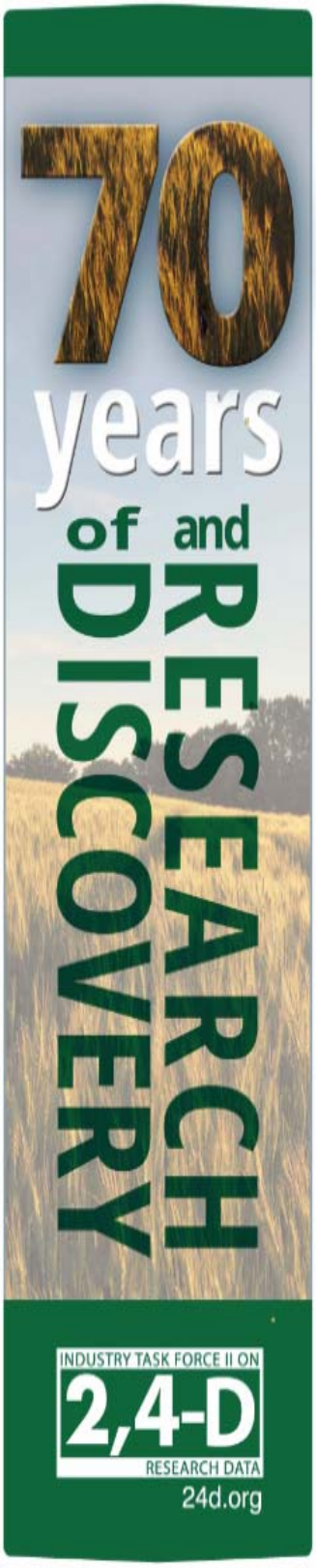


2,4-D and Industry Good Laboratory Practice – "GLP Research"

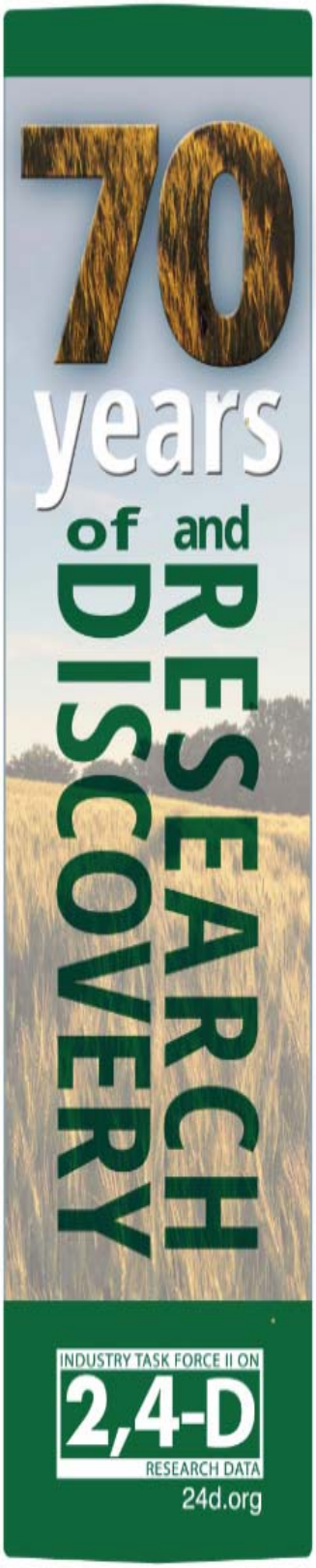
Many advocacy groups simply dismiss industry research as biased and unworthy of serious consideration. That is far from the truth. Data development for the more than 300 2,4-D reregistration studies required by the U.S. Environmental Protection Agency (EPA) were conducted by contract laboratories following very stringent Good Laboratory Practices (GLP) standards. The Task Force funded the studies, but more than 30 different EPA/GLP[1] qualified laboratories conducted the research, documented every step and then authored the reports sent to EPA and other authorities.

What is an EPA or Organisation for Economic Co-operation and Development (OECD) GLP qualified laboratory and what is the significance of its qualified research?[2] GLP standards are concerned with the integrity, organisational process and the conditions under which laboratory, field and analytical studies are planned, performed, monitored, recorded, archived and reported.

