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Report of the OECD Workshop on Sharing the Work of Agricultural Pesticide Reviews, 12-14 February 2001, Brussels, European Commission

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About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation composed of 30 industrialised countries in North America, Europe and the Pacific. The OECD works to co-ordinate and harmonise government policies, address issues of mutual concern, and respond to international problems.

The Pesticide Programme was created in 1992 within the OECD's Environmental Health and Safety Division to help OECD countries:

- harmonise their pesticide review procedures,
- share the work of evaluating pesticides, and
- reduce risks associated with pesticide use.

The Pesticide Programme is directed by the Working Group on Pesticides, composed primarily of delegates from OECD Member countries, but also including representatives from the European Commission and other international organisations (*e.g.* United Nations Food and Agriculture Organization, United Nations Environment Programme, World Health Organization, Council of Europe), and observers from the pesticide industry and public interest organisations (NGOs).

In addition to the **Series on Pesticides**, the Environment, Health and Safety (EHS) Division publishes documents in five other series: **Testing and Assessment**; **Good Laboratory Practice and Compliance Monitoring**; **Risk Management**; **Harmonization of Regulatory Oversight in Biotechnology**; and **Chemical Accidents**. More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (see next page).

This publication was produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC). It was approved for derestriction by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, the governing body of the Environment, Health and Safety Division.

The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) was established in 1995 by UNEP, ILO, FAO, WHO, UNIDO and the OECD (the Participating Organizations), 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. UNITAR joined the IOMC in 1997 to become the seventh Participating Organization. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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Report of the OECD Workshop on Sharing the Work of Agricultural Pesticide Reviews 12-14 February 2001 European Commission, Brussels

Part 1: Introduction and Overview of the Workshop

This report presents the conclusions and recommendations made by the OECD Workshop on Sharing the Work of Agricultural Pesticide Reviews, held in Brussels on 12-14 February 2001. The purpose of the workshop was to explore ways to increase the efficiency of agricultural pesticide evaluations through improved international co-operation. The objectives of the workshop were to:

- share the experiences of, and lessons learned by governments, the pesticide industry and other stakeholders who have already been involved in sharing the work of pesticide reviews;
- understand what governments, industry and others expect to gain from work sharing;
- identify incentives for work sharing, the barriers that may be encountered and the ways in which these barriers may be overcome;
- identify where the greatest opportunities and benefits for work sharing exist;
- recommend:
  - practices and procedures for how work can be shared more routinely in the future;
  - further projects that would help to define the roles and responsibilities of governments and other stakeholders, develop mutual trust and increase the extent of work sharing; and
  - develop ways to measure the success of work sharing;
- identify ways in which the products from work sharing activities among OECD countries could be used by other countries and international organisations involved in pesticide assessment (*e.g.* IPCS/WHO, FAO).

The workshop was co-hosted by the European Commission, DG Health and Consumer Protection (EC DG SANCO) and the United States Environment Protection Agency (USEPA) and chaired by Vibeke Bernson of the National Chemicals Inspectorate of Sweden (KEMI).

Ninety-one people attended, representing the following 25 countries (OECD and non-OECD) and 6 organisations: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Egypt, Finland, France, Germany, Greece, Hungary, Ireland, Korea, Netherlands, New Zealand, Norway, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, United Kingdom, United States, The Sahelian Pesticide Committee, European Commission, Food and Agriculture Organization (FAO), World Health Organization (WHO), Grower Groups, and Global Crop Protection Federation (GCPF). The participant list is attached in Annex 4.

Background

OECD countries invest significant resources in evaluating agricultural pesticides before they are marketed to ensure that they do not pose unacceptable risks to human health and the environment. They are also re-evaluating pesticides that have been in use for many years to be sure that they meet modern scientific and safety standards. 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. Improved efficiency in pesticide evaluations is important at a time of diminishing resources in governments and industry and when pressures to make decisions more quickly are increasing.

OECD countries have been working together since 1992 to harmonise regulatory approaches to pesticide registration and to co-operate in sharing the work of pesticide review. Harmonised approaches make it easier for countries to share the work and in 1998 common formats for industry pesticide data submissions ('dossiers') and country data review reports ('monographs') were agreed. With the success of agreeing common formats, and against a background of other harmonisation activities on data requirements, test guidelines and risk assessment methods, more attention is now being given to putting work sharing into practice. For some time, work sharing has already taken place. For example, joint pesticide evaluations have been carried out for a number of years within the EU and by the NAFTA countries, and through the OECD Pesticide Programme over 700 review reports were exchanged between 1995 and 1999. However, countries realise that more efficiency could be gained if work sharing was more extensive and routine.

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.

Structure of the workshop

The agenda for the workshop is provided in Annex 1.

The workshop was organised in alternating plenary and breakout sessions to address issues relating to both new and existing active substances. For the purpose of this workshop, active substance and active ingredient were considered to be equivalent. Also, a new active substance was considered to be one that was undergoing its first evaluation, while an existing active substance was one undergoing a re-evaluation.

Each of the following questions was addressed by the workshop participants in five breakout groups in two separate sessions, the first for new active substances and the second for existing active substances.

1. What are the experiences in work sharing with new or existing active substances?
2. What is the vision of work sharing?
3. What are the incentives or drivers for work sharing?
4. What are the hurdles or barriers for work sharing?
5. Whom would you have to convince to make your vision possible? Who is responsible?
6. Identify the most important actions to be taken both in the short and in the long term (five key areas for improvement).

Plenary sessions with presentations by individuals experienced in work sharing of new or existing active substances were used to introduce the corresponding breakout sessions. At the end of each day, breakout group reports were produced by each group and reviewed by all participants of the group. The breakout group reports can be found in Annex 3 of this report.

Following each of the breakout group discussions, one consolidated presentation incorporating ideas from all of the reports from the breakout groups was given during a plenary session. This was followed by a general discussion of the issues. In a final concluding plenary session, all workshop participants agreed on a combined set of "Main Conclusions and Recommendations" and made recommendations for an action plan for further work (see following pages).

Part 2: Summary of Plenary and Breakout Group Discussions

The following text is a summary of the reports of the breakout groups and of the plenary discussions following the feedback presentations. It is presented, broadly, in terms of the questions discussed by the breakout groups. Individual breakout group reports are provided in Annex 3.

1. What is the vision of work sharing?

For both new and existing active substances

- Continued reduction in risk to human health and the environment from the use of chemical pesticides.
- The submission of one common dossier which is reviewed once to an agreed timeline and is made available to others (later national requirements are added and national risk assessments made).
- Creation of a world forum of experts from different countries working for a period of time on pesticides, which would increase communication between experts.
- Improve the transparency and quality of the work sharing process and the process for decision making within work sharing
- Exchange and co-ordination of policies, evaluation plans and the evaluations themselves.
- Providing predictable timelines, for both the long and short term.
- Recognisable benefits from work sharing, such as eliminating the duplication of work, increased efficiency, shorter timelines for registration decisions, and earlier access to markets for industry and growers.
- Production of common data requirements and guidelines.
- Global agreement on registration end points, with one global list of registration end-points.
- Globally harmonised models for national risk assessments.
- A contact list of, and communication line to, experts.
- Exchange of scientific experts.
- Development of mutual trust between participants so that studies would not have to be re-reviewed by second or subsequent countries.
- Suitable technological and electronic capabilities, and Internet use; electronic submissions to all agencies.
- Faster access to the market place for manufacturers of chemical products and for growers of treated products.
- Agreed global zones for residue data and residue databases by active substance.

- Use by JMPR of OECD formatted dossiers; preparation of JMPR reports / monographs in line with OECD monograph format.
- Standardised, global MRLs, which should lead to a reduction in trade barriers.
- Greater participation by non-OECD countries.
- Sharing of evaluations and risk assessments with smaller or under-resourced countries.

For existing active substances

- Improved safety standards.
- Establishing a "level playing field" between existing active substances and new active substances; existing active substance should be evaluated using the same standards as new active substances.
- Completion of on-going re-evaluation programmes.
- Strategic planning for global re-evaluations and assessments.
- Regular exchange and co-ordination of re-evaluation plans and policies.
- Sharing the burden and workload of reviews.
- Maintaining an adequate number of pesticides for minor crops.

2. What are the incentives or drivers for work sharing?

- Increased public confidence in pesticide registration systems.
- Worldwide risk reductions from pesticide use.
- Increased efficiency in the use of resources.
- Increased capacity for evaluation of existing active substances.
- Reduced costs for all stakeholders.
- Harmonisation of data requirements to eliminate the duplication of studies and reduce development costs.
- Reduction of the problems resulting from the use of different methodologies in different countries and from discrepancies in hazard and risk assessment.
- Providing faster access to markets for industry and growers.
- Greater confidence in processing and interpreting data (*e.g.* more confidence in MRL setting).
- Reducing trade barriers.
- Better understanding of science.
- More predictable timelines.
- More robust and reliable technical databases.
- Increasing staff experience.
- Simultaneous access for both small and large countries to newly developed pesticides (newer "safer" chemistry).
- Transfer of plant protection and risk evaluation technologies to developing countries.
- Increased and improved harmonisation.

3. What are the hurdles or barriers for work sharing?

- Lack of trust and confidence in the abilities of others.
- Scarce and decreasing resources.
- Lack of acceptance of work sharing at all levels – the need to "sell the idea".
- Lack of harmonisation in:
  - data (registration) requirements (common)
  - test guidelines
  - reporting format
  - risk assessment methodologies (*e.g.* cumulative risk assessment, probabilistic methods, and assessment of endocrine disrupters)
  - languages/cultures
  - electronic software issues (non-compatibility, *e.g.* Word *vs* Word Perfect).
- Lack of access to e-mail and Internet.
- Non-acceptance by some governments of OECD guidance document.
- JMPR not using OECD guidance.
- Reviews by other bodies not being used, *e.g.* evaluations of persistent organic pollutants (POPs) and PIC.
- Non-simultaneous dossier submissions.
- Non-simultaneous registration decisions.
- Lack of incentives for industry to develop some markets (minor use, small countries).
- Lack of scientific expertise and suitably trained staff.
- Lack of global co-ordination in the re-evaluation of existing active substances.
- Lack of consultation and communication between stakeholders on the consequences of non-support of certain existing active substances.
- Legal impediments.

4. What are good practices of work sharing?

- Ensure close communication.
- Define and agree the process.
- Set goals, timelines and milestones.
- Start simply.
- Be positive, don't give up.
- Look for solutions to problems, do not just identify the problems.
- Involve all stakeholders in the process (active communication).
- Encourage pre-submission consultation between industry and governments.
- Make use of OECD dossier / monograph formats.
- Open exchange of reviews.
- Encourage active, on-going communication between industry and government carrying out the review/evaluation process.
- Base discussions on science (separate science and politics).

5. Five key areas for improvement

5.1. Just do it and be flexible

- Actively look for solutions to problems, and not just identify the problems.
- Consider ways to measure success of work sharing.
- Solve / resolve (be aware of) legal implications, including confidentiality and data protection issues (especially with off-patent, existing active substances).

5.2. Improve communication

- Lists of substances under first evaluation or re-evaluation.
- Lists of uses and MRLs (use of regional / geographic zones).
- Lists of schedules for submissions and evaluations.
- Lists of contacts, administrative and experts.
- Lists of reviews that have been completed.
- Easy access to and between scientific and regulatory experts, *etc*.
- Improve transparency for others.

5.3. Improve contacts

- Facilitate staff exchange programmes.
- Organise workshops.
- Invite outsiders to review discussions.

5.4. Harmonise content

- Harmonise data requirements.
- Harmonise test guidelines.
- Common end-points.
- Harmonise hazard and risk assessment methodologies (*e.g.* OECD zoning project, FOCUS scenarios, *etc*.).

5.5. Harmonise formats

- Use OECD dossier and monograph guidance documents.
- Harmonise information technology.
- Harmonise study report formats.

Supplementary information

Six short papers were presented during the opening plenary panel, “Expectations about work sharing from other stakeholders (“What is your ‘vision’ for work sharing?”). These papers are provided in Annex 2.

Part 3: Main Conclusions and Recommendations

This section summarises the main conclusions and recommendations reached by the workshop participants in the concluding plenary session.

Main conclusions

1. Work sharing works:
   - Work sharing is already happening and is supported.
   - The outcomes of work sharing are of higher quality and are more efficient.
   - More work sharing is possible and it could be done more effectively.

2. Work sharing has wider international applications; for example, it should now be possible to share work with: JMPR and CODEX; the Rotterdam Convention on PIC (Prior Informed Consent); and the forthcoming Stockholm convention on POPs (Persistent Organic Pollutants). There are also increasing opportunities for sharing work between regions, *e.g.* EU and NAFTA, and OECD and non-OECD countries.

3. Effective communications, planning and commitment are essential to establishing work sharing. In addition, they help to build confidence and trust between work sharing partners, *e.g*. among governments, between governments and industry, small countries and large countries, exporting and importing countries, government and growers, *etc.*

Main recommendations

"Just do it"!

1. A commitment from all stakeholders is needed to improve the process of work sharing and satisfy the growing public demand for effective chemical pesticides with increased human and environmental safety.

2. Transparency is needed to establish good work sharing practices, to help build confidence between stakeholders and to develop public confidence in the process.

3. Investment of both human and monetary resources is needed if work sharing is going to progress.

4. Work sharing should become the normal way of evaluating pesticides, and should receive high level support and promotion.

5. Keep the process of work sharing simple and concentrate initial efforts on projects that will be successful in the short term, whilst not losing sight of the longer term objectives.

6. Improved global communications are needed. Existing platforms for communication should be used and enhanced, *e.g.* the OECD.

7. The harmonisation process should be accelerated where appropriate.

8. Strategic planning is required to ensure better co-ordination between governments, and within industry and grower groups. Better planning would help streamline the co-ordination of evaluations of new and existing substances.

9. An infrastructure should be developed to facilitate work sharing.

10. Flexibility is important, including a willingness to accept and agree that there are differences between different stakeholders in the way that their assessments and their regulatory processes are conducted. The final outcome can be a decision at the national level.

Recommendations for actions to increase work sharing

The following table presents some important actions identified in the concluding plenary session. These actions will be discussed by the Registration Steering Group (RSG) of the OECD Working Group on Pesticides (WGP). The RSG will identify projects and suggest priorities, and will present their ideas to the Working Group on Pesticides. A work plan will be developed and lead countries or individuals identified.

Objective	**Recommendation / Action**	**How?**
"Selling the idea" of work sharing	Write an international (high level) report on the benefits of work sharing to influence decision makers (senior managers). Reports should / could be prepared by OECD WGP, national governments, and industry to sell the vision.	Make use of what already exists (regional high level reports, *e.g.* NAFTA, EU) and build it up, quantify benefits. Also use industry papers, background documents, WGP reports.
	Communicate our vision and incentives for work sharing to everyone who needs to know: the public, growers, industry (marketing managers), governments, international organisations…	*i.e.* Determine how to convince and inform government policy makers, growers, trade organisations, JMPR/CODEX, consumers of treated products/general public and reviewers, *etc*.
1. Just do it	1.1. Overcome hurdles.	• Start discussions between industry and regulators, identify issues and look for solutions. • Encourage discussions within industry. • Develop (or extend/revise) a code of conduct for work sharing, including a consideration of proprietary data issues. • Identify and resolve legal implications.

