GENETICALLY MODIFIED ORGANISMS ACT

In force from the 01.06.2005

Prom. SG. 27/29 Mar 2005, amend. SG. 88/4 Nov 2005, amend. SG. 99/9 Dec 2005, amend. SG. 30/11 Apr 2006, amend. SG. 31/13 Apr 2007, amend. SG. 36/4 Apr 2008, amend. SG. 43/29 Apr 2008, amend. SG. 54/13 Jun 2008, amend. SG. 74/15 Sep 2009, amend. SG. 80/9 Oct 2009, amend. SG. 82/16 Oct 2009, amend. SG. 25/30 Mar 2010, amend. SG. 8/25 Jan 2011, amend. SG. 99/16 Dec 2011, amend. SG. 68/2 Aug 2013, amend. SG. 14/20 Feb 2015, amend. SG. 58/26 Jul 2016, amend. SG. 58/18 Jul 2017

Chapter one.
GENERAL PROVISIONS

Art. 1. (1) This Act shall provide for the public relations, related to:

1. the work with genetically modified organisms (GMOs) in controlled conditions;

2. the release of the GMOs in the environment;

3. the Placing 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 Act 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) (Suppl. – SG, 25/2010) This Act shall be applied for GMO, obtained through at least one of the following techniques and methods of genetic modification:

1. (amend. And suppl. – SG, 25/1010) recombinant techniques with using nucleic acids, which include 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 permanently to reproduce;

2. techniques at which present direct incorporation of inherited genetic material, produced extracorporealy, incl. microinjecting, macroinjecting and microencapsulation;

3. (suppl. – SG, 25/2010) cell fusion (including fusion of protoplasts) or hybridization techniques, in which the living cells with new combinations of inherited genetic material are created by fusion of two or more cells with methods which do not exist naturally;

(2) (Amend. – SG, 25/2010) The provisions of this Act shall not be applied to:

1. the work in controlled conditions with GMO, obtained through one or more of the following techniques and/or methods:

a) mutagenesis;

b) cell fusion (including fusion of protoplasts) of prokaryote types, which may perform exchange of genetic material through traditional physiological processes;

c) cell fusion (including fusion of protoplasts) of cells of any eukaryote type, including

obtaining of hybridomes or fusions of plant cells;

d) auto cloning, where it is not probable the obtained micro-organism to cause illness in humans, animals and plants; for the purposes of the indicated cloning may be used recombinant vectors with long history of safe usage in certain microorganisms, under the condition, that they do not include use of molecules of recombinant nucleonic acids or DMOs, obtained through techniques and/or methods, different from the listed in letters a-d;

2. release in the environment and placing of the market GMO or products, which consist of or contain GMO, obtained through one or more of the following techniques and/or methods:

a) mutagenesis;

b) cell fusion of eukaryotic types, (including protoplast fusion) of plant cells of organisms, which may perform exchange of genetic material by traditional methods of reproducing, under the conditions, that the do not include using molecules of recombinant nucleonic acids or GMO, obtained through techniques and/or methods, different from the listed in letters a-b;

3. placing on the market, import, export and transit of:

a) genetically modified organisms for use in/or as food genetically modified foods, foods, containing ingredients, produced form GMO. Which are provided by the Foodstuffs Act;

b) genetically modified organisms for using in/or as fodder, genetically modified fodders, fodders, containing components, produced from GMO, provided for by the Fodders Act and the Veterinary Practice Act;

c) veterinary-medical products, which consist of or contain GMO or a combination of GMO or have been produced from GMO, provided by the Veterinary Practice Act;

4. the work in controlled conditions, release in the environment, placing on the market, import, export and transit of medical products for the humane medicine, which consist or contain GMO or a combination of GMO or have been produced from GMO, provided by the Medicinal Products in Humane Medicine Act;

5. keeping, cultivation, transportation, destroying, treating as waste or using genetically modified microorganisms (GMM), which have received permit for placing on the market in compliance with the requirements Chapter IV, Section III or another normatively established order, requiring performing a specific assessment of the risk, similar to that, determined in Chapter IV, Section III,, under the conditions, that the work with these GMM in controlled conditions is in compliance with the conditions, indicated in the permit for placing on the market, where such have been determined in it.

(3) (Amend. – SG, 25/2010) The provisions of Chapter III shall not apply in relation to work in controlled conditions with GMO, which have been included in a list by an order of the Minister of the Environment and Waters. The Minister of the Environment and Waters shall include in the list GMO, which respond to the conditions for safety, determined in the Ordinance under Para. 4.

(4) (New – SG, 25/2010) The Council of Ministers shall adopt an ordinance on work with genetically modified organisms in controlled conditions.

(5) (Former Para. 4 – SG, 25/2010) Regarding the transportation by railway, road, sea, air or internal international roads of GMO, 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 Railway Transport Act, Automobil Transport Act, Civil Aviation Act, the Merchant Shipping Code and the secondary legislation on their application shall be applied.

Art. 2a (New – SG, 25/2010) The following techniques and/or methods are considered that do not lead to genetic modification:

1. in-vitro fertilization;

2.natural processes as conjugation, transduction and transformation;

3. poliploid induction;

Under the condition, that they do not include using molecules of recombinant nucleon acids or GMO, created through techniques and/or methods. Different from those, indicated in Art. 2, Para. 2.

Chapter two.
COMPETENT BODIES

Art. 3. (amend. – SG 36/08; amend. - SG 54/08, amend. – SG 58/17, in force from 18.07.2017) The Minister of the Environment and Water and the Minister of the Agriculture, Foods and Forestry shall conduct the state policy in the field of GMOs and shall coordinate the activity of the controlling bodies related to the implementation of the Act.

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 Act;

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 Act;

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 Cartahena 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, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry shall:

1. issue, amend and cancel the permits for placing on the market of GMO or combination of GMO 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 into the environment;

b) the registration of the rooms for work with GMOs in controlled conditions;

2. (amend. – SG 36/08; amend. - SG 54/08, amend. – SG 58/17, in force from 18.07.2017) provide with opinions the Minister of Agriculture, Foods and Forestry 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, amend. – SG 58/17, in force from 18.07.2017)

provide with opinions the Minister of Environment and Water and the Minister of the Agriculture, Foods and Forestry on other matters of their competence arising from application of this Act;

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; amend. – SG 74/09, in force from 15.09.2009; amend. – SG 68/13, in force from 02.08.2013, amend. – SG 58/17, in force from 18.07.2017) The Minister of Education and Science, the Minister of Environment and Water, the Minister of Agriculture, Foods and Forestry 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, amend. – SG 58/17, in force from 18.07.2017) Ministry of Agriculture, Foods and Forestry;

c) Ministry of Health;

d) (amend. – SG 82/09, in force from 16.10.2009; amend. – SG, 14/2015) Ministry of Economy;

e) (amend., SG 88/05) Ministry if Transport;

f) (amend. – SG 74/09, in force from 15.09.2009; amend. – SG 68/13, in force from 02.08.2013) 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 Cartahena 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 Commerce Act 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 Act;

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) (amend. - SG 99/11, in force from 01.01.2012) The members of the Commission under Art. 7, Para 1 shall remunerated for each participation in its sessions in amount determined in an order of the Minister of Environment and Waters in coordination with the Minister of Finance, which shall be published on the internet site of the Ministry of Environment and Waters.

(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. (Suppl. – SG, 25/2010) (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 unless in the cases, where confidential information is discussed, as provided by Chapter Six.

(3) (Amend. – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) The Commission shall present written opinions to the Minister of Environment and Waters and/or the Minister of Agriculture, Foods and Forestry on the applications, filed under this Act, and on other issues of its competence upon their request.

(4) The Commission shall obligatory record minutes of its sessions.

(5) (Suppl. – SG, 25/2010) The documents of the sessions of the Commission shall be kept by the unit under Art. 12 for 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 Act, 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 Act, 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 GMO 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 GMO in controlled conditions, the persons under Para 1 shall perform risk assessment concerning:

1. the potential unfavourable consequences from GMO 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. (amend. – SG, 25/2010) the gravity of the potential unfavourable consequences.

