REPUBLIC OF TAJIKISTAN

LAW
on Biological Safety

Chapter I. General provisions

Article 1. Objective

The Law regulating the activity related to the development, production, testing, export and release at the market and in the environment the genetically modified organisms, is aimed at ceasing the risk of negative impact of genetically modified organisms on human health, biological diversity, ecological balance and the environment state.

Article 2. Main terms

Law includes the following main terms:

Organism – any kind of biological formation able to transfer or replicate genetic material;

Genetically modified organism – is presented by any organism with exception of human one, with genetic material being changed by the method varying from cross breeding and/or natural recombination;

Microorganism – is any microbe, cellular or non-cellular formation able to reproduce, transfer or replicate genetic material;

Modern biotechnology – is an application of methods of recombination of nucleic acids and methods of cells fusion varying from methods of selection and traditional improvement, which remove natural physiological barriers of reproduction or genetic recombination;

Use of genetically modified organisms – activity aimed at production and release at the market of genetically modified organisms and its products, including investigation, testing and industrial production;

Contained use – any procedure changing microorganisms/organisms at genetic level or cultivating, reproducing, storing, using, transporting, destroying and/or neutralizing genetically modified organisms, carrying at isolated, self-contained spaces or environments to limit or exclude their contact with people and environment;

User – a person responsible for the activity related to production, testing and commercialization of genetically modified organisms in terms of contained and non-contained use, as well as production, testing and commercialization of their products;

Deliberate release into the environment – deliberate release of genetically modified organisms and their combinations into the environment, requiring no specific isolation measures and safe for people and the environment;

Non-deliberate release into the environment – any case of release of genetically modified organisms and their combinations not resulting from deliberate release;

Release at the market – supply of genetically modified organisms or their products to a third party subject to payment or free of charge;

Accident – incident causing a considerable non-deliberate release into the environment of genetically modified organisms in the process of their contained use having immediate or distant impacts on human health and the environment;

GM-products – a product consisting of one genetically modified organism or a combination of such organisms released at the market;

Processed product – a product received by processing of genetically modified organisms, some parts or some metabolites and substances produced by them;

Refined product – a product received from genetically modified organisms by way of processing including depuration (e.g. insulin, various enzymes, oils, etc.);

Field testing – experiment studying genetically modified organisms on fields if sure that these organisms will not remain in the environment after completion of the experiment;

Culture, field production, territory spreading – deliberate release into the environment a genetically modified organism with the purpose of its cultivation, production or reproduction having no experimental character or purpose any more;

Risk assessment – assessment of direct or non direct immediate or distant impacts of the release of genetically modified organisms into the environment for human health and environment itself;

Risk management – development and application of activities on risk monitoring as well as actions taken in case of accident;

Transboundary movement of genetically modified organisms – any movement of genetically modified organisms or their combinations and products from the territory of one country to the territory of another one;

Deliberate transboundary movement – any export-import procedure with genetically modified organisms or their combinations carried out with permission of competent national authorities in accordance with national and international regulations;

Non-deliberate transboundary movement – any non-deliberate movement of genetically modified organisms through the border with consequences to be assessed from biological safety point of view, as well as safety for human health taking relevant measures;

Importer – physical or juridical person under the jurisdiction of state carrying and responsible for import of genetically modified organisms, their combinations or products;

Exporter – physical or juridical person under the jurisdiction of state carrying and responsible for export of genetically modified organisms, their combinations or products;

Notification – a paper notifying the National Biosafety Commission on the activity to be carried out to receive permission;

Area of genetic safety – the territory where any activity related to the use of genetically modified organisms is prohibited;

Genetic material – materials produced by genetic method separately or as a result of combinations of several organisms by way of genetic changes;

Genetic engineering – activity changing fructiferous composition of organisms by new biotechnological method and creating qualitative new organisms.

Article 3. Legislation of the Republic of Tajikistan on biological safety

Legislation of the Republic of Tajikistan on biological safety is based on the Constitution (main legal document) of the Republic of Tajikistan, consists of the present Law, other regulation documents, as well as international legal documents admitted by the Republic of Tajikistan.

