Chapter one.
GENERAL PROVISIONS

Art. 1. (1) This law shall stipulate the social relations, connected with:
1. the work with genetically modified organisms (GMOs) in controlled conditions;
2. the release of the GMOs in the environment;
3. the putting on the market of GMOs or combination of them as products or ingredient of products;
4. the transfer of GMOs;
5. the import, the export and the transit of GMOs;
6. the control over the activities under items 1-5.

(2) The purpose of the law is to provide protection of the human health and of the environment at the performance of the activities as under Para 1 under observation of the principle of precaution, which means a priority of human health protection and environment protection in case of presence of danger of potentially unfavourable impacts, not depending on the existing economical interests or on the lack of sufficient scientific data.

Art. 2. (1) This law shall be applied for GMOs, obtained through the following techniques and methods of genetic modification:
1. recombinant DNA technology, which includes forming of new combinations of genetic material by introducing of nucleic molecules, produced out of the organism, in viruses, bacterial plasmids or other vector systems and their incorporation in the host-organism, where they do not meet naturally, but where they are able to reproduce.
2. techniques at which present direct incorporation of inherited genetic material, produced extracorporealy, incl. microinjecting, macroinjecting and microencapsulation;
3. cell fusion or hybridization techniques, in which the livingcells with new combinations of inherited genetic material are created by fusion of two or more cells with methods which do not exist naturally.

(2) The provisions of this law shall not be applied regarding:
1. organisms obtained through methods of genetic modification, in which recombinant DNA technology is not used, or in which are used GMOs, obtained through the following methods:
a) mutagenesis;
b) cell fusion of prokaryotic and eukaryotic organisms, including protoplast fusion and plant cells fusion, which may perform exchange of genetic material by traditional methods.
of reproducing, as well as obtaining of hybridoma;
2. microorganisms obtained through methods of genetic modification, in which recombinant DNA technology is not used, or in which are used GMOs, obtained through the following methods
   a) mutagenesis;
   b) cell fusion of prokaryotic and eukaryotic organisms, including protoplast fusion and plant cells fusion, which may perform exchange of genetic material by traditional methods of reproducing, as well as obtaining of hybridoma;
   c) autoclonal reproduction;
3. (amend. – SG 31/07, in force from 13.04.2007; suppl. - SG 54/08) putting on the market of genetically modified foods, food components, medicines for the human medicine and veterinary-sanitarian products, which consist of or contain GMOs or combination of GMOs, genetically modified fodder, GMOs for use in or as fodder and are regulated respectively by the Law on the Foods, by the Law on Medicinal Products in Human Medicine, Law on the Fodder and by the Law on the Veterinary Activity.
(3) The provisions of the Chapter Three shall not be applied regarding work in controlled conditions with GMOs, which have been included by an order of the Minister of Environment and Water in a list. The Minister of Environment and Water shall include in the list such GMOs, which meet the requirements for safety, as defined by an ordinance on the work with GMOs, adopted by the Council of Ministers.
(4) Regarding the transportation of GMOs, which are not subject of work in controlled conditions, by railway, automobile, sea or air roads or by internal international roads, the respective provisions for transportation of dangerous cargo of the international treaties of which the Republic of Bulgaria is party and the provisions of the Law on the Railway Transport, Law on the Road Transport, Law on the Civil Aviation, the Commercial Sailing Code and the secondary legislation on their application shall be applied.

Chapter two.
COMPETENT BODIES

Art. 3. (amend. – SG 36/08; amend. - SG 54/08) The Minister of the Environment and Water and the Minister of the Agriculture and Food shall conduct the state policy in the field of GMOs and shall coordinate the activity of the controlling bodies related to the application of the law.

Art. 4. (1) The Minister of the Environment and Water shall:
1. issue, amend and cancel the permits for:
   a) work with GMOs in controlled conditions in the cases defined in this Law;
   b) release of GMOs into the environment;
2. register the rooms for work with GMOs in controlled conditions;
3. organise the public discussions for release of GMOs into the environment, provided by this Law;
4. co-ordinate the controlling powers of the other bodies of the executive power regarding GMOs.
(2) The Ministry of Environment and Water shall create and maintain information
system "Clearing - House of Biosafety" for implementation of commitments arising from the Cartagena Protocol on Biological Safety to the Convention on the biological diversity and exchange of scientific, technical, ecological and legislation information regarding GMO.

(3) The data in the system shall be public.

Art. 5. (amend. – SG 36/08; amend. - SG 54/08) The Minister of Agriculture and Food shall:

1. issue, amend and cancel the permits for putting on the market of GMOS or combination of GMOS as products or ingredient of products;
2. organise the public discussions on the release of GMOS on the market.

Art. 6. (1) To the Minister of the Environment and Water shall be established a consultative commission on the GMOS, refereed hereinafter the "Commission".

(2) The Commission shall:

1. provide opinions to the Minister of the Environment and Water regarding:
   a) issuing, amendment and cancellation of permits for work with GMOS in controlled conditions and for the release of the GMOS nto the environment;
   b) the registration of the rooms for work with GMOS in controlled conditions;
2. (amend. – SG 36/08; amend. - SG 54/08) provide with opinions the Minister of Agriculture and Food regarding the issuing, amendment and cancellation of the permits for the release of GMOS or combination of them as products or ingredient of products;
3. (amend. – SG 36/08; amend. - SG 54/08) provide with opinions the Minister of Environment and Water and the Minister of the Agriculture and Food on other matters of their competence arising from application of this Law;
4. participate in the development of related to the biosafety-related drafts of legislation

(3) The Commission shall take decisions by a consensus. The decisions of the Commission shall be public and shall be a part of the information system under Art. 4, Para 2.

Art. 7 (1) The Commission shall consist of 15 scientists with academic rank in the field of molecular genetics, molecular biology, ecology and preservation of ecology, contemporary biotechnologies, agriculture, stock – breeding, biology and medicine and other related scientific fields, representatives of the BAS and other scientific organisations.

(2) (amend. – SG 36/08; amend. - SG 54/08) The Minister of Education and Science, the Minister of Environment and Water, the Minister of Agriculture and Food shall propose as members of the Commission 4 scientist with academic rank, and the Minister of Health shall propose 3 scientists with academic rank.

(3) The members of the Commission shall be appointed by an order of the Minister of Environment and Water for a period of 4 years.

(4) At its first session the Commission shall elect a Chairman among its members.

(5) In the work of the Commission shall participate with no right of voting:

1. by one representative of:
   a) Ministry of Environment and Water;
   b) (amend. – SG 36/08; amend. - SG 54/08) Ministry of Agriculture and Food;
   c) Ministry of Health;
d) Ministry of Economy;
e) (amend., SG 88/05) Ministry if Transport;
f) Ministry of Education and Science
g) (amend., SG 99/05) Commission of Protection of Consumers;

2) Three representatives of nongovernmental ecological organizations, nominated through an approved by them procedure.

6) Representatives under Para 5 shall be determined by an order of the Minister of Environment and Water on the base of proposal of the heads of the relevant institutions and organisations under Para 5.

7) On the grounds of relevant decision of the members of the Commission, experts from the experts list of the Cartagena Protocol on Biosafety to the Convention on Biodiversity may participate in its work.

Art. 8. The Chairman of the Commission shall:
1. organise and conduct the activity of the Commission;
2. appoint and preside the sessions of the Commission;
3. inform the society of the Commission’s activity through the mass media.

Art. 9 (1) Member of the Commission may not be a person who:
1. is interested in release of GMOs at the market, as well as in the import of export of GMO;
2. is a related person in the meaning of the Trade Law to some of the persons under Art. 16 and 42.

(2) The members of the Commission shall submit affidavit on the circumstances of Para 1.

Art. 10. (1) Members of the Commission shall be dismissed ahead of due:
1. by their written request, addressed to the Ministry of Environment and Water;
2. in case of termination of their official or labour legal relationships with the appointing body or the employer, and in case of a civil contract – at its termination or not prolongation after expiration of the term for which term it has been concluded;
3. in case of an entered in force sentence for committed malicious crime of general nature
4. in case of durable actual incapability to perform their obligations longer than 6 months.
5. in case of significant or systematic violations of this Law;
6. in case of death.

(2) Within one month from the date of the dismissing ahead of the due of a member of the Commission, the Minister of the Environment and Water shall appoint, following the order of the Art. 7, a new member on his place for the period to the end of the mandate of the dismissed member.

Art. 11. (1) The members of the Commission under Art. 7, Para 1 shall remunerated for each participation in its sessions with a minimal working salary, as defined by Decree of the Council of Ministers of the relevant year.
(2) The representatives under Art. 7, Para 5 shall not be remunerated for their participations in the sessions of the Commission.

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

Art. 13. (1) The Commission shall adopt regulations on its activity, which regulations shall be approved by the Minister of the Environment and Water.
(2) At the performance of their activity, the members of the Commission shall be independent and governed only by the scientific and technical achievements. The sessions of the Commission shall be public.
(3) Members of the Commission shall present written opinions on each of the discussed matters.
(4) The Commission shall obligatory record minutes of its sessions.
(5) The documents of the sessions of the Commission shall be kept within 20 years.

Art. 14. (1) The members of the Commission, officials from the specialised administration under Art. 12, the persons under Art. 7, Para 5, the experts under Art. 7, Para 7 and the officials, who execute control as under this Law, shall not announce the information, sustaining protected by the law secret, which has become known to them at or in connection with the performance of their activities. They shall sign an affidavit of confidentiality.
(2) Within tree years of termination or expiration of their mandate, the members of the commission shall be obligated not to announce the information under Para 1.

Art. 15. The amounts of the fees, collected on the grounds of this Law, shall be approved by a Tariff of the Council of Ministers.

Chapter three.
WORK WITH GMOs IN CONTROLLED CONDITIONS

Section I.
Risk Assessment for the Human Health from work with GMOs in Controlled Conditions

Art. 16. (1) Work with GMOs in controlled conditions shall be performed by natural or legal persons, scientific institutes or high schools, which have received permit following the order of this chapter.
(2) Before starting work with GMOs in controlled conditions, the persons under Para 1 shall perform risk assessment concerning:
   1. the potential unfavourable consequences from GMOs for the human health and the environment.
   2. the nature of the work in controlled conditions;
3. the possibility of occurrence of the potential unfavourable consequences;
4. the impact of the potential unfavourable consequences.

(3) The risk assessment shall be documented and kept by the persons under Para 1 and shall be provided to the Ministry of Environment and Water and to the controlling bodies at request.

Art. 17. On the grounds of the risk assessment, the persons under Art. 16, Para 1 shall classify the work in controlled conditions as follows:
1. class 1 – activities of a minimal risk, for which activities application of the first level protection of the human health and environment is appropriate;
2. class 2 – activities of low degree risk, for which activities application of the second level of protection of the human health and environment is appropriate;
3. class 3 – risk activities, for which activities application of the third level of protection of the human health and environment is appropriate;
4. class 4 – high risk activities, for which activities application of the fourth level of protection of the human health and environment is appropriate;

Art. 18. (1) Work with genetically modified microorganisms in controlled conditions shall be classified as class 1, if:
1. data that the recipient or the parental microorganism causes disease to humans, animals or plants does not exist;
2. the nature of the vector and of the included genetic material is such, that the received genetically modified organism is little possible to cause disease to humans, animals or plants or to cause unfavourable impact on the environment in case it falls in it as a result of emergency;

(2) Work with genetically modified microorganisms in controlled conditions shall be classified as class 2, if:
1. the recipient or the parental microorganism can cause disease to humans, animals or plants, which is not possible to spread and an effective prophylaxis or treatment means exist, and is little possible to impact unfavourably on the environment in case it falls there as a result of emergency;

(3) Work with genetically modified microorganisms in controlled conditions shall be classified as class 3, if:
1. the recipient or the parental microorganism can cause disease to humans, animals or plants, which is possible to spread, but for such case effective prophylaxis or treatment means exist and is rarely possible to impact unfavourably the environment if it falls in as a result of emergency;
2. the nature of the vector and of the included genetic material is such, that the received genetically modified microorganism can directly, through a horizontal transfer of genetic material or in another way to cause disease to humans, animals or plants, which is possible to spread, but for such case effective prophylaxis or treatment means exist and is rarely possible to impact unfavourably the environment if it falls in as a result of emergency;

(4) Work with genetically modified microorganisms in controlled conditions shall be classified as class 4, if:
1. the recipient or the parental microorganism can cause disease to humans, animals or plants, which is possible to spread, and for such case effective prophylaxis or treatment
means do not exist or can impact unfavourably the environment if it falls into as a result of emergency;
2. the nature of the vector and of the included genetic material is such, that the received genetically modified microorganism can directly, through a horizontal transfer of genetic material or in another way to cause disease to humans, animals or plants, which is possible to spread, and for such case effective prophylaxis or treatment means do not exist or can impact unfavourably the environment if it falls into as a result of emergency;

(5) For determining of the pathogenetic nature of the donating and the recipient organism shall be used the classification as per the Ordinance No. 4 of 2002 on the protection of the employees against risks, related to exposure to biological agents at work (SG 105/2002).