Objective	Recommendation / Action	How?

1. Just do it	1.2. Continue with, and expand and improve on, work sharing.	• Keep your eyes open, seek opportunities and use them.
		• Start with relevant parts of reviews by others.
		• Provide information for others to use:
		  • list chemicals to work on first,
		  • list schedules / plans for reviews,
		  • list reviews underway,
		  • the OECD web site on reviews available on national web sites.

2. Improve communication	2.1. Lists of substances.	
	2.2. Lists of uses / MRLs.	
	2.3. Lists of review schedules (timelines). 2.4. Lists of reviews underway. 2.5. List of completed reviews. 2.6. Lists of contacts.	*e.g.* Use OECD database on pesticide reviews (ensure that it is up to date, and that all information is provided by governments).
	2.7. Easy access to and between scientific and regulatory experts.	
3. Improve contacts	3.1. Facilitate exchange programmes.	
	3.2. Organise workshops.	
	3.3. Invite outsiders to review discussions (*e.g.* invite non-EU country regulators to ECCO meetings, or non-NAFTA country regulators to NAFTA discussions).	

Objective	Recommendation / Action	How?
4. Harmonise content	4.1. Common data requirements and test guidelines.	RSG to assess regional differences in data requirements and test guidelines in order to identify a basis for further alignment of data requirements, and to develop recommendations in relation to the harmonisation of test guidelines for consideration by the Test Guidelines Programme.
	4.2. Common end-points for risk assessment.	
	4.3. Harmonise risk assessment methodologies.	
5. Harmonise formats	5.1. Use OECD dossier and monograph guidance documents.	"Use them, use them, use them."
	5.2. Harmonise information technology between regions.	*e.g.* Workshop in 2002 (hosted by Canada and the US).
	5.3. Harmonise study report format.	

Annex 1

Final Agenda: OECD Workshop on Sharing the Work of Agricultural Pesticide Reviews, 12-14 February 2001, European Commission, Brussels.

Monday 12th February

08.30 Registration

09.30 **Opening Plenary 1: Workshop Objectives and Expectations for Work Sharing**

(5 mins)
- **Welcome** *(Chair: Vibeke Bernson, Sweden)*

(15 mins)
- **Opening remarks**, including expectations from work sharing, by hosts:
  - United States / EPA (*Marcia Mulkey*)
  - European Commission / DG SANCO (*Goffredo Del Bino*)

- **Practical Information** *(Canice Nolan, EC)*
- **Workshop objectives and structure** *(Libby Harrison, OECD Secretariat)*

(15 mins)
- **Panel discussion** *(to be moderated by Vibeke Bernson, Sweden)*
  Expectations about work sharing from other stakeholders ("what is your 'vision' of work sharing?")

(40 mins)

Panel members (from countries with limited or no experience of work sharing and representing other stakeholders) will give short (5 minutes) statements on their interest in work sharing and what they would like to achieve from doing it (their 'vision'). The short statements will be followed by open discussion between the panel and the audience.

- New Zealand (*John Reeve, MAF Regulatory Authority*)
- Hungary (*Zoltan Ocsko, Ministry of Agriculture*)
- Greece (*Kostas Markakis, Ministry of Agriculture*)
- Sahelian Pesticide Committee *(François Abolia, Senegal)*
- Industry (GCPF) (Bernhard Johnen, Syngenta, UK)
- Grower association (Jean-Mari Peltier, California Citrus Quality Council)

10.45 Coffee

11.00	**Plenary 2: Sharing the work to review new active substances**

15 mins for each presentation

- **Presentations** on experiences gained, lessons learned to date, and expectations for work sharing
  The speakers will describe their motives for sharing work, the barriers that arose and how they were overcome. The government speakers will also describe their approaches to decision-making following shared reviews, and industry will describe the challenges companies face in making multiple submissions (i.e. to more than one country at the same time).

  - By the US and Canada (*Claire Franklin, Canada-PMRA*)
  - In the EU (joint presentation by the EC and a EU Member state; *Canice Nolan, EC, and Mark Lynch, Ireland*)
  - By Australia (*Les Davies, Department of Health*)
  - By industry (*Martin Maerkl, GCPF/Aventis, France*)

- **Discussion**

12.25 • **Identification of Break-out Groups**

12.30 Lunch

14.00	**Break-out Sessions A: Sharing the work to review new active substances**

Workshop participants will divide into 5 break-out groups to discuss and answer the following questions:

1. What is your experience of work sharing as far as **new active substances** are concerned?

Then, imagine yourself in 5-10 years from now:

2. What would be your 'vision' of work sharing? What would you like to see achieved or made possible?
3. What will drive you (as representative from a small/large country, from industry, etc.) to reach this 'vision'? i.e. what would be the incentives for the work of pesticide review to be shared?
4. What would you have to do to achieve this 'vision'? What would be your approach/strategy? Considering the categories of resources, people, laws/policy, science, infrastructure/technology, describe steps to be taken, possible problems or barriers that could be encountered, and possible solutions to overcome these problems.
5. Who would you have to convince to make your 'vision' possible? And who are the responsible parties to carry out the steps to achieving the vision of work sharing?

6. Looking at all the actions you have identified during the break-out group session, identify the most important steps (up to 5) to be taken, both in the short-term and in the long-term? *(Answers to these questions should help identify further projects in the final plenary session)*

(to be continued on next page)

All of the above-mentioned questions would need to be answered from different perspectives, e.g. for small and large countries, for OECD and non-OECD countries, for representatives of governments, industry, grower and consumer groups.

Coffee break will be taken some time during the afternoon (each group to decide when).

17.00 **Breakout Sessions A** (cont.)

- Discussions should stop; groups should start to review and agree on the outcomes of their discussions (for inclusion in their break-out group report).

17.30	Finish for day 1

Late afternoon *Preparations of break-out reports by Chairs and Rapporteurs*

18.30 **Evening Reception**

(Charlemagne building, Rue de la Loi, 170)

Tuesday 13th February

8.00-9.00 *Meeting of all Chairs/Rapporteurs/Secretariat to:*
Review and agree on the consolidated report from day 1.

9.00 Plenary 3: Sharing the work to review new active substances – outcome of break-out group discussions

(30 min)

- **Report back** to plenary on the break-out group discussions
  This will be done by one selected Presenter who will present a consolidated report for Day 1 (presenting all common elements discussed by the different groups). Other Chairs/Rapporteurs will have the opportunity to add issues that were specifically raised in their group.

- **Discussion** between the Panel (Chairs and Rapporteurs) and the audience *(to be moderated by Vibeke Bernson, Sweden).*

Note: Members of break-out groups will be also asked to review their group's individual, written reports of Monday's discussions and return comments to their Chair/Rapporteurs during the day.

10.45 Coffee

11.00 Plenary 4: Re-evaluation programmes and sharing the work on existing active substances

15 mins for each presentation

- **Presentations** on experiences and lessons learned to date, and expectations for work sharing:
  Representatives from the US and the EU – who both have extensive re-evaluation/re-registration programmes - will highlight specific issues related to re-evaluating existing active substances including, where possible, barriers to work sharing and possible solutions. A presentation from Australia will outline their experiences with using other countries' reviews to support their own national reviews and the problems encountered. An industry representative will describe their experiences and concerns.

  - In the US and Canada (*Susan Lewis, US-EPA*)
  - In the EU (*Louis Smeets, EC*)
  - By Australia *(Les Davies, Department of Health)*
  - By industry (*Karen Pither, GCPF/Bayer, US*)

- **Discussion**

12.30 Lunch

14.00 **Breakout Sessions B: Sharing the work to re-evaluate existing active substances**

Breakout Groups will discuss and answer the same questions as those identified for break-out group sessions for Day 1, as it concerns the **re-evaluation of existing substances**. Break-out groups should pay particular attention to issues unique to re-evaluation.

1. What is your experience of work sharing as far as **existing active substances** are concerned?

Then, imagine yourself in 5-10 years from now:

2. What would be your 'vision' of work sharing? What would you like to see achieved or made possible?
3. What will drive you (as representative from a small/large country, from industry, etc.) to reach this 'vision'? i.e. what would be the incentives for the work of pesticide review to be shared?
4. What would you have to do to achieve this 'vision'? What would be your approach/strategy? Considering the categories of resources, people, laws/policy, science, infrastructure/technology, describe steps to be taken, possible problems or barriers that could be encountered, and possible solutions to overcome these problems.
5. Who would you have to convince to make your 'vision' possible? And who are the responsible parties to carry out the steps to achieving the vision of work sharing?

6. Looking at all the actions you have identified during the break-out group session, identify the most important steps (up to 5) to be taken, both in the short-term and in the long-term? *(Answers to these questions should help identify further projects in the final plenary session)*

All of the above-mentioned questions would need to be answered from different perspectives, e.g. for small and large countries, for OECD and non-OECD countries, for representatives of governments, industry, grower and consumer groups.

Coffee break will be taken some time during the afternoon (each group to decide when).

17.00 **Breakout Sessions B** (cont.)

- Discussions should stop; groups should start to review and agree on the outcomes of their discussions (for inclusion in their break-out group report).

17.30 Finish for day 2

Late afternoon *Preparations of break-out reports by Chairs and Rapporteurs*

Wednesday 14th February

8.00-
9.00 *Meeting of all Chairs/Rapporteurs/Secretariat to:*
review and agree on the consolidated report from day 2.

9.30 **Plenary 5: Sharing the work to re-evaluate existing active substances – outcome of break-out group discussions**

(30 min)

- **Report back** to plenary on the break-out group discussions
  This will be done by one Presenter who will present a consolidated report for Day 2 (presenting all common elements discussed by the different groups). Other Chairs/Rapporteurs will have the opportunity to add issues that were specifically raised in their group.

- **Discussion** between the Panel (Chairs and Rapporteurs) and the audience *(to be moderated by Vibeke Bernson, Sweden).*

Note: Members of break-out groups will be also asked to review their group individual, written report of Tuesday's discussions and return comments to their Chair/Rapporteurs during the day.

11.30 Lunch
(Working lunch for of all Chairs/Rapporteurs/Secretariat to prepare for afternoon closing session.)

13.30 **Closing Plenary 6: Conclusions and Recommendations**

- **Summary of conclusions and recommendations** on work sharing for new and existing active ingredients proposed *(Chair/Secretariat)*
- **Discussion** and development of overall workshop conclusions and recommendations. As well as addressing further work that could be done to improve the opportunities for sharing the work of pesticide review among OECD Member countries, the workshop should also consider how such could benefit non-OECD countries and other international organisations involved in pesticide assessment.
- **Review of actions** for producing workshop report and for initiating (immediate) next steps.

- **Closing remarks** by hosts.

16.00 Workshop ends

Annex 2

Statements presented in the opening Plenary Panel "Expectations about work sharing from other stakeholders (What is your 'vision' of work sharing?)"

GCPF Expectations for "Work Sharing"

Presented by Richard Nielsson

The crop protection industry companies represented by the Global Crop Protection Federation support, in principle, governments sharing the work to evaluate new and existing active substances, which is called, in short, "Work sharing." From the start, the industry has been involved in work sharing, and supports the goal of improving the efficiency in evaluations of pesticides. We share the view that this is an important activity coming at a time when resources in governments and industry are declining, and concerns are growing over the time it takes to make regulatory decisions. The GCPF Background Paper for this workshop covers in more detail current experiences, incentives and barriers, and proposals for the future of work sharing, as well as examples of active projects.

The industry hopes that this workshop will be a positive step forward towards having its vision and expectations for "work sharing" and, for harmonisation in general, advanced,
namely:

- To gain early market entry for its products;
- To achieve global acceptance of the studies supporting the registration submission;
- To prepare one submission and have one review on the active substance. **NOTE:** Product reviews should be maintained as separate national reviews;
- To have agreement on data requirements and study protocols; and,
- To strive for improved scientific quality through peer review.

As a general principle, GCPF advocates that "work sharing" should be limited to the evaluation of individual study reports and the generation of a list of critical endpoints.

We do not believe, that, in general, risk assessment can be harmonised and be part of "work sharing," because it is unlikely that critical elements, such as, country specific uses, agricultural practices, environmental and climatic conditions, and dietary habits will be similar and can be harmonised between countries on a global basis. It is, therefore, appropriate that risk assessments will be different because of the differing situations between countries.

Looking further ahead, and trying to think "outside the box," so to speak, the workshop might like to ponder if there are other areas which could be considered in the future, such as the development of global reporting guidelines for original study reports which mirror the structure and headings of the Tier II summaries. In addition, to provoke thought about activities in the future, is there any way that the OECD harmonisation efforts can be implemented jointly with CCPR/JMPR?

Importance of Regional Co-operation

Written Statement from Hungary

presented by Zoltán Ocskó

Background: In spite of remarkable *differences*, due to the former general political system and economical structure, the countries of this region have many *similarities* like institutions, decision making procedure or sometimes it comes back to permanent contacts for hundreds of years.

Topic: This special condition is a fact, but at the same time it is also *a possibility*, which makes the regional co-operation evident. Any kind of such a co-operation (information exchange, or work sharing etc.) could only be really effective if it becomes an integrated part of a "global" aspiration. This is what should be emphasised.

Aim: The main goal of the establishment of *CEUREG* Forum was to spread information, to bring people to work together and to help the integration to relevant national movement of pesticide registration Because of the *general responsibility* of pesticide use not only the Central but also East European pesticide registration experts were involved.

Results: The six meetings of the Forum have proved that the basic idea was good, but further *efforts* are required to improve the activity. A comparable *institutional* (registration) structure, and *technical* facilities, similar level of legislation and well *trained* experts are some of the basic elements of future co-operation.

Conclusion: To use the human and technical resources more efficiently the only possibility is to share the work to be done. In addition to the intention, well prepared *partners* are required. Regional organisations could be also a good one.

Statement from California Citrus Quality Council

Presented by Jean-Mari Peltier

The pace of change in management of agricultural pests is accelerating for a variety of reasons;

- pest resistance;
- exotic pest introductions; and
- emergence of secondary pests, coupled with regulatory restrictions on the management of existing pests

Management strategies are forcing growers to shift to alternative technologies. In the international arena, traditional approaches to review and acceptance of these emerging pesticides cannot always keep pace with this change. At the same time, international trade liberalisation and expansion make harmonisation of pesticide standards a serious consideration in order to avoid costly disruption of trade.

Growers shifting to new, often less toxic pesticides may find their products unacceptable in international markets due to the lack of global residue standards. Work sharing, and other efforts at international harmonisation of pesticide issues, may offer a practical approach to addressing this serious trade issue.

Vision of Work Sharing

Sahelian Committee for Pesticides
Institut du Sahel, BP 1530 Bamako, Mali

Prepared by Amadou Diarra and François Abiola
Permanent Secretary and President

Presented by François Abiola

Introduction

To ensure that pesticides used in the different countries in the Sahel region of West Africa are effective, of suitable quality and of low hazard to man and the environment, the CILSS Member States signed in 1992 the Common Regulation for the Registration of Pesticides in CILSS Member States.

The objective of the Common Regulation is to combine the experience and expertise of Member States with respect to the evaluation and registration of pesticides in order to ensure their rational and judicious use, as well as the protection of human health and the environment .