(3) (New, - SG, 25/2010) While performing the risk assessment, the waste management after work with DMOs shall be taken into consideration in controlled conditions and where necessary, the needed safety and protection measures shall be envisaged, in view to protection of the human health and environment

(4) (Former Para. 3, suppl. – SG, 25/2010) The risk assessment shall be documented and kept for the term of 10 years 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. (1) (Former text of Art. 17, amend. – SG, 25/2010) On the grounds of the risk assessment, the persons under Art. 16, Para 1 shall classify the work in controlled conditions with genetically modified microorganisms (GMM), as follows:

1. (amend. – SG, 25/2010) class 1 – activities of a insignificant 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. (amend. and suppl. – SG, 25/2010) class 3 – risk activities, with moderate level of risk, about which the application of the third level of protection of the human health and environment is appropriate;

4. (amend. and suppl. – SG, 25/2010) class 4 – high risk activities, for which activities application of the fourth level of protection of the human health and environment is appropriate;

(2) (New – SG, 25/2010) On the basis of the risk assessment, the persons under Art. 16, Para. 1 shall classify the work in controlled conditions with DMO, different from GMM, as follows:

1. class A – activities, in which the risk is not higher in comparison with the genetically

non-modified organism and about which the application of the first level of protection of human health and environment is appropriate;

2. class B - class A – activities, in which the risk is higher in comparison with the genetically non-modified organism and about which depending on the concrete case, the application of the second level of protection measures is appropriate, corresponding to second level or higher level of protection of human health and environment;

Art. 18. (Amend. – SG, 25/2010) In cases of hesitation to which class ris to refer the work with GMO in controlled conditions, the protection measures for higher class shall be applied, with exception of the cases, where there is a written consent of the Minister of Environment and Waters, which approve the application of the protection measures for the lower class risk.

Art. 19. (Repealed, - SG, 25/2010).

Art. 20. (Repealed, - SG, 25/2010).

Art. 21. (Amend. – SG, 25/2010). The criteria for classification of the work with GMO in controlled conditions, the terms and order of performance of the risk assessment of the work with GMO in controlled conditions, as well as the safety and protection measures for the relevant class of work with GMO in controlled conditions shall be stipulated by the ordinance under Art. 2, Para 3.

Art. 22. (Suppl. – SG, 25/2010) The risk assessment of the work with GMO in controlled conditions and the applied protective measures shall be revised and updated by the applicant in every two years immediately, or where:

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 GMO in Controlled Conditions

Art. 23. (1) Work with GMO in controlled conditions shall be performed in rooms, which rooms shall be registered at the Ministry of Environment and Water.

(2) (Amend. – SG, 25/2010).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 GMO, 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 GMO.

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 GMO in controlled conditions.

(2) The application shall contain:

1. (Amend. – SG, 25/2010) identification of the applicant: name, number of the identity document and permanent address – regarding the natural persons, or name, seat and registered office, and single identification code or code on BULSTAT- registration – regarding the sole traders and legal persons;

2. location and description of the room, where the work with GMO 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 GMO in controlled conditions;

4. information regarding the training and qualification of the persons under ietm 3;

5. (amend. – SG, 25/2010) 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. (repealed, - SG, 25/2010).

(3) (amend. – SG, 25/5010). The application for registration of the premises for work with GMO in controlled conditions shall contain attached a document for paid charge, determined by the tariff under Art. 15, and for foreign persons – also a document, certifying the legal status of the applicant, issued in compliance with his national legislation up to 3 months before filing the application.

(4) (New – SG, 25/2010). In the cases of performing for the first time of class 1 work with GMM and class A work with GMO, different from GMM in controlled conditions, the application under Para. 2 shall contain attached also:

1. a summary of the risk assessment according to the conditions and order, determined by the ordinance under Art. 2, Para. 1;

2. information about the waste management.

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) (New – SG, 25/2010) The Ministry of Environment and Waters through the regional inspections on the environment and waters (RIEW) shall perform an initial inspection of the premises under Art. 23, Para. 1 for establishing adequacy of the protection measures.

(4) (New – SG, 25/2010). On the basis of the performed inspection, RIEW shall draw up a protocol and if needed, shall propose concrete amendments of the protection measures, which are taken into consideration while preparing the opinion under Para. 7.

(5) (New – SG, 25/2010). The protocol under Para. 4 shall be sent to the commission within 14-day term after filing the application.

(6) (Former Para. 3, amend. – SG, 25/2010) The commission shall check up the authenticity and completeness of the information, contained in the filed application, including the correctness of the risk assessment and of the determined class of work in controlled conditions.

(7) (Former Para. 4, - SG, 25/2010) Within 30day term after filing the application, the commission shall draw up an opinion and shall submit it to the Minister of Environment and Waters.

(8) Former Para. 5, amend – SG, 25/2010) The term under Para. 7 shall stop to run by removing the incompleteness and incorrectness 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 GMO in controlled conditions or shall issue a motivated

refusal within 150-days period from the receipt of the opinion of the Commission.

(2) (Amend. – SG, 25/2010).The Minister of the Environment and Water shall issue a certificate of registration with which shall confirm the determined class of work in controlled conditions, according to the check up of the commission under Art. 25, Para. 6.

(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 GMO in controlled conditions.

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

(3) (Suppl. – SG, 25/2010). The data and circumstances under Art. 24, Para 2 and 4 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 GMO 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 GMO in controlled conditions and for each class work with GMO.

(3) (New – SG, 25/2010) Class 1 work with GMM and class A work with GMO, different from GMM in a premise, which has been registered as provided by Section II, shall be done without permit under Para. 1.

(4))New – SG, 25/2010) In the cases under Para. 3, the persons under Art. 16 shall keep the performed risk assessments and shall submit them to the Ministry of Environment and Waters at starting work or to RIEW, upon request in the process of work.

(5) (Former Para. 3) Managers of laboratories or productions, where a work with GMO 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 GMO in controlled conditions, shall submit a written application to the Minister of Environment and Water.

(2) (Suppl. – SG, 25/2010). The application for performing of first and following class 2 work with GMO shall contain:

1. (amend. – SG, 25/2010) identification of the applicant: name, number of the identity document and permanent address – regarding the natural persons, or name, seat and registered address, and single identification code and code on BULSTAT registration – for the sole traders and legal persons;

2. (suppl. – SG, 25/2010) date of filing the application under Art. 24 and 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 GMO in controlled conditions;

4. information regarding the training and qualification of the persons under item 3;

5. (suppl. – SG, 25/2010) the recipient, donating and/or the parental organism, which are used, and the system hosting – vector, in cases, where such has been used 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. (amend. and suppl. – SH, 25/2010) description of the envisaged protection and safety measures, including information on the management of wastes regarding their processing, final form and destination, as well as description of the separate parts of the installation – for work in controlled conditions with GMO of classes 3 and 4;

11. the period for which the work with GMO in controlled conditions shall be performed;

12. (amend. – SG, 25/2010) copy of the risk assessment, drawn up according to the conditions and order, determined by the ordinance under Art. 2, Para. 4;

13. needed for the Commission information for the assessment of the emergency plan under Art. 31, Para 4.

(3) (New – SG, 25/2010) The applied work under Para. 1 may start immediately after filing the application, when it will be performed in a premise, for which there is an issued permit for class 2 or higher class work with GMM and all its conditions have been fulfilled. The applicant may request a written permit form the Minister of Environment and Waters, which shall be issued within 15 days after filing the application.

(4) (New – SG, 25/2010) The applied work under Para. 1 may start 45 days after filing the application or earlier with a written consent of the Minister of Environment and Waters, when it will be performed in a premise, for which there is no issued permit for class 2 or higher class work with GMM.

(5) (Former. 3, amend. – SG, 25/2010) To the application under Para 2 for work with GMO in controlled conditions of classes 3 and 4 work with GMM and class B work with GMO, different from GMM shall contain the information, determined in Para. 2, p. 1-11, as well as:

1. the specific risks arrising 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;

a) the specific risks, comprising from the place of the installation;

b) the applied safety measures as safe equipment, alarm systems and methods for protection;

c) the procedures and plans for check up of the effectiveness of the protection measures;

d) description of the information, available to the persons, working with GMO under controlled conditions;

e) information about the persons, responsible for the supervision on applying the safety measures, identified in the plan (name, responsibilities, telephone N for contacts, e mail address).

(6) (New – SG, 25/2010) Work with GMM in controlled conditions of class 3 and 4 and class B work with GMO, different from GMM shall not start before receiving a permit from the Minister of Environment and Waters;

(7) (New – SG, 25/2010) In cases, where as a result of a performed risk assessment it has been established that violation of protection measures may lead to serious immediate or later danger for people outside the registered for work with GMO in controlled conditions premise and/or for the environment, the application for work with GMO in controlled conditions shall contain:

1. plans for preventing emergencies and for urgent acts in emergencies;

2. confirmation on behalf of the applicant, that the information of the plans for prevention of emergencies and for urgent acts in emergencies has been presented, without preliminary request by all the bodies and organizations, which might be concerned in case of emergency.

