seven

CONTROL

Article 108. (1) The Ministry of Environment and Water, acting through the Regional Inspectorates of Environment and Water, shall exercise control over the release of GMOs into the environment with a view to protecting the environment.

(2) For exercise of the control referred to in Paragraph (1), a specialized laboratory shall be established at the Executive Environment Agency with the Ministry of Environment and Water.

Article 109. (1) The Ministry of Agriculture and Forestry shall exercise control through the Executive Agency of Plant Variety Testing, Crops Approbation and Seed Control, the National Plant Protection Service, the National Veterinary Service, the National Grain and Forage Service, the Vine and Wine Executive Agency, the National Agency for Fisheries and Aquaculture, the National Forestry Board, and the Executive Agency for Animal Breeding.

(2) Each within the competences thereof, the authorities covered under Paragraph (1) shall exercise control over:

1. field testing of GMOs, use of genetically modified products for plant protection, and manuring;
2. the placing on the market of genetically modified seeds and planting stock, plants and animals, forage and forage additives, and genetically modified plant protection products.

Article 110. The Ministry of Labour and Social Policy, acting through the General Labour Inspectorate Executive Agency and the structures thereof, shall exercise control as to compliance with this Act in respect of the application of the preventive and protective measures assigned for each class of contained use of GMOs, with a view to ensuring health and safety at work to the persons working in premises for contained use of GMOs.

Article 111. The Ministry of Economy, acting through the Commission on Trade and Consumer Protection, shall exercise control over the labelling of GMOs as or in products upon the placing thereof on the market.

Article 112. (1) The National Customs Agency shall exercise control upon import, export and transit of GMOs according to Article 65 (3) of the Customs Act in the cases of:

1. doubt as to whether the goods correspond to the information declared in the documents accompanying the said goods;
2. declared GMO which is not accompanied by an authorization according to the procedure established by Chapter Three or Four herein or by a certificate referred to in Article 87 or Article 100 herein;

3. advance notification from the authorities referred to in Article 3 herein.

(2) The directors of the regional structures of the control authorities covered under this Chapter, exercising geographical jurisdiction over the location of the border-crossing checkpoint, and the Chairperson of the Commission on Trade and Consumer Protection, shall assist the customs authorities in clarification of the cases referred to in Paragraph (1) and for the taking of a decision on such cases.

Article 113. Upon ascertainment of a violation of the requirements of this Act or if there is reason to suspect that any such violation has been committed, the control authorities shall immediately inform the Minister of Environment and Water and the Minister of Agriculture and Forestry.

Article 114. The control authorities shall conduct inspections at least twice a year, as well as when alerted about violations of the requirements of this Act, upon accidents, upon occurrence or likelihood of occurrence of harmful effects for human health or the environment from contained use of GMOs, deliberate release of GMOs into the environment and placing of GMOs on the market.

Article 115. (1) The Minister of Environment and Water, the Minister of Agriculture and Forestry, the Minister of Labour and Social Policy, [and] the Chairperson of the Commission on Trade and Consumer Protection shall designate by an order the officials who have the right to conduct inspections and to draw up written statements ascertaining violations.

(2) The officials who exercise control under this Act shall have the right:

1. to access to the premises and sites where contained use of GMOs, deliberate release of GMOs into the environment and placing on the market is carried out;
2. to require the documents and information necessary in connection with the control exercised thereby;
3. to take samples for laboratory tests.
4. to give mandatory prescriptions for curing of violations as ascertained.

(3) The inspections shall be conducted in the presence of the person inspected or of a representative authorized thereby.

(4) The officials shall have the right to seize or withdraw from the market and to destroy GMOs or products consisting of GMOs or containing GMOs, upon ascertainment of any violations of the standard specifications and requirements established by this Act or by the statutory instruments of secondary legislation on the application thereof and in the cases referred to in Article 72 (3) herein and Article 75 (1) herein.

(5) The rules for seizure and withdrawal from the market and for destruction of GMOs or of products consisting of GMOs or containing GMOs shall be laid down by the ordinance referred to in Article 45 herein.