Art. 19. (1) Work with genetically modified plants in controlled conditions shall be classified into 2 classes.
(2) Work with genetically modified plants in controlled conditions shall be classified as class 1, if:
1. the genetically modified plants have limited abilities to transfer genetic material to local plant species or due to the nature of the transformation determining absence of or reduced transfer of the pollen;
2. the used in the transformation plant pathogens are of unviable sample
(3) Work with genetically modified plants in controlled conditions shall be classified as class 2, if:
1. the genetically modified plants have limited abilities to transfer genetic material to local plant species;
2. the genetically modified plants are potential pests;
3. the used in the transformation plant pathogens are of viable sample;
4. horizontal transfer of genetic material from genetically modified plants to other species is possible and as a result of which unfavourable consequences may occur.

Art. 20. (1) Work with genetically modified animals in controlled conditions shall be classified into two classes.
(2) Work with genetically modified animals in controlled conditions shall be classified as class 1, if one of the following conditions occurs:
1. the genetically modified animals are not able to survive on the Bulgarian environment;
2. the genetically modified animals have a limited ability to transfer genetic material to local animal species;
3. the genetically modified animals are not infected with genetically modified microorganisms or other pathogens and the genetic modification does not lead to higher risk for the human health and the environment than this from the not-modified parental organisms;
4. genetically modified farm animals have easily deferrable external marks in result of the genetic modification
(3) Work with genetically modified animals in controlled conditions shall be classified as class 2, if one of the following conditions occurs:
1. the genetically modified animals are able to survive in the Bulgarian environment;
2. the genetically modified animals may damage the human or the i may participate environment, if they leave the controlled room and have ability to transfer the imported
genetic material to local animal species;
3. the genetically modified animals are not infected with genetically modified microorganisms or other pathogens, but the genetic modification lead to higher risk for the human health and the environment than this from the not-modified parental organisms;

Art. 21. The terms and order of performance of the risk assessment of the work with GMOs in controlled conditions shall be stipulated by the ordinance under Art. 2, Para 3.

Art. 22. The risk assessment of the work with GMOs in controlled conditions and the applied protective measures shall be revised and updated by the applicant in every two years or if:
1. the protection measures already do not meet the defined class of risk;
2. the defined class is not relevant to the degree of risk;
3. the risk assessment is not actual in view of a new scientific or technical information.

Section II.
Registration of the Rooms for work with GMOs in Controlled Conditions

Art. 23. (1) Work with GMOs in controlled conditions shall be performed in rooms, which rooms shall be registered at the Ministry of Environment and Water.
(2) The rooms shall be registered, if the persons under Art. 16 have provided the protection and safety measures in the rooms, as defined by the ordinance under Art. 2, Para 3 for the relevant class work with GMOs, for the purposes of providing healthy and safe conditions of labour for the persons working in the rooms and prevention of the exposure if the environment to the impact of GMOs.

Art. 24. (1) The persons under Art. 16, referred hereinafter "applicants", shall submit to the Minister of Environment and Water a written application for registration of the room, in which room for the first time shall be performed work with GMOs in controlled conditions.
(2) The application shall contain:
1. identification of the applicant: name, number of the identity document and permanent address – regarding the natural persons, or name, seat and registered office, BULSTAT- registration – regarding the sole traders and legal persons;
2. location and description of the room, where the work with GMOs in controlled conditions is to be performed;
3. the names and the permanent address of the natural persons, who shall be responsible for the supervision and safety of the work with GMOs in controlled conditions;
4. information regarding the training and qualification of the persons under item 3;
5. information regarding the established by the applicant committees and groups for biosafety, which shall perform the activities enlisted in ordinance under Art. 2, Para 3;
6. description of the types of activities which shall be performed;
7. the defined class under Art. 17;
8. resume of the risk assessment and information regarding the management of the
wastes. 

(3) Certificate of good standing of the applicant and a document evidencing paid fee for application for registration of rooms for work with GMOs shall be attached to the application.

Art. 25. (1) If diminutions or inexactitudes are found, the applicant shall be notified within 7- days from the receipt of the application.

(2) The applicant shall be obliged to remove the found diminutions or inexactitudes.

(3) The Commission shall check the authenticity and the exhaustiveness of the information contained in the submitted application, the preciseness of the performed risk assessment and defined class of work in controlled conditions and the adequacy of the protection measures.

(4) Within 30-days period from the submission of the application, the Commission shall draw up an opinion and shall present it before the Minister of the Environment and Water.

(5) The term under Para 4 shall stop running up to the moment of removal of the diminutions or inexactitudes in the application.

Art. 26. (1) The Minister of Environment and Water shall issue an order of inscribing the room in the register of the rooms for work with GMOs in controlled conditions or shall issue a motivated refusal within 150-days period from the receipt of the opinion of the Commission.

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

(3) The Minister of Environment and Water shall refuse the registration of the room, if it does not meet the terms of Art. 23.

(4) The Ministry of Environment and Water shall notify the applicant of the refusal of the Minister of Environment and Water within 7-days period of its issuing.

(5) (amend. - SG 30/06, in force from 12.07.2006) The refusal to register the room shall be appealed following the order of the Administrative procedure code.

Art. 27. (1) At the Ministry of Environment and Water shall be established and maintained electronic-format public register of the rooms for work with GMOs in controlled conditions.

(2) The Public Register under Para 1 shall be a part of the information system under Art. 4, Para 2.

(3) The data and circumstances under Art. 24, Para 2 shall be subject of entry.

(4) In case of change of the data and circumstances under Para 3, the persons who have acquired certificate of registration, shall notify within 7 –days period the Minister of the Environment and Water. The new circumstances shall be inscribed in the register.

(5) The Minister of Environment and Water shall delete the rooms from the register:

1. by a written request of the person, who has acquired the certificate of registration of the room;

2. if in result of the control under Chapter Seven is found that the room does not meet the requirements of the Art. 23.
Art. 28 The Ministry of Environment and Water shall collect fee for the registration under this section.

Section III.
Terms and procedures of work with GMOs in controlled conditions

Art. 29. (1) Work with GMOs in controlled conditions shall be performed by the persons under Art. 16, who have acquired permit by the Minister of Environment and Water in registered in accordance with the Section II of this chapter rooms.

(2) In case of a positive opinion of the Commission, the permits shall be issued for each separate case of work with GMOs in controlled conditions and for each class work with GMOs.

(3) Managers of laboratories or productions, where a work with GMOs is performed, shall be persons, who have acquired higher education and professional practice at least 5 years at a similar laboratory or production.

Art. 30. (1) The persons under Art. 16, who intent to perform work with GMOs in controlled conditions, shall submit a written application to the Minister of Environment and Water.

(2) The application shall contain:
1. identification of the applicant: name, number of the identity document and permanent address – regarding the natural persons, or name, seat and registered address, BULSTAT registration – for the sole traders and legal persons;
2. registration number of the room for work;
3. the names of the natural persons, who shall be responsible for the supervision and safety at work with GMOs in controlled conditions;
4. information regarding the training and qualification of the persons under item 3;
5. the recipient, donating and/or the parental organism, which are used, and the system hosting – vector shall be quoted;
6. the source, respectively sources and quotation of functions of the genetic material, used in the modification;
7. identification and characteristic of the GMO;
8. the purpose of the work in controlled conditions, including the expected results;
9. the approximate volume of the selection to be used;
10. description of the work in controlled conditions, including information on the management of wastes regarding their processing, final form and destination;
11. the period for which the work with GMOs in controlled conditions shall be performed;
12. resume of the risk assessment for classes 1 and 2 and a copy of the risk assessment for classes 3 and 4;
13. needed for the Commission information for the assessment of the emergency plan under Art. 31, Para 4.

(3) To the application under Para 2 for work with GMOs in controlled conditions of classes 3 and 4 plans for prevention of emergencies and of actions in case of emergency shall be attached, which plans shall contain data regarding:
1. the specific risks arising from the location of the installation;
2. applied prevention measures such as safe equipment, alarm systems and methods of protection;
3. procedures and plans for testing of the efficiency of the precaution measures;
4. description of the information provided to the persons who work with GMOs in controlled conditions.

(4) The application shall be submitted in the Bulgarian language and in the English languages. The application may be submitted by electronic connection.
(5) To the application under Para 2 a certificate of good standing of the applicant and a document evidencing paid fee shall be attached.

Art. 31. (1) In case diminutions and inexactitudes are found, the applicant shall be notified within 7-days period from the receipt of the application.
(2) The applicant shall be obliged to remove the diminutions and inexactitudes within 14-days period form the receipt of the notification under Para 1.
(3) The Commission shall check the authenticity and the exhaustiveness of the information contained in the submitted application, the preciseness of the performed risk assessment and of the defined class of work in controlled conditions, the adequacy of the precaution measures, the wastes management and the measures of urgent action in cases of emergency.
(4) The Commission shall check:
1. the developed plan of urgent action in cases of emergency at work with GMOs in controlled conditions, in the cases where violation of the precaution measures may lead to a serious danger for the humans outside the rooms and/or for the environment;
2. if the information of the plan under item 1 and of the appropriate precaution measures which shall be applied has been provided to the persons who may be impacted by emergencies.
(5) The information under Para 4, item 2 shall be public and shall be periodically updated.
(6) After finalisation of the researches under Para 1 – 4, the Minister of Environment and Water, on the grounds of the opinion of the Commission, may:
1. require from the applicant to:
   a) provide additional information;
   b) amend the conditions of the proposed work in controlled conditions;
   c) to amend the defined class of risk of work in controlled conditions;
2. limit the period for which the work in controlled conditions may be performed or to specify additional conditions of work.
(7) Within 30-days period from the submission of the application, the Commission shall draw up an opinion and shall provide it to the Minister of Environment and Water.

Art. 32. (1) (amend. – SG 36/08; amend. - SG 54/08) On the grounds of the opinion of the Commission and after a coordination with the Minister of Agriculture and Food, the Minister of Environment and Water shall issue a permit for work with GMOS of all classes within a period:
1. up to 45 days from the submission of the application for class 1 and class 2;
2. up to 90 day from the submission of the application for class 3 and class 4;
3. up to 45 days from the submission of the application, if the rooms for work have been used for work with GMOS of class 3 or higher class and the performed work has been in accordance with the issued by the Minister of Environment and Water permission.

(2) The term under Para 1 shall stop running:
1. until the diminutions and inexactitudes are removed from the application;
2. until the applicant provides the additional information under Art. 31, Para 6, item 1, letter "a".

(3) The permit shall contain requirements for the performance of the work in controlled conditions, including regarding their transportation.

Art. 33. (1) The Minister of the Environment and Water shall refuse the issuing of a permit under Art. 32 in case of a negative opinion of the Commission and if:
1. the risk assessment made is inaccurate, the class of work in controlled conditions is not determined correctly, the prevention measures, the waste management and the emergency action measures in the case of emergency are not adequate to the respective class of working in controlled conditions;
2. the applicant has not remedied the diminutions and inexactitudes in his application within the term laid down in Art. 31, Para 2.

(2) (amend. - SG 30/06, in force from 12.07.2006) The refusal under Para 1 shall be subject to appeal under the procedure of the Administrative procedure code.

Art. 34. (1) The permit under Art. 32 shall be issued for a term not longer than five years.

(2) Within 6 months before the expiry of the permit term under Para 1, the persons can apply for its extension.

Art. 35. The Minister of the Environment and Water shall inform the applicant about the permit under Art. 32 or the refusal under Art. 33 within 14 days from its enactment.

Art. 36. (1) At the Ministry of the Environment and Water shall be created and maintained electronically a public register of the issued permits for working with GMOs in controlled conditions.

(2) The public register under Para 1 shall be a part of the information system under Art. 4, Para 2.

(3) The circumstances and data contained in the permit for working with GMOs in controlled conditions shall be entered in the register.

(4) The changes in the data and circumstances under Para 3 shall also be entered in the register.

Art. 37. (1) In the case of emergency the person who has acquired a permit for working with GMOs in controlled conditions shall be obligated within 24 hours from the emergency to inform the Minister of the Environment and Water about:
1. the circumstances in which the emergency took place;
2. the type and range of the respective GMOs;
3. any other information needed to assess the consequences from the emergency for human health and the environment;
4. the undertaken emergency protection measures.
(2) In the cases under Para 1 the Commission shall:
1. propose to the Minister of the Environment and Water the implementation of the necessary emergency measures;
2. collect the necessary information, analyse the reasons for the emergency and propose measures for their prevention in the future and for restricting the consequences thereof.

Art. 38. Before changing the conditions of working in controlled conditions, resulting from which changes may occur in the risk level of the performed work, the person who has acquired permit shall be obligated to inform the Minister of the Environment and Water and file a new application under Art. 30.