The Common Regulation concerns the authorisation, placing on the market, use and control of the active ingredients and formulated products of pesticides in the Member States. The Common Regulation is also applicable to the authorisation, placing on the market, use and control of biopesticides. It defines the following areas among others:

- scope and area of competence;
- registration conditions;
- registration procedure of a formulation;
- protection of confidential data;
- information;
- labelling and packaging;
- experimentation;
- control;
- composition, attributes and functions of the Sahelian Pesticide Committee

The Sahelian Pesticide Committee (CSP the French acronym), the common pesticide registration body, became operational in 1994. It assesses registration dossiers submitted by the agro-chemical industry and grants sales permits valid for all its Member States. A Permanent Secretariat is created to manage the daily activities of the CSP.

Evaluation and registration of active ingredients and formulated products falls within the competence of the Sahelian Pesticide Committee. It is carried out for all Member States.

Control of import, export, placing on the market, use and destruction of pesticides registered under this Common Regulation falls within the competence of the responsible authorities of the Member States.

The Sahelian Pesticide Committee is responsible for :

- the examination and follow-up of registration applications ;
- the preparation of a list of public institutions authorized to carry out trials ;
- the preparation of a list of laboratories authorized to carry out analyses for assessments ;

- the definition of methods for the control of the composition and the quality of products and their evaluation with respect to man, animals and to the environment ;
- the definition of technical guidelines on the data to be provided and the studies to be conducted for the registration by the applicant ;
- the updating of a register of registrations and authorizations ;
- the establishment of an inventory of pesticides used or commercialized in the CILSS Member States ;
- the preparation of a list of pesticides which use is banned or severely restricted in the CILSS Member States ;
- the maintaining of relations with the National Pesticide Management Committees in the CILSS Member States.

The Sahelian Pesticide Committee meets twice a year. An extraordinary session can be convened at the request of the President .

The Sahelian Pesticide Committee is composed of :

- two experts of each Member State ;
- three toxicologists working in the Sahel ;
- the Permanent Secretary of the CSP ;
- representatives of organizations working on pesticides in the region ;
- representatives of international organizations such as FAO and WHO ;

The experts are selected within different sectors of plant protection, toxicology, eco-toxicology or chemistry.

How does the Sahelian Pesticide Committee proceed with registration of pesticides ?

First step

The applicant sends a complete dossier required for the registration request to the Permanent Secretariat of the Sahelian Pesticide Committee (CSP), at Institut du Sahel in Bamako, Mali. For this purpose, the Permanent Secretariat of the CSP has available for each applicant the model registration dossier.

The Permanent Secretariat of the CSP registers the dossier and acknowledges receipt to the applicant.

The applicant pays the examination fees.

The Permanent Secretariat of the CSP verifies the completeness of the dossier and, if essential information is missing, informs the applicant to complete the dossier.

The Permanent Secretariat submits the dossier to the experts of the CSP.

Second step

The CSP examines the dossier and may either:

- decide to fully register the pesticide in the Sahel for five (5) years,
- deliver a provisional registration for a duration of three (3) years while waiting for additional studies,

- maintain a dossier under assessment, awaiting additional information,
- deny registration of the pesticide.

The registered or provisionally registered pesticide bears a single number for all the CILSS Member States.

Third step

The Permanent Secretariat of the CSP informs the applicant and the Member States of the decisions by the CSP.

The Permanent Secretariat publishes the list of registrations and provisional registration in a CILSS publication.

Vision of work sharing

As seen from the registration procedure, the experts of the Sahelian Pesticide Committee rely solely on information given by the pesticide industry. The main work has been so far based on verification for completeness of the registration dossier. The first question is : Is the information requested by the experts given or not ? The second question, that is the most important is : Is the given information correct ? A third question is : Is the information good enough to grant a provisional registration ?, a definitive registration ?or is there a need to request another set of data for further evaluation.

The first question is easy to answer.

In order for the Sahelian Pesticide Committee to answer the other questions, it needs information from other sources for “cross checking”.

Some information is available on the “Net” but most of the times the in-depth studies are not available. Further more with the limited human resources, the Sahelian Pesticide Committee can not afford to evaluate primary data. Its evaluation is mainly based on summaries.

The OECD data base for pesticide reviews (mainly for new material) can be of great value to the Sahelian Pesticide Committee in order to take more accurate decisions. Harmonized monographies developed by OECD could become a reference for the registration of pesticides in Africa.

The Sahelian Pesticide Committee registers pesticide formulations and not active ingredients because formulations are the end products used by farmers. The quality of the product greatly depends on the formulation. Different formulations of the same active ingredient may greatly differ in toxicity levels. This is the reason why evaluations results of new active substances are necessary for the Sahelian Pesticide Committee.

The work conducted in the Sahel region is mainly based on evaluation of efficacy data. This data is part of the dossier and is quite easy to evaluate. Most toxicological data are not conducted in the Sahel. The experts rely only on work conducted in Europe, the USA and Japan. Most countries in the Sahel do not have their own residue limits. They rely on what is given in the dossier.

With the OECD studies, the Sahelian Pesticide Committee could become a focal point for information on pesticides for the nine CILSS member states. We at the Sahelian Pesticide Committee, would like to develop close relationship with OECD as far as pesticide evaluation is concerned.

Work Sharing in the Pesticides Field:
Present Experience and Future Expectations from a Small Country Point of View

Presented by K. Markakis, Ministry of Agriculture, Greece

Dear Ladies and gentlemen,

It is really a pleasure for me to be here to speak about a very interesting issue that is the work sharing of Agricultural Pesticide Reviews.

It is a long time that discussions started at an international level on this issue but until now only bilateral agreements have been achieved. Nevertheless, in the last years many countries have expressed in one way or the other their wish to collaborate at an international level in an effort to reduce the workload at the national level.

In this context Greece, as a member of the EU, is very proud for taking actively part in the evaluation of dossiers of existing or new compounds and to share this work with the other Member States.

In the first stage of the review program, Greece was rapporteur for 5 compounds (2,4-D, 2,4-DB, Quintozene, Chlozolinate, Fention). All monographs have been prepared and submitted to the Commission on time.

In the context of the second stage of the review program Greece is rapporteur for 3 compounds (Cadusafos, Trifluralin, Prometrin).

In the meantime Greece was selected by industry to be rapporteur for two new for the European Union market compounds: Cyclanilide and Acetamiprid. The monograph for Cyclanilide has been prepared and was submitted to the Commission long time ago while for Acetamiprid the monograph is expected to be submitted on the first days of February 2001.

Therefore, we have already gained a lot of experience in the evaluation of dossiers and in writing Review Reports of high-level standards. It is also beyond any doubt that Greece itself has gained a lot from the close contacts with the experts from other Member States and the international community.

Nevertheless, for a small country like my country it is rather difficult to run and to maintain such an organization. The human and financial resources involved are quite remarkable.

Greece is expecting constructive proposals from this workshop in that direction enabling organization to share the work performed at national level with other countries of the international community. An effort should be made to avoid duplication of work.

We are particularly interested to share the work in the evaluation of the data for most of the sections a modern dossier is composed. We have the feeling that the data requirements at international level are quite close. What it required at this stage is the mutual understanding and trust in the evaluation of these data to reach certain important conclusions like the ADI, ArfD, MRL's etc.

Certainly the registration of the products should remain at national level taking into account the specific environmental and agricultural conditions.

In our opinion an agreement at international level will contribute to release a big part of the work done at national level and to concentrate our efforts in the local problems and in the post-registration control of pesticides.

From the prospective of a small country like Greece and in connection with the initiative undertaken by OECD on work sharing these are our future expectations:

- Small countries that have already proven their capacity to cope with this work to be actively involved in the program
- Countries in which agriculture is an important sector in the national economy and as a consequence of that, the amount of pesticides used is quite relevant, should be actively involved in the development of test guidelines matching the specific climatic/agronomic conditions prevailing in these countries
- Small countries should be active members in the decision making process concerning the development of "positive lists" of compounds.
- It is for the benefit of all stakeholders but also for an effective protection of the environment and humans to remove the barriers in the area of the evaluation of pesticides and to make it more an international process rather than a national one. Overall, the effective protection of the environment and humans it is a concern for all.

Written Statement from New Zealand

Presented by J. Reeve, Ministry of Agriculture

- New Zealand would like to see the workshop achieve the sharing of experiences of regulatory authorities in how the sharing of assessments are being used, and as to whether there has been any issues arising out of this sharing

- New Zealand specifically uses the work sharing to ease pressure on very scarce toxicology resources. We currently have access to up to only three experienced assessors, but because we have an agriculturally based economy, we will get almost the same range of pesticides being registered, and in the same sort of time frame that the larger authorities experience. We utilise the toxicology monographs prepared by other OECD counties as if they were our assessments (after checking that the data we hold matches that in the monograph), but putting our own conclusions (taking into account the regulatory framework within which we work, and the specific New Zealand environment). The assessment of the toxicology package, and preparation of the monograph are time consuming. Thus, the utilisation of other monographs in this way enables us to considerably shorten the time frame needed to have a new pesticide properly reviewed prior to its registration, and also ensure that we can keep pace with the numbers of applications for registration of new pesticides. We are a cost-recovered agency and charge applicants for the time taken to work on their applications, and the utilisation of other countries monographs therefore can considerably cut the costs of obtaining a pesticide registration in New Zealand.

- The considerable assistance the sharing of toxicology assessments has given the New Zealand Regulatory Authority has meant that we are able to maintain a high level of efficiency in handling applications for registration while not compromising the robustness of the registration process. This has also enabled New Zealand to keep its registration fees to a level that is affordable to the pesticide industry, given the relatively low level of pesticide use (the total use rate of all active ingredients is estimated to be approximately 3500 tonnes per year). New Zealand toxicology assessments are now much more weighty documents (to try to ensure their usefulness to a requesting authority, and to meet the requirements of the OECD Guidelines), and hence more robust also. Minuses include the resource implications in the need to keep up with our international commitments arising from this work (eg supplying statistics to OECD), and the requirements for much more detailed reviews than were written previously.

- Our vision for the future is that we hope to be able to increase the level of our own input into the preparation of monographs that can be used by others, and that monographs become available electronically (particularly via the internet). This would appear to require the resolution of any issues relating to the confidentiality of data and monographs.

Annex 3

Breakout Group Reports

This section presents each of the five breakout groups' reports for both new and existing active substances. Reports for 'Sharing the Work on New Active Substances' are included in A.3.1, while reports for 'Sharing the Work on Existing Active Substances' are in A.3.2. The composition of each breakout group can be found in A.3.3. In general, the breakout groups have presented their discussions as bullet point statements in answer to each of the six questions, reflecting the views of all of the participants in each group. These reports were written by the rapporteurs and reviewed by all members of each breakout group before submission to the OECD Secretariat for inclusion in the final report. The OECD Secretariat may have made minor editorial changes during the writing of the final workshop report.

A.3.1 Sharing the Work on New Active Substances

Report of Group 1 – New Active Substances

1. What were some of the experiences in sharing work on new active substances?

- Joint reviews within Nordic countries; use of monographs from one country to make decisions in all countries worked well; harmonised data requirements and dossiers.
- Review of monographs from other countries for national authorisation.
- Registration for a seed treatment replacement - grower participation, common MRLs were given important consideration.
- Assessment of dossiers within EU; new project with the US.
- EU member states sharing tasks of rapporteur/co-rapporteur.
- US/Canada/Australia/Ireland joint review programme.
- Use of OECD database and reviews of other countries to facilitate national reviews.
- Canada/US reviews have shown that the more countries work together, the more they appreciate each other's capabilities and trust each other.

What has worked well

- Common application form.
- Harmonising guidelines, criteria.
- Transparent and open communication.
- Good, complete dossiers and monographs.
- Reaching agreement on endpoints.
- Close communication with growers on label application use rates and timing of registration relative to use season.
- Good collaboration with co-rapporteur.
- Harmonising data requirements.
- EU dossier format helpful, unified format.
- Flexibility of ECCO process.
- Transparency, especially after the monograph has been produced.
- Work sharing between participating countries.

- Sharing reviews, which reduced timelines.
- Management commitment.
- Better science over time.
- Common data sets.
- Reduction of trade problems.

What did not work well

- Balancing work sharing and work required for national reviews; increased effort on work sharing left fewer resources for national reviews.
- Variable quality of monographs.
- Variable quality of OECD database; data incomplete, especially for future planning.
- Guidelines for risk assessment not harmonised.
- Lack of discussion of potential problems with legal services.
- Establishing the same priorities in participating countries.
- Different uses in the submission, which complicates the process.

2. What is the vision of work sharing?

- Mutual trust by participants, so studies would not have to be re-reviewed by second and subsequent countries.
- Common data requirements and common guidelines.
- Common submissions on global/regional basis; improved communications within companies.
- In monographs, regulators using summaries prepared by industry.
- All crops covered.
- Electronic monographs.
- Scientific exchanges.
- Global agreement on endpoints, with one global list of endpoints.
- Smaller countries contributing to specialised areas.
- World forum with experts from different countries working for a period of time on pesticides; increased communication between experts.
- Electronic submissions to all agencies.
- Submission of common dossier of data, reviewed once and used by others, and adding national requirements and making national risk assessment.
- Greater participation by non-OECD countries.

3. What are the incentives or drivers for work sharing?

- Efficiency gains.
- Heightened public awareness of different standards between countries, and increased public confidence in pesticide registration system.
- Trade, harmonised MRLs.
- Improving quality of science.
- Reducing risk of pesticide use worldwide.
- For industry, earlier and less costly market entry, reduced development cost and faster return on investment.

- Eliminating duplication of studies and reducing development cost through harmonised and well understood data requirements.
- Dealing with declining registration resources; increasing flexibility in how such resources can best be used, *i.e.* through re-prioritising regulatory resources in other areas.
- With work sharing, there is more time to study chemicals and make appropriate risk assessments.

4. What approaches should be used to overcome the hurdles or barriers for work sharing?

- Use OECD guidance document.
- Establish a forum to address harmonised requirements, studies and endpoints and encourage their global acceptance; consider common data requirements.
- Better co-ordination by industry of global registration submissions, with a clear demonstration of the advantages this would bring.
- Increased communication and exchanges between scientists.
- Workshops/forums to develop guidance documents, and increase trust through personal acquaintances.
- Encourage those working with electronic submissions to share experiences with others. (Canada and US to host a workshop which will be held in October 2002.)
- Work on harmonised guidelines by the OECD Working Group on Pesticides & Test Guideline Programme.
- Progressively expand involvement of non-OECD countries.
- Develop scientist exchange programmes.
- Develop regulatory staff exchange programmes.

5. Whom would you have to convince to make your vision possible? Who is responsible?

- OECD Member countries, regulatory agencies of those countries, EC Commission.
- Convince OECD Member countries first, then extend effort to non-OECD countries.
- Marketing managers of chemical companies.
- Scientists in the agencies carrying out the reviews.
- Consumers.
- Environmental Non-Governmental Organisations (NGO).
- Animal welfare activists.
- Grower groups.

6. Identify the most important actions to be taken both in the short and in the long term (five key areas for improvement).

- Establish a forum, through the OECD WGP, to assess technical problems.
- Have the OECD WGP consider confidentiality issues, and discuss with industry or change legislation to permit early information exchanges.
- Overcome possible misuse that could occur if reviews are released before they are made final.
- Member countries/regions need to investigate national legislation to determine limitations on work sharing.
- Share information on ongoing reviews.
- Include non-EU countries in ECCO reviews.