(8) (New – SG, 25/2010) The information under Para. 7, p 1 shall:

1. be updated every 5 years and shall be presented to the public by the applicant;

2. be presented immediately to the Ministry of Environment and Waters to the relevant competent authorities in other EU Member States, which might be concerned in cases of emergency.

(9)(Former Para. 4 – SG, 25/2010) The application shall be submitted in the Bulgarian language and in the English languages. The application may be submitted by electronic connection.

(10) (former Para. 5, amend. 25/2010) To the application under Para 2 and 5 a document for paid charge, determined by the tariff under Art. 15, and for foreign persons – a document, certifying the applicant's legal status, issued in compliance with his national legislation up to 3 months before filing the application, 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) (New – SG, 25/2010) The Ministry of Environment and Waters through RIEW shall perform initial inspection of the premises under Art. 30, Para. 3, 4 and 6 for establishing adequacy of the protection measures.

(4) (Amend – SG, 25/2010) The commission shall check up the developed plan for urgent measures in emergencies with work with GMO in controlled conditions, in cases, where the breaches of the protection measures may lead to serious danger, notwithstanding whether it is immediate or postponed in time for the people outside the premises and/ or for the environment.

(5) (Amend. – SG, 25/2010) On the basis of the performed inspection, RIEW shall draw up a protocol and in case of need shall propose concrete amendment of the undertaken measures, which are taken into consideration while drawing up the opinion under Para. 8. The protocol shall be submitted to the commission within 14 day term after filing the application.

(6) (Former Para. (3), amen. – SG, 25/2010) 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 wastes management and the measures of urgent action in cases of emergency.

(7) (Former Para. 6, amen. – SG, 25/2010) After finalisation of the check-up under Para 1, 3 and 6, 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;

d) to postpone the initiation of the applied work until issuing a permit on the basis of the information or the changed conditions under letter a) – c);

e) to interrupt the work in the cases, where it has already started, until issuing the permit on the basis of the information or the changed conditions under letter a) – c);

2. to specify additional conditions of work.

(8) (Former Para. 7, amend. – SG, 25/2010) The Commission shall draw up an opinion and shall provide it to the Minister of Environment and Water by:

1. 30 days after submitting the application for class 2;

2. 30 days after submitting the application for classes 3, 4 or B, where the work will be done in a premise, for which there is a former permit for work with GMO of classes 3, 4 or B and the conditions in it are observed;

3. 60 days after submitting the application for classes 3, 4 or B, where the work will be done in a premise, for which there is a former permit for work with GMO of classes 3, 4 or B.

Art. 31a (New – SG, 25/2010) (1) After drawing up the opinion under Art. 31, Para. 8, p. 2 and 3, the Minister of Environment and Waters shall organize a public discussion, which shall be held not later than:

1. 30 days after drawing up the opinion under Art. 31, Para. 8, p.2;

2. 45 days after drawing up the opinion under Art. 31, Para. 8, p.3;

(2) At the public discussion a summary of the technical file, a copy of the risk assessment under art. 30, Para. 2, p. 12 and the opinion of the commission under art. 31, Para. 8, p. 2 and 3 shall be presented.

(3) The information, specified as confidential, as provided by Chapter Six shall not be subject to discussion.

(4) Not later than 30 days before the date of the discussion in one national daily newspaper, through the local mass media, through announcements in the relevant municipalities in the region of the premises for work with GMO in controlled conditions of class risk 3, 4 or B, as well as on the internet site of the information system under Art. 4, Para. 2, shall be announces the subject of the public discussion and the place, where the needed information is at disposal to persons, interested. The announcement shall contain also the date and place of the public discussion.

(5) any person may give opinion on the subject of the discussion, in writing or in electronic form.

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

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

Art. 32. (1) (Amend. – SG 36/08; amend. - SG 54/08, amen. – SG, 25/2010) On the grounds of the opinion of the Commission and the results of the public discussion, the Minister of Environment and Water shall issue a permit for work with GMO within a period:

1. 45 days after submitting the application for class 2;

2. 45 days after submitting the application for class 3, 4 or B, where the work will be done in a premise, for which there is a former permit for work with GMO of classes 3, 4 or B and all the conditions in it have been observed;

3. 60 days after submitting the application for class 3, 4 or B, where the work will be done in a premise, for which there is a former permit for work with GMO of classes 3, 4 or B.

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

1. until the diminutions and inexactitudes are removed from the application;

2. (amend – SG, 25/2010) until the applicant provides the additional information under Art. 31, Para 7, item 1, letter "a".

3. (new – SG, 25/2010) while holding the public discussion under Art. 31a, an the term in Para. 1 shall not be extended by more than 30 days.

(3) (Amend. – SG, 25/2010) With the permit under Para. 1 shall be confirmed the final classification of the work in controlled conditions and the requirements, under which the work will be done, including the requirements, related to transporation of GMO shall be indicated.

(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) (amend. SG 25/10) The permit under Art. 32 shall be issued for a term, indicated in Art. 30, Para. 2, p. 11.

(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 Para3 shall also be entered in the register.

Art. 37. (1) (New, 25/2010) Before the work in controlled conditions, the Minister of the Environment and Waters shall give the information under Art. 30, Para. 5, p. 3 to the competent authorities of the EU Member States, which may be concerned in case of emergency and shall have

consultations with the, on applying the proposed plans for emergency acts.

(2) (Former Para. 1 – SG, 25/2010) In case of emergency, the person, received permit for work with GMO in controlled conditions shall be obliged within the frames of 24 hours after the emergency to notify the Minister of Environment and Waters about

1. the circumstances in which the emergency took place;

2. the type and range of the respective GMO;

3. any other information needed to assess the consequences from the emergency for human health and the environment;

4. the undertaken emergency protection measures.

(3) (Former Para 2, amend. – SG, 25/2010)

(2) In the cases under Para 2 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.

(4) (New – SG, 25/2010) In the cases under Para. 2, the Minister of Environment and Waters shall:

1. provide for the application of all the needed measures for protection, as well as on behalf of the applicant, also on behalf of the competent authorities;

2. immediately notify the competent authorities of the EU Member States, which might be concerned by the emergency;

3. inform as soon as possible the European Commission for any appeared emergency and shall give information about:

a) the circumstances, in which the emergency appeared;

b) the type and quantities of the concerned GMO;

c) the undertaken measures for protection and their effectiveness;

d) analysis of the reasons for the emergencies and the measures for their prevention in future and for restriction of their consequences;

Art. 38. (Amend- SG, 25/2010) 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) (Suppl. – SG, 25/2010) In the presence of new scientific and other information related to increasing the risk to human health or the environment after the issue of a permit for work with GMO 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) (Amend. – SG, 25/2010) 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 GMO in controlled conditions to change the working conditions or to discontinue temporarily or to stop its performing.

(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. 40a. (New – SG, 25/2010) The Minister of Environment and Waters shall submit to the European Commission:

1. by 31 December of the current year – a report on the applied for during the year activities with GMM in controlled conditions of classes 3 and 4, including description, purpose and risk of performing these activities;

2. every 3 years – a report on the experience from applying the requirements of Chapter Three.

Art. 41. (Suppl. – SG, 25/2010) For issuing the permits under this section, the Ministry of the Environment and Water shall levy a fee, specified by the tariff in Art. 15.

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

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

Art. 42. (1) (Amend. – SG, 25/2010) Before releasing GMO in the environment or placing them on the market as products or ingredient of products, the applicant 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 GMO in the environment and placing 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 Placing GMOs on the market, including an analysis of the potential cumulative consequences from the release or Placing 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 Placing 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 Placing 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. (Suppl. – SG, 25/2010)The terms and procedure for drawing up a risk assessment of the release and placing GMO on the market the rules and conditions for mutual existence of genetically modified culture with the traditional and biological agriculture, 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 GMO in the environment and placing 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 an application in writing from a person under Art. 42.

(3) (New – SG, 25/2010) The Minister of Environment and Waters may permit the release of one and the same GMO or a combination of GMO at one place or different places, but with the same purpose with one permit, for the term, specified in it under the conditions, that has been performed a risk assessment for each place and under observation of the procedure as provided by art. 47-52.

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 GMO 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.

3. (new – SG, 25/2010) summary of the application, according to a form, specified in compliance with the ordinance under Art. 45;

4. (new – SG, 25/2010) economic analysis of the impact over the Bulgarian agriculture from the release in the environment of genetically modified species of economic significance for the country.

