**GM Risk Assessment Form**

**Genetically Modified Microorganisms (GMMs), including cell cultures [GMCC (human, animal, plant cell cultures)]**

A GM risk assessment for human health and the environment should be carried out for any work involving the use of genetically modified microorganisms (including cell cultures). The completed form shall be retained and made available to the gene technology authority upon request. Please read the guidance provided on GM risk assessment, which is available [here](https://gmo.kormany.hu/download/7/ec/43000/Kock%C3%A1zat%C3%A9rt%C3%A9kel%C3%A9si%20t%C3%A1j%C3%A9koztat%C3%B3%202024.pdf).

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| **1. General information** |
| The purpose of the activity |
| Szöveg beírásához kattintson ide. |
| The number of the existing official permit | Engedély szám beírásához kattintson ide. |
| Name of the Institute | Szöveg beírásához kattintson ide. |
| Location of work (Building and room numbers) |
| Szöveg beírásához kattintson ide. |
| The number of the existing official permit for the establishment of the facility (if applicable) | Engedély szám beírásához kattintson ide. |
| Name, email address and telephone number of the Hungarian contact person | Szöveg beírásához kattintson ide. |

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| **2. Information on the activity, on the project***This section should describe the project, host organisms, vectors and genetic materials which should be reasonably detailed but not exhaustive. For different types of genetically modified microorganisms (including cell cultures), the responses are given into groups.*  |
| 2.1. Description of the project and contained used activities including the methods to be used and the purpose of the genetic modification |
| Szöveg beírásához kattintson ide. |
| 2.2. Expected maximum GMM and GMCC volumes |
| Mennyisége beírásához kattintson ide. |
| 2.3. Host organisms and hazard groups |
| Szöveg beírásához kattintson ide. |
| 2.4. Vector systems |
| Szöveg beírásához kattintson ide. |
| 2.5. Genetic inserts or materials (eg origins, nature of genetic modifications and intended or modified functions) |
| Szöveg beírásához kattintson ide. |

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| **3. Risk Assessment***This section contains the risk assessment, the elements of which require an examination of the potential adverse effects on human health and the environment.* *It should include a clear and explicit justification of any statements made about the risks with a logical* *explanation and any relevant evidence or references. The level of risk is estimated using the matrix given at the end of this form and then stating the risk as either:**Effectively zero, Low, Low / Medium, Medium or High.**In case of different types of genetically modified microorganisms (including cell cultures), the responses should be divided into groups.* |
| **3.1. Risks to human health** |
| 3.1.1. Characteristics of the host and any hazards associated with it |
| Szöveg beírásához kattintson ide. |
| 3.1.2. Characteristics of the vector system and any hazards associated with it |
| Szöveg beírásához kattintson ide. |
| 3.1.3. . Source and characteristics of the inserted gene products and any hazards arising directly from their use including an estimation of the level of expression and biological activity of the recombinant gene product (eg toxins, allergens, virulence or immunomodulatory products)  |
| Szöveg beírásához kattintson ide. |
| 3.1.4. Hazards arising from the emergence or the alteration of any existing pathogenic traits, if applicable  |
| Szöveg beírásához kattintson ide. |
| 3.1.5. Potential hazards of sequences within the GMM and the GMCC being transferred to related organisms  |
| Szöveg beírásához kattintson ide. |
| 3.1.6. Does this work pose a specific risk to susceptible individuals such as immunocompromised people, pregnant women, new mothers, etc.? If so, please provide details below. |
| [ ]  Yes | [ ]  No |
| Szöveg beírásához kattintson ide. |
| 3.1.7. What is the likelihood that in the event of exposure the GMM and the GMCC could cause to human health?  |
| Szöveg beírásához kattintson ide. |
| 3.1.8. Overall assessment of risk to human health based on the answers to questions 3.1.1 - 3.1.7. and using the matrix given at the end of this form (if applicable). If there is more than one type of GMOs, select the highest risk.  |
| Level of risk (Select one) | [ ]  Effectively zero |
| [ ]  Low |
| [ ]  Medium/Low |
| [ ]  Medium |
| [ ]  High |
| **3.2. Risks to environment** |
| 3.2.1. What is the capacity of the GMM and the GMCC to survive and establish in the environment, disseminate with or displace other organisms? |
| Szöveg beírásához kattintson ide. |
| 3.2.2. What is the likelihood that the GMM and the GMCC cause harm to animals?  |
| Szöveg beírásához kattintson ide. |
| 3.2.3. What is the likelihood that the GMM and the GMCC cause harm to plants? |
| Szöveg beírásához kattintson ide. |
| 3.2.4. What is the likelihood that the GMM and the GMCC cause harm to other organisms? |
| Szöveg beírásához kattintson ide. |
| 3.2.5. What is the potential for and the mechanism of transfer of genetic material between the GMM or the GMCC and other organisms, in particular the coding sequences for antibiotic resistance?  |
| Szöveg beírásához kattintson ide. |
| 3.2.6. Describe the adverse effects resulting from phenotypic or genetic instability, (if applicable)! |
| Szöveg beírásához kattintson ide. |
| 3.2.7. Overall assessment of risk to environment based on the answers to questions 3.2.1 - 3.2.6. and using the matrix given at the end of this form |
| Level of risk (Select one) | [ ]  Effectively zero |
| [ ]  Low |
| [ ]  Medium/Low |
| [ ]  Medium |
| [ ]  High |
| **3.3. Risk classification for GMM and GMCC** |
| Level of risk (Select one) | [ ]  1 | [ ]  3 |
| [ ]  2 | [ ]  4 |