Article 116. The laboratory analyses for quantitative and qualitative identification of genetic modification shall be carried out at the request of the control authorities under this Chapter at laboratories designated by the Minister of Environment and Water, which are accredited by the Bulgarian Accreditation Service Executive Agency or by a foreign accreditation body which is a full member of the European co-operation for Accreditation.

Chapter Eight

COERCIVE ADMINISTRATIVE MEASURES AND ADMINISTRATIVE PENALTY PROVISIONS

Section I

Coercive Administrative Measures

Article 117. (1) For prevention and cessation of administrative violations under this Act, as well as for prevention and mitigation of the harmful effects of any such violations, the Minister of Environment and Water or the Minister of Agriculture and Forestry shall apply the following coercive administrative measures:

1. suspension of the operation of premises for contained use of GMOs and of installations for placing on the market of GMOs as or in products;
 2. destruction of GMOs and of products consisting of GMOs or containing GMOs;
 3. withdrawal from the market of GMOs and of products consisting of GMOs or containing GMOs.
- (2) A coercive administrative measure shall be applied by a reasoned order of the authority referred to in Paragraph (1).
- (3) The order referred to in Paragraph (2) shall specify the type of the coercive administrative measure and a suitable time limit for the execution thereof.
- (4) The order referred to in Paragraph (2) shall be served on the party concerned according to the procedure established by the Code of Civil Procedure.
- (5) Any order referred to in Paragraph (2) shall be appealable according to the procedure established by the Supreme Administrative Court Act.
- (6) An appeal of any order referred to in Paragraph (2) shall not suspend the effect thereof.
- (7) Upon failure to comply with a directive to suspend the operation of premises for contained use of GMOs or of installations for placing on the market of GMOs as or in products, the said operation shall be suspended with the assistance of the authorities of the Ministry of Interior.

Section II

Administrative Penalty Provisions

Article 118. Any members of the Commission, any officials of the specialized administration referred to in Article 12 herein, any persons covered under Article 7 (5) herein, and any officials exercising control under this Act, who divulge confidential information in violation of Article 14 herein, shall be liable to a fine of BGN 5,000.

Article 119. Any person, who or which carries out contained use of GMOs in unregistered premises, in violation of Article 23 herein, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 20,000 or exceeding this amount but not exceeding BGN 60,000.

Article 120. Any person, who carries out Class 2 or a higher class of uses of a GMO without authorization for contained use of GMOs in violation of Article 29 herein, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 50,000 or exceeding this amount but not exceeding BGN 150,000.

Article 121. Any person, who carries out contained use of a GMO without applying the containment measures for the relevant class of use for which an authorization has been granted, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 10,000 or exceeding this amount but not exceeding BGN 20,000.

Article 122. Any person, who or which has submitted factually incorrect information in the application for contained use of GMOs for the purpose of obtaining an authorization, shall be liable

to a fine or to a pecuniary penalty, as the case may be, of BGN 15,000 or exceeding this amount but not exceeding BGN 50,000.

Article 123. Any person, who or which, acting in violation of Article 39 (2) herein, fails to implement measures determined by the Minister of Environment and Water, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 30,000.

Article 124. Any person, who or which has submitted factually incorrect information in the application for deliberate release of GMOs into the environment for the purpose of obtaining an authorization, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 80,000 or exceeding this amount but not exceeding BGN 200,000.

Article 125. Any person, who or which deliberately releases GMOs into the environment without authorization in violation of Article 46 herein, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 500,000.

Article 126. Any person, who deliberately releases GMOs in violation of the conditions specified in the authorization for deliberate release into the environment, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 150,000 or exceeding this amount but not exceeding BGN 450,000.

Article 127. Any person, who or which has submitted factually incorrect information in the application for placing of GMOs on the market for the purpose of obtaining an authorization, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 150,000 or exceeding this amount but not exceeding BGN 450,000.

Article 128. Any person, who or which places on the market GMOs as or in products without an authorization in violation of Article 59 herein or after withdrawal of any such authorization, or after expiry of the period of validity thereof, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 300,000 or exceeding this amount but not exceeding BGN 500,000.

Article 129. Any person, who places on the market GMOs as or in products in violation of the conditions envisaged in the authorization for placing on the market, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 200,000 or exceeding this amount but not exceeding BGN 500,000.

