HOW TO ENSURE TRUST IN PESTICIDE SAFETY DATA

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Good Laboratory Practice is the OECD's internationally accepted quality control system that sets the conditions under which non-clinical health and environmental safety studies for pesticides are planned, performed, monitored, recorded, archived and reported. We asked the OECD's Richard Sigma and Bob Diderich whether GLP was still relevant and trustworthy.

What is the OECD's role assessing pesticide safety data?

The OECD does not require data, review data or tell governments what data they should demand to approve a new pesticide. Instead we have a list of what data governments require from applicants who wish to register a pesticide active substance, and what tools and methods they could use to generate the data.

We have developed guidance and formats for the presentation of the documentation to be submitted to governments (i.e., "dossiers"). Our job is to work with governments to develop OECD Test Guidelines and guidance for the implementation of Good Laboratory Practices (GLP), to ensure that studies submitted to regulatory authorities are scientifically valid, of sufficient quality and rigour and are verifiable.

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Why has this job fallen to OECD?

Because it is an economic question. It is economically efficient for countries to work together to develop tools for generating and assessing chemicals, rather than developing such tools independently. And by using the same tools, data from a test performed in one country can be reused in another without the need for duplication. This is where Mutual Acceptance of Data (MAD) comes from.

Why is Mutual Acceptance of Data important?

The primary goal of the MAD system is to help governments protect human health and the environment in a way that optimises the use of their resources and reduces non-tariff barriers to trade.

If you generate your data in accordance with the OECD Test Guidelines and OECD GLP in one OECD country, it must be accepted by all 36 OECD members as well as six non-members who adhere to the MAD system. Other countries might have variations of GLP, but they cannot be part of MAD system until their GLP compliance monitoring programmes have been evaluated by OECD to ensure they comply with the requirements of MAD. For example, China has some GLP compliance monitoring programmes, but until they are evaluated by OECD, countries who are party to the MAD system are not required to accept GLP data generated in China.

How independent is the process for data generation?

One of the main advantages of the OECD Test Guidelines is that data generated has gone through serious review from governments and has reproducibility.

Under GLP requirements the receiving regulatory authority has access to the full study report including all laboratory data and the government can verify if the data was generated under GLP conditions. This is unlike studies that can appear in scientific literature, where tests may not have been conducted according to GLP, and where the test facility that conducted a study may not have been inspected by a government.

Can the public trust studies published in scientific journals?

That's not for us to say. What we can say is the GLP process is a requirement of submissions to governments, but it is usually not required for publication in a scientific journal.

Under GLP, the protocol is clear and robust, and transgressions are illegal. On the other hand, data used to write a study for a scientific journal may not have been conducted under GLP, and the laboratory data is usually not provided, although there is a move to make more data available through scientific journals.

Is the GLP system open to exploitation?

Our system is robust and can be trusted. We developed it for that reason, to avoid fraud. I don't see justification for a breakdown in trust from the public. Of course, a system can be perfected, but if you had to reinvent something to put public minds at ease you would come up with something very similar.

Is it a concern that safety data can be generated by the company submitting the application?

There is a perception that if a company conducts a study it has influence to change results, but the system prevents that. Whether the test facility is owned by a company seeking approval for a product, or a third party, doesn't matter – it is still inspected by the government.

If the government regulators find that some numbers don't add up, or that the results don't match the data, they can call for a study audit where the government will go back to the test facility to compare the laboratory data and associated records with the final report in order to determine whether the data has been accurately reported.

So not only is the original test conducted in a facility inspected by government, if the government wants to question the results it can require a study audit.

Can industry do more to build trust in its data?

If industry can find ways to bring more data into the public domain without jeopardizing their confidential and proprietary information, that might help to build trust. We are currently exploring possible approaches for governments to make more industry data available in the public domain, but in a way which also protects the intellectual property rights of companies and does not create disincentives to innovation.

Could governments take over the testing, to provide added independence in the process?

Possibly, but I think governments would be reluctant to take on the significant burden and bureaucracy associated with generating safety data, not to mention the liability.