

Classification of Breaches

by VLOG-Recognised Laboratories

Minor breaches

- The documents to be submitted for maintaining VLOG recognition were incomplete or not submitted in a timely manner (deadline for the previous calendar year: no later than 31 March of the following year) and not submitted or completed within two months (by 14 April) after the expiration of the deadline.
- The period of four weeks for sending the updated accreditation certificate in the event of re-accreditation or change to the scope of accreditation was not complied with and also not submitted within two weeks after expiration of the deadline.
- VLOG was not informed of changes to outsourcing.
- Issuance of a test report that does not comply with the requirements of the VLOG Standard and exhibits merely deviations in form (e.g. failure to cite the uncertainty of measurement, mandatory information on test reports). On the other hand, the requirements put on the testing method and the scope of testing pursuant to the VLOG requirements were complied with.

Significant breaches

- Occurrence of more than two minor breaches within one year.
- Failure to perform corrective measure for minor violation.
- Noncompliance with requirements of the VLOG Standard and/or the “Guidelines for VLOG Recognition of Laboratories” (e.g. failure to use the correct method or dysfunction in the laboratory’s QM system) that have no effect on the test result and the legal assessment.
- Results are wrongly interpreted (e.g. a botanical impurity is classified as subject to compulsory labelling although the sample would nevertheless be suitable for VLOG and vice versa).
- Lack of cooperation in VLOG’s integrity checks or in submission of documents to VLOG for review (e.g. insufficient provision of information or documents).
- Failure to submit a statement regarding a violation on time or only response after a repeated request.

Major breaches

- Occurrence of more than two significant breaches within one year.
- Failure to take corrective action after a significant and major violation.
- Significant deviations from the VLOG requirements and/or the “Guidelines for VLOG Recognition of Laboratories” (e.g. confirmation of VLOG Standard, although the scope of testing does not comply

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with VLOG requirements; unequivocally false assessment) that have an effect on the test result and the legal assessment.

- The laboratory awarded GMO testing according to the VLOG Standard as subcontracts or outsourcing to a “**non**-VLOG-recognized laboratory”.
- Deliberate manipulation of test reports or other documents.
- Deliberate or grossly negligent issuing of test reports despite the failure to comply with the VLOG Standard and/or the "Guidelines for VLOG Recognition of Laboratories".
- Denial of access to the laboratory for VLOG employees or a person contracted by VLOG on the previously-announced day of the Integrity Laboratory Audit, although notice of the auditor and date of the audit had been given at last 2 weeks in advance.
- Testing methods used are not accredited.
- VLOG was not informed of the withdrawal of accreditation for individual methods according to ISO/IEC 17025 within the contractually stipulated period of five business days.
- Use of wrong documents with effect on the test result (e.g. wrong version of the Standard, wrong version of the Guidelines for VLOG Recognition of Laboratories in the event that the requirements have changed, e.g. for the scope of testing).

The above-listed breaches are intended to serve as guidance in evaluating and classifying breaches not mentioned here. The four-eyes principle will be used to assess and categorise breaches.