PROJECT OF IMPLEMENTATION OF
NATIONAL BIOSAFETY FRAMEWORK FOR TURKEY

GUIDE ON APPLICATION PROCEDURES

REPUBLIC OF TURKEY
MINISTRY OF FOOD AGRICULTURE
AND LIVESTOCK

TAGEM
R&D AND INNOVATION

GEF

UNEP

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FOREWORD

In an effort to protect the environment and biodiversity against the potential risks of genetically modified organisms, the Cartagena Protocol on Biosafety -the first international document that is of a binding nature in this area- took effect around the world on 11 September 2003 and in Turkey on 24 January 2004. The protocol seeks to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, also considering its risks to human health, and specifically focusing on transboundary movements.

The Biosafety Law, which was prepared by taking the Cartagena Protocol, the EU Acquis, the situation and needs of the country into consideration, was approved by the Turkish Grand National Assembly on 18 March 2010, published in the Official Gazette no. 27533 of 26 March 2010 and entered into force on 26 September 2010. The Biosafety Law aims to establish and implement a biosafety system in order to prevent the potential risks of the genetically modified organisms and products thereof obtained through modern biotechnological means within the context of scientific and technological advancements and protect human, animal and plant health; safeguard and ensure the sustainable use of the environment and biological diversity and to determine the procedures and principles governing the control, regulation and monitoring of these activities.

Within the scope of the Biosafety Law the "Regulation on the Genetically Modified Organisms and Their Products" and the "Working Principles and Procedures of the Biosafety Board and Committees" were published on the Official Gazette No. 27671 of 13 August 2010.

In order to develop the capacity needed for ensuring biosafety within the scope of the national and international legislations, the project titled "Support for

the Implementation of the National Biosafety Framework of the Republic of Turkey" was prepared and accepted by the Global Environment Facility (GEF). The project was implemented between 2013 and 2017 under the coordination of the Directorate General of Agricultural Research and Polices (GDAR). Within the scope of the project, five guidelines were prepared by considering the works of national consultants and the contributions of the relevant partners obtained during the workshops, which were conducted at the preparation stages of some of the guidelines. The following guidelines have been developed: "Application Guideline", "Technical Guideline for the Risk Assessment of Genetically Engineering Crops and Derived Food And Feed", "Socio-economic Evaluation Criteria for the Decision-Making Process Regarding GMOs and Products", "Guidelines on Control and Traceability of Genetically Modified Organisms and Products" and "Legal Guideline".

Our General Directorate considers the works conducted for raising public awareness during the project, the documents prepared as outputs of the project and overall project experience significant gains. I hope that these guidelines, which were prepared within the scope of the project, will be useful. I also congratulate and thank everyone who contributed to the project, especially the UNEP-GEF Portfolio Manager (Biosafety) Alex Owusu-BINEY, Project Assistant Birgül GÜNER, Project team consisting of Hilal YÜCE ARSLAN, Ayfer ŞAHİN and Serdar AYDEMİR, national consultants Professor Emine OLHAN, Professor Mustafa Fadıl YILDIRIM, Associate Professor Remziye YILMAZ, Dr. Seval ÜNALAN and Fatih KAYA.

Dr. Yusuf ARSLAN
Project Coordinator

PROJECT OF IMPLEMENTATION OF NATIONAL BIOSAFETY FRAMEWORK FOR TURKEY

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Project executing organization	:	Ministry of Food, Agriculture and Livestock (MFAL), General Directorate of Agricultural Research and Policies (GDAR)
Cost of Project	:	1.292.650$
Cost to the GEF Trust Fund	:	542.650 $
Co-financing	:	750.000 $
Project Coordinator	:	Dr. Yusuf ARSLAN
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CHAPTER 1

INTRODUCTION

In an effort to protect the environment and biodiversity against the potential risks of genetically modified organisms, the Cartagena Protocol on Biosafety -the first international document that is of a binding nature in this area- took effect around the world on 11 September 2003 and in Turkey on 24 January 2004 (upon the Law No. 4898, and the Official Gazette No. 25148 of 24.06.2003).

Having also taken the initial steps for establishing a nation-wide biosafety system while the Protocol negotiations were under way, Turkey applied for the financial resources which can be the provided to the state parties by the Global Environment Facility (GEF) - the financial mechanism of the Agreement.

With a view to meeting the requirements of the Cartagena Protocol on Biosafety, and setting out the legislative, administrative and institutional system for ensuring biosafety on a national level, the GEF-funded "Project on the Development of the National Biosafety Framework" was implemented by the General Directorate of Agricultural Research between 2002 and 2005.

At the end of the project, the National Biosafety Frameworks (NBF), Draft Biosafety Law and an action plan for ensuring public awareness and participation were developed.

National Biosafety Frameworks are composed of;

- a legislative system,
- an administrative system,
- an institutional mechanism,
- a decision-making system that includes risk assessment and management,
- an inspection system that includes monitoring, determination and identification of LMOs
- a mechanism for public participation and information.

The primary output of the Project would be the "Draft Biosafety Law".

The Draft Biosafety Law was developed at the end of numerous meetings, workshops and surveys with the participation 99 experts from 55 different institutions and organizations including governmental agencies and bodies, universities, non-governmental organizations and professional organizations and as the product of the 6-month work by a commission 27 members selected from among specialists from this field by taking account of:

- the EU Acquis,
- Cartagena Protocol on Biosafety,
- Situation and needs of the country.

In an effort to develop the capacity needed for the National Biosafety Frameworks a country-wide project titled "Support for the Implementation of the National Biosafety Framework of the Republic of Turkey" was prepared and accepted by GEF. The project was implemented between 2013 and 2017 under the coordination of the Directorate General of Agricultural Research and Polices (GDAR).

The objective of the Biosafety Law is to establish and implement a biosafety system in order to prevent the potential risks of the genetically modified organisms and products thereof obtained through modern biotechnological means within the context of scientific and technological advancements; protect human, animal and plant health; safeguard and ensure the sustainable use of the environment and biological diversity and to determine the procedures and principles governing the control, regulation and monitoring of these activities.

Drawn up as pieces of secondary legislation under the Biosafety Law, the "Regulation on the Genetically Modified Organisms and Their Products" and the "Working Principles and Procedures of the Biosafety Board and Committees" were published on the Official Gazette No. 27671 of 13 August 2010.

Biosafety Law and regulations were carried into effect together on 26 September 2010.

The **"Biosafety Board"** has been formed to evaluate the applications regarding GMOs and products thereof, and to carry out the other duties indicated in the Biosafety Law and regulations.

The Board consists of a total of 9 members: four designated by the Ministry of Food, Agriculture and Livestock (at least one of the two members should be selected from among the candidates nominated by universities and one from among the ones nominated by professional organizations), one by the Ministry of Environment and Urbanization, one by the Ministry of Forestry and Water Affairs, one by the Ministry of Health, one from the Ministry of Science, Industry and Technology, and one by the Ministry of Economy. The secretarial functions of the Biosafety Board are performed by GDAR.

Based on an assessment by the Biosafety Board, a **List of Specialists** is being formed, which is compiled from among academics or experts working at the Scientific & Technological Research Council of Turkey as well as those who are working in areas deemed necessary by the Board, via the applications submitted to the Biosafety Information Exchange Mechanism of Turkey (BIEMT).

With a view to scientifically evaluating each application, **scientific committees** are being formed by the Board, where each of the members are selected from the list of specialists from different scientific fields, who are experts in their respective areas.

To make sure that each application is scientifically evaluated, the Biosafety Board is forming scientific committees by selecting eleven people from the list of specialists from different scientific fields, who are experts in their respective areas.

