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

OVERVIEW OF COUNTRY AND REGIONAL REVIEW PROCEDURES FOR AGRICULTURAL PESTICIDES AND RELEVANT DOCUMENTS

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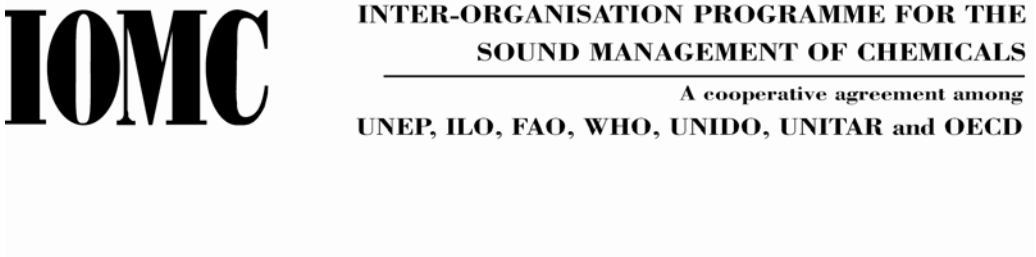
Series on Pesticides

No. 33

OVERVIEW OF COUNTRY AND REGIONAL REVIEW PROCEDURES FOR AGRICULTURAL PESTICIDES AND RELEVANT DOCUMENTS



Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
Paris 2006

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No. 29 *Report of the OECD Pesticide Risk Reduction Steering Group Seminar on Risk Reduction through Good Pesticide Labelling*
No. 30 *Report of the OECD Pesticide Risk Reduction Steering Group: The Second Risk Reduction Survey*
No. 31 *Guidance Document on the Definition of Residue*
No. 32 *Guidance Document on Overview of Residue Chemistry Studies*

Published separately

OECD Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances-Monograph Guidance (1998, revised 2001, 2005)

OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances-Dossier Guidance (1998, revised 2001, 2005)

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

About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 30 industrialised countries in North America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

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

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

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

FOREWORD

One of the main conclusions from the OECD Workshop on Work Sharing (Washington, DC; 31 January to 2 February, 2005) was the need for a document which would provide an overview of country and regional registration/re-registration procedures for agricultural pesticides, and relevant documents. Such a document would help government regulators gain a better understanding of the processes followed in other governments in which they may work share, as well as the relevant documents produced during each step of the process.

This document contains entries from Australia, Canada, the EU, Japan and the US, and it will be updated regularly.

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

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Template for Overview of country and regional review procedures and documents

This template should be completed by all countries/organisations who conduct pesticide evaluations, and who wish to contribute to worksharing across countries by making (parts of) their evaluation documents available to other governments. It is intended to help government regulators to gain a better understanding of the processes followed in other governments in which they may work share, as well as the relevant documents produced during each step of the process.

Organisation	
Contact for questions & feedback	
Brief overview of the evaluation process (Executive summary)	
Are complete reference lists (lists of studies submitted for a pesticide substance) available? **If yes, where can they be obtained?**	

Major steps / phases of the evaluation process and monograph preparation	Brief description of this step (who, what, when)	Name of document(s) produced which are available for worksharing	Brief description of document(s) (what does it cover)	Status of document(s) (internal memo; draft, final; published)	If not published: Available to whom? (governments only; public)	Clearance needed before release?	Where to get the document (contact name, website)	Remarks / Other
Evaluation of <u>individual</u> studies								
Summary of study results per discipline / study area, including risk assessment for that area								
<u>Internal</u> peer review (within one country)								
<u>External</u> peer review (across countries)								
Regulatory /decision making								
Remarks/Other								

List of contact names

Country	Australia	Canada	EU	Japan	US
Contact for questions & feedback	**Dr. Eva BENNET-JENKINS** Program Manager (Pesticides) Australian Pesticides & Veterinary Medicines Authority (APVMA) PO Box E240 Kingston ACT 2604 Australia Tel : +61 2 6272 5248 Fax : +61 2 6272 3195 Email : eva.bennet-jenkins@apvma.gov.au	**Mr. Richard AUCOIN** Acting Chief Registrar Pest Management Regulatory Agency (PMRA) Sir Charles Tupper Building, 7th fl. 2720 Riverside Drive Ottawa Ontario K1A 0K9 Canada Tel : (613) 736-3705 Fax : +1 613 736 3707 Email : Richard_Aucoin@hc-sc.gc.ca	**Mr. Herbert KOEPP** Head of unit 'EU Review of Active Substances' Federal Office of Consumer Protection and Food Safety (BVL) Messeweg 11/12 D-38104 Braunschweig Germany Tel : +49 531 299 3456 Fax : +49 531 299 3003 Email : Herbert.Koepp@bvl.bund.de	**Mr. Akio YAMAMOTO** Director, Planning and Strategy Office Agricultural Chemicals Inspection Station (Incorporated Administrative Agency) 2-772 Suzuki-Cho Kodaira-Shi, Tokyo 187-0011 Japan Tel : +81 423 83 2151 Fax : +81 423 85 3361 Email :	**Ms. Lois ROSSI** Director, Registration Division US EPA Office of Pesticide Programs (7505-C) 1200 Pennsylvania Avenue, N.W. Washington D.C. 20460 United States Tel : +1 703 308 8162 Fax : +1 703 305 6920 Email : rossi.lois@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 United States Tel : +1 703 308 8009 Fax : +1 703 308 7042 Email : lewis.susan@epa.gov

