

Gene Technology Authority

General information

**Application form** of the Environmental, Agricultural and Industrial Gene Technology Authority for the **deliberate release of genetically modified organisms other than higher plants[[1]](#footnote-1) and their products into the environment for purposes other than placing on the market**

Based on the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, and Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, and subpoint 2 of point c of section 1 of Article 1 of Act No. XXVII of 1998 on gene technology activities (Gene Technology Act) **the deliberate release of genetically modified organisms and their products for purposes other than placing on the market** is subject to authorisation.

According to section 1 of Article 8 of Government Decree No. 132/2004 (IV. 29.) on the authorisation procedure for gene technological activity as well as on liaison with the European Commission the applicant shall submit the application for an authorisation to the gene technology authority **in Hungarian as well as in English**.

Based on the section 1 of Article 10/A of the Gene Technology Act the gene technology authority decides on the application within **130 days** from the receipt of the application.

The applicant shall pay **an administrative service fee of 300 000 HUF** per gene technological modification and per site of release to the gene technology authority according to Decree No. 138/2004 (IX.23.) of the Ministry of Agriculture.

The application form in the annex to guidance shall be sent to the Ministry of Agriculture, Department of Biodiversity and Gene Conservation (Environmental, Agricultural and Industrial Gene Technology Authority) **in one original hard copy as well as in electronic format** to the following addresses:

Postal address: 1052 Budapest, Apáczai Csere János u. 9.

Email: gmo@am.gov.hu

Application

**Information required in applications concerning releases of genetically modified organisms other than higher plants[[2]](#footnote-2)**

**I. General information**

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| **A. Information relating to the Applicant** |
| Name | Click here to enter text. |
| Address | Click here to enter text. |
| Email address | Click here to enter text. |
| Telephone number | Click here to enter text. |

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| **B. Information relating to the Hungarian contact person of the Applicant** |
| Name | Click here to enter text. |
| Position | Click here to enter text. |
| Workplace | Click here to enter text. |
| Email address | Click here to enter text. |
| Telephone number | Click here to enter text. |

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| **C. Information relating to the responsible scientist(s)** |
| Name | Click here to enter text. |
| Qualification | Click here to enter text. |
| Scientific experience (particularly regarding the experience in relation to the genetically modified organisms, including publications) (A curriculum vitae must be attached to the application.) |
| Click here to enter text. |

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| **D. Title of the project** |
| Click here to enter text. |

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| **E. Information relating to the conditions of release and the receiving environment:** |
| 1. Information on the release |
| *a) description of the proposed deliberate release, including the purpose(s) and foreseen products* |
| Click here to enter text. |
| *b) foreseen dates of the release and time planning of the experiment including frequency and duration of releases* |
| Click here to enter text. |
| *c) preparation of the site previous to the release* |
| Click here to enter text. |
| *d) size of the site* |
| Click here to enter text. |
| *e) method(s) to be used for the release* |
| Click here to enter text. |
| *f) quantities of GMOs to be released* |
| Click here to enter text. |
| *g) disturbance on the site (type and method of cultivation, mining, irrigation, or other activities)* |
| Click here to enter text. |
| *h) worker protection measures taken during the release* |
| Click here to enter text. |
| *i) post-release treatment of the site* |
| Click here to enter text. |
| *j) techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment* |
| Click here to enter text. |
| *k) information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems* |
| Click here to enter text. |
| 2. Information on the environment (both on the site and in the wider environment): |
| *a) geographical location and grid reference of the site(s) (in case of notifications under part C the site(s) of release will be the foreseen areas of use of the product)* |
| Click here to enter text. |
| *b) physical or biological proximity to humans and other significant biota* |
| Click here to enter text.  |
| *c) proximity to significant biotopes, protected areas, or drinking water supplies* |
| Click here to enter text. |
| *d) climatic characteristics of the region(s) likely to be affected* |
| Click here to enter text. |
| *e) geographical, geological and pedological characteristics* |
| Click here to enter text. |
| *f) flora and fauna, including crops, livestock and migratory species* |
| Click here to enter text. |
| *g) description of target and non-target ecosystems likely to be affected* |
| Click here to enter text. |
| *h) a comparison of the natural habitat of the recipient organism with the proposed site(s) of release* |
| Click here to enter text. |
| *i) any known planned developments or changes in land use in the region which could influence the environmental impact of the release* |
| Click here to enter text. |