Art. 39. (1) In the presence of new scientific information related to increasing the risk to human health or the environment after the issue of a permit for work with GMOs in controlled conditions, the person who has acquired a permit for this, shall be obligated to immediately inform the Minister of the Environment and Water.

(2) In the cases under Para 1 the Minister of the Environment and Water shall obligate the person who has acquired a permit for work with GMOs in controlled conditions to change the working conditions or to discontinue performing it.

(3) The provision of Para 2 shall also be applied to the cases when the information under Para 1 comes in at the Ministry of the Environment and Water or becomes known to the Commission members.

Art. 40. The Minister of the Environment and Water shall revoke the permit for working with GMOs in controlled conditions in the event of a committed violation of the conditions determined with the issued permit, from which unfavourable consequences have occurred for human health and the environment.

Art. 41. For issuing the permits under this section, the Ministry of the Environment and Water shall levy a fee.

Chapter four.
PROCEDURE OF RELEASING GMOs IN THE ENVIRONMENT AND PUTTING ON THE MARKET GMOs OR A COMBINATION THEREOF AS PRODUCTS OR INGREDIENT OF PRODUCTS

Section I.
Risk assessment to human health and to the environment from GMOs release in the environment and putting on market GMOs or a combination
of GMOs as products or ingredient of products

Art. 42. (1) Before releasing GMOs in the environment or putting them on the market as products or ingredient of products, every natural person or legal person shall be obligated to draw a risk assessment to human health and the environment.

(2) The risk assessment shall include results from performed monitoring and a detailed monitoring plan for potential short-term and long-term consequences for human health and the impact on the environment of the release of GMOs in the environment and putting them on the market.

Art. 43. (1) The risk assessment shall cover an evaluation for each individual case of all potential unfavourable consequences for human and animal health, the environment and biological diversity, which may arise directly or indirectly in the event of releasing in the environment or putting GMOs on the market, including an analysis of the potential cumulative consequences from the release or putting GMOs on the market.

(2) The risk assessment shall be made on the grounds of the existing scientific and technical data from national and international sources.

(3) The risk assessment shall be made in conformity with the principles and methodology in accordance with Annex No. 1.

(4) On the grounds of the risk assessment, the persons under Art. 42 shall determine the necessity and methods of risk management.

(5) The risk assessment shall also include a conclusion about the potential impact on human health and the environment of the release of GMOs in the environment or putting them on the market.

Art. 44. (1) In the presence of new scientific information about a GMO and the consequences from its release in the environment or putting it on the market on human health or the environment, a new risk assessment shall be drawn.

(2) The risk assessment shall determine whether the risk has changed and whether a change in its management is necessary.

Art. 45. The terms and procedure for drawing up a risk assessment of the release and putting GMOs on the market as well as the information, which shall be contained in the conclusion under Art. 43, Para 5, shall be determined in an ordinance on the release of GMOs in the environment and putting them on the market, adopted by the Council of Ministers.

Section II.
Release of GMOs in the environment

Art. 46. (1) The release of GMOs or a combination of them in the environment shall be made after obtaining a permit issued by the Minister of the Environment and Water, after a positive opinion of the Commission.

(2) The permit under Para 1 shall be issued for each individual case on the grounds of
Art. 47. (1) The application under Art. 46, Para 2 shall be filed to the Minister of the Environment and Water and shall consist of:

1. a technical dossier, which shall include the information necessary for making the risk assessment for the environment from the release of GMOs or a combination of them in the environment;
2. a risk assessment and a conclusion under Section I of this chapter, including a description of the methods used and reference to standard or internationally recognised methods, and a bibliographical record.

(2) The technical dossier shall contain:
1. general information, including:
   a) identification of the applicant: names, number of the identification document and fixed address – for natural persons, or name, headquarters and registered address, BULSTAT registration – for sole traders and legal persons;
   b) names, qualification and experience of the researchers and specialists responsible for the project;
   c) name of the project;
2. information about the GMO, including the marker genes contained in it;
3. information about the terms and mechanisms of release and the hosting environment;
4. information about the interactions between the GMO and the environment;
5. monitoring plan in view of identification of the consequences from the GMO for human health and/or the environment;
6. information about the control, remediation methods, waste treatment and emergency actions plan in the case of emergency;
7. a map of the farm declared for cultivating transgenic crops and its neighbours, a list of the owners of the neighbouring fields and the manner of production (biological or conventional);
8. the resume of the dossier.

(3) The data, which the information under Para 2 shall contain and the form of the application shall be determined in the ordinance under Art 45.

(4) The application shall be filed in the Bulgarian and the English languages. The application may be also filed by electronic connection.

(5) Attached to the application shall be a certificate of good standing of the applicant and a document of paid fee.

Art. 48. (1) The applicant can refer to information, data or results from studies and analyses undertaken under previous applications filed by other persons to the Minister of the Environment and Water or to the respective competent authorities of other states, provided that they do not have a confidential nature or the previous applicants have given their consent in writing for using them.

(2) The applicant may submit additional information beside that specified in Art. 47, which he considers necessary.
Art. 49. (1) In the event of established diminutions or inaccuracies, the applicant shall be notified within 7 days from filing his application.

(2) The applicant shall be obligated to remedy the diminutions or inaccuracies within 14 days from receiving the notification under Para 1.

(3) The Commission shall verify the authenticity and the adequacy of the information contained in the filed application, the accuracy of the risk assessment made, the adequacy of the observation plan, of the envisaged control, of the methods of remediation, of the manners of waste treatment and the emergency actions plans in the case of emergency.

(4) The Minister of the Environment and Water, on the grounds of an opinion of the Commission, can ask the applicant to submit additional information beside that specified in Art. 47, motivating the request in writing.

(5) Within 60 days from filing the application the Commission shall work out an opinion and submit it to the Minister of the Environment and Water.

Art. 50. (1) After working out the opinion under Art. 49, Para 5, the Ministry of the Environment and Water shall organise a public discussion, which shall be held not later than 45 days.

(2) At the public discussion shall be submitted the resume of the technical dossier, the resume of the risk assessment under Art. 43 and the Commission’s opinion under Art. 49, Para 5.

(3) The information determined as confidential under the procedure of Chapter Six cannot be an object of discussion.

(4) Not later than 30 days before the date of the discussion, in a central daily, through the local mass media, by placing notices at the respective mayoralties in the area of releasing a GMO in the environment as well as on the Internet page of the information system under Art. 4, Para 2, shall be announced the subject of public discussion and the place where the necessary information is at the disposal of the interested persons. Both the date and venue of holding the public discussion shall be announced in the notice.

(5) Any person can submit an opinion on the subject of discussion in writing or electronically.

(6) For participation in the public discussion shall be invited also the applicant or his representatives and the members of the Commission.

(7) Minutes shall be kept for the public discussion, which shall be attached to the documents for issuing the permit.

Art. 51. (1) (amend. – SG 36/08; amend. - SG 54/08) On the grounds of the Commission’s opinion and the results from the public discussion and after coordination with the Minister of Agriculture and Food, the Minister of the Environment and Water shall issue or refuse the issuing of a permit for GMOs release or a combination of GMOs in the environment within 90 days from receiving the application.

(2) The term under Para 1 shall stop running:

1. until the diminutions or inexactitudes in the application are removed;
2. until the applicant has submitted additional information under Art. 49, Para 4;
3. while the public discussion under Art. 50 is held, which cannot extend the term under Para 1 by more than 30 days;

(3) The release of a GMO in the environment shall be carried out by stages, in
accordance with the terms laid down in the permit, whereas at the execution of each stage a protocol shall be executed. The next stage shall be taken up only if at the preceding stage no unfavourable impacts have been caused to the environment or human and animal health and biodiversity.

(4) In the permit under Para 1 shall be determined the period of time and the conditions in which the release of a GMO in the environment shall be carried out, including the mandatory distances in accordance with Appendix No. 2.

Art. 52. (1) The Minister of the Environment and Water shall refuse to issue a permit for releasing GMOs in the environment when the applicant has not removed the diminutions and inexactitudes in his application within the term under Art. 49, Para 2 or if the Commission’s opinion is that there are risks to human health or the environment and that the undertaken protection measures are insufficient or ineffective.

(2) The Minister of the Environment and Water shall refuse to issue a permit for releasing GMOs in the environment in the presence of a contiguous field with a biological manner of production.

(3) (amend. - SG 30/06, in force from 12.07.2006) The refusal under Paras 1 and 2 shall be subject to appeal under the procedure of the Administrative procedure code.

Art. 53. The Ministry of the Environment and Water shall notify the applicant about the decision under Art. 51 or about the refusal under Art. 52 within 14 days from its enactment.

Art. 54. (1) In the event of changes, which have occurred at the release of a GMO or a combination of GMOs and which may increase the risk to human health or the environment after the issue of a permit, the applicant shall be obligated immediately to:

1. undertake the necessary measures for the protection of human health and the environment;
2. inform the Minister of the Environment and Water about the changes or the new circumstances;
3. reconsider the applied prevention measures and change them, if necessary.

(2) When the information under Para 1 comes in at the Ministry of the Environment and Water or becomes known to the Commission members, it shall be subject to assessment by the Commission. The information under Para 1 and the Commission’s assessment shall be made public.

(3) The requirement under Para 1 shall be also applied in the presence of new scientific information related to increasing the risk to human health or the environment – both in the course of considering the application and after the issue of a permit for release.

(4) In the cases under Para 1 – 3 the Minister of the Environment and Water, on the grounds of a opinion of the Commission, shall change the terms or discontinue temporary or definitively the release of a GMO in the environment, pointing out the motives for this, and shall notify the public.

Art. 55. (1) After the release of a GMO in the environment the person who has acquired a permit for this shall be obligated, within the terms specified therein, to notify the
Minister of the Environment and Water about the results from the release as regards the risk to human health and the environment.

(2) The information under Para 1 shall be provided in a way determined in the ordinance under Art. 45.

Art. 56. The Minister of the Environment and Water shall suspend the permit for releasing a GMO in the environment in the event of committed violations of the terms determined in the issued permit.

Art. 57. (1) At the Ministry of the Environment and Water shall be created and maintained in electronic-format public registers of:
1. the issued permits for release of GMOs in the environment;
2. the areas on which the release of GMOs is permitted.
(2) The registers under Para 1 shall be a part of the information system under Art. 4, Para 2.
(3) The circumstances and data specified in the ordinance under Art. 45 shall be entered in the registers.
(4) The changes in the data and circumstances under Para 3 shall also be entered in the registers.

Art. 58. For issuing the permits under this section, the Ministry of the Environment and Water shall levy a fee.

Section III.
Putting on market GMOs or a their combination as products or ingredient of products

Art. 59. (1) (amend. – SG 36/08; amend. - SG 54/08) Putting on the market GMOs or a their combination as products or ingredient of products, which are not foods or food components in the sense of the Foods Act, shall be carried out only after obtaining a permit from the Minister of Agriculture and Food.
(2) (amend. – SG 36/08; amend. - SG 54/08) The Minister of Agriculture and Food shall issue a permit on the grounds of an application in writing from a person under Art. 42 who intends to put on market GMOs or their combination as products or ingredient of products, and a positive opinion in writing of the Commission.

Art. 60. (1) (amend. – SG 36/08; amend. - SG 54/08) The application under Art. 60, Para 2 shall be filed to the Minister of Agriculture and Food and shall contain:
1. identification of the applicant:
a) names and number of the identification document and fixed address – for natural persons;
b) name, headquarters, registered address and BULSTAT registration – for sole traders and legal persons.
2. information about the GMOs;
3. information about the conditions and manners of releasing the GMOs and the receiving environment;
4. information about the interactions between the GMOs and the environment;
5. information as regards the observation, control, waste treatment and the emergency actions plans in the case of emergencies;
6. risk assessment and conclusion under Section I of this chapter;
7. the terms on which the product can be put on the market, if any, including the manner of use;
8. a proposal for the term of effect of the permit for putting on the market, which cannot be longer than 5 years;
9. a monitoring plan and a proposal for its term of effect;
10. a proposal for the manner of labelling the product;
11. a proposal for the product packaging;
12. a resume of the entire dossier;
13. additional information.

(2) The application shall be filed in the Bulgarian and in the English languages. The application may also be filed by electronic connection.

(3) Attached to the application shall be a certificate of good standing of the applicant and a document of paid fee.

(4) The information under Para 1, Items 2 – 5, the requirements to the observation plan under Para 1, Item 9, the additional information under Para 1, Item 13 and the form of the application shall be determined in the ordinance under Art. 45.

(5) The information under Para 1, Items 2 – 5 and Item 13 shall take into consideration the diversity of the places in the country for the use of GMOs as products or ingredient of products and shall include data and results obtained from research and development releases of GMOs in view of exploring the impact of the release on human health and the environment.

Art. 61. A separate application for putting on the market shall be required when a GMO or a combination of GMOs, for which an application has already been filed, will be used for purposes different from those specified in the original application.