(2) The technical dossier shall contain:

1. general information, including:

a) (amend. – SG, 25/2010) identification of the applicant: names, number of the identification document and fixed address – for natural persons, or name, headquarters and registered address, and single identification code or code of 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. (amend. – SG, 25/2010) information about the control, the techniques for removal or deactivation of GMO after finalization of the activity, waste treatment and emergency actions plans in the case of emergency;

7. a map of the farm declared for cultivating transgenetic 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) (Amend. – SG, 25/2010 Attached to the application under Para. 1 shall be:

1. a document for paid fee, specified by the tariff under Art. 15, and for the foreign persons – a document, certifying the legal status of the applicant, issued in compliance with his national legislation up to 3 months before issuing the application;

2. a declaration for consent by the owners, where the applicant is not the owner and a declaration for consent for growing GMO by the owner of the land, where the applicant is not the owner.

(6) (New – SG, 25/2010) The lands, needed for observing the distances under this Act shall be provided by the applicant, which shall present a declaration, certifying this fact.

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) (New – SG, 25/2010) The minister of Environment and Water shall send to the European Commission a summary of the application under Art. 47, Para. 1, p. 3 within the term of 30 days after the application has been filed under Art. 46, Para. 2.

(5) (Former Para. 3, amen. – SG, 25/2010) 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, the techniques for removal or inactivation of the methods of waste treatment.

(6) (Former Para. 4 – SG, 25/2010) The Minister of the Environment and Water, on the grounds of a opinion of the Commission, can ask the applicant to submit additional information beside that specified in Art. 47, motivating the request in writing.

(7) (Former Para. 5 – SG, 25/2010) Within 60 days from filing the application the Commission shall work out a opinion and submit it to the Minister of the Environment and Water.

Art. 50. (1) (Amen. – SG, 25/2010) After working out the opinion under Art. 49, Para 2, the Ministry of the Environment and Water shall organise a public discussion, which shall be held not later than 45 days after drawing up the opinion.

(2) (Amend. – SG, 25/2010) 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 7.

(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 a 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, amen. – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) On the grounds of the Commission's opinion, the economic analysis under Art. 47, Para. 1, p. 4, the results from the public discussion, the comments, made by the rest of the EU Member Statesand after coordination with the Minister of Agriculture, Foods and Forestry, the Minister of the Environment and Water, within the term of 14 days after the date of the public discussion, shall draw up a draft permit for GMO release or a combination of GMO in the environment, and shall present it for approval to the Council of Ministers.

(2) (New – SG, 25/2010) The Council of Ministers shall pronounce with a decision within 14 days after filing the materials under Para. 1.

(3) (New – SG, 25/2010) Within 90 days after filing the application, the Minister of Environment and Water shall:

1. issue a permit for GMO release or a combination of GMO in the environment after a positive decision of the Council of Ministers;

2. refuse the issuing of a permit upon own consideration on the basis of the information under Para. 1, or after a negative decision of the Council of Ministers.

(4) (Former Para. 2, amen. – SG, 25/2010) The term under Para 1 shall stop running:

1. until the diminutions or inexactitudes in the application are removed;

2. (amen. – SG, 25/2010) until the applicant has submitted additional information under Art. 49, Para 6;

3. while the public discussion under Art. 50 is held, which cannot extend the term under Para 1 by more than 30 days;

(5) (Former Para. 3 – SG, 25/2010) 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.

(6) (Former Para. 4, amen. – SG, 25/2010) In the permit under Para 3 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 of the lands, planted with genetically modified plants of:

1. the fields with traditional way of production – not smaller than those, specifies in Annex N 2;

2. the fields with biological way of production – not less than 7 km;

3. stationary bee-gardens, registered as provided by the Apiculture Act – not less than 10km;

(7) (New – SG, 25/2010) The material, obtained from GMO after their release in the environment may be placed on the market after issuing the permit, as provided by Section III of this Chapter.

Art. 52. (1) The Minister of the Environment and Water shall refuse to issue a permit for releasing GMO 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) (Amen. – SG, 25/2010) The Minister of the Environment and Water shall refuse to issue a permit for releasing GMO in the environment in the presence of a contiguous field with a traditional way of production, at a distance, less than the specified in Annex No 2, and from a field with a biological manner of production and from stationary bee-gardens, registered as provided by the Apiculture Act, placed at a distance less than those, specifies in Art. 51, Para. 6, p. 2 and 3.

(3) (Amend. - SG 30/06, in force from 12.07.2006, in force from 12.7.2006, amen. – SG, 25/2010) The refusal under Para. 1 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) (Suppl. – SG, 25/2010)The requirement under Para 1 shall be also applied in the presence of new scientific and other 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. 56a (New – SG, 25/2010) (1) In cases, where another EU Member State submits to the Ministry of Environment and Water a summary of an application for release of GMO in the environment on its territory, it shall be given immediately to the Commission.

(2) The Minister of Environment and Water may request from the EU Member State to give the whole information, contained in the application under Para. 1.

(3) Within 21-day term after receiving the summery, the commission shall draw up an opinion, and shall submit it to the Minister of Environment and Water.

(4) (amend. – SG 58/17, in force from 18.07.2017) Within 30 day term after receiving the summery, the Minister of Environment and Water, on the basis of the commission opinion and after the consent of the Minister of Agriculture, Foods and Forestry may submit the European Commission the comment on the application.

Art. 56b (New – SG, 25/2010) The Minister of the Environment and Water shall inform the European Commission about all the decisions as provided by this Section, including about the reasons for refusal for issuing permits, as well as about the results from releasing, as provided by Art. 55.

(2) The Minister of Environment and Water shall submit to the European Commission every 3 years a report on the gathered experience from applying the requirements of this Section.

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. (suppl. – SG, 25/2010) the place and size of the areas on which the release of GMO 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. (Suppl. – SG, 25/2010) For issuing the permits under this section, the Ministry of the Environment and Water shall levy a fee, specified in the tariff in Art. 15.

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

Art. 59. (1) (amend. – SG 36/08; amend. - SG 54/08, amen. – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) Placing on the market GMO 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, Foods and Forestry.

(2) (amend. – SG 36/08; amend. - SG 54/08, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry 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, amend. – SG 58/17, in force from 18.07.2017) The application under Art. 60, Para 2 shall be filed to the Minister of Agriculture, Foods and Forestry and shall contain:

1. identification of the applicant:

a) names and number of the identification document and fixed address – for natural persons;

b) (amen. – SG, 25/2010)name, headquarters, registered address and single identification code or code on BULSTAT registration – for sole traders and legal persons.

2. information about the GMO;

3. information about the conditions and manners of releasing the GMO and the receiving environment;

4. information about the interactions between the GMO and the environment;

5. information as regards the observation, control, waste treatment and the emergency actions plans in the case of emergency s;

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. (amen. – SG, 25/2010) a proposal for the term of effect of the permit for placing on the market, which cannot be longer than 10 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. (suppl. – SG, 25/2010) a resume of the entire dossier, according to a form, specified in the ordinance under Art. 45;;

12a. (new – SG, 25/2010) a declaration, certifying provision of required distances under this Act from the applicant;

13. additional information.

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

(3) (Amen. – SG, 25/2010) The application under Para. 1 shall contain a document for paid fee, specified by the tariff under Art. 15, and for the foreign persons – also a document, certifying the legal status of the applicant, issued in compliance with his national legislation up to 3 months before filing the application. The application shall have attached a declaration for consent for growing GMO by the owner of the land, where the applicant is not the owner.

(4) (New – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) After receiving the application, the Minister of Agriculture, Foods and Forestry shall immediately submit the summary of the file under Para. 1, p. 12 to the European Commission and to the other EU Member States.

(5) (Former Para. 4 – SG, 25/2010) 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.

(6) (Former Para. 5 – SG, 25/2010) 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 GMO as products or ingredient of products and shall include data and results obtained from research and development releases of GMO in view of exploring the impact of the release on human health and the environment.

Art. 60a. (New – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) The minister of Agriculture, Foods and Forestry shall publish immediately on the internet site the information system under Art. 4, Para. 2:

1. the summary of the application;

2. the report under Art. 66, Para. 1;

3. The information about the possibility for participation of the public in the procedure for public discussion, which shall be held at European Union level.

Art. 61. A separate application for Placing 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 Placing 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, amend. – SG 58/17, in force from 18.07.2017) After completing the verifications the Minister of Agriculture, Foods and Forestry, 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, amend. – SG 58/17, in force from 18.07.2017) Within 60 days from filing the application the Commission shall work out a opinion and submit it to the Minister of Agriculture, Foods and Forestry.