Article 4. Activity related to biological safety

The present Law is focused on the activity related to:

- production, reproduction, import, export, testing in contained use of microorganisms, plants and animals, genetically modified with application of modern biotechnology;
- deliberate release of living modified organisms into the environment and at the market with application of modern biotechnology including any living organisms able to reproduce, that is

seeds, cuttings, pollen, tubers, spores, etc.;

- non-deliberate release of genetically modified organisms into the environment;
- deliberate release into the environment and at the market of the processed products containing genetically modified organisms and/or processed or non-processed non-living components of living genetically modified organisms;
- any type of survey of genetically modified organisms including laboratory, clinic, field and production testing;
- non-deliberate or illegal transboundary movement of genetically modified organisms;
- storage, burial, elimination of genetically modified organisms and/or their products, waste utilization being the result of modern biotechnology methods.
- activity on deliberate import and export of genetically modified organisms and their products.

The present Law shall not apply to:

a) organisms produced by genetic engineering, considered by the Regulation on permission and licensing of activities related to producing, testing, using and commercialization of genetically modified organisms (further Regulation); processed products including pharmaceuticals for humans and animals,

b) transportation activity not depending on the way of transportation, as well as procedures on import/export regulated by other legal agreements of the Republic of Tajikistan.

Article 5. Key requirement for identifying risk level

Depending on the degree of potential threat for human health and environment arising from activities regulated by the Law, the following risk levels are established:

- level I – relates to the activity with genetically modified microorganisms having small risk level compared with risk of use of non-pathogenic microorganisms, or with no risk;
- level II – relates to the activity with genetically modified microorganisms having low risk level compared with risk of use of relatively pathogenic microorganisms;
- level III – relates to the activity with genetically modified microorganisms having medium risk level compared with risk of use of microorganisms potentially able to spread infections;
- level IV – relates to the activity with genetically modified microorganisms having high risk level compared with risk of use of microorganisms able to spread dangerous infections.

A wide-scale activity carrying with genetically modified microorganisms in contained systems in volumes out of laboratory tests, and carrying in non-contained systems relates to risk levels III and IV.

Article 6. Licensing of biological safety activity

License on activities regulated by the Law is issued by special authorized state institution on biological safety.

The following persons are allowed to activities regulated by the Law:

- persons with health state and professional training providing safety of the activity in this field;
- juridical persons having placement, equipment and labor able to provide activity in safe conditions for human health and the environment.

Juridical persons implementing the activity related to risk levels III and IV receive the permission for the activity only under the license issued in accordance with legislation of the Republic of Tajikistan.

Order and conditions of licensing, list of activities for which license is issuing are compulsory, are identified in the order stipulated by legal documents of the Republic of Tajikistan.

Chapter II. State management on biological safety

Article 7. Competence of Government of the Republic of Tajikistan in regulation the relations to provide biosafety

- establishment of state policies on biological safety, financing and technical supply of the activities in this area;
- coordination of the activity of ministries, institutions and local state authorities on biosafety issues;
- establishment of special authorized state institution to provide biosafety;
- policy focusing on biodiversity conservation and ensuring biosafety in the country;
- other functions in accordance with legislation of the Republic of Tajikistan.

Article 8. National Competent Authority on biosafety

It organizes the activity on biosafety and is in charge of:

- realization of a single state policy on ecological safety;
- regulation and coordination of the activity on realization of National Biodiversity Strategy and Action Plan;
- development of projects and activity on biodiversity conservation and biosafety issues;
- development of national nature conservation reports, ecological passports, projects, etc.;
- identifying biological resources storage;
- development and implementation of international projects and coordination activity with international organizations;
- other functions in accordance with legislation of the Republic of Tajikistan.

Chapter III. Contained use of genetically modified microorganisms/organisms

Article 9. Organizing of activity and risk assessment in contained use

Before starting the activity on the contained use of genetically modified microorganisms (organisms) and obtaining license for carrying such kind of activity, a user has to carry out the risk assessment on the point of threat to human health and environment referring it to one of the risk levels noted in Article 5, Part 1, and then submit notification with information to the National Commission.

Assessment should consider the aspects relating to waste utilization and taking required measures for protection of human health and environment.