In November 1983, EPA regulations 40 Code of Federal Regulations (CFR) Part 160 established the Good Laboratory Practice Standards, or GLPs. A significant expansion of GLPs took effect in October, 1989. These prescribe laboratory standards for conducting any research funded by industry to be used for regulatory purposes. All research activities or data development must be recorded in minute detail, from start to finish.

The GLP principles have been developed to ensure the quality and validity of data generated in the testing of chemicals in order to facilitate their recognition for purposes of assessment and other uses relating to the protection of human health and the environment.

Each step of the process requires identification and a signature from the research person involved. Each step must be replicable, so records, tissue slides, samples etc. are required to be maintained indefinitely or until the study involved has no more value from a regulatory standpoint. EPA can ask to see these records, retained samples etc. at any time, and the study can be invalidated should they not be available. GLPs establish detailed standard operating procedures (SOPs) which must be implemented for both personnel training and for all laboratory procedures.



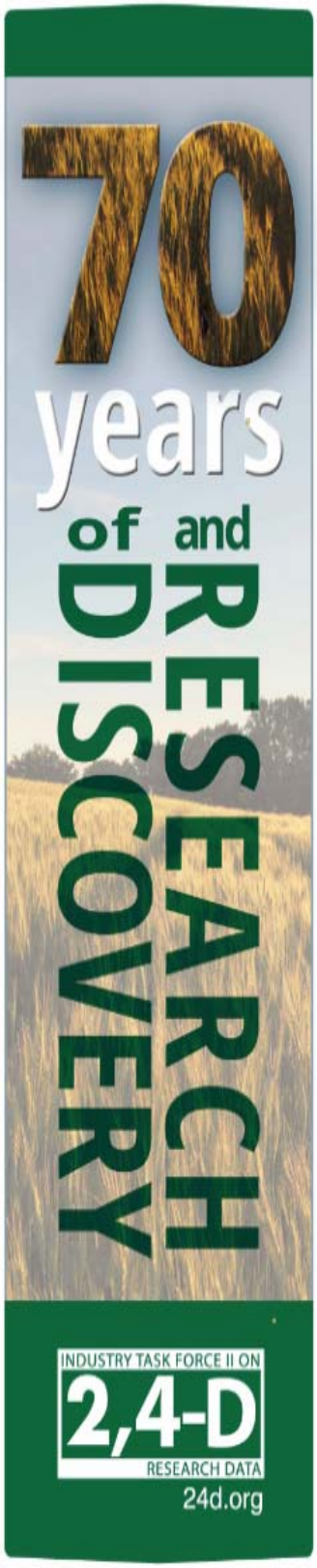
Each EPA/GLP qualified laboratory must have independent quality assurance, and methods must be validated by a second, independent laboratory. While this makes such research expensive, it also makes it demonstratively valid.

EPA periodically audits EPA/GLP laboratories, and reviews all submitted studies for GLP compliance. An unintentional GLP violation can invalidate the study, requiring it to be done over, and the violator may be fined as well. Since many of the required research studies are very expensive (i.e., a million dollars or more per study), having to repeat a study due to an unintentional GLP violation can be a very costly mistake. An intentional GLP violation, such as the deliberate understating of toxicity, is a felony. The laboratory and/or registrant personnel involved can be imprisoned.

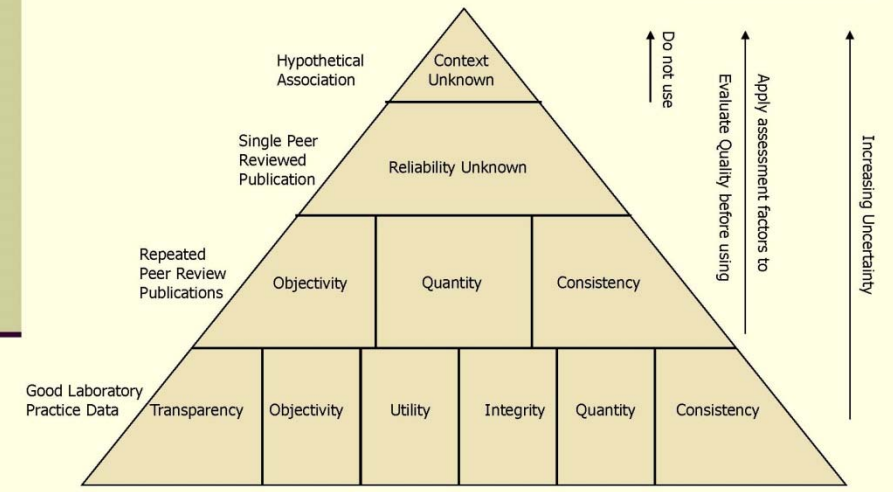
Test data generated in accordance with the principles of GLP is recognized by the authorities in several countries which avoids duplicative testing, is beneficial to animal welfare, and reduces costs for industry and governments. Also, common principles for GLP ease the exchange of information and prevent the development of non-tariff barriers to trade, while also contributing to the protection of human health and the environment.

