

The Argentinian Guidelines for Testing Genetically Modified Plants

Table of Contents

- **Instructions**
- **Application Form**
- **Supplementary Information**
- **Rules and Regulations**

Application for the licensing of experimentation on and/or releases into the environment of genetically modified plant organisms INSTRUCTIONS

The Department of Agriculture, Stockbreeding and Fisheries is the authority responsible for licensing experimentation on and/or releases into the environment of genetically modified plant organisms, subject to a favourable decision by the National Advisory Commission for Agricultural Biotechnology (CONABIA).

1. Manipulation of organisms through recombinant DNA techniques at official and other institutions;
2. Laboratory-hothouse testing;
3. Small-scale field testing;
4. Large-scale field testing;
5. Pre-commercial breeding of the material.

Licensing does not constitute exemption from checks that may be carried out during commercial distribution of the seed.

The term "seed" is to be construed as defined in the Seed and Plant Breeding Act (Law No. 20247), i.e., any plant organism used for propagation.

In order to release genetically modified plant organisms into the environment, it is necessary to complete the attached application, which comprises the parts listed below:

- A. Form
- B. Supplementary information
- C. Rules

The particulars contained in this application are to be used solely for assessing the suitability of granting licenses for genetically modified organisms (GMOs). A license will not be issued until the application has been approved. Any experimentation on and/or releases into the environment of GMOs that has not been duly licensed by this authority is/are expressly prohibited.

Two copies of this application should be sent to the headquarters of the National Advisory Commission for Agricultural Biotechnology attached to the Department of Agriculture, Stockbreeding and Fisheries. Applications are processed initially by the National Seed Institute (INASE) at the following address:

Paseo Colón 922, 3rd Floor, Office 302, P.O. Box 1063,
Federal Capital (Tel.: 362-3988/5352, Fax: 362-4733).

Each copy of the application is to be signed by a legal officer, who is to be the person responsible for ensuring compliance with all the licensing requirements.

A renewal application (point 1 of the form) refers to a repetition of the same experiment. In such cases, it will only be necessary to complete the form; no supplementary information will be required.

The following are treated as additional applications (point 1 of the form): (a) the back-crossing insertion process; (b) harvesting delayed beyond the period agreed in the first application; and (c) an extension of or amendment to a previous application still in force. In such cases, only the form is to be completed. However, CONABIA reserves the right to request a full application if it deems it necessary.

Affirmations made in the supplementary information must be accompanied by the relevant bibliographical references. It is also requested that data of foreign origin be attached in the original language.

In the supplementary information submitted, reports presented to other countries (with any amendments or additions applicable to local conditions) shall be accepted, as shall references to previous reports submitted to CONABIA.

The form is to be signed by the legal officer, and the supplementary information and rules are to bear the signatures of the legal officer and the technical officer.

A. FORM

Please complete this form concisely. The details required in support of the application are to be included on sheets attached as supplementary information.

1. This application to CONABIA is (please mark with a X)

A new application

A renewal application - file No.:

An additional application

2. Particulars of the applicant

Name:

Address:

Telephone:

Fax:

2.1 Legal officer

Name:

Address:

Telephone:

Fax:

Institution:

Post:

2.2 Technical officer

Name:

Address:

Telephone:

Fax:

Institution:

Post:

3. Type of licence applied for (please mark with a X)

Manipulation of organisms through recombinant DNA techniques at official or other institutions

Laboratory-hothouse testing

First small-scale field test

Repeat small-scale field test

in Argentina abroad

License or file No.:

Issued by:

Date:

First large-scale field test

Repeat large-scale field test

in Argentina abroad

License or file No.:

Issued by:

Date:

Pre-commercial breeding

4. Aims and details of the experiment: Please describe, in not more than one paragraph, the aims and details of the experiment giving rise to this application. Any existing data, whether in Argentina or abroad, should be included under point 4 of the supplementary information

5. Method of introduction of the genetically modified organism (GMO) into the country (please mark with a X)

Locally developed material

Official mail

Private mail

By hand or baggage

Other (please state)

6. Characteristics of the GMO introduction into the country

6.1 Quantity of material to be introduced

6.2 Type of material to be introduced (Type of plant organism to be introduced)

6.3 Proposed introduction programme

7. Date (or dates) of:

7.1 Importation (entry into the country)

7.2 Transport within the country

7.3 Field or laboratory release

8. Country, place and institution of origin of the material

9.

