APPLICATION

**Information required in application concerning premises to be used for contained use of genetically modified organisms and their products[[1]](#footnote-1)**

**Information to be provided in the application**

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| **1. Information relating to the Applicant (User)[[2]](#footnote-2)** |
| 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. |
| Website | Click here to enter text. |

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| **2. Information relating to the Hungarian contact person of the Application** |
| 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. |
| Website | Click here to enter text. |

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| **3. The purpose of the Application** |
| *(Please use crosses (meaning x or X) into the space provided)* |
| * new application
 | ( … ) |
| * new application, supplementing an existing permit by new premises / laboratories / rooms or modifications of techniques
 | ( … ) |
| * + the number of the permit application to be completed:
 | ( … ) |

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| **4. Information on the premises where the genetic modification of organisms or the contained use will actually be conducted of the GMOs and the products thereof** |
| 1. Name of organisation
 |
| Click here to enter text. |
| 1. Address of the premise, or parcel number, if applicable
 |
| Click here to enter text. |
| 1. Brief description of the premise
 |
| Click here to enter text. |
| 1. List of rooms / laboratories to be involved in the gene technology activity and their indication on the layout of the premise *(The layout of the premise should be attached as an attachment of this application indicating the precise place of the laboratories to be involved in the gene technology activity.)*
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| Click here to enter text. |

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| **5. The nature of the premise and the assignment of the containment level** ***Note:*** *The assignment of the containment level shall be defined based on the criteria of the corresponding table of Annex 2 of the Government Decree No. 132/2004 (IV. 29.). After meeting the conditions specified for containment level indicated in the tables, it is necessary to classify the type of the premise.* *The relevant table (Table Template 1, 2, 3 or 4) shall be attached as part of the application, indicating in the last column of the table the fulfilment of the requirements for the maximum containment level achievable for the premise concerned, possibly supplemented by additional details specific to the premise concerned.**(Please use crosses (meaning x or X) into the space provided)* |
|  | Laboratory[[3]](#footnote-3)(The Annex can be found [**here**](https://gmo.kormany.hu/download/a/c8/13000/1A%20laborat%C3%B3rium%20132_2004_EN.docx)**.)** | Glasshouse[[4]](#footnote-4)(The Annex can be found [**here**](https://gmo.kormany.hu/download/f/d8/13000/1B%20%C3%BCvegh%C3%A1z_hajtat%C3%B3h%C3%A1z%20132_2004_EN.docx)**.)** | Growth Room[[5]](#footnote-5)(The Annex can be found [**here**](https://gmo.kormany.hu/download/f/d8/13000/1B%20%C3%BCvegh%C3%A1z_hajtat%C3%B3h%C3%A1z%20132_2004_EN.docx)**.)** | Animal Unit[[6]](#footnote-6)(The Annex can be found [**here**](https://gmo.kormany.hu/download/0/e8/13000/1C_%C3%A1llath%C3%A1z%20132_2004_EN.docx)**.)** | Other activities, premises suitable for non-laboratory activities [[7]](#footnote-7)\*(The Annex can be found [**here**](https://gmo.kormany.hu/download/1/e8/13000/2%20egy%C3%A9b%20tev%C3%A9kenys%C3%A9g_%20132_2004_EN.docx)**.)** |
| Class 1 | ( … ) | ( … ) | ( … ) | ( … ) | ( … ) |
| Class 2 | ( … ) | ( … ) | ( … ) | ( … ) | ( … ) |
| Class 3 | ( … ) | ( … ) | ( … ) | ( … ) | ( … ) |
| Class 4 | ( … ) | ( … ) | ( … ) | ( … ) | ( … ) |
| \*Please specify: |
| Click here to enter text. |

