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**ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY**

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**OECD SERIES ON PESTICIDES
Number 20**

Report of the OECD Workshop on Electronic Tools for Data Submission, Evaluation and Exchange for the Regulation of new and Existing Industrial Chemicals, Agricultural Pesticides and Biocides, Ottawa, October 2002

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English - Or. English

**OECD Workshop on Electronic Tools for
data submission, evaluation and exchange
for the Regulation of new and existing
industrial chemicals, agricultural
pesticides and biocides**

2-4 October 2002

Ottawa, Canada

SUMMARY REPORT

Also published in the Series on Pesticides:

No. 1, *Data Requirements for Pesticide Registration in OECD Member Countries: Survey Results* (1993)

No. 2, *Final Report on the OECD Pilot Project to Compare Pesticide Data Reviews* (1995)

No. 3, *Data Requirements for Biological Pesticides* (1996)

No. 4, *Activities to Reduce Pesticide Risks in OECD and Selected FAO Countries. Part I: Summary Report* (1996)

No. 5, *Activities to Reduce Pesticide Risks in OECD and Selected FAO Countries. Part II: Survey Responses* (1996)

No. 6, *OECD Governments' Approaches to the Protection of Proprietary Rights and Confidential Business Information in Pesticide Registration* (1998)

No. 7, *OECD Survey on the Collection and Use of Agricultural Pesticide Sales Data: Survey Results* (1999)

No. 8, *Report of the OECD/FAO Workshop on Integrated Pest Management and Pesticide Risk Reduction* (1999)

No. 9, *Report of the Survey of OECD Member Countries' Approaches to the Regulation of Biocides* (1999)

No. 10, *Guidance Notes for Analysis and Evaluation of Repeat-Dose Toxicity Studies* (2000)

No. 11, *Survey of Best Practices in the Regulation of Pesticides in Twelve OECD Countries* (2001)

No. 12, *Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control* (2001)

No. 13, *Report of the OECD Workshop on Sharing the Work of Agricultural Pesticide Reviews.*

No. 14, *Guidance Notes for Analysis and Evaluation of Chronic Toxicity and Carcinogenicity Studies.*

No. 15, *Persistent, Bioaccumulative and Toxic Pesticides in OECD Member Countries, (2002)*

No. 16, *OECD Guidance for Industry Data Submissions for Pheromones and Other Semiochemicals and their Active Substances (Dossier Guidance for Pheromones and Other Semiochemicals) (2003)*

No. 17, *OECD Guidance for Country Data Review Reports for Pheromones and Other Semiochemicals and their Active Substances (Monograph Guidance for Pheromones and other Semiochemicals)*, (2003)

No. 18, *Guidance for Registration Requirements for Microbial Pesticides* (2003)

No 19; *Registration and Work sharing, Report of the OECD/FAO Zoning Project* (2003)

Published separately:

OECD Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances - Monograph Guidance (1998, revised 2001)

OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances - Dossier Guidance (1998, revised 2001)

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

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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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TABLE OF CONTENTS

Section	Page
Introduction	9
Background	9
Background Documents	9
Workshop Objectives and Scope.....	10
Workshop Documents	10
Workshop Participants	10
Workshop Structure.....	10
Workshop Discussions	12
Breakout Group Reports	12
Breakout Group 1 Report	12
Breakout Group 2 Report	14
Breakout Group 3 Report	17
Workshop Conclusions & Recommendations.....	20
Appendix 1 - Workshop Organising Group Members	22
Appendix 2 - List of Background Documents.....	23
Appendix 3 - Workshop Participants	24
- Breakout Group Members	36
Appendix 4 - Workshop Agenda	37
Appendix 5 - Presenters &Titles of Presentation/Demonstration Sessions on day 2.....	43

INTRODUCTION

Background

1. This draft report presents the conclusions and recommendations made by the OECD Workshop on Electronic Tools for data submission, evaluation and exchange for the regulation of new and existing industrial chemicals, agricultural pesticides and biocides. The workshop was held in Ottawa, Canada on 2-4 October 2002. It was funded by the Canadian Pest Management Regulatory Agency (PMRA) and hosted jointly by the US EPA and the Canadian PMRA. It was chaired by Wendy Sexsmith of PMRA.