7. Identify the most important actions discussed during the breakout session.

Short term

- Need for additional resources in the short –term.
- Agree common data requirements.
- Develop guidance documents for reporting studies, drafting dossiers and drafting monographs.
- Expand common requirements from toxicology to ecotoxicology and environmental fate of pesticides.
- Hold technical workshop to agree on common endpoints, *e.g.* ecotoxicology and avian toxicology.
- Investigate legislative barriers in different countries.
- Develop zoning project for residue trials.
- Build trust between scientists through greater interactions (global ECCO).

Long term

- Change legislation.
- Publish reviews, so that others can benefit from them.
- Create electronic formats (mid term).
- Set up staff exchange programmes.
- Communicate assessment summaries to public.
- Develop one common dossier.
- Establish an international database on products.

Report of Group 2 – New Active Substances

1. What were some of the experiences in sharing work on new active substances?

Experiences included the following areas:

- CODEX.
- Rapporteur/Co-Rapporteur system.
- Regional co-operation, *e.g*. Nordic countries, Austria/Germany mutual recognition, *etc*.
- Joint evaluations – involving various countries.
- SAHELIAN initiative – pooling of expertise.
- No experience yet – but willing to participate.

2. What is the vision of work sharing?

- Need to see a return (reward) for time and effort already invested in work-sharing, such as elimination of duplication of work, build-up of trust between expert evaluators, increased efficiency.
- Global, harmonised data requirements and guidelines.
- Parallel reviews by 2 countries, globally peer reviewed resulting in a single revised assessment report.
- Conducting national risk assessments, using globally harmonised models.
- Co-ordination and exchange of evaluations, evaluation plans and policies.
- Evaluations to identify hazard and endpoints.
- Earlier access to markets.
- Sharing of evaluations/risk assessments with smaller or under-resourced countries.
- Development of a database and lines of communication for experts/expertise – to be used for specific consultation on a bilateral basis.

3. What are the incentives or drivers for work sharing?

- Increased efficiency in the use of (scarce or decreasing) resources.
- Lower costs to all stakeholders.
- Risk reduction arising from earlier registration of newer and better products.
- Common data requirements.
- Criteria and assessment based on science.
- Satisfying public demand for increased food and environmental safety, increased transparency and increased efficiencies.
- An internationally agreed process will have greater credibility.

4. What approaches should be used to overcome the hurdles or barriers for work sharing?

- Exchange experiences, experts, plans, *etc*.
- Set realistic goals.

- Develop an international report on the benefits of work sharing so as to help influence policy makers.
- Provide adequate staffing and competence.
- Examine and understand national legislation and procedures.
- Internationally harmonise IT software.

5. Whom would you have to convince to make your vision possible? Who is responsible?

- Government policy makers and reviewers.
- General public – users and consumers.
- Industry.

6. Identify the most important actions to be taken both in the short and in the long term (five key areas for improvement).

Short term

- Begin the harmonisation of common data requirements, guidelines for studies, reporting and dossier preparation.
- Begin the harmonisation of common assessment formats and models.
- Exchange of key experts – technical and administrative.
- Identify and overcome the barriers in information exchange, *e.g.* language, IT compatibility.
- Identify the benefits of harmonisation in an international report.

Long term

- Finalise common data requirements.
- Establish a common approach to risk assessment models.
- Generate the methods to obtain appropriate data for the models.
- Establish the 'joint evaluations' procedure as an accepted practice.

Report of Group 3 – New Active Substances

1. What were some of the experiences in sharing work on new active substances?

- Better use of resources.
- Transparency of decisions.
- Improved collaboration on science and decisions.
- Guidance documents for protocols for all scientific disciplines.
- Harmonised protocols and endpoints.
- Improved access to databases.
- Lack of industry support for work sharing and exchange of risk assessments.
- Predictable, more timely decisions.

2. What is the vision of work sharing?

- Seamless and apparent process.
- Predictable and global schedules.
- Effective collaboration and communication with all stakeholders.
- Improved technological capabilities for developing countries.
- Information (including dossiers and monographs) is readily exchanged electronically.
- Harmonised science (data requirements, endpoints, exposure scenarios, evaluation process) and common submission.

3. What are the incentives or drivers for work sharing?

- Improved communication and education, and convincing senior managers of benefits of work sharing.
- Reacting to pressure to do more in order to improve quality and efficiency.
- Quicker market access for producers**.**
- Identification of goals.
- Technology transfer to developing countries.
- Harmonisation of processes and data requirements.
- Improved planning for activities.
- Co-operation between countries, government, industry, and growers.
- Better sharing of reviews and decisions.
- Reduction of trade barriers – provisional MRLs.
- Incentives to participate.

4. What approaches should be used to overcome the hurdles or barriers for work sharing?

- Submitting complete dossiers:
  - Incentives/rewards
  - Disincentives /penalties.
- Access to e-mail and Internet.

- Building information resources, regional systems.
- Support by all management levels:
  - Inter and intra-organisational.
- Consistent communications and processes.
- Shared vision, with support from others.
- Participation by ALL parties.
- Document sharing without impediments.
- Identification of legal and policy constraints in all countries:
  - Work to eliminate them.
- Instituting scheduling process.
- Identify process – steps/schedule:
  - Individual countries, companies
  - Multiple countries.
- Pilot projects.
- Establish work groups to solve problems, build processes (*e.g.* NAFTA).
- Incentives.

5. Whom would you have to convince to make your vision possible? Who is responsible?

- Convince all staff managers; educate stakeholders, growers and trade organisations.

6. Identify the most important actions to be taken both in the short and in the long term (five key areas for improvement).

- **OECD WORKING GROUP ON PESTICIDES TO TAKE THE LEAD**
- Identify incentives for participation by industry, government, and all other stakeholders (including consumers).
- Define clear goals, and set up process for this to succeed – with transparency for all stakeholders
  - Documentation.
- Agreed upon endpoints, protocols, processes, submissions, residue zones, PHED/EUROPOEM, environmental scenarios (FOCUS),
  - Documentation.
- Pilot projects (to be identified)
  - Measure progress, costs and benefits, then communicate these
  - Documentation.
- Reassess, improve the process
  - Documentation.
- Full-scale work sharing on new active substances.

Report of Group 4 – New Active Substances

Aims of global work sharing:

- To improve public and occupational health and safety
- To reduce risks to the environment
- To reduce assessment workloads
- To increase public confidence in regulatory decision-making
- To reduce trade barriers

1. What were some of the experiences in sharing work on new active substances?

- Some non-EU countries moving towards compatibility with EU/OECD guidance.
- EU – harmonisation of legal basis, data requirements.
- Need to talk to each other, understand each other's perspectives.
- Concern that work sharing will cause too much work, need to show others the benefits.
- Concern with non-compatibility of Electronic Data Submission systems.
- Standardised monograph format has been a big advance in EU
- Regulatory experts have learned from each other.
- Involvement of grower groups important.
- Some countries need assistance in developing assessment expertise, and have little experience in work sharing.
- Other countries have at least 7 years experience in work sharing; building trust may take 3-5 years; face-to-face contact important. Time to decision only marginally faster, but reduction in trade irritants.
- Up-front costs with work sharing; need to know whom to contact in other agency.
- Work-sharing success can depend on quality of reviews obtained.
- 'Opportunistic' use of reviews by others *vs.* full joint reviews - benefits in both.

2. What is the vision of work sharing?

- Move towards joint reviews for greatest efficiency (ultimately more useful than parallel review).
- JMPR to make use of OECD formatted dossiers and to prepare their reports/monographs in line with OECD format.
- Countries to make national reviews in OECD format, available to JMPR, and co-ordinating this with industry submissions of the supporting data.
- Better standardisation of joint review formats.
- Easy access to each other's databases at an international level.
- Companies take a more active role in getting joint work sharing started.
- Countries share review schedules, draft hazard/risk assessments, *etc*.
- Transparency in process.
- Establishment of an OECD co-ordinating group, assisting countries seeking work sharing opportunities. It could also provide a co-ordination point for sponsor applications.

- A faster rapporteur/ECCO system in EU.
- Much better work by agencies on re-registration; new agricultural chemicals are driven by industry/commercial considerations.
- Common format; each chemical reviewed once; common, streamlined, modular processes (including database requirements, test guidelines, *etc.*), with more interaction between regulators and industry.
- Mutual recognition of core data evaluation (hazard assessment).
- Extension of advances to other chemical types.
- Public, OHS and environmental safety is paramount!
- More regional co-operation,such. as is occurring with EU, NAFTA, Sahel.

3. What are the incentives or drivers for work sharing?

- Fewer trade irritants, reduction in barriers to trade.
- Reduction of workload (industry and regulatory agencies), and a more equitable distribution of workload; fewer industry and regulatory resources needed.
- Heightened public perception of the risks posed by pesticides – need for national regulators to justify regulatory decisions *vis-à-vis* decisions in other jurisdictions.
- More opportunities for staff; more interaction with other agencies, and staff exchanges. Increase in available time may give people opportunity to be involved in other areas within their agencies, *e.g.* research, registration, and thus motivate staff.
- Need for more streamlined process for harmonisation of MRLs, including increased standardisation of approaches.

4. What approaches should be used to overcome the hurdles or barriers for work sharing?

- Staff interaction, exchanges.
- Get more guidance on OECD guidance documents.
- Encourage JMPR to use OECD guidance.
- Need for increased buy-in from all levels, all areas.
- Commence/continue with 'work sharing' at all levels, from simple information exchange, face-to-face visits, *etc.* – 'hasten slowly'!
- Work sharing in groups according to the pesticide, *e.g.* a rice insecticide.
- 'Convince my bosses!' Spread the message that work sharing will not complicate the work and will lead to greater efficiencies.
- Continue preparation of guidance documents for OECD Member countries on different technical issues; continue harmonisation of data requirements, TGs, formats, *etc.*
- Education of company dossier writers.
- Work sharing activities must show quickly that they reduce the workload.

5. Whom would you have to convince to make your vision possible? Who is responsible?

- Legal barriers, *e.g.* California legal requirement to legal review.
- Legal barriers – data confidentiality issues; industry and/or country laws.

- Smaller countries – addressing their concern that their views will not hold ground among larger players.
- User groups - not commonly a part of the process.
- CCPR member countries need to be informed of OECD harmonisation/work sharing activities and encouraged to support JMPR use of OECD-formatted dossiers and national reviews.
- Senior and middle management need to be convinced, along with technical staff. (Caution not to hasten too quickly.)
- National laws may need to be amended.
- Industry needs to use the dossier guidance.
- Pragmatic approach – try work sharing.

6. Identify the most important actions to be taken both in the short and in the long term (five key areas for improvement).

- Continue moving forward on harmonisation of data requirements, test guidelines, level of reporting, using OECD dossier and monograph guidance; stepwise approach on data reviews for some successful 'wins' – 'hasten slowly'. Start simply (*e.g.* hazard assessment), ultimately moving towards exposure and risk assessment where possible.
- Implement what we've agreed on within 5 years – follow-up in the intervening time, *i.e.* 'Get on with it'! For whatever is done, set milestones and targets, and meet them (and develop indicators to measure whether we have succeeded).
- Identify the problems and issues arising from previous work sharing exercises and identify some new active substances for further work sharing.
- Demonstration of benefits will lead to buy-in at all levels, including all stakeholders, *e.g.* consumers, pesticide industry, regulators, grower groups. Exchange of scientific staff will lead to development of trust.
- Draft a process description/SOPs for joint reviews and develop a 'road map' of similarities and differences in data requirements, study protocols, *etc*.
- Establish a mechanism for co-ordinating assessments of new active substances and review schedules (and encourage countries to examine the possibility of advising such, if they currently can't do so.)

Report of Group 5 – New Active Substances

1. What were some of the experiences in sharing work on new active substances?

- First experience was difficult; second experience was better. Limited possibilities with minor crops… this needs more attention.
- Too many surprises at the end of the process. Anticipate problems!! Communication up front should have been improved.
- Frequent communication is essential… need lead contacts at regulatory agencies.
- Work sharing, especially initially, is time consuming. Need guidance documents and processes to reach decisions.
- Cannot harmonise around products… must focus on active substances.
- Recommend parallel review initially to pilot work sharing. Start with a simple case to build trust and confidence. Do not select an active substance which has concerns.
- Face to face meetings between regulators were important. Also need management buy in up front.
- EU reviews at the country level first and then peer reviews afterwards.
- Need to begin the process with hazard identification…risk comes later.
- Parallel review is but a first step to bring countries together.
- Several countries have no direct experience beyond EU with formal work sharing.
- Commonly agreed upon risk models do not exist.
- Problems expand with number of countries involved.

2. What is the vision of work sharing?

- A single data package is preferable.
- Need a final review document (amended after peer review) to share with other countries. Free exchange of review drafts leading to a common final report.
- WHO and EU need to work closer together.
- More work sharing between US/Canada and Europe.
- Know which active substances are being reviewed by country… a collective picture. Will facilitate work sharing.
- Faster time to market.
- Agreed upon common list of requirements and protocols. Also agreed upon regional requirements.
- Standardised OECD review formats and a single data numbering system.
- Work sharing also involves less developed countries. Also addresses minor crop issues. More use of bridging data… extrapolation.
- Standardised MRL (globally) which leads to a reduction in trade barriers.
- Reduction of local data requirements.
- Agreed upon residue zones and developed global residue bases by product.

3. What are the incentives or drivers for work sharing? (Not Addressed)

4. What approaches should be used to overcome the hurdles or barriers for work sharing? (Not Addressed)

5. Whom would you have to convince to make your vision possible? Who is responsible? and

6. Identify the most important actions to be taken both in the short and in the long term (five key areas for improvement).

Top five priorities

1. OECD harmonisation efforts should be expedited. (test guidelines, guidance documents on tox studies, MRL, *etc*).
2. Industry needs to take more of a global approach to submissions, where possible. Inform regulators where submissions are being made to facilitate exchange of information between countries. Industry needs to harmonise use patterns between countries.
3. File import tolerances earlier to remove trade barriers and submission to CODEX.
4. Start with a simple case to build trust and confidence.
5. A common list of data requirements and test guidelines must be developed by OECD with a common numbering system.

Other steps

- Identify minor crops on which the active substance might work.
- Industry should serve as a focal point for minor crops.
- Industry should submit reviews from other countries to regulator (questions about confidentiality still need to be resolved).
- Make the MRL chapter public.
- Industry should seek, where feasible and practical, to reduce the number of formulations it registers.
- Regulators should use extrapolation of data more.
- A global plan to identify where work sharing opportunities exist needs to be developed by OECD countries.
- Predictable timelines and science up-front, *i.e.* don't change requirements during the middle of the review. Communication throughout the review.
- Provide economic incentives, through harmonisation, for industry to register on minor crops.
- Reduction in fees for industry.
- Accept modelling for MRL calculations.
- Consistent instruction on screens and preliminary evaluations.
- A single data numbering system should be adopted.
- Increase training for developing countries.