Art. 62. (1) The applicant shall include in the application information or results from putting on the market the same GMOs or the same combination of GMOs, for which he/she has filed applications, or has released them in or outside the territory of the country.

(2) The applicant can refer to information or results from previous applications filed by other applicants or submit additional information, which he considers to be appropriate, provided that the information and results are not confidential or the other applicants have given their consent in writing.

Art. 63. (1) In the event of established diminutions or inexactitudes, the applicant shall be notified within 7 days from filing his application.

(2) The applicant shall be obligated to remedy the diminutions or inaccuracies within 14 days from receiving the notification under Para 1.
(3) The Commission shall verify the authenticity and exhaustiveness of the information contained in the filed application, the accuracy of risk assessment made, the adequacy of the monitoring plan, the manners of waste treatment and the emergency actions plans in the case of emergency as well as the proposals for the manner of labelling and packaging the product.

(4) (amend. – SG 36/08; amend. - SG 54/08) After completing the verifications the Minister of Agriculture and Food, on the grounds of a opinion of the Commission, may ask the applicant to submit additional information, motivating the request in writing.

(5) (amend. – SG 36/08; amend. - SG 54/08) Within 60 days from filing the application the Commission shall work out a opinion and submit it to the Minister of Agriculture and Food.

Art. 64. (1) (amend. – SG 36/08; amend. - SG 54/08) After working out the opinion under Art. 63, Para 5, the Ministry of Agriculture and Food shall organise a public discussion, which cannot last for more than 45 days.

(2) At the public discussion shall be submitted the resume of the technical dossier, the resume of the risk assessment under Art. 43 and the Commission’s opinion under Art. 63, Para 5.

(3) The information determined as confidential under the procedure of Chapter Six cannot be an object of discussion.

(4) Not later than 30 days prior to the date of the discussion, in a central daily and through the local mass media, as well as on the Internet page of the information system under Art. 4, Para 2, shall be announced the subject of public discussion and the place where the necessary information is at the disposal of the interested persons. Both the date and venue of holding the public discussion shall be announced in the notice.

(5) Any person can submit an opinion on the subject of discussion in writing or electronically.

(6) For participation in the public discussion shall be invited also the applicant or his representatives and the members of the Commission.

(7) Minutes shall be kept for the public discussion, which shall be attached to the documents for issuing the permit.

Art. 65. In the presence of new scientific information as regards the increase of the risk to human health or the environment prior to the issue of a permit for putting on the market, the applicant shall be obligated immediately to:

1. propose the necessary measures for the protection of human health and the environment;

2. (amend. – SG 36/08; amend. - SG 54/08) inform the Minister of Agriculture and Food about the new information and the measures proposed under Item 1;

3. reconsider the available information and propose changes in the terms of putting on the market.

Art. 66. (1) (amend. – SG 36/08; amend. - SG 54/08) On the grounds of the Commission’s positive opinion and the results from the public discussion and after coordination with the Minister of the Environment and Water, the Minister of Agriculture and
Food shall issue a permit for putting a GMO on the market or refuse the issue of a permit within 90 days from receiving the application.

(2) The term under Para 1 shall stop running:
1. until the remediation for the diminutions or inaccuracies in the application;
2. until the applicant has submitted additional information under Art. 63, Para 4;
3. while the public discussion under Art. 64 is held, which cannot extend the term under Para 1 by more than 30 days.

(3) The permit shall be forwarded to the applicant within 14 days from its enactment.

Art. 67. (1) The permit for putting GMOs on the market shall contain:
1. the identity of the GMO, put on the market in the form of products or product component, marked with a unique code;
2. the term for which it is issued;
3. the terms of putting the GMO on the market, including the special terms of use, processing and packaging the GMO and the terms of protecting certain ecosystems or geographical areas;
4. it shall be an obligation of the applicant to keep control samples, which shall be supplied at the request of the control authorities;
5. the labelling requirements;
6. the requirements to the observation plan and its term of effect as well as the obligations, if any, of the persons selling the product, or of the product consumers in the case of GMOs, which are cultivated.

(2) The rules for composing the unique code under Para 1, Item 1 shall be settled in the ordinance under Art. 45.

(3) The permit shall be issued for a term not longer than 5 years.

(4) As regards GMOs, intended for production and putting on the market as seed and planting material, the term under Para 3 shall start running from the day of entering the variety in the official variety list in accordance with the Seed and Planting Material Act.

(5) For forest reproduction material, the term under Para 3 shall start running from the day of entering the basic source containing the GMO in the National Register of the Forest Seed-Production Base.

Art. 68. (1) (amend. – SG 36/08; amend. - SG 54/08) The Minister of Agriculture and Food shall refuse with motivation the issue of a permit for putting on the market, should the Commission’s opinion be that there are risks to human health or the environment and that the undertaken protection measures are insufficient or ineffective, and when the applicant has not remedied the diminutions or inaccuracies in his/her application within the term specified in Art. 63, Para 2.

(2) (amend. - SG 30/06, in force from 12.07.2006) The refusal under Para 1 shall be subject to appeal under the procedure of the Administrative procedure code.

Art. 69. (1) (amend. – SG 36/08; amend. - SG 54/08) At the Ministry of Agriculture and Food shall be created and maintained electronically a public register of the issued permits for putting GMOs on the market.

(2) The electronic register under Para 1 shall be a part of the information system
under Art. 4, Para 2.

(3) The circumstances and data contained in the permit for putting GMOs on the market shall be subject to entering in the register.

(4) The changes in the data and circumstances under Para 3 shall also be entered in the register.

Art. 70 (1) (amend. – SG 36/08; amend. - SG 54/08) The person, who has acquired permit, shall conduct a monitoring on several stages of the plan under Art. 67, Para 1, item 6, as approved with the permit and shall draw up reports on the results of the monitoring of the release of GMOs at the market as products or ingredient of products, which reports the person shall provide to the Minister of Agriculture and Food.

(2) (amend. – SG 36/08; amend. - SG 54/08) After the expiration of the first stage of monitoring of the monitoring plan and on the grounds of the reports under Para 1, the Minister of Agriculture and Food may obligate the person, who has acquired the permit to amend or supplement the monitoring plan in accordance with the issued permit within the frames of the approved monitoring plan. The Minister of Agriculture and Food shall take the decision on the grounds of the opinion of the Commission.

(3) The results under the monitoring plan shall be available to the society.

Art. 71. (1) (amend. – SG 36/08; amend. - SG 54/08) At the Ministry of Agriculture and Food shall be created and maintained in electronic format a public register of the lands seeded with genetically modified plants and for which a permit for putting on market exists, in order to provide monitoring of the impact of these genetically modified plants on the human health and environment as prescribed in Art. 70.

(2) The register under Para 1 shall be a part of the information system under Art. 4, Para 2.

(3) The persons, who breed genetically modified plants under the conditions of Para 1, shall keep obligatory distance between the lands seeded with genetically modified plants and the adjoining lands, seeded with not-modified plants of the same species according to the Appendix No. 2.

(4) (amend. – SG 36/08; amend. - SG 54/08) The persons who breed genetically modified plants under the conditions of the Para 1, shall inform the Ministry of Agriculture and Food of the location and the square of the seeded lands.

(5) (amend. – SG 36/08; amend. - SG 54/08) The Ministry of Agriculture and Food shall notify the Ministry of Environment and Water of the location and square of the lands.

Art. 72. (1) In case of new available scientific information concerning the increasing risk for the human health and the environment from the putting on market, the person, who has acquired the permit, shall immediately:

1. to undertake the needed precaution measures for protection of the human health and the environment;
2. (amend. – SG 36/08; amend. - SG 54/08) inform the Minister of Agriculture and Food of the new information and the undertaken measures under item 1;
3. revise the conditions of putting on market.

(2) (amend. – SG 36/08; amend. - SG 54/08) When the information under Para 1 is
received at the Ministry of Agriculture and Food, or becomes known to the members of the Commission, it shall be a subject of assessment.

(3) (amend. – SG 36/08; amend. - SG 54/08) In the cases of Para 1 and 2, the Minister of Agriculture and Food, on the grounds of the opinion of the Commission, shall amend the conditions of putting on market of the GMOs as a product or ingredient of a product or shall definitively stop the release at market and shall quote the motives for such decision and shall inform the society.

Art. 73. (1) (amend. – SG 36/08; amend. - SG 54/08) The Minister of Agriculture and Food may extend the term of the permit on the grounds of a new application, submitted not later than 9 months before expiration of the permit.

(2) The application under Para 1 shall contain:
1. identification of the applicant:
   a) name, number of the identity document and permanent address – regarding the natural persons;
   b) name, seat, registered address, registration BULSTAT – regarding the sole traders and legal persons;

2. new available information concerning the risks from the product for the human health and/or the environment;

3. proposal for amendment or supplementation of the conditions of the permit for which prolongation of the term is requested, if this needed for the purposes of avoiding of the risk for the human health and environment.

(3) To the applications shall be attached a copy of the permit for GMOs putting on market and a report on the results from the monitoring under Art. 70.

(4) (amend. – SG 36/08; amend. - SG 54/08) The Minister of Agriculture and Food shall take decision to prolong the term of the permit within the period under Para 1 on the grounds of the opinion of the Commission. The term of the permit shall be prolonged for not more than 5 years.

(5) (amend. – SG 36/08; amend. - SG 54/08) The Ministry of Agriculture and Food shall notify the applicant of the decision under Art. 4 within 14 days from its issuing.

(6) (amend. – SG 36/08; amend. - SG 54/08) The applicant may keep releasing GMO at the market under the conditions provided by the permit for which the prolongation of the term is requested, until the Minister of Agriculture and Food announces the decision.

Art. 74. (1) (amend. – SG 36/08; amend. - SG 54/08) At each of the stages of the GMOs putting on market as products or ingredient of products, the labelling and packing shall be in accordance with the requirements of the permit, issued by the Minister of the Agriculture and Food.

(2) On the label of the product the following minimal information shall be marked:
1. commercial name of the product;
2. the expression: "This product contains genetically modified organisms;;
3. the name of the GMO;
4. name, respectively name and address, respectively seat of the person, who shall be responsible for the GMOs putting on market – producer, importer or distributor;
5. information concerning the way of access to the register under Art. 69.

(3) The provisions of Art. 1 and 2 shall not be applied for products:
1. in which occasionally appearing or technically unavoidable traces of GMOs exist, for which an issued permit for putting on market has been acquired, and are in quantities under the minimal admissible as defined under the ordinance of Art. 45.

2. geared for direct processing, in which occasionally appearing or technically unavoidable traces of GMO exist, for which an issued permit for putting on market has been obtained, and are in quantities not more than 0.5 under cent or in as defined by the ordinance of Art. 45 smaller quantity.

(4) On the label may be marked summary additional information:
1. description of the usage of the product, including description of the differences of usage in comparison with similar not-modified products;
2. description of the geographic region/regions and types of environment where the product is intended to be used and if possible – the degree in which the relevant region is intended to be used;
3. measures which shall be undertaken in case of inappropriate usage or in case of unintentional release;
4. specific instructions for work and storage;
5. specific instructions regarding monitoring and notifying the applicant under Art. 59, Para 2 and in case of necessity – notification the controlling bodies in case of occurrence of harmful consequences for the human health and the environment;
6. limitations of the permitted usage of GMO.

(5) (amend. – SG 36/08; amend. - SG 54/08) The information under Para 4 shall be labelled under the condition that it has been quoted in the application under Art. 60 and is approved by the Minister of the Agriculture and Food with the issued by him permit.

Art. 75. (1) (amend. – SG 36/08; amend. - SG 54/08) The Minister of the Agriculture and Food, after a co-ordination with the Minister of Environment and Water may temporary limit or prohibit the usage or sales of GMO as a product or ingredient of product, for which a permit has been issued, if grounds to conclude that this GMO sustain risk for the human health and environment arise on the base of information, which has become known after the issuing of the permit and which information impacts the risk assessment, or on the grounds of revision of the assessment of existing information on the base of new or additional scientific knowledge.

(2) (amend. – SG 36/08; amend. - SG 54/08) In the cases of Para 1, the Minister of Agriculture and Food shall notify the society of the undertaken precautions and the motives for them.

(3) (amend. – SG 36/08; amend. - SG 54/08) On the base of the information of Para 1, the person who has acquired permit for release at the market of GMO envisaged in Para 1, shall revise the risk assessment and shall provide the revision to the Ministry of Agriculture and Food.

(4) (amend. – SG 36/08; amend. - SG 54/08) The Minister of Agriculture and Food on the base of a opinion of the Commission, may require additional information from the person under Para 3, and shall motivate in written his request.

(5) (amend. – SG 36/08; amend. - SG 54/08) In 60-days period from providing the revised risk assessment, the Minister of Agriculture and Food shall:
1. suspend the issued permit, or
2. issue a new permit, in which the new conditions of release at the market shall be
quoted, or
3. suspend the limitation or prohibition of usage and sales of the relevant GMO.

