European Food Safety Authority

Pesticides and GLP

Content

- GLP requirement for pesticide studies
- EFSA guidance scientific peer-reviewed open literature

Legal background

- Data requirements for active substances (Reg. 544/2011) and plant protection products (Reg. 545/2011): tests and analyses must be conducted in accordance with the GLP where testing is done to obtain data on properties and/or safety with respect to human and animal health or the environment

GLP audits

- The European Commission and EFSA have reminded the Member States several times about the possibility to ask GLP audits where they have doubts
- EFSA is aware of some cases where MSs have asked GLP audits indeed
- EFSA as well has asked a number of audits of GLP studies

GLP audit report

- A GLP audit report typically include *i.a.* the following subjects:
  - Quality assurance programme
  - Equipment and facilities
  - Training of study personnel
  - Test systems; test and reference items
  - Review of raw data
  - Reporting

GLP audit report

- Some examples of comments in audit reports:
  - « Raw data generated (…) was reviewed in some detail. The raw data supported all conclusions made in the final study report »
  - « All raw data were verified and appeared to be complete (…). The study report was reviewed and results were compared to original records and other raw data »

EFSA guidance literature

- Page 13: « For the purpose of this EFSA Guidance, the fact that a study may not be conducted in accordance with GLP does not imply that the study is irrelevant »

EFSA guidance literature

- On Page 28, EFSA has cited « some possible classification schemes » for reliability (as an alternative)
- 5 examples are given, ordered chronologically
- « However, attention must be paid to the advantages, disadvantages (…) of such schemes (…). It must be emphasised that compliance with GLP standards should not be considered as a guarantee of reliability »

EFSA guidance literature

- Even in the Klimisch study, GLP is not the determining factor for reliability
- **1 = reliable without restrictions**: “studies or data...generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline...or in which all parameters described are closely related/comparable to a guideline method.”

EFSA guidance literature

- **2 = reliable with restrictions:** “studies or data...(mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.”