A.3.2 Sharing the work on Existing Active Substances

Report of Group 1 – Existing Active Substances

1. What were some of the experiences in sharing work on existing active substances?

- Dossiers from different notifiers are difficult to handle, prefer task forces.
- Incomplete dossiers; better completeness check and whether standard guidelines were used.
- Quality of older studies, level of acceptance between countries different.
- Different specifications between substances from different notifiers may pose big problems for the review.
- With several manufacturers of the same product, who fills data gap?
- Not always possible to form task force, proprietary rights issues.
- Difficulty using published studies; do not know purity of substance used; test protocols not standard. Variable quality of science.
- Monograph should contain evaluation of quality of studies submitted.
- Submit all information and justify selection of relevant data; needed to verify differences or similarities of results from published studies, and to answer industry questions on worthwhile use of resources; provides predictability to regulators/reviewing scientists.
- No requirement (in US) to submit duplicate studies with same result.
- Reviewers need to know about other studies.
- Different databases in different countries, as a result of the different times submissions were made.

2. What is the vision of work sharing?

Process

- Internet listing of all work done by others, full access to databases and fully detailed reviews.
- Consultation with growers, particularly regarding uses that are not supported, mitigation considerations in light of actual use patterns, development of alternatives, and impact of MRLs not supported on trade.
- Communication with exporting countries regarding loss of substances and replacement with newer substances; replacements may be higher priced; trade implications.
- Get over backlog of reviews so that programme is current regarding adverse effects assessments.
- Industry provides on regular basis, as required by local legislation, reports of adverse effects (*already on-going programme in US [6(a)(2)]),* and updates all available reports. Post reports on the OECD web site.
- Establish forward-looking system for simultaneous reviews for plant protection products with identical/similar uses (already in operation in Norway and Sweden).
- Compare reviews on active substances with reviews from non-EU countries, to build mutual confidence and understand differences between countries; identify areas for harmonisation.

- Joint assessments based on cumulative risk assessment methodology.
- Methodologies developed for endocrine effects assessments.
- Have review programme completed in the EU. [*NB*: When a substance is listed in Annex 1 in the EU, an overall summary on the regulatory decision and how it was reached will be published on the Internet, with 3 background documents: background document A - monograph; background document B - peer review; and background document C - how data gaps are satisfied, and addenda to original monograph. In the US, when the risk assessment is completed (Phase 5), the risk assessment and the endpoint selection are published on the Internet, saying why endpoints were selected, but giving no full detail on assessment of individual studies.
- Develop common formatting guidance for monographs. US jointly developing templates with Canada, which are more detailed than EU monograph; noted that there is an insufficient level of detail in OECD monograph.

  Harmonised templates for studies and harmonised summaries considered by some more important than extent of monograph.
- Electronic data transfer and communication between countries.
- Gain experience on the OECD formats within 5 years, and undertake to review the formats at the end of that period.

(In the case of MRLs not supported in the EU, they are reduced to the LOQ. Study Codex tolerances to determine which of the non-supported MRLs are based on non-EU data. Publishing list of tolerances, which will disappear in 2003, and what will be required to maintain them. For exports to EU, large programme to support tolerance efforts by developing countries. Requirements for import tolerances published on Internet. Aggregating residue legislation this year will permit changes to be made. Import tolerances based only on dietary assessment, at this time, and certain number of trials required to give confidence in MRL.)

Prioritisation

- Open, transparent publication of review schedules to assist others in prioritising their review schedules.

3. What are the incentives or drivers for work sharing?

- Global risk reduction.
- Harmonised reviews globally minimise negative trade impacts on growers.
- Efficiency gains.
- Work sharing will minimise issues resulting from different methodologies and discrepancies in hazard and risk assessment.
- A more predictable and more harmonised process may result in lower cost for support which may result in maintaining support for a product, as opposed to making decisions on a regional/national basis, as is the case now.
- Work sharing for import tolerances, as a result of no notification for support in Europe.

4. What approaches should be used to overcome the hurdles or barriers for work sharing?

- Publicise availability of review documents for use by others.
- Consultation with growers so they are aware of likely consequences, with industry regarding replacement strategies, and with exporting countries on consequences (unless import tolerances are put in place).
- Finish reviews - **JUST DO IT**. Ensure timely finalisation of existing programmes.
- Decisions to cancel substances may increase awareness of the availability of alternatives or their development.
- Implement global adverse effects reporting system, analyse periodically to determine trends.
- Use reviews from other countries to build confidence and identify areas needing harmonisation.
- JMPR might use country reviews, note differences between country approaches.
- Jointly develop new scientific approaches, such as cumulative risk assessment, probabilistic methods and assessment of endocrine disrupters.
- Need to complete work along current directions before considering changes in policies.
- Encourage use of OECD formats.

5. Whom would you have to convince to make your vision possible? Who is responsible?

- Governments/JMPR have to be convinced to harmonise review schedules, on a limited basis initially, to start work sharing process. Need a master list to start.
- Encourage flexibility of EU member states and others in their review process. For example, EU rapporteurs can use reviews of non-EU countries in preparing their monographs.
- Need to convince regulators and administrators that efficiencies can be achieved and standards maintained through work sharing.
- Fine tune schedules within the limits of existing schedules.

6. Identify the most important actions to be taken both in the short and in the long term (five key areas for improvement).

- Develop pilot project, with co-ordinated review of an (or few) existing substance, to identify problems.
- Increased utilisation of the OECD formats for dossiers and monographs.
- Global list of planned and ongoing reviews.
- Plan for work –sharing.
- Communication with growers regarding global list of planned reviews.
- Links from OECD web site to sites for national/regional reviews.
- OECD Working Group on Pesticides would be the lead agency.
- Conduct meta-analysis of reviews from the EU with the work of others to identify differences in hazard analysis, risk assessment methodologies and decisions made. From that, suggest a programme of work for harmonisation. This work might be contracted out and funded jointly.

Note the US probabilistic approach may result in large differences compared to EU results. Suggest widely publicising differences in approach, such as probabilistic assessments, so that considerations for harmonisation can be started.

Report of Group 2 – Existing Active Substances

1. What were some of the experiences in sharing work on existing active substances?

Experiences included the following areas:

- CODEX.
- Assistant rapporteur system.
- Regional co-operation, *e.g*. Nordic countries, Austria/Germany mutual recognition, *etc*.
- Joint and opportunistic evaluations – involving various countries.
- SAHELIAN initiative – pooling of expertise.
- No experience yet – but willing to participate.
- Peer review programme.

Issues:

- Circulation of draft re-evaluation reports – industry co-operation required.
- The need for proper planning between countries and international organisations.
- Sometimes re-evaluation reports were not complete – references missing.

2. What is the vision of work sharing?

- Need to see a return (reward) for time and effort already invested in work sharing, such as elimination of duplication of work, build-up of trust between expert evaluators, increased efficiency.
- Fully co-ordinated and strategically planned peer review programme (*e.g*. JMPR evaluation to follow national or regional re-evaluation of the substance).
- Global, harmonised data requirements and guidelines.
- Parallel reviews by 2 countries, globally peer reviewed resulting in a single revised assessment report.
- National risk assessments conducted using globally harmonised models.
- Re-evaluations, re-evaluation plans and policies to be exchanged and co-ordinated.
- Re-evaluations to identify hazard and endpoints.
- A single dossier – formation of task forces.
- Internationally co-ordinated peer review strategy.
- Criteria and assessment based on science.
- Sharing of evaluations/risk assessments with smaller or under-resourced countries.
- Involve growers (particularly of minor crops) to actively participate.
- Application of the substitution principle (to replace the more hazardous compounds after comparison with alternatives).
- Develop a database and lines of communication for experts/expertise – to be used for specific consultation on a bilateral basis.
- Set up a harmonised timetable for ongoing re-evaluations.
- Use information gathered outside the registration process (*e.g.* monitoring data).

3. What are the incentives or drivers for work sharing?

- Increased efficiency in the use of (scarce or decreasing) resources.
- Lower costs to all stakeholders.
- Risk reduction arising from earlier registration of newer and better products.
- Current science being applied to old technology, potentially generating a market opportunity for better old/new active substances.
- Common data requirements.
- Satisfying public demand for increased food and environmental safety, increased transparency and increased efficiencies.
- An internationally agreed process will have greater predictability and credibility.

4. What approaches should be used to overcome the hurdles or barriers for work sharing?

- International co-ordinated strategy based on national priority lists.
- Harmonise current re-evaluation schedules as opportunities allow (*e.g* identify pilot projects).
- Exchange experiences, experts, plans, *etc*.
- Set realistic goals.
- Develop an international report on the benefits of work sharing so as to help influence policy makers.
- Provide adequate staffing and competence.
- Examine and understand national legislation and procedures.
- Address data protection issues.
- Internationally harmonise IT software.

5. Whom would you have to convince to make your vision possible? Who is responsible?

- Government policy makers and reviewers.
- General public – growers/users, consumers and NGOs.
- Industry – generic and research-based companies.

6. Identify the most important actions to be taken both in the short and in the long term (five key areas for improvement).

- Establish baselines with respect to reviews.
- Co-ordinate the strategy to identify the opportunities for parallel/joint reviews, include CCPR and JMPR.
- Prioritise further reviews in consultation with industry, and identify new pilot projects.
- Re-assess the procedures of the re-evaluation process and the science used.
- Establish an understanding of the links between the re-evaluation process, the registered uses and the MRLs.
- Develop a global strategy to ensure that, over time, support data and evaluation methods for pesticides continue to meet current scientific standards.

- Harmonise common data requirements, guidelines for studies, reporting and dossier preparation.
- Begin the harmonisation of common assessment formats and models.
- Exchange of key experts – technical and administrative.
- Identify and overcome the barriers in information exchange, *e.g.* language, IT compatibility, legal issues.
- Identify the benefits of harmonisation in an international report.
- Establish a common approach to risk assessment models.
- Generate the methods to obtain appropriate data for the models.
- Establish the work sharing procedure as an accepted practice.

Report of Group 3 – Existing Active Substances

1. What were some of the experiences in sharing work on existing active substances?

- EU member states sharing work through ECCO expert peer review.
- Use of OECD database and of other countries' data reviews to facilitate national reviews.
- Canada/US reviews have shown that the more countries work together, the more they appreciate each other's capabilities and develop trust.
- CODEX.
- Regional co-operation, *e.g*. Nordic countries, Austria/Germany mutual recognition, CEUREG, SAHELIAN initiative (pooling expertise).
- Improved collaboration on science and decisions.
- Need to talk to each other, understand each other's perspective.
- Involvement of grower groups important, especially in identifying essential (minor) uses.
- US public consultation phase.
- Some countries need assistance in developing expertise, and have little experience in work sharing.
- Work sharing initially is time consuming. Need guidance documents and process to reach decisions.
- Quality of database can be poor/old, or database can even be absent.
- Quality of old reviews may not be up to standard.
- Complexity of dealing with multiple data–holders.
- Involvement of public consultation can be positive and negative.
- Evolving policies/mandates affect risk assessment decision making process.

2. What is the vision of work sharing?

- Submission of common dossier of existing/new data (as appropriate), reviewed once and used by others. Later national requirements are added and national risk assessments made.
- Need to see a return (reward) for time and effort already invested in work sharing, such as elimination of duplication of work, build-up of trust between expert evaluators, and increased efficiency, thereby releasing resources for evaluation of new active substances.
- National risk assessments are conducted using globally harmonised models.
- Development of a database and line of communication for experts/expertise - to be used for specific consultation on a bilateral basis.
- Harmonisation of review schedules on a global basis, helps planning for both regulators and industry.
- Technological capabilities are improved for developing countries.
- Information (including dossiers and monographs) is readily exchanged electronically.
- JMPR to use same format as OECD; better and more timely co-ordination of JMPR reviews with national reviews.
- Improved resources for JMPR and timely decisions of CCPR to aid world trade.
- Transparency is needed in the process for ensuring increased public confidence in the regulatory system, the safety of the food supply and protection of the environment.
- Agreed upon residue zones and developed global residue databases by active substance.
- Maintain adequate pesticides for minor crops.

3. What are the incentives or drivers for work sharing?

- Increased efficiency in the use of (scarce or decreasing) resources.
- Lower costs for all stakeholders.
- Desire for reduced trade barriers.
- Harmonisation of data requirements and of process. An internationally agreed process will have greater credibility and transparency.
- Capacity-building through interaction with other agencies, staff exchanges. Technology transfer to developing countries.
- Criteria and assessment based on sound science.
- Satisfying public demand for increased food and environmental safety.
  Heightened public perception of the risks posed by pesticides.
  Need for national regulators to justify regulatory decisions *vis-à-vis* decisions in other jurisdictions.
- Need for more streamlined harmonisation of MRLs - JMPR evaluations through use of standard approach.
- Risk reduction arising from mitigation measures.
- Commitment to meet grower needs, especially for minor uses.
- Acknowledge economic dependency of some countries on export of agricultural commodities.

4. What approaches should be used to overcome the hurdles or barriers for work sharing?

Process

- Use OECD guidance documents for formatting dossiers and monographs (at industry, OECD/non-OECD country and JMPR levels).
  - Get more guidance on the guidance documents (!)
- Set realistic goals/plans/steps.
- Co-ordinate global re-evaluation schedules.
- Encourage industry to develop global approach to review submissions.
- Remove legal impediments to work sharing.

Communication

- Get support from all (management) levels, inter and intra-organisational.
- Improve staff interaction, exchanges, face-to-face meetings/workshops (to increase mutual trust and confidence)
  - between scientists
  - between regulatory staff
  - between regulatory and industry staff (including growers).

Communication on/marketing of work sharing

- Share vision and spread the message that work sharing will not complicate the work (in the long term) and will lead to greater efficiencies.
- Explain benefits of harmonised risk assessments for consumers.

- Develop an international report on the benefits of work sharing so as to influence decision-makers.
- Show that work sharing activities reduce amount of work (demonstrate advantages).

Technical communication

- Use internationally compatible IT software for *electronic* submissions and reviews (make use of e-mails and Internet).
- Report back on use/usefulness of electronic means (OECD workshop in 18 months?).
- Technical harmonisation.
- Common data requirements.
- Testing methods.
- Use OECD formats for submissions.
- For newly generated studies, create study report formats / level of detail of assessment.
- Develop clear executive summaries for "old style" study reports.

5. Whom would you have to convince to make your vision possible? Who is responsible?

- Industry - especially marketing managers.
- Government policy makers and reviewers.
- Inform stakeholders, growers and trade organisations.
- Reassure consumers that safety is not compromised by work sharing.
- Those who make laws; address issues of legal barriers, data confidentiality.
- User groups - not commonly part of the process.
- CCPR - re JMPR use of national reports (reports must be to OECD standard and reflecting the same data package submitted to JMPR).

6. Identify the most important actions to be taken both in the short and in the long term (five key areas for improvement).

- Electronic issues (long, mid and short term).
- Involve all countries in their review programmes.
- OECD working group on pesticides to take the lead.
- Identify incentives for participation by all stakeholders.
- Define clear goals, process to proceed, with transparency for all.
- Continue to refine the process, learning from experience.
- Measure progress in quality, costs and resource saving and communicate.
- Document all stages.
- Agree upon endpoints, protocols, submissions, residue zones, environmental scenarios.
- Start simply, hazard assessment - move toward exposure and risk assessment; where possible, build confidence.
- Develop schedules and work plans and get on with it.
- Identify problems from previous experience.
- Demonstrate benefits, get buy in from all stakeholders.
- Draft a work sharing process description.