AUSTRALIA's Review Procedures and Documents

Organisation	**Australian Pesticides & Veterinary Medicines Authority (APVMA), Canberra**
Contact for questions & feedback	**Dr. Eva BENNET-JENKINS** Program Manager (Pesticides) Australian Pesticides & Veterinary Medicines Authority PO Box E240 Kingston ACT 2604 Australia Tel : +61 2 6272 5248 Fax : +61 2 6272 3195 Email : eva.bennet-jenkins@apvma.gov.au
Brief overview of the evaluation process (Executive summary)	
Are complete reference lists (lists of studies submitted for a pesticide substance) available? **If yes, where can they be obtained?**	

Major steps / phases of the evaluation process and monograph preparation	Brief description of this step (*who, what, when*)	Name of document produced and available for worksharing	Brief description of document(s) (*what does it cover*)	Status of document(s) (*internal memo; draft, final; published*)	If not published: Available to whom? (*governments only; public*)	Clearance needed before release?	Where to get the document? (contact name, website)	Remarks/ Other
Evaluation of individual studies	APVMA advisory agencies undertake evaluation of individual studies and prepare a draft component assessment report (summary of all submitted studies). The Australian assessment reports contain both the hazard assessment and risk assessment for both the Active and End Use Product.	The individual component reports are named according to the discipline. (e.g. Draft Toxicology assessment report).	Evaluation of individual studies and risk assessment, as separate documents for each component of the evaluation (eg Tox, OH&S, Environment, Residues and trade, Efficacy).	Final after submission to APVMA and found to be acceptable and combined into a single document with all assessment components. After finalisation a Public Release Summary (PRS) is published and the public is invited to comment before registration is granted. The full assessment report is available to the public on request.	The documents (individual components) could be made available to governments prior to publication of the PRS with consent of the applicant.	Only for unpublished documents	The PRS is made available in hard copy as well as published on the APVMA website. The full assessment reports can be requested through the APVMA international coordinator or the registration contact officer. A new process is being developed to publish all assessment reports and registration decisions on the APVMA website.	A pre-screen (30 days) to determine acceptability of studies and data package is followed by the hazard and risk assessment (12 months).
Summary of study	APVMA advising	Draft component	As above	As above	As above	As above	As above	

Major steps / phases of the evaluation process and monograph preparation	Brief description of this step (*who, what, when*)	Name of document produced and available for worksharing	Brief description of document(s) (*what does it cover*)	Status of document(s) (*internal memo; draft, final; published*)	If not published: Available to whom? (*governments only; public*)	Clearance needed before release?	Where to get the document? (contact name, website)	Remarks/ Other
results per discipline / study area including risk assessment for that area	agencies perform a risk assessment based on the individual study assessments (within the 12 month timeframe as stated above).	assessment report.						
Internal peer review (within one country)	Internal peer review of assessments are carried out within each APVMA advisory agency, and submitted to the APVMA evaluator for final quality check and review.							
External peer review (across countries)	Currently not in our processes							
Regulatory / decision making	APVMA	Following the public comment period on the PRS the decision of granting or refusing the registration is made. This decision is published in the APVMA gazette and is available on the APVMA web site.	Mostly abbreviated details of the product and end use, including date of registration and label approval numbers.					
Remarks/Other								

APVMA timeline of dossier assessment and regulatory decision making process

Pre screen	Evaluation of individual studies and risk assessment, peer review and draft component report undertaken by APVMA advisory agencies	APVMA review, quality check and final report compilation	PRS Public consultation (clock off time)	APVMA regulatory decision, finalisation and gazette notice
1 month	12 months	2 months	1 month	1 month

CANADA's Regional Review Procedures and Documents

Organisation	**Pesticide management regulatory Authority (PMRA), Ottawa**
Contact for questions & feedback	**Mr. Richard AUCOIN** Acting Chief Registrar Pest Management Regulatory Agency Sir Charles Tupper Building, 7th fl. 2720 Riverside Drive Ottawa Ontario K1A 0K9 Canada Tel : (613) 736-3705 Fax : +1 613 736 3707 Email : Richard_Aucoin@hc-sc.gc.ca
Brief overview of the evaluation process (Executive summary)	
Are complete reference lists (lists of studies submitted for a pesticide substance) available? **If yes, where can they be obtained?**	

Major steps / phases of the evaluation process and monograph preparation	Brief description of this step (*who, what, when*)	Name of document produced and available for worksharing	Brief description of document(s) (*what does it cover*)	Status of document(s) (*internal memo; draft, final; published*)	If not published: Available to whom? (*governments only; public*)	Clearance needed before release?	Where to get the document? (contact name, website)	Remarks /Other
Evaluation of individual studies	Preliminary review of studies by evaluator within 45 days	Science screening. Deficiency Notes/missing studies	Templated identification of submission / studies/ deficiencies	Final (Internal Gov't)	Applicant/submittor /registrant		Applicant's discretion	
	Comprehensive review of studies by evaluator For joint review with the U.S., there is a Joint Review Standard Operating Procedure (SOP) Overall timeline for preparation and peer review of the Evaluation Report (ER) and Monograph chapters can range from about 9 to 18 months depending on the category of submission (e.g. reduced risk versus conventional; joint review or Canada only).	DERs/Evaluation Report	Review of studies using NAFTA templates.	Draft and then final after internal or external peer review.	Currently available to other regulatory agencies for joint and work-sharing reviews. In the future will be available for public viewing in reading room.	Yes. Approval required from applicant/registrant or data owner.In the future under the new *Pest Control Products Act* (PCPA) clearance will not be needed.	Contact PMRA at pmra_infoserv@hc-sc.gc.ca, or Lynn Lee at: Lynn_Lee @ hc-sc.gc.ca.	

Summary of study results per discipline / study area including risk assessment for that area	Evaluator after peer review of Evaluation Report/DER	Monograph chapters	Summary of study results per discipline / study area including risk assessment	Draft and then final after internal divisional peer review.	Currently available to other regulatory agencies for joint and work-sharing reviews. In the future will be available for public viewing in reading room. Note: the Risk Assessment is internal and the final risk assessment is public: Proposed Regulatory Decision Document (PRDD)	Approval required from applicant/ registrant	Contact PMRA at: pmra_infoserv @hc-sc.gc.ca	
Internal peer review (<u>within</u> one country)	Applies to draft Evaluation Reports/DERs and Monograph chapters as they are produced (primary review of DERs)							
External peer review (<u>across</u> countries)	Applies to Joint Review draft Evaluation Reports (ERs) /DERs as they are produced (secondary review of ERs) prepared by partner in a joint review.							

Regulatory /decision making	PMRA regulatory decision made by Science Management Committee (SMC) comprised of Division Directors and the Chief Registrar.	Full registration: Proposed Regulatory Decision Document (PRDD) available for 75-day public comment period, followed by final Regulatory Decision Document (RDD), (or for temporary registration, a Regulatory Note).	Summary of discipline / study areas including risk assessment and regulatory decision.	Final	Public/PMRA website	Yes (clearance from company needed before release). In the future under the new *Pest Control Products Act* (PCPA), clearance will not be needed.	PMRA website	
Remarks / Other								

EU's Regional Review Procedures and Documents

Organisation	**European Union**
Contact for questions & feedback	**Mr. Herbert KOEPP** Head of unit 'EU Review of Active Substances' Federal Office of Consumer Protection and Food Safety Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) Messeweg 11/12 D-38104 Braunschweig Germany Tel : +49 531 299 3456 Fax : +49 531 299 3003 Email : Herbert.Koepp@bvl.bund.de
Brief overview of the evaluation process (Executive summary)	The EU system is based on worksharing between member states. Active substances are evaluated by this EU review program, while end-use product registration still rests with the individual member states. Notifiers have to submit a dossier (according to the OECD Dossier Guidance) to a Rapporteur Member State (RMS). The RMS evaluates the dossier and prepares the DAR (Draft Assessment Report; former name: Monograph) which contains all study evaluations as well as the risk assessments for the different scientific disciplines and a proposal for an overall decision. The DAR is then peer-reviewed by all member states. The peer review used to be organised by the European Commission but has now been taken over by EFSA. All member states, the notifier, and (in the EFSA procedure) third parties can comment. All comments are compiled in tabular form, and responses/conclusions to each point raised are added to the table. Specific expert groups (formerly ECCO meetings, then EPCO, now PRAPeR) discuss difficult issues. EFSA publishes a report covering the peer review (the EFSA Conclusion). The regulatory decisions are taken done by a political body. Public consultation is restricted to the commenting on the DAR. Due to changes in the system triggered by the establishment of EFSA, names of some procedural steps and documents have changed over time. The decision (in the positive case, a listing of the substance in Annex I of directive 91/414) is valid for a maximum of ten years. So far, the procedure for how to renew the Annex I listing has not yet been decided.

Are complete reference lists (lists of studies submitted for a pesticide substance) available? **If yes, where can they be obtained?**	Yes. Depending on when the substance was evaluated, the reference lists are included • in the DAR, in Addenda to the DAR, and the Review Report • in the DAR, in Addenda to the DAR, and in the List of studies maintained by the RMS and EFSA

Major steps / phases of the evaluation process and monograph preparation	Brief description of this step (*who, what, when*)	Name of document produced and available for worksharing	Brief description of document(s) (*what does it cover*)	Status of document(s) (*internal memo; draft, final; published*)	If not published: Available to whom? (*governments only; public*)	Clearance needed before release?	Where to get the document? (contact name, website)	Remarks /Other
Evaluation of individual studies	RMS (Rapporteur Member State) evaluates the dossier. Country-specific process but overall timeline for producing the DAR (Draft Assessment Report; formerly Monograph) is normally 12 months.	All study evaluations are reported in the respective (sub-)section in the DAR, Volume 3 and, if CBI, in Volume 4 For data submitted later during the process, respective Addenda to the DAR, Vol. 3 or 4 are prepared.	Evaluation of individual studies	Final after submission of the DAR to COM and EFSA	To governments: after submission of the DAR to COM and EFSA To public after submission of the DAR to COM and EFSA	only for internal drafts	RMS contact person (see list of contacts on DG SANCO website): http://ec.europa.eu/food/plant/protection/evaluation/contact_points.xls For public: country-specific	
Summary of study results per discipline / study area including risk assessment for that area	RMS (Rapporteur Member State) evaluates the dossier and performs risk assessments.	Summary sec-tions of DAR, Vol.3/4; List of endpoints (DAR, Vol 1); Section in DAR, Vol 1; [Consultation Report RMS]	Summary of study results per discipline / study area including risk assessment for that area	as above	as above	as above	as above	