Article 130. Any person, who or which places on the market GMOs as or in products in violation of the labelling requirement in violation of Article 74 herein, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 200,000 or exceeding this amount but not exceeding BGN 500,000.

Article 131. Any person, who or which grows genetically modified plants for which the said person holds an authorization for placing of such plants on the market, without complying with the requirement of Article 71 (3) herein, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 100,000.

Article 132. Any person, who or which grows genetically modified plants without holding an authorization for placing of such plants on the market, without complying with the requirement of Article 71 (4) herein, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 10,000.

Article 133. Any person, who or which deliberately releases GMOs into the environment or place on the market a GMO or a combination of GMOs in violation of the prohibition imposed under Article 79 herein, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 1,000,000.

Article 134. Any person, who or which deliberately releases GMOs into the environment in violation of the prohibition imposed under Article 80 herein, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 1,000,000.

Article 135. Any person, who or which deliberately releases GMOs into the environment or places a GMO or a combination of GMOs on the market in violation of the prohibition imposed under Article 81 herein, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 1,000,000.

Article 136. Any person, who or which deliberately releases GMOs into the environment or places on the market GMOs as or in products in violation of the prohibition imposed under Article 82 herein, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 1,000,000.

Article 137. Any person, who or which violates the requirements of Article 27 (4), Article 36 (4), Article 57 (4) and Article 69 (4) herein, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 5,000 or exceeding this amount but not exceeding BGN 15,000.

Article 138. Any person, who or which fails to afford officials access and fails to furnish thereto the necessary information and documents in violation of Article 115 (2) herein, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 20,000.

Article 139. Upon repeated commission of the violations covered under Articles 118 to 138 herein, the fines or pecuniary penalties as provided for shall be imposed in a double amount.

Article 140. Any person, who or which fails to comply with the coercive administrative measures covered under Article 117 herein, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 50,000 or exceeding this amount but not exceeding BGN 100,000.

Article 141. Any person, who or which exports GMOs or products consisting of GMOs or containing GMOs in violation of the requirements of Section II of Chapter Five herein, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 100,000 or exceeding this amount but not exceeding BGN 300,000.

Article 142. Any person, who or which has submitted factually incorrect information in the application for export of GMOs or products consisting of GMOs or containing GMOs, shall be liable to a fine or to a pecuniary penalty, as the case may be, of BGN 100,000 or exceeding this amount but not exceeding BGN 300,000.

Article 143. (1) The written statement ascertaining the violations referred to in Articles 125 and 126 herein shall be drawn up by the officials designated by the Minister of Environment and Water upon inspection of the activities under Article 108 herein.

(2) The written statements ascertaining the violations referred to in Articles 128 and 129 herein shall be drawn up by the officials designated by the Minister of Agriculture and Forestry upon inspection of the activities covered under Article 109 (2) herein.

(3) The written statements ascertaining the violations referred to in Articles 119 to 123 herein shall be drawn up by the officials designated by the Minister of Labour and Social Policy upon inspection of the activities referred to in Article 110 herein.

(4) The written statements ascertaining the violations referred to in Article 130 herein shall be drawn up by the officials designated by the Chairperson of the Commission on Trade and Consumer Protection upon inspection of the labelling of genetically modified products upon the placing thereof on the market.

(5) The written statements ascertaining the violations referred to in Article 138 herein shall be drawn up by the relevant officials covered under Article 115 herein.

(6) The penalty decrees shall be issued by the Minister of Environment and Water, the Minister of Agriculture and Forestry, the Minister of Labour and Social Policy, the Chairperson of the Commission on Trade and Consumer Protection, or by officials designated thereby.

(7) The ascertainment of violations, the issuance, appeal against and execution of penalty decrees shall follow the procedure established by the Administrative Violations and Sanctions Act.