- Develop a global plan (list?) to identify where work sharing opportunities exist.
- Have predictable time scale - don't change during process (without loss of flexibility).
- Communication throughout the review.

Short term

- Establish a forum through OECD WGP to assess technical problems.
- Share information on on-going reviews.
- Identify additional resources needed.
- Agree common data requirements.
- Continue harmonisation of common data requirements, guidelines for studies, reporting and dossier preparation.
- Develop / continue guidance for reporting studies, drafting dossiers and monographs.
- Continue zoning project for residue trials - share outcome widely.
- Build trust between scientific reviewers through greater interactions.
- Exchange key experts, technical and administrative.
- Identify and overcome barriers in information exchange, *e.g.* language, IT compatibility.
- International report - identifying the benefits of harmonisation.

Long term?

- Submission of one common dossier for active substances.
- International database of approved uses including the approved MRLs (our MRLs).
- Establish a common approach to risk assessment models.
- Establish and take advantage of opportunities for joint evaluation procedures.

Report of Group 4 – Existing Active Substances

Aims of global work sharing:

- To improve public and occupational health and safety.
- To reduce risks to the environment.
- To reduce assessment workloads.
- To increase public confidence in regulatory decision-making.
- To reduce trade barriers.

Complications/differences:

- More than one notifier and wider use patterns.
- Data ownership and protection matters – who pays for the 'investment' in the dossier?
- Less incentive for industry, especially if they think their active substance may be withdrawn; grower groups may have a greater interest in maintaining a level playing field.
- Regional reviews prepared simultaneously with mandated national reviews.
- Level of detail in NAFTA reports of concern?
- Country-specific legal issues related to release of draft reviews.
- At the end of the day, we are mainly concerned with our national needs and/or schedules – often pay only scant attention to other country/organisation review schedules.
- Data sets on old chemicals can be of poor quality, or very limited.
- Re-review driven by governments, new active substances driven by industry.
- Competition for resources between re-registration review areas and other areas (new actives with statutory timeframes, special reviews of 'hot' issues).
- Potential for non-tariff trade barriers if review programmes lead to different 'knock-outs' in different countries.
- Difficult to change national/regional programmes at this stage – in the longer term do better forward planning for review cycles.
- Need for harmonisation of policies relating to withdrawal of chemicals, especially issue of tolerances – trade problems!
- Some jurisdictions (*e.g*. California) are mandated to do *de novo* reviews.
- Agencies need to do much better on re-registration; new agricultural chemicals are driven by industry/commercial considerations.

1. What were some of the experiences in sharing work on existing active substances?

- There are different ways to co-operate – regional co-operation may be initially more successful, *e.g*. Nordic co-operation. National timing of reviews to date has not been very good, with duplicate reviews of the same OPs at a global level.
- Within EU, rapporteur state could use assessment report from another country in its drafting.
- Need to involve industry in commenting on drafts at the time of inter-country exchange.
- Co-ordination of risk mitigation activities has been very useful (NAFTA experience) – co-operation in risk management has been important.

- Work sharing works at EU level.
- Work sharing on risk assessment for a particular use pattern.
- JMPR sometimes has a different database compared to what is supplied for national reviews.
- Difficult to do a national risk assessment – even more difficult globally at Codex level.
- Opportunistically use anything in reviews of other countries that is relevant to your country.
- Some non-EU countries moving towards compatibility with EU/OECD guidance.
- EU – harmonisation of legal basis, data requirements.
- Need to talk to each other, understand each other's perspective.
- Concern that work sharing will cause too much work, need to show others the benefits.
- Concern with non-compatibility of electronic data submission systems.
- Standardised monograph format has been a big advance in EU.
- Regulatory experts have learned from each other.
- Involvement of grower groups is important.
- Some countries need assistance in developing assessment expertise, and have little experience in work sharing.
- Other countries have at least 7 years experience in work sharing; building trust may take 3-5 years; face-to-face contact important. Time to decision only marginally faster, but reduction in trade irritants.
- Up-front costs with work sharing; knowing whom to contact in other agency important.
- Work sharing success can depend on quality of reviews obtained.
- 'Opportunistic' use of reviews by others *vs* full joint reviews – benefits in both.

2. What is the vision of work sharing?

- Joint reviews (especially within regions) for greatest efficiency.
- Parallel reviews will lead to development of trust.
- Pick up on any opportunities for work sharing between regions, countries.
- Prevention of loss of essential uses.
- JMPR to make use of OECD formatted dossiers and to prepare their reports/monographs in line with OECD format.
- Countries to make national reviews in OECD format available to JMPR, co-ordinating this with the industry submission of the supporting data.
- Better standardisation of joint review formats.
- Easy access to each other's databases at an international level.
- Countries need to share review schedules, draft hazard/risk assessments, *etc.*
- Transparency needed in process.
- OECD should have a co-ordinating group, assisting countries seeking work sharing opportunities. It could also provide a co-ordination point for sponsor applications (to help with legal issues?).
- Rapporteur/ECCO system in EU needs to be faster.
- Common format; each chemical reviewed once; common, streamlined, modular processes (including database requirements, test guidelines, *etc*.), with more interaction between regulators and industry.
- Mutual recognition of core data evaluation (hazard assessment).
- Extend advances to other chemical types.

- Public, OHS and environmental safety is paramount!
- More regional co-operation, as is occurring with EU, NAFTA, Sahel.

3. What are the incentives or drivers for work sharing?

- Review workload should be a major driver. Review programmes in place may facilitate work sharing.
- Working together for common review outcomes, to prevent barriers to trade; reducing need for industry resources and regulatory resources.
- Co-ordinated approach may encourage industry to continue to support older but useful compounds.
- Reduction of workload (industry and regulatory agencies), and a more equitable distribution of workload.
- Heightened public perception of the risks posed by pesticides – need for national regulators to justify regulatory decisions *vis-à-vis* decisions in other jurisdictions.
- More opportunities for staff; more interaction with other agencies, staff exchanges. Increase in available time may give people opportunity to be involved in other areas within their agencies *e.g.* research, registration, and thus motivate staff.
- Need for more streamlined process for harmonisation of MRLs, including increased standardisation of approaches.

4. What approaches should be used to overcome the hurdles or barriers for work sharing?

- Growers need a useful armory of pesticides, therefore it is important to involve grower groups.
- Establish a concise global database with a list of a limited number of critical endpoints [*e.g.* ADI (RfD), ARfD, residence time in soil, residue definition for environment and human health].
- Staff interaction, exchanges.
- Preparation of further detailed OECD guidance notes for evaluators.
- Get more experience in using OECD guidance documents, and review them if necessary.
- Where appropriate, encourage JMPR to use OECD formats/guidance.
- Need for increased buy-in from all levels, all areas.
- Commence/continue with 'work sharing' at all levels, from simple information exchange, face-to-face visits, *etc.* – 'hasten slowly'!
- Work sharing in groups according to the pesticide, *e.g.* a rice insecticide.
- 'Convince my bosses!' Spread the message that work sharing will not complicate the work and will lead to greater efficiencies.
- Continued preparation of guidance documents for OECD Member countries on different technical issues; continue harmonisation of data requirements, TGs, formats, *etc*.
- Education of company dossier writers.
- Work sharing activities must show quickly that they reduce the workload.

5. Whom would you have to convince to make your vision possible? Who is responsible?

- Legal barriers, *e.g.* California legal requirement to legal review.
- Legal barriers – data confidentiality issues; industry and/or country laws.
- Smaller countries – addressing their concern that their views will not hold ground among larger players.
- User groups - not commonly a part of the process.
- CCPR member countries need to be informed of OECD harmonisation/work sharing activities and encouraged to support JMPR use of OECD-formatted dossiers and national reviews.
- Senior and middle management need to be convinced, along with technical staff. (Caution not to hasten too quickly.)
- National laws may need to be amended.
- Industry needs to use the dossier guidance (where appropriate).

6. Identify the most important actions to be taken both in the short and in the long term (five key areas for improvement).

- Move forward on harmonisation of data requirements, test guidelines, level of reporting (using the OECD dossier and monograph guidance where possible).
- Implement what we've agreed on within 5 years – follow-up in the intervening time, *i.e.* 'Get on with it'! For whatever is done, set milestones and targets, and meet them (and develop indicators to measure whether we have succeeded).
- At the national/regional/international level, make a serious effort to see what reviews are available and, where useful and possible, make use of relevant parts. (Accept that there will be differences, but use [and re-jig format] what is relevant.)
- Compare the outcomes arising from separate national/regional reviews and identify the degree of commonality in conclusions and outcomes, both in the assessment and in the risk mitigation strategies (an OECD project?).
- Identify some existing active substances for work sharing; use stepwise approach on re-registration reviews for some successful 'wins' – 'hasten slowly'. Start simply (*e.g.* hazard assessment), ultimately moving towards exposure and risk assessment where possible.
- Demonstration of benefits will lead to buy-in at most levels, including all stakeholders, *e.g.* consumers, pesticide industry, regulators, grower groups.
- Exchange of scientific staff will lead to development of trust.
- Draft a process description/SOPs[1] for joint reviews and develop a 'road map' of similarities and differences in data requirements, study protocols, *etc*.
- Establish a mechanism for co-ordinating assessments and review schedules for existing actives (and encourage countries to examine the possibility of advising such, if they currently can't do so).
- Facilitate technical interaction, even at draft review stage, to strengthen quality of data interpretation.
- Co-ordinated country/regional approach may encourage industry to continue to support older but useful compounds.

[1] Standard Operating Procedure

Report of Group 5 – Existing Active Substances

1. **What were some of the experiences in sharing work on existing active substances?**

   - Loss of active substances and MRLs leads to reduction of uses.
   - Communication is important with respect to uses, current patterns and scope of review.

2. **What is the vision of work sharing?**

   - Globally harmonised MRLs.
   - Increased safety standard for old active substances.
   - International discussion on specific issues of hazard and risk assessment.
   - Work sharing in fields where there is little activity.
   - Linking evaluation activities between biocides and agricultural pesticides
   - 'Level playing field' between existing active substances and new active substances; existing active substances are held to the same standards as new active substances.
   - Discussions should be science based.

3. **What are the incentives or drivers for work sharing?**

   - A plan for re-registration by government authorities which leads to incentives for industry.
   - Harmonisation of MRLs.
   - Lack of co-ordination between countries.
   - Support of growers.
   - Minor uses.
   - Avoiding unnecessary animal testing.
   - Increased capacity for evaluation of existing active substances.
   - Cost–recovery.

4. **What approaches should be used to overcome the hurdles or barriers for work sharing?**

   - Start work sharing on existing active substances.
   - Tracking system for biocides and agricultural pesticides evaluations.
   - Bibliography of studies used for evaluation.
   - Common database and common review formats.
   - Use of reviews by other international organisations for evaluation (*e.g.* POPs, PIC).
   - OECD proceed with common data requirements.
   - Bibliography of global uses.

5. **Whom would you have to convince to make your vision possible? Who is responsible?**

   - Regulatory authorities, senior level as well as working level.
   - Commodity organisations, grower groups (to support essential uses).
   - Industry.

6. Identify the most important actions to be taken both in the short and in the long term (five key areas for improvement).

- Producing a time-table with information on re-registration programmes schedules.
- Pilot re-registration project on existing active substances applied on global level – establishing list of uses of global interest (growers and industry) with aim to set global MRLs.
- Exchange of final evaluation documents and use by economies in transition, with feedback to OECD and to the 'donor' country.

A.3.3 Composition of Breakout Groups

Group 1 Participants

Chair: **Greg HOOPER, Australia, National Registration Authority for Agriculture and Veterinary Chemicals**
Rapporteur: *Richard NIELSSON, Global Crop Protection Federation*
Rapporteur: *Wolf MAIER European Commission, DG SANCO*

Joanne BUTH
Canola Council of Canada

Richard DIRKS
Global Crop Protection Federation (US)

Inge KRAUL
Denmark, Environmental Protection Agency

Sylvie MALEZIEUX
France, Ministry of Agriculture and Fisheries

Alison McREATH
Global Crop Protection Federation (UK)

Heidi MORKA
Norwegian Agricultural Inspection Service

Salah SOLIMAN
Egypt, Alexandria University

Margaret STASIKOWSKI
United States, Environmental Protection Agency

Bernd STEIN
Germany, Federal Office for Environment

Roman VAGNER
Czech Republic, State Phytosanitary Administration

Elina VALCARCE DE ANGULO
Spain, Ministry of Health and Consumer Affairs

Christiane VLEMINCKX
Belgium, Scientific Institute of Public Health

Sanja VRANAC
Slovenia, Ministry of Agriculture, Forestry and Food

Group 2 Participants

Chair: **Anne LINDSAY, US Environmental Protection Agency**
Rapporteur: *Dermot SHERIDAN, Ireland, Department of Agriculture, Food and Rural Development*
Rapporteur: *John REEVE, New Zealand, MAF Regulatory Authority*

François ABIOLA
Comité Sahélien des Pesticides (CSP)

Mark BRIGGS
United Kingdom, Pesticides Safety Directorate

Barbara CLEMENTE TALJAT
Slovenia, Ministry of Health, National Chemicals Bureau

Lene LORENZEN
Denmark, Environmental Protection Agency

Kostas MARKAKIS
Greece, Ministry of Agriculture

Jeroen MEEUSSEN
Netherlands, Board for the Authorization of Pesticides

Thierry MERCIER
France, Ministry of Agriculture

Tim MEREDITH
World Health Organisation

Franz MICHLITS
Austria, Syngenta

Pavel MINAR
Czech Republic, State Phytosanitary Administration

Agneta OHLSSON
Sweden, National Chemicals Inspectorate (KemI)

Terje ROYNEBERG
Norway, National Agricultural Inspection Service

Gabriele TIMME
Global Crop Protection Federation (GER)

Paul WATERHOUSE
Crop Care Australasia Pty Ltd

Group 3 Participants

Chair:	**Mark LYNCH, Ireland, Department of Agriculture, Food and Rural Development**
Rapporteur:	*Jay ELLENBERGER, US Environmental Protection Agency*
Rapporteur:	*Henry DE HEER, Netherlands, Ministry of Agriculture, Nature Management and Fisheries*

Richard Paul DAVIS
United Kingdom, Pesticides Safety Directorate

Bas DRUKKER
European Commission, DG SANCO

Thomas GILDING
Global Crop Protection Federation (US)

Juergen HELBIG
COLEACP

Thomas MOUSSEAU
France, Ministry of Regional Planning and Environment

Zoltan OCSKO
Hungary, Ministry of Agriculture and Regional Development

Karen PITHER
Global Crop Protection Federation) (US)

Lennart ROMERT
Sweden, National Chemicals Inspectorate (KemI)

Jin Sup SHIN
Korea, NIAST, Rural Development Administration

Jose SOBREIRO
Portugal, Ministry of Agriculture, Rural Development and Fisheries

Diana SOMERS
Canada, Pest Management Regulatory Agency

Paul WHYLIE
Observer

Robert WOMASTEK
Austria, Federal Office and Research Center for Agriculture

Group 4 Participants

Chair: **Wendy SEXSMITH, Canada, Pest Management Regulatory Agency**
Rapporteur: *Darren FLYNN, United Kingdom, Pesticides Safety Directorate*
Rapporteur: *Les DAVIES, Australia, Therapeutic Goods Administration*