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Internal peer review (within one country)	Country-specific							
External peer review (accross countries)	RMS submits the DAR to COM and EFSA EFSA sends it to all member states and the notifier for comments (60 days) RMS compiles all comments in the reporting table. Notifier responds to each comment in the table. RMS responds to each comment (and notifier's response) in the table and proposes how to deal with each comment. This finalises the reporting table.	[Reporting table]	Table of all comments on the DAR and respective responses of the notifier and RMS	internal, final	governments	no	see above	

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	RMS prepares the Consultation Report and sends it together with the Reporting Table to EFSA..	*RMS Consultation Report*	RMS's main conclusions & areas of concern, based on own evaluation and the comments on the DAR	internal, final	governments	no	see above	
	The Evaluation meeting (all member states) discusses the reporting table; identifies issues for the Peer Review meetings. All points under discussion are taken up in the Evaluation table.	Evaluation table	discussion points, data requirements, response notifier, response RMS, decision WG evaluation	living document; final only after decision	governments When final, published as Background Document ...	no	see above	

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	Peer Review expert meetings (formerly ECCO meetings, then EPCO, now PRAPeR) discuss RMS evaluation and comments on points where member states disagree.	[Report of ECCO / EPCO meeting(s)]	records of expert peer review meetings	internal, final	governments	no	see above	
	ECCO/EPCO (a secretariat) compiles all records and comments in one report.	[Full Report / Peer Review Report]	above, plus all comments	final Published as Background Document	governments public	no	see above	

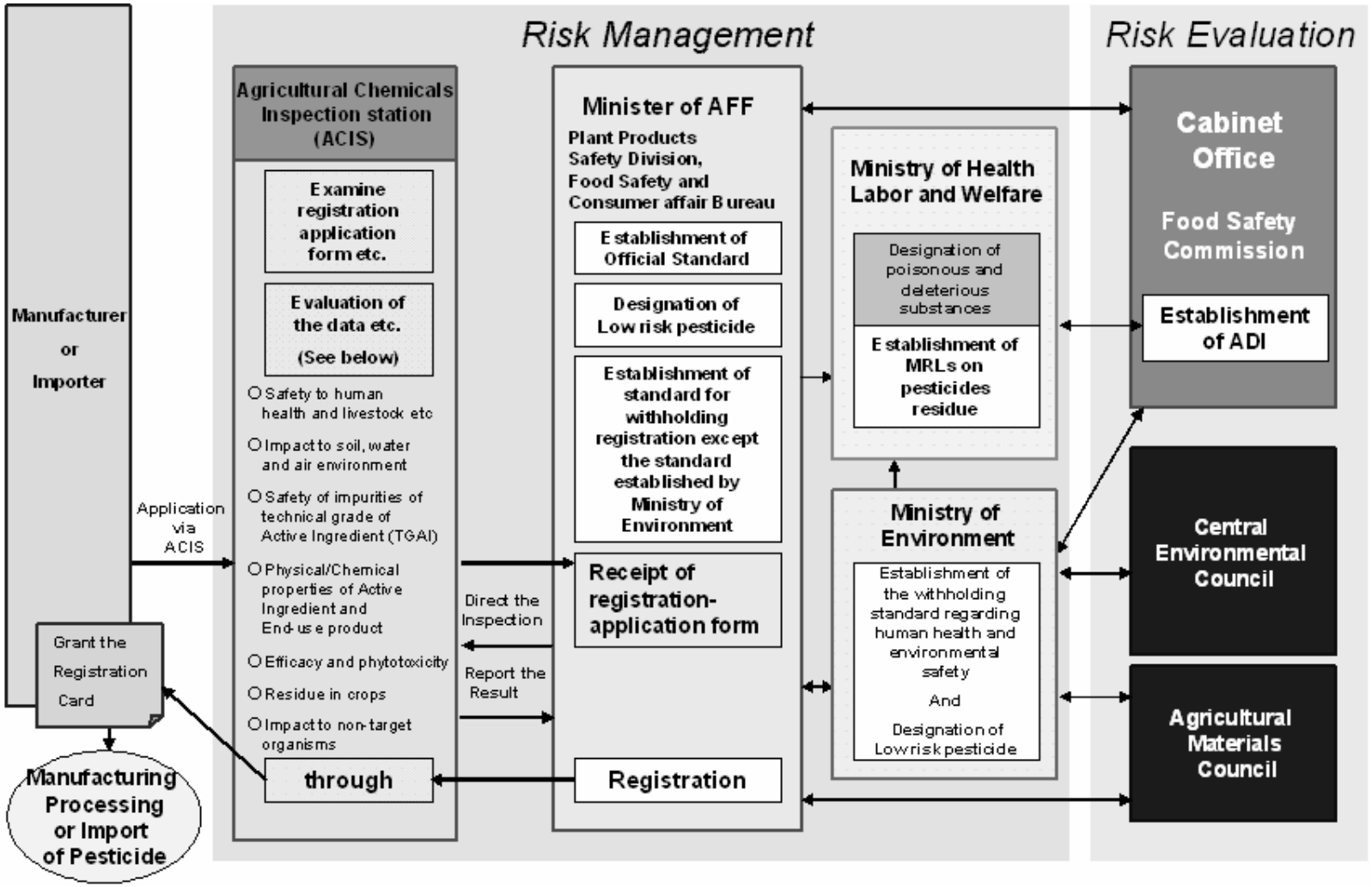
Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	EFSA summarises the peer review, including areas of concern and disagreement, identifies data reqiurements, etc	[EFSA Consultation Report]	report of EFSA to COM (result of peer review)	final Published on website	governments public	no	EFSA website for PPR (since 2003) http://www.efsa.europa.eu/en/science/praper.html DG SANCO website for SCP (until 2003): http://ec.europa.eu/food/fs/sc/scp/index_en.html	