(a) Port of entry

(b) Destination within the country and/or place where the release will be carried out

10. Description of the GMO

Please complete the relevant items

10.1 Donor organism

Scientific name:

Non-proprietary name:

Commercial name:

Other designation:

10.2 Recipient organism

Scientific name:

Non-proprietary name:

Commercial name:

Other designation:

10.3 Vector or vector agent

Scientific name:

Non-proprietary name:

Commercial name:

Other designation:

10.4 Controlled organism or product

Scientific name:

Non-proprietary name:

Commercial name:

Other designation:

10.5 In the case of a product, please name the components:

11. Brief description of any biological material (e.g. culture medium or host material) accompanying the GMO during the controlled process

I swear that the particulars contained in this form and in the supplementary information are complete and true to the best of my knowledge and belief

Note:

Misrepresentation under any item in this form or in the supplementary information shall incur the penalties applicable under the Seed and Plant Breeding Act (Law No. 20247) and its regulatory provisions.

12. Date of submission:

13. Signature of the legal officer:

14. Full name and professional title:

B. SUPPLEMENTARY INFORMATION

1. Names, addresses and telephone numbers of the persons who have developed and/or supplied the genetically modified organism (GMO)

2. Characteristics of the material

2.1 With regard to the controlled organism, the details required under this item shall include:

2.1.1 Scientific name and brief phenotypic description

2.1.2 Full particulars of the:

(a) Possibilities of cross-pollination with individuals of the same species and/or indigenous relatives;

(b) Propagation mechanisms and periods of latent life or inactivity;

(c) Weed conversion potential of the organism;

(d) Taxonomically related weeds (stating type and species) that are usually present at the site where the GMO release is to take place.

2.2 Detailed description of the molecular biology of the donor- recipient- vector system that has been or will be used in the production of the controlled GMO.

Under this item, the applicant shall:

(a) Briefly describe the donor species of the gene;

(b) Identify the vectors, attaching a map of the vector plasmids (if such a system was used), describe the vector characteristics such as marker genes, promoters, etc., indicate the level of expression of such genes, and identify their nucleotide sequence homologies with pathogens such as viruses, and the possibilities and foreseeable consequences of any potentially pathogen-generating genetic recombination (e.g., generation of new pathogenic strains);

(c) Identify (if known) the genetic product and the metabolic pathway affected;

(d) Describe the effect of the genetic product on the plant material (e.g., resistance to insects), tissue specifics and production of secondary metabolites, in order to evaluate the compounds that could enter the food chain;

(e) Enclose existing data on gene transfer to the same or other species.

3. Country, locality and institution (name, address and fax number of the scientist responsible) where the donor organism, recipient organism and vector or vector agent were obtained, developed and/or produced

4. Detailed description of the aim of the experiment and the proposed schedule of operations to be carried out with the GMO

If cross-breeding is planned, the genotypes to be used shall be identified.

The details and results of any trials previously conducted, either in the country or home or abroad, but not described in point 4 of the form should also be included under this item.

5. Detailed description of the biosafety methods and procedures used in the country of origin and to be employed in Argentina with a view to preventing the contamination, release or dispersal into the environment, during the production stage, of the donor organism, recipient organism, vector or vector agent or of any component of the GMO to be controlled

Under this item, a description of the hothouses, laboratories and culture chambers, the experimentation and breeding sites and the processing plants shall be given.

5.1 In the case of laboratory-hothouse testing, the following particulars are required:

(a) A description of the site and its location;

(b) The maximum quantity of plant material to be cultivated;

(c) The isolation and biosafety measures;

(d) The methods proposed for monitoring potential vectors of recombinant genetic material of any kind;

(e) The techniques for detecting gene transfer from the GMO to the biotic environment.

5.2 In the case of field testing, the information required shall include:

- (a) A description of the site and its exact location on a map;
- (b) Details of the size and number of plots;
- (c) The quantity of seeds (in units) to be used;
- (d) The sowing plan;
- (e) Information on the breeding isolation measures proposed (specifying the number of control varieties suggested and the isolation distances planned);
- (f) The methods proposed for monitoring potential vectors of recombinant genetic material of any kind (aphids, farm work, etc.);
- (g) The techniques for detecting gene transfer from the GMO to the biotic environment.

6. Detailed description of the proposed destination (including the final destination and all intermediate destinations), uses and/or distribution of the GMO, products and by-products, and of all the material included in the experiment

7. Detailed description of the method suggested for final disposal of the GMO and of all the material included in the experiment

7.1 In the case of laboratory-hothouse testing, information shall be provided on the intended application of the harvested material, stating what treatment the residual material will undergo after harvesting.

