# Investigation, assessment and classification according to chapter 9, 4 § , 6 § and 8 §

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| This part of the form follows the approach of the attachment 2 of the regulations and general advice (AFS 2023:13) from the Swedish Work Environment Authority about the risk regarding specific types of work and are designed for contained use of GMMs in an L-verksamhet (L-activity). More information can be found in the attachment 2 AFS 2023:13 as well as under the chapter “How to fill the form” in this document. There is also more general information about contained use of GMM on our webpage [www.av.se.](https://kise-my.sharepoint.com/personal/carina_bengtsson_ki_se/Documents/Biosäkerhet/GMM/Angela%20Översättning%20GMM/www.av.se.)  The correctly filled document can compose the form that is required according to chapter 9, 5 § AFS 2023:13. Therefore, this form must be kept available at the department and be able to be presented at the request of the Work Environment Authority but should be not submitted when notifying L-uses. |

*Use one form for each GMM-use. Copy all what is written between the dotted lines and paste it under last dotted line as often as needed.*

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| **GMM-use (nr)** |  | *OBSERVE! The basic information on GMM-use is filled in under the points 4 and 5 of the first part of the form.* |
| **GMM-use title** | | |
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## 1. Identification of potential harmful effects associated with GMM

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| **a) Can cause sickness for human, animals or plants.** (namn disease) | |
| **GMM** | **Recipient Organism** (GMM before modifying) |
|  |  |
| **Vector with inserted genetic material 2)** | **Vector without inserted genetic material** |
|  |  |
|  |  |
| **b) Can have allergic or toxic effects** (applies only for human) | |
| **GMM** | **Recipient Organism** (GMM before modifying) |
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| **Vector with inserted genetic material 2)** | **Vector without inserted genetic material** |
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| **c) Treatment of the disease is not available or (current) prophylaxis is not sufficient** | |
| **GMM** | **Recipient Organism** (GMM before modifying) |
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| **Vector with inserted genetic material 2)** | **Vector without inserted genetic material** |
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| **d) Establishing or spread into the environment** (describe how) | |
| **GMM** | **Recipient Organism** (GMM before modifying) |
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| **Vector with inserted genetic material 2)** | **Vector without inserted genetic material** |
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| **e) Inserted genetic material can be transmitted to other organism on a natural way** (different species/equivalent) | |
| **Via GMM** | **Via vector or the inserted genetic material** |
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|  |  |
| **f) Other potential harmful effects e. g. due to replicable-competent vector** | |
| **GMM** | **Recipient Organism** (GMM before modifying) |
|  |  |
| **Vector with inserted genetic material 2)** | **Vector without inserted genetic material** |
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*2) Including the donor organism, if present in the use.*

## 2. Assessment of the identified potentially harmful effects

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| **Potentially harmful effect** | **How serious it is**  (negligible – low – moderate - high) | **Likelihood of occurrence**  (due to the characteristics of the GMMs) |
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*Add rows if necessary.*

## 3. Identification of the factors in the specific GMM use that may increase the likelihood of the potentially harmful effects of occurring or of the GMM entering the environment

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| **Factors to consider** | **Increase the likelihood of adverse effects** (describe how) | **Increase the likelihood of GMMs being released into the environment** |
| **Characteristics of the activities**  *e.g. scope and nature of the activity as described under point 5 of the notification above* |  |  |
| **The methods used**, e.g.   * *aerosol generating capacity* * *stabbing/cutting tools* * *toxic substances (large scale)* * *animal handling (bites, claws) or excretion of GMMs (animal activities)* * *other* |  |  |
| **The characteristics of the(external) environment likely to be exposed** |  |  |
| **Need for specific possibilities to decontaminate GMMs in waste and wastewater** |  |  |

