Verification of GLP status of facilities conducting GMO studies

AD HOC MEETING BETWEEN EFSA AND GM APPLICANTS

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Background

On 25 June 2025, EFSA informed applicants of an update on the acceptance of GLP claimed studies submitted in support of a GMO application in the EU.

For all applications submitted as of 2025, the test facilities need to be GLP-certified for the relevant area of expertise as defined in the OECD Document No. 2, Appendix to Annex III, section 4.

The new approach creates a lot of uncertainty for applicants.

- The difference of approaches of monitoring authorities (such as between the EU and USA) to ensure GLP compliance of facilities is beyond the applicant's responsibility and control.
- No transition period has been implemented.
- Potential implications of the new approach.

Challenges of the new approach

EFSA indicated that *"In case a test facility was inspected more than 3 years prior to the conduct of a study … EFSA may request the GLP monitoring authority to perform a study audit to verify the GLP status of studies in accordance with EFSA's relevant procedure"*.

- The receiving authority should only verify the GLP status of the facility in case of concerns.
- The OECD Document 20 (Section 4.1) does not require a 3-year interval for inspections:

"Most GLPMAs operate a program of routine full inspections (test facility inspections including study audits) conducted every two to three years. However some GLPMAs may not routinely inspect all test facilities in their country on a two to three year cycle … For that reason, information on the GLP status of a specific test facility or test site in some countries may not always be available…".

- While the first requested audit by EFSA was conducted in a swift manner, it can be expected that it will not be the case with a higher number of submissions.

Outstanding questions

1. Given that the OECD's 3-year GLP inspection interval is a guideline rather than a fixed rule, could EFSA clarify its reasoning for treating it as a strict expiration period? How does this align with OECD principles, and would EFSA consider a more flexible approach to avoid excluding valid studies and creating unnecessary administrative burdens?
2. What is the procedure for requesting an audit in a third country, considering that EFSA does not act as a monitoring authority?
3. How does such a request affect the status of an application under EFSA's assessment (completeness check & risk assessment)?

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