Art. 64. (Repealed – SG, 25/2010)

Art. 65 (Suppl. – SG, 25/2010) In case of availability of new scientific and other information as regards the increase of the risk to human health or the environment prior to the issue of a permit for

placing 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, amend. – SG 58/17, in force from 18.07.2017) inform the Minister of Agriculture, Foods and Forestry about the new information and the measures proposed under Item 1;

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

Art. 66. (1) (amend. – SG 36/08; amend. - SG 54/08, amen. – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) On the grounds of the Commission's opinion and the results from the public discussion and after coordination with the Minister of the Environment and Water, within the term of 90 days after receiving the application, the Minister of Agriculture, Foods and Forestry shall draw up and submit to the applicant a report about the assessment of the application. The report shall contain the information, specified in Annex N 3.

(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. (Repealed – SG, 25/2010).

(3) (Repealed – SG, 25/2010).

Art. 66a. (New – SG, 25/2010) (1) (amend. – SG 58/17, in force from 18.07.2017) Where the report under Art. 66, Para. 1 indicates, that GMO may be placed on the market, the Minister of Agriculture, Foods and Forestry shall submit it to the European Commission together with the additional information under Art. 63, Para. 4, as well as any other information, taken into consideration at its drawing up within the term of 90 days after receiving the application.

(2) (amend. – SG 58/17, in force from 18.07.2017) After submitting the report under Art. 66, Para. 1 to the European Commission, the Minister of Agriculture, Foods and Forestry shall present to the public the summary of the file and the report for discussion through internet site of the information system under Art. 4, Para. 2. The discussion shall be held within the frames of 30 days. The Minister of Agriculture, Foods and Forestry shall summarize the notes and comments and shall submit them to the European Commission.

(3) (amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry shall issue permit for placing on the market in cases, where:

1. within the term of 60 after submitting the report fail to come motivated objections or there are no motivated argument issues from the European Commission or from the EU Member States;

2. the argument issues, set by the European Commission or the EU Member States have been solved within 105 days after submitting the report.

(4) The term under Para. 3 shall stop to run by the presentation to the applicant additional information, requested by the European Commission or by the EU Member States.

(5) (amend. – SG 58/17, in force from 18.07.2017) Where in the term of Para. 3, p. 2 the arrived objections or the set argument issues by the European Commission of by the EU Member States are not solved, the Minister of Agriculture, Foods and Forestry shall issue a permit only after positive decision of the European Commission of the EU Council.

(6) The permit for placing on the market shall be sent to the Applicant within 30day term after expiry of the terms under Para. 3 or after the EU decision's publication.

(7) (amend. – SG 58/17, in force from 18.07.2017) Within the term under Para. 6, the Minister of Agriculture, Foods and Forestry shall notify the European Commission and the EU Member States

about the issued permit.

Art. 67. (1) The permit for Placing 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 Placing 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) (Amen. – SG 25/2010) The permit shall be issued for the maximum term not longer than 10 years.

(4) (Amen. – SG, - 25/2010)As regards GMO, intended for production and placing 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 Common catalogue of varieties farm plant kinds and the Common catalogue of varieties of vegetable kinds.

(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, amend. – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry, on the basis of the report under Art. 66, Para. 1 shall refuse with motivation the issue of a permit for placing on the market, in cases, where:

1. the Commission's opinion be that there are risks to human health or to the environment and that the undertaken protection measures are insufficient or ineffective;

2. applicant has not remedied the diminutions or inaccuracies in his/her application within the term specified in Art. 63, Para 2;

(2) (New – SG, 25/2010) The applicant shall be notified about the refusal for issuing permit within the term under Art. 66.

(3) (New – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) In case of a refusal for issuing permit, the Minister of Agriculture, Foods and Forestry shall submit the report under Art. 66, Para. 1 to the European Commission with the additional information under Art. 63, Para. 4, as well as any other information, taken into consideration for its issuing, not earlier than 15 days after the notification of the applicant and not later than 105 days after the application filing.

(4) (Amend. - SG 30/06, in force from 12.07.2006, former Para. 2 – SG, 25/2010) 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, amend. - SG 25/10, amend. – SG 58/17, in force from 18.07.2017) At the Ministry of Agriculture, Foods and Forestry shall be created and

maintained electronically a public register of:

1. the issued permits for Placing GMOs on the market;

2. the information on genetic modification to facilitate control and post-market monitoring of the GMO as a product or ingredient of a product.

(2) (amend. - SG 25/10) The electronic registers under Para 1 shall be a part of the information system under Art. 4, Para 2.

(3) (amend. - SG 25/10) The information that is a subject to entering in the register under Para 1 shall be determined by the ordinance under the Art. 45.

(4) (amend. - SG 25/10) The changes in the data and circumstances under Para 3 shall also be entered in the registers.

Art. 70 (1) (Amend. – SG 36/08; amend. - SG 54/08, suppl. – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) 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 GMO at the market as products or ingredient of products, which reports the person shall provide to the Minister of Agriculture, Foods and Forestry. Minister of Agriculture, Foods and Forestry shall submit the reports to the European Commission and to the EU Member States.

(2) (amend. – SG 36/08; amend. - SG 54/08, amen. – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) 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, Foods and Forestry 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, Foods and Forestry 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, suppl. – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) At the Ministry of Agriculture, Foods and Forestry 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 placing on the EU 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) (Amen. – SG, - 25/2010) The persons, who breed genetically modified plants under the conditions of Para 1, shall observe the rules and conditions for mutual existence of genetically modified plants with traditional and biological agriculture, specified by the ordinance under Art. 45, as well as the obligatory distances under Art. 51, Para. 6.

(4) (amend. – SG 36/08; amend. - SG 54/08, amend. – SG 58/17, in force from 18.07.2017) The persons who breed genetically modified plants under the conditions of the Para 1, shall inform the Ministry of Agriculture, Foods and Forestry of the location and the square of the seeded lands.

(5) (amend. – SG 36/08; amend. - SG 54/08, amend. – SG 58/17, in force from 18.07.2017) The Ministry of Agriculture, Foods and Forestry shall notify the Ministry of Environment and Water of the location and square of the lands.

(6) (New – SG, 25/2010) The areas, needed for observing the distance under Para. 3 shall be provided by the applicant, who shall give a declaration, certifying this circumstance, as well as declaration for consent for growing GMO by the owners of the land, where the applicant is not the owner.

Art. 72. (1) (Suppl. – SG, 25/2010) In case of new available scientific and other information concerning the increasing risk for the human health and the environment from the placing 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, amend. – SG 58/17, in force from 18.07.2017) inform the Minister of Agriculture, Foods and Forestry of the new information and the undertaken measures under item 1;

3. revise the conditions of placing on market.

(2) (amend. – SG 36/08; amend. - SG 54/08, amend. – SG 58/17, in force from 18.07.2017) When the information under Para 1 is received at the Ministry of Agriculture, Foods and Forestry, 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, amen. – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) In the cases of Para 1 and 2, the Minister of Agriculture, Foods and Forestry, on the grounds of the opinion of the Commission, shall draw up a report about the need for amendment of the conditions of placing on market or for termination of placing on the market of the GMO. The report shall be drawn up and submitted to the European Commission within the term of 60 days after receiving the new information.

(4) (New – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry shall amend the conditions or terminate the permit for placing on the market, where:

1. within the term of 40 days after submitting the report there are no motivated objections or there are no raised argument issues by the European Commission or by the EU Member States;

2. the argument issues, set by the European Commission or the EU Member States have been solved within 75 days after the report submission.

(5) (New – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) In cases, where within the term under art. 4, p. 2 the objections or the set argument issues by the European Commission or by the EU Member States have not been solved, the Minister of Agriculture, Foods and Forestry shall amend the conditions or terminate the permit for placing on the market only upon positive decision of the European Commission or the EU Council.

(6) (New – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry shall notify the applicant, the EU and the EU Member States about the decision under Para. 4 or 5 within 30 day term after its issuing.

Art. 73. (1) (Amend. – SG 36/08; amend. - SG 54/08, amen. – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry may renew 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) (amen. – SG- 25/2010) name, seat, registered address, single identification code or code on 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. (amen. – SG, 25/2010) proposal for amendment or supplementation of the conditions of the permit for which renovation is requested, if this needed for the purposes of avoiding of the risk for the

human health and environment.

(3) (Amen. – SG, 25/2010) To the applications shall be attached a report on the results of the monitoring under Art. 70.