2. Whilst OECD Member countries and other stakeholders have worked through the separate OECD programmes on the development and use of electronic tools for data submission and regulatory purposes, communication among the four areas has been limited. Given the similarity of functions performed in the programmes related to data submission and evaluation, monograph production and archiving of dossier documents, it was thought timely to consider opportunities for harmonisation of the electronic tools used. It was anticipated that the workshop would provide an opportunity for government regulatory authorities and industry to share their experiences and discuss how these electronic tools have supported harmonisation, work sharing and archiving. This would be the first workshop bringing together people involved in these different regulatory processes. The workshop was not intended to be a forum for promotion of the electronic tools themselves, but rather an opportunity to share practical “hands on” experiences of the use of the various electronic tools currently available.

3. The workshop was set up by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. An Organising Group was established consisting of 22 members from the following countries, organisations and industry groups: Canada, Germany, Japan, the UK, the USA, the EC, BIAC, Croplife International, CEFIC, and the OECD Secretariat. A list of the members of the Organising Group is attached at Appendix 1. The Organising Group developed the outline and scope for the workshop and prepared a number of background documents that were made available on the internet prior to the workshop taking place.

Background Documents

4. The background documents included brief descriptions of the four regulatory areas covered under the three OECD Programmes (New Chemicals, Existing Chemicals and Pesticides (which includes Biocides)), specifying where in each regulatory process electronic tools were used. They described at a high level the electronic tools currently in use or under development in the four regulatory areas and also described the features that each electronic tool offers to facilitate the regulatory process including:

- data assembling and submission (“dossiers”);
- data review and evaluation;
- production of review reports (“monographs”);
- archiving.

A list of the background documents can be found in Appendix 2.

Workshop Objectives and Scope

5. The workshop objectives were to:

- Exchange information and share experiences on the use of electronic tools in use or under development in the three OECD Programmes for data assembly and submission, data review and evaluation, production of review reports and archiving;
- Discuss current approaches and ongoing developments of electronic tools with a view to enabling the possibility to transfer electronic data from one regulatory area to another;
- Identify possible OECD activities that can provide added value including recommendations for further work.

6. In meeting these objectives, the workshop participants should identify opportunities to: improve efficiency; encourage sharing of work; harmonise, where possible, the various aspects of the use of electronic tools for regulatory purposes, and to increase awareness of the potential benefits of such electronic tools.

Workshop Documents

7. All relevant documents for this workshop, including the workshop agenda, the workshop outline and the background documents were made available to the participants on a password protected site. All of the presentations made at the workshop are available on the Chemical Safety page of the OECD Environment Directorate website at <http://www.oecd.org/env>.

Workshop Participants

8. 68 participants attended the workshop, a list of the participants is attached as Appendix 3 (this Appendix also shows the composition of the three breakout groups). Participants were drawn mainly from two groups - government regulators and industry - each with a range of knowledge across the four regulatory areas. Representatives were from Australia, Austria, Canada, Finland, Germany, Japan, Korea, New Zealand, Poland, Sweden, the United Kingdom, the United States, the European Commission, Business and Industry Advisory Committee (BIAC), CEFIC, CropLife International and the OECD secretariat. A small number of participants were responsible for the design/maintenance of electronic tools, however most participants considered themselves "non-IT experts".

Workshop Structure

9. Discussions at the workshop were organised around a series of plenary sessions, a demonstration/presentation session and breakout group sessions. A copy of the workshop agenda is attached at Appendix 4.

10. At the start of the workshop, after a welcome address by **Clare Franklin** (PMRA) and introductory remarks by **Geoff Wilson** (OECD Secretariat), the chair (**Wendy Sexsmith**) gave a presentation which:

- Reviewed the workshop's objectives;
- Provided a brief review of the regulatory process in each of the four regulatory areas;

- Summarised the purpose and expectations of the workshop and set the stage for participants to consider the potential opportunities and benefits that could result from the discussions.

