



# Are There Really “non-GLP” Studies?

LOOKING BEYOND GLPS FOR GUIDANCE

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A man with a beard, wearing a blue long-sleeved shirt, is sitting at a black table outdoors. He is holding a black mug with white text. On the table in front of him is another black mug, a microphone, a white cloth, and some papers. A sign is attached to the front of the table. The sign is white with black text. The background shows a paved patio area with a black metal chair and some greenery.

**THERE ARE NO  
NON-GLP STUDIES.**

**CHANGE MY MIND**


**Thank You!**

## § 160.3 Definitions

- ▶ Study means any experiment at one of more test sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, product performance (efficacy studies only as required by 40 CFR 158.400 or 161.640, as applicable), environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media. The term “study” does not include basic exploratory studies carried out to determine whether a test substance or a test method has any potential utility.

# Basic Exploratory Studies?


- ▶ EPA's GLP Advisory No. 2 states: "The term 'exploratory studies' does not have the regulatory meaning as suggested."
- ▶ This means EPA does not recognize "exploratory studies" as a category that is automatically exempt from GLP.
- ▶ Efficacy Trial?
- ▶ Method Development?
- ▶ Dose range-finding?



# 40 CFR, Part 158 Data Requirements for Pesticides

# § 158.400 Product performance data requirements table

- ▶ 810-2700 – Prion Related Claims = Indoor
- ▶ 93-16 – Mycotoxins = Conditional Food Crop and Food
- ▶ 96-5 – Avian Toxicants = Food and Nonfood Crops, Residential
- ▶ 96-6 – Avian Repellents = Food and Nonfood Crops, Residential
- ▶ 96-7 – Avian Frightening Agents = Food and Nonfood Crops, Res.
- ▶ 96-9 – Bat Toxicants = Indoor Residential
- ▶ 96-10 – Commensal Rodenticides = Food and Nonfood Crops, Res.
- ▶ Etc...



40 CFR, Part 161  
Data Requirements  
for Registration of  
Antimicrobial  
Pesticides

# § 161.640 Antimicrobial Pesticides Data Requirements

- ▶ 810-2700 – Prion Related Claims = Indoor
- ▶ 93-16 – Mycotoxins = Conditional Food Crop and Food
- ▶ 96-5 – Avian Toxicants = Food and Nonfood Crops, Residential
- ▶ 96-6 – Avian Repellents = Food and Nonfood Crops, Residential
- ▶ 96-7 – Avian Frightening Agents = Food and Nonfood Crops, Res.
- ▶ 96-9 – Bat Toxicants = Indoor Residential
- ▶ 96-10 – Commensal Rodenticides = Food and Nonfood Crops, Res.
- ▶ Etc...

40 CFR part 169

**BOOKS AND RECORDS OF PESTICIDE  
PRODUCTION AND DISTRIBUTION**

**§ 169.1 Definitions.**

**§ 169.2 Maintenance of records.**

**§ 169.3 Inspection.**

# § 169.2 Maintenance of records.

- ▶ All producers of pesticides, devices, or active ingredients used in producing pesticides subject to this Act, including pesticides produced pursuant to an experimental use permit and pesticides, devices, and pesticide active ingredients produced for export, shall maintain the following records:
  - ▶ (k) Records containing research data relating to registered pesticides including all test reports submitted to the Agency in support of registration or in support of a tolerance petition, all underlying raw data, and interpretations and evaluations thereof, whether in the possession of the producer or in the possession of the independent testing facility or laboratory (if any) which performed such tests on behalf of the producer. **These records shall be retained as long as the registration is valid and the producer is in business.**

# What Makes a GLP Study Compliant?

## Systemic

- ▶ §160.15 Inspection of Testing facility
- ▶ §160.29 Personnel
- ▶ §160.31 TFM
- ▶ §160.33 Study Director
- ▶ §160.35 QAU
- ▶ Subpart C – Facilities
- ▶ Subpart D – Equipment
- ▶ Subpart E – TF Operation

## Study

- ▶ Subpart F – TCR Substances
- ▶ §160.120 Protocol
- ▶ §160.130 Conduct of Study
- ▶ §160.135 P&C Char. Studies
- ▶ §160.185 Reporting Results
- ▶ §160.190 Storage of Data

# May be GLP-exempt?

- ▶ EPA explains that:
- ▶ Some method development or validation work could be exploratory.
- ▶ Some exploratory work may have nothing to do with method development.
- ▶ Exploratory studies performed entirely for internal use and not intended for EPA submission do not require GLP compliance.
- ▶ Example: early feasibility work, preliminary screening, internal R&D assays.

# But exploratory studies can be GLP-required!

- ▶ EPA emphasizes:
- ▶ If a study is intended to support an EPA submission (registration, EUP, tolerance petition, etc.), **then it must follow GLP**—even if the sponsor calls it exploratory.
- ▶ Some method development or validation studies are required for registration and therefore must be GLP-compliant.

# Case Study

- ▶ Sponsor driven “efficacy” study
- ▶ Pressure Can Pesticide evaluation
- ▶ Outdoor knockdown study on wasps
- ▶ 10 reps on wild nests
- ▶ Spray from 20’ for 3-5 secs
- ▶ Wait 5 minutes
- ▶ Count dead/dying insects on ground
- ▶ Non-GLP