**II. Information relating to the GMO**

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| **A. Characteristics of the donor, the recipient or (where appropriate) parental organism(s):** |
| 1. scientific name | Click here to enter text. |
| 2. taxonomy | Click here to enter text. |
| 3. their names (usual name, strain name, etc.) | Click here to enter text. |
| 4. phenotypic and genetic markers |
| Click here to enter text. |
| 5. degree of relatedness between donor and recipient or between parental organisms |
| Click here to enter text. |
| 6. description of identification and detection techniques |
| Click here to enter text. |
| 7. sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques |
| Click here to enter text. |
| 8. description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors, symbionts and hosts |
| Click here to enter text. |
| 9. organisms with which transfer of genetic material is known to occur under natural conditions |
| Click here to enter text. |
| 10. verification of the genetic stability of the organisms and factors affecting it |
| Click here to enter text. |
| 11. pathological, ecological and physiological traits |
| *a) classification of hazard according to existing Community rules concerning the protection of human health and/or the environment* |
| Click here to enter text. |
| *b) generation time in natural ecosystems, sexual and asexual reproductive cycle* |
| Click here to enter text. |
| *c) information on survival, including seasonability and the ability to form survival structures* |
| Click here to enter text. |
| *d) 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 colonise other organisms* |
| Click here to enter text. |
| *e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy* |
| Click here to enter text. |
| *f) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.* |
| Click here to enter text. |
| 12. Nature of indigenous vectors |
| *a) sequence* |
| Click here to enter text. |
| *b) frequency of mobilisation* |
| Click here to enter text. |
| *c) specificity* |
| Click here to enter text. |
| *d) presence of genes which confer resistance* |
| Click here to enter text. |
| 13. History of previous genetic modifications |
| Click here to enter text. |

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| **B. Characteristics of the vector** |
| 1. nature and source of the vector |
| Click here to enter text. |
| 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 |
| Click here to enter text. |
| 3. frequency of mobilisation of inserted vector and/or genetic transfer capabilities and methods of determination |
| Click here to enter text. |
| 4. information on the degree to which the vector is limited to the DNA required to perform the intended function |
| Click here to enter text. |

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| **C. Characteristics of the modified organism** |
| 1. Information relating to the genetic modification |
| *a) methods used for the modification* |
| Click here to enter text. |
| *b) methods used to construct and introduce the insert(s) into the recipient or to delete a sequence* |
| Click here to enter text. |
| *c) description of the insert and/or vector construction* |
| Click here to enter text. |
| *d) 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* |
| Click here to enter text. |
| *e) methods and criteria used for selection* |
| Click here to enter text. |
| *f) sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence* |
| Click here to enter text. |
| 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* |
| Click here to enter text. |
| *b) structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism* |
| Click here to enter text. |
| *c) stability of the organism in terms of genetic traits* |
| Click here to enter text. |
| *d) rate and level of expression of the new genetic material. Method and sensitivity of measurement* |
| Click here to enter text. |
| *e) activity of the expressed protein(s)* |
| Click here to enter text. |
| *f) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector* |
| Click here to enter text. |
| *g) sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques* |
| Click here to enter text. |
| *h) history of previous releases or uses of the GMO* |
| Click here to enter text. |
| *i) considerations for human health and animal health, as well as plant health:* |
| *ia) toxic or allergenic effects of the GMOs and/or their metabolic products* |
| Click here to enter text. |
| *ib) comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity* |
| Click here to enter text. |
| *ic) capacity for colonisation* |
| Click here to enter text. |
| *id) if the organism is pathogenic to humans who are immunocompetent* |
| *- diseases caused and mechanism of pathogenicity including invasiveness and virulence* |
| Click here to enter text. |
| *- communicability* |
| Click here to enter text. |
| *- infective dose* |
| Click here to enter text.  |
| *- host range, possibility of alteration* |
| Click here to enter text. |
| *- possibility of survival outside of human host* |
| Click here to enter text. |
| *- presence of vectors or means of dissemination* |
| Click here to enter text. |
| *- biological stability* |
| Click here to enter text. |
| *- antibiotic resistance patterns* |
| Click here to enter text. |
| *- allergenicity* |
| Click here to enter text. |
| *- availability of appropriate therapies* |
| Click here to enter text. |
| *ie) other product hazards* |
| Click here to enter text. |