Ursula BANASIAK
Food and Agricultural Organisation of the United Nations

Hans BLOMQVIST
Finland, Plant Production Inspection Centre

Daniel GUT
Switzerland, Swiss Federal Research Station for Fruit-Growing, Viticulture and Horticulture

Peter CAULKINS
United States, Environmental Protection Agency

Muriel DUNIER-THOMANN
European Commission

Edwin FERNANDES
Portugal, Ministry of Agriculture

Herman FONTIER
Belgium, Ministry of Middle-class and Agriculture

Byung Youl OH
Korea, National Institute of Agricultural Science and Technology (NIAST)

Stepan KUZMA
Czech Republic, State Phytosanitary Administration

Joerg-Rainer LUNDEHN
Germany, Biological Federal Institute for Agriculture and Forestry

Felix MEIER-MANZ
Global Crop Protection Federation (SWI)

Jean-Mari PELTIER
California Citrus Quality Council

Zsuzsa TORONYI
Hungary, Association of Hungarian Chemical Industry

Connie WELCH
United States, Environmental Protection Agency

Group 5 Participants

Chair: **Louis SMEETS, European Commission**
Rapporteur: *Rick HOLT, Global Crop Protection Federation*
Rapporteur: *Elisabeth BOSSHARD, Switzerland, Swiss Federal Office of Agriculture*

Catherine GUICHARD
COLEACP

Pia KORJUS
Finland, National Product Control Agency for Welfare and Health

Susan LEWIS
United States, Environmental Protection Agency

Roy LIDSTONE
Canada, Pest Management Regulatory Agency

Martin MÄRKL
Global Crop Protection Federation (FR)

Bill MURRAY
Food and Agricultural Organisation of the United Nations

Luc PEETERS
COPA/COGECA

L'ubomira RAUCINOVÁ
Slovak Republic, Ministry of Agriculture

Susanna SCHRAGNER
Austria, Federal Ministry of Agriculture, Forestry, Environment and Water Management

Judy SHAW
Global Crop Protection Federation (CAN)

Roland SOLECKI
Germany, Federal Institute for Consumer Health Protection and Veterinary Medicine

Angel Yagüe MARTINEZ DE TEJADA
Spain, Ministry of Agriculture, Fisheries and Food

Annex 4

Participants List

OECD Workshop on Sharing the Work of Agricultural Pesticide Reviews

12-14 February 2001, Brussels

Agricultural Pesticides Representatives

AUSTRALIA

Mr Les DAVIES
Manager, Chemical Review & International Harmonisation Section
Therapeutic Goods Administration
Department of Health and Aged Care
P.O. Box 100
Woden ACT 2606
Australia

Tel: +61-2 6270 4378
Fax: +61-2 6270 4353
E-mail: les.davies@health.gov.au

Mr Greg HOOPER
Deputy Chief Executive
National Registration Authority for Agricultural and Veterinary Chemicals
P.O. Box E240
Kingston, ACT 2604
Australia

Tel: +61-2 6271 6319
Fax: +61-2 6272 3195
E-mail: ghooper@nra.gov.au

AUSTRIA

Mr Matthias LENTSCH
Federal Ministry of Agriculture and Forestry, Environment and Water Management
Stubenring 12
A-1012 Wien
Austria

Tel: +43 1 711 00 2870
Fax: +43 1 711 00 65 07
E-mail: matthias.lentsch@bmlf.gv.at

Mr. Franz MICHLITS
D.I.
Syngenta
Brunnerstrasse 59
Objekt 59
A-1235 Wien
Austria

Tel: +43 1 86 381 9167
Fax: +43 1 86 381 524
E-mail: franz.michlits@syngenta.com

Mr Robert WOMASTEK
Federal Office & Research Center for Agriculture
Institute for Plant Protection Products Evaluation
Spargelfeldstr. 191
A-1226 Wien
Austria

Tel: +43-1 732 16 5134
Fax: +43-1 732 16 5194
E-mail: rwomastek@bfl.at

BELGIUM

M. Herman FONTIER
Ministère des Classes Moyennes et de l'Agriculture
Service Qualité des Matières premières et Analyses
WTC 3, 8ème étage
Boulevard Simon Bolivar 30
B-1000 Bruxelles
Belgium

Tel: +32-2 208 38 52
Fax: +32-2 208 38 66
E-mail: herman.fontier@cmlag.fgov.be

Ms. Christiane VLEMINCKX
Scientific Institute of Public Health
Division Toxicology
16, rue Juliette Wytsman
B-1050 Bruxelles
Belgium

Tel: +32-2 642 53 51
Fax: +32-2 642 52 24
E-mail: c.vleminckx@iph.fgov.be

CANADA

Ms Claire FRANKLIN
Executive Director
Pest Management Regulatory Agency
Sir Charles Tupper Bldg 6607 D2
2250 Riverside Dr.
Ottawa, ON K1A 0K9
Canada

Tel: +1 613 736 3708
Fax: +1 613 736 3707
E-mail: Claire_Franklin@hc-sc.gc.ca

Mr Roy LIDSTONE
Section Head, Submission Screening Section
Pest Management Regulatory Agency
Sir Charles Tupper Bldg./6607D
2250 Riverside Drive
Ottawa, Ontario K1A 0K9
Canada

Tel: +1 613 736 3585
Fax: +1 613 736 3666
E-mail: Roy_Lidstone@hc-sc.gc.ca

Ms Wendy SEXSMITH
Chief Registrar, Executive Director's Office
Pest Management Regulatory Agency
2250 Riverside Drive, Room D707
Ottawa, Ontario K1A 0K9
Canada

Tel: +1 613 736 3705
Fax: +1 613 736 3707
E-mail: Wendy_Sexsmith@hc-sc.gc.ca

Ms Diana SOMERS
Director, Health Evaluation Division
Pest Management Regulatory Agency
2250 Riverside Dr
Ottawa, Ontario K1A Ok9
Canada

Tel: +1 613 736 3510
Fax: +1 613 736 3505
E-mail: diana_somers@hc-sc.gc.ca

CZECH REPUBLIC

Mr. Stepan KUZMA
Dipl.-Ing.
State Phytosanitary Administration
Zemedelska 1a
CZ-613 00 Brno
Czech Republic

Tel: +420 5 4513 7039
Fax: +420 5 4521 1078
E-mail: kuzma@srs.cz

Mr. Pavel MINAR
Dipl.-Ing.
State Phytosanitary Administration
Zemedelska 1a
CZ-613 00 Brno
Czech Republic

Tel: +420 5 4513 7031
Fax: +420 5 4521 1078
E-mail: minar@srs.cz

Mr. Roman VAGNER
State Phytosanitary Administration
Tesnov 17
CZ-11705
Praha 1
Czech Republic

Tel: +420 2 218 12270
Fax: +420 2 218 12804
E-mail: roman.vagner@atlas.cz

DENMARK

Ms. Lene LORENZEN
Toxicologist
Danish Environmental Agency
Strandgade 29
DK-1401 Kobenhavn K
Denmark

Tel: +45 32 66 0570
Fax: +45 3266 0479
E-mail: llo@mst.dk

FINLAND

Mr Hans BLOMQVIST
Head of Division
Plant Production Inspection Centre
Pesticide Division
Vilhonvuorenkatu 11C
V Floor
P.O. Box 42
FIN - 00501 Helsinki
Finland

Tel: +358 9 5765 2770
Fax: +358 9 5765 2780
E-mail: hans.blomqvist@kttk.fi

Ms Pia KORJUS
Senior Officer
National Product Control Agency for Welfare and Health
Chemicals Department
P.O. Box 210
FIN-00531 Helsinki

Tel: +358-9 3967 2772
Fax: +358-9 3967 2797
E-mail: pia.korjus@STTV.fi

FRANCE

Ms Sylvie MALEZIEUX
Ministère de l'agriculture et de la pêche
DGAL/SDQPV
251 rue de Vaugirard
75732 Paris Cedex 15
France

Tel: +33-1 49 55 81 85
Fax: +33-1 49 55 59 49
E-mail:
sylvie.malezieux@agriculture.gouv.fr

Mr. Thierry MERCIER
Ministry of Agriculture/SSM
étoile de choisy
route de St. Cyr
78026 Versailles Cedex
France

Tel: +33 1 30 83 30 50
Fax: +33 1 30 83 31 49
E-mail: mercier@versailles.inra.fr

Mr. Thomas MOUSSEAU
Ecotoxicologue
Ministère de l'amènagement du territoire et de l'environnement (MATE)
Direction de la Prevention des Pollutions et des Risques (DPPR)
Sous-Direction des Produits et des Dechets (SDPD)
Bureau des Substances et Preparations Chimiques (BSPC)
20 avenue de Ségur
F-75302 Paris 07 SP
France

Tel: +33-1 42 19 15 45
Fax: +33 1 42 19 14 68
E-mail:
Thomas.Mousseau@environnement.gouv.

GERMANY

Mr Joerg-Rainer LUNDEHN
Biologische Bundesanstalt fur Land- und Forstwirtschaft
-Koordinierungsgruppe-
Messeweg 11/12
D-38104 Braunschweig
Germany

Tel: +49-531 299 3450
Fax: +49-531 299 3003
E-mail: j.r.lundehn@bba.de

Mr Roland SOLECKI
Bundesinstitut für gesundheitlichen
Verbraucherschutz und Veterinärmedizin (BgVV)
Thielallee 88-91
D-14195 Berlin
Germany

Tel: +49 188 8412 3827
Fax: +49 188 8412 3260
E-mail: r.solecki@bgvv.de

Mr Bernd STEIN
Umweltbundesamt
Fachgebiet IV.1.3
Seecktstr. 6-10
D-13581 Berlin
Germany

Tel: +49-30 8903 3131
Fax: +49-30 8903 3138
E-mail: bernd.stein@uba.de

GREECE

Mr Kostas MARKAKIS
Department of Pesticides
Ministry of Agriculture
3-5 Ippokratous Str.
10164 Athens
Greece

Tel: +30-1 364 2975
Fax: +30-1 361 7103
E-mail: k.markakis@minagr.gr

HUNGARY

Mr Zoltán OCSKO
Chief Councellor
Ministry of Agriculture & Regional Development
Plant Protection Department
Kossuth tér 11
P.O. Box 1
H-1860 Budapest 55 Pf.1
Hungary

Tel: +36-1 301 4248
Fax: +36-1 301 4644
E-mail: zoltan.ocsko@fvm.hu

Mrs. Zsuzsa TORONYI
Secretary
Association of Hungarian Chemical Industry
Erzsébet királyné útja 1/c
1146 Budapest
Hungary

Tel: +36 1 46 09442
Fax: +36 1 363 6680
E-mail: mavesz-nisz@matavnet.hu

IRELAND

Mr Mark LYNCH
Head of Registration
Department of Agriculture, Food and Rural Development
Pesticide Control Service
Abbotstown Laboratory Complex
Abbotstown, Castleknock
Dublin 15

Tel: +353 1 607 26 13
Fax: +353 1 820 42 60
E-mail: mark.lynch@daff.irlgov.ie

Mr Dermot SHERIDAN
Scientific Co-ordinator
Department of Agriculture, Food and Rural Development
Pesticide Control Service (Registration)
Abbotstown Laboratory Complex
Abbotstown , Castleknock
Dublin 15
Ireland

Tel: 353-1 607 2615
Fax: 353-1 820 4260
E-mail: dermot.sheridan@daff.irlgov.ie

KOREA

Mr. Byung Youl OH
Director of Pesticide Safety Division
National Institute of Agricultural Science and Technology (NIAST)
Rural Development Administration
249 Seodun-Dong Kwonseon-Ku Suwon 441-707
Korea

Tel: +82 31 290 0405
Fax: +82 31 290 0521
E-mail: byoh@rda.go.kr

Mr Jin Sup SHIN
Head of Ecotoxicological Lab.
Pesticide Safety Division
NIAST, Rural Development Administration
249 Seodun-dong
Suwon-city kyungki-do 441-707
Korea

Tel: 82 331 290 0518
Fax: 82 331 290 0521
E-mail: shinjs@rda.go.kr

NETHERLANDS

Mr Henry De HEER
International Phytopharmaceutical Coordinator
Ministry of Agriculture, Nature Mgmt. & Fisheries
Department of Agriculture
Bezuidenhoutse weg 73
P.O. Box 20401
NL-2500 EK The Hague
Netherlands

Tel: +31 70 378 5685
Fax: +31 70 378 6156
E-mail: h.de.heer@dl.agro.nl

Mr. Jeroen MEEUSSEN
Board for the Authorization of Pesticides
P.O. Box 217
Wageningen 6700 AE
Netherlands

Tel: +31 317 471 858
Fax: +31 317 471 899
E-mail: j.j.meeussen@ctb.agro.nl

NEW ZEALAND

Mr. John REEVE
National Manager (Toxicology/Pesticides)
MAF Regulatory Authority
Agricultural Compounds and Veterinary Medicines Group
PO Box 2526
Wellington
New Zealand

Tel: +64 4 460 8733
Fax: +64 4 460 8771
E-mail: reevej@maf.govt.nz

NORWAY

Ms Heidi MORKA
Supervisor
Norwegian Agricultural Inspection Service
P.O. Box 3
N-1431 As
Norway

Tel: +47-64 94 44 00
Fax: +47-64 94 44 10
E-mail:
heidi.morka@landbrukstilsynet.dep.no

Mr Terje ROYNEBERG
Assistant Director
National Agricultural Insp. Service
Landbrukstilsynet
P.O. Box 3
N-1431 Aas
Norway

Tel: +47-64 94 44 00
Fax: +47 64 94 44 10
E-mail:
terje.royneberg@landbrukstilsynet.dep.no

PORTUGAL

Mr José BRAZ SOBREIRO
Ministère de l'Agriculture, de Desenvolvimento Rural e das Pescas
Direcçao-Geral de Protecçao das Cultura
Quinta do Marquês
P-2780 Oeiras
Portugal
Tel: +351 21 446 40 70
Fax: +351 21 442 06 16
E-mail: dgpc.pest@mail.telepac.pt

Mr. Edwin FERNANDES
Ministry of Agriculture
Direccao-Geral de Proteccao das Culturas
Quinta do Marques
2780155 Oeiras
Portugal
Tel: +351 2144 64070
Fax: +351 2144 20616
E-mail: dgpc.dh@mail.telepac.pt

SLOVAK REPUBLIC

Ms. L'ubomira RAUCINOVÁ
Central Control and Testing Institute of Agriculture
Ministry of Agriculture of the Slovak Republic
91A Hanulova Street
84429 Bratislava
Slovak Republic
Tel: +421 7 6446 2085
Fax: + 421 7 6446 2084
E-mail: uksup@internet.sk

SPAIN

Mr. Angel Yagüe MARTÍNEZ DE TEJADA
Head Unit Residues Pesticides
Ministry of Agriculture, Fisheries and Food
Avda. Ciudad de Barcelona 118-120
28007 Madrid
Spain
Tel: +34 91 347 8273
Fax: +34 91 347 8263
E-mail: mpaniagu@mapya.es

Mme Elina VALCARCE DE ANGULO
Head Unit Pesticides
Ministerio de Sanidad y Consumo
Subdirección Gen. de Sanidad Ambiental
Paseo del Prado 18/20
E-28014 Madrid
Spain
Tel: +34 91 596 2016
Fax: +34 91 360 1341
E-mail: evalcarce@msc.es