7.2 In the case of field testing, details shall be provided of the:

- (a) Land treatment and site monitoring after harvesting;
- (b) Future use of the land;
- (c) Follow-up checks to be implemented;
- (d) Period during which checks on the likelihood of the spread of the GMO will be carried out (e.g., spontaneously appearing plants and taxonomically related weeds) in correlation with point 2.1.2 of the supplementary information;
- (e) The intended application of the harvested material, stating what treatment the plant material and seeds will undergo after harvesting.

7.3 The method for controlling possible escapes should be indicated.

8. Transport

Under this item, the method proposed for transferring the GMO to its destination (final or intermediate) within Argentina shall be specified.

The supplementary information shall bear the signatures of the legal officer and the technical officer in charge of the experiment.

For use solely by the Department of Agriculture, Stockbreeding and Fisheries - National Advisory Commission for Agricultural Biotechnology

FILE No.:

Applicant:

Type of application:

Date of receipt of the application:

Supplementary information submitted: YES NO

Confidential information submitted: YES NO

Record No.:

Date of CONABIA decision:

CONABIA approval: YES NO

Date of authorization:

Licence expiry date:

Number of years during which the site is to remain free of the crop concerned:

Signature of the authorizing official:

Notification of issue of the licence

Place and date:

Signature and full name of the technical officer:

Signature and full name of the legal officer:

C. RULES

Requirements for licensing experimentation on and/or releases into the environment of genetically modified plant organisms

Any licensed person and his employees or agents shall comply with the requirements set out below and with those contained in the form and supplementary information. Compliance with the requirements shall be evaluated by the National Advisory Commission for Agricultural Biotechnology attached to the Department of Agriculture, Stockbreeding and Fisheries.

1. The inspectors empowered by the appropriate authority shall have periodic access to the place where the genetically modified organism (GMO) is located. Such inspections shall be paid for by the applicant in the manner laid down by the appropriate authority. Also, any licensed person shall inform CONABIA, through the National Seed Institute (INASE) - Paseo Colón 922, 3rd Floor, Office 302, P.O. Box 1063, Federal Capital, Tel.: 362- 3988/5352, Fax: 362-4733 - sufficiently in advance of the times when the proposed schedule of operations (introduction, sowing, flowering, harvesting, final disposal of the experiment and all experimentation treatments proposed under point 4 of the supplementary information) will be carried out, with a view to facilitating the inspections.
2. The GMO shall be subject to the regulations laid down by CONABIA for the avoidance of accidental releases.
3. The GMO shall be subject to the plant health regulations laid down by the appropriate authority for the prevention of the spread of plant pests.
4. Any persons licensed to experiment on GMOs and/or to release GMOs into the environment shall report the behaviour of the GMO to CONABIA in accordance with such reporting requirements as may be specified in the authorization issued by CONABIA.
5. CONABIA shall, within the periods and in the manner specified, be notified:
 - (i) Orally immediately upon the discovery and in writing within 24 hours of the occurrence of an accidental GMO release;
 - ii) In writing within five working days if the GMO or associated host organism exhibits substantially different characteristics from those detailed in the licence application or if any abnormal situation arises (excessive mortality, disease or unforeseen effect on other organisms).
6. The technical officer must be qualified to assess the risks involved in experimenting with transgenic material (e.g., possess a reliable knowledge of the ecosystem in which the experiment is to be carried out).
7. The authorization shall specify the post-experimentation period during which the legal and technical representatives of the enterprise shall be responsible for the plot of land on which the experiment was authorized.
8. The legal officer shall inform the Commission of any change in the holder of his post during the evaluation period.
9. The experiment shall at all times meet the biosafety requirements laid down in the application with a view to preventing any accidental GMO release.
10. The personnel must be technically qualified to conduct the experiment.
11. If it deems it necessary, CONABIA shall have access to diagnostic reagent data

for the purpose of detecting any possible transgene escape.

12. Confidential information

If the particulars required in the form or in the supplementary information necessitate the disclosure of trade secrets or confidential information (CI), those parts that are deemed confidential information may be deleted from one of the copies, and the place or places where such information has been deleted shall be indicated by the insertion of the abbreviation "&CID" (confidential information deleted) in the right-hand margin. On each page of the application on which confidential information has been deleted, the phrase "Copy with CI deleted" shall be entered in the top margin.

A second copy containing all the confidential information that has been deleted from the previous copy shall be submitted. Each page of the application on which information of this kind appears shall bear the phrase "Copy with CI".

This copy with confidential information included shall be deposited in safe keeping at the National Seed Institute and may, subject to prior notification to the applicant and with his consent, be disclosed solely to experts in the matter for decision-making purposes if CONABIA deems it necessary. Any persons having access to confidential information shall sign a safe-keeping undertaking.

Notification of the licensing rules

Place and date:

Signature and full name of the technical officer:

Signature and full name of the legal officer: