PEST COMMITTEE MEETING OF 19 JUNE 2018

PUBLIC HEARING

EU AUTHORISATION PROCEDURE FOR PESTICIDES - COMMISSION APPROVAL OF ACTIVE SUBSTANCES

PREPARATORY QUESTIONS

Responses by Bob Diderich, OECD

In the context of the PEST Committee meeting of 19 June, an exchange of views will take place to give Members an insight into the approval of active substances by the European Commission.

To prepare for this exchange of views, political groups have submitted the following questions. These questions, which address many of the topics at stake, should be answered in writing beforehand.

Questions to the OECD:

1. Could you explain the concept of Good Laboratory Practice (GLP) and the GLP Guidelines? Particularly, how is GLP certified, who can apply for a GLP certification, how is the compliance with the principles of GLP audited?

   The OECD Principles of Good Laboratory Practice (GLP) are a managerial quality control system covering the organisational process and the conditions under which non-clinical health and environmental studies are planned, performed, monitored, recorded, reported and retained (or archived). The Principles are followed by test facilities carrying out studies to be submitted to government agencies for the purposes of assessing the health and environmental safety of chemicals and chemical products. The Principles define the responsibilities of test facility management, study director, study personnel and quality assurance personnel that are operating within a GLP system, and minimum standards concerning the suitability of facilities and equipment to perform studies, the need for standard operating procedures, documentation of raw data, study reports, the archiving of records, etc.

   OECD countries in which non-clinical health and environmental safety testing is carried out according to the OECD Principles of GLP have established national GLP Compliance Monitoring Programmes (CMP) with responsibilities for monitoring GLP compliance of test facilities within their territories. GLP compliance is verified by CMPs through inspections of GLP test facilities, and audits of GLP studies. A test facility which has been subject to periodic inspections by a CMP, and found to be operating in compliance with the Principles of GLP, is recognised as a GLP compliant test facility. In most countries, facilities that wish to become recognised as GLP compliant can apply to the national CMP. The CMP then conducts an inspection to determine if the test facility complies with the OECD Principles of GLP. In other countries, CMPs can inspect any test facility claiming to conduct studies according to GLP.

   Any test facility implementing the Principles of GLP can apply to be recognised as GLP compliant.

The OECD Mutual Acceptance of Data (MAD) system is a multilateral agreement which allows participating countries (including non-member economies) to share the results of various non-clinical tests done on chemicals. Under MAD, a non-clinical chemical safety study developed using OECD Test Guidelines and OECD Principles of Good Laboratory Practice (GLP) in one Member country or non-Member full adherent, must be accepted for assessment purposes in all member and adhering countries. This is the concept of "tested once, accepted for assessment everywhere."

To enhance mutual confidence among participating OECD member countries and non-member economies, each National CMP that is part of the MAD system must be periodically evaluated by a team of inspectors from other countries in MAD. This ensures that inspections and study audits are performed according to a consistent standard across all countries adhering to MAD.

2. How important is compliance with the OECD Principles of Good Laboratory Practice (GLP) when ensuring that studies are of sufficient scientific quality for consideration within the approval process?

   When a test facility complies with the Principles of GLP, governments have confidence that the studies generated at that facility will be of high quality. And, should questions arise once a government receives a study, the government knows that the traceability standards built into the GLP approach (e.g., recordkeeping, archiving, etc.), will allow inspectors to audit the results of the study long after it has been completed.

   GLP, in and of itself, does not guarantee the scientific validity of a test study; rather, it ensures that the study was carried out as prescribed by a particular test method. However, governments can be assured of the scientific validity of a study if it was based on an OECD test method (i.e., Test Guideline). These Guidelines are a collection of the most relevant internationally agreed testing methods used by governments, industry and independent laboratories to assess the safety of chemical products. During the development of OECD Test Guidelines, the methods are subjected to a rigorous validation phase to establish the reliability and relevance of a particular test method. To be judged reliable, the test results must be reproducible within and among laboratories when performed using the same standardised protocol. The test method must also be relevant – it has to correctly measure or predict the (biological) effect of interest, and it has to meet a regulatory need. The validation reports are made public.

3. Can you explain how the OECD works together with the Commission to ensure that the EU's testing protocols are fully aligned with its test guidelines?

   The OECD does not monitor whether EU's testing protocols are fully aligned with OECD Test Guidelines. To the best of our knowledge they are. Test results only benefit from Mutual Acceptance of Data if they are generated in accordance with GLP and OECD Test Guidelines. So any major deviations from the OECD Test Guideline would jeopardise the benefits from this system. So there is a clear disincentive to deviate from OECD Test Guidelines.

4. Could you explain to what extend the authorisation procedure for PPPs under Regulation 1107/2009 follows available relevant OECD guidance? Compared to other international authorisation procedures, how would you evaluate the performance of the

European authorisation system, particularly with a view to scientific soundness of risk assessments as well as of authorisations granted?

In response to requests from governments, OECD's Pesticides Programme has developed a number of guidance documents and reporting formats that promote the harmonisation of assessment approaches that support PPP authorisation, in order to facilitate work-sharing amongst governments on common pesticides. However, as such guidance is not mandatory, OECD does not monitor the extent to which member governments adhere to them, but rather responds to issues raised by governments (e.g., responding to concerns about new emerging technologies).