

Procedure for internal checks when working with genetically modified organisms

Introduction

The aim of this procedure is to outline the checks that must be carried out on working with genetically modified organisms. In accordance with the Regulation on Genetically Modified Organisms, Environmental Management 2013, Art. 7, the Biosafety Officer (BSO) must carry out a check to verify compliance with the pertinent legislation. The appointment letter for the employee responsible (VM), research leader (OL), and Departmental Expert for Biosafety (ABV) sets out the tasks and responsibilities of the respective roles.

Procedure

- Employees responsible/research leaders are audited at least once every two years.
- Larger departments with multiple VMs/OLs are visited annually, with VMs/OLs audited on an alternating basis (but at least once every two years).
- Audits are scheduled by the HSB secretariat.
- GMO laboratories are inspected as part of the audits. The Departmental Expert for Biosafety must be present during the inspection, at a minimum. The VM/OL may also be present. The GMO laboratories of the UNS50 will be inspected during the yearly maintenance window. In this case, the inspection of the GMO laboratories will not be part of the GMO audit.
- In addition to the inspection of GMO laboratories, there is also a meeting with the employee responsible for the GMO permit, lasting approximately one hour. During this meeting, the responsibilities of the VM/OL are verified as specified in the appointment. Future plans and the impact on the current GMO permit, bottlenecks, and points for improvement or other biological safety-related issues may also be discussed. The ABV may also be present during the meeting.
- The BSO carries out random checks of work, including literature searches to ensure that the outlined work is licensed, lab journal checks, and checks in the order system and DEC. Shortcomings are discussed during the audit or in interim meetings with the VM/OL, where necessary.
- The BSO will prepare a report of the internal GMO audit, containing a list of action points. There will also be deadlines by which the actions must be completed. The head of the department will receive a letter informing him of the key findings from the audit and the corrective actions that are expected. The ABV and VM/OL will receive a copy of the letter. The BSO will verify that the action points have been completed after the deadline has passed. If they have not, the permit holder may be informed.
- The BSO will regularly tour the building and visit the GMO laboratories and hold meetings with the ABV/VM/OL. Irregularities observed during these visits will be reported, with a request that they be resolved. If follow-ups on action points, the audit report, and irregularities observed in the interim prove unsatisfactory, the BSO may revoke access or close a GMO laboratory. These authorities are documented in the mandate issued by the EB/BoD.

Other checks

In addition to the routine audits, the DEC work protocols (WPs) are sent to the BSO for approval. These are checked to verify the requested GMO animals and the GMO microorganisms to be used. The BSO sends a report of approval to the IvD secretary. It is agreed that a researcher cannot receive approval for a work protocol if no final approval has been received from the BSO.

Work protocols involving the use of biological agents, including GMOs, are also assessed by the BSO and approved, if necessary after receiving sufficient guarantee of the purity of the microorganisms to be used. To this end, Appendix A to the work protocol must be signed by the BSO. Animals can be ordered once an approved work protocol has been issued.

Abbreviations

ABV	Departmental Expert for Biosafety
BSO	Biosafety Officer
DEC	Animal Testing Committee
EB/BoD	Executive Board/Board of Directors
GMO	Genetically Modified Organism
IvD	Animal Welfare Body
RGGO	Regulation on Genetically Modified Organisms, Environmental Management 2013, IenW April 2014
UM	Maastricht University
UN50	Universiteitssingel 50
VM	Responsible Investigator
WP	Work protocol for the DEC application

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](#).