SUPPLEMENTARY PROVISIONS

§ 1. Within the meaning given by this Act:

1. "Organism" shall be any biological entity capable of replication or of transferring genetic material;
2. "Micro-organism" shall be any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cells in culture;
3. "Genetically modified organism" shall be any organism, including any micro-organism, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. Human beings shall not be considered as organisms.
4. "Plasmid" shall be an independently existing, most commonly circular DNA molecule found in the cytoplasm of bacteria, capable of self-replication (synthesis of a new DNA molecule copying the parental one).
5. "Protoplast" shall be an actively metabolizing portion of a cell (including nucleus, plastids, mitochondria etc.), from which the cell wall has been removed.
6. "Mutagenesis" shall be the induction of mutations in the genetic material.
7. "Prokaryotic organisms" shall be lower organisms of a specific cell type (viruses, bacteria, blue-green algae) whereof the cell has a cell wall or capsule but lacks well defined organoids (nucleus, plastids, mitochondria etc.).
8. "Eukaryotic organisms" shall be organisms whereof the genetic material is located in one or two cell nuclei, separated from the cytoplasm by a nuclear membrane (such as yeasts, some algae, fungi, plants and animals).
9. "Self-cloning" shall be multiplication consisting in the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid sequence or part thereof (or a synthetic equivalent thereof) with or without prior enzymic reaction or mechanical steps, into cells of the same species or into cells of phylogenetically closely related species, which can exchange genetic material by natural physiological processes, where the resulting micro-organism is unlikely to cause disease to humans, animals or plants. Self-cloning may furthermore include the use of recombinant vectors with an extended history of safe use in the particular micro-organisms.
10. "Genetic instability" shall be the loss of consistency in the genetic constitution (genotype) caused by the activity of movable genetic elements (transposons).
11. "Phenotype" shall be the visible appearance of an organism with respect to a set of traits and characteristics, which results from the interaction of the genotype with the conditions of the external environment.
12. "Invasive organisms" shall be organisms, most commonly weeds, which have acquired the ability to spread beyond the geographical range of the natural habitat thereof.
13. "Target organisms" shall be organisms which may potentially become subject of interaction with the GMOs released into the environment.
14. "Similar organisms" shall be organisms produced through use of identical or similar gene constructs and techniques of genetic manipulation.
15. "Competitor populations" shall be populations which compete for the occupation of a particular habitat range.

16. "Symbiosis" shall be a form of association of two different kinds of living organisms wherefrom both receive an advantage for the existence and development thereof. A prominent example is the colonization of nitrogen-fixing bacteria inside the roots of leguminous plants.
17. "DNA" (deoxyribonucleic acid) shall be a linear, double-stranded molecule, consisting of base nucleotide pairs and carrying genetic information.
18. "Modern biotechnology" shall be methods of application of nucleic acids, including recombinant DNA and direct injection of nucleic acids into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.
19. "Host" shall be a cell or an organism susceptible to a specific infectious agent or enabling the replication of a plasmid, a virus or another form of foreign DNA.
20. "Vector" shall be a DNA molecule, isolated from a plasmid or a virus, which is capable of integrating or cloning foreign DNA fragments. A vector contains one or more specific restriction sites and can self-replicate under specific conditions.
21. "Marker genes" shall be nucleic acid sequences serving to detect the occurrence of gene transfer upon creation of a GMO.
22. "Unique identifier" shall be a combination of figures and Roman characters which serves to identify a GMO.
23. "Deliberate release into the environment" shall be any intentional introduction into the environment, with the exception of placing on the market, of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with the environment and to provide a high level of safety for human health and the environment.
24. "Placing on the market" shall be the making of a product available, whether in return for payment or free of charge, for the first time, whereupon the said product proceeds from the stage or production or import to the stage of distribution and/or use.
25. "Product" shall be a material consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market. A product shall be considered to be consisting of, or containing, a GMO if the proportion of adventitious or technically unavoidable traces of GMOs present therein exceeds 0.5 per cent.
26. "Contained use" shall be any activity in which organisms are genetically modified or in which such genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific physical barriers or a combination of physical and chemical and/or biological barriers are used to limit the contact of the GMOs with the general population and the environment;
27. "Accident" shall be any incident involving a significant and unintended release of GMOs in the course of their contained use, which could present an immediate or delayed hazard to human health or the environment;
28. "Immediate effects" shall be the effects on human health or the environment which are observed during the period of the release of the GMO into the environment or of the placing of the GMO on the market. Immediate effects may be direct or indirect.
29. "Cumulative long-term effects" shall be the accumulated effects on human health and the environment, including *inter alia* soil fertility, soil degradation of organic material, the food chain, biological diversity, animal health and resistance problems in relation to antibiotics.
30. "Basic material" shall be a source for obtaining forest reproductive material included in the basic forest reproductive material.

