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FREQUENTLY ASKED QUESTIONS ABOUT WORK SHARING ON PESTICIDE REGISTRATION REVIEWS

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Series on Pesticides

No. 34

FREQUENTLY ASKED QUESTIONS ABOUT WORK SHARING ON PESTICIDE REGISTRATION REVIEWS

IOMC

INTER-ORGANISATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among

UNEP, ILO, FAO, WHO, UNIDO, UNITAR and OECD

Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
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OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances-Dossier Guidance (1998, revised 2001, 2005)

Report of the Pesticide Aquatic Risk Indicators Expert Group (2000)

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The Environment, Health and Safety Division publishes free-of-charge documents in ten different series: **Testing and Assessment**; **Good Laboratory Practice and Compliance Monitoring**; **Pesticides and Biocides**; **Risk Management**; **Harmonisation of Regulatory Oversight in Biotechnology**; **Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; Emission Scenario Documents; and the Safety of Manufactured Nanomaterials.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (http://www.oecd.org/ehs/).

This publication was produced within the framework of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC).

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The participating organisations are FAO, ILO, OECD, UNEP, UNIDO, UNITAR and WHO. The World Bank and UNDP are observers. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

FOREWORD

OECD countries invest significant resources in evaluating agricultural pesticides before they are marketed (or re-evaluating pesticides that have been in use for many years) to ensure that they do not pose unacceptable risks to human health and the environment. Since many pesticides used in OECD countries are the same, governments have recognised the substantial benefits that can be gained if the task of pesticide evaluations for registration and re-registration is shared, rather than duplicating each others' work. The OECD Pesticides Programme is working to establish the infrastructure that will facilitate such work sharing. The recent adoption of an OECD-wide future "vision," with specific deadlines for work sharing, should lead to additional (and more routine) work sharing arrangements between governments and industry.

Harmonised approaches make it easier for countries to share the work. In this context "work sharing" means, for example, dividing the work required to review a pesticide data submission among two or more countries, or one country using another's evaluation to help it with its own national review. The objective of work sharing is to reduce the overall workload. While respecting the rights of each country to make its own regulatory decision, work sharing should result in the same or a higher quality of assessment and should not delay decision-making. Greater international harmonisation of pesticide registration approaches could also reduce the need for duplicative testing by industry, thereby saving resources and preventing unnecessary loss of animal life, and could help ease barriers to trade.

Work sharing can be done by dividing up the review of each individual pesticide, with two or more governments reviewing different parts of the registration package. Work sharing can also be done by dividing up pesticides among two or more governments, with each government conducting the entire review of its assigned pesticide.

Work sharing can also be implemented stepwise, by co-ordinating schedules of reviews and re-reviews, exchanging drafts for information or comment, identifying and resolving controversial issues, and organising staff exchange programs.

This document provides responses to questions that are frequently asked by governments and industry about the concept of work sharing, and how it would operate in practice. Many of the questions were raised at an OECD seminar on work sharing, held on 31 May, 2006, at the Pesticide Control Service in Ireland. The answers were prepared by a panel of OECD government representatives at that seminar.

There are now several practical examples of work sharing between regulatory authorities and this document will be updated, from time-to-time, as more experience with work sharing is gained.

This document is published on the responsibility of the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology.

QUESTIONS AND ANSWERS ABOUT WORK SHARING ON PESTICIDE REGISTRATION REVIEWS

"Joint Reviews of Data Submissions"

Q 1: How do you get all levels of staff within each regulatory authority to share the new way of working?

A: Countries have signed up to the OECD "Vision" of work sharing and managers in each authority are championing the principles with the staff of their organisation. For the initial projects we will select teams of progressive members of staff who are prepared to challenge current working practice, staff who are good communicators and open to sharing best practice. We will also hold more workshops such as that in 2005 in Washington[1] where scientific evaluators can meet face-to-face to share experiences and exchange views on scientific issues in a regulatory context.

Q 2: What plans have we to handle the situation where differences of decision making may remain? Does the panel envisage there might be a need for some form of "arbitration" process to resolve major differences? How can OECD demonstrate that the decision making will not become more precautionary as a result of differences of opinion between countries?

A: We will encourage discussions between specialist staff as soon as issues arise and not just wait until the peer review stage. If, at the end of the day following peer review, consensus cannot be reached it will be up to each region/country to come to its own conclusion.

We see no difficulty arising where risk assessments based on the same data could result in different regulatory decisions in the relevant jurisdictions as reflected in the Monograph. While the evaluations of individual tests and studies should be agreed by the evaluating scientists, differences (for example in climate, soils, flora and fauna etc.) between regions and countries, may well lead to differences in the risk posed by the proposed use. Hence, this could logically result in different regulatory decisions.

At this stage we do not see the need for a formal "arbitration" process. Experience thus far has shown that where regions have different risk management policies then different interpretations at the risk assessment stage can be accommodated.

Q 3: How do we propose to convince the public that pesticide regulation is based on sound scientific principles, especially if different decisions are made in different regions or countries following a work share?

A: Risk communication and transparency by each Regulatory Authority will be the key. It needs to be made clear that the final decisions on risk assessment and risk management will be made by each Authority in accordance with their own previously agreed appropriate level of protection as has always been the case.

[1] OECD Workshop to Advance Work Sharing of Agricultural Pesticide Reviews (Washington DC, 31 January to 2 February, 2005)

The rock upon which public confidence can be built has to be the peer review process which will involve a wider group of scientific experts from different countries and regions and should result in a more scientifically robust conclusion. Development of a communication strategy to engage the NGOs and the public should be a high priority as work sharing becomes common practice.