Assessment and the protection measures noted in Part 1 of this Article, have to be periodically reviewed, as well as in case if:

- there exists an evidence that the assessment is not proper, therefore the updated information of research and technical surveys are taken into account; or
- isolation measures taken became inadequate or the established risk level of contained use has changed.

Article 10. Confidential information on the genetically modified microorganisms/organisms

In the Notification sent to the National Commission an Applicant can note information as confidential basing on the facts.

Decision on the acknowledgement of confidential information is made by the National Commission

after consultations with an Applicant who is informed on the decision made.

The following information is not considered as confidential:

- general characteristics of genetically modified microorganisms/organisms, name and address of an Applicant, purpose and place of use;
- risk level relating to the activity on the contained use of genetically modified microorganisms/organisms and actions on their isolation;
- summary provided as a result of investigation the risk assessment for human health and the environment;
- methods and plans of monitoring as well as measures taken in case of accident.

The National Commission shall protect any information considered as confidential, particularly with respect to intellectual property rights.

In case of recalling the Notification by an Applicant, the National Commission has to keep confidentiality of the information received.

Article 11. Testing before the contained use of genetically modified microorganisms/organisms

Before the contained use of genetically modified microorganisms/organisms the National Commission provides testing on the issues:

- if the operational plan is developed for the contained use in case when the ineffectiveness of the isolation actions may have immediate or distant consequences for human health and/or the environment.
- if the information submitted concerning operational plans, including security measures for the institutions to prevent an accident. The information has to be actual and open to the public.

The National Commission submits information to the relevant competent authorities of other countries, stipulated in Part 1 of this Article according to the international regulations in this area.

Article 12. Notification on providing biological safety

On receiving the updated information or in case of change the terms of contained use having serious impacts from the point of possible risks, the user has to inform immediately the National Commission and change the notification.

If upon the receiving of the permission the National Commission will be informed that the contained use may have negative impacts on human health and the environment, it has to request the user the change of terms of use and in case the request ignoring, suspend or ban the activity.

Article 13. User's responsibilities in case of accident

In case of accident the user has to inform immediately the National Commission and submit:

- information on the terms of the accident;
- information on the type and number of used genetically modified microorganisms/organisms;
- any information required for the assessment of the accident's impact on human health and the environment;
- information on the measures taken.

In case of accident the National Commission:

- informs immediately the public, having assessed the degree of risk for human health and the environment;
- makes full assessment of the accident and if required provides recommendations on further prevention of such accidents and elimination of the accidents possible impacts;

- takes required measures, informs competent authorities which may be impacted by such accidents.

Chapter IV. Deliberate release of genetically modified organisms into the environment

Article 14. The process of release of genetically modified organisms into the environment

Any physical or juridical person before release of genetically modified organisms or their combinations into the environment for the purpose of investigation, testing, development and/or other purposes, with exception of production for release at the market, has to submit a Notification to the National Commission.

The Notification comprises:

- technical record with the information stipulated in the Regulation, required for the assessment of foreseeable risks, being immediate or distant, which may come from genetically modified organisms or their combination and their impact for human health and/or the environment;
- assessment of risk impacts for human health and/or the environment caused by release of genetically modified organisms into the environment.
- information obtained by an Applicant at the territory of the Republic of Tajikistan and/or outside, on the results of introduction of genetically modified organisms or their combination, being notified on earlier or at once.

The National Commission can allow the release of the combination of genetically modified organisms into the environment on the point identified, or a particular genetically modified organism at various points, which is attached by one notification with one purpose.

On further release of the same genetically modified organism or same combination, notified earlier as a part of the investigation program, an Applicant has to submit a new notification comprising the information from prior notifications and/or information of the registered results of prior release.

In case of change the terms of deliberate release causing possible impact on human health and/or the environment or revealing the updated information and risks an Applicant is committed:

- revise the measures stipulated in the notification;
- inform the National Commission on this issue;
- take required actions for protection of human health and the environment;

If the information on possible impacts of the release of genetically modified organism into the environment became popular after receiving a relevant permission by the user, the National Commission has to request the change of the release terms. In case of ignoring the request the National Commission suspends or prohibits such activity.