Major steps / phases of the evaluation process and monograph preparation	Brief description of this step (*who, what, when*)	Name of document produced and available for worksharing	Brief description of document(s) (*what does it cover*)	Status of document(s) (*internal memo; draft, final; published*)	If not published: Available to whom? (*governments only; public*)	Clearance needed before release?	Where to get the document? (contact name, website)	Remarks /Other
	For scientific issues, COM, EFSA and member states may ask the PPR (formerly SCP) for an opinion.	[Opinion of the SCP or the EFSA PPR]	response of an independent scientific advisory committee to specific science questions (not on risk management)	final Published on EFSA PPR website			Published on EFSA PPR website or on DG SANCO website (or SCP, until 2003):	
Regulatory /decision making		Decision on (non-) inclusion (=> **Official Journal**), supported by the **Review Report** (very brief summary of the process and of main areas of concern, includes final List of endpoints)	Decision: Legal text Review Report: mostly administrative text but with areas of concern, restrictions, and the **Final list of endpoints**	final Published on DG SANCO website			Published on DG SANCO website	
Remarks/Other								

JAPAN's Review Procedures and Documents

Organisation	**Ministry of Agriculture, Forestry and Fisheries** (Registration, and Risk management) **Food Safety Commission** (Risk assessment fo human health) **Ministry of the Environment** (Rsik assessment for environment) **Ministry of Health, Labour and Welfare** (Establishment of MRLs) **Agricultural Chemicals Inspection Station** (Assessment for agricultural chemicals quality and ensuring proper and safe use)
Contact for questions & feedback	**Mr. Akio YAMAMOTO** Director, Planning and Strategy Office Agricultural Chemicals Inspection Station (Incorporated Administrative Agency) 2-772 Suzuki-Cho Kodaira-Shi, Tokyo 187-0011 Japan Tel : +81 423 83 2151 Fax : +81 423 85 3361 Email :

Brief overview of the evaluation process (Executive summary)	**The following figure is the flow chart on the agricultural chemicals products registration program in Japan**



Are complete reference lists (lists of studies submitted for a pesticide substance) available? **If yes, where can they be obtained?**	No, lists of studies submitted for a pesticide substance are not available For reference, Data Requirement and Test guideline for agricultural chemicals registration (English) are published in the following website. http://www.acis.go.jp/eng/shinsei/index.htm

(1) As to human health ,
(2) As to risk to aquatic organisms,

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Evaluation of individual studies	(1)Food Safety Commission(FSC) evaluates the data . (2) Ministry of the Environment (MOE) evaluates the data on aquatic toxicity	(1)The evaluation of all studies is reported in Section □ of Evaluation Report (ER). (2) (now preparing)	(1)Evaluation of individual studies (2)Evaluation of individual studies on aquatic toxicity	(1)Final (2) (now considering)	(1)After submission of the ER to Ministry of Health, Labour and Welfare (MHLW) (2) (now considering)		(1)The website of FSC (2) (now considering)	(1)Delay in publishing of English version ER
Summary of study results per discipline / study area including risk assessment for that area	(1)FSC evaluates the summary report of data.	(1)Abstract section of the ER Section with endpoints list of the ER	(1)Summary of study results and the risk assessment	(1)Final	(1)As above		(1)As above	

Major steps / phases of the evaluation process and monograph preparation	Brief description of this step (*who, what, when*)	Name of document produced and available for worksharing	Brief description of document(s) (*what does it cover*)	Status of document(s) (*internal memo; draft, final; published*)	If not published: Available to whom? (*governments only; public*)	Clearance needed before release?	Where to get the document? (contact name, website)	Remarks /Other
	(2)MOE performs risk assessment on damage to aquatic animals and plants, and makes a draft summary report and a proposal of Registration Withholding Standard on Damage to Aquatic Animals and Plants (RWSDAAP)	(2) (now preparing)	(2) Draft summary of study results and risk assessment on damage to aquatic animals and plants, and a proposal of RWSDAAP	(2) (now considering)	(2) (now considering)		(2) (now considering)	

Major steps / phases of the evaluation process and monograph preparation	Brief description of this step (*who, what, when*)	Name of document produced and available for worksharing	Brief description of document(s) (*what does it cover*)	Status of document(s) (*internal memo; draft, final; published*)	If not published: Available to whom? (*governments only; public*)	Clearance needed before release?	Where to get the document? (contact name, website)	Remarks /Other
Internal peer review (within one country)	(1)Response to public comments for 30 days (2)Central Environment Council reviews and finalizes the summary and make a recommendation on the proposed RWSDAAP to the Minister of the Environment MOE requests public comments on the proposed RWSDAAP.	(1)Draft ER (2) (now preparing)	(1)study results on human health and the risk assessment (2)summary of study results and risk assessment on damage to aquatic animals and plants, and the proposed RWSDAAP	(1)Draft (2)Final	□ After drafting of ER (2) (now considering)		□ As above (2) (now considering)	
External peer review (accross countries)	(1)As above	(1)As above	(1)As above	(1)As above	(1)As above		(1)As above	(1)Draft ER is Japanese only