**III. Information relating to the interactions between the GMOs and the environment**

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| **A. Characteristics affecting survival, multiplication and dissemination** |
| 1. biological features which affect survival, multiplication and dispersal |
| Click here to enter text. |
| 2. known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.) |
| Click here to enter text. |
| 3. sensitivity to specific agents |
| Click here to enter text. |

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| **B. Interactions with the environment** |
| 1. predicted habitat of the GMOs |
| Click here to enter text. |
| 2. studies of the behaviour and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses |
| Click here to enter text. |
| 3. genetic transfer capability |
| *a) post release transfer of genetic material from GMOs into organisms in affected ecosystems* |
| Click here to enter text. |
| *b) post release transfer of genetic material from indigenous organisms to the GMOs* |
| Click here to enter text. |
| 4. likelihood of post release selection leading to the expression of unexpected and/or undesirable traits in the modified organism |
| Click here to enter text. |
| 5. measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimise dispersal of genetic material. Methods to verify genetic stability |
| Click here to enter text. |
| 6. routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc. |
| Click here to enter text. |
| 7. description of ecosystems to which the GMOs could be disseminated |
| Click here to enter text. |
| 8. potential for excessive population increase in the environment |
| Click here to enter text. |
| 9. competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s) |
| Click here to enter text. |
| 10. identification and description of the target organisms if applicable |
| Click here to enter text. |
| 11. anticipated mechanism and result of interaction between the released GMOs and the target organism(s) if applicable |
| Click here to enter text. |
| 12. identification and description of non-target organisms which may be adversely affected by the release of the GMO, and the anticipated mechanisms of any identified adverse interaction |
| Click here to enter text. |
| 13. likelihood of post release shifts in biological interactions or in host range |
| Click here to enter text. |
| 14. known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens |
| Click here to enter text. |
| 15. known or predicted involvement in biogeochemical processes |
| Click here to enter text. |
| 16. other potential interactions with the environment |
| Click here to enter text. |

**IV. Information on monitoring, control, waste treatment and emergency response plans**

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| **A. Monitoring techniques** |
| 1. methods for tracing the GMOs, and for monitoring their effects |
| Click here to enter text. |
| 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 |
| Click here to enter text. |
| 3. techniques for detecting transfer of the donated genetic material to other organisms |
| Click here to enter text. |
| 4. duration and frequency of the monitoring |
| Click here to enter text. |

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| **B. Control of the release** |
| 1. methods and procedures to avoid and/or minimise the spread of the GMOs beyond the site of release or the designated area for use |
| Click here to enter text. |
| 2. methods and procedures to protect the site from intrusion by unauthorised individuals |
| Click here to enter text. |
| 3. methods and procedures to prevent other organisms from entering the site |
| Click here to enter text. |

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| **C. Waste treatment** |
| 1. type of waste generated |
| Click here to enter text. |
| 2. expected amount of waste |
| Click here to enter text. |
| 3. description of treatment envisaged |
| Click here to enter text. |

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| **D. Emergency response plans** |
| 1. methods and procedures for controlling the GMOs in case of unexpected spread |
| Click here to enter text. |
| 2. methods for decontamination of the areas affected, for example eradication of the GMOs |
| Click here to enter text. |
| 3. methods for disposal or sanitation of plants, animals, soils, etc., that were exposed during or after the spread |
| Click here to enter text. |
| 4. methods for the isolation of the area affected by the spread |
| Click here to enter text. |
| 5. plans for protecting human health and the environment in case of the occurrence of an undesirable effect |
| Click here to enter text. |

