

Gene Technology Authority

General informatioN

**Application form** of the Environmental, Agricultural and Industrial Gene Technology Authority for the **deliberate release of** **genetically modified higher plants (Gymnospermae and Angiospermae)[[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](mailto:gmo@am.gov.hu)

Application

**Information required in applications concerning deliberate releases of genetically modified higher plants (GMHPs) (Gymnospermae and Angiospermae)[[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 shall 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 release** | |
| 1. Purpose of the release | |
| Click here to enter text. | |
| 2. Foreseen date(s) and duration of the release | |
| Click here to enter text. | |
| 3. Method by which the GMHP will be released | |
| Click here to enter text. | |
| 4. Method for preparing and managing the release site, prior to, during and post release, including cultivation practices and harvesting methods | |
| Click here to enter text. | |
| 5. Approximate number of plants (or plants per m2) | Click here to enter text. |

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| **F. Information relating to the site of release** |
| 1. Location and size of the release site(s) |
| Click here to enter text. |
| 2. Description of the release site ecosystem, including climate, flora and fauna |
| Click here to enter text. |
| 3. Presence of sexually compatible wild relatives or cultivated plant species |
| Click here to enter text. |
| 4. Proximity to officially recognised biotopes or protected areas which may be affected |
| Click here to enter text. |

**II. Scientific information**

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| **A. Information relating to the recipient plant or, where appropriate, to the parental plants** | |
| 1. Complete name | |
| *a) family name* | Click here to enter text. |
| *b) genus* | Click here to enter text. |
| *c) species* | Click here to enter text. |
| *d) subspecies* | Click here to enter text. |
| *e) cultivar or breeding line* | Click here to enter text. |
| *f) common name* | Click here to enter text. |
| 2. Geographical distribution and cultivation of the plant within the Union | |
| Click here to enter text. | |
| 3. Information concerning reproduction | |
| *a) mode(s) of reproduction* | |
| Click here to enter text. | |
| *b) specific factors affecting reproduction, if any* | |
| Click here to enter text. | |
| *c) generation time* | |
| Click here to enter text. | |
| 4. Sexual compatibility with other cultivated or wild plant species, including the distribution in Europe of the compatible species. | |
| Click here to enter text. | |
| 5. Survivability | |
| *a) ability to form structures for survival or dormancy* | |
| Click here to enter text. | |
| *b) specific factors affecting survivability, if any* | |
| Click here to enter text. | |
| 6. Dissemination: | |
| *a) ways and extent of dissemination* | |
| Click here to enter text. | |
| *b) specific factors affecting dissemination, if any* | |
| Click here to enter text. | |
| 7. Where a plant species is not normally grown in the Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts | |
| Click here to enter text. | |
| 8. Potential interactions of the plant, that are relevant to the GMHP, with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms | |
| Click here to enter text. | |

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| **B. Molecular characterisation** |
| 1. Information relating to the genetic modification |
| *(a) Description of the methods used for the genetic modification* |
| Click here to enter text. |
| *(b) Nature and source of the vector used* |
| Click here to enter text. |
| *(c) Source of the nucleic acid(s) used for transformation, size, and intended function of each constituent fragment of the region intended for insertion* |
| Click here to enter text. |
| 2. Information relating to the GMHP |
| *(a) General description of the trait(s) and characteristics which have been introduced or modified* |
| Click here to enter text. |
| *(b) Information on the sequences actually inserted/deleted:* |
| • size and copy number of all insert(s) and methods used for its/their characterisation |
| Click here to enter text. |
| • in case of deletion, size and function of the deleted region(s) |
| Click here to enter text. |
| • subcellular location(s) of the insert(s) in the plant cells (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination |
| Click here to enter text. |
| *(c) Parts of the plant where the insert is expressed.* |
| Click here to enter text. |
| *(d) Genetic stability of the insert and phenotypic stability of the GMHP* |
| Click here to enter text. |
| 3. Conclusions of the molecular characterisation |
| Click here to enter text. |

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| **C. Information on specific areas of risk** |
| 1. Any change to the persistence or invasiveness of the GMHP, and its ability to transfer genetic material to sexually compatible relatives and the adverse environmental effects thereof |
| Click here to enter text. |
| 2. Any change to the ability of the GMHP to transfer genetic material to microorganisms and the adverse environmental effects thereof |
| Click here to enter text. |
| 3. Mechanism of interaction between the GMHP and target organisms (if applicable) and the adverse environmental effects thereof. |
| Click here to enter text. |
| 4. Potential changes in the interactions of the GMHP with non-target organisms resulting from the genetic modification and the adverse environmental effects thereof |
| Click here to enter text. |
| 5. Potential changes in agricultural practices and management of the GMHP resulting from the genetic modification and the adverse environmental effects thereof |
| Click here to enter text. |
| 6. Potential interactions with the abiotic environment and the adverse environmental effects thereof |
| Click here to enter text. |
| 7. Information on any toxic, allergenic or other harmful effects on human and animal health arising from the genetic modification |
| Click here to enter text. |
| 8. Conclusions on the specific areas of risk |
| Click here to enter text. |

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| **D. Information on control, monitoring, post-release and waste treatment plans:** |
| 1. Any measures taken, including: |
| *(a) spatial and temporal isolation from sexually compatible plant species, both wild and weedy relatives and crops* |
| Click here to enter text. |
| *(b) any measures to minimise or prevent the dispersal of any reproductive part of the GMHP* |
| Click here to enter text. |
| 7. Description of methods for post-release treatment of the site |
| Click here to enter text. |
| 8. Description of post-release treatment methods for the genetically modified plant material including wastes |
| Click here to enter text. |
| 9. Description of monitoring plans and techniques |
| Click here to enter text. |
| 10. Description of any emergency plans. |
| Click here to enter text. |
| 11. Description of the methods and procedures to: |
| *(a) avoid or minimise the spread of the GMHPs beyond the site of release* |
| Click here to enter text. |
| *(b) protect the site from intrusion by unauthorised individuals* |
| Click here to enter text. |
| *(c) prevent other organisms from entering the site or minimise such entries* |
| Click here to enter text. |

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| **E. Description of detection and identification techniques for the GMHP** |
| Click here to enter text. |

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| **F. Information about previous releases of the GMHP, if applicable** |
| Click here to enter text. |

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

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| Click here to enter text. |

**IV. A summary of the application (i.e. Summary Notification Information Format or SNIF) in accordance with 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/1/6b/b2000/Council%20decision%202002_813%20SNIF_Part2_Part%20B_EN.docx)**.**

**V. 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. |

**VI. 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/Segédlet%202_%20KKÉ%20%20kibocsátás.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 7.1.2. 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:**

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 included 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 included in this form) | **(** … **)** |
| **5. Environmental risk assessment** (optionally as an attachment or included 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); Genetically modified plant (GMP); Genetically modified Higher Plant (GMHP) [↑](#footnote-ref-1)
2. Based on Part B 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)