The application manual provides the information and documents requested as part of the applications for GMOs and products thereof.

We would like to thank GEF/UNEP for their support for the Project on the Implementation of the National Biosafety Framework of the Republic of Turkey, and extend our best regards to Ms. Alex-Owusu Biney, Regional Coordinator, Biosafety UNEP/GEF for her contributions throughout the project.

CHAPTER 2

APPLICATION, EVALUATION AND DECISION-MAKING

With a view to protecting human, animal and plant life and ensuring the protection and sustainable use of the environment and biological diversity; the importation, exportation, experimental release into the environment, placing on the market of GMOs and products thereof and contained use of genetically modified microorganisms are permitted in accordance with the results of scientific risk assessments.

Each application submitted under the Biosafety Law is separately subjected to a risk assessment and socio-economic evaluation based on scientific principles.

The evaluation process for the GMO applications submitted to the Biosafety Board is explained below:

Prior to the first importation of each GMO or product thereof, applications are submitted to the GDAR by the importer or the proprietor of the gene, or in the case of locally developed GMOs by a private or corporate person. Separate scientific committees are formed for the food, feed or other purposes of use decided by the applicant.

Received applications are conveyed to the Board by the GDAR.

The Board notifies the GDAR within ninety days whether the application is accepted or not, as well as whether it would be processed as a new application or addressed under the simplified procedure.

GDAR informs the applicant to this effect within fifteen days.

The Board's final decision time line starts upon the GDAR's notification to the applicant of the result of the initial evaluation. However, this period cannot exceed 270 days.

In the event that the submitted information is not deemed sufficient throughout the 90-day evaluation period and the 270-day final decision-making process, renewed experiments, tests, analyses and research works may be requested from the applicant by the Board or committees; therefore, time elapsed for the presentation of additional information and documentation does not count towards this period.

The 270-day final decision-making process of the Board:

Risk assessment and socio-economic evaluation committees are established by the Board in order evaluate the applications submitted for GMOs and products thereof.

Evaluation reports are drawn up by the risk assessment and socio-economic evaluation committees.

Evaluation reports are made public via the Biosafety Information Exchange Mechanism of Turkey (BIEMT) at "www.tbbdm.gov.tr" in an effort to make sure that the society becomes involved in the decision-making process. However, where the Board rules that the application would be addressed under simplified procedure, the evaluation reports by the committees are not made public. The only difference between the simplified procedure and new application process is that in one of the cases, the evaluation reports by the scientific committees are not made public.

The committees produce an evaluation report on the opinions presented during the public consultation.

Taking due account of the evaluation reports by the scientific committees, the opinions presented during the public consultation on the committee reports, the evaluation reports by the committees on the opinions of the public as well as the needs and priorities of the country, the Board presents its final Decision to the GDAR.

While making the final decision, the Board convenes in the presence of at least seven members and **the decisions are adopted by at least a majority vote of five.**

Where the decision is **favorable**, it is published on the Official Gazette. Decisions are valid for **ten years.**

In the event that the application is **refused**, the applicant is notified in writing by the GDAR. Should there be new information that may warrant a change of decision, the applicant may request for review of the decision within a period of sixty days. In this case, the Board makes its final decision considering the presented new information within 60 days (Figure-1)

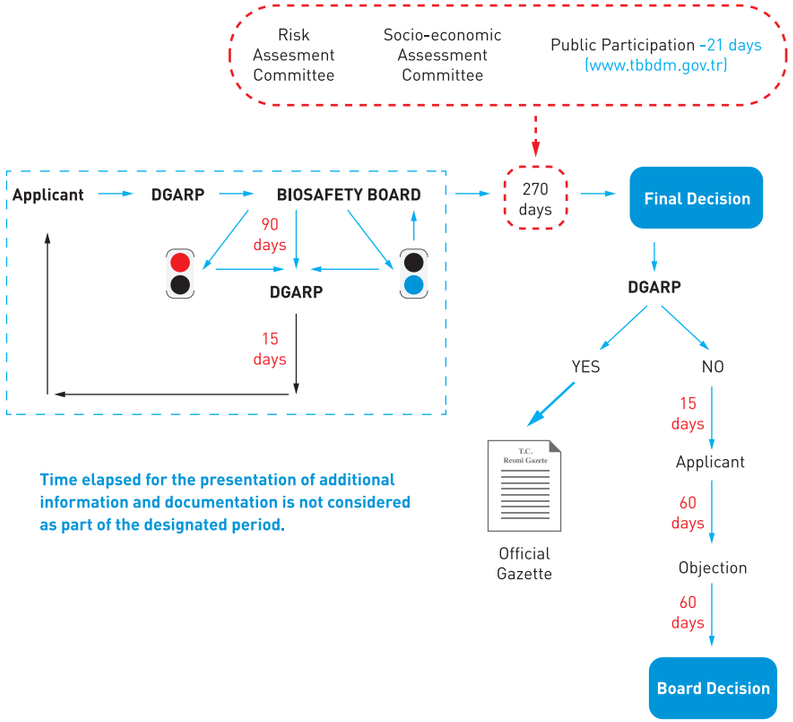

Figure 1 | **Application Evaluation Chart**

Decisions may be **revoked** by the Board, in the event of a breach of the conditions stated therein or emergence of new scientific information about any risks related to the GMO or product thereof.

The contents of a Board Decision are provided in Figure 2.

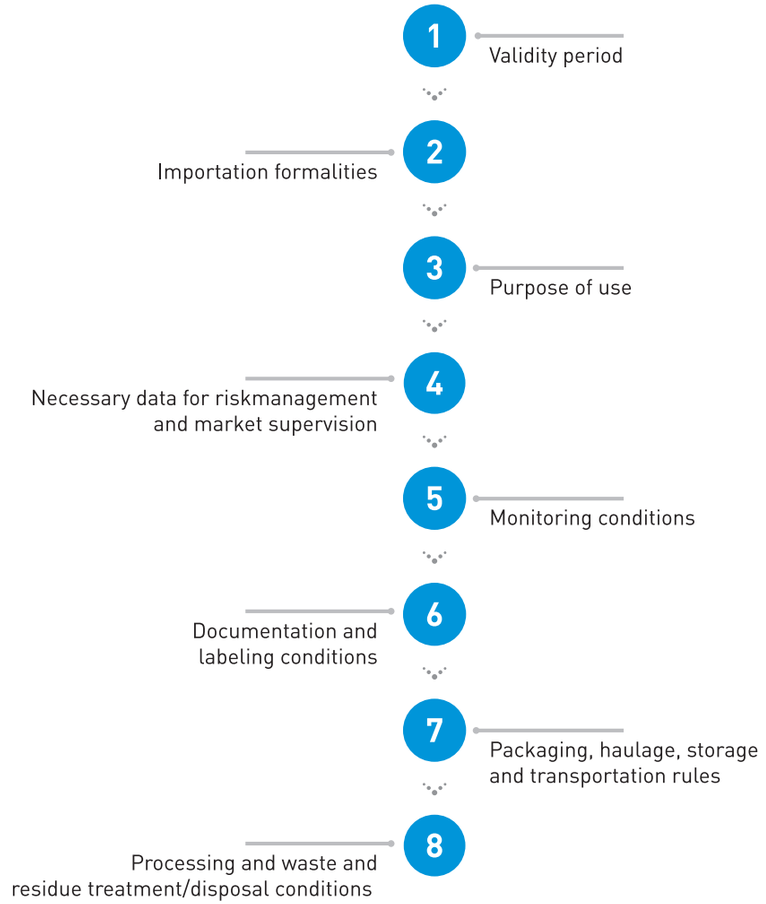

Figure 2 | **The contents of a Board Decision**

Application for the approval of GMO and products thereof will be **rejected** under the following conditions;

a) It threatens human, animal and plant health, the environment and biological diversity,
b) It undermines the freedom of choice of the producers and consumers,
c) It disrupts the ecological equilibrium of the environment and of the ecosystem,
ç) If there is a risk of GMO propagating itself or its characteristics in the environment,
d) It endangers the sustainability of biological diversity,
e) Where it is concluded that the applicant does not have sufficient technical capacity to implement the measures to ensure biosafety.