11. After the presentation from the chair, there was a series of plenary sessions with presentations by government and industry representatives on the use of electronic tools in the regulatory areas covered by the workshop.

12. On the second day of the workshop, participants were divided into three breakout groups (designated 1, 2 and 3). This division was done to achieve a broad mix of experience and geographic locations represented by the participants within each group. A list of the members of the three breakout groups is given in Appendix 3. Each breakout group attended a series of demonstration/presentation sessions (designated A, B and C), each of which was dedicated to a particular electronic tool or tools. A list of the presenters and the titles of their presentations/demonstrations is attached as Appendix 5. These presentations provided participants with more detailed information of each electronic tool, which helped the breakout groups to better understand a number of details, namely:

- The process for using electronic tools during the regulatory submission, review, reporting and archiving processes;
- How the electronic tools worked;
- The approach taken and challenges overcome during development;
- How electronic tools might develop for future support to the three programme areas.

13. On the final day the three breakout groups discussed, for each electronic tool: the strengths and weaknesses; the results, benefits and challenges; opportunities for harmonisation or convergence of the electronic tools and recommendations and future work for OECD. Following the discussions, each breakout group presented their conclusions and recommendations to a plenary session. The workshop ended with a plenary session at which the chair gave the overall conclusions and recommendations including those for future work.

WORKSHOP DISCUSSIONS

14. This section begins with summaries of the discussions of each of the breakout groups - written by representatives of the breakout groups themselves. The section ends with a summary of the workshop conclusion and recommendations.

Breakout Group Reports

15. Breakout Group 1 Report

Workshop Value

There was general agreement that the workshop had great value. It has increased understanding of available and planned electronic tools, including their diversity and similarities. ***Workshop participants also learned how the differences in regulatory systems led to differences in electronic tools.*** The wide range in size of companies affected by electronic submission also influenced the electronic tools. Participants enjoyed the opportunity to leverage experiences by learning from each other and networking with others from different OECD program areas and different countries.

Electronic Tool Efficiencies

Breakout group 1 agreed that electronic tools offer the potential for great efficiencies. Authorities' reviews and decisions should be faster and initial experience substantiates this projection. ***There is a need for both registrants and authorities to transform document management and other internal processes to fully achieve potential gains.*** For companies, this must begin at the laboratory where studies originate. ***Electronic review tools hold the potential to greatly expand work sharing*** among authorities, where confidentiality is not an impediment. For example, the new version of CADDY will allow electronic sharing of reviewers' study annotations among European national authorities. ***Authorities need to consider the capacity of and benefits to both large and small companies in the regulated community.*** New chemical notifications, for example, are made by both small and large companies. Many companies may make only one or several submissions per year. While new and existing pesticide submissions at the active level involve principally large registrants, new uses and "me-too" pesticide products involve smaller businesses. The capabilities of the whole regulated community must be considered to achieve maximum gains and greater use of electronic submissions.

Opportunities

Breakout group 1 identified the importance of common submission/review structures as opposed to common formats. The structure relates to the organisation of the submission, while format specifies the software. Software capabilities to migrate data are expanding rapidly, and storage costs are cheap. Some redundancy in use of software may have positive benefits in meeting short term needs and long term assurance of continued

accessibility to legacy formats. For example, use of TIFF images, Adobe Acrobat PDF, Extensible Mark-up Language (XML) tags, and embedded file attachments in a variety of formats in the same submission is feasible and many combinations are beginning to occur. However, companies' major costs are in changing submission structures to meet national requirements. ***If the structural backbone is common, then the software format can present the data in the way preferred by a national authority without great difficulty. Software is making it easier to link across structures and formats.*** For example, it appears feasible to hyperlink pesticide CADDY submissions and existing chemical/biocide IUCLID submissions, possibly gaining efficiencies in European reviews. There was also interest in pesticide program access to IUCLID information for existing industrial chemicals to aid in the review of pesticide inert ingredients. The imminent move toward a common new and existing chemical regulatory structure in Europe has created an uncertain environment for OECD member countries planning tools. XML is reportedly the preferred method for data interchange between companies and authorities for REACH-IT, the next generation EC chemicals data base. As the EC considers development of tags and enumeration values to permit use of the XML data interchange tool to migrate new chemical data, ***there should be ongoing dialogue with OECD member countries so that all can benefit from the XML standard*** that is developed and build it into other tools to the extent practicable, particularly the OECD Standard Notification Form initiative.

