

# Sanctions policy for failing to observe GMO rules

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**Abbreviations:**

BSO = biosafety officer; BSU = biological safety unit; ABV = departmental biological safety expert; OL = research leader; VM = responsible employee

**Background**

In the context of the biological safety mandate, the BSU reports to the Executive Board. During this report, it transpired that some departments do not always observe GMO rules. It was then asked at what point and/or based on which documentation the BSU may use the powers provided under the biological safety mandate (i.e. denying employees access or closing GMO laboratories). The Executive Board advised the BSU to draw up a step-by-step plan/procedure with UM Legal Affairs, describing how to act when GMO rules are found not to have been observed. The following sanctions policy has been drawn up with UM Legal Affairs.

**Introduction**

The ABV or VM/OL informs everyone scheduled to work in a GMO laboratory of the applicable rules before they enter GMO laboratories. Appendix 1 lists the GMO rules.

The sanctions policy comes into effect if the GMO rules are found not to have been observed. The sanctions policy has two forms: a policy for individuals who systematically fail to observe the GMO rules and a policy for departments and faculty services in the FHML and/or FSE where various forms of failing to observe GMO rules are repeatedly established.

The BSO may personally establish that GMO rules are not being observed, but they can also be informed of a violation by a report from a VM/OL/employee. Following a finding by the BSO or a report to the BSO that GMO rules are not being observed, a step-by-step protocol comes into effect. This protocol aims to remove and/or explain any lack of clarity concerning the GMO rules. If nothing improves, sanctions are imposed to ensure compliance with laws and regulations. The actions and penalties associated with a certain number of findings of failing to observe GMO rules are described below. Each e-mail from the BSO sent in the procedure below will include a delivery and read receipt.

**Sanctions policy for individual violation**

*Examples: wearing hand and wrist jewellery in a GMO laboratory or leaving the GMO laboratory without washing hands*

1. The first established failure to observe GMO rules is noted in the BSO's records. The employee concerned receives an e-mail about this from the BSO asking them to respond. If the failure was correctly established, the note remains. The ABV\* and VM/OL of the relevant section or faculty department receive a copy.
2. A second established failure to observe GMO rules is again noted by the BSO. The employee concerned is again informed by e-mail, this time copied to the relevant section chair or head of the faculty department concerned, ABV, and VM/OL.
3. In case of a third established failure to observe the GMO rules, the procedure as described under point 2 is followed with the added requirement of a meeting between the BSO, the employee concerned, and the section chair or head of the faculty department concerned. The aim of this meeting is to once again remind the employee concerned of the GMO rules and make it clear that the next established failure to observe those rules will result in a sanction, namely denial of access to all GMO laboratories. A report is made of this meeting, which is shared with the meeting partners and copied to ABV and VM/OL. The dean of the relevant faculty is then also informed by the BSO.
4. In case of an established fourth failure to observe the GMO rules, the employee concerned is denied access to all GMO laboratories with immediate effect, for seven days. The employee

concerned will be informed by e-mail, copied to the relevant section chair or head of the relevant faculty department, ABV, VM/OL and dean of the relevant faculty.

5. If the employee concerned subsequently fails to observe the GMO rules again, the BSO will consult with the relevant section chair or the head of the relevant faculty department and extend the period of denied access to the GMO laboratories for up to six weeks.

This denial of access to the GMO laboratories will be recorded in the personnel file and can lead to a sanction relating to the employee's legal status being imposed.

\*If the employee works in a Central Research Facility (COV), the COV laboratory manager and COV head will be included in this communication.

### **Sanctions policy for violation by departments and/or faculty services**

*Examples: performing unlicensed work, work at a lower containment level than obliged, several individuals not observing the GMO rules*

1. If five instances of failing to observe the GMO rules, or a combination of GMO rules, are registered within a department and/or faculty service, the relevant section chair or head of the faculty department will receive an e-mail from the BSO requesting a response. The e-mail will also mention that the repeated failure to observe GMO rules can result in the temporary closure of one or more GMO laboratories in the faculty unit. The VM/OL of the relevant group will receive a copy of that e-mail.
2. If a failure to observe the GMO rules is subsequently established, a meeting between the BSO, VM/OL, and the department chair or head of the faculty service will follow to discuss the GMO rules and the failure to observe them, after which the parties will make further arrangements to prevent this happening again. A report is made of that meeting and shared with the meeting partners. The BSO also then informs the dean of the relevant faculty.
3. If it is established after some time that the GMO rules are still not being observed or there is another failure to observe, then one or more GMO laboratories in a department and/or faculty service will be closed temporarily for up to six weeks.

If the GMO work happens in a Central Research Facility (COV), the laboratory will not be closed but the employees of the relevant in a department and/or faculty service will be denied access to the COV as a joint department or section for up to six weeks.

### **Appendix 1: the GMO rules**

1. Any act performed with GMOs must be licensed or notified (host vector, insert, origin insert) under the GMO Decree and Regulations.
2. The additional conditions stipulated in the GMO license/notice must be fulfilled at all times.
3. A relevant activity must be performed at the containment level (or higher containment level) specified in the GMO license/notice for that activity.
4. Each GMO worker must be admitted by the BSO.
5. Wearing hand and wrist jewellery in GMO laboratories (while working) is prohibited.
6. Long hair must be tied back.
7. Personal belongings must be kept outside the GMO laboratory.
8. Mobile equipment must be operated with clean hands only. Prior to operating the equipment, the operator must wash their hands with soap and water.
9. The GMO worker must disinfect the workstation after completing their work.
10. Before leaving the GMO laboratory, everyone must wash their hands with soap and water.
11. GMO laboratory coats may not be taken outside the respective GMO laboratory. Entering a non-GMO laboratory or room while wearing a GMO laboratory coat, even for a very short period, is prohibited.
12. All GMO waste must be deposited in the appropriate GMO waste bins. Once these GMO waste bins are full, the GMO worker must seal and disinfect them properly before placing them at the 'collection point'. This refers to where the logistics employee collects the full drums.
13. The GMO worker must release equipment before it is presented for repairs. The ABV (and BSO\*\*) must sign this release.
14. If maintenance is being carried out in the GMO laboratory, the room manager or ABV must release the laboratory before this maintenance starts. The ABV (and BSO\*\*) must sign this release.
15. When being transported internally, GMOs must be kept in a double-contained unbreakable container that can be secured and disinfected.

\*\* the ABV (or room manager) signs for containment category ML-I; the ABV (or room manager) and the BSO sign for containment category ML-II, DM-II and higher.