Art. 76. (amend. – SG 36/08; amend. - SG 54/08) The Minister of the Agriculture and Food shall suspend the permit for release of GMO at the market in case of admitted offence of the conditions defined in it.

Art. 77. The persons who release GMOs at the market as products or ingredients of products shall observe the rules of tracking of products as defined in the ordinance under Art. 45.

Art. 78. (amend. – SG 36/08; amend. - SG 54/08) For the issuing of permits under this Section, the Ministry of Agriculture and Food shall collect a fee.

Section IV.
Prohibitions

Art. 79 (*)(1) Prohibited shall be the release in the environment and putting on market of the following GMOs: tobacco, vine, after rose, grain and of all vegetable and fruit crops.
(2) (amend. – SG 36/08; amend. - SG 54/08) The Minister of Agriculture and Food, coordinated with the Minister of Environment and Water, shall supplement the list under Para 1 with an order, which order shall be promulgated in the State Gazette.

Art. 80. (suppl. – SG 43/08) Prohibited shall be the release of GMOs on the territories, included in the National Ecological Net in the meaning of the Law on the Biological Diversity, as well as on the adjoining territories including 30-kilometers band surrounding them. With regard to genetically modified cotton plant the adjoining territory shall cover 400-meter zone.

Art. 81. Prohibited shall be the release in the environment and putting on the market of GMOs containing marker genes for antibiotic resistance.

Art. 82. Prohibited shall be release of GMO as products or ingredients of products in the environment and at the market, for which products or ingredients a refusal is issued in the states – members of the European Union.

Chapter five.
IMPORT, EXPORT AND UNINTENDED TRANSBOUNDARY TRANSFERENCE OF GMO

Section I.
Import

Art. 83. (amend. – SG 36/08; amend. - SG 54/08) The import of GMO and of GMO as products or ingredient of products shall be performed after a permit by the Minister of Environment and Water or by the Minister of Agriculture and Food is acquired following the order of Chapter Three or Four, depending of the purpose of the GMO.

Art. 84. In cases of import, in the veterinary or phyto-sanitary certificate shall be obligatory inscribed the information concerning presence of GMOs.

Section II.
Export. General Provisions

Art. 85. In cases of export shall be applied the procedure of preliminary mutual notification as under the Cartahena Protocol on the Biosafety to the Convention on Biodiversity, referred hereinafter "the Protocol".

Art. 86. (1) The exporters shall quote in the documents accompanying GMO, that the good contains or consists of GMO and the unique code, if such ahs been defined for the relevant GMO.

(2) The information under Para 1 shall be provided to the person, who shall receive the GMO in the country-importer.

(3) In cases of export of GMO intended for direct usage, such as food, fodder or for processing, to the information, quoted under Para 1, the exporter shall attach an affidavit, in which shall be quoted:

1. that the GMO are purposed for usage, such as food, fodder or for processing and not purposed to be released in the environment.

2. name, address, telephone and person for contacts and additional information.

(4) The provision of Para 3, item 2 shall not be applied for products consisting or containing mixture of GMO, geared for usage only and directly as a food or forage or for processing. For these products shall be applicable the provisions of Art. 74 and 77.

(5) In cases of export of GMO geared for work in controlled conditions, the exporter shall attach a declaration to the information under Para 1, in which declaration he shall quote:

1. the requirements for safety usage, preserving and transportation of these GMO;

2. name, address, telephone of a person for contact and additional information, including name, address and telephone of the person who shall receive the GMO in the importing country.

(6) In events of export of GMO geared for release in the environment, the exporter shall provide also a declaration to the information under Para 1, in which declaration shall be quoted:

1. the identity, the relevant parameters an characteristics of GMO;

2. the requirements for safe usage, preservation and transportation of these GMO;

3. name, address and telephone of a person for contact for additional information and if appropriate – name, address and telephone of the person, who shall receive the GMO in the
importing country;
4. declaration that the export is in accordance with the requirements of the Protocol.

Art. 87. (amend. – SG 36/08; amend. - SG 54/08) The Minister of Environment and Water and the Minister of the Agriculture and Food shall issue a written certificate to the exporter of GMO, who has acquired consent for import from the importing country.

Art. 88. (amend. – SG 36/08; amend. - SG 54/08) The Ministry of Environment and Water and the Ministry of Agriculture and Food shall notify the Agency "Customs" of each decision of the importing country.

Art. 89. In event of failure to observe the procedures stipulated in Sections II, III and IV of this chapter, export of GMO shall not be admitted.

Section III.
Export of GMOs geared for release in the environment.

Art. 90. Export of GMOs, geared for release in the environment shall be performed only after acquiring a preliminary written consent from the importing country, taken in accordance with the procedure provided in Art. 9 and 10 of the Protocol.

Art. 91. (1) The exporters of GMOs, intended for release in the environment shall submit written notifications regarding this to the Ministry of Environment and Water.
2. The notification under Para 1 shall contain the following minimal information:
1. name, telephone and address for contacts of the person, who exports GMOs;
2. name, telephone and address for contacts of the person, who receive the GMOs in the importing country.
3. name and identity of the GMOs;
4. expected date of the execution of the export;
5. taxonomic status, universally accepted name, place of collection or obtaining and characteristics of the accepting or the parental organism, related to the biosafety.
6. centres of origin and centres of genetic diversity, if known, of the accepting and/or of the parental organism, and a description of the places of inhabit, where the organisms can be preserved or reproduced;
7. taxonomical status, universally accepted name, collection or obtaining, and the characteristics of the donor/donors, related to the biosafety;
8. description of the nucleic acid or performed modification, used techniques and obtained characteristics of the GMOs;
9. intended usage of the GMOs or of the products of them, including the processed materials, which originate from the GMO and contain a provable and distinguishable new combinations of the reproductive genetic material, obtained by way of using of the techniques envisaged in the Art. 2, Para 1;
10. the quantity or the volume of the GMOs, which shall be a subject of export;
11. prior and current risk assessments done in accordance with Chapter Four, Section I.
12. proposed methods for safe processing, preservation, transport and usage, including packing, labelling, documenting, termination and emergency procedures;
13. reference of the legal regulation and status of the exported GMO – if it is prohibited and reasons for this, or of another limitations related with it are laid;
14. information regarding the results and purposes of the all other applications submitted by the exporter to other countries for this GMO;
15. declaration that the quoted under items 1-14 circumstances are true.

(3) The Ministry of Environment and Water shall forward the application to the competent body of the importing country and shall notify, through the Clearing-House of Biosafety, the countries of the Protocol regarding the submitted application.

Art. 92. (1) In the cases, in which the competent body of the importing country does not announce its decision concerning the submitted application within 270 days from the receipt of the application, the Ministry of Environment and Water shall send a written reminder with a copy to the Secretariat of The Protocol, in which reminder the Ministry shall give additional 60-days term for answer.
(2) The term under Para 1 shall stop running, in cases where additional information shall be provided.
(3) Lack of a decision of the importing country within the envisaged in Para 1 term shall not be considered as consent for performance of the export.

Art. 93. Copy of the application under Art. 91, Para 1, the confirmation of the received application, as well as the decision of the importing country shall be kept at the Ministry of Environment and Water for a period not shorter than 5 years.

Art. 94. (1) The exporter may propose to the Ministry of Environment and Water to require from the importing country to revise their decision in event of change of the circumstances, which circumstances, in opinion of the exporter, may influence the result of the risk assessment, on the grounds of which the decision had been taken, or if a new additional scientific or technical information has become available.
(2) In event the importing country does not answer the request within 90 days, the Ministry of Environment and Water shall send a reminder and a copy of it to the Secretariat, in which reminder a definite term for answer after the receipt of the reminder shall be imposed.

Art. 95. The provisions of the Art. 90 – 94 shall not be applied for export of GMOs, if:
1. are geared for work in controlled conditions, when the export has been undertaken in accordance with the legislation of the importing country;
2. for which the importing country has notified in advance, through the Clearing House of Biosafety, that regarding their export, the procedure of preliminary mutual notification shall not be applied, and for them adequate measures of safe transboundary transfer, in accordance with the purposes of the Protocol, are applied.
Section IV.
Export of GMOs intended for direct usage as food or as forage or for processing

Art. 96. Export of GMOs intended for direct usage as food or as forage or for processing shall be performed only after acquiring of a prior written consent of the importing country.

Art. 97. (1) (amend. – SG 36/08; amend. - SG 54/08) The ministry of Agriculture and Food, through the Clearing-House of Biosafety, shall inform the interested countries about each taken decision for putting on the market of intended for direct usage as food or as forage or for processing GMOs through the Clearing-House of Biosafety

(2) The information shall contain minimum:
1. name, telephone and address for contacts of the person, who has submitted the application;
2. (amend. – SG 36/08; amend. - SG 54/08) telephones and numbers for contacts of the responsible officials from the Ministry of Agriculture and Food;
3. name and identity of the GMOs;
4. description of the genetic modification, used techniques and characteristics of the obtained GMOs;
5. the unique code of GMO, if such has been determined;
6. taxonomical stays, universally accepted name, place of collection or obtaining and the characteristics of the accepting or the parental organism, related to the biosafety.
7. centres of origin and centres of genetic diversity, and if known – of the accepting and/or the parental organism, and description of the places of inhabit in, where the organisms can preserve themselves or to reproduce;
8. taxonomic status, universally accepted name, place of collection or obtaining, and the characteristics of the donor/ donors, related to the biosafety;
9. approved usages of the GMOs;
10. risk assessment for the environment under the Chapter Four, Section I;
11. proposed methods for safe processing, preservation, transport and usage, including packing, labelling, documenting, termination and emergency proceedings;

(3) The information under Para 2 shall be sent within 15 days after the issue of the permit under Para 1.

(4) (amend. – SG 36/08; amend. - SG 54/08) The Ministry of Agriculture and Food shall consider each request of other countries for additional information concerning the decision under Para 1.

(5) A copy of the information, quoted in Para 1- 4, shall be sent in written to the persons for contacts in the countries, which have notified in written the Secretariat, that they have no access to the Clearing-House of Biosafety.

Art. 98. The exporter shall observe each of the decisions of the importing country regarding the import of GMOs, intended for direct usage as food or as forage or for processing GMOs, which decision is taken in accordance with the Art. 11, Paragraph 4 of the Protocol.
Section V.
Transit

Art. 99 (1) The persons, who shall transit GMOs through the territory of the Republic of Bulgaria, shall submit written notifications regarding this to the Ministry of Environment and Water.

(2) The notification under Para 1 shall be submitted at least 14 days before the transiting of GMOs and shall contain:
   1. name, telephone and address for contacts of the person, who shall perform the transit of GMOs;
   2. name, telephone and address for contacts of the person, who receive the GMOs;
   3. name and identity of the GMOs;
   4. date of the execution of the transit;
   5. taxonomic status, universally accepted name, place of collection or obtaining and characteristics of the accepting or the parental organism, related to the biosafety;
   6. centres of origin and centres of genetic diversity, if known, of the accepting and/or of the parental organism, and a description of the places of inhabit, where the organisms can be preserved or reproduced;
   7. taxonomical status, universally accepted name, collection or obtaining, and the characteristics of the donor/donors, related to the biosafety;
   8. description of the nucleic acid or performed modification, used techniques and obtained characteristics of the GMOs;
   9. intended usage of the GMOs or of the products of them, including the processed materials, which originate from the GMO and contain a provable and diferrable new combinations of the reproductive genetic material, obtained by way of using of the techniques envisaged in the Art. 2, Para 1;
   10. the quantity or the volume of the GMOs, which shall be a subject of transit;
   11. the undertaken measures of safety for transport and for usage, including packing, labelling, documenting, termination and procedures in case of emergency;
   12. declaration that the quoted under items 1-11 circumstances are true.

Art. 100. The Minister of Environment and Water shall issue a written certificate to each person, who transits GMOs through the territory of the Republic of Bulgaria not later than three days before the transit.

Art. 101. (amend. – SG 36/08; amend. - SG 54/08) The Ministry of Environment and Water shall notify Agency "Customs" and the Ministry of Agriculture and Food regarding each of the issued certificates for transit of GMOs through the territory of the country.

Art. 102. In case of violation of the procedures, provided in this Section, transit of GMOs through the territory of the country shall not be admitted.

Section VI.
Art. 103. (1) In cases of finding of unintended transboundary transfer of GMOs, the procedure of preliminary mutual notification shall be applied.

(2) If information about release of GMOs in the environment, which release may lead to a unintended transboundary transfer appears, the Ministry of Environment and Water shall:

1. through the Clearing-House of Biosafety, notify the society, impacted states and these, which can be impacted, the states of the Protocol and the Secretariat, as well as the respective international organizations;
2. conduct consultations with the impacted states or these, which can be impacted, in order to facilitate them at the undertaking of precaution measures and plans of action;

(3) The notification under Para 1 shall contain the whole available information regarding:

1. the approximate quantity and characteristics or parameters of GMOs;
2. the circumstances and approximate date of the release of GMOs;
3. the manner of usage of the GMOs;
4. the potential unfavourable consequences for the preservation and stable usage of the biological diversity and the human health.
5. the measures of risk management.

