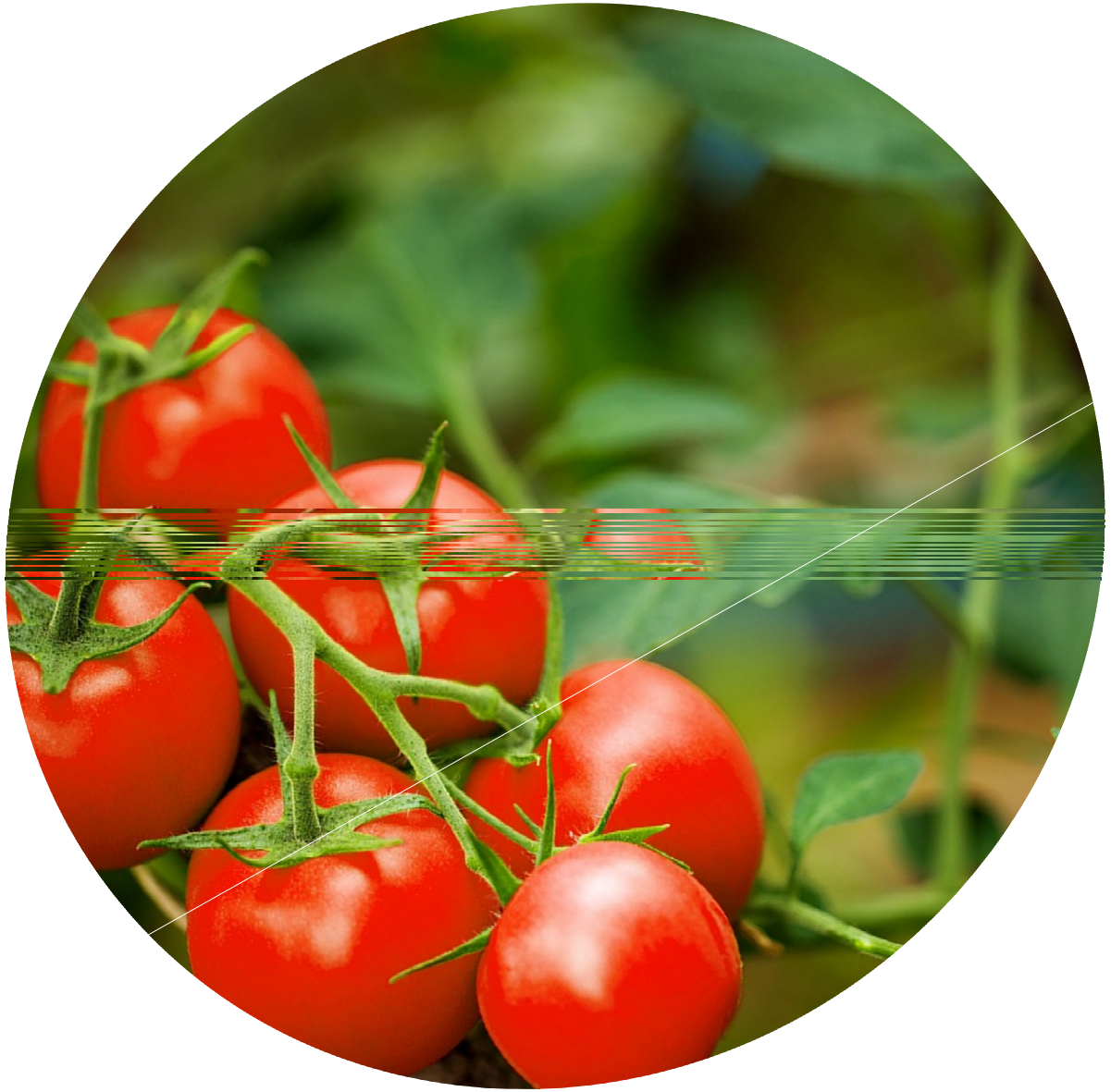
33rd PSN meeting – 6 May 2025



GLP STUDIES VERIFICATION BY EFSA

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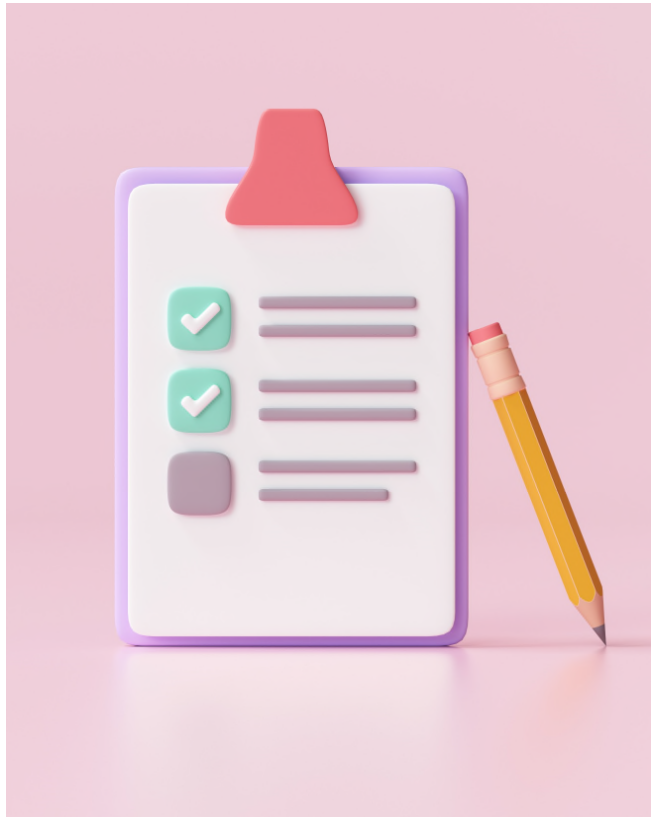
CONTENT