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| **6. Information relating to the person responsible for supervision** |
| Name | Click here to enter text. |
| Workplace | Click here to enter text. |
| Telephone number | Click here to enter text. |
| Qualification | Click here to enter text. |
| Training experience *(particularly regarding the experience in relation to the genetically modified organisms) (A curriculum vitae must be attached to the application.)* |
| Click here to enter text. |
| Information relating to the person responsible for supervision *(if more than one person is responsible)* |
| Name | Click here to enter text. |
| Workplace | Click here to enter text. |
| Telephone number | Click here to enter text. |
| Qualification | Click here to enter text. |
| Training experience *(particularly regarding the experience in relation to the genetically modified organisms) (A curriculum vitae must be attached to the application.)* |
| Click here to enter text. |

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| **7. Information relating to the person responsible for safety** |
| Name | Click here to enter text. |
| Workplace | Click here to enter text. |
| Telephone number | Click here to enter text. |
| Qualification | Click here to enter text. |
| Training experience *(particularly regarding the experience in relation to the genetically modified organisms) (A curriculum vitae must be attached to the application.)* |
| Click here to enter text. |
| Information relating to the person responsible for safety *(if more than one person is responsible)* |
| Name | Click here to enter text. |
| Workplace | Click here to enter text. |
| Telephone number | Click here to enter text. |
| Qualification | Click here to enter text. |
| Training experience *(particularly regarding the experience in relation to the genetically modified organisms) (A curriculum vitae must be attached to the application.)* |
| Click here to enter text. |

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| **8. Description of the work to be undertaken at the premises** |
| 1. Type of the activity to be undertaken at the premises *(Please use crosses (meaning x or X) into the space provided, check all boxes which apply)*
 |
| Basic research | ( … ) | Applied research | ( … ) |
| Research and development | ( … ) | Research with educational purpose | ( … ) |
| Other \* | ( … ) | Storage and maintenance of collections | ( … ) |
| \*Please specify: Click here to enter text. |
| 1. Nature of the work to be undertaken at the premises

*(Please use crosses (meaning x or X) into the space provided, check all boxes which apply)**(Please also indicate in which rooms what activities you plan to carry out, this must be indicated in the appropriate part of the table.)* |
|  | Precise indication of the appropriate room |
| Virology | ( … ) | Click here to enter the specific premise. |
| Bacteriology | ( … ) | Click here to enter the specific premise. |
| Mycology | ( … ) | Click here to enter the specific premise. |
| GM plant | ( … ) | Click here to enter the specific premise. |
| GM animal | ( … ) | Click here to enter the specific premise. |
| Other\* | ( … ) | Click here to enter the specific premise. |
| \* Please specify: Click here to enter text. |

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| 1. Methods used

*(Please use crosses (meaning x or X) into the space provided, check all boxes which apply)* |
| Recombinant nucleic acid techniques[[8]](#footnote-8) | ( … ) |
| Techniques involving the direct introduction into a micro-organism of heritable material prepared outside the micro-organism, including micro-injection, macro-injection and micro-encapsulation | ( … ) |
| Cell fusion or hybridisation techniques[[9]](#footnote-9) | ( … ) |
| New genomic techniques: |
| * CRISPR
 | ( … ) |
| * TALEN
 | ( … ) |
| * Zinc-finger nucleases technique
 | ( … ) |
| * Mega nucleases technique
 | ( … ) |
| * Prime editing
 | ( … ) |
| * Oligonucleotide-directed mutagenesis (ODM)
 | ( … ) |
| * RNS-dependent DNA methylation (RdDM)
 | ( … ) |
| Other\* | ( … ) |
| \*Please specify: Click here to enter text. |
| 1. Summary of the nature of the planned work (minimum 100 words)
 |
| Click here to enter text. |