(4) In the notification under Para 2 shall be quoted any other appropriate information, related to the unintended transboundary transfer, as well as telephones and numbers of a person for contacts at the Ministry of Environment and Water for additional information.

Chapter six.
CONFIDENTIAL INFORMATION

Art. 104. (1) (amend. – SG 36/08; amend. - SG 54/08) The applicant under Chapters Three and Four, respectively the exporter under Chapter Five, may submit at the Ministry of Environment and Water and at the Ministry of Agriculture and Food a grounded request for announcement of a definite information from the submitted by him application as confidential for the purposes of defence of his commercial interests.

(2) (amend. – SG 36/08; amend. - SG 54/08) The Minister of Environment and Water or the Minister of Agriculture and Food shall determine with an order which of the requested information shall be considered confidential. In case a part of it or the whole information is not determined as confidential, the respective minister shall quote his motives for this.

(3) Confidential shall be such information, which is pointed out by the applicant, respectively by the exporter, and defined as such by the body under Para 2, and revealing of which information to third persons leads to harming of his commercial interests and his competitiveness as well as the information, a subject of protection by a patent or other rights of intellectual property.

Art. 105. Shall not be confidential information:
1. in the cases of work with GMOs in controlled conditions:
a) the characteristics of the GMOs, incl. the marker genes;
b) the name and the address of the applicant;
c) the location of work with GMOs
g) the defined class and precaution measures at work with GMOs;
d) the assessment of the possible unfavourable consequences for the human health
and the environment;
2. in cases of release if GMOs in the environment and putting on the market as
products or ingredients of products:
a) the description of the GMOs;
b) the name and the address of the applicant;
c) the purpose and place of release;
d) methods and plans of monitoring of GMOs and plans of emergency action;
e) place of preservation;
f) the ways of transportation;
g) the usage of the GMOs;
h) risk assessment;
3. in the cases of import and export of GMOs:
a) the name of the exporter and the importer;
b) description of GMOs;
c) the resume of the risk assessment of the impact to he human health, as well as on
the preservation and stable usage of the biological diversity;
d) the methods and plans of monitoring of GMOs and plans of emergent actions.

Art. 106. Access to the information regarding the used vectors, DNA sequences,
marker genes.

Art. 107. If the GMOs are protected by patent or other rights of intellectual property,
the provisions of the special legislation in this field shall be applied.

Chapter seven.
CONTROL

Art. 108. (1) The Ministry of Environment and Water, through the regional
inspectorates of Environment and Water, shall perform control on the release of GMOs in the
environment in view of its preservation.
(2) For the performance of the control under Para 1, a special laboratory shall be
established to the Executive Agency of the Environment to the Ministry of Environment and
Water.

Art. 109. (1) (amend. – SG 36/08; amend. - SG 54/08) The Ministry of Agriculture
and Food shall perform control through the Executive agency for variety trial, approbation and
seed control, the National service for plant protection, the National Office for the grain and
fodder, the Executive Agency for the vine and wine, the Executive agency for fishery and
aquacultures, the State Forestry Agency and the Executive agency for selection and
reproduction in animal breeding.

(2) Within the frames of their competences, the bodies under Para 1 shall perform control over:

1. conduction of field experiments with GMOs, usage of genetically modified products for plant protection and fertilization on biological base;
2. putting on market of genetically modified seeds and seeding material, forages and forage additives and genetically modified products for plant protection.

Art. 110. The Ministry of Labour and Social Policy, through the Executive Agency "Head Inspectorate of Labour" and its structures, shall perform control on the observation of this law regarding the prevention and protection measures, as defined for each class of work with GMOs in controlled conditions in order to provide healthy and safe conditions of labour for the employees who are working in the rooms for work with GMO in controlled conditions.

Art. 111. (amend., SG 99/05) The Ministry of Economy and the Commission of Protection of the Consumers shall perform control on the labelling of GMOs as products or ingredients of products at their putting on market.

Art. 112. (1) The Agency "Customs" shall perform the control at import, export and transit of GMOs, as per Art. 65, Para 3 of the Law on the Customs, in the cases of:

1. doubt in the identity of the cargo with the declared in the accompanying documents;
2. declared GMO, which is not accompanied by a permit under the order of Chapter Three or Four or by a certificate under Art. 87 or Art. 100;
3. preliminary notification from the bodies under Art. 3.

(2) (amend., SG 99/05) The directors of the regional structures of the controlling bodies under this Chapter, on which territory is located the boundary check-point, and the Chairman of the Commission of Protection of the Consumers shall assist the customs bodies to clarify the cases under Para 1 and to take decision on them.

Art. 113. (amend. – SG 36/08; amend. - SG 54/08) At finding of a breach of the requirements of this law or in cases of suspicion about a breach, the controlling bodies shall immediately notify the Minister of Environment and Water and the Minister of Agriculture and Food.

Art. 114. The controlling bodies shall perform checks at minimum twice per year, as well as in event of a signal about admitted breaches of the requirements of this law, in cases of accidents, in case of unfavourable consequences for the human health or environment form work with GMO in controlled conditions, release in the environment and putting on market occurred or of possibility they may occur.

Art. 115. (1) (amend., SG 99/05; amend. – SG 36/08; amend. - SG 54/08) The Minister of Environment and Water, the Minister of Agriculture and Food, The minister of Labour and Social Policy, The Chairman of The Commission of Protection of the Consumers
shall determine by an order the officials, who shall have the right to conduct checks and to draw up acts of findings of breaches.

(2) The officials, who shall perform the control under this law, shall have right:
1. of access to the rooms and places, where the work with GMOs in controlled conditions, release of GMOs in the environment or putting on market of GMOs is performed;
2. to require the needed documents and information in connection with the performed by them control;
3. to take samples for laboratory examination;
4. to give obligatory prescriptions to remove the found breaches;

(3) The checks shall be performed in the presence of the person who is checked, or in the presence of authorised by him representative.

(4) The officials shall have the right to expropriate or withdraw from the market or to terminate GMOs, or the products which consist of GMOs or contain GMOs if breaches of the norms and requirements of this law or of the secondary legislation on its application are found and in the cases of Art. 72, Para 3 and Art. 75, Para 1.

(5) The rules of expropriation and withdrawal from the market and termination of GMOs or of products which consist of GMO or contain GMO, shall be determined by the ordinance under Para 45.

Art. 116. The laboratory analysis for determining of the quality and quantity of the genetic modification shall be executed at the request of the controlling bodies under this chapter in laboratories as defined by the Minister of the Environment and Water, which are accredited by the Executive Agency "Bulgarian Office of Accreditation" or by a foreign body of accreditation, which body shall be a full member of the European Organisation of Accreditation.

Chapter eight.
COMPULSORY ADMINISTRATIVE MEASURES AND ADMINISTRATIVE-PUNNITIVE PROVISIONS

Section I.
Compulsory Administrative Measures

Art. 117. (1) (amend. – SG 36/08; amend. - SG 54/08) On order to prevent and stop the administrative breaches of this law, as well as to prevent and remove the unfavourable consequences form them, the Minister of Environment and Water and the Minister of Agriculture and Food shall apply the following administrative measures:
1. suspension from operation of rooms for work with GMOs in controlled conditions and sites for putting on market of GMOs as products or ingredient of products;
2. termination of GMOs or products which consist of or contain GMOs;
3. withdrawing from the market of GMOs or products, which consist of or contain GMOs.

(2) Application of the compulsory measure shall be executed with a motivated order of the body under Para 1.
In the order under Para 2 the type of the compulsory administrative measure and appropriate term for its execution shall be determined.

(4) The order under Para 2 shall be handled to the interested person following the order of the Civil Procedure Code.

(5) (amend. - SG 30/06, in force from 12.07.2006) The order under Para 2 may be appealed under the order of the Administrative procedure code.

(6) Appeal of the order under Para 2 shall not stop its effectiveness.

(7) In case of failure to execute the order to suspend from operation of rooms for work with GMOs in controlled conditions and sites for putting on market of GMOs as products or as ingredient of products, they shall be suspended with the assistance of the bodies of the Ministry of Interior.

Section II.
Administrative-Punitive Provisions

Art. 118. The members of the Commission, the officials of the specialised administration under Art. 12, the persons under Art. 7, Para 5, the experts under Art. 7, Para 7 and the officials who shall perform the control under this law, if announce confidential information in offence of the Art. 14, shall be punished by a fee in amount of 5 000 BGN.

Art. 119. Person, who performs work with GMOs in controlled conditions in a room, which is not registered, in offence of the Art. 23, shall be punished with a fee, respectively with a property sanction, in amount from 20 000 to 60 000 BGN.

Art. 120. Person, who performs work with GMOs of class 2 and of a higher class without permit for work with GMOs in controlled conditions in offence of the Art. 29, shall be punished with a fee, respectively with a property sanction, in amount from 50 000 to 150 000 BGN.

Art. 121. Person, who performs work with GMOs in controlled conditions without observation of the precaution measures for the respective class of work for which the permit has been issued, shall be punished with a fee, respectively with a property sanction, in amount from 10 000 to 20 000 BGN.

Art. 122. Person, who has submitted false information in the application for work with GMOs with the purpose to acquire permit, shall be punished with a fee, respectively with a property sanction, in amount from 15 000 to 50 000 BGN.

Art. 123. Person, who in offence of the Art. 39, Para 2 does not execute measures, determined by the Minister of the Environment and Water, shall be punished with a fee, respectively with a property sanction, in amount of 30 000 BGN.

Art. 124. Person, who has submitted false information in the application for GMOs
release in the environment with purpose to acquire permit, shall be punished with a fee, respectively with a property sanction, in amount of 80 000 to 200 000 BGN.

Art. 125. Person, who releases GMOs in the environment, without permit, in offence of the Art. 46, shall be punished with a fee, respectively with a property sanction, in amount of 500 000 BGN.

Art. 126. Person, who releases GMOs in the environment breaking the conditions as enlisted in the permit for release in the environment, shall be punished with a fee, respectively with a property sanction, in amount from 150 000 to 450 000 BGN.

Art. 127. Person, who has submitted false information in the application for putting GMOs on market with the purpose to acquire permit, shall be punished with a fee, respectively with a property sanction, in amount from 150 000 to 450 000 BGN.

Art. 128. Person, who releases GMOs on market as products or as ingredients of products without permit, in offence of the Art. 59 or after suspension of the permit, or after the expiration of its term, shall be punished with a fee, respectively with a property sanction, in amount from 300 000 to 500 000 BGN.

Art. 129. Person, who puts GMOs on market as products or as ingredients of products breaking the conditions provided in the permit for putting on market, shall be punished with a fee, respectively with a property sanction, in amount from 200 000 to 500 000 BGN.

Art. 130. Person, who puts GMOs on market as product or ingredient of product, breaking the requirements for labelling, in offence of the Art. 74, shall be punished with a fee, respectively with a property sanction, in amount from 200 000 to 500 000 BGN.

Art. 131. Person, who breeds genetically modified plants, for which he has acquired permit for putting on the market, without observing the requirement of Art. 71, Para 3, shall be punished with a fee, respectively with a property sanction in amount of 100 000 BGN.

Art. 132. Person, who breeds genetically modified plants, for which he has acquired permit for putting on the market, without observing the requirement of Art. 71, Para 4, shall be punished with a fee, respectively with a property sanction in amount of 10 000 BGN.

Art. 133. Person, who releases GMOs in the environment or puts GMOs on the market or a combination of them, breaking the prohibition of Art. 79, shall be punished with a fee, respectively with a property sanction in amount of 1 000 000 BGN.

Art. 134. Person, who releases GMOs in the environment, breaking the prohibition of Art. 80, shall be punished with a fee, respectively with a property sanction in amount of 1 000
Art. 135. Person, who releases GMOs in the environment or puts GMOs on the market, breaking the prohibition of Art. 81, shall be punished with a fee, respectively with a property sanction in amount of 1 000 000 BGN.

Art. 136. Person, who releases GMOs in the environment or puts GMOs as products or ingredients of products on the market, breaking the prohibition of Art. 82, shall be punished with a fee, respectively with a property sanction in amount of 1 000 000 BGN.

Art. 137. Person, who offences the requirements of Art. 27, Para 4, Art. 36, Para 4, Art. 57, Para 4 and Art. 69, Para 4, shall be punished with a fee, respectively with a property sanction in amount from 5 000 to 15 000 BGN.

Art. 138. Person, who does not provide access the officials and does not provide needed information and documents, breaking Art. 115, Para 2 shall be punished with a fee, respectively with a property sanction in amount of 20 000 BGN.