The applicant presents a letter of request stating those items of information to be kept confidential. Before deciding to fully or partially honor such request, the Ministry interactively exchanges information with applicant on the confidentiality request. Following this process, the Ministry takes the necessary measures and informs the applicant.

Name and address of the applicant or importer, purpose of use of the GMO or product thereof, their characteristics, unique identification data, common and scientific names, donor organism of the transferred gene, country of origin of the receptor and donor organisms, general description of the transfer method, all emergency procedures and plans and summary of the risk assessment cannot be considered as confidential.

The following acts regarding GMOs and products thereof are prohibited:

- Putting GMO and products thereof to the market without approval.
- Using or letting others use the GMOs and products thereof in breach of Board decisions.
- Producing genetically modified plants and animals.
- Using GMOs and products thereof beyond the purpose and area indicated by the Board in the placing on the market decision.
- Using GMOs and products thereof in baby food and baby formula, follow-on food and follow-on formula, baby and young children nutritional supplement.

The applications made are investigated according to their purposes under six main topics mentioned below. The information and documents requested for the applications of each purposes are presented between the third and eight chapters.

1. Application for placing on the market
2. Application for GMOs and products thereof developed locally
3. Application for experimental release
4. Application for contained use of genetically modified microorganisms (GMMOs)
5. Application for simplified procedure
6. Application with research and development purposes

CHAPTER 3

APPLICATION FOR PLACING ON THE MARKET

Applications are submitted to the DGARP prior to the first importation of GMOs or products thereof.

Information and documents required for submitting an application;

- Differential identification information,
- Request for purpose of use and limitations as well as information and documentation supporting this request,
- Information and documentation explaining the conditions of use and production in the country where the GMO and products thereof are developed,
- Information and documentation with regard to risk management,
- Haulage, storage and transportation conditions of the GMO and products thereof for which the application is submitted,
- Document showing that the GMO or product thereof is approved in the country where it is developed or registered for release into the environment, placing on the market for consumption and that such approval is currently valid, the production and consumption is continuing and it has been on the market for a certain length of time as indicated by the Ministry.

GENETICALLY MODIFIED ORGANISMS OTHER THAN PLANTS

I. BACKGROUND INFORMATION

A. Name and address of the applicant

B. Field of operation of the applicant

C. Names, qualifications and experiences of the people in charge

Ç. Organizational technical capacity of the applicant

D. Differential ID number

E. Intended purpose of the GMO

II. INFORMATION ON THE GMO:

A. Characteristic of the donor, recipient or parental organism(s):

1. Scientific name,
2. Taxonomy,
3. Other names (usual name, strain, name, etc.),
4. Phenotypic and genotypic markers,
5. Degree of relation between donor and recipient or between parental organisms,
6. Description of identification and detection techniques,
7. Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques,
8. Description of the geographic distribution and of the natural habitat of the organism including information on natural predators, prey, parasites and competitors symbionts and hosts,
9. Organisms with which transfer of genetic material is known to occur under natural conditions,

10. Verification of the genetic stability of the organisms and factors affecting it,
11. Pathological, ecological and physiological traits:
    a) Classification of hazard according to existing international rules concerning the protection of human and animal health as well as the environment and biological diversity;
    b) Generation tune in natural ecosystems, sexual or non-sexual reproductive cycle;
    c) Information on survival, including seasonability and the ability to form survival structures;
    ç) Pathogenicity: Infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). Ability to colonize other organisms;
    d) Antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;
    e) Involvement in environmental processes: Primary production, nutrient turnover, decomposition of organic matter, respiration etc.;
12. Nature of indigenous vectors:
    a) Sequence;
    b) Frequency of mobilization;
    c) Specificity;
    d) Presence of genes which confer resistance.
13. History of previous genetic modifications.

B. Characteristics of the vector

1. Nature and source of the vector;
2. Sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO;
3. Frequency of mobilization of inserted vector and/or genetic transfer capabilities and methods of determination;
4. Information on the degree to which the vector is limited to the DNA required to perform the intended function.

C. Characteristics of the modified organism

1. Information related to the genetic modification:
   a) Methods used for the modification,
   b) Methods used to construct and introduce the insert(s) into the recipient or to delete a sequence,
   c) Description of the insert and/or vector construction,
   ç) Purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function,
   d) Methods and criteria used for selection,
   e) Sequence, functional identity and location of the altered/inserted/deleted nucleic acid segments in question with particular reference to any known harmful sequence.
2. Information on the final GMO:
   a) Description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;
   b) Structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;
   c) Stability of the organism in terms of genetic traits;
   ç) Rate and level of expression of the new genetic material. Method and sensitivity of measurement;
   d) Activity of the expressed proteins;
   e) Description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and the vector;
   f) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
   g) History of previous releases or uses of the GMO
   ğ) Considerations for human health and animal health, as well as plant health:
      (i) Toxic or allergenic effects of the non-viable GMOs and/or their metabolic products;
      (ii) Comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
      (iii) Capacity for colonization;
      (iv) If the organism is pathogenic to humans who are immunocompetent:
         – diseases caused and mechanism of pathogenicity including invasiveness and virulence;
         – communicability;
         – infective dose;

- host range, possibility of alteration;
- possibility of survival outside of human host;
- presence of vectors or means of dissemination;
- biological stability;
- antibiotic-resistance patterns;
- allergenicity;
- availability of appropriate therapies;

(v) other product hazards.

IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOS AND THE ENVIRONMENT

A. Characteristics affecting survival, multiplication and dissemination

1. Biological features which affect survival, multiplication and dispersal;
2. Known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH etc.);
3. Sensitivity to specific agents.

B. Interactions with the environment

1. Predicted habitat of the GMOs;
2. Studies of the behavior and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses, animal houses etc. may also be of relevance to medicinal products;
3. Genetic transfer capability:
   a) Post-release transfer of genetic material from GMOs into organisms in affected ecosystems;
   b) Post-release transfer of genetic material from indigenous organisms to the GMOs;
4. Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the modified organism;
5. Measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimize dispersal of genetic material, and methods to verify genetic stability;
6. Known routes of biological dispersal or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact etc.;
7. Description of ecosystems to which the GMOs could be disseminated;
8. Potential for excessive population increase in the environment;
9. Competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s);
10. Identification and description of the target organisms if applicable;
11. Anticipated mechanism and result of interaction between the released GMOs and the target organism if applicable;
12. Identification and description of non-target organisms which may be adversely affected by the release of the GMO, and the anticipated mechanism of any identified adverse reactions;
13. Likelihood of post-release shifts in biological interactions or in host range;
14. Known or predicted interactions with non-target organisms in the environment including competitors, preys, hosts, symbionts, predators, parasites and pathogens;
15. Involvement in biogeochemical processes;
16. Other possible interactions with the environment

V. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

A. Monitoring Techniques

1. Methods for tracing the GMOs, and for monitoring their effects;
2. Specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques;
3. Techniques for detecting transfer of the donated genetic material to other organisms;
4. Duration and frequency of monitoring.