(4) (Amend. – SG 36/08; amend. - SG 54/08, amen. – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry on the grounds of the opinion of the Commission shall draw up and submit to the applicant a report on the renewal of the permit within 60 day term after the application filing.

take decision to prolong the term of the permit within the period under Para 1. The term of the permit shall be prolonged for not more than 5 years.

(5) (New. – SG 25/2010, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry shall immediately submit the report with the application to the European Commission and to the competent authorities of the EU Member States.

(6) (New – SG 25/2010, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry shall renew the permit, in cases where:

1. within the term of 60 days after submitting the report there are no filed motivated objections or no raised argument issues by the European Commission or by the EU Member States;

2. the argument issues, set by the European Commission or by the EU Member States have been solved within 75 days after submitting the report.

(7) (New – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) Where within the term under Para. 6, p 2 the filed objections or the set argument issues by the European Commission or the EU Member States are not solved, the Minister of Agriculture, Foods and Forestry shall renew the permit for placing on the market in case of positive decision of the European Commission or the EU Council.

(8) (new – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) The term of action of the permit under Para. 1 is 10 years. The Minister of Agriculture, Foods and Forestry may shorten or extend the term in case of available specific reasons, by indicating the motivation about this.

(9) (New – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) The Ministry of Agriculture, Foods and Forestry shall notify the applicant, the European Commission and the EU Member States about their decision on renewal of the permit under Para. 1 within 30day term after its enacting.

(10) (Amen. – SG, 36/2008, amen. – SG, 54/2008, former Para. 5, amen. – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) The Ministry of Agriculture, Foods and Forestry shall notify the applicant about the decision under Para. 6 within 14 day term after its enacting.

(11) (Amen. – SG, 36/2008, amen. – SG, 54/2008, former Para. 6, amen. – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) The applicant may continue to place GMO on the market under the conditions, provided by the permit, about which a renewal shall be requested by the pronouncing of the Minister of Agriculture, Foods and Forestry.

Art. 74. (1) (Amend. – SG 36/08; amend. - SG 54/08, amend. – SG 58/17, in force from 18.07.2017) At each of the stages of the GMO placing 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, Foods and Forestry.

(2) (Amen. SG, 25/2010) On the label of the product shall be placed the information, specified in Regulation (EC) N 1830/2003 of the European Parliament and of the Council of 22 September, 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. The size of the letters describing the contents of GMO in products, according to Art. 4, Para. 6 of the Regulation shall be twice larger in comparison with the rest of the inscriptions and in colour and style, different from the basic one.

(3) The provisions of Art. 1 and 2 shall not be applied for products:

1. (Amen. – SG, 25/2010) in which occasionally appearing or technically unavoidable traces of GMO exist, for which an issued permit for placing on market has been acquired, and are in quantities under the minimal admissible as defined under the ordinance of Art. 45.

2. (repealed, - SG, 25/2010)

(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, amend. – SG 58/17, in force from 18.07.2017) 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, Foods and Forestry with the issued by him permit.

Art. 75. (1) (Amend. – SG 25/2010, amend. – SG 58/17, in force from 18.07.2017) The Minister of the Agriculture, Foods and Forestry, after a co-ordination with the Minister of Environment and Water and the Minister of Health may propose to the Council of Ministers temporary to 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:

1. new or additional information, which has become known after the issuing of the permit and which information impacts the risk assessment, or

2. revision of the existing information on the base of new or additional scientific knowledge.

(2) (amend. – SG 58/17, in force from 18.07.2017) In the cases of Para 1, in case of risk for the human health and environment, the Minister of Agriculture, Foods and Forestry shall apply all needed measures for protection, and shall immediately notify the society of the undertaken measures and the motives for them.

(3) (amend. – SG 58/17, in force from 18.07.2017) In the cases under Para 1, the commission shall revise the risk assessment upon request of the Minister of Agriculture, Foods and Forestry.

(4) (amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry shall introduce to the Council of Ministers the information under Para. 1 with the revised risk assessment for adoption of a decision on applying the ban under Para. 1.

(5) (amend. – SG 58/17, in force from 18.07.2017) In the cases of introduced ban under Para. 1, the Minister of Agriculture, Foods and Forestry shall inform immediately the European Commission and the EU Member States about the measures, undertaken under Para. 2 and the motivation for them, by presenting:

1. a revised risk assessment, which indicates which conditions and in what way should be changed in the permit for placing on the market or the permit to be repealed;

2. the information under Para. 1, p. 1;

(6) The appeal of the Council of Ministers decision under Para. 4 shall not stop its

implementation.

Art. 76. (Amend. – SG 36/08; amend. - SG 54/08, amend. – SG 58/17, in force from 18.07.2017) The Minister of the Agriculture, Foods and Forestry 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 GMO 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. 77a (New – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry shall every 3 years submit to the European Commission a report on the gathered experience in applying the requirements of this Section.

Art. 78. (Amend. – SG 36/08; amend. - SG 54/08, suppl. – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) For the issuing or renewal of permits under this Section, the Ministry of Agriculture, Foods and Forestry shall collect a fee, specified in the tariff under Art. 15..

Section IV.
Prohibitions

Art. 79 (*) (1) Prohibited shall be the release in the environment and Placing 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, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry, 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, amen. – SG, 25/2010) Prohibited shall be the breeding and the release of GMO in the environment, including as provided by Section II and Section III of Chapter Four of this Act in the following territories:

1. in the boundaries of the protected territories under the Protected Areas Act and in the boundaries of the protected zones of the National Ecological Net, as provided by the Biological Diversity Act;

2. at a distance less than 30 km from the territory boundaries under p. 1;

3. at a distance less than 10 km from stationary bee gardens, registered as provided by the Apiculture Act;

4. at a distance less than 7 km from areas with biological way of production of agriculture production;

5. at distances, less than those, indicated in Annex N 2 in relation to areas with traditional way of production.

Art. 81. Prohibited shall be the release in the environment and Placing on the market of GMOs

containing marker genes for antibiotic resistance.

Art. 82. (1) (Amen. – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) With prohibition, imposed in another EU Member State, grounded on the protective clause, the Minister of Agriculture, Foods and Forestry, referring to the received information, shall initiate the procedure under Art. 75.

(2) (amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry and the Minister of Environment and Water shall apply the protective clause also for the traditional varieties of exceptional economic significance for Bulgaria, specified in §1, p. 40 of the Additional Provisions.

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

Section I.
Import

Art. 83. (amend. – SG 36/08; amend. - SG 54/08, amend. – SG 58/17, in force from 18.07.2017) 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, Foods and Forestry is acquired following the order of Chapter Three or Four, depending of the purpose of the GMO.

Art. 84 (Repealed – SG, 25/2010)

Section II.
Export. General Provisions

Art. 85. (Repealed – SG, 25/2010).

Art. 86. (Repealed – SG, 25/2010).

Art. 86a (New – SG, 25/2010) (1) In relation to the export and unconscientious moving of GMO, Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms shall be applied.

(2) The competent body in the meaning of Regulation (EC) No 1946/2003 shall be:

1. The Minister of Environment and Water, where GMO – subject to export or unconscientious transboundary movement have been intended for release in the environment;

2. (amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry, where GMO – subject to export or unconscientious transboundary movement have been intended for placing on the market.

Art. 87. (Amen. – SG, 36/2008, amen. – SG, 54/2008, repealed, - SG, 25/2010).

Art. 88. (Amen. – SG, 36/2008, amen. – SG, 54/2008, repealed, - SG, 25/2010).

Art. 89. (Repealed, - SG, 25/2010).

Section III.
EXPORT OF GMO, INTENDED FOR RELEASE IN THE ENVIRONMENT (Repealed – SG, 25/2010)

Art. 90. (Repealed – SG, 25/2010).

Art. 91. (Repealed – SG, 25/2010).

Art. 92. (Repealed – SG, 25/2010).

Art. 93. (Repealed – SG, 25/2010).

Art. 94. (Repealed – SG, 25/2010).

Art. 95. (Repealed – SG, 25/2010).

Section IV.
Export of GMO, intended for direct use as food or feed or for processing (Repealed – SG, 25/2010)

Art. 96. (Repealed – SG, 25/2010).

Art. 97. (Repealed – SG, 25/2010).

Art. 98. Repealed – SG, 25/2010).

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 biosaftey.

