Pesticide Action Network Europe

GLP – does it create reliable and high quality studies?

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GLP – why was it put in place?

- 1976, Industrial Bio-Test laboratories data and study fraud. Many pesticide companies involved and around 20.000 studies, creating favorable outcome
- 1987/88 EU adopts GLP Directives
- 1990, Craven Laboratories, Texas, fraud in residue testing, massive institutional fraud
- 1997 Interdek, Texas, more than 59.000 projects worldwide, manipulating instruments
- Do we have any idea of the level of fraud now?

GLP – what is it?

- An administrative management system
- Plans, procedures and internal approvals
- Study director, principal investigator and laboratory personel identified
- To ensure “comparability and quality”
- OECD: “mutual recognition”
- Started to prevent fraud but in the end it looks more like a tool for promoting trade and reducing costs of industry.

What does literature tell us about reliability of GLP studies?

- Industry GLP tests claim 88x more often than independent literature that passive smoking is not harmful
- Industry GLP tests on soft drinks report in 0% of the cases negative effects, while independent studies report in 37% of the cases negative effects;
- 94 in vivo tests out of a total of 115 in independent literature report negative effects of Bisphenol A, while 4 industry GLP tests claim Bisphenol A is safe (EFSA based their assessment on exactly these 4)
- German BAuA finds correlation between outcome studies and type of funding on nano materials (2011)

What type of bias are we talking about (example pharmaceuticals, Lexchin, 2011)?

Poorer methodology not a likely reason, but:

- Reinterpreting data submitted to regulatory agencies
- Discordance between results and conclusions
- Conflict-of-interest leading to more positive conclusions (sponsor-contractor relationship)
- Ghostwriting, with a ‘spin’ favourable to the chemical

What more do we know about reliability of GLP studies?

- Inspection reports of Member States only check administrative system (pre-warning)
- Study audits on adequate reporting never heard of
- Study design many times outdated
- Published reviews show bias towards an industry-friendly outcome
- Reliability questionable, at best unknown
- But still Klimisch-ranking (BASF) nr.1

What do we know about quality of GLP studies?

- Official objective GLP Directive to ensure quality
- But how is this quality ensured?
- If MS have doubts on studies, they can request an audit (but did they ever?)
- GLP generally not published (claim confidentiality); public scrutiny on quality not possible
- Conclusion: quality unknown.

GLP (industry) studies vs. scientific research studies

- Industry studies generally not published
- Industry studies not peer-reviewed
- Industry studies not independently repeated
- Industry studies not part of a scientific discussion
- How come risk assessors love industry GLP studies that much?

Who scrutinises the content of GLP studies?

- Mostly civil servants on national level go through the piles, checking general topics (cage temperature, etc.)
- Sometimes national institutes are involved
- But rarely toxicologists involved
- Risk assessment panels generally only see summaries
- No real scrutiny (lack of time)

How can EFSA claim industry studies are of highest reliability and quality?

- EFSA opinion saying:
- Reliability: “some possible classification schemes as illustrated by Klimisch et al., etc.”
- Quality: guidance on data requirements (= GLP/OECD)
- Relevance: OECD/GLP
- But based on WHAT?

As a result the work of the entire scientific community is disregarded

- Do top-ranking scientists at universities and institutes work of no value that can be disregarded just for the reason of being non-GLP, non-OECD?
- In what way does Europe take their responsibility on health serious if the latests scientific findings are ignored?
- How can EFSA claim to be a scientific institute as long as they are based solely on industry-sponsored studies and disregard the work of the entire independent scientific community?

Conclusion

- GLP is useful because of the information generated, but it does not garantee reliability and quality
- EU MS show no interest in assessing reliability & quality of GLP-studies
- GLP is unjustified put at a platform in risk assessment and -as a result- functions as a shield to keep independent science at a distance
- Independent science needs to be taken into account without restrictions
- Industry-sponsored studies have to be put to an end and replaced by studies in independent laboratories