31. "Level of protection" shall be a complex of protective and safety measures for humans and the environment, intended to keep the contact between the premises for use and the environment, on the one hand, and GMOs, on the other hand, to the lowest practicable level upon contained use of GMOs.

32. "Repeated violation" shall be any violation which is committed within one year after the entry into force of a penalty decree whereby the offender was penalized for a violation of the same kind.

33. "Import" shall be the placing under a customs procedure, other than transit procedure, of GMOs introduced into the customs territory of the Republic of Bulgaria.

34. "Export" shall be:

1. the permanent or temporary leaving of the customs territory of the Republic of Bulgaria of GMOs which have been produced within Bulgarian territory or have been placed under an import procedure;

2. the re-export of GMOs which do not meet the conditions referred to in Item 1 and which are placed under a customs procedure other than transit procedure.

35. "Exporter" shall be any natural or legal person by whom or on whose behalf the application for export is submitted, that is to say the person who or which, at the time when the application is submitted, holds the contract with the consignee in the Party of import and has the power to determine that the genetically modified organism is to be sent out of the customs territory of the Republic of Bulgaria. If no export contract has been concluded or if the holder of the contract does not act on its own behalf, the power to determine that the genetically modified organism is to be sent out of the customs territory of the Republic of Bulgaria shall be decisive.

36. "Transboundary movement" shall be movement of GMOs between one Party and another Party.

37. "Biological diversity" shall be the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part, including diversity within species, between species and of ecosystems.

§ 2. The following shall not be considered to result in genetic modification:

1. *in vitro* fertilization;

2. natural processes such as: conjugation, transduction, and transformation;

3. polyploidy induction.

§ 3. The following shall not be regarded as placing on the market:

1. making available GMOs for contained use;

2. making available GMOs to be used exclusively for experimental release into the environment in accordance with the provisions of Section II of Chapter Four herein.

§ 4. (1) Any genetic modifications of damask rose, vine and tobacco within Bulgarian territory are hereby prohibited.

(2) The release into the environment and the placing on the market of genetically modified animals is hereby prohibited.

TRANSITIONAL AND FINAL PROVISIONS

§ 5. (1) The authorizations granted under the terms and according to the procedure established by the Regulations for Spread of Genetically Modified Higher Plants Created through Recombinant DNA Technology (promulgated in the *State Gazette* No. 70 of 1996, amended in No. 47 of 2000) shall be considered by the Commission which shall determine whether the said authorizations conform to the requirements of this Act and shall confirm or terminate the effect of the said authorizations within three months after the entry of this Act into force.

(2) Within one year after the entry of this Act into force, the Commission shall issue a report on the spread of GMOs in the environment prior to the passage of this Act, which shall be laid before the Ministry of Environment and Water and the Ministry of Agriculture and Forestry.

§ 6. Any premises for contained use of GMOs, which have been commissioned prior to the entry of this Act into force, shall be brought into conformity with the requirements of the Act and the ordinance referred to in Article 2 (3) herein within six months after the entry of this Act into force.

§ 7. In Article 20 of the Seed Stock and Planting Stock Act ([promulgated in the] *State Gazette* No. 20 of 2003), Paragraph (6) shall be amended to read as follows:

"(6) The decision referred to in Paragraph (5) on recognition and recording of a genetically modified plant variety shall be taken after the grant of an authorization for the placing of the said variety on the market by the Minister of Agriculture and Forestry under the terms and according to the procedure established by Section III of Chapter Four of the Genetically Modified Organisms Act."

§ 8. (1) Within one month after the entry of this Act into force, the Minister of Environment and Water and the Minister of Agriculture and Forestry shall endorse by an order a list of GMOs which have been refused consent in the Member States of the European Union, which shall be promulgated in the *State Gazette*.