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 biosafty;

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, amend. – SG 58/17, in force from 18.07.2017) The Ministry of Environment and Water shall notify Agency "Customs" and the Ministry of Agriculture, Foods and Forestry 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.
Unintended transboundary transfer of GMO. (Repealed, - SG, 25/2010)

Art. 103. (Repealed - SG, 25/2010)

Chapter six.
CONFIDENTIAL INFORMATION

Art. 104. (1) (amend. – SG 36/08; amend. - SG 54/08, amend. – SG 58/17, in force from 18.07.2017) 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, Foods and

Forestry 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, suppl. – SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) The Minister of Environment and Water or the Minister of Agriculture, Foods and Forestry shall determine with an order, after consultation with the applicant 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.

(4) (New – SG, 25/2010) The information under Para. 2 shall be treated as confidential also in the cases of withdrawal of the application on behalf of the applicant.

Art. 105. Shall not be confidential information:

1. in the cases of work with GMO in controlled conditions:

a) (amen. – SG, 25.2010) the general characteristics of the GMO, incl. the marker genes;

b) the name and the address of the applicant;

c) the location of work with GMO

g) the defined class and precaution measures at work with GMO;

d) the assessment of the possible unfavourable consequences for the human health and the environment;

2. in cases of release if GMO in the environment and placing on the market as products or ingredients of products:

a) (amen. – SG, 25.2010) the general characteristics of the GMO;

b) the name and the address of the applicant;

c) the purpose and place of release;

d) methods and plans of monitoring of GMO and plans of emergency action;

e) place of preservation;

f) the ways of transportation;

g) the usage of the GMO;

h) risk assessment;

3. in the cases of import and export of GMO:

a) the name of the exporter and the importer;

b) description of GMO;

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 GMO and plans of emergent actions.

Art. 106. (Amen. – SG, 25/2010) Access to the bodies under Art. 4, 5 and 6 shall not be denied to information regarding the used vectors, nucleotide sequences and 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) (Amen. – SG, 25/2010) The Ministry of Environment and Water, through the regional inspectorates of Environment and Water, shall perform control

1. on the observation of this Act on the application of the precaution and protection measures, specified for each class of work with GMO in controlled conditions;

2. on the release of GMO in the environment.

(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; amend. – SG 80/09, amend. – SG 58/17, in force from 18.07.2017) The Ministry of Agriculture, Foods and Forestry shall perform control through the Executive agency for variety trial, approbation and seed control, Bulgarian Food Safety Agency, the Executive Agency for the vine and wine, the Executive agency for fishery and aquacultures, the Executive 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. Placing 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 Act 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 amend. – SG 82/09, in force from 16.10.2009; amend. – SG, 14/2015) 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 Placing on market.

Art. 112. (1) (amend. - SG 58/16) Customs authorities in accordance with Art. 134, paragraph 1 of Regulation (EU) № 952/2013 of the European Parliament and of the Council of 9 October 2013 on establishing a Union Customs Code (OJ, L 269/1 of 10 October 2013) shall carry out control during import, export and transit of GMOs and notify the controlling authorities under para. 2 in the event of:

1. suspicion in the conformity of goods with 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. 100;

3. preliminary notification from the competent authorities 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, amend. – SG 58/17, in force from 18.07.2017) At finding of a breach of the requirements of this Act 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, Foods and Forestry.

Art. 114. (Amen. – SG, 25/2010) The controlling bodies shall perform checks in compliance with the requirements and conditions in the permit under Art. 32, Para. 1, Art. 51, Para. 3, t.1, Art. 67, Para. 1, and Art. 73, Para. 1.at minimum twice per year, as well as in event of a signal about admitted breaches of the requirements of this Act, in cases of accidents, in case of unfavourable consequences for the human health r environment form work with GMO in controlled conditions, release in the environment and placing on market occurred or of possibility they may occur.

Art. 115. (1) (amend., SG 99/05; amend. – SG 36/08; amend. - SG 54/08, amend. – SG 58/17, in force from 18.07.2017) The Minister of Environment and Water, the Minister of Agriculture, Foods and Forestry, 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 an to draw up acts of findings of breaches.

(2) The officials, who shall perform the control under this Act, 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 Placing 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 Act 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.

(6) (New, - SG, 25/2010, amend. – SG 58/17, in force from 18.07.2017) By 31 January the officials shall present to the Minister of Environment and Water or to the Minister of Agriculture, Foods and Forestry reports on the performed check ups during the previous year, under Para. 1 and their results.

Art. 116, The laboratory analysis for determining of the quality and quantity of the genetic modification shall be executed at the request of he 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, amend. – SG 58/17, in force from 18.07.2017) On order to prevent and stop the administrative breaches of this Act, as well as to prevent and remove the unfavourable consequences form them, the Minister of Environment and Water and the Minister of Agriculture, Foods and Forestry shall apply the following administrative measures:

1. suspension from operation of rooms for work with GMOs in controlled conditions and sites for Placing 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 marker 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.

(3) 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 Placing 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 Act, if announce confidential information in offence of the Art. 14, shall be punished by a fee in amount of 5 000 BGN.

Art. 119. Anyone, 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. (Suppl. – SG, 25/2010) Anyone, who performs work with GMO of class 2 and of a higher class without permit for work with GMO in controlled conditions in offence of the Art. 29, or in violation of Art. 30, Para. 3 and 4, shall be punished with a fee, respectively with a property sanction, in amount from BGN 50 000 to 150 000.

Art. 121. Anyone, 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. Anyone, 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. Anyone, 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. Anyone, 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. Anyone, 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. Anyone, 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. Anyone, who has submitted false information in the application for Placing 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. Anyone, 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. Anyone, who puts GMOs on market as products or as ingredients of products breaking the conditions provided in the permit for Placing on market, shall be punished with a fee, respectively with a property sanction, in amount from 200 000 to 500 000 BGN.

Art. 130. Anyone, 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. Anyone, who breeds genetically modified plants, for which he has acquired permit for Placing 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. Anyone, who breeds genetically modified plants, for which he has acquired permit for Placing 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. (Repealed, - SG, 25/2010)

Art. 134. (Amen. – SG, 25/2010) Anyone, who violates the provision of Art. 79, or Art. 80, or fails to implement obligation under Art. 82, shall be punished with a fee, respectively with a property sanction in amount of BGN 1 000 000.

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

Art. 136. (Amen. – SG, 25/2010) Anyone, who violates the imposed by a decision of the Council of Ministers for prohibition under Art. 75, Para. 1, shall be punished with a fee, respectively with a property sanction in amount of BGN 500 000 to 1 000 000.

Art. 137. Anyone, 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. Anyone, 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. Anyone, 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 (Amen. – SG, 25/2010) Anyone who performs export of GMO or products, containing or consisting of GMO in violation of the requirements of Regulation (EC) No 1946/2003 of the

European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms, shall be punished by a fine, or property sanction from BGN 100 000 to 300 000.

Art. 142. (Repealed – SG, 25/2010)

Art. 143. (Amen. – SG, 25/2010) (1). The acts for establishing the violations shall be drawn up by the relevant officials under Art. 115.

(2) The penal provisions shall be issued by the relevant competent body or by an official, authorized by him, according to the specified in Chapter Seven Competence.

(3) The establishment of violations, issuing, appeal and implementation of the penal provisions shall be done, as provided by the Administrative Violations and Penalties Act.

(4) The administrative punishment under Art. 143 shall be imposed by the Supreme Administrative Court. The administrative violation shall be established by a report of a commission, determined by the Prime Minister, which shall be sent to the court.

(5) The Supreme Administrative Court shall examine the case in substance and shall pronounce with a decision, which shall impose the administrative punishment, or decides that there is no administrative violation.

(6) The decision under Para. 5 shall be subject to cassation appeal, as provided by the Administrative Procedure Code.

(7) The amounts of fines and property sanctions for violations under this Act shall come into the budgets of the relevant Ministries depending on the competent body, who has issued the penal enactment.

Chapter nine.
CIVIL RESPONSIBILITY (NEW, - SG, 25/2010)

Art. 144 (New – SG, 25/2010) Anyone, who breeding GMO, causes another person harms of contamination of plants, raises in neighbouring properties with those GMO or with the genes, isolated for the relevant genetic modification and/or with the marker genes, including in established horizontal transfer of genes, shall be obliged to compensate him.

(2) The responsibility under Para. 1 shall cover also the missed benefits as a result of this contamination.

(3) Plants of genetically modified plants, bred in violation of this Act, shall be destroyed on the account of the violator.

Art. 145 (New, - SG, 25/2010) The harmed persons under Art. 114 may claim against the violator for termination of the violation and for removal of the consequences of the contamination.