B. Control of the Release

1. Methods and procedures to avoid and/or minimize the spread of the GMOs beyond the site of the release or the designated areas of use;
2. Methods and procedures to protect the site from intrusion by unauthorized individuals;
3. Methods and procedures to prevent other organisms from entering the site.

C. Waste treatment

1. Type of waste generated;
2. Expected amount of waste;
3. Description of treatment envisaged.

Ç. Emergency response plans

1. Methods and procedures for controlling the GMOs in case of unexpected spread;
2. Methods for decontamination of the areas, e.g. eradication of the GMOs;

3. Methods for disposal or sanitation of plants, animals, soils, etc., that were exposed to the GMO during or after its uncontrolled spread;
4. Methods for the isolation of the area affected by the uncontrolled spread of GMOs;
5. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

EXPERIMENTAL RELEASE OF GENETICALLY MODIFIED PLANTS (GMHP)

I. BACKGROUND INFORMATION

A. Name and address of the applicant
B. Field of operation of the applicant
C. Names, qualifications and experiences of the people in charge
Ç. Organizational technical capacity of the applicant
D. Differential ID number
E. Intended purpose of the GMHP

II. A. INFORMATION RELATING TO THE RECIPIENT AND/OR PARENTAL PLANTS

1. Full name:
   a) Family,
   b) Genus,
   c) Species,
   ç) Subspecies,
   d) Cultivar/breeding line,
   e) Common name of the plant.

2. Reproduction of the plant:
   a) Description of the reproduction modes,
   b) Specific factors affecting reproduction, if any,
   c) Generation time.
3. Survivability of the plant:
   a) Ability to form structures for survival or dormancy
   b) Factors affecting survivability
4. Dissemination of the plant:
   a) Ways and extent of dissemination (for example an estimation of how viable pollen and/or seeds declines with distance)
   b) Factors affecting dissemination.
5. Geographic distribution of the plant.
6. Description of the natural habitat and of the environmental conditions in which the plant lives in nature, if it grows in the Republic of Turkey, including information on natural pests, parasites, competitors and symbionts.
7. Other possibly important interactions of the plant with the organisms in the ecosystem where it usually grows or elsewhere including information about toxic effects on humans, animals and other organisms.

B. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification
2. Nature and source of the vector used.
3. Size, source (name of donor organism(s) and intended function of each constituent fragment of the region intended for insertion.

C. INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

1. Description of the trait(s) and characteristics which have been introduced or modified.
2. Information on the sequences actually inserted/deleted
   a) size and structure of the insert and methods used for its characterization, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP;
   b) in case of deletion, size and function of the deleted region(s);
   c) copy number of the insert;
   ç) location of the insert in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination.
3. Information on the expression of the insert:
   a) Information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterization;
   b) Parts of the plant where the insert is expressed (e.g. roots, stem, pollen etc.).
4. Information on how the genetically modified plant differs from the recipient plant in:
   a) mode(s) and/or rate of reproduction,
   b) dissemination,
   c) survivability.
5. Genetic stability of the insert and phenotypic stability of the GMHP.
6. Any change to the ability of the GMHP to transfer genetic material to other organisms
7. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.

8. Information on the safety of the GMHP to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the GMHP is intended to be used in animal feedstuffs.
9. Mechanism of interaction between the genetically modified plant and target organisms.
10. Potential changes in the interactions of the GMHPs with non-target organisms resulting from the genetic modification.
11. Potential interactions of the GMHPs with the abiotic environment.
12. Description of detection and identification techniques for the GMHPs.
13. Information about previous releases of the GMHPs.

E. INFORMATION ON CONTROL, MONITORING, POST-RELEASE AND WASTE HANDLING PLANS

1. All precaution measures: Any measures to minimize/prevent dispersal of any reproductive organ of the GMHP (for example pollen, seeds, tuber).
2. Description of methods for post-release treatment of the site.
3. Description of post-release treatment methods for the genetically modified plant material including wastes.
4. Description of monitoring plans and techniques of the released GMHPs
5. Description of all emergency plans.
6. Methods and procedures to protect the site.

- Other information and documentation to be announced by the Board,
- Bank receipt indicating that the application fee has been paid (Application fees are announced every January on the website of Biosafety Information Exchange Mechanism of Turkey (www.tbbdm.gov.tr).)

CHAPTER 4

APPLICATION FOR GMOS AND PRODUCTS THEREOF DEVELOPED LOCALLY

Before GMOs and products thereof developed locally are placed on the market, an application is submitted to the Ministry.

Information and documents required for submitting an application;

- Differential identification information,
- Request for purpose of use and limitations as well as information and documentation supporting this request,
- Information and documentation with regard to risk management,
- Haulage, storage and transportation conditions of the GMO and products thereof for which the application is submitted,

EXPERIMENTAL RELEASE OF GENETICALLY MODIFIED ORGANISMS OTHER THAN PLANTS

I. BACKGROUND INFORMATION

A. Name and address of the applicant
B. Field of operation of the applicant
C. Names, qualifications and experiences of the people in charge
Ç. Organizational technical capacity of the applicant
D. Differential ID number
E. Intended purpose of the GMO

II. INFORMATION ON THE GMO:

A. Characteristic of the donor, recipient or parental organism(s):

1. Scientific name,
2. Taxonomy,
3. Other names (usual name, strain, name, etc.),
4. Phenotypic and genotypic markers,
5. Degree of relation between donor and recipient or between parental organisms,
6. Description of identification and detection techniques,
7. Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques,
8. Description of the geographic distribution and of the natural habitat of the organism including information on natural predators, prey, parasites and competitors symbionts and hosts,
9. Organisms with which transfer of genetic material is known to occur under natural conditions,
10. Verification of the genetic stability of the organisms and factors affecting it,
11. Pathological, ecological and physiological traits:
    a) Classification of hazard according to existing international rules concerning the protection of human and animal health as well as the environment and biological diversity;
    b) Generation tune in natural ecosystems, sexual or non-sexual reproductive cycle;
    c) Information on survival, including seasonability and the ability to form survival structures;
    ç) Pathogenicity: Infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). Ability to colonize other organisms;
    d) Antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;
    e) Involvement in environmental processes: Primary production, nutrient turnover, decomposition of organic matter, respiration etc.;
12. Nature of indigenous vectors
    a) Sequence;
    b) Frequency of mobilization;
    c) Specificity;
    d) Presence of genes which confer resistance.
13. History of previous genetic modifications.

B. Characteristics of the vector

1. Nature and source of the vector;
2. Sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO;
3. Frequency of mobilization of inserted vector and/or genetic transfer capabilities and methods of determination;
4. Information on the degree to which the vector is limited to the DNA required to perform the intended function.

C. Characteristics of the modified organism

1. Information related to the genetic modification:
    a) Methods used for the modification,
    b) Methods used to construct and introduce the insert(s) into the recipient or to delete a sequence,
    c) Description of the insert and/or vector construction,

ç) Purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function,

d) Methods and criteria used for selection,

e) Sequence, functional identity and location of the altered/inserted/deleted nucleic acid segments in question with particular reference to any known harmful sequence.