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| **9. Only for class 1 contained uses, a summary of the risk assessment****The risk assessment for contained use activity planned in the premises should be carried out in accordance with the Annex 3 of the Government Decree No. 132/2004 (IV. 29.) taking into account Annex 1, which is available** [**here**](https://gmo.kormany.hu/download/c/c8/13000/risk%20assessment%20GMM%20132_2004%20Kormrendelet%203%20%20mell%C3%A9klet%20_%20z%C3%A1rt%20rendszer%20K%C3%89%20EN.pdf)**.** The following four types of risk assessment forms are available for the risk assessment of contained used activities:* [Risk Assessment Form for Genetically Modified Microorganisms for contained use](https://gmo.kormany.hu/download/f/09/13000/GM%20kock%C3%A1zat%C3%A9rt%C3%A9kel%C3%A9si%20formanyomtatv%C3%A1ny%20GMM_EN.docx);
* [Risk Assessment Form for Genetically Modified Viruses and Virus Vectors for contained use](https://gmo.kormany.hu/download/1/19/13000/GM%20kock%C3%A1zat%C3%A9rt%C3%A9kel%C3%A9si%20formanyomtatv%C3%A1ny%20GMV%20%C3%A9s%20VV_EN.docx);
* [Risk Assessment Form for Genetically Modified Plants for contained use](https://gmo.kormany.hu/download/2/19/13000/GM%20kock%C3%A1zat%C3%A9rt%C3%A9kel%C3%A9si%20formanyomtatv%C3%A1ny%20GMP_EN.docx);
* [Risk Assessment Form for Genetically Modified Animals for contained use](https://gmo.kormany.hu/download/3/19/13000/GM%20kock%C3%A1zat%C3%A9rt%C3%A9kel%C3%A9si%20formanyomtatv%C3%A1ny%20GMA_EN.docx).

**Only for class 1 contained uses, the completed appropriate form of the risk assessment of the contained use must be attached as an attachment to this Application.** |

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| **10. Only for class 1 contained uses, describe the waste management measures, including the type and form of wastes to be generated, their treatment, final form and destination (minimum 100 words)** |
| Click here to enter text. |

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

|  |  |
| --- | --- |
| **1. The layout of the premises indicating the laboratories** | ( … ) |
| **2. Template table for the type of installation and for determining the level of containment** | ( … ) |
| **3. Curriculum vitae(s) of the person responsible for supervising** | ( … ) |
| **4. Curriculum vitae(s) of the person responsible for safety** | ( … ) |
| **5. Risk assessment(s) (only for class 1 contained uses)** | ( … ) |
| **6. Statement of the producer and user of the declaration of compliance of the OECD GLP requirements[[10]](#footnote-10)** | ( … ) |
| **7. Statement of confidential information** | ( … ) |
| **8. Proof of payment of the administrative service fee, or of the exemption** | ( … ) |
| **9. Other (optional)** | ( … ) |
| \*Please specify: Click here to enter text. |

*I declare and certify with y 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. Based on Part A of Annex 4 of Decree 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-1)
2. User (point m) of Article 2 of the Gene Technology Act): any natural or legal person responsible for the contained use of GMMs and for the establishment of the premises. The User is normally a University, Institution, Company and Organisation. Where there is more than one address for the premises being submitted, the address given should be the main contact address. This might be the headquarters or administration office address. [↑](#footnote-ref-2)
3. Considering *Table I. A* of Annex 2 of the Government Decree No. 132/2004 (IV. 29.). [↑](#footnote-ref-3)
4. Considering *Table I. B* of Annex 2 of the Government Decree No. 132/2004 (IV. 29.). [↑](#footnote-ref-4)
5. Considering *Table I. B* of Annex 2 of the Government Decree No. 132/2004 (IV. 29.). [↑](#footnote-ref-5)
6. Considering *Table I. C* of Annex 2 of the Government Decree No. 132/2004 (IV. 29.). [↑](#footnote-ref-6)
7. Considering *Table II* of Annex 2 of the Government Decree No. 132/2004 (IV. 29.). [↑](#footnote-ref-7)
8. Recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation. [↑](#footnote-ref-8)
9. Where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally. [↑](#footnote-ref-9)
10. According to pharagraph 2 of Article 2 of Decree 82/2003. (VII.16.) [↑](#footnote-ref-10)