**V. Research plan[[3]](#footnote-3) (may also be attached as an attachment to the Application)**

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| Click here to enter text. |

**VI. A summary of the application (i.e. Summary Notification Information Format or SNIF) in accordance with Part 1 of Annex of Council Decision 2002/813/EC (may also be attached as an attachment to the Application))[[4]](#footnote-4)**

The form to be completed is available [here](https://gmo.kormany.hu/download/a/5b/b2000/Council%20decision%202002_813_SNIF%20Part%20B.docx).

**VII. The summaries and results of the studies referred to in the Application, including an explanation about their relevance to e.r.a., where applicable[[5]](#footnote-5) (may also be attached as an attachment to the Application)**

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| Click here to enter text. |

**VIII. Environmental risk assessment (e.r.a.) (may also be attached as an attachment to the Application)**

**The environmental risk assessment should be carried out in accordance with the Annex 1 of the Decree No. 142/2004. (IX. 30.) FVM-GKM, which is available** [**here**](https://gmo.kormany.hu/download/8/21/a2000/Seg%C3%A9dlet%202_%20KK%C3%89%20%20kibocs%C3%A1t%C3%A1s.pdf)**.** **Conclusions on the potential environmental impact in relevant receiving environments from the release or the placing on the market of GMOs shall be drawn for each relevant area of risk listed point 7.1.1. of the Annex**, on the basis of an e.r.a. carried out in accordance with the principles outlined in point 5 and following the methodology described in point 6 of the Annex and on the basis of the information required pursuant to Annex 1 of Decree No. 82/2003. (VII.16.).

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| Click here to enter text. |

**In addition to the aforementioned information the Applicant may:**

1. The Applicant may refer to data or results from applications previously submitted by other applicants, provided that the information, data and results are non-confidential or these applicants have given their agreement in writing, or may submit additional information he considers relevant.[[6]](#footnote-6)
2. The deliberate release of the same GMO or of a combination of GMOs on the same site or on different sites for the same purpose and within a defined period may be submitted to the Gene Technology Authority in a single application.[[7]](#footnote-7)

**Attachments** (Please use crosses (meaning x or X) into the space provided):

|  |  |
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| **1. Curriculum vitae(s) of the responsible scientist(s) for the deliberate release**  | (…**)** |
| **2. Research plan** (optionally as an attachment or completed in this form) | **(**…**)** |
| **3. Summary of the application**  | **(**…**)** |
| **4. The summaries and results of the studies referred to in the Application** (optionally as an attachment or completed in this form) | **(**…**)** |
| **5. Environmental risk assessment** (optionally as an attachment or completed in this form) | **(**…**)** |
| **6. Other** (optional) | **(**…**)** |

*I declare and certify with my signature that to the best of my knowledge and belief, the content data in the application is correct and true.*

**Place and date:** Click here to enter text. **,** Click here to enter date.

**………………………………..**

*Signature*

*l.s.*

1. Genetically modified Organisms (GMO) [↑](#footnote-ref-1)
2. Based on Part A of Annex 1 of Decree No. 82/2003. (VII. 16.) of the Ministry of Agriculture and Rural Development on the registering and supply of data regarding the gene technological activity [↑](#footnote-ref-2)
3. Section 6 of Article 10/A of Act No. XXVII of 1998 on gene technology activities [↑](#footnote-ref-3)
4. Council Decision of 3 October 2002 establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market [↑](#footnote-ref-4)
5. Point b of section 2 of Article 1 of Decree No. 82/2003. (VII.16.) [↑](#footnote-ref-5)
6. Section 2 of Article 8 of Government Decree No. 132/2004. (IV. 29.) [↑](#footnote-ref-6)
7. Section 3 of Article 8 of Government Decree No. 132/2004. (IV. 29.) [↑](#footnote-ref-7)