The U.S. High Production Volume (HPV) Challenge program is resulting in a large increase in existing chemical data, but much of it is in PDF or hard copy. Ways of ***migrating non-confidential U.S. HPV information to IUCLID*** should be explored to achieve wider accessibility to this information. ***Standardised use of robust study summaries*** across new and existing chemicals programs in OECD Member countries is recommended to ensure uniform quality of these summaries. The pesticide program would benefit from ***consistent use of harmonised study templates and study screens*** at the laboratory level. These have been developed in North America to advance OECD harmonisation efforts. PMRA and U.S. OPP anticipate great efficiency gains from receiving study submissions in template formats that mirror the structure of North American data reviews for individual studies. Use of XML tags downstream would facilitate migration of data to other OECD program areas.

OECD can help facilitate an ongoing dialogue among authorities and the regulated community within each OECD program area and across program areas. ***Room documents*** at the OECD Working Group on Pesticides and Joint Meetings should be used to report on progress in developing specific electronic tools. OECD should consider developing a ***Web clearinghouse*** to encourage ongoing communication among the diverse communities represented at this workshop. However, the breakout group did not see a need for creation of an OECD IT group at this time. One or more groups may form as needs are identified in the future, and could meet virtually through the Internet.

OECD member countries also need to consider ***public accessibility issues***. Countries are moving toward greater transparency in posting national risk assessments and risk management decisions on the Internet. Greater use of electronic tools will facilitate this trend. The public should have access to as much information as possible without subscription fees within the constraints of national statutory requirements.

16. Breakout Group 2 Report

The group started by making some general observations then considered what could be done with them before firming up on recommendations to the OECD, regulatory authorities and industry.

Observations

These observations are not in order of priority and are summarised in point form.

- With respect to the Ag/Pest/Biocides area, the CADDY system looks useful but PDF may be better.
- All program areas seem to be going in the same direction and may be looking at similar solutions to manage their business needs.
- It is evident that the use of the web/internet is important.
- It is important to provide a secure environment as needed.
- There seems to be some opportunities regarding the use of 'data pumps', where common data can be collected and distributed/shared based on business requirements.
- There needs to be more clarification about the evaluators' requirements for areas such as hyperlinks, their cost/benefit, and whether these can be done by the study directors during the early stages of dossier assembly. It was noted the EPA guidance is specific to the hyperlink requirement.

Other points noted were:

- There is a need to consider smaller companies when designing electronic tools and systems;
- There is interest in the OECD existing chemicals repository;
- The PMRA templates were of interest for assisting in harmonisation across programs;
- There is a need to be flexible when developing systems to allow broad use;
- The systems that were demonstrated were more similar than dissimilar with many common themes;
- There seemed to be a common theme among programs with respect to the need for tagging data/information to allow extraction and sharing;
- There is a need to consider the ability of accepting electronic signatures - some countries accept and some are unable to do so;
- It was noted that some use an assessment template for incoming information;
- IUCLID seems to have acceptance by workshop participants. It may be possible to expand to existing chemicals;
- The use of third party solutions could be problematic where some vendors may not exist some years from now and solutions may be unavailable due to incompatibility issues;
- There is a need for good IT infrastructure when implementing electronic tools;
- There is a benefit if programs could extract information from one system and put into another;
- IUCLID is potentially a common database for new chemicals, existing chemicals, pesticides and biocides;

- When working with electronic tools, there is a need to ensure the reliability of data;
- There is a need for systems to capture expert information;
- There is interest for using XML to map information from one system to another to allow seamless integration of information;
- There is a need for guidelines for risk assessment;
- There is a need for a more global vision - is this an OECD role?
- The human factor must be considered during design and implementation of electronic tools;
- It is difficult to consider global harmonisation when faced with competing priorities and the requirement to manage day to day work;
- The cost/benefit must be considered with a caution to not 'overbuild' systems;
- Clear user needs and requirements must be identified before developing electronic systems;
- The pesticides experience is a valuable model for use by new chemicals;
- It was noted the pesticide and new chemicals groups have different requirements and these must be considered.