SWEDEN

Ms Vibeke BERNSON (Chair of the Workshop)
Director,Pesticides Biotechnical Products
National Chemicals Inspectorate
P.O. Box 1384
S-171 27 Solna
Sweden
Tel: +46 8 783 1139
Fax: +46-8 735 7698
E-mail: vibekeb@kemi.se

Ms. Agneta OHLSSON
Ass. Professor
National Chemicals Inspectorate (KemI)
Box 1384
S-171 27 Solna
Sweden

Tel: +46 8 783 1241
Fax: +46 8 735 7698
E-mail: agnetao@kemi.se

Lennart ROMERT
Ass. Prof.
National Chemicals Inspectorate (KemI)
Box 1384
S-171 27 Solna
Sweden

Tel: +46 8 783 12 66
Fax: +46 8 735 76 98
E-mail: lennartr@kemi.se

SWITZERLAND

Ms Elisabeth BOSSHARD
Swiss Federal Office of Agriculture
Section Crop Protection Products and Fertilizers
Mattenhofstrasse 5
CH-3003 Bern
Switzerland

Tel: +41 31 324 9080
Fax: +41 31 322 7080
E-mail:
Elisabeth.Bosshard@blw.admin.ch

Mr. Daniel GUT
Swiss Federal Research Station for Fruit-Growing,
Viticulture and Horticulture
CH-8820 Waedenswil
Switzerland

Tel: +41 1 783 6320
Fax: +41 1 780 6341
E-mail: daniel.gut@faw.admin.ch

UNITED KINGDOM

Mr. Mark BRIGGS
Pesticides Safety Directorate
Mallard House
Kings Pool
3 Peasholme Green
York Y01 7PX
United Kingdom

Tel:
Fax:
E-mail: mark.briggs@psd.maff.gsi.gov.uk

Mr Richard Paul DAVIS
Pesticides Safety Directorate
Mallard House, Kings Pool
3 Peasholme Green
North Yorkshire
York YO1 7PX
United Kingdom

Tel: +44 1904 455 928
Fax: +44 1904 455 763
E-mail: richard.davis@psd.maff.gsi.gov.uk

Mr Darren FLYNN
Reviews Branch
Mallard House
Pesticides Safety Directorate
Kings Pool
3 Peasholme Green
York Y01 7PX
United Kingdom

Tel: +44-1904 455 898
Fax: +44-1904 455 722
E-mail: d.j.flynn@psd.maff.gov.uk

UNITED STATES (Co-Host Country)

Ms. Marcia MULKEY
Director, Office of Pesticide Programs (7501C)
US EPA
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460
United States

Tel: +1 703 305 7090
Fax: +1 703 308 4776
E-mail: mulkey.marcia@epa.gov

Mr. Peter CAULKINS
Associate Director, Registration Division
US EPA
Office of Pesticide Programs
7505C
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460
United States

Tel: +1 703 305 6550
Fax: +1 703 305 6920
E-mail: caulkins.peter@epa.gov

Mr Jay ELLENBERGER
Acting Director, Field and External Affairs Division
US Environmental Protection Agency
Office of Pesticide Programs
7506C
Ariel Rios Building
1200 Pennsylvania Ave.
Washington D.C. 20460
United States

Tel: +1 703 305 7102
Fax: +1 703 305 6244
E-mail: ellenberger.jay@epa.gov

Ms. Susan LEWIS
Branch Chief, Special Review and Reregistration Division
US EPA
7508C
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Tel: +1 703 308 8009
Fax: +1 703 308 7042
E-mail: lewis.susan@epa.gov

Ms Anne LINDSAY
Acting Deputy Director
Office of Pesticide Programs (7501C)
US Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W
Washington, D.C. 20460
United States

Tel: +1 703 305 5265
Fax: +1 703 3056244
E-mail: lindsay.anne@epa.gov

Ms. Margaret STASIKOWSKI
Health Effects Division
Office of Pesticide Programs
Environmental Protection Agency
Arial Rios Building 7509C
1200 Pennsylvania Ave.
Washington DC 20460
United States

Tel: +1 703 305 7351
Fax: +1 703 305 5147
E-mail: stasikowski.margaret@epa.gov

EUROPEAN COMMISSION (Co-Host Organisation)

Mr. Geoffredo DEL BINO
European Commission
DG health and Consumer Protection
Rue de la Loi 200
B-1049 Bruxelles
Belgium

Tel: +32 2 299 1111
Fax: +32 2 296 5963

Mr Bas DRUKKER
European Commission
Rue de la Loi 200 (L86/1/8)
1049 Bruxelles
Belgium

Tel: +32 2 2965779
Fax: +32 2 296 5963
E-mail: Bas.Drukker@cec.eu.int

Ms. Muriel DUNIER-THOMANN
European Commission
DG ENV, BU-5 2/74
Rue de la Loi 200
B-1049 Bruxelles
Belgium

Tel: +32 2 29 92 809
Fax: +32 2 29 59 696
E-mail:
muriel.dunier-thomann@cec.eu.int

Mr Wolf-Martin MAIER
European Commission
DG health and Consumer Protection
Rue de la Loi 200
B-1049 Bruxelles
Belgium

Tel: +32 2 295 8716
Fax: +32 2 296 5963
E-mail: wolf-martin.maier@cec.eu.int

Mr. Canice NOLAN
Commission of the European Communities
DG SANCO.E.1
rue de la Loi, 200
B-1049 Brussels
Belgium

Tel: +32 2 296 1633
Fax: +32 2 296 5963
E-mail: canice.nolan@cec.eu.int

Mr Louis SMEETS
Commission of the European Communities
DG SANCO.E.1
Rue de la Loi 200
L84 1/12
B-1049 Bruxelles
Belgium

Tel: +32 2 295 9612
Fax: +32 2 296 5963
E-mail: louis-maria.smeets@cec.eu.int

EGYPT

Dr. Salah SOLIMAN
Department of Pesticide Chemistry
Faculty of Agriculture
Alexandria University
El Shatby, Alexandria, 21545
Egypt

Tel: +20 3 592 0067
Fax: +20 3 592 2780
E-mail: samsoliman@link.net

SLOVENIA

Ms. Barbara CLEMENTE TALJAT
Advisor to the Director
Ministry of Health, National Chemicals Bureau
Breg 14
Ljubljana 1000
Slovenia

Tel: +386 1 478 6282
Fax: +386 1 478 6266
E-mail: barbara.clemente-taljat@gov.si

Ms. Sanja VRANAC
Councellor to the Minister
Ministry of Agriculture, Forestry and Food
Dunajska 56-58
Ljubljana 1000
Slovenia

Tel: +386 1 478 90 18
Fax: +386 1 478 9021
E-mail: sanja.vranac@gov.si

SAHELIAN PESTICIDE COMMITTEE

Prof. François ABIOLA
President of Comité Sahélien des Pesticides (CSP)
Ecole Inter-Etats des Sciences et Médicine Vétérinaires
P.O. Box 5077
Dakar
Senegal

Tel: +221 8 65 10 29
Fax: +221 8 25 42 83
E-mail: faabiola@eismv.refer.sn

FOOD AND AGRICULTURAL ORGANIZATION OF THE UNITED NATIONS (FAO)

Ms. Ursula BANASIAK
Federal Biological Research Centre for Agriculture and Forestry
Stahnsdorfer Damm 81
14532 Kleinmachnow
Germany

Tel: +49 33203 48338
Fax: +49 33203 48425
E-mail: u.banasiak@bba.de

Mr Bill MURRAY
Senior Officer, Interim Secretariat
to the Rotterdam Convention
Food and Agriculture Organization of the United Nations (B-751)
c/o Pesticide Management Group
Plant Production and Protection Division (AGPP)
Via della Terme di Caracalla
00100 Rome

Tel: +39 06 570 56289
Fax: +39 06 570 56347
E-mail: William.Murray@fao.org

WORLD HEALTH ORGANIZATION (WHO)

Mr. Tim MEREDITH
Coordinator
World Health Organisation
International Programme on Chemical Safety
20, avenue Appia
CH-1211 Geneva 27
Switzerland

Tel: +41 22 791 3590
Fax: +41 22 791 4848
E-mail: merediththt@who.int

GROWER GROUP REPRESENTATIVES

Ms Joanne BUTH
Vice President Crop Production
Canola Council of Canada
400-167 Lombard Avenue
Winnipeg, Manitoba R3B 0T6
Canada

Tel: +1 204 982 2100
Fax: +1 204 942 1841
E-mail: buthj@canola-council.org

Ms. Catherine GUICHARD
Delegate General
COLEACP
5, rue de la Corderie
Centra 342
94586 Rungis Cedex
France

Tel: +33 1 41 80 02 10
Fax: +33 1 41 80 02 19
E-mail: coleacp@coleacp.org

Mr. Juergen HELBIG
COLEACP
4, rue de la Presse
1000 Bruxelles
Belgique

Tel: +32 2 227 11 31
Fax: +32 2 218 31 41
E-mail: coleacp.pesticides@wanadoo.be
E-mail: juergen.helbig@coleacp.org

Ms. Jean-Mari PELTIER
President
California Citrus Quality Council
210 Magnolia Avenue, Suite 3
Auburn, CA 95603
United States

Tel: +1 530 885 1894
Fax: +1 530 885 1546
E-mail: jpeltier@cwo.com

Mr. Luc PEETERS
Expert
COPA/COGECA
23-25, Rue de la Science
1040 Bruxelles
Belgium

Tel: +32 2 287 2711
Fax: +32 2 287 2700

GLOBAL CROP PROTECTION FEDERATION (GCPF)

Mr. Richard DIRKS
Director Chemical Registration and Regulatory Affairs
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167
United States

Tel: +1 314 694 5037
Fax: +1 314 694 4028
E-mail: richard.c.dirks@monsanto.com

Mr Thomas GILDING
Director, Environmental Affairs
ACPA
1156 Fifteen Street, NW
Suite 400
Washington DC 20005
United States

Tel: +1 202 872 3873
Fax: +1 202 463 0474
E-mail: tom@acpa.org

Mr Richard HOLT
Director, Global Regulatory Affairs and
Regulatory Sciences
DuPont de Nemours
Barley Mill Plaza
P.O. Box 80038
Wilmington, DE 19880-0038
United States

Tel: +1 302 992 6277
Fax: +1 302 992 6470
E-mail: richard.f.holt@usa.dupont.com

Mr. Bruce JULIN
DuPont (Belgium)
A. Spinoystraat 6
2800 Mechelen
Belgium

Tel: +32 15 28 87 42
Fax: +32 15 28 87 46
E-mail: bruce.g.julin-1@usa.dupont.com

Mr. Martin MÄRKL
Global Regulatory Affairs
Aventis CropScience
14-20 rue Pierre Baizet
69263 Lyon Cedex 09
France

Tel: +33 472 85 3144
Fax: +33 472 85 3074
E-mail: martin.maerkl@aventis.com

Ms. Alison McREATH
Global Product Registration
Dow AgroSciences
Letcombe Laboratory
Letcombe Regis
Wantage, Oxon OX12 9JT
United Kingdom

Tel: +44 1235 77 4741
Fax: +44 1235 77 4749
E-mail: amcreath@dow.com

Mr. Felix MEIER-MANZ
Head Regulatory Support
Syngenta, Crop Protection AG
R-1058.7.66
P.O. Box
CH-4002 Basel
Switzerland

Tel: +41 61 323 2721
Fax: +41 61 323 4966
E-mail:
felix.meier-manz@syngenta.com

Mr. Richard NIELSSON
GCPF Technical Executive
BASF Agro-Research
P.O. Box 400
Princeton
New Jersey 08543-0400
United States

Tel: +1 609 716 2354
Fax: +1 609 275 5226
E-mail: nielssr@basf-corp.com

Ms. Karen PITHER
NAFTA Registration Manager
Bayer Corporation, Agriculture Division
8400 Hawthorn Road
P.O. Box 4913
Kansas City, MO 64120-0013
United States

Tel: +1 816 242 2327
Fax: +1 816 242 2738
E-mail: karen.pither.b@bayer.com

Ms. Judy SHAW
Government Affairs Director
Syngenta Crop Protection Canada, Inc
140 Research Park, University of Guelph
Guelph, Ontario N1G 4Z3
Canada

Tel: +1 519 837 5328
Fax: +1-519 836 1032
E-mail: judy.shaw@syngenta.com

Ms Gabriele TIMME
Bayer AG
Entwicklung-Registrierungsstrategie
Landwirtschaft Monheim
D-51368 Leverkusen Bayerwerk
Germany

Tel: +49 2173 38 38 82
Fax: +49 2173 38 3572
E-mail: gabriele.timme.gt@bayer-ag.de

Mr. Paul WATERHOUSE
Regulatory and Stewardship Manager
Crop Care Australasia Pty Ltd
P.O. Box 167
Hamilton Central, Qld 4007
Australia

Tel: +61 7 3867 9125
Fax: +61 7 3867 9137
E-mail:
paul.waterhouse@cropcare.com.au

OBSERVERS

Mr. James RUSCOE
Via Zanardelli 36
00186 Roma
Italy

Tel: +39 06 687 3420
E-mail: jamesruscoe@tin.it

Mr Paul WHYLIE
30B rue des cheminets
01630, Pregnin Saint Genis Pouilly
France

Tel: +33 4 50 42 07 46
E-mail: pwhylie@unep.ch

Biocides/Non-Agricultural Pesticides Representatives

AUSTRIA

Ms Susanna SCHRAGNER
Federal Ministry of Agriculture, Forestry, Environment and Water Management
Stubenbastei 5
A-1010 Vienna
Austria

Tel: +43 1 515 22 2348
Fax: +43 1 513 1679 1481
E-mail: susanna.schragner@bmu.gv.at

DENMARK

Ms. Inge KRAUL
Danish Environmental Protection Agency
Biocides and Chemicals
Assessment Division
Strandgade 29
DK-1401 Kobenhavn K
Denmark

Tel: +45 32 66 05 66
Fax: +45 32 66 03 69
E-mail: ik@mst.dk

UNITED STATES

Ms. Connie WELCH
Branch Chief, Antimicrobials Division
Office of Pesticide Programs 7501C
US EPA
Ariel Rios Building
1200 Pennsylvania Avenue, N. W.
Washington, DC 20460
United States

Tel: +1 703 308 8218
Fax: +1 703 308 8481
E-mail: welch.connie@epa.gov

SECRETARIAT

Ms. Béatrice GRENIER
OECD
Environmental Health & Safety Division
2 Rue André-Pascal
75775 Paris Cedex 16
France

Tel: +33 1 45 24 76 96
Fax: +33 1 45 24 16 75
E-mail: Beatrice.GRENIER@oecd.org

Ms Libby HARRISON
OECD
Environmental Health & Safety Division
2, Rue André Pascal
75775 Paris Cedex 16
France

Tel: +33 1 45 24 16 76
Fax: +33 1 45 24 16 75
E-mail: Libby.HARRISON@oecd.org

Mrs. Myropi PANELI
OECD
Environmental Health & Safety Division
2, Rue André Pascal
75775 Paris Cedex 16
France

Tel: +33 1 45 24 14 85
Fax: +33 1 45 24 16 75
E-mail: Myropi.Paneli@oecd.org