Article 15. Proceedings

An Applicant can launch the activity only after the permission issued by the National Commission and following all the terms stipulated by it, including identification of the area of genetic safety. Nature protected areas (reserves, site management areas, national parks and botanical gardens) are free from use and spread of genetically modified organisms, being genetically safe area.

If the National Commission considers there is enough experience for the release of the relevant genetically modified organisms into the environment, then considering the criteria stipulated in the Regulation it can allow the simplified release procedure.

Permission for deliberate release of genetically modified plants into the environment issued by the National Commission, is needed for sorts registration when testing on agronomic and technological value carried by the State Committee on plants sorts testing for their production in the Republic of Tajikistan.

All sorts produced from genetically modified organisms corresponding to the terms of testing on agronomic and technological value, are listed in the Register of plants sorts of the Republic of Tajikistan.

Chapter V. Release of genetically modified organisms and their products at the market

Article 16. The process of release of genetically modified organisms and their products at the market

Release of genetically modified organisms and their products at the market is carried only on the basis of permission issued by the National Commission according to the regulations of Chapter IV.

If the activity on the release of genetically modified organisms and their products at the market includes import/export, it is covered by the articles 18-24.

The permission stipulated at Part 1 is issued only if:

- the organisms and products noted correspond to the regulations of the national legislation;
- their correspondence to the requirements related to risk assessment for human health and the environment.

Article 17. Notification on the first release of genetically modified organisms at the market

Before the first release of genetically modified organisms at the market the developer or importer submits a Notification to the National Commission comprising:

- information envisaged in the Regulation containing also the data obtained by the user in the process of investigation, testing and development carried according to the regulations of Chapter IV;
- risk assessment for human health and the environment;
- terms of the release of the product at the market including special conditions of use and handling as well as recommendations on packaging, labeling and marking.

If on the basis of the results of any release of genetically modified organisms into the environment notified earlier and with the permission obtained according to the regulations of the present Law, or on the basis of the survey results an Applicant concluded that release at the market and use of the product have no any risk for human health and/or the environment, he/she may request in the Notification of a simplified procedure of the permission in relation to him/her.

The Applicant includes information into the Notification, received as a result of the release of the same genetically modified organisms or their combinations into the environment, notified earlier or which he carried earlier on the territory of the Republic of Tajikistan or outside.

Notification is submitted separately for each new product containing same genetically modified organisms or same combination but oriented for other use.

Chapter VI. Import and export of genetically modified organisms or their products

Article 18. Main activity on import/export of genetically modified organisms and/or their products

Activity on import/export of genetically modified organisms and/or products can be carried in case of the fulfillment of terms of the notification and terms of the permission envisaged by the Articles 20 and 21, or if special requirements concerning notification, agreement and permission stipulated by the international legal documents are acknowledged by the Republic of Tajikistan.

Activity on import/export has to meet the following requirements:

- applying of the procedure of advanced informed agreement according to the Article 19 by the National Commission;
- risk assessment in accordance with regulations of the Article 23;
- meet the requirements on packaging, labeling, transportation and handling;
- providing exchange of information;
- confidentiality and enforcement of the intellectual property rights;
- prevention of illegal carriage, non-deliberate transboundary movement and providing adequate measures in case of accidents.

Article 19. Advanced informed agreement procedure

Advanced informed agreement procedure includes:

- identification of the activities upon which the procedure is applied;
- notification on import/export;
- permission of the activity on import/export;
- revise, if required, the decision made earlier by the National Commission.

Advanced informed agreement procedure covers the activity on import/export of genetically modified organisms or their products, carried with a purpose of:

- contained use on the country's area;
- field tests on the country's area;
- deliberate release of genetically modified organisms into the environment.

Article 20. Notification for the National Commission

Importers before importing the genetically modified organisms and/or their products have to notify the National Commission in written format.

The National Commission provides procedure of the notification and informs the stakeholders.

An Applicant is responsible for the information validity that is submitted to the National Commission upon its request.

The National Commission in 90 days from the date of receiving notification provides written approval on its receiving for an Applicant.