What can we do?

This discussion focussed on what industry and governments could do to assist with finding common solutions towards work sharing and harmonisation. These formed the basis for the recommendations. The points are not expressed in any order of priority.

- Continue to communicate with each other and amongst our program groups;
- Consider whether OECD has a role to help define a global vision;
- Continue to exchange and share expertise and experiences across programs;
- Hold another workshop in 2 years;
- Create a mechanism, such as a web site, to share information and experience across programs before the next workshop;
- Share information early to help support designs that do not create barriers to work sharing and harmonisation;
- Suggest that OECD facilitate training in the use of electronic tools;
- Harmonise the structure of study templates across programs where ever possible;
- Harmonise other types of templates where possible;
- Consider resource issues before developing and implementing solutions to ensure these are adequate;
- Be prepared to accept that during transition from one system to another, or from paper to electronic systems, there is a double workload / effort. Resource this adequately;
- Ensure there is a process for the management of legacy data;
- Use electronic tools to support decision making
- Harmonise the tags for XML to ensure their use in the various programs - pesticides, new chemicals, existing chemicals
- Establish closer collaboration between governments and industry to ensure the needs of both are met;
- Continue with ongoing activities within programs but ensure there is a mechanism to share information and to report back.

Presentation to Plenary

This was presented as recommendations to the OECD and to regulatory authorities and industry. A recommendation to both groups was that programmes should contain harmonised tags for XML as much as possible.

(1) Recommendations to OECD

Facilitate the definition of a global vision.

Hold another workshop in 2 years.

Create and support a web site to share experiences early and prior to the workshop.

Support and facilitate harmonisation of study templates across programs.

(2) Recommendations to regulatory authorities and industry

Continue with close collaboration to define needs such as paper / hyper linking requirements.

17. Breakout Group 3 Report

The group started by making some general points, exchanged some ideas and then agreed recommendations to the OECD, regulatory authorities and industry.

- Data are not exchanged electronically for Canadian new substances, their development of electronic tools is still in the beginning and no particular direction has been chosen. This WS has inspired a number of ideas for future development of the Canadian system. There is a potential for harmonisation of notification forms.

- Canada experiences a communication problem between departments, possibly electronic exchange can (partly) overcome this problem. This problem was recognised to be general.

- Canadian new substances: Data is not exchanged electronically (work flow is paper). PDF, XML, IUCLID would be studied further. In general, for all programmes, electronic tools were seen to be a way to ensure maximum data exchange and a way to make the information accessible to all evaluators.

- For the process, standardised tools incl. assessment report is very important. This issue is a general one and the better the standardisation the easier the data exchange.

- CBI is a major obstacle both for the process and electronic submission for new chemicals.

In general, it takes time to build confidence in each other's work and understand the best fundamentals for work sharing.

Human factors will slow down changes and adoption of new tools unless a proper change management process is put in place. For example in Sweden currently only one person uses CADDY; after the demonstration on day two the great functionality of the new CADDY version was realised. This illustrates also a need for good marketing - for all electronic tools.

A possibility to link IUCLID (database) and CADDY (Document management) should be explored.

Database / Document Management are two distinct functionality's and the technology solutions are different. Difference between IT tools - and regulatory info. Content / technology - information exchange. Separate IT and process issues. IT people cannot solve process problems. Good Project management requires attention both to the process and the technology and these elements must be in balance.

The user interface is critical to the success of the tool. Front-end and Back-end tool can be very different levels in terms of complexity.

Cost effectiveness

Efficiencies have to come with the investment of an electronic tool . Archiving. Cost to companies has to give a return on investment. Rebates (e.g. lower price if you do use e-submission). Real needs have to be balanced against wish list. The needs should be shared.