Major steps / phases of the evaluation process and monograph preparation	Brief description of this step (*who, what, when*)	Name of document produced and available for worksharing	Brief description of document(s) (*what does it cover*)	Status of document(s) (*internal memo; draft, final; published*)	If not published: Available to whom? (*governments only; public*)	Clearance needed before release?	Where to get the document? (contact name, website)	Remarks /Other
Regulatory /decision making	MRL (by MHLW), RWSDAAP (by MOE), are noticed through the Official Journal , and pesticide registration (by Ministry of Agriculture, Forestry and Fisheries (MAFF)),etc will be noticed through the **Official Journal.** **Pesticide Registration Card** will be granted to the applicant by the Minister of AFF	MRL (by MHLW), RWSDAAP (by MOE), Pesticide registration (by Ministry of Agriculture, Forestry and Fisheries (MAFF)), **Pesticide Registration Card** (by the Minister of AFF)	(1)(2)Official Journal: legal text Pesticide Registration Card: Legal text	(1)(2)Final			(1)MRL on the website of MHLW Published the information of pesticide registration on the website of MAFF and Agricultural Chemicals Inspection Station. (2) (now preparing)	
Remarks/Other	(2) RWSDAAP and risk assessment scheme on damage to aquatic animals and plants was revised in 2003(enforced in April 2005). Therefore, the aquatic ecological risk assessment of a specific pesticide has not been completed yet.							

U.S. EPA's Review Procedures and Documents—NEW CHEMICALS (registration)

Organisation	**Environmental Protection Agency (EPA), Washington**
Contact for questions & feedback	**Ms. Lois ROSSI** Director, Registration Division US EPA Office of Pesticide Programs (7505-C) 1200 Pennsylvania Avenue, N.W. Washington D.C. 20460 United States Tel : +1 703 308 8162 Fax : +1 703 305 6920 Email : rossi.lois@epa.gov

Brief overview of the evaluation process (Executive summary)	Although the basic data evaluations and risk assessments produced for registration and reregistration are the same, the processes differ substantially in what information is available to the public and when it is available. The differences are highlighted below: • Data Evaluation Records (DERs) will be available to the public, at the end of the process, for registration (new chemicals). They are not currently available for reregistration. • The reregistration process is subject to a well-established public participation process which requires publication of preliminary risk assessments for public comment. Preliminary risk assessments are not publically available for registration chemicals. (An exception to this is that for certain low use and/or low risk pesticides the reregistration process may consist of preparation of a decision document and issuance of this document, the risk assessments, and related documents for public comment, in a single step. In this case it would be expected that the preliminary and final risk assessments are the same document.) All publically available documents are reviewed for CBI prior to posting on the web site. • In addition, the public process for reregistration requires that the public have access to any additional information that affects the risk assessment, for example, the evaluation of new data, addendums to the risk assessments, etc. Thus, a careful perusal of the reregistration website should ensure that all available pieces of the preliminary risk assessment are found. In contrast, obtaining the preliminary risk assessment document for a registration chemical will not necessarily ensure that all pertinent revisions, addendums, etc. have been obtained—for this it would be necessary that someone in OPP has checked for all of the available information. However, at the end of the registration process all relevant risk assessment documents will be made available on the new chemical website. • The regulatory document produced for public dessimination at the end of the reregistration process is more detailed than that produced for registration. Efforts are on-going to provide more detail in the new chemical regulatory documents, for example, the fact sheet now includes a bibliography which should be extemely useful in work sharing efforts.
Are complete reference lists (lists of studies submitted for a pesticide substance) available? **If yes, where can they be obtained?**	

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
Evaluation of individual studies	(1) Draft DERs (Data Evaluation Records). These are the study reviews (first draft developed by contractors), second draft reviewed and approved by EFED or HED scientists. Subject to change in the risk assessment/ risk management processes.	Data Evaluation Record (DER) (identified by EPA assigned MRID number, study type, and chemical name).	Evaluation of individual studies.	Internal; draft final only after completion of risk assessment/ risk management processes.	Potentially available to governments involved in workshares.	Clearance required		
	(2) Final DERs, final documents contain all changes that may have resulted from peer review; questions from managers; rebuttals by registrant; etc. Available at the conclusion of the risk management decision.	As above	As above	Final; published	Public	No	Website: Docket for New Chemicals	

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
Summary of study results per discipline/ study area including risk assessment for that area	Environmental Fate and Effects Risk Assessment							
	(1) Drinking Water Exposure Assessment Part of (2) below, but often produced as a separate document because it is required early in the HED process. Prepared by EFED chemistry/fate reviewer and exposure modellers.	Drinking Water Exposure Assessment For: Chemical Name	Contains the drinking water exposure estimates; including models used, model input parameters and model outputs.	Internal; draft	Potentially available to governments involved in workshares.	Clearance required		Drinking water residues are now included directly in the dietary exposure calculation (i.e. food and water residues combined).

