

REGULATIONS

on the deliberate release into the environment of genetically modified higher plants  
OBTAINED BY RECOMBINANT DNA TECHNOLOGY

Chapter one

General provisions

Article 1./1/ Deliberate release of genetically modified higher plants (GMPs) may be carried out by persons who possess a licence issued in compliance to these regulations.

/2/ Release of GMPs is controlled by the Minister of Agriculture and Food-processing Industry and by the Minister of Environment with the aim to limit risks to human health and environment.

/3/ Gathering and submitting of information on the release of GMPs is done in compliance to these regulations.

/4/ Approval of new cultivars of GMPs as well as the import and export of GMPs, GMP seeds and planting material, is carried out according to standing rules if and after a licence for their release is issued in compliance to these regulations.

Article 2. A new Council for Safe Use of Genetically Modified Higher Plants (Council) is established under the Ministry of Agriculture and Food-Processing Industry.

Chapter two

Organisation and activities of the Council for Safe Use of Genetically Modified Higher Plants

Article 3./1/ The Council for Safe Use of Genetically Modified Higher Plants consists of a Chairman, a Secretary, and five Members. The Council Members include one representative of the Ministry of Environment and one representative of the Ministry of Health.

/2/ Council members are appointed by a written order of the Minister of Agriculture and Food-processing Industry at the tender of the respective ministers and the Chairman of the Agricultural Academy.

/3/ The Council Chairman is a Deputy Minister of Agriculture and Food-processing Industry. The Chairman is in charge of the overall activity of the Council and serves as its representative.

/4/ The Council Secretary is an eminent scientist with an academic rank in the field of Genetic Engineering who co-ordinates the activity of the Council.

/5/ Experts in the respective fields including foreign experts may be drawn in the activity of the Council as consultants.

/6/ The Council adopts regulations for its own activity.

/7/ The administrative, technical, and accounting staff of the Council is provided by the Ministry of Agriculture and Food-Processing Industry.

Article 4./1/ The Council for Safe Use of Genetically Modified Higher Plants:

1. issues licenses for release of GMPs;
2. maintains registers of the research and commercial release of GMPs;
3. evaluates the quality of the assessments of environmental hazards posed by the release of GMPs and the effect of the proposed safety measures on the basis of information submitted by the notifier;
4. supervises compliance to regulations governing the permission for release of GMPs;
5. issues binding writs to persons having permission to release GMPs to take extra measures inclusive destroying of the plant species in case of ascertaining any deviation from the risk assessment adopted under Article 11;

6. submits data to the Minister of Agriculture and Food-processing Industry and prepares annual reports for release of GMPs;

7. represents the Republic of Bulgaria at national councils, committees, and international organisations on the problems of the release of GMPs;

8. at the request of the State Cultivar Selection Committee works out attitudes towards proposals for approval of new cultivars based on GMPs as well as their use;

9. carries out other activities in the field of release of GMPs for which it has been given permission by the Minister of Agriculture and Food-processing Industry.

/2/ With regard to the control of GMPs release, Council members and experts appointed by the Council Chairman may enter and pass through properties and carry out investigations and other tasks after written notice to the concerned owners and users.

Article 5./1/ The register of research GMPs releases under Article 4, Paragraph 1, 2 contains data about:

1. persons who obtained licence for release of GMPs;
2. host (parental plant);
3. genetic modification;
4. GMPs;
5. place of release (plot, ground, terrain, map region);
6. release period;
7. purpose of release;
8. environmental influence;
9. number and date of the official decision of the Council;
10. number and date of the licence.

/2/ In addition to the data under Paragraph 1, the register for commercial release of GMPs contains:

1. name of product and GMPs concerned;

2. field of licensed use: agriculture, specialised trade of seeds and planting material.

/3/ The register is kept by a person appointed by the Council Chairman who need not be a member of the Council.

Article 6./1/ Council members and persons under Article 3, Paragraph 4 and Article 5, Paragraph 3 may not make public or allow outside access to data entrusted to them.

/2/ Persons under Paragraph 1 endorse a written statement for keeping confidential information in the form shown in Annex I.

Article 7./1/ The Council for Safe Use of Genetically Modified Higher Plants is convened by its Chairman when necessary.

/2/ The Council adopts its decisions by open vote ballot by a majority of half of its members plus one.

/3/ Each session of the Council is recorded in minutes signed by all attending Council members. Dissents expressed in the session are appended to the minutes.

/4/ The Chairman of the Council is in charge of its overall activities.

Article 8./1/ The Council for Safe Use of Genetically Modified Higher Plants is funded by BUDGETARY GRANTS OF THE ORGANISATIONS EMPLOYING THE COUNCIL MEMBERS, FEES COLLECTED FROM NOTIFIERS, returns, and aid from international organisations.

/2/ Incomes and expenditures for the Council are kept in a separate account.

### Chapter Three

Rules and regulations for the release of genetically modified higher plants

Article 9./1/ Persons wishing to release GMPs on the territory of the Republic of Bulgaria, submit applications to the Council for Safe Use of Genetically Modified Higher Plants for each release.

/2/ The following are attached to the applications:

1. registration licence or other document for the establishment of legal entity;
2. a tax form stating that all taxes, fees and others claims by the State are settled;
3. expert statement on the environmental effect and human health hazards posed by the release in the form shown in Annex II, for research purposes and Annex III, for commercial purposes.

