APPLICATION

**Information required in application concerning genetic modification of organisms, and contained used activities 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. Information relating to the User of the premises, where the genetic modification or the contained used activity will be carried out** |
| a) Information relating to the User |
| 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. |
| b) No. of the permit for premises | Click here to enter the permit number. |
| * Indicate those laboratories / rooms where the contained used activity will be carried out *(Please use crosses (meaning x or X) into the space provided) (Please also indicate in which rooms what activities you plan to carry out, this must be indicated in the appropriate part of the table, if appropriate.)*
 |
|  | Precise indication of the appropriate room |
| Please specify the specific step of the contained used activity as a workflow. | Click here to enter the location. |
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| **4. Information relating to the activity** |
| a) Containment level *(Please use crosses (meaning x or X) into the space provided)* |
| Class 2 | ( ... ) |
| Class 3 | ( ... ) |
| Class 4 | ( ... ) |
| b) Short description of the contained used activity |
| Click here to enter text. |
| c) Purpose of the contained use, including the expected results (minimum 100 words) |
| Click here to enter text. |
| d) Type of the activity *(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. |
| e) 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. |
| GM cell cultures (human, animal, plant cell cultures)  | ( ... ) | Click here to enter the specific premise. |
|  Other\* | ( ... ) | Click here to enter the specific premise. |
| \*Please specify: Click here to enter text. |
| f) Methods used*(Please use crosses (meaning x or X) into the space provided, check all boxes which apply)* |
| Recombinant nucleic acid techniques[[3]](#footnote-3) | ( ... ) |
| 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[[4]](#footnote-4) | ( ... ) |
| 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. |

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| **5. Information relating the GMO(s)** |
| Characteristics of the GMO(s) |
| a) Recipient or parental organism |
| Click here to enter text. |
| b) Host / vector systems, where appropriate |
| Click here to enter text. |
| c) Origins and intended functions of the genetic material involved |
| Click here to enter the quantity. |
| d) GMO |
| identity | Click here to enter text. |
| origin | Click here to enter text. |
| characteristics | Click here to enter text. |
| e) The approximate culture volumes to be used |
| Click here to enter text. |

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| **6. 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/7/d8/13000/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 (GMM) – including cell cultures (GMCC) –­ for contained use](https://gmo.kormany.hu/admin/download/a/ec/43000/GM%20kock%C3%A1zat%C3%A9rt%C3%A9kel%C3%A9si%20formanyomtatv%C3%A1ny%20GMM_GMCC_EN.docx);
* [Risk Assessment Form for Genetically Modified Viruses (GMV) and Virus Vectors (GMVV) for contained use](https://gmo.kormany.hu/admin/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 (GMP) for contained use](https://gmo.kormany.hu/admin/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 (GMA) for contained use](https://gmo.kormany.hu/admin/download/3/19/13000/GM%20kock%C3%A1zat%C3%A9rt%C3%A9kel%C3%A9si%20formanyomtatv%C3%A1ny%20GMA_EN.docx).
 |
| Brief summary of the risk assessment (minimum 100 words) |
| Click here to enter text. |

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| **7. Description of the containment and other protective measures to be applied** |
| Click here to enter text. |

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| **8.Information relating to the waste management measures of GMOs** |
| a) The type and form of wastes to be generated |
| Click here to enter text. |
| b) The quantity of the wastes to be generated (by type) |
| Click here to enter text. |
| c) The treatment, final form and destination of the wastes, including the name and contact details of the company contracted to dispose of the waste (minimum 100 words) |
| Click here to enter text. |

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| **9. The description of the parts of the installation** *(only for class 3 or class 4 contained use)* |
| Click here to enter text. |

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| **10. Information about accident prevention and emergency response plans, if any:** (*only for class 3 or class 4 contained use)* |
| a) Any specific hazards arising from the location of the installation |
| Click here to enter text. |
| b) The preventive measures applied, such as safety equipment, alarm systems and containment methods |
| Click here to enter text. |
| c) The procedures and plans for verifying the continuing effectiveness of the containment measures |
| Click here to enter text. |
| d) A description of information provided to workers |
| Click here to enter text. |
| e) The information necessary for the competent authority to evaluate any emergency response plans |
| Click here to enter text. |

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| **11. 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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| **12. 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. |

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

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| **1. Risk assessment(s)** | ( ... ) |
| **2. Curriculum vitae(s) of the person responsible for supervising** | ( ... ) |
| **3. Curriculum vitae(s) of the person responsible for safety** | ( ... ) |
| **4. Statement of confidential information** | ( ... ) |
| **5. Proof of payment of the administrative service fee, or of the exemption** | ( ... ) |
| **6. 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 B and C 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. 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-3)
4. 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-4)