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Position Paper

Harmonisation of Pesticide Registration

Position Paper Concerning the OECD Harmonisation Project

The international harmonization of selected elements of pesticide registration¹ is necessary if OECD-member governments are to efficiently regulate a global crop protection industry. For governments to succeed in this endeavor, they must establish:

1. mutually agreed upon common data requirements,
2. common guidelines and protocols for studies which fulfill each of these data requirements,
3. common quality criteria for determining the acceptability of study reports, and
4. scientific reviews of these studies written by governments in a language (English) and format which allows them to be mutually acceptable to all governments of the OECD.

The CropLife International supports the establishment of harmonized data generation and use as specifically outlined in this paper and we support mutually acceptable reviews of critical endpoints because these two elements are the necessary foundations for any meaningful global regulatory cooperation. We do not envision a common dataset as inclusive of all National or Regional requirements and CropLife International would actively oppose the globalization of risk assessment and registration decisions. The CropLife International position on global harmonization of pesticide registration is based on three fundamental principles. Within these we support five specific and measurable endpoints of success.

The three fundamental principles CropLife International strongly supports are that:

1. Harmonization must reduce the time from submission of a registration package to a decision on that package.
2. Harmonization must provide measurable financial benefit in data generation.
3. Harmonization must permit increased cooperation among regulators.

The five measurable endpoints of success CropLife International supports are related to data generation, data submission, and data evaluation which support the fundamental principles. The CropLife International believes it is essential that a common dataset be identified. We define a common dataset as being composed of individual reports, each of which meets five criteria for all OECD-member countries:

1. the report satisfies a specific data requirement which is common to all OECD countries,
2. the experiment on which the report is based is conducted in accordance with a protocol common to all OECD countries,
3. the report format is acceptable to all OECD-member countries and does not have to be modified to be submitted to any OECD-member country or regional authority,
4. the experimental results are evaluated in a consistent method by OECD-member countries, and
5. the government review of the study is mutually acceptable to each OECD-member government or regional authority that is part of the group.

The outcome from harmonization which has the greatest mutual value to governments, consumers, the environment, and the industry, lies in the mutual acceptance of reviews and the improved decision making which will result. For this outcome to be realized, specific contributions from governments, industry, and international associations of both government and industry are required.

The establishment of data requirements is a National Government responsibility. Only those data requirements which are common among governments should lead to a shared review.

The development or acceptance of protocols for experiments which generate data to fulfill a data requirement is primarily a government responsibility, but the industry has contributed substantial technical expertise in the development of such protocols and will continue to do so. The OECD has been a major contributor in developing guidelines which are accepted by all member countries. The CropLife International believes this must continue.

The preparation of reports which clearly delineate methodology, results, and conclusions and the formatting of those studies to meet National or Regional government criteria is industry's responsibility, but governments have express formatting criteria. The CropLife International continues to support this paradigm with the exception that for studies in the common dataset, one format will be acceptable for all OECD member countries (longer term, CropLife International would also support the eventual harmonization of formatting criteria beyond the common data set). Under the auspices of the

OECD, the member governments have recently developed submission formats which are accepted by all member countries.

The CropLife International supports the use of quality control criteria for studies to ensure consistency of data generation, but these criteria must also be mutually acceptable to all OECD-member countries for studies in the common dataset. Quality control criteria for study reports have been utilized in various forms by several national registration authorities. These have been called data summaries, acceptance criteria, rejection criteria, technical sifts, Tier 1 summaries, or screens. The CropLife International support for these quality control criteria for studies in the common dataset has the caveat that one set of criteria must be acceptable to all OECD-member countries for the submitted reports.

Finally, for the full scientific review of each report within the common dataset clear accountability should be established such that one government accepts the responsibility to complete specific reviews within the time-frame agreed upon with all other governments accepting that review. The CropLife International recognizes this as a fundamental principle of pesticide regulation. Inherent in this fundamental principle is the need to communicate clearly. All governments currently have the obligation to produce unambiguous conclusions derived from a clearly delineated series of results. The need to do this is even greater if a government's reviews are to be relied upon by another government. The CropLife International strongly supports the use, by governments, of the OECD Monograph Guidance for governments writing reviews.

There is a need by governments to communicate in a timely manner with the owner/submitter of the common data to obtain clarification of the existing data or request additional information about a study. In addition, governments and industry need to formalize a transparent process to resolve substantive scientific disagreements between data owners and data reviewers. Such a process exists in all National governments and an extension of this process for shared reviews should be created and implemented. The CropLife International expects that the reviewing government for the common data will continue to use existing communication practices, and CropLife International would support government efforts to formalize and publicly document the process they will use.

The criteria for a mutually acceptable government review are:

1. it is independently written by a government;
2. it is acceptable, as written, to all OECD-member countries;
3. it reaches unambiguous conclusions derived from a clearly delineated series of results, and

4. the reviewing government has obtained and documented any additional relevant information about the study that it deemed necessary.

Any information submitted with an application for registration of a pesticide which is not part of the common dataset will be submitted separately from the common dataset. The CropLife International has termed these data the National/Regional data. The National/Regional data must be reviewed by the government receiving the data, however, the common data will be reviewed only by the first government to receive the submission and other governments will use the review without independently re-reviewing the common data.

The review process supported by the CropLife International is presented as a diagram in Figure 1. The CropLife International supports a shared process only for data review. We expect the proportion of common data versus National/Regional data will change with time. The CropLife International believes that Risk Assessments for consumer health, environmental safety, and occupational health, as well as Registration Decisions are the clear responsibility of individual National governments or a legally constituted joint government entity of which the European Union is the single example in existence today.

