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

|  |
| --- |
| 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.  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-verksamhet. |

*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.*

. . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . .

|  |  |  |
| --- | --- | --- |
| **GMM-use (nr)** |  | *OBSERVE! The basic information on GMM-use is filled in under the points 10 and 11 of the first part of the form.* |
| **GMM-use title** | | |
|  | | |

## 1. Identification of potential harmful effects associated with GMM

|  |  |
| --- | --- |
| **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) |
|  |  |
| **Vector with inserted genetic material 2)** | **Vector without inserted genetic material** |
|  |  |
|  |  |
| **c) Treatment of the disease is not available or (current) prophylaxis is not sufficient** | |
| **GMM** | **Recipient Organism** (GMM before modifying) |
|  |  |
| **Vector with inserted genetic material 2)** | **Vector without inserted genetic material** |
|  |  |
|  |  |
| **d) Establishing or spread into the environment** (describe how) | |
| **GMM** | **Recipient Organism** (GMM before modifying) |
|  |  |
| **Vector with inserted genetic material 2)** | **Vector without inserted genetic material** |
|  |  |
|  |  |
| **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** |
|  |  |
|  |  |
| **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** |
|  |  |

*2) Including the donor organism, if present in the use.*

## 2. Assessment of the identified potentially harmful effects

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

*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

|  |  |  |
| --- | --- | --- |
| **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

|  |  |
| --- | --- |
| **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 |  |
|  | |
| **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 |  |

|  |  |
| --- | --- |
| **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

|  |  |
| --- | --- |
| **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:** |  |
|  | |

|  |  |  |
| --- | --- | --- |
| **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

|  |
| --- |
|  |

. . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . .

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