## 4. Assessment of the protective measurements needed, and which will be applied

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| **Table 4 a) mandatory measures for laboratory, animal and plant activities** | |
| 1. The facility is separated from other activities |  |
| 7. Lab-benches and floors are resistant to water, acids, chemicals, solvents, disinfectants and are easy to clean |  |
| 8. Hand washing device, preferable operable without touching with hands, and hand disinfection |  |
| 14. Sign with biohazard symbol |  |
| 15. Aerosol dissemination is minimized |  |
| 16. Access only for people who are informed about the risks |  |
| 17. GMM is stored in a manner so that no one will be exposed by mistake or unauthorized persons can access the material |  |
| 18. Appropriate protective clothing which is removed when leaving the work area |  |
| 21. Effective pest control (e. g. for rodents and insects) |  |
| 22. Autoclave adjacent to the facility |  |
| 23. Used material containing GMMs is decontaminated with a method chosen depending on the results of the investigation in chapter 9, 4 **§**, before it is washed, reused, disposed |  |
| 24. Waste containing GMMs is decontaminated with a method chosen depending on the results of the investigation in chapter 9, 4 **§** |  |
| 25. Written instructions for spills and other unwanted events are written |  |
| **Table 4 a) Measures depend on the outcome of the investigation in chapter 9, 4 §** | |
| 4. The facility can be decontaminated using fumigation |  |
| 6. Observation window or the equivalent provided, so that occupants can be seen |  |
| 10. Microbiological safety cabinet for handling infected material at substantial risk of aerosolization or airborne contamination or otherwise if necessary |  |
| 11. Alarm system for the safety cabinets and otherwise if necessary |  |
| 13. The laboratory equipment is kept within the restricted area |  |
| 19. Gloves are used |  |
|  | |
| **b) additions and amendments for GMM animal activities** | |
| 1. Isolated animal facility (building or a separate area within a building containing one or more animal facilities and other facilities such as changing rooms, showers, autoclaves or food storage) |  |
| 7. Floor and any bench are resistant to water, acids, chemicals, solvents, disinfectants and are easy to clean |  |
| 26. Animal facilities are separated by lockable doors |  |
| 27. Isolators or equivalent containment have HEPA filters, needed according to the investigations in chapter 9, 4 § |  |
| 28. Materials and equipment are designed to facilitate cleaning and contamination |  |
| 29. Measures to limit the risk of animals escaping the demarcation |  |
| 30. Incineration of animal bodies |  |
| 31. Litter and waste are decontaminated |  |
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| **c) additions and amendments for GMM plant activities** | |
| 1. Greenhouses or growth chambers with walls, roofs and floors, intended for growing plants in a controlled and protected environment |  |
| 2. Entrance only through the lock, needed according to chapter 9, 4 § |  |
| 21. Effective pest control (e. g. for rodents and insects) |  |
| 32. Permanent structures with continuous waterproof covering, designed to prevent entry of surface-water run-off and with lockable doors |  |
| 33. Runoff of contaminated runoff water is minimized if spread of GMMs can occur through the soil |  |
| 34. Procedures for transferring living material between different locations e. g. greenhouses/growth chambers and laboratories are performed that the dissemination of GMMs is minimized |  |

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| **Table 5 mandatory measures for large-scale operations (= over 500 liters)** | |
| 1. Viable GMMs are contained in a closed system(s) that the process is isolated from the environment |  |
| 2. Venting is done to minimize the release of GMMs |  |
| 3. Sealing are designed to minimize the release of GMMs |  |
| 6. Closed systems are located within a controlled area |  |
| 12. Floors and any benches are resistant to water, acids, chemicals, solvents, decontaminants and are easy to clean |  |
| 13. Hand washing device, preferable operable without touching with hands, and hand disinfection |  |
| 16. Sign with biohazard symbol |  |
| 17. Aerosol formation during sampling, adding, removal or transfer of material is minimized |  |
| 18. Access only for persons who are informed about the risks |  |
| 19. Protective clothing used within the controlled area |  |
| 21. Effective pest control (e. g. for rodents and insects) |  |
| 22. GMM is stored in a way that no one is accidentally exposed, or any unauthorized persons can access the material |  |
| 24. Used material containing GMMs is decontaminated with a method chosen depending on the results of the investigation before it is washed, reused, disposed |  |
| 25. Large quantities of culture fluid, including the process effluent, are decontaminated by validated methods of killing before leaving the closed system for further handling |  |
| 26. Specific routines for dealing with spills and other unwanted events are written |  |
| **Table 5 measurement depending on the outcome of the investigation in chapter 9, 4** **§** | |
| 4. Alarm system provided to indicate whether any technical safety equipment is out of order |  |
| 7. Access only through the air-lock |  |
| 8. The controlled area is maintained at an air pressure negative to the immediate surroundings |  |
| 9. Separate ventilation system with HEPA-filtration of the air |  |
| 10. Specific measurements to minimize air pollution |  |
| 11. The controlled area is sealable for fumigation |  |
| 15. The own equipment is kept within the restricted area |  |

## 5-7. Comparison of the protective measures needed with those in the table in the attachment 3 AFS 2023:13, classification including the confirmation that the level of protection is sufficient

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| **Select the table/table combination that contains the protective measures that are needed** | |
| **Table 4 a) above include all protective measures that are needed** (laboratory verksamhet) |  |
| **Table 4 a) + b) above include all protective measures that are needed** (animal verksamhet) |  |
| **Table 4 a) + c) above include all protective measures that are needed** (plant verksamhet) |  |
| **Table 5 above include all protective measures that are needed** (large-scale verksamhet) |  |
| **No table is applicable** (other activity)  **Describe which actions are needed:** |  |
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| **Level of protection which is enough for the GMM-use** | **Yes** | **No** |
| Level of protection 2 is enough for the GMM-use |  |  |

*If level of protection 2 is not enough, then you need to apply for a GMM-use in an R-verksamhet.*

*End of the form for GMM-use*

## Space for own comments

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*Copy and paste a new section here if you have more GMM-use*