Art. 139. In cases of repeated commitment of the breaches under Art. 118 – 138, the stipulated fees or property sanctions shall be applied in a doubled amount.

Art. 140. Person, who does not execute the compulsory administrative measures under Art. 117, shall be punished with a fee, respectively with a property sanction from 50 000 to 100 000 BGN.

Art. 141. Person, who performs export of GMOs or products consisting of or containing GMOs breaking the requirement of Chapter Five, Section II, shall be punished with a fee, respectively with a property sanction, in amount from 100 000 to 300 000 BGN.

Art. 142. Person, who has submitted false information in the application for export of GMOs or products consisting or containing GMOs, shall be punished with a fee, respectively with a property sanction, in amount from 100 000 to 300 000 BGN.

Art. 143. (1) (amend. – SG 36/08) The acts of findings of breaches under Art. 125 and 126 shall be drawn up by the officials, who have been appointed by the Minister of Environment and Water, if the activities under Art. 108 are being checked.

(2) (amend. – SG 36/08; amend. - SG 54/08) The acts of findings of breaches under Art. 128 and 129 shall be drawn up by the officials, who have been appointed by the Minister of Agriculture and Food, if the activities under Art. 109, Para 2 are being checked.

(3) The acts of findings of breaches under Art. 119-123 shall be drawn up by the officials, who have been appointed by the Minister of Labour and Social Policy, if the activities under Art. 110 are being checked.

(4) (amend., SG 99/05) The acts of findings of breaches under Art. 130 shall be
drawn up by the officials, who have been appointed by the Chairman of the Commission of Protection of the Consumers, if the labelling of the genetically modified products at putting on the market is being checked.

(5) The acts of findings of breaches of Art. 138 shall be drawn up by the officials under Art. 115.

(6) (amend., SG 99/05; amend. – SG 36/08; amend. - SG 54/08) The punitive decrees shall be issued by the Minister of Environment and Water, the Minister of Agriculture and Food, the Minister of Labour and Social Policy, the Chairman of the Commission of Protection of the Consumers or by authorised by them officials.

(7) Findings of breaches, issuing, appealing and execution of the punitive decrees shall be performed under the order of Law on the Administrative Offences and Sanctions.

Additional provisions

§ 1. In the meaning of this law:
1. "Organism" shall be each biological unit, able to reproduce itself or to transfer genetic material.
2. "Microorganism" shall be each microbiological unit, cellular or not-cellular, able to reproduce itself or to transfer genetic material, including viruses, viroides, animal or plant cell cultures.
3. "Genetically modified organism" shall be an organism, including a microorganism, in which the genetic material has been changed in a such way, that does nor occur naturally at pairing and/or natural recombination. In this definition shall not be included the human organism.
4. "Plasmid" shall be a separately existing, most frequently a circular DNA molecule in the cytoplasm of the bacteria, with the ability of autonomic replication (synthesis of a new molecule of DNA, a copy of the parental)
5. "Protoplast" shall be actively metabolizing part of the cell, including nuclear, plastids, mitochondria, etc, but without cellular membrane.
6. "Mutagenesis" shall be a process of appearance of mutagenic changes in the genetic material.
7. "Prokaryotic organisms" shall be lower organisms with specific cellular organization (viruses, bacteria, algae), which cell has cell wall or capsule but well formed organoids (nucleus, plastids, mitochondria, etc.) are missing.
8. "Eukaryotic organism" shall be organisms, which genetic material is located in one or several cell nuclei, divided by the cytoplasm with nuclear membrane (such as yeast, some algae, fungus, plants and animals).
9. "Autoclonal reproduction" shall be reproduction, which sustains of the replacement of nuletic-acid sequences of the cell of the organism which may be followed by incorporation of whole nuleic acid or part of it (or its synthetic equivalent) by a preceding enzyme reaction or mechanic action in cells of relative organisms or in cells of phylogenetic close species, which can exchange genetic material by way of natural physiological processes, in result of which a microorganism is obtained, which microorganism could not cause diseases at the human, the animals and the plants. The autoclonal reproduction may include recombinant vectors, the usage of which has proved in the time its harmlessness in certain organisms.
10. "Genetic instability" shall be the loss of the permanency of the genetic constitution (the genotype), due to the impact of flexible genetic elements (transposons).

11. "Phenotype" shall be the complex of all visible external symptoms and qualities of the organism, which are formed at the interaction of the genotype and the environment conditions.

12. "Invasive organisms" shall be organisms, most frequently – weed plants, obtained the ability to multiply outside the area of their natural inhabit.

13. "Target organisms" shall be organisms, which can potentially become subject of interaction with the released GMOs in the environment.

14. "Genetic constructs" shall be organisms, obtained by way of using of identical or similar genetic constructs and techniques of genetic manipulation.

15. "Populations of competitors" shall be populations, which compete in the inhabiting of a certain areal of inhabit.

16. "Symbiosis" shall be a form of associated existence of two different species of living organisms, at which both of the organisms obtain benefits for their existence and evolution. A classical example of symbiosis is the evolution of nitrogen fixating bacteria in the roots of the bean plants.

17. "DNA" (deoxyribonucleic acid) is a linear, double-chain molecule, consisting of basic nucleotide pairs and carrying genetic information.

18. "Contemporary biotechnologies" shall be methods with usage of nucleic acids, including recombininant DNA and direct injecting of nucleic acid into cells or organelles or fusion of cells from different taxonomic families, by which the natural physiological, reproductive or recombinant barriers are overcame and which methods are not techniques used in the traditional reproduction and selection.

19. "Host" shall be a cell or organism, receptive to a specific infection agent or supporting the replication of the plasmid, virus or another foreign DNA.

20. "Vector" shall be a molecule of DNA, isolated from a plasmid or virus, in which fragments from another DNA can be included or cloned. The vector shall contain one or more places of restriction and can autonomously (independently) replicate in certain conditions.

21. "Marker genes" shall be nucleic-acids sequences, serving for identification of gene transfer at the creation of GMO.

22. "Unique code" shall be a combination of numbers and Latin letters, which serves for the GMOs identification.

23. "Release in the environment" shall be each conscious inserting into the environment, except the putting on the market, of GMOs or combination of them, for which specific measures for limitation of the contact with the environment and for providing of high level of safety for the human health and environment are not used.

24. "Putting on market" shall be providing of the product, free of charge or against payment, for the first time, at which it passes from the stage of production or import to the stage of distribution and/or usage.

25. "Product" shall be a material consisting of or containing GMOs or combination of GMOs, which is subject of putting on the market. Assumed shall be that the product is a consisting of or containing GMOs, if the accidentally fallen in it or technically unavoidable traces of GMOs in it are not more than 0.5 per cent.

26. "Work in controlled conditions" shall be each activity, at which the organisms are being modified and at which these genetically modified organisms are being cultivated, preserved, transported, terminated, eliminated or are used in another way an for which work
physical barriers or combination of physical or chemical and/or biological barriers are used for the purpose to limit the contact of the GMOs with the population and the environment.

27. "Emergency" shall be each accident, including significant and unintentional release of GMOs as a consequence of work with them, which can sustain immediate or after coming danger for the human health and the environment.

28. "Immediate consequences" shall be the consequences for the human health and for the environment, which appear during the period of the release of the GMOs in the environment or of the putting on the market of the GMOs. The immediate consequences can be direct or indirect.

29. "The cumulative long-term consequences" shall be the gained consequences in total for the human health and for the environment, including for the productiveness of the soil, the decomposition of organic components of the soil, food chain, biological diversity, health of the animals and the problems of the stability of antibiotics.

30. "Basic source" shall be a source for obtaining of forestry reproductive materials, included in the forestry seed-production base.

31. "Protection level" shall be a complex of measures for defence and safety of the humans and the environment, which aims to limit to the lowest possible degree the contact between the rooms for work and the environment, on one hand, and GMOs, on the other hand, at work with them in controlled conditions.

32. "Repeated" shall be the breach committed within one-year period from the entering in force of the punitive decree by which a punishment to the offender for a breach of same type.

33. "Import" shall be the putting under a customs regime of GMOs, different than the transit regime, of the GMOs entered on the customs territory of the Republic of Bulgaria.

34. "Export" shall be:
1) the permanent or temporary leaving the customs territory of the Republic of Bulgaria of GMOs, which have been produced on the territory of the country or have been put under export regime;
2) the re-export of the GMOs, which do not meet the conditions under item 1 and which are put under a customs regime, different than the transit regime.

36. "Exporter" shall be each natural or legal person, who has submitted or on behalf of which has been submitted the application for export, i.e. the person, who at the moment of application submission is a party of the contract with the consignee in the other country and is empowered to determine that the genetically modified organism is a subject of transportation outside the customs territory of the Republic of Bulgaria. If an export contract has not been concluded, or the person who is a party of the contract, does not act on his own behalf, decisive shall be the power to determine that the genetically modified organism is a subject of transportation outside the customs territory of the Republic of Bulgaria.

36. "Transboundary transfer" shall be a movement of GMOs from the territory of one state to another.

37. "Biological diversity" shall be the diversity among the living organisms of all species, including the land, sea or other water ecosystems and ecological complexes, which they are part of, including the inter-species diversity and this between the species and the ecosystems.

§ 2. Methods of genetic modification shall not be:
1. in-vitro fertilization;
2. natural processes such as conjugation, transduction and transformation;
3. polyploidy induction.

§ 3. Putting on the market shall not be:
1. providing GMOs for work in controlled conditions;
2. providing of GMOs, which shall be used only for release in the environment with experimental purposes in accordance with the provisions of the Chapter Four, Section II.

§ 4. (1) (suppl. – SG 43/08) Performance of genetic modifications of affar rose, vine and tobacco shall be prohibited, except for research studies under the conditions and following the provisions of Chapter Three.
(2) Release in the environment and putting on the market of genetically modified animals shall be prohibited.

Transitional and concluding provisions

§ 5. (1) The licenses, issued under the terms and following the order of the Regulations of the Spreading of Genetically Modified Higher Plants, Created Through Recombinant DNA Technology (SG, 70/1996; amend., - SG 47/2000) shall be considered by the Commission, which shall assess their adequacy to the requirements of this law and shall acknowledge or suspend their validity in three-month term from the date of the enacting of the Law.
(2) In one-year term from the date of the enacting of the Law, the Commission shall prepare a report concerning the spreading of GMOs in the environment before the enacting of this Law, which report shall be tabled at the Ministry of Environment and Water and at the Ministry of Agriculture and Forestry.

§ 6. The rooms for work in controlled conditions with GMOs put into operation before the enacting of the law, shall be brought in compliance to the requirements of the law and the ordinance of Art. 2, Para 3 in up to 6 months term from the date of the enacting of the law.

§ 7. Art. 20 of the Law of the Sowing and Planting Materials (SG, 20/2003) Para 6 shall be amended as follows:
"(6) The decision under Para 5 for recognizing and registration of a genetically modified variety shall be taken after a license for its putting on market is issued by the Minister of Agriculture and Forestry under the terms and following the order of Chapter Four, Part III of the Law on Genetically Modified Organisms.

§ 8. (1) In one-month term from the date of the enacting of the Law, the Minister of Environment and Water and the Minister of Agriculture and Forests shall adopt by order a list of GMOs for which GMOs an issued denial in the countries – members of EU exists, and it
shall be promulgated in the State Gazette.
(2) The list under Para 1 is periodically updated.

§ 9. (revoked – SG 43/08)

§ 10. The Law shall become effective on June 1st 2005.

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This Law was adopted by the XXXIX National Assembly on March 15th 2005 and was affixed with the official seal of the National Assembly.

Transitional and concluding provisions
TO THE ADMINISTRATIVE PROCEDURE CODE

(PROM. – SG 30/06, IN FORCE FROM 12.07.2006)

§ 36. In the Law on the genetically modified organisms (prom. SG 27/05; amend. SG 88 and 99/05) the words "the Law on the Supreme administrative court" shall be replaced by "the Administrative procedure code".

§ 142. The code shall enter into force three months after its promulgation in State Gazette, with the exception of:
1. division three, § 2, item 1 and § 2, item 2 – with regards to the repeal of chapter third, section II "Appeal by court order", § 9, item 1 and 2, § 15 and § 44, item 1 and 2, § 51, item 1, § 53, item 1, § 61, item 1, § 66, item 3, § 76, items 1 – 3, § 78, § 79, § 83, item 1, § 84, item 1 and 2, § 89, items 1 - 4 § 101, item 1, § 102, item 1, § 107, § 117, items 1 and 2, § 125, § 128, items 1 and 2, § 132, item 2 and § 136, item 1, as well as § 34, § 35, item 2, § 43, item 2, § 62, item 1, § 66, items 2 and 4, § 97, item 2 and § 125, item 1 – with regard to the replacement of the word "the regional" with the "administrative" and the replacement of the word "the Sofia City Court" with "the Administrative court - Sofia", which shall enter into force from the 1st of May 2007;
2. paragraph 120, which shall enter into force from the 1st of January 2007;
3. paragraph 3, which shall enter into force from the day of the promulgation of the code in State Gazette.