What the OECD can do to assist harmonisation

In addition to the presentation in the plenary:

Same formats via test methods. Robust summaries and standard templates. Harmonise structure. One master document for the input, data repository, XML,

OECD can compile a wish list with common wishes. Steering groups for the different programmes under the OECD need to meet.

OECD has a role to keep everybody informed about developments.

What Governments and Industry can do to assist harmonisation

Incentives for e-submission. Find common benefits. How do you get regulators to use the e-tools. How do you keep staff up to speed. Changing work habits to get all to use the e-tools. Addressing human factors. Research why evaluators do not want to use e.g. CADDY – blockers?. ‘Change management’.

Invest in infrastructure (good computers – large screens). Ergonomic element.

OECD can make an overview of CBI info within each government. Government and industry can work together on this. Protection for proprietary data / intellectual property rights.

Collaborate on data mapping tools to provide more flexible data submission technique (transfer of information).

Explore the optimisation of approaches for archiving. Facilitate the exchange of info. for different archiving standards (OECD task).

Recommendations

What OECD can do

- Continue work on structure harmonisation. Needs to be done before IT solutions can be implemented.
- Identify common elements of submissions across programs
- Promote IT participation in appropriate meetings re process / contents
- OECD to promote detailed definition specification of robust summaries and standard templates, incl. IT considerations
- Annual report by OECD on different E-tools, overview on applications incl. latest development, etc.
- Research on blockers for the adoption of electronic tools (→ human factor)
- Use OECD website to facilitate access to information on IT systems. This needs to be adequately resourced.
- OECD to encourage their various programs to clearly define their needs and processes through an appropriate project management process.

- Steering groups of individual programs should keep an eye on the IT tools in their respective programs
- OECD to serve as a discussion forum for the development of new technologies such as XML
- Information sharing will lead to work sharing.
- Facilitate information exchange between programs on archiving approaches.

What Governments and Industry can do

- Provide incentives to E-submissions related to efficiency gains
- Address human elements and introduce professional change management
- Systems need to have adequate user support / help-lines
- Invest in infrastructure
- Explore ways to overcome barriers with CBI and intellectual property rights.
- Assist with providing mapping tools to allow more flexible data submission techniques.
- Share information on progress towards resolving long-term electronic archiving

WORKSHOP CONCLUSIONS AND RECOMMENDATIONS

18. In terms of value, it was considered that all three programmes were moving in the same direction and that the workshop had provided excellent opportunities for networking. Potential barriers to more use of electronic tools were the resource requirements associated with more use, the need for staff to develop new skills and the need to ensure that the new technology was backwards compatible. Other potential barriers were the need to obtain a balance between the requirements and resources for large and small countries and different industries and that there was no current OECD group or process for co-ordinating such work.

19. Specific recommendations made to the OECD were to:

- (1) facilitate dialogue across the regulatory programmes;
- (2) share information across the programmes by the use of web sites, virtual workshops and future workshops;
- (3) support harmonisation where possible by the use of templates and emerging technologies such as the use of XML;
- (4) explore archiving issues for the documents submitted under the regulatory requirements.

20. Specific recommendations made to Member countries and industry were to:

- (1) have IT participation at the beginning of all new projects;
- (2) provide more incentives for electronic submissions;
- (3) provide user support for all IT systems
- (4) resolve confidential business and intellectual property issues
- (5) facilitate public access to data submitted for regulatory purposes
- (6) encourage work sharing between regulators (especially across regulatory areas)
- (7) encourage industry and regulators to work in close collaboration
- (8) consider carefully how data is archived.

21. At the end of the workshop, participants agreed that it had been very successful and there was a great deal of follow up work that should be done. In particular, the use of harmonised XML tags seemed an exciting approach for the future sharing and automated transfer of information across files and databases.

1 April 2003

Appendix 1

Workshop Organising Group Members

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Appendix 2

List of Background Documents

- ♦ **A Matrix of Electronic Tools for Agricultural Pesticides and Biocides**
- ♦ **Agricultural Pesticides & Biocide Background Document**
- ♦ **New Industrial Chemicals Background Document**
- ♦ **A Matrix of Electronic Tools for New Industrial Chemicals**
- ♦ **Existing Chemicals & Biocides Background Document**
- ♦ **A Matrix of Electronic Tools for HPV Existing Chemicals and Biocides**

These Background Documents can be found on the OECD password protected website.

