

Procedure for appointing the BSO/ESO, VM/OL, and ABV

Introduction

The aim of this procedure is to meet the requirements set out in the Decree and Regulation on Genetically Modified Organisms, Environmental Management 2013 concerning the appointment of employees with tasks related to working with and supervising genetically modified organisms (GMO). These employees are the employee responsible (VM), research leader (OL), Biosafety Officer (BSO), and Environmental Safety Officer (ESO) in the event of introduction into the environment, such as gene therapy. In addition, Maastricht University (UM) and Maastricht University Medical Centre+ (MUMC+) have appointed a Departmental Expert for Biosafety (ABV) to each department to support the employees responsible/research leaders.

Procedure

- The BSO and ESO are personally accredited by the Ministry of IenW, after the BSO or the Board of the institution submits an authorization form.
- The Board of the institution prepares an appointment letter for the BSO and the ESO and mandates them for the statutory authorities, such as access to all relevant rooms and information, suspending work, and possible authorities such as applying for notifications/permits from IenW.
- The Board will report the appointments and any expansion of tasks to a higher risk level to IenW.
- In the event of exemption from the task as BSO or ESO, the Board will send a letter to the officer and a copy to Bureau GGO. In the event of the continuation of the GMO work, the Board will send a notification of a new BSO and/or ESO to Bureau GGO within one week.
- The dean of the faculty (UM) or head of department (MUMC+) will appoint a researcher authorized by the BSO or ESO as an employee responsible for a permit at the recommendation of the BSO or ESO.
- The dean of the faculty (UM) and the head of department (MUMC+) will discharge the employee responsible on the condition that a new employee responsible is appointed or that the permit is terminated. Both will be reported to the BSO or ESO.

N.B. In the event of an appointment for more than one month, a deputy BSO/ESO/OL/VM/ABV must also be appointed in accordance with the above.

Table 1 outlines the tasks, responsibilities, and authorities of the BSO, ABV, and OL/VM.

Table 1 - Tasks, responsibilities, and authorities of the BSO, ABV, and OL/VM

| Task | BSO | ABV | OL/VM |
|--------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|--------------------|---------------------------------------------------------|
| Drawing up company-wide procedures | | | |
| Drawing up department work protocols | Evaluating | | Preparing and implement |
| Daily management of GMO activities | | | |
| Supervising compliance with company-wide procedures and department protocols | Audit | | |
| Routinely checking the correct function of facilities such as the biosafety cabinet, etc. | | | |
| Granting (written) permission for and supervising the execution of repairs in work spaces | Permission level II and above | Permission level I | |
| Handling incidents | Advising and investigating, reporting to Inspectorate | Executive | Reporting to BSO, implementing measures for improvement |
| Informing employees about biosafety risks of work and about legislation | ABV and OL/VM | | Employees |
| Instructing employees on management measures (company requirements) | | | |
| Reporting on risky work situations and deviations from statutory requirements | Manager | OL/VM and BSO | BSO |
| Appointing competent employees | | | |
| Assessing qualification for work in contained work spaces | Granting authorization | Monitoring | Monitoring and revoking access, if applicable |
| Carrying out statutory central administration tasks and maintaining overview of decentralized administration tasks | | | |
| GMO risk assessments | | | Supplying information |
| Submitting notifications and changes to notifications | | | |

Green indicates with whom responsibility rests.

Abbreviations

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|-------|-----------------------------------------------------------------------------|
| ABV | Departmental Expert for Biosafety |
| BSO | Biosafety Officer |
| ESO | Environmental Safety Officer |
| GMO | Genetically Modified Organism |
| IenW | Ministry of Infrastructure and Water Management; executive body: Bureau GGO |
| MUMC+ | Maastricht University Medical Centre+ |
| OL | Research leader |
| UM | Maastricht University |
| VM | Responsible Investigator |

References

- Decree and Regulation on Genetically Modified Organisms, Environmental Management 2013, IenW April 2014
- [Website HSB Maastricht](#)

Further information

For further information, please contact the [BSO](#).