2. Information on the final GMO:

a) Description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;

b) Structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;

c) Stability of the organism in terms of genetic traits;

ç) Rate and level of expression of the new genetic material. Method and sensitivity of measurement;

d) Activity of the expressed proteins;

e) Description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and the vector;

f) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;

g) History of previous releases or uses of the GMO;

ğ) Considerations for human health and animal health, as well as plant health:

(i) Toxic or allergenic effects of the non-viable GMOs and/or their metabolic products;

(ii) Comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

(iii) Capacity for colonization;

(iv) If the organism is pathogenic to humans who are immunocompetent:

- diseases caused and mechanism of pathogenicity including invasiveness and virulence;
- communicability;
- infective dose;
- host range, possibility of alteration;
- possibility of survival outside of human host;
- presence of vectors or means of dissemination;
- biological stability;
- antibiotic-resistance patterns;
- allergenicity;
- availability of appropriate therapies;

(v) other product hazards.

III. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOS AND THE ENVIRONMENT

A. Characteristics affecting survival, multiplication and dissemination

1. Biological features which affect survival, multiplication and dispersal;
2. Known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH etc.);
3. Sensitivity to specific agents.

B. Interactions with the environment

1. Predicted habitat of the GMOs;
2. Studies of the behavior and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses, animal houses etc. may also be of relevance to medicinal products;
3. Genetic transfer capability:
   a) Post-release transfer of genetic material from GMOs into organisms in affected ecosystems;
   b) Post-release transfer of genetic material from indigenous organisms to the GMOs;
4. Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the modified organism;
5. Measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimize dispersal of genetic material, and methods to verify genetic stability;
6. Known routes of biological dispersal or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact etc.;
7. Description of ecosystems to which the GMOs could be disseminated;
8. Potential for excessive population increase in the environment;
9. Competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s);
10. Identification and description of the target organisms if applicable;
11. Anticipated mechanism and result of interaction between the released GMOs and the target organism if applicable;
12. Identification and description of non-target organisms which may be adversely affected by the release of the GMO, and the anticipated mechanism of any identified adverse reactions;

13. Likelihood of post-release shifts in biological interactions or in host range;
14. Known or predicted interactions with non-target organisms in the environment including competitors, preys, hosts, symbionts, predators, parasites and pathogens;
15. Involvement in biogeochemical processes;
16. Other possible interactions with the environment

IV. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

A. Monitoring Techniques

1. Methods for tracing the GMOs, and for monitoring their effects;
2. Specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques;
3. Techniques for detecting transfer of the donated genetic material to other organisms;
4. Duration and frequency of monitoring.

B. Control of the Release

1. Methods and procedures to avoid and/or minimize the spread of the GMOs beyond the site of the release or the designated areas of use;
2. Methods and procedures to protect the site from intrusion by unauthorized individuals;
3. Methods and procedures to prevent other organisms from entering the site.

C. Waste treatment

1. Type of waste generated;
2. Expected amount of waste;
3. Description of treatment envisaged.

Ç. Emergency response plans

1. Methods and procedures for controlling the GMOs in case of unexpected spread;
2. Methods for decontamination of the areas, e.g. eradication of the GMOs;
3. Methods for disposal or sanitation of plants, animals, soils, etc., that were exposed to the GMO during or after its uncontrolled spread;
4. Methods for the isolation of the area affected by the uncontrolled spread of GMOs;
5. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

EXPERIMENTAL RELEASE OF GENETICALLY MODIFIED PLANTS (GMHP)

I. BACKGROUND INFORMATION

A. Name and address of the applicant
B. Field of operation of the applicant
C. Names, qualifications and experiences of the people in charge
Ç. Organizational technical capacity of the applicant
D. Differential ID number
E. Intended purpose of the GMHP

II. A. INFORMATION RELATING TO THE RECIPIENT AND/OR PARENTAL PLANTS

1. Full name:
   a) Family,
   b) Genus,
   c) Species,
   ç) Subspecies,
   d) Cultivar/breeding line,
   e) Common name of the plant.
2. Reproduction of the plant:
   a) Description of the reproduction modes,
   b) Specific factors affecting reproduction, if any,
   c) Generation time.
3. Survivability of the plant:
   a) Ability to form structures for survival or dormancy
   b) Factors affecting survivability
4. Dissemination of the plant:
   a) Ways and extent of dissemination (for example an estimation of how viable pollen and/or seeds declines with distance)
   b) Factors affecting dissemination.
5. Geographic distribution of the plant.
6. Description of the natural habitat and of the environmental conditions in which the plant lives in nature, if it grows in the Republic of Turkey, including information on natural pests, parasites, competitors and symbionts.
7. Other possibly important interactions of the plant with the organisms in the ecosystem where it usually grows or elsewhere including information about toxic effects on humans, animals and other organisms.

B. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification
2. Nature and source of the vector used.
3. Size, source (name of donor organism(s) and intended function of each constituent fragment of the region intended for insertion.

C. INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

1. Description of the trait(s) and characteristics which have been introduced or modified.
2. Information on the sequences actually inserted/deleted
   a) size and structure of the insert and methods used for its characterization, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP;
   b) in case of deletion, size and function of the deleted region(s);
   c) copy number of the insert;
   ç) location of the insert in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination.
3. Information on the expression of the insert:
   a) Information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterization;
   b) Parts of the plant where the insert is expressed (e.g. roots, stem, pollen etc.).
4. Information on how the genetically modified plant differs from the recipient plant in:
   a) mode(s) and/or rate of reproduction,
   b) dissemination,
   c) survivability.

5. Genetic stability of the insert and phenotypic stability of the GMHP.
6. Any change to the ability of the GMHP to transfer genetic material to other organisms
7. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.
8. Information on the safety of the GMHP to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the GMHP is intended to be used in animal feedstuffs.
9. Mechanism of interaction between the genetically modified plant and target organisms.
10. Potential changes in the interactions of the GMHPs with non-target organisms resulting from the genetic modification.
11. Potential interactions of the GMHPs with the abiotic environment.
12. Description of detection and identification techniques for the GMHPs.
13. Information about previous releases of the GMHPs.

Ç. INFORMATION ON CONTROL, MONITORING, POST-RELEASE AND WASTE HANDLING PLANS

1. All precaution measures: Any measures to minimize/prevent dispersal of any reproductive organ of the GMHP (for example pollen, seeds, tuber).
2. Description of methods for post-release treatment of the site.
3. Description of post-release treatment methods for the genetically modified plant material including wastes.
4. Description of monitoring plans and techniques of the released GMHPs
5. Description of all emergency plans.
6. Methods and procedures to protect the site.

- Other information and documentation to be announced by the Board,
- Bank receipt indicating that the application fee has been paid (Application fees are announced every January on the website of Biosafety Information Exchange Mechanism of Turkey (www.tbbdm.gov.tr).)

CHAPTER 5

APPLICATION FOR EXPERIMENTAL RELEASE

Experimental release applications are submitted to the GDAR. The application is communicated to the Board by GDAR.

The measures to be taken and the rules to be followed during open field, greenhouse and laboratory conditions and studies to be conducted within the scope of experimental release are defined by the Board. GMOs and products thereof to be imported in this context as well as those to be obtained at the end of experiments to be conducted cannot be traded. Experiments within the scope of experimental release are undertaken by the research institutes assigned by the Ministry. Where necessary, research institutes may collaborate with universities and the Scientific & Technological Research Council of Turkey on condition that the permission of the Ministry has been asked. Principles and procedures regarding the experiments are defined by the Board.