The address is: <http://www1.oecd.org/ehs/wood/electronic-tools/>

User name: Wood Account
Password: WAccount

Appendix 3

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Appendix 3 (continued)**Breakout Group Members**

	<u>Breakout Group 1</u>	<u>Breakout Group 2</u>	<u>Breakout Group 3</u>
Chair	Kennan GARVEY (US, Gov)	Carmen KROGH (CAN, Gov)	Felix MAIER_MANZ (SWISS, CROPLF)
Rapporteur 1	Tom GILDING (US, CROPLF)	Rebecca COOL (US, Gov)	Kate BOUVE (US, Gov)
Rapporteur 2	Steve DOBSON (UK, Gov)	Kotaro YOSHIDA (JAP, Gov)	Kirsten RASMUSSEN (EU, Gov)
	BALLANTINE Jennifer (CAN, Ind)	CIESLA Jacek (PO, Gov)	BORKHOFF Joyce (CAN, BIAC)
	BARKER Craig (SWISS, BIAC)	DEPREZ Catherine (BELG, BIAC)	DE LA FOSSE Tony (AUS, Gov)
	BHUSHANA Siva RAO (BIAC)	DESJARDINS Yves (CAN, Gov)	DOGHERTY Michael (US, Gov)
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		HENNING, Bruno	WOLFORD Valerie (US, BIAC)
			DEILY, Dennis

Appendix 4

Workshop Agenda

**OECD Workshop on
electronic tools for data submissions,
evaluation and exchange for the regulation
of new and existing industrial chemicals,
agricultural pesticides and biocides**

Hosted by:

***PMRA Health Canada
and
US EPA***

Ottawa, 2-4 October, 2002

FINAL AGENDA

OECD Workshop on Electronic Information Systems for Industry Data Submission, Evaluation and Exchange

Ottawa, October 2-4, 2002

AGENDA

DAY 1 Wednesday 2nd October

08.00-09:00 **Registration**

09.00 **Opening Plenary 1: Workshop Objectives and Overview**

- **Welcome:**
 - Welcome address - Dr Clare Franklin
 - Objectives, structure and logistics
 - Wendy Sexsmith (Chair) and Geoffrey Wilson (OECD Secretariat)
- **Benefits and Challenges of Electronic tools for data submission , evaluation and exchange (overview presentation by Wendy Sexsmith - Chair of Workshop)**

(State-of-the-art with electronic tools in the four programme areas: agricultural pesticides; biocides; new industrial chemicals and existing industrial chemicals. Strengths and weaknesses and challenge for the future)

Plenary 2:

10.00 **Presentations on Electronic Tools used for Specific Agricultural Pesticides and Biocides Regulatory Processes.**

- **Karen Pither: Global Industry Activities with electronic tools used for Agricultural Pesticides to include Biocides as they relate to Agricultural Pesticides**

Questions & short discussion

10:45-11:15 **Coffee break**

DAY 1 Wednesday 2nd October

Plenary 2 (continued):

11.15 Presentations on Electronic Tools used for Specific Agricultural Pesticides and Biocides Regulatory Processes.

- **Steve Dobson: Global Government Activities with electronic tools used for Agricultural Pesticides to include Biocides as they relate to Agricultural Pesticides**

Questions & Short Discussion

12.00-13:30 Lunch - *provided by PMRA*

Plenary 2 (continued):

13:30 Presentations on Electronic Tools used for Specific New Chemicals Regulatory Processes.

- **Mike Irwin: Global Industry Activities with electronic tools used for New Chemicals**
- **Rebecca Cool: Global Government Activities with electronic tools used for New Chemicals**

Questions & Short Discussion

15:00-15:30 Coffee break

Plenary 2 (continued):

15:30 Presentations on Electronic Tools used for Specific Existing Chemicals and Biocides Regulatory Processes.