- GLP requirements
- EFSA GLP grant and GLP checklist
- GLP check for non-pesticides applications (EFSA)
- GLP check for pesticides applications (EMS/RMS)
- GLP study audits
- Follow-up questions

GLP REQUIREMENTS



- ✓ GLP aims to ensure **high standard of quality and reliability of tests** through the organisation and management of test facilities and the standardised way of performing and reporting studies
- ✓ **For non-pesticides**: different food **sectoral acts require GLP for certain types of studies**
- ✓ **For pesticides**: GLP mandatory requirement for all studies related to the characterisation of the properties or safety, with specific derogations

⇩

GLP check for non-pesticides (EFSA) and pesticides (RMS/EMS)

EFSA GLP GRANT GP/EFSA/FDP/2022/02

Project

- December 2022 - June 2024
- Establishment of a GLP verification methodology and tools (through a fit for purpose GLP verification checklist)
- Covering different regulated product areas withing EFSA's remit, **including pesticides**
- 784 studies (+ 200 for development of the methodology) were checked in total

Outcome

- External Scientific Report on the establishment of a GLP verification checklist for verifying GLP studies
- GLP checklist
- Training material

GLP CHECKLIST - STRUCTURE

1. **GLP legal requirement check**
   - GLP mapping for different regulated product areas
2. **Formal GLP criteria** – completeness check (CC)
   - 10 blocks of questions with follow-up actions
   - 4 possible decision options:
     a) Study has been performed without GLP observations
     b) Applicant or national monitoring authorities should be consulted (pending clarification)
     c) Scientific units / risk assessors should be consulted (pending clarification)
     d) Study has been performed with GLP observations
3. **GLP observations versus study robustness** – scientific check of study validity (RA)
   - in case of pending clarifications or GLP observations during the formal check
   - 3 blocks of questions with follow-up actions
   - 3 possible decision options:
     a) Information could not be retrieved, and more information is needed to verify the reliability of the study (pending clarification).
     b) Study is considered scientifically valid.
     c) Study is not considered scientifically valid

GLP CHECKLIST – INSTRUCTIONS & TRAINING

- Instructions/explanations are **in the GLP checklist**
- Training material on the use of this checklist is available **on the EU academy platform** (link)
  - Part 1 – Introduction into OECD principles
  - Part 2 – Introduction into GLP verification checklist
  - Part 3 – Practical demonstration include examples on specific studies
    a) Genotoxicity studies
    b) Repeated dose toxicity studies
    c) Ecotoxicity studies
    d) Residue studies

GLP CHECK FOR NON-PESTICIDES APPLICATIONS (EFSA)

as of January 2025

GLP systematic check

- for **ALL GLP claimed studies** during completeness check
- GLP compliance statement, Quality Assurance certificate, GLP status of test facility

GLP checklist

- for **% number of studies**
- risk-based & randomly selection

Ad hoc study audit

- in case of **pending GLP concerns** that require an audit by a national GLP Monitoring Authority (SOP_022)

GLP SYSTEMATIC CHECK FOR NON-PESTICIDES (EFSA)

Formal criteria

- GLP compliance statement signed by the Study Director
- Quality assurance certificate signed by QA personnel
- **GLP compliance status of test facility** at time of conduct of the study and for the area of expertise

✓ GLP compliance status of the test facility can be checked in the **OECD Annual Overviews** (pass-word protected website)
✓ Receiving authorities can **request access** via their national GLP Monitoring Authority

GLP CHECKLIST FOR NON-PESTICIDES (EFSA)

For % number of studies

- Implemented by risk-based approach
  - ✓ for studies with identified issues during GLP systematic check
  - ✓ for studies performed at test facilities or in specific countries with former identified not-in-compliance (NIC) studies (based on OECD NIC notifications and outcome of former study audits)
- Complemented with randomly selected studies
  - ✓ across the different food sector areas

GLP CHECK FOR PESTICIDES APPLICATIONS (EMS/RMS)

During admissibility and risk assessment (EMS/RMS)

- info on GLP/GEP certification of studies is included in Lists of tests and study reports
- GLP check under the responsibility of the **EMS/RMS, to include at minimum verification of the formal criteria**
- GLP checklist can be used for a more thorough verification
- Sheet 1 (GLP legal requirement check) includes the GLP provisions for pesticides and applicable derogations (conduction date, i.e. before or after the 25 July 1993, or the type of study in case of microorganisms)

During peer review (EFSA, MS)

- EFSA and other MS in case of pending GLP questions

GLP STUDY AUDITS

EFSA's Annual audit programme, covering both pesticides and non-pesticides applications

- **EFSA** requests study audits according to its procedure SOP_022
- **Outcome is shared with EMS/RMS** in case of identified GLP deviations and when pesticides' application is under evaluation by MS
  - **Minor GLP deviations and/or amended study report**: EMS/RMS to liaise with applicant for asking for amended study report where relevant
  - **Major GLP deviations/GLP non-compliant study:** EMS/RMS to ensure appropriate follow-up

Ad hoc study audits for non-pesticides' applications in case of specific GLP-related concerns during completeness check or risk assessment

Receiving authorities (also EMS/RMS) can ask a GLP monitoring authority to carry out a study audit to verify the GLP status of submitted studies

FOLLOW-UP QUESTIONS

- **EFSA GLP webpage** (link): information to applicants
- **Ask a Question tool** (link): RMS/EMS can contact EFSA in case of GLP questions
- **GLP activities @EFSA**: coordinated by FDP and GLP Task Force members, liaising with European Commission (DG GROW and EU GLP WG) & ECHA/EMA
- **EFSA GLP WG experts** (link): meets 3 times/year, advising on specific GLP issues