Additional provisions

§ 1. In the meaning of this Act:

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, animal or plant cell cultures.

3. (Suppl. – SG, 25/2010) "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, as well as an organism, obtained through techniques and/or methods, indicated in Art. 21a.

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. (Amen. – SG, 25/2010) "Autoclonal reproduction" shall be cutting of nucleotide sequences of the cell of the organism which may be, or not followed by incorporation of whole or part of this nucleotide sequence (or its synthetic equivalent) (with, or without preliminary enzyme or mechanic processing) in cells of the same of phylogenetic close variety, with which they may exchange genetic material in a natural way.

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 GMO 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 livingorganisms, 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 GMO identification.

23. "Release in the environment" shall be each conscious inserting into the environment, except the placing on the market, of GMO 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. "Placing 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. (Amen. – SG, 25/2010) "Product" shall be a material consisting of or containing GMO or combination of GMO, which is subject of placing on the market.

26. (Suppl. – SG, 25/2010) "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 GMO with the population and the environment, as well as providing high level of safety.

27. "Emergency" shall be each accident, including significant and unintentional release of GMO 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 GMO in the environment or of the placing on the market of the GMO. 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 GMO, 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. (Repealed – SG, 25/2010).

34. (Amen. – SG, 25/2010) “Export” is export in the meaning of Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms.

35. 0(amen. – SG, 25/2010) “Exporter” shall be exporter in the meaning of Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms.

36. (Amen. – SG, 25/2010) "Transboundary transfer" shall be transboundary movement in the meaning of Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms.

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 eco-systems.

38. (New – SG, 25/2010) "Applicant" shall be any natural or legal person, who files an application.

39. (New – SG, 25/2010) "Application" shall be a written filing of information to the competent bodies under Art. 3 in compliance with the requirements of this Act.

40. (New – SG, 25/2010) "Traditional varieties of exceptional economic significance" shall be tobacco, vines, oil rose, wheat and all the vegetable and fruit plants.

41. (New – SG, 25/2010) Protective clause" shall be the procedure, provided by Art. 23 of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms repealing Council Directive 90/220/EEC - Commission Declaration.

42. (New – SG, 25/2010) "Horizontal transfer of genetic material" is the transfer of genetic material of genetically modified organism in another organism, made by viruses, without human intervention.

§2. (Repealed, - SG, 25/2010)

§ 3. Placing 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 Placing on the market of genetically modified animals shall be prohibited.

§ 4a. (New – SG, 25/2010) This Act shall introduce the requirements of Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms, last amended by Council Directive 98/81/EC of 26 October, 1998 and of Directive 2001/18EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, repealing Council Directive 90/220/EEC.

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 Act and shall acknowledge or suspend their validity in three-month term from the date of the entry into force of the Act.

(2) In one-year term from the date of the enacting of the Act, the Commission shall prepare a report concerning the spreading of GMOs in the environment before the entry into force of this Act,

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 entry into force of the Act, shall be brought in compliance to the requirements of the Act and the ordinance of Art. 2, Para 3 in up to 6 months term from the date of the entry into force of the Act.

§ 7. Art. 20 of the Seed and Planting Stock Act (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 Placing 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 Genetically Modified Organisms Act.

§ 8. (Repealed – SG, 25/2010)

§ 9. (revoked – SG 43/08)

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

This Act 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 Genetically Modified Organisms Act (prom. SG 27/05; amend. SG 88 and 99/05) the words "the Supreme Administrative Court Act" 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 Placing 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 Placing 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 vie each risk managing strategy proposed.

IV. Conclusions concerning the possibility influence of release of GMOs in the environment or their Placing 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 Placing 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 Placing 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 areals of inhabit in the conditions of release in the environment or Placing 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 Placing on the market;

c) the possibility of genes transfer to other species in the conditions of the proposed release in the environment or Placing 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 areals 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 theemployees, 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 MEDICINAL PRODUCTS IN HUMAN MEDICINE ACT

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

§ 37. The Act 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 Act.

Transitional and concluding provisions
TO THE ACT ON AMENDMENT AND SUPPLEMENTATION OF THE FISHERIES AND AQUACULTURE ACT

(PROM. - SG 36/08)

§ 61. In the Genetically Modified Organisms Act (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 ACT ON AMENDMENT AND SUPPLEMENTATION OF THE FODDER ACT

(PROM. - SG 54/08)

§ 80. In the Genetically Modified Organisms Act (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 Act the word "Food Supply" shall be replaced by "Food".

Concluding provisions
TO THE ACT ON AMENDMENT AND SUPPLEMENTATION OF THE VOCATIONAL EDUCATION AND TRAINING ACT

(PROM. – SG 74/09, IN FORCE FROM 15.09.2009)

§ 48. The Act shall enter into force from the date of its promulgation in the State Gazette, except for § 1, which shall enter into force from the 15th of September 2009 and § 47, which shall enter

into force from the 1st of October 2009.

Transitional and concluding provisions
TO THE ACT ON THE STATE BUDGET OF THE REPUBLIC OF BULGARIA FOR 2012

(PROM. - SG 99/11, IN FORCE FROM 01.01.2012)

§ 100. This Act shall enter into force from 1 January 2012, except for § 76, which shall enter into force from 15 December 2011.

Concluding provisions
TO THE ACT AMEDNING AND SUPPLEMENTING THE YOUTH ACT
(PROM. - SG 68/13, IN FORCE FROM 02.08.2013)

§ 55. This Act shall enter into force from the day of its promulgation in State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTATING THE ACT ON PROHIBITION OF CHEMICAL WEAPONS AND ON CONTROL OF TOXIC CHEMICAL AGENTS AND THEIR PRECURSORS

§ 42. In the Genetically Modified Organisms Act the words "the Minister of Economy, Energy and Tourism" and "the Ministry of Economy, Energy and Tourism" shall be replaced by "the Minister of Energy" and "the Ministry of Energy" everywhere.

Concluding provisions
TO THE ACT AMENDING THE ACT ON BULGARIAN FOOD SAFETY AGENCY
(PROM. - SG 58/17, IN FORCE FROM 18.07.2017)

§ 13. Everywhere in the text of Genetically Modified Organisms Act words "Minister of Agriculture and Food" and "Ministry of Agriculture and Food" shall be replaced with words "Minister of Agriculture, Food and Forestry" and "Ministry of Agriculture, Food and Forestry".

.....

§ 76. This Act shall enter into force on the day of its promulgation in the State Gazette.

Appendix No. 2 to Art. 51, Para 4 and Art. 71, Para 3
(suppl. – SG, 43/2008, amen. – SG 25/2010)

Technological standards for distant isolation of groups of crops

	Crops	Minimum distance, m
I.	Cereals	
	Barley	150
	Oats	150
	Rice	150
	Millet	150
	Sudan-Grass	150

	Rye	1000
	Triticale	200
	Corn	800
	Canary Grass	800
II.	Legumes	
	Gram	150
	Beans	200
	From other varieties of Ph.coccineus L.	2000
III.	Oleaginous and Fibrous	
	Peanuts	100
	Shallard	400
	Hemp dioecious	800
	Hemp monoecious	3000
	Cotton	400
	Safflow, caraway, cumin	
	Italian	400
	Soybean	200
	Rape	400
	Sunflower	3000
	Flax Oleaginous and Fibrous	200
	Castor-oil plant	1000
	Sesame	1000
	Poppy	400
IV.	Fodder	1000
V.	Potatoes	400

Annex N3 to Art. 66, Para. 1
(New – SG, 25/2010)

Instructions for drawing up an assessment report

The assessment report according to Art. 66, Para. 1 shall include at least the following information:

1. Identification of the characteristics of the reception organism, which have relation to the assessment, of the applied for GMO.

2. Identification of the known risks for human health and environment as a result of release into the environment of genetically non-modified reception organism.

3. Description of the results of the genetic modification of GMMO.

4. Assessment if the genetic modification has been characterized in a sufficient extend in view to specifying the risks for the human health and the environment.

5. Identification of each new risk for the human health and environment form the release of the applied for GMO into the environment in comparison with the release of the relevant genetically non-modified organism in the environment on the basis of risk assessment according to Chapter Four, Section 1.

6. Motivated conclusion whether :

a) the applied for GMO should be placed on the market as a product or ingredient of a product and the conditions, at which it shall be placed; or

b) the applied for GMO should not be placed on the market;

c) should be requested an opinion of the EU Member States and the European Commission on concrete issues, related to the risk assessment.

The conclusion shall clearly indicate the proposed:

- use of the applied for GMO;
- risk management;
- monitoring plan.