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(2) Draft Environmental Fate and Effects Division (EFED) integrated risk assessment—combines the environmental fate and ecological effects assessments. Prepared by EFED lead risk assessor.	Environmental Fate and Ecological Risk Assessment For: Chemical Name	Contains summary DER information for environmental fate and ecological effects; terrestrial and aquatic exposure estimates, including input parameters used in models and all model outputs; endpoints selected for risk assessment; calculated risk quotients; and integrated ecological effects assessment.	Internal; draft	Potentially available to governments involved in workshares.	Clearance required		

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(3) Final Environmental Fate and Effects Division (EFED) integrated risk assessment. Final version of ecological fate and effects risk assessment. Prepared by EFED lead risk assessor.	As above	Final EFED risk assessment. Same document as (2) above that now contains all changes resulting from review by risk managers or rebuttals by registrant in risk management/ risk mitigation phase.	Final; published	Public	No	Website: Docket for New Chemicals	
	Health Effects Risk Assessment							

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(1) Draft Health Effects Division (HED) Risk Assessment Document. First draft document reviews and integrates the results of all relevant toxicology studies; states and explains endpoints to be used and types of risk assessments to be conducted. Prepared by HED toxicologist.	Draft Human Health Risk Assessment for: Chemical Name	HED Risk Assessment Document. First draft document reviews and integrates the results of all relevant toxicology studies; states and explains endpoints to be used in risk assessments, time frames, and certain other exposure parameters. Decisions on Safety Factors are also included.	Internal; draft	Potentially available to governments involved in workshares.	Clearance required		There is no independent document for toxicology. The first draft of the toxicology is done in the format of the final risk assessment document and is changed there, when necessary, throughout the process.

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(2) Cancer Assessment Review Committee (CARC) Memorandum Memorandum summarizing the decisions on the cancer assessment for the chemical. Prepared by the CARC.	CARC Memo for: Chemical Name	Reviews and integrates the results of all relevant studies and states and explains the decision on the cancer classification and method of cancer assessment for the chemical.	As above	As above	As above		

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(3) Residue Chemistry Assessment Detailed residue chemistry assessment. Prepared by the residue chemist.	Residue Chemistry Memo for: Chemical Name	Contains summary DER information; analysis and determination of the nature of the residues, the residues to be included in the tolerance expression, residues to be considered in the risk assessment, and the environmental degradates of concern.	As above	As above	As above		

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(4) Dietary Risk Assessment Memo Summary of input and results from the dietary risk assessment. Prepared by the dietary exposure modeller.	(DEEM Memo) or Dietary Exposure Analysis for: Chemical Name	Summary of the input and results from the dietary risk assessment run with DEEM or Lifeline	As above	As above	As above		Potential residues in drinking water are now included directly in the dietary exposure calculation (i.e. food and water residues combined).
	(5) Occupational and Residential Exposure (ORE) Assessment Risk assessment for occupational and residential exposure prepared by ORE reviewer.	Occupational and Residential Exposure Assessment for: Chemical Name	Contains summary DER information; analysis of relevant exposure scenarios and estimates of exposure; derivation of risk estimates (MOEs).	As above	As above	As above		

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(6) Draft Health Effects Division (HED) Risk Assessment Document A new, but still draft, version of (1) above that now contains the summary risk assessment for all aspects of the chemical—it integrates all of the documents 1-5 above. Prepared by the HED lead risk assessor.	Draft Human Health Risk Assessment for: Chemical Name	Draft integrated risk assessment—summary document which combines the above assessments on toxicology, residue chemistry, dietary exposure and occupational and residential exposure into a complete assessment of the human health risk.	As above	As above	As above		

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(7) Final Health Effects Division integrated risk assessment. Final version of human health risk assessment (6) above. Prepared by the HED lead risk assessor.	Final Human Health Risk Assessment for: Chemical Name	Same document as (6) above that contains all changes resulting from review by risk managers or rebuttals by registrant in risk management/ risk mitigation phase.	Final; published	Public	No	Website: Docket for New Chemicals	

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
Regulatory /decision making	(1) Federal Register Notice for Tolerance Decisions. Summary of the tolerance decision. Prepared by the registration division risk manager.	Chemical Name; Pesticide Tolerance Action: Final Rule	Brief summary of the risk assessment and risk management decisions for tolerances; and establishment or changes in tolerances. It is the announcement to the public through the Federal Register.	Final; published	Public	No	Website: Federal Register	

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(2) Decision memorandum--prepared by the registration division risk manager.	Decision Memorandum Subject: Registration of Chemical Name	Summary of the risk assessment and risk management decisions and establishment or changes in tolerances. It is the document that is signed by management to make the decision official.	Internal; Final	Potentially available to governments involved in workshares.	No		
	(3) Fact Sheet—brief summary of risk assessment and risk management decision. Prepared by the registration division risk manager.	Pesticide Fact Sheet Name of Chemical: ____	Brief summary of risk assessment and risk management decisions and their basis; includes the bibliography.	Final; published	Public	No	Website: Docket for New Chemicals	
Remarks/Other								

U.S. EPA's Review Procedures and Documents—Reassessment of Older Chemicals (Reregistration)

Organisation	**USA; Environmental Protection Agency (EPA), Washington**
Contact for questions & feedback	**Ms. Susan LEWIS** Branch Chief, Special Review and Reregistration Division US EPA 7508C, Ariel Rios Building 1200 Pennsylvania Avenue, NW Washington, DC 20460 United States Tel : +1 703 308 8009 Fax : +1 703 308 7042 Email : lewis.susan@epa.gov