/3/ The risk assessment under item 3 of the previous paragraph is assigned by a notifier on his expense and is carried out by independent experts who:

1. are professionally competent;
2. declare that they do not have a personal interest in and profit of activities connected to the release and they have not participated in the working out of the plan for release;
3. declare that they will not make public or allow outside access to data entrusted to them.

Article 10./1/ The Council passes its decision within one month.

/2/ The Council has the right to ask notifiers to complement or specify data given in Annex II or Annex III.

/3/ The period under Paragraph 1 is extended with the time necessary for the notifier to submit the additional information required by the Council.

Article 11./1/ The applications are put forward by a Council member or a consulting expert appointed by the Chairman. The speaker presents a written expert opinion on the quality of risk assessment appended to the application.

/2/ The Council passes a decision about:

1. issuing a licence for release;
2. complementing and specifying the data under Article 10, Paragraph 2;
3. extending the period of release;

4. motivated rejection of the application for release.

Article 12./1/ Based on decisions under Article 11, Paragraph 2, items 1 and 3 the Council issues licences for release with a research or commercial purpose that contain data about:

1. the notifiers in whose behalf the licence is issued;
2. species and name of GMP;
3. amount of seed or planting material;
4. purpose of release (research or commercial);
5. geographic region of release;
6. area of release;
7. period of release;
8. circumstances of release.

/2/ The Council may consider an application for release of one and the same GMP with the same purpose not earlier than one year since the previous application as of the date of rejection under Article 11, Paragraph 2, 4.

Article 13. /1/ The notifier shall submit to the Council the complete information at his disposal including also the release of identical GMPs outside the territory of the Republic of Bulgaria;

/2/ The person in whose behalf the licence for release of GMPs is issued shall:

1. immediately advise the Council in case of ascertaining any deviation from the accepted risk assessment under Article 11 during the period of permitted release of GMPs;
2. provide the controlling bodies with access to the GMPs during the period of their permitted release;
3. provide written information to buyers and users on delivery of GMPs and write it out in Bulgarian language on the GMP packing;
4. provide the Council with the preliminary and final reports of results for each case of release within one month after flowering and after

expiration of the GMP licensing period. The Council gives instructions on the obligatory contents of the report.

## Chapter Four

### Responsibilities

Article 14. Persons who have committed contamination and damages to the environment through release of GMPs are responsible under the Environmental Protection Law, Chapter Six.

Article 15. /1/ Infringers of these regulations who release GMPs without a licence or in digression from the issued licence are fined if they are not liable to a greater penalty and the plants and crops are taken away from them in favour of the state. The confiscated plants and crops are destroyed by the controlling bodies.

/2/ Infringement ascertaining acts under the previous paragraph are issued by the body under Article 2 and the ordinances for penalty are issued by the Minister of Agriculture and Food-processing Industry or persons empowered by him.

## Chapter Five

### ADDITIONAL PROVISIONS

N 1. /1/ "Higher plants" are plants species of divisions Gymnospermae and Angiospermae.

/2/ "Genetically modified higher plants" are plants in which the genetic material has been modified in a way that does not occur in Nature and/or is not a result of natural recombination and on which the following have been applied:

1. recombinant DNA techniques with a creation of new genetic material outside the plant;

2. molecular techniques for transfer and insertion of new genetic material in the plant through vector systems constructed on the basis of bacterial plasmids as well as direct transfer through osmosis, micro-injection, micro capsules and micro-bombardment.

/3/ BY THE MEANING OF THESE REGULATIONS, plants that are not genetically modified are such obtained by application of the following methods and techniques:

1. tissue cultures, embryo cultures, in vitro insemination, haploids, cell mutagenesis and selection, somaclonal variation and somatic hybridisation;

2. conjugation, transduction and transformation or any other natural process occurring in the natural plant development;

3. induction of polyploids, sexual crossings and selection, intra- and inter-specific hybridisation and experimental mutagenesis in vivo.

/4/ "Release of GMPs" is a deliberate release into the environment of genetically modified higher plants or a combination of genetically modified higher plants without restraining of their spread by material barriers or a combination of material barriers and chemical and/or biological barriers used for restricting the contact of genetically modified higher plants with the human population and the environment.

/5/ "Commercial release of GMPs" is production AND TRADE WITH PLANT PRODUCTS CONTAINING GMPs and trade with GMP seeds and planting material (reproductive material).

## Chapter Six

### TRANSIENT AND FINAL PROVISIONS

N 2. These regulations are issued by virtue of Article 20 of the Law for Seeds and Planting Material (published, J. Presidium Natl. Assembly, issue 13 of 1958; amended, State J., issue 99 of 1963 and issue 36 of 1979; supplemented, State J., issue 103 of 1990) and Article 21, 1, 8 and 10 of the Decree of the Council of Ministers No. 131 on defining the structure and principal activities of the Ministry of Agriculture and Food-Processing Industry (published, State J., issue 59 of 1992; amended, State J., issues 11, 57, 95 and 107 of 1993, issues 34 and 74 of 1994 and issue 11 of 1995).

N 3. It is recommended that the Chairman of Agricultural Academy puts forward the proposal under Article 2, Paragraph 2 within one month of coming of these regulations into effect.

N 4. These regulations do not rescind the regulations for co-ordination and licensing of activities and projects related to the release of GMPs provisioned by other legal acts.

Annexes to these regulations will be published in official bulletins of the Ministry of Agriculture and Food-Processing Industry.

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