(2) The list referred to in Paragraph (1) shall be updated at appropriate intervals.

§ 9. In respect of the cotton plant, the prohibition under Article 79 herein shall take effect as from the 1st day of January 2008.

§ 10. This Act shall enter into force as from the 1st day of June 2005.

This Act was passed by the 39th National Assembly on the 15th day of March 2005 and the Official Seal of the National Assembly has been affixed thereto.

Chairman of the National Assembly:

Borislav Velikov

Annex No. 1 to Article 43 (3)

Principles for Performing an Assessment of the Risk to the Environment and Human Health

I. Objective

The objective of the risk assessment is, on a case by case basis, to identify and evaluate potential adverse effects of the GMOs, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or placing on the market of GMOs may have.

The risk assessment should be conducted with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used.

II. General Principles

The following general principles should be followed when performing a risk assessment:

1. identified characteristics of the GMO and the use thereof, which have the potential to cause adverse effects, should be compared to those presented by the non-modified organism from which the GMO is derived and the use thereof under corresponding situations;
2. the risk assessment should be carried out in a scientifically sound and transparent manner, based on available scientific and technical data;

3. the required information may vary depending on the type of the GMOs concerned, the intended use thereof and the potential receiving environment, taking into account, *inter alia*, GMOs already released into the environment;

4. if new information on the GMO and the effects thereof on human health or the environment becomes available, the risk assessment may need to be readdressed in order to determine whether the risk has changed and whether there is a need for amending the risk management accordingly.

III. Methodology

A. Characteristics of GMOs and Releases

Depending on the particular case, the risk assessment has to take into account the relevant technical and scientific data regarding characteristics of:

1. the recipient and parental organism;
2. the genetic modification, be it inclusion or deletion of genetic material, and relevant information on the vector and the donor;
3. the GMO;
4. the intended release or use, including the scale thereof;
5. the potential receiving environment;
6. the interaction between the characteristics covered under Items 1 to 5.

The risk assessment should take into account the available information from releases of similar organisms and organisms with similar traits, as well as their interaction with similar environments.

B. Steps in Performing the Risk Assessment

The following steps shall be observed in performing the risk assessment:

1. Identification of characteristics which may cause adverse effects:

Any characteristics of the GMOs linked to the genetic modification that may result in adverse effects on human health or the environment shall be identified. In identifying the particular potential adverse effects arising from the genetic modification, a comparison shall furthermore be made of the characteristics of the GMOs with those of the non-modified organism under corresponding conditions of the release or use.

Potential adverse effects of GMOs will vary from case to case, and may include:

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

Identifying characteristics which may cause adverse effects, account should be taken of such effects as may occur directly or indirectly through mechanisms including:

- (a) the spread of the GMO(s) in the environment;

- (b) the transfer of the inserted genetic material to other organisms, or the same organism, whether genetically modified or not;
- (c) phenotypic and genetic instability;
- (d) interactions with other organisms;
- (e) changes in risk management, including, where applicable, in agricultural practices.

2. Evaluation of the potential consequences of each adverse effect:

The evaluation of the consequences of each potential adverse effect should extend to the magnitude of the said consequences. Any such evaluation should mandatorily assume that such an adverse effect will occur, and the said evaluation should be carried out by taking into account the characteristics of the receiving environment and the manner of the release of the GMOs.

3. Evaluation of the likelihood of the occurrence of each identified potential adverse effect:

In evaluating the likelihood of adverse effects occurring, account should be taken of the receiving environment and the manner of the release of the GMOs.

4. Estimation of the risk posed by each identified characteristic of the GMO which has the potential to cause adverse effects:

An estimation of the risk posed by each identified characteristic of the GMO which has the potential to cause adverse effects should be made, given the state of the art, by combining the likelihood of the adverse effect occurring and the magnitude of the consequences.

5. Application of management strategies for risks from the deliberate release of GMOs or their placing on the market:

Where the risk assessment identifies a risk that requires management, the applicant shall be obligated to define a risk management strategy.

6. Determination of the overall risk of the GMO(s):

An evaluation of the overall risk of the GMO(s) should be made taking into account any risk management strategies which are proposed.