Information and documents required for submitting an application;

- Differential identification information,
- Request for purpose of use and limitations as well as information and documentation supporting this request,
- Information and documentation explaining the conditions of use and production in the country where the GMO and products thereof are developed,
- Information and documentation with regard to risk management,
- Haulage, storage and transportation conditions of the GMO and products thereof for which the application is submitted,
- Document indicating that experimental release into the environment and placing on the market of GMOs and products thereof for consumption purposes is permitted in the country where the GMO and products thereof are developed, the permit is still valid, their production and consumption are still under way, and they are on the market for the period designated by the Ministry,
- Other information and documentation to be announced by the Board,

EXPERIMENTAL RELEASE OF GENETICALLY MODIFIED ORGANISMS OTHER THAN PLANTS

I. BACKGROUND INFORMATION

A. Name and address of the applicant
B. Field of operation of the applicant
C. Names, qualifications and experiences of the people in charge
Ç. Organizational technical capacity of the applicant
D. Differential ID number
E. Intended purpose of the GMO

II. INFORMATION ON THE GMO

A. Characteristic of the donor, recipient or parental organism(s):

1. Scientific name,
2. Taxonomy,
3. Other names (usual name, strain, name, etc.),
4. Phenotypic and genotypic markers,
5. Degree of relation between donor and recipient or between parental organisms,
6. Description of identification and detection techniques,
7. Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques,
8. Description of the geographic distribution and of the natural habitat of the organism including information on natural predators, prey, parasites and competitors symbionts and hosts,
9. Organisms with which transfer of genetic material is known to occur under natural conditions,
10. Verification of the genetic stability of the organisms and factors affecting it,
11. Pathological, ecological and physiological traits:
    a) Classification of hazard according to existing international rules concerning the protection of human and animal health as well as the environment and biological diversity;
    b) Generation tune in natural ecosystems, sexual or non-sexual reproductive cycle;
    c) Information on survival, including seasonability and the ability to form survival structures;
    ç) Pathogenicity: Infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). Ability to colonize other organisms;

d) Antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;

e) Involvement in environmental processes: Primary production, nutrient turnover, decomposition of organic matter, respiration etc.;

12. Nature of indigenous vectors:
    a) Sequence;
    b) Frequency of mobilization;
    c) Specificity;
    d) Presence of genes which confer resistance.
13. History of previous genetic modifications.

B. Characteristics of the vector

1. Nature and source of the vector;
2. Sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO;
3. Frequency of mobilization of inserted vector and/or genetic transfer capabilities and methods of determination;
4. Information on the degree to which the vector is limited to the DNA required to perform the intended function.

C. Characteristics of the modified organism

1. Information related to the genetic modification:
    a) Methods used for the modification,
    b) Methods used to construct and introduce the insert(s) into the recipient or to delete a sequence,
    c) Description of the insert and/or vector construction,
    ç) Purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function,
    d) Methods and criteria used for selection,
    e) Sequence, functional identity and location of the altered/inserted/deleted nucleic acid segments in question with particular reference to any known harmful sequence.
2. Information on the final GMO:
    a) Description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;
    b) Structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;
    c) Stability of the organism in terms of genetic traits;
    ç) Rate and level of expression of the new genetic material. Method and sensitivity of measurement;
    d) Activity of the expressed proteins;
    e) Description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and the vector;
    f) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
    g) History of previous releases or uses of the GMO;
    ğ) Considerations for human health and animal health, as well as plant health:
        (i) Toxic or allergenic effects of the non-viable GMOs and/or their metabolic products;
        (ii) Comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
        (iii) Capacity for colonization;

(iv) If the organism is pathogenic to humans who are immunocompetent:
- diseases caused and mechanism of pathogenicity including invasiveness and virulence;
- communicability;
- infective dose;
- host range, possibility of alteration;
- possibility of survival outside of human host;
- presence of vectors or means of dissemination, ¾ biological stability,
- antibiotic-resistance patterns;
- allergenicity;
- availability of appropriate therapies;

(v) other product hazards.

III. INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT

A. Information on the release

1. Description of the proposed deliberate release, including the purpose(s) and foreseen products;
2. Foreseen dates of the release and time planning of the experiment including frequency and duration of releases;
3. Preparation of the site previous to the release;
4. Size of the site;
5. Method(s) to be used for the release;
6. Quantities of GMOs to be released;
7. Measures to be taken in case of disturbance on the site (type and method of cultivation, mining, irrigation, or other activities);
8. Worker protection measures taken during the release;
9. Post-release treatment of the site;

10. Techniques foreseen for elimination or inactivition of the GMOs and waste thereof at the end of the experiment;
11. Information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

B. Environmental Issues to Consider While Planning the Release and Information to Be Provided

1. Geographical location and grid reference of the site(s);
2. Physical or biological proximity to humans and other significant biota;
3. Proximity to significant biotopes, protected areas, or drinking water supplies;
4. Climatic characteristics of the region(s) likely to be affected;
5. Geographical, geological and pedological characteristics;
6. Flora and fauna, including crops, livestock and migratory species;
7. Description of target and non-target ecosystems likely to be affected;
8. A comparison of the natural habitat of the recipient organism with the proposed site(s) of release;
9. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOS AND THE ENVIRONMENT

A. Characteristics affecting survival, multiplication and dissemination

1. Biological features which affect survival, multiplication and dispersal;
2. Known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH etc.);
3. Sensitivity to specific agents.

B. Interactions with the environment

1. Predicted habitat of the GMOs;
2. Studies of the behavior and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses, animal houses etc. may also be of relevance to medicinal products;
3. Genetic transfer capability:
   a) Post-release transfer of genetic material from GMOs into organisms in affected ecosystems;
   b) Post-release transfer of genetic material from indigenous organisms to the GMOs;
4. Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the modified organism;
5. Measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimise dispersal of genetic material, and methods to verify genetic stability;
6. Known routes of biological dispersal or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact etc.;
7. Description of ecosystems to which the GMOs could be disseminated;
8. Potential for excessive population increase in the environment;
9. Competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s);
10. Identification and description of the target organisms if applicable;
11. Anticipated mechanism and result of interaction between the released GMOs and the target organism if applicable;
12. Identification and description of non-target organisms which may be adversely affected by the release of the GMO, and the anticipated mechanism of any identified adverse reactions;

13. Likelihood of post-release shifts in biological interactions or in host range;
14. Known or predicted interactions with non-target organisms in the environment including competitors, preys, hosts, symbionts, predators, parasites and pathogens;
15. Involvement in biogeochemical processes;
16. Other possible interactions with the environment

V. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

A. Monitoring Techniques

1. Methods for tracing the GMOs, and for monitoring their effects;
2. Specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques;
3. Techniques for detecting transfer of the donated genetic material to other organisms;
4. Duration and frequency of monitoring.

B. Control of the Release

1. Methods and procedures to avoid and/or minimize the spread of the GMOs beyond the site of the release or the designated areas of use;
2. Methods and procedures to protect the site from intrusion by unauthorized individuals;
3. Methods and procedures to prevent other organisms from entering the site.