Appendix № 1 to Art. 43, Para 3
Principles of Risk Assessment for the environment and human health.
I. Purposes.
The purpose of the risk assessment (RA) shall be carried out on the basis of identification and evaluation of the possibility unfavourable consequences of GMO for each concrete case, direct or indirect, immediate or delayed, on human health and the environment, which can result from the release of GMOs in the environment or its putting on the market.
The risk assessment shell determine the necessity of managing the risk and the most
appropriate methods which shall be used.

II. General principles
The following principles shall be applied:
1. The identified indications of GMOs and its use which can result in unfavourable consequences shall be compared to those of the unmodified organism that the GMOs has descended from and its use in similar situations;
2. The assessment of the risk shall be done in scientific and transparent way, grounded on the available scientific and technical data;
3. The necessary information shall vary depending on the type of the respective GMOs, their intended use and the potential host environment, taking in view, for example, GMOs already released in the environment.
4. In cases of new information about GMOs and their consequences on human health or the environment, RA shall be revised in order to determine if the risk has been altered and if a necessity of changing the methods for managing the risk appears.

III. Methodology
A. Characteristics of GMOs and the releases:
Depending on the concrete case, the RA shall report the relevant technical and scientific data regarding the characteristics of
1. the host and the parental organism;
2. the genetic modification, including adding and removing of genetic material, and the relevant information about the vector and the donor;
3. GMO;
4. the intended release or use, including their range;
5. the potential host environment;
6. the interaction of the characteristics of items 1 - 5.
The assessment of the risk shall report the available information about releases of similar organisms and organisms of similar characteristics, as well as their interaction with environments with identical conditions.

B. Stages in carrying out the AR.
The AR shall include the following stages:
1. Identification the characteristics, that can lead to unfavourable consequences:
All the characteristics of GMOs, related to the genetic modification, that can unfavourably affect human health or the environment, shall be identified. During the identification of possible unfavourable consequences, related to the genetic modification, a comparison shall be made between the characteristics of GMOs and those of the not-modified organism in corresponding conditions of the release or the use.
The possible unfavourable consequences of GMOs shall be identified for each concrete case and may include:
a) causing disease to people, including allergic and toxic effects;
b) causing disease to animals and plants, including allergic and toxic effects;
c) affecting the dynamics of the species populations in the host environment and the genetic diversity of each of these populations;
d) causing increased sensitivity (vulnerability) to pathogens, leading to spreading contagious diseases or creating new reservoirs or vectors;
e) unfavourable influence on the effectiveness of preventive or therapeutic medical treatments and on the plant protection measures applied, for instance, through transfer of genes, determining resistance to antibiotics, used in human and veterinary medicine;
f) affecting the biogeochemistry (biogeochemical cycles), especially the carbon and nitrogen circle, by changes in the breakdown of organic matter in the soil.

At the identification of the characteristics which can lead to unfavourable consequences, those that can arise from direct or indirect mechanisms shall be reported, which mechanisms include:

a) the spread of GMOs in the environment;
b) transfer of the included genetic material into other types of organisms of the same species, including genetically modified ones;
c) phenotype or genetic instability;
d) interactions with other organisms;
e) change of the risk management measures, including, when applicable, in the agricultural practices.

2. Assessment of the possible consequences of each unfavourable effect which can occur:

The assessment of the possible consequences of each unfavourable effect which can occur shall report their range. At the assessment shall be always assumed that the specific unfavourable consequence will occur and the assessment itself is carried out with consideration of the characteristics of the host environment and the manner in which the GMOs are released.

3. Assessment of the probability of occurrence of each identified possible unfavourable effect:

The assessment of the probability of occurrence of each identified possible unfavourable effect shall report the characteristics of the host environment and the way of releasing GMOs.

4. Assessment of the risk, coming from each identified characteristic of GMOs that can lead to unfavourable consequences:

The assessment of the risk, coming from each identified characteristic of GMOs that can lead to unfavourable consequences shall be done in accordance with the available scientific and technical data by combining the possibility of occurrence and the range of the unfavourable consequences.

5. Application of strategies for risk management of releasing GMOs in the environment or their putting on the market:

Whereas the risk assessment identifies risk which demands taking measures for its management, the applicant shall be obliged to develop a strategy for its management.

6. The overall risk assessment of the GMOs.

The assessment of the overall risk of the GMOs shall be done, taking in view each risk managing strategy proposed.

IV. Conclusions concerning the possibility influence of release of GMOs in the environment or their putting on the market on the environment.

As a result of the RA carried out, a conclusion regarding the possibility influence of GMOs release in the environment or their putting on the market on the environment shall be drawn up. The information of the conclusion shall be an integral part of the application under Art. 46, Para 2 and Art. 59, Para 2 and shall have the purpose to assist the Commission in drawing up an opinion on the possible influence of GMOs release or their putting on the market on the environment.

1. In cases of GMO, different from higher plants, the conclusion shall include information about:
a) the ability of GMOs to become resistant and invasive in natural areas of inhabit in the conditions of release in the environment or putting on the market;

b) each selective advantage or disadvantage, transferred to the GMOs and the probability for it to occur in the conditions of the proposed release in the environment or putting on the market;

c) the possibility of genes transfer to other species in the conditions of the proposed release in the environment or putting on the market and each selective advantage or disadvantage that can be transferred to those species;

d) the possibility of immediate or delayed influence on the environment, related to the direct and indirect interactions between GMOs and the objective organisms, if applicable;

e) the possibility immediate or delayed influence on the environment, related to the direct and indirect interactions between GMOs and the objective organisms, including interaction on the level of rivals populations, hosts, symbionts, parasites and pathogens;

f) the probable immediate or delayed consequences on men’s health resulting from the possibility direct and indirect interactions between GMOs and the employees coming into contact or being near the place of GMOs release;

g) the probable immediate and/or delayed consequences on animals’ health and the consequences for the nutrition resulting from consuming GMOs and any product, made from it, if intended as food for animals;

h) the probable immediate and/or delayed consequences on biogeochemical processes resulting from the possibility direct or indirect interactions between GMOs and the objective and non-objective organisms in the proximity of the place of release of GMO;

i) the probable immediate or delayed, direct or indirect consequences on the environment arising from the specific techniques for managing the risk of GMO, in case the techniques are different from those, which are used for the unmodified organisms.

2. In the cases of genetically modified higher plants (GMHP) the conclusion shall include information about:

a) the possibility of GMOs to become more resistant than the host or parental plants in agro-ecosystems or more invasive in natural areas of inhabit;

b) each selective advantage or disadvantage, transferred to GMHP;

c) the possibility of gene transfer of the same or of other sex-compatible plant species in the conditions of planting GMHP and each selective advantage or disadvantage that can be transferred to those plant species;

d) the possibility immediate or delayed influence on the environment, resulting from the direct and indirect interactions between GMHP and the objective organisms, including predators, parasites and pathogens, if applicable;

e) the possibility immediate or delayed influence on the environment, resulting from the direct and indirect interactions between GMHP and the non-objective organisms, including interaction on the level of rivals populations, herbivores, symbionts, where applicable, parasites and pathogens; the conclusion also takes into consideration the interactions with organisms, interacting with the objective organisms;

f) the probable immediate or delayed consequences on human health arising from the possibility of direct and indirect interactions between GMHP and the employees, coming into contact or being near the place of release of GMHP;

g) the probable immediate or delayed consequences on animals’ health and the consequences for the nutrition resulting from consuming GMOs and any product, made from it, if intended as food for animals;
h) the probable immediate or delayed consequences on biogeochemical processes resulting from the possibility direct or indirect interactions between GMOs and the objective and non-objective organisms on areas in the proximity of the place of release of GMO;

i) the probable immediate or delayed, direct or indirect consequences on the environment resulting from the specific techniques for cultivating, managing and gathering the crop, used for GMHP, in case these techniques are different from the ones, used for the unmodified higher plants.

Transitional and concluding provisions
TO THE LAW ON MEDICINAL PRODUCTS IN HUMAN MEDICINE

(PROM. – SG 31/07, IN FORCE FROM 13.04.2007)

§ 37. The Law shall enter in force from the day of its promulgation in State Gazette, except for § 22, which shall enter in force one year after the entry into force of this Law.

Transitional and concluding provisions
TO THE LAW FOR AMENDMENT AND SUPPLEMENTATION OF THE LAW FOR THE FISHERY AND AQUACULTURES

(PROM. - SG 36/08)

§ 61. In the Law for genetically modified organisms (prom. – SG 27/05; amend. SG 88 and 99/05; SG 30/06 and SG 31/07) everywhere the words "the Minister of Agriculture and Forests", "Minister of Agriculture and Forests", "the Ministry of Agriculture and Forests" shall be replaced respectively with "the Minister of Agriculture and Food Supply", "Minister of Agriculture and Food Supply" and "the Ministry of Agriculture and Food Supply", and the words "National Administration of Forests" shall be replaced with "State Forestry Agency".

Transitional and concluding provisions
TO THE LAW ON AMENDMENT AND SUPPLEMENTATION OF THE LAW ON FODDER

(PROM. - SG 54/08)

§ 80. In the Law on the Genetically Modified Organisms (prom. - SG 27/05; amend. - SG 88 and 99/05, SG 30/06, SG 31/07 and SG 36 and 43/08) shall be made the following amendments and supplementations:

..........................................................

2. Everywhere in the Law the word "Food Supply" shall be replaced by "Food".
Appendix No. 2 to Art. 51, Para 4 and Art. 71, Para 3  
Technological standards for distant isolation of groups of crops  
(Suppl. – SG 43/08)

<table>
<thead>
<tr>
<th>Crops</th>
<th>Minimum distance, m</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I. Cereals</strong></td>
<td></td>
</tr>
<tr>
<td>Barley</td>
<td>60</td>
</tr>
<tr>
<td>Oats</td>
<td>60</td>
</tr>
<tr>
<td>Rice</td>
<td>60</td>
</tr>
<tr>
<td>Millet</td>
<td>60</td>
</tr>
<tr>
<td>Sudan-Grass</td>
<td>60</td>
</tr>
<tr>
<td>Rye</td>
<td>2000</td>
</tr>
<tr>
<td>Triticale</td>
<td>50</td>
</tr>
<tr>
<td>Corn</td>
<td>800</td>
</tr>
<tr>
<td>Canary Grass</td>
<td>600</td>
</tr>
<tr>
<td><strong>II. Legumes</strong></td>
<td></td>
</tr>
<tr>
<td>Gram</td>
<td>60</td>
</tr>
<tr>
<td>Beans</td>
<td>300</td>
</tr>
<tr>
<td>From other varieties of Ph.coccineus L.</td>
<td>4000</td>
</tr>
<tr>
<td><strong>III. Oleaginous and Fibrous</strong></td>
<td></td>
</tr>
<tr>
<td>Peanuts</td>
<td>20</td>
</tr>
<tr>
<td>Shallard</td>
<td>800</td>
</tr>
<tr>
<td>Hemp dioecious</td>
<td>800</td>
</tr>
<tr>
<td>Hemp monoecious</td>
<td>6000</td>
</tr>
<tr>
<td>Cotton</td>
<td>150</td>
</tr>
<tr>
<td>Safflow, caraway, cumin Italian</td>
<td>400</td>
</tr>
<tr>
<td>Soybean</td>
<td>20</td>
</tr>
<tr>
<td>Rape</td>
<td>400</td>
</tr>
<tr>
<td>Sunflower</td>
<td>6000</td>
</tr>
<tr>
<td>Flax Oleaginous and Fibrous</td>
<td>20</td>
</tr>
<tr>
<td>Castor-oil plant</td>
<td>2000</td>
</tr>
<tr>
<td>Sesame</td>
<td>400</td>
</tr>
<tr>
<td>Poppy</td>
<td>1000</td>
</tr>
<tr>
<td><strong>IV. Fodder</strong></td>
<td></td>
</tr>
<tr>
<td>Cabbage, phacelia, apera</td>
<td>800</td>
</tr>
<tr>
<td>Field pea</td>
<td>100</td>
</tr>
<tr>
<td>Clover, multi-mown (Italian)</td>
<td></td>
</tr>
<tr>
<td>rye-grass, pasture</td>
<td></td>
</tr>
<tr>
<td>rye-grass, alfalfa, black medic</td>
<td>800</td>
</tr>
<tr>
<td>For all sorts or varieties of fodder except:</td>
<td>400</td>
</tr>
<tr>
<td>Cabbage, phacelia, field pea,</td>
<td></td>
</tr>
</tbody>
</table>
apera, clover,
Multi-mown (Italian)
rye-grass, pasture rye-grass,
alfalfa, black medic

V. Potatoes
From fields sown with tobacco and
mass sown potato fields 200