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| **4. Control Measures to Eliminate or Reduce Risks of Exposure or Release***This section contains the minimum requirements and measures necessary for each level of containment.* *Containment is also achieved through the use of good work practices, training, containment equipment and special installation design.* |
| 4.1. Containment level (Select one) | [ ]  1  | [ ]  3 |
| [ ]  2  | [ ]  4 |
| 4.2. Containment laboratories or facilities |
| Select all that apply | [ ]  Laboratory  |
| [ ]  Animal facility |
| [ ]  Plant facility |
| [ ]  Other\* |
| \*Please specify: Szöveg beírásához kattintson ide. |
| 4.3. Microbiological safety cabinets and isolators |
| Select all that apply | [ ]  Class 1  |
| [ ]  Class 2. |
| [ ]  Class 3.  |
| [ ]  Isolator |
| [ ]  Other\* |
| \* Please specify: Szöveg beírásához kattintson ide. |
| 4.4. Special controls |
| Szöveg beírásához kattintson ide. |
| 4.5. Personal protective equipment |
| Select all that apply | [ ]  Lab coat |
| [ ]  Lab gown |
| [ ]  Surgical scrubs |
| [ ]  Disposable clothing |
| [ ]  Apron |
| [ ]  Safety spectacles |
| [ ]  Face shield |
| [ ]  Gloves |
| [ ]  Headwear |
| [ ]  Footwear |
| [ ]  Other\* |
| \* Please specify: Szöveg beírásához kattintson ide. |
| 4.6. Respiratory protective equipment |
| Select all that apply | [ ]  Filter mask |
| [ ]  Half face respirator |
| [ ]  Full face respirator |
| [ ]  Powered respirator |
| [ ]  Breathing apparatus |
| [ ]  Other\* |
| \* Please specify: Szöveg beírásához kattintson ide. |
| 4.7. Storage controls  |
| Szöveg beírásához kattintson ide. |
| 4.8. Controls for on-site transport of the GMM and the GMCC |
| Szöveg beírásához kattintson ide. |
| 4.9. Inactivation controls of the GMM and the GMCC |
| Select all that apply | [ ]  Disinfection |
| [ ]  Autoclave |
| [ ]  Fumigation |
| [ ]  Incineration |
| [ ]  Other\* |
| \* Please specify: Szöveg beírásához kattintson ide. |
| 4.10. Waste disposal routes |
| Szöveg beírásához kattintson ide. |
| 4.11. Immunisations (if applicable) |
| Szöveg beírásához kattintson ide. |
| 4.12. Instructions, training and supervision |
| Szöveg beírásához kattintson ide. |
| 4.13. Import, export or other licence of the GMM and the GMCC (if applicable) |
| Szöveg beírásához kattintson ide. |

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| **5. Emergency Procedures***This section should describe an emergency plan which is drawn up for contained uses where failure of the containment measures could lead to serious danger, whether immediate or delayed, to humans outside the premises and/or to the environment.* |
| 5.1. Description of the emergency procedures |
| Szöveg beírásához kattintson ide. |
| 5.2. Emergency contact(s) |
| Name | Position | Telephone |
| Szöveg beírásához kattintson ide. | Szöveg beírásához kattintson ide. | Szöveg beírásához kattintson ide. |

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| **6. Approval***This section should be signed and dated both by the assessor and the principal investigator (who is responsible for the activity).* |
| 6.1. Risk assessor |
| Name | Name | Dátum |
| Szöveg beírásához kattintson ide. |  | Dátum beírásához kattintson ide. |
| 6.2. Principal investigator |
| Name | Aláírás | Dátum |
| Szöveg beírásához kattintson ide. |  | Dátum beírásához kattintson ide. |
| *As the principal investigator for this project you have a legal responsibility to ensure that all those involved or working on the project have an appropriate level of training and expertise to enable safe working. This includes ensuring that workers read and understand this risk assessment and that all the control measures are in strict accordance with those approved for the project.* |

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| **7. Review***The risk assessment must be reviewed periodically, at least annually, and immediately if there are any significant changes to the work or where the risk assessment is no longer valid.* |
| 7.1. Risk assessor |
| Name | Aláírás | Dátum |
| Szöveg beírásához kattintson ide. |  | Dátum beírásához kattintson ide. |
| 7.2. Principal investigator |
| Name | Name | Name |
| Szöveg beírásához kattintson ide. |  | Dátum beírásához kattintson ide. |

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| **Risk estimation matrix** |
| **Consequence of****hazard** | **Likelihood of hazard** |
| **High** | **Medium** | **Low** | **Negligible** |
| **Severe** | High | High | Medium | Effectively zero |
| **Modest** | High | Medium | Medium / Low | Effectively zero |
| **Minor** | Medium / Low | Low | Low | Effectively zero |
| **Negligible** | Effectively zero | Effectively zero | Effectively zero | Effectively zero |