Brief overview of the evaluation process (Executive summary)	Although the basic data evaluations and risk assessments produced for registration and reregistration are the same, the processes differ substantially in what information is available to the public and when it is available. The differences are highlighted below: • Data Evaluation Records (DERs) will be available to the public, at the end of the process, for registration (new chemicals). They are not currently available for reregistration. • The reregistration process is subject to a well-established public participation process which requires publication of preliminary risk assessments for public comment. Preliminary risk assessments are not publically available for registration chemicals. (An exception to this is that for certain low use and/or low risk pesticides the reregistration process may consist of preparation of a decision document and issuance of this document, the risk assessments, and related documents for public comment, in a single step. In this case it would be expected that the preliminary and final risk assessments are the same document.) All publically available documents are reviewed for CBI prior to posting on the web site. • In addition, the public process for reregistration requires that the public have access to any additional information that affects the risk assessment, for example, the evaluation of new data, addendums to the risk assessments, etc. Thus, a careful perusal of the reregistration website should ensure that all available pieces of the preliminary risk assessment are found. In contrast, obtaining the preliminary risk assessment document for a registration chemical will not necessarily ensure that all pertinent revisions, addendums, etc. have been obtained—for this it would be necessary that someone in OPP has checked for all of the available information. However, at the end of the registration process all relevant risk assessment documents will be made available on the new chemical website. • The regulatory document produced for public dessimination at the end of the reregistration process is more detailed than that produced for registration. Efforts are on-going to provide more detail in the new chemical regulatory documents, for example, the fact sheet now includes a bibliography which should be extemely useful in work sharing efforts.
Are complete reference lists (lists of studies submitted for a pesticide substance) available? **If yes, where can they be obtained?**	**Yes – Complete list of studies can be fond in Appendix C of the Reregistration Decision document. The appendix is called bibliography.**

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
Evaluation of individual studies	(1) Draft DERs (Data Evaulation Records). These are the study reviews (first draft developed by contractors), second draft reviewed and approved by EFED or HED scientists. Subject to change in the risk assessment/ risk management processes.	Data Evaluation Record (DER) (identified by EPA assigned MRID number, study type, and chemical name).	Evaluation of individual studies.	Internal; draft final only after completion of risk assessment/ risk management processes.	Potentially available to governments involved in workshares.	Clearance required		
	(2) Final DERs, final documents contain all changes that may have resulted from peer review; questions from managers; rebuttals by registrant; etc. Available at the conclusion of the risk management decision.	As above	As above	Final; internal	Potentially available to governments involved in workshares.	Clearance Required		

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
Summary of study results per discipline/ study area including risk assessment for that area	Environmental Fate and Effects Risk Assessment							
	(1) Drinking Water Exposure Assessment Part of (2) below, but may also be produced as a separate document. Prepared by EFED chemistry/fate reviewer and exposure modelers.	Drinking Water Exposure Assessment For: Chemical Name	Contains the drinking water exposure estimates; including models used, model input parameters and model outputs.	Preliminary	Public; after posting on website	No, not after posting on website	www.epa.gov/pesticides/reregistration/status.htm	Drinking water residues are now included directly in the dietary exposure calculation (i.e. food and water residues combined).

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(2) Preliminary Environmental Fate and Effects Division (EFED) integrated risk assessment—combines the environmental fate and ecological effects assessments. Prepared by EFED lead risk assessor.	Preliminary Environmental Fate and Ecological Risk Assessment For: Chemical Name	Contains summary DER information for envirnomental fate and ecological effects; terrestrial and aquatic exposure estimates, including input parameters used in models and all model outputs; endpoints selected for risk assessment; calculated risk quotients; and integrated ecological effects assessment.	Preliminary	Public; after posting on website	No, not after posting on website	www.epa.gov/pesticides/reregistration/status.htm	

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(3) Final Environmental Fate and Effects Division (EFED) integrated risk assessment. Final version of ecological fate and effects risk assessment. Prepared by EFED lead risk assessor.	Final Environmental Fate and Ecological Risk Assessment For: Chemical Name	Final EFED risk assessment. Same document as (2) above that now contains all changes resulting from review by risk managers, public comments, or rebuttals by registrant in risk management/ risk mitigation phase.	Final; published	Public	No	www.epa.gov/pesticides/reregistration/status.htm	
	Health Effects Risk Assessment							

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(1) Preliminary Health Effects Division (HED) Risk Assessment Document. First draft document reviews and integrates the results of all relevant toxicology studies; states and explains endpoints to be used and types of risk assessments to be conducted. Prepared by HED toxicologist.	Preliminary Human Health Risk Assessment for: Chemical Name	HED Risk Assessment Document. First draft document reviews and integrates the results of all relevant toxicology studies; states and explains endpoints to be used in risk assessments, time frames, and certain other exposure parameters. Decisions on Safety Factors are also included.	Internal; draft	Potentially available to governments involved in workshares.	Clearance required		There is no independent document for toxicology. The first draft of the toxicology is done in the format of the final risk assessment document and is changed there, when necessary, throughout the process. (**NOTE:** Documents #1-5 which are the basis of the preliminary HED risk assessment (Document #6) may be posted on the internet with document #6—in which case the status, availability etc. would correspond to Document #6)

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(2) Cancer Assessment Review Committee (CARC) Memorandum Memorandum summarizing the decisions on the cancer assessment for the chemical. Prepared by the CARC.	CARC Memo for: Chemical Name	Reviews and integrates the results of all relevant studies and states and explains the decision on the cancer classification and method of cancer assessment for the chemical.	As above	As above	As above		(**NOTE:** Documents #1-5 which are the basis of the preliminary HED risk assessment (Document #6) may be posted on the internet with document #6—in which case the status, availability etc. would correspond to Document