C. Waste treatment

1. Type of waste generated;
2. Expected amount of waste;
3. Description of treatment envisaged.

Ç. Emergency response plans

1. Methods and procedures for controlling the GMOs in case of unexpected spread;
2. Methods for decontamination of the areas, e.g. eradication of the GMOs;
3. Methods for disposal or sanitation of plants, animals, soils, etc., that were exposed to the GMO during or after its uncontrolled spread;
4. Methods for the isolation of the area affected by the uncontrolled spread of GMOs;
5. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

EXPERIMENTAL RELEASE OF GENETICALLY MODIFIED PLANTS (GMHP)

I. BACKGROUND INFORMATION

A. Name and address of the applicant
B. Field of operation of the applicant
C. Names, qualifications and experiences of the people in charge
Ç. Organizational technical capacity of the applicant
D. Differential ID number
E. Intended purpose of the GMHP

II. A. INFORMATION RELATING TO THE RECIPIENT AND/OR PARENTAL PLANTS

1. Full name:
   a) Family,
   b) Genus,
   c) Species,
   ç) Subspecies,
   d) Cultivar/breeding line,
   e) Common name of the plant.
2. Reproduction of the plant:
   a) Description of the reproduction modes,
   b) Specific factors affecting reproduction, if any,
   c) Generation time.
3. Survivability of the plant:
   a) Ability to form structures for survival or dormancy
   b) Factors affecting survivability
4. Dissemination of the plant:
   a) Ways and extent of dissemination (for example an estimation of how viable pollen and/or seeds declines with distance)
   b) Factors affecting dissemination.
5. Geographic distribution of the plant.
6. Description of the natural habitat and of the environmental conditions in which the plant lives in nature, if it grows in the Republic of Turkey, including information on natural pests, parasites, competitors and symbionts.
7. Other possibly important interactions of the plant with the organisms in the ecosystem where it usually grows or elsewhere including information about toxic effects on humans, animals and other organisms.

B. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification
2. Nature and source of the vector used.
3. Size, source (name of donor organism(s) and intended function of each constituent fragment of the region intended for insertion.

C. INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

1. Description of the trait(s) and characteristics which have been introduced or modified.
2. Information on the sequences actually inserted/deleted
   a) size and structure of the insert and methods used for its characterization, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP;
   b) in case of deletion, size and function of the deleted region(s);
   c) copy number of the insert;
   ç) location of the insert in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination.
3. Information on the expression of the insert:
   a) Information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterization;
   b) Parts of the plant where the insert is expressed (e.g. roots, stem, pollen etc.).
4. Information on how the genetically modified plant differs from the recipient plant in:
   a) mode(s) and/or rate of reproduction,
   b) dissemination,
   c) survivability.

5. Genetic stability of the insert and phenotypic stability of the GMHP.
6. Any change to the ability of the GMHP to transfer genetic material to other organisms
7. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.
8. Information on the safety of the GMHP to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the GMHP is intended to be used in animal feedstuffs.
9. Mechanism of interaction between the genetically modified plant and target organisms.
10. Potential changes in the interactions of the GMHPs with non-target organisms resulting from the genetic modification.
11. Potential interactions of the GMHPs with the abiotic environment.
12. Description of detection and identification techniques for the GMHPs.
13. Information about previous releases of the GMHPs.

Ç. INFORMATION RELATING TO THE SITE OF RELEASE *

1. Location and size of the release site(s).
2. Description of the release site ecosystem, including climate, flora and fauna.
3. Proximity to officially recognized biotopes or protected areas which may be affected.

D. INFORMATION RELATING TO THE RELEASE

1. Purpose of the release.
2. Foreseen date(s) and duration of the release.
3. Method by which the genetically modified plants will be released.
4. Method for preparing and managing the release site, prior to, during and post-release, including cultivation practices and harvesting methods.
5. Approximate number of plants (or plants per m^2).

E. INFORMATION ON CONTROL, MONITORING, POST-RELEASE AND WASTE HANDLING PLANS

1. All precaution measures: Any measures to minimise/prevent dispersal of any reproductive organ of the GMHP (for example pollen, seeds, tuber).
2. Description of methods for post-release treatment of the site.
3. Description of post-release treatment methods for the genetically modified plant material including wastes.
4. Description of monitoring plans and techniques of the released GMHPs
5. Description of all emergency plans.
6. Methods and procedures to protect the site.

* *: The information listed here with regard to Experimental Release application will be presented after the application has been accepted.*

- Bank receipt indicating that the application fee has been paid (Application fees are announced every January on the website of Biosafety Information Exchange Mechanism of Turkey (www.tbbdm.gov.tr).)

CHAPTER 6

APPLICATION FOR CONTAINED USE OF GENETICALLY MODIFIED MICROORGANISMS (GMMOS)

Standards, conditions and rules on the contained sites where research, development and industrial activities related to the GMMO are carried out under controlled conditions are defined by the Board considering the following:

a) International rules and standards,
b) Risk classification of micro-organisms,
c) Competency of the arrangement for the design and operation of the contained site as well as the activity conducted with the GMMO in terms of measures for the prevention of biosafety risks,
ç) Measures to prevent any biosafety risks posed by accidents that may occur during the contained use of GMMO,
d) Internationally harmonized standards on contained sites to be fulfilled by the relevant individuals working with GMMOs.

- Differential identification information,
- Request for purpose of use and limitations as well as information and documentation supporting this request,
- Information and documentation explaining the conditions of use and production in the country where the GMO and products thereof are developed,

- Information and documentation with regard to risk management,
- Haulage, storage and transportation conditions of the GMO and products thereof for which the application is submitted,
- Document indicating that experimental release into the environment and placing on the market of GMOs and products thereof for consumption purposes is permitted in the country where the GMO and products thereof are developed, the permit is still valid, their production and consumption are still under way, and they are on the market for the period designated by the Ministry,
- Other information and documentation to be announced by the Board,
- Whether transfer or use would be permitted, and where permitted, the conditions to be fulfilled,

EXPERIMENTAL RELEASE OF GENETICALLY MODIFIED ORGANISMS OTHER THAN PLANTS

I. BACKGROUND INFORMATION

A. Name and address of the applicant

B. Field of operation of the applicant

C. Names, qualifications and experiences of the people in charge

Ç. Organizational technical capacity of the applicant

D. Differential ID number

E. Intended purpose of the GMO

II. INFORMATION ON THE GMO

A. Characteristic of the donor, recipient or parental organism(s):

1. Scientific name,
2. Taxonomy,
3. Other names (usual name, strain, name, etc.),

4. Phenotypic and genotypic markers,
5. Degree of relation between donor and recipient or between parental organisms,
6. Description of identification and detection techniques,
7. Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques,
8. Description of the geographic distribution and of the natural habitat of the organism including information on natural predators, prey, parasites and competitors symbionts and hosts,
9. Organisms with which transfer of genetic material is known to occur under natural conditions,
10. Verification of the genetic stability of the organisms and factors affecting it,
11. Pathological, ecological and physiological traits:
    a) Classification of hazard according to existing international rules concerning the protection of human and animal health as well as the environment and biological diversity;
    b) Generation tune in natural ecosystems, sexual or non-sexual reproductive cycle;
    c) Information on survival, including seasonability and the ability to form survival structures;
    ç) Pathogenicity: Infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). Ability to colonize other organisms;
    d) Antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;
    e) Involvement in environmental processes: Primary production, nutrient turnover, decomposition of organic matter, respiration etc.;

12. Nature of indigenous vectors:
    a) Sequence;
    b) Frequency of mobilization;
    c) Specificity;
    d) Presence of genes which confer resistance.
13. History of previous genetic modifications.

B. Characteristics of the vector

1. Nature and source of the vector;
2. Sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO;
3. Frequency of mobilization of inserted vector and/or genetic transfer capabilities and methods of determination;
4. Information on the degree to which the vector is limited to the DNA required to perform the intended function.