IV. Conclusions on the Potential Environmental Impact from the Release of GMOs into the Environment or the Placing on the Market of GMOs

As a result of the risk assessment carried out, a conclusion on the potential environmental impact from the release of GMOs into the environment or the placing on the market of GMOs should be drawn. The information of the said conclusion shall constitute part of the application referred to in Article 46 (2) and Article 59 (2) herein and is intended to assist the Commission in preparing an opinion regarding the potential environmental impact from the release of GMOs into the environment or the placing on the market of GMOs.

1. In the case of GMOs other than higher plants, the conclusion shall include information regarding:

- (a) likelihood of the GMO to become persistent and invasive in natural habitats under the conditions of the proposed release into the environment or placing on the market;
- (b) any selective advantage or disadvantage conferred to the GMO and the likelihood of this becoming realized under the conditions of the proposed release into the environment or placing on the market;
- (c) potential for gene transfer to other species under conditions of the proposed release into the market or placing on the market, and any selective advantage or disadvantage conferred to those species;
- (d) potential immediate or delayed environmental impact of the direct and indirect interactions between the GMO and target organisms, if applicable;

- (e) potential immediate or delayed environmental impact of the direct and indirect interactions between the GMO with target *[sic]* organisms, including impact on population levels of competitors, hosts, symbionts, parasites and pathogens;
 - (f) possible immediate or delayed effects on human health resulting from potential direct and indirect interactions of the GMO and persons working with, coming into contact with, or in the vicinity of the GMO release site;
 - (g) possible immediate and/or delayed effects on animal health and consequences for the food chain resulting from consumption of the GMO and any product derived from it, if it is intended to be used as animal feed;
 - (h) possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release site;
 - (i) possible immediate or delayed, direct or indirect environmental impacts resulting from the specific techniques used for management of the risk posed by the GMO, where the said techniques are different from those used for non-modified organisms.
2. In the case of genetically modified higher plants (GMHP), the conclusion shall include information regarding:
- (a) likelihood of the GMHP becoming more persistent than the recipient or parental plants in agroecosystems or more invasive in natural habitats;
 - (b) any selective advantage or disadvantage conferred to the GMHP;
 - (c) potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species;
 - (d) potential immediate or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, including predators, parasites, and pathogens, if applicable;
 - (e) possible immediate or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens. The conclusion shall also take into account organisms which interact with target organisms;
 - (f) possible immediate or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with, or in the vicinity of the GMHP release site;
 - (g) possible immediate or delayed effects on animal health and consequences for the food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed;
 - (h) possible immediate or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release site;
 - (i) possible immediate or delayed, direct or indirect environmental impacts resulting from the specific cultivation, management and harvesting techniques used for the GMHP, where these are different from those used for non-modified higher plants.

Annex 2 to Article 51 (4) and Article 71 (3)

Technological Standards for Isolation Distances by Crop Group

Crop		Minimum distance, metres
I.	Cereals	
	Barley	60
	Oats	60
	Rice	60
	Hog millet	60
	Sudan grass	60
	Rye	2,000
	Triticale	50
	Maize	800
	Canary grass	600
II.	Legumes	
	Chick-pea	60
	Common bean	300
	(of other runner bean varieties <i>Ph. coccineus</i>)	4,000
III.	Oilseed and fibre crops	
	Peanuts	20
	Mustard	800
	Dioecious fibre hemp	800
	Monoecious fibre hemp	6,000
	Safflower, caraway, cumin	400
	Soya bean	20
	Rape	400
	Sunflower	6,000
	Linseed and fibre flax	20
	Castor bean	2,000
	Sesame	400
	Poppy	1,000
	IV.	Forage crops
Brassica, lacy phacelia, meadow grass		800
Field pea		100
Clover, Italian ryegrass, perennial ryegrass, alfalfa, bur medic		800
For all forage crop species or varieties, with the exception of:		
Brassica, lacy phacelia, field pea, meadow grass, clover, Italian ryegrass, perennial ryegrass, alfalfa, bur medic		400
V.	Potatoes	
	From tobacco plantings and mass potato plantings	200