- **Kirsten Rasmussen: Global Government /Industry Activities with electronic tools used for Existing Chemicals to include Biocides as they relate to Existing Chemicals - EU perspective**
- **Kotaro Yoshida: Global Government/Industry Activities with electronic tools used for Existing Chemicals to include Biocides as they relate to Existing Chemicals – Japanese perspective**
- **Leslie Scott: Global Government/Industry Activities with electronic tools used for Existing Chemicals to include Biocides as they relate to Existing Chemicals – USA perspective**

Questions & Short Discussion

17:00	<u>Logistics:</u> Explanation of the proceedings for the remainder of the Workshop. Allocation of individuals into specific breakout groups. - <i>OECD Secretariat</i>
17:30	End of Day 1
	Workshop Dinner – <i>provided by PMRA</i>

DAY 2 – Thursday 3rd October

Day 2 is given over to the presentation, demonstration and discussion of specific electronic tools used by the three different regulatory areas (agricultural pesticides and biocides; new chemicals and existing chemicals and biocides). Participants will be assigned to one of three breakout groups (1, 2 or 3). These three breakout groups will rotate between the three demonstration sessions A, B and C. The demonstrations will cover the use of the electronic tools as they apply to data assembly and submission, data review and evaluation, production of review reports and archiving.

Time	Session A Agricultural pesticides and biocides	Session B New Chemicals	Session C Existing chemicals and biocides
08.00 – 10.30	Breakout group 1	Breakout group 2	Breakout group 3
10.30 – 11.00	<i>Coffee break</i>	<i>Coffee break</i>	<i>Coffee break</i>
11.00 – 13.30	Breakout group 3	Breakout group 1	Breakout group 2
13.30 – 14.30	<i>Lunch</i>	<i>Lunch</i>	<i>Lunch</i>
14.30 – 17.00	Breakout group 2	Breakout group 3	Breakout group 1
17.00- 18.00	Open house: participants can return to any of the Sessions to ask questions – the presentation teams will remain in the rooms until 18.00.		

DAY 3 Friday 4th October

08:00 **Breakout Group Session D:**
Identification of key points, discussion and preparation of proposed feedback to Plenary

Workshop breakout groups discuss strengths, weaknesses, benefits and challenges of the various electronic tools.

10:30 **Coffee break**
(Chairs and rapporteurs prepare presentations)

11:00 ***Plenary 5: Feedback from Breakout Group Discussions***

12.00- Breakout Group presentations
12.30 Short break

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

- **Brief summary of conclusions and recommendations**
- **Closing remarks by hosts.**

13.00 Workshop ends

Appendix 5

Presenters and Titles of Presentation/Demonstration sessions (on day 2)

The three regulatory areas were:

- A: agricultural pesticides and biocides
- B: new chemicals
- C: existing chemicals and biocides

The three breakout groups were designated 1, 2 and 3 and rotated between the three sessions.

Session A (agricultural pesticides and biocides)

- Hans Mattar** (Aventis CropScience, Netherlands): CADDY
- Bob Manfre** (BASF Corporation, USA): PDF submissions (to EPA and PMRA)
- Steve Dobson** (Pesticide Safety Directorate, UK): CADDY
- Karen Pither** (CropLife International)
- Diana Somers** (PMRA, Canada): PDF / EDDE (Electronic templates in pdf format)
- Mike Doherty** (US EPA): Electronic tools used for submission review by the US EPA
NAFTA harmonized review templates; PDF; JMP (Statistical Discovery Software)
- Carmen Krogh** (PMRA, Canada): Archiving and records - Role of XML

Session B (new chemicals)

- Anna Coutlakis** (US EPA): PDF
- Mike Irwin** (Procter & Gamble, US): OECD format
- Peter Schenk & Marcus Oenicke** (Chemie Daten, Germany): XML
- Kerry Nugent** (NICNAS, Australia): The NICNAS notification template (WORD based)

Session C (existing chemicals and biocides)

- Gerhard Rosner** (Consultant to Fraunhofer ITA, Germany): IUCLID 4.0
- Leslie Scott** (US EPA): CIMS (Chemical Information Management System)