Q 4: Will different conclusions be reflected in the final Monograph?

A: It is expected that the hazard assessments undertaken during a work share project will be commonly agreed. Risk assessments reflecting the conditions of use and risk assessments methodologies used in the participating regions will be reflected in Monographs prepared. Proposals for the regulatory decisions to be taken will be included in such Monographs at least for some regions. However, decision-making in each jurisdiction while taking account of Monographs prepared must reflect the legislative requirements in place in each jurisdiction.

Q 5: At what stage can the applicant company make an input to resolving any difficulties which arise?

A: It is envisaged that the applicant will be alerted to issues as early as possible. Indeed this is one of the benefits of planning discussions at the earliest stage possible. For example if the applicant can discuss their development plans and knowledge of the "active" well in advance of submission then many issues can be addressed prior to submission. We suggest that it would be beneficial to commence discussions at least 2 years prior to planned submission.

It is accepted that every active has its own safety profile including strengths and weaknesses. The applicant should have open discussions with regulators as to how they hope to address those issues and regulators can offer their advice.

Q 6: What are the opportunities to design the process from the beginning?

A: Applicant companies are encouraged to consider opportunities for work sharing by identifying potential markets and regulatory partners at the earliest stage possible during the development programme. Consequently a team can be identified and the agreed work plan developed between all of the partners. This would include the development of a Global Dossier which would reflect the regulatory requirements in the different countries/regions.

Q 7: How can we bring in a wider selection of countries as partners?

A: This can best be achieved through dialogue, through demonstrating the benefits of the system and through demonstrating that the system works. The onus is on work share partners to champion the success of this way of working and to spread the word.

Q 8: Can companies (inc CLI) help bring in countries from outside OECD?

A: Thus far work sharing projects have been identified which will involve partners from across the globe. Hopefully the success of these projects will encourage other countries to participate. In addition those of us who have already been actively involved in projects are very happy to discuss with industry how we can include more countries both within the OECD and wider. A potential starting point may be provided through the engagement of key food exporting countries in relation to residues profiles and MRL setting.

Q 9: How do we envisage the time lines actually operating and how will Monograph production relate to decision making in the different partner countries? Presently there are marked differences in the time lines achieved by different countries how will you avoid the pressures to work to the pace of the slowest?

A: We are committed to improving the efficiency of the evaluation process and reducing the time taken to complete evaluations. Strict timelines for the evaluation, Monograph production and peer review process will be agreed from the outset of each project. These will take account of commitments and legal obligations in each partner country. Final decision making will still rest with each country but experience indicates that work sharing leads to quicker decision making. Furthermore, we believe that a key benefit of work sharing from the perspective of the Regulatory Authorities is that efficiency gains will accrue leading to reduced time lines for preparing Monographs and for decision-making.

Q 10: Have we / can we agree the central Monograph format from which countries can build their risk assessment conclusions?

A: We have agreed that all joint reviews based on work shares under the auspices of the OECD will use the agreed OECD format both for Dossiers and Monographs.

Q 11: What about change in guidance? When is it taken account of? When/what to re-review?

A: Guidance documents should be considered to be "living" documents. Issues which arise and resolved during a work share could indicate a need to revise guidance documents. Such revisions would be subject to consultation, agreement and adoption by the Working Group on Pesticides (WGP).

The next change in the Guidance will be to reflect use of the OECD-xml templates for preparation of robust study summaries which were recently adopted. Applicants are encouraged to use the templates immediately. Experience of their use will influence the revision of the Dossier and Monograph guidance which will be required to be used from a date to be decided by agreement at the WGP.

Q 12: Does encouraging industry to put more uses on label conflict with the EU one safe use concept?

A: No. The majority of applications for new active substances already include an evaluation of a wide range of uses. We see one of the benefits of work sharing is a sharing of the total work load so evaluation of more uses does not have the same resource impact as if each country had to conduct its own evaluation.

Q 13: Are there opportunities to help resolve minor crop issues?

Are there incentives to encourage minor crops?

A: We believe that work sharing gives a greater opportunity for the inclusion of more uses to be evaluated and included on product labels. Invariably there are major crops in some countries which would be considered as minor crops in other countries. The potential for early simultaneous access to wider markets will make it more attractive for companies to register products for use on crops that otherwise would be considered economically marginal in some countries.

Q 14: What steps can be taken to harmonise residue and MRL issues?

A: Applicants should ensure that sufficient metabolism data is submitted to permit definition of the residue as well as sufficient residues data to support regional, national and CODEX MRLs.

The OECD WGP maintains a close working relationship with FAO and WHO and intends facilitating the use of OECD Monographs by the JMPR to facilitate the elaboration of CODEX MRLs.

We recognise that this is a difficult topic as methods for determining MRLs do differ currently between regions and authorities. Furthermore, country GAP (Good Agricultural Practice) varies because of different pest/disease pressures. Nevertheless, the harmonisation of residue data requirements is a part of ongoing OECD work, and we see no problem in this reaching an acceptable conclusion.

Q 15: It is envisaged that each country involved in a work share will receive the full data package including studies not necessarily required in its legislation but required by other authorities. Will these studies have data protection in the country not requiring them?

A: Work-sharing arrangements do not impact on data protection. The rules in place in each authority remain in force. Data protection will only be applied where studies are used by the regulatory authority in reaching a decision and conclusion concerning authorisation.

Q 16: Would OECD and its member countries be prepared to start the INTERSAC process (i.e. a consultation group of country specialists initially for companies to seek specific advice on issues of residues chemistry)?

A: This proposal is still under consideration. Specialist evaluators involved in current projects are being encouraged to discuss scientific issues with other country partners as and when those issues arise.