As a result, EPA/GLP research is costly, much more so than the standard sort of research done by most university and government laboratories. Research done by government laboratories or government research institutions is not required to meet EPA/GLP standards, even when such research is used in support of government regulatory actions.

The Industry position on EPA/GLP research is that it does not object to meeting the higher costs of funding such research, but strongly recommends that all research conducted in support of governmental regulatory actions be of EPA/GLP quality. Many scientific conflicts could be avoided if all research done for regulatory purposes met the same high standards. For example, much of the current endocrine disrupter controversy, and many cancer controversies, could have been avoided if the research involved had been of EPA/GLP quality.



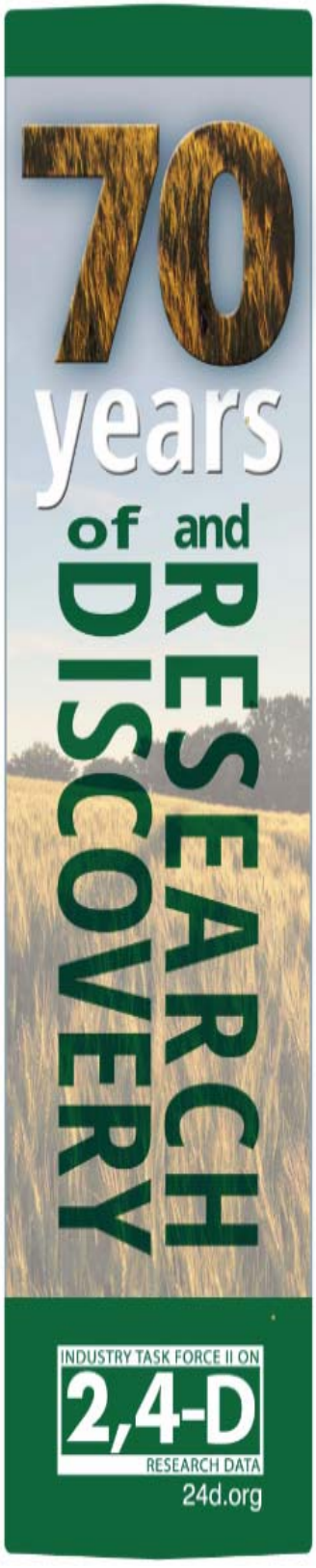
Data Quality Pyramid



Industry generated scientific data has its transparency, objectivity, utility, consistency and integrity assured by GLP standards

What is GLP Research?

- Under several statutes, government requires Good Laboratory Practice (GLP) studies from corporations.
- Research must follow specified protocols with each step documented.
- Only GLP qualified facilities and personnel can be used.
- GLP research is demonstratively valid. In other words, if anyone wishes to conduct the research – then the results should be reproducible.
- An unintentional GLP violation can invalidate the study. An intentional GLP violation can be a criminal offense.
- If studies that make the headlines in the news media today were of GLP quality, quite likely the debate we are witnessing would not be occurring.



About the Task Force

The Industry Task Force II on 2,4-D Research Data is organized to provide funding for the on-going Good Laboratory Practice (GLP) research studies required to respond to the US EPA registration review and PMRA pesticide re-evaluation programs. The 2,4-D Task Force is comprised of those companies holding technical 2,4-D registrations: Dow AgroSciences (U.S.), Nufarm, Ltd. (Australia) and Agro-Gor Corp., a U.S. corporation jointly owned by Albaugh, LLC. (U.S.) and PBI-Gordon Corp. (U.S.).

References:

[1] http://www.access.gpo.gov/nara/cfr/waisidx_00/40cfr160_00.html

[2] http://europa.eu.int/comm/enterprise/chemicals/legislation/glp/whatis.htm

March 17, 2016