**GM Risk Assessment Form**

**Genetically Modified Animals (GMA)**

A GM risk assessment for human health and the environment should be carried out for any work involving the use of genetically modified animals. 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/2/e8/13000/K%C3%89%20t%C3%A1j%C3%A9koztat%C3%B3%20final.pdf).

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| **1. General information** | | |
| The purpose of the activity | | |
| Click here to enter text. | | |
| The number of the existing official permit | | Click here to enter the number of permit. |
| Name of the Institute | Click here to enter text. | |
| Location of work (Building and room numbers) | | |
| Click here to enter text. | | |
| The number of the existing official permit for the establishment of the facility (if applicable) | | Click here to enter the number of permit. |
| Name, email address and telephone number of the Hungarian contact person | Click here to enter text. | |

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| **2. Information on the activity**  *This section should describe the project, host organisms, vectors and genetic materials which should be reasonably detailed but not exhaustive.* |
| 2.1. Description of the project and contained used activities including the methods to be used and the purpose of the genetic modification |
| Click here to enter text. |
| 2.2. Host organisms |
| Click here to enter text. |
| 2.3. Vector systems |
| Click here to enter text. |
| 2.4. Genetic inserts or materials (eg origins, nature of genetic modifications and intended or modified functions) |
| Click here to enter text. |

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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.* | | | | | |
| **3.1. Risks to human health** | | | | | |
| 3.1.1. What are the novel hazards to human safety (eg toxicity, allergenicity, behavioural, human disease reservoir) posed by the GM animal? | | | | | |
| Click here to enter text. | | | | | |
| 3.1.2. Describe the GM animal’s potential to be more toxic to humans than the unmodified equivalent | | | | | |
| Click here to enter text. | | | | | |
| 3.1.3. Describe the GM animal’s potential to be more allergenic to humans than the unmodified equivalent | | | | | |
| Click here to enter text. | | | | | |
| 3.1.4. Describe the GM animal’s potential to exhibit any other potential hazards to humans when compared with the unmodified equivalent | | | | | |
| Click here to enter text. | | | | | |
| 3.1.5. Does the GM animal pose a greater risk to humans than the unmodified equivalent? | | | Yes | | No |
| 3.1.6. Does this GM animal work involve the use of any microorganism or pathogen? Please identify these microorganisms or pathogens. | | | Yes | | No |
| Click here to enter text. | | | | | |
| 3.1.6.1. If so, is it hazardous to humans? Please provide details below. | | | Yes | | No |
| Click here to enter text. | | | | | |
| 3.1.7. 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 |
| Click here to enter text. | | | | | |
| 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 | | | | | |
| 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 GM animal to survive and establish in the environment, disseminate with and or displace other animals? | | | | | |
| Click here to enter text. | | | | | |
| 3.2.2. What is the potential for and the mechanism of transfer of genetic material between the GM animal and other organisms, in particular the transgene and the coding sequences for antibiotic resistance? | | | | | |
| Click here to enter text. | | | | | |
| 3.2.3. What are the adverse effects of products derived from the expression of the inserted gene and/or inserted mutations, deletions, gene silencing? | | | | | |
| Click here to enter text. | | | | | |
| 3.2.4. Describe the adverse effects resulting from phenotypic or genetic instability? | | | | | |
| Click here to enter text. | | | | | |
| 3.2.5. What is the likelihood that the animal is acting as novel animal disease vector? | | | | | |
| Click here to enter text. | | | | | |
| 3.2.6. Will the insert be integrated into the host chromosome in a heritable manner? | | | | | |
| Click here to enter text. | | | | | |
| 3.2.7. If released into the environment, does the modified organism have the potential to cause harm to animals? Please specify! | | | | | |
| Click here to enter text. | | | | | |
| 3.2.8. If released into the environment, does the modified organism have the potential to cause harm to plants? Please specify! | | | | | |
| Click here to enter text. | | | | | |
| 3.2.9. If released into the environment, does the modified organism have the potential to cause harm to microorganisms? Please specify! | | | | | |
| Click here to enter text. | | | | | |
| 3.2.10. Does this GM animal work involve the use of any microorganism or pathogen? Identify these microorganisms or pathogens. | | | Yes | | No |
| Click here to enter text. | | | | | |
| 3.2.10.1. If so, is it hazardous to the environment? Please provide details below. | | | Yes | | No |
| Click here to enter text. | | | | | |
| 3.2.11. Overall assessment of risk to environment based on the answers to questions 3.2.1. - 3.2.10. 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 GM animals** | | | | | |
| 3.3.1. Assign the risk class to human health (Select one) | | | | | |
| Harmful | Non-Harmful | | | | |
| 3.3.2. Assign the risk class to environment (Select one) | | | | | |
| Harmful | Non-Harmful | | | | |
| **3.4. Risk classification for GM microorganisms (Only required if work involves GMM)** | | | | | |
| 3.4.1. Assign the risk class (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: Click here to enter text. | | | |
| 4.3. Microbiological safety cabinets and isolators | | | |
| Select all that apply | Class 1 | | |
| Class 2 | | |
| Class 3 | | |
| Isolator | | |
| Other\* | | |
| \* Please specify: Click here to enter text. | | | |
| 4.4. Special controls | | | |
| Click here to enter text. | | | |
| 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: Click here to enter text. | | | |
| 4.6. Respiratory protective equipment | | | |
| Select all that apply | Filter mask | | |
| Half face respirator | | |
| Full face respirator | | |
| Powered respirator | | |
| Breathing apparatus | | |
| Other\* | | |
| \* Please specify: Click here to enter text. | | | |
| 4.7. Storage controls | | | |
| Click here to enter text. | | | |
| 4.8. Controls for on-site transport of the GMA | | | |
| Click here to enter text. | | | |
| 4.9. Inactivation controls of the GMA | | | |
| Select all that apply | Disinfection | | |
| Autoclave | | |
| Fumigation | | |
| Incineration | | |
| Other\* | | |
| \* Please specify: Click here to enter text. | | | |
| 4.10. Waste disposal routes | | | |
| Click here to enter text. | | | |
| 4.11. Immunisations (if applicable) | | | |
| Click here to enter text. | | | |
| 4.12. Instructions, training and supervision | | | |
| Click here to enter text. | | | |
| 4.13. Import, export or other licence of the GMA (if applicable) | | | |
| Click here to enter text. | | | |

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| **5. Emergency Procedures**  *This section should describe an emergency plan which is drawn up for contained uses (especially for work of GMAs and their products) 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 | | |
| Click here to enter text. | | |
| 5.2. Emergency contact(s) | | |
| Name | Position | Telephone |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |

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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 | Signature | Date |
| Click here to enter text. |  | Click here to enter date. |
| 6.2. Principal investigator | | |
| Name | Signature | Date |
| Click here to enter text. |  | Click here to enter date. |
| *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 | Signature | Date |
| Click here to enter text. |  | Click here to enter date. |
| 7.2. Principal investigator | | |
| Name | Signature | Date |
| Click here to enter text. |  | Click here to enter date. |

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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 |