C. Characteristics of the modified organism

1. Information related to the genetic modification:
    a) Methods used for the modification,
    b) Methods used to construct and introduce the insert(s) into the recipient or to delete a sequence,
    c) Description of the insert and/or vector construction,
    ç) Purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function,
    d) Methods and criteria used for selection,
    e) Sequence, functional identity and location of the altered/inserted/deleted nucleic acid segments in question with particular reference to any known harmful sequence.
2. Information on the final GMO:
    a) Description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;
    b) Structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;
    c) Stability of the organism in terms of genetic traits;
    ç) Rate and level of expression of the new genetic material. Method and sensitivity of measurement;
    d) Activity of the expressed proteins;
    e) Description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and the vector;
    f) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
    g) History of previous releases or uses of the GMO;
    ğ) Considerations for human health and animal health, as well as plant health:
        (i) Toxic or allergenic effects of the non-viable GMOs and/or their metabolic products;
        (ii) Comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
        (iii) Capacity for colonization;
        (iv) If the organism is pathogenic to humans who are immunocompetent:
            – diseases caused and mechanism of pathogenicity including invasiveness and virulence;
            – communicability;

- infective dose;
- host range, possibility of alteration;
- possibility of survival outside of human host;
- presence of vectors or means of dissemination;
- biological stability;
- antibiotic-resistance patterns;
- allergenicity;
- availability of appropriate therapies;

(v) other product hazards.

III. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOS AND THE ENVIRONMENT

A. Characteristics affecting survival, multiplication and dissemination

1. Biological features which affect survival, multiplication and dispersal;
2. Known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH etc.);
3. Sensitivity to specific agents.

B. Interactions with the environment

1. Predicted habitat of the GMOs;
2. Studies of the behavior and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses, animal houses etc. may also be of relevance to medicinal products;
3. Genetic transfer capability:
   a) Post-release transfer of genetic material from GMOs into organisms in affected ecosystems;
   b) Post-release transfer of genetic material from indigenous organisms to the GMOs;
4. Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the modified organism;
5. Measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimize dispersal of genetic material, and methods to verify genetic stability;
6. Known routes of biological dispersal or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact etc.;
7. Description of ecosystems to which the GMOs could be disseminated;
8. Potential for excessive population increase in the environment;
9. Competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s);
10. Identification and description of the target organisms if applicable;
11. Anticipated mechanism and result of interaction between the released GMOs and the target organism if applicable;
12. Identification and description of non-target organisms which may be adversely affected by the release of the GMO, and the anticipated mechanism of any identified adverse reactions;
13. Likelihood of post-release shifts in biological interactions or in host range;
14. Known or predicted interactions with non-target organisms in the environment including competitors, preys, hosts, symbionts, predators, parasites and pathogens;
15. Involvement in biogeochemical processes;
16. Other possible interactions with the environment

IV. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

A. Monitoring Techniques

1. Methods for tracing the GMOs, and for monitoring their effects;
2. Specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques;
3. Techniques for detecting transfer of the donated genetic material to other organisms;
4. Duration and frequency of monitoring.

B. Control of the Release

1. Methods and procedures to avoid and/or minimize the spread of the GMOs beyond the site of the release or the designated areas of use;
2. Methods and procedures to protect the site from intrusion by unauthorized individuals;
3. Methods and procedures to prevent other organisms from entering the site.

C. Waste treatment

1. Type of waste generated;
2. Expected amount of waste;
3. Description of treatment envisaged.

Ç. Emergency response plans

1. Methods and procedures for controlling the GMOs in case of unexpected spread;
2. Methods for decontamination of the areas, e.g. eradication of the GMOs;
3. Methods for disposal or sanitation of plants, animals, soils, etc., that were exposed to the GMO during or after its uncontrolled spread;
4. Methods for the isolation of the area affected by the uncontrolled spread of GMOs;
5. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

* *: The information listed here with regard to Experimental Release application will be presented after the application has been accepted.*

- Bank receipt indicating that the application fee has been paid (Application fees are announced every January on the website of Biosafety Information Exchange Mechanism of Turkey (www.tbbdm.gov.tr).)

CHAPTER 7

APPLICATION FOR SIMPLIFIED PROCEDURE

Applications based on the available information and previous risk assessment indicating that there is no risk that may arise from a GMO or product thereof and that it does not harm human, animal and plant health, the environment and the biological diversity can be subjected to a simplified procedure by the Board, considering also the results of the socioeconomic evaluation.

In order to apply under the simplified procedure, GDAR is contacted. Received applications are conveyed to the Board by the GDAR. The Board discusses whether the application would be approved or not at its first meeting following the date of application. Where the application is approved, the Board sends the folder it has previously received to the scientific committees. Committees carry out their assessments within the period designated by the Board and submit their reports to the Board. The Board makes its decision at its first meeting and notifies GDAR about the result within fifteen days.

Where the decision is favourable, it is published on the Official Gazette.

Where an objection on the refusal is submitted along with new information and documentation, the Board discusses the objection at its first meeting. Agreeing

on the procedures to be undertaken with regard to the objection and the period within which the procedures would be finalized, the Board notifies GDAR about the result to be communicated to the applicant.

The information and documentation required for applications under simplified procedure;

- Official documents showing that the GMO or product thereof is approved in the country where it is developed or registered for release into the environment and placing on the market for consumption should be submitted,
- Official documents showing that such approval is currently valid, it is on the market and its production and consumption is continuing should be submitted,
- Taxonomy and biology of the gene source and the receptor live organism should be known,
- Sufficient information should be available regarding the possible effects on the human, animal and environmental health and biological diversity.
- Previous risk assessments that can be used regarding the relations of the GMO with other live organisms should not have indicated any negative effects.
- Detailed methods and data should be available to enable the definition of the transferred genetic material and its identification within the live organism where it is transferred.
- Results from previous risk assessments as well as socioeconomic and ethical evaluations, where available should be presented,
- Other information and documentation to be decided by the Board.
- Bank receipt indicating that the application fee has been paid (Application fees are announced every January on the website of Biosafety Information Exchange Mechanism of Turkey (www.tbbdm.gov.tr).)

CHAPTER 8

APPLICATION FOR RESEARCH AND DEVELOPMENT PURPOSES

Submitting an application is not a requisite for research and development activities related to GMOs. Nevertheless, it is mandatory to inform the Ministry (GDAR) about the subject and result of the activity to be undertaken for research and development purposes.

On the other hand, Ministry/GDAR permit is sought for the GMO and products thereof to be imported for research and development purposes. Applications are submitted to GDAR with an official letter to which the application form shown in Figure 3 would be attached.

GDAR finalizes the procedures related to the permit within fifteen days and submits the permit document to the relevant official to be presented to the customs administration so that importation procedures could be completed. Importation procedures are carried out in accordance with the conditions listed in the permit.

The quantity of the material to be imported is decided by the GDAR. Within three months after the finalization of the research and development activity conducted in the country with regard to the GMO and products thereof for whose importation a permit was issued, the Ministry is notified about the result.

Figure 3 | **Application for Permit for Importing GMOs and Products Thereof for Research and Development Purposes**

1. Applicant's and other researchers'[1]	
1.1. Full Name	
1.2. Organization	
1.3. Title	
1.4. Address	
1.5. Phone No	
1.6. Fax No	
2. Biological Features of the GMO	
2.1. Common Name	
2.2. Scientific / Latin Name	
2.3. Taxonomic traits	
2.4. Pathological	
2.5. Ecological	
2.6. Physiological	
3. Modified trait(s)[2] of the organism	
4. Site where the requested activity would be conducted [2]	
5. Abstract information on the Research / Study/ Project [2]	
6. CVs and publications [2]	
7. A letter of commitment guaranteeing that the provisions of the Regulation would be respected [2]	
[1]: Details of other researchers will be provided on a separate page with their respective signatures. [2]: It will be attached to this form and composed separately for each material.	
Applicant's First and Last Name Signature	Applicant Official's First and Last Name Signature, Stamp

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GUIDE ON APPLICATION PROCEDURES

GENERAL DIRECTORATE OF AGRICULTURAL RESEARCH AND POLICIES

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