FIGURE 1

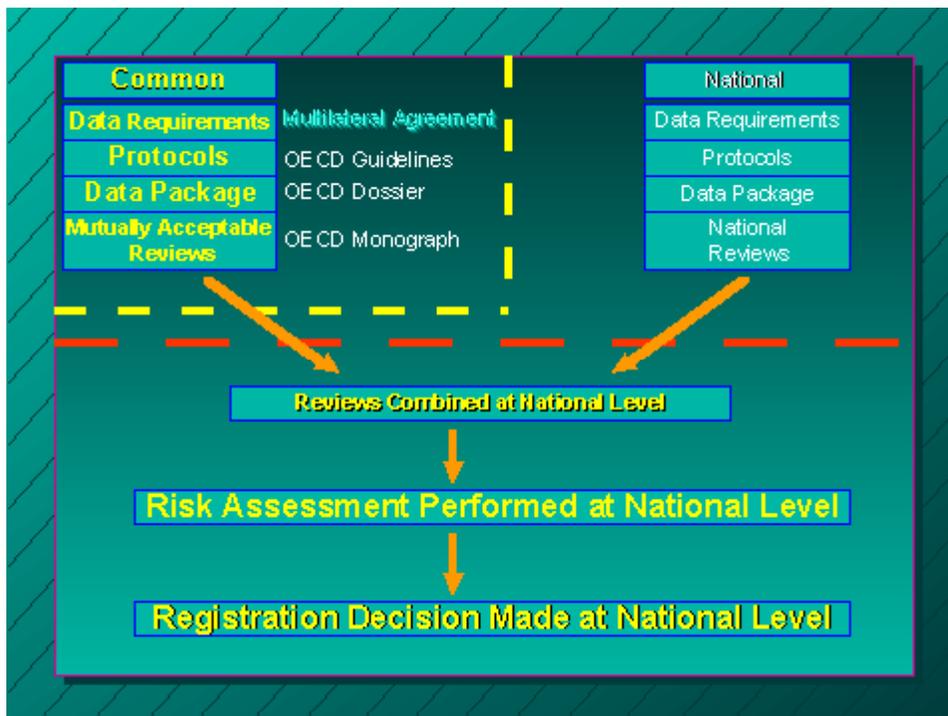


Figure 1 Legend: The diagram¹ above assumes that a data package submitted by the owner of the data for first registration will contain two sets of reports. One set of reports will fulfill the common data requirements. The second set of reports will fulfill the National² requirements. The diagram depicts two review processes. A review of the common data package and a review of the National or Regional data package. Both of these may occur in one country or may be shared. When all reviews are completed a government will combine both sets of reviews, do their risk assessment according to National policy and make a registration decision in accordance with their own National laws.

A data package submitted by the owner of the data for subsequent registrations in different countries will also contain two sets of reports, one set of reports to fulfill the common data requirements and a separate set of reports to fulfill the National requirements. The data owner will also submit the mutually acceptable reviews of the reports which fulfill the common data requirements. The government receiving this submission need review only the reports which fulfill the National requirements. When a government completes this review it will combine its reviews with the mutually acceptable reviews, do a risk assessment according to National policy and make a registration decision in accordance with their National laws.

In summary, the CropLife International strongly supports the global harmonization and intergovernmental sharing of data reviews in the context of Pesticide Regulation. The mutual acceptance of government reviews must be based on a common set of data requirements, common guidelines or protocols for conducting experiments which fulfill each of the data requirements, and common quality control criteria for determining the acceptability of study reports. The scientific reviews by governments for each submitted report need to be written in a common format which allows the review to be mutually acceptable for use by all governments of the OECD for making regulatory decisions.

Appendix

Definitions of Terms Used in the CropLife International Position Statement on Harmonization of

Regulatory Requirements for Crop Protection Products.

Data requirement - a specific end point required by a government to complete an application for registration of a pesticide in that country, e.g. acute oral LD50 and hydrolysis are each data requirements. A data requirement is specified by a government.

Protocol - the prescribed scientific process which must be followed in conducting an experiment to satisfy a data requirement. Information which must be included in a report may also be specified. A protocol is specified by a government, usually in their guidelines.

Experiment - the scientific processes which generate the result to satisfy a data requirement. The information generated during an experiment will be included in a report which demonstrates that the protocol was followed and the data requirement was satisfied..

Report - the document in which the scientific processes and data collection are presented and in which the results and conclusions are presented in sufficient detail to allow the reader to determine if the protocol was followed, if the data requirement was satisfied, and to clearly see how the conclusions were reached.

Review - the document in which an independent expert writes an assessment of the scientific processes and data collection in a report, and either concurs with or refutes the conclusions in sufficient detail to allow the reader of the review to clearly see how the reviewer's conclusions were reached. The review is generally produced by the government or its designee.

Mutually acceptable - All OECD-member governments agree that another government's review of a report which satisfies a common data requirement is sufficient information on which to make regulatory decisions without further review of the original report on which it is based. Mutual acceptability has two criteria; it can only apply to reviews of reports which satisfy common data requirements, and the government using the review must also have received a submission of the report. A government must receive a report either from the owner of the data on which the report is based or from a second party who has authorized permission from the owner of the data. Alternatively, the owner of the data may give a government permission to use another government's review.