Article 21. Decision of the National Commission on the import permission

Decision of the National Commission on the import permission is based on the regulations of Article 18, in particular, on the risk assessment information.

The National Commission in the term stipulated in Chapter 4 Article 20, has to inform an Applicant on the issues:

- import is carried without issuing permission noting the terms of its carrying, or
- import is carried only with the permission issued by the National Commission.

In 90 days the National Commission after receiving confirmation on the notification, makes one of the decisions:

- allow the import with terms or without, noting how they apply for further import of the same genetically modified organism or its products;
- prohibit import;
- require additional information according to the Regulation;
- prolong the term of decision making for the period of the evaluation of additional information obtained from an Applicant or other sources;

Article 22. Reconsideration or review of the National Commission's decision

The National Commission can reconsider the decision made according to Article 21 and change it basing on the updated research information on possible affect of a product on human health and/or the environment. In such cases the National Commission informs immediately an Applicant on its decision and on the reasons of rejection or change.

Applicant may request the review of the decision by the National Commission, made according to Article 20, by submitting the notification, if considers that:

- the circumstances changed, which identified the results of risk assessment being the base of decision making;
- he/she has additional technical and research information or there is evidence that the decision was not scientifically confirmed.

The National Commission has to make a decision on the notification according to the regulations in Part 2 and inform an Applicant of this.

Article 23. Risk assessment

Risk assessment has to be carried on scientific principles and transparence taking into account the requirements of the Regulation and applying relevant methods of risk assessment. The assessment goal is revealing and identifying the negative impact of genetically modified organisms or their products on human health and the environment considering social-economic status.

The National Commission makes a decision which competent authorities or research institutions will carry the risk assessment.

The National Commission has to confirm the risk assessment implementation, being the basis of decision making according to Article 21.

The National Commission is responsible for carrying the risk assessment relating to microorganisms and sometimes other genetically modified organisms in contained use.

Financial expenditures on risk assessment are covered by an Applicant.

Article 24. Packaging and movement of the genetically modified organisms

Importer before carrying import has to confirm that the exporter of genetically modified organisms and/or their products provides:

- packaging, identification, labeling and transportation at the level of such arrangements on the part of export;
- implementing of other terms envisaged by the present Law.

Importer has to provide the relation of the documentation accompanied to the requirements of the national and international legislation on transboundary movement of genetically modified organisms and their products.

Article 25. Actions in case of illegal transportation of the genetically modified organisms

In case of illegal transportation of the genetically modified organisms a special authorized state institution on biological safety has to request from the country-exporter their repatriation or elimination on its own account according to the regulations of international legislation, admitted by the Republic of Tajikistan.

Competent international institutions are informed of the illegal transportation of genetically modified organisms according to the procedures stipulated by international legislation in this area.

In case of non-deliberate transboundary movement of genetically modified organisms and/or their products a special authorized state institution on biological safety provides notification stipulated in the

international legislation as well measures to exclude any risks for human health and the environment.

The National Commission informs the public on preventing situations while carrying non-deliberate transboundary movement of genetically modified organisms and/or their products.

Article 26. Public awareness of the import of genetically modified organisms

Permission procedure of the deliberate release of genetically modified organisms and/or their products into the environment and at the market is opened to the public. National Commission provides transparency of the activity for which the permission is inquired.

In 10-days term from the date of receiving the notification the National Commission has to inform the public providing the source of information.

The public comments are received during 30 days from the date of informing and considered by the National Commission in decision making on the activity permission. Public discussions of any aspects of the issue will be organized depending on the comments received.

The National Commission provides public participation in decision making on allowing the activity regulated by the present Law according to the regulations of national and international legislation admitted by the Republic of Tajikistan.

Chapter VII. Final provisions

Article 27. Order of settlement the disputes on biological safety issues

Disputes on biological safety issues and the related property debates are settled by legal proceedings.

Article 28. Liability for the present Law violation

Physical and juridical persons are liable for violation of the present Law regulations according to the legislation of the Republic of Tajikistan.

Article 29. Order of acting of the present Law

The present Law will put into operation after its official publication.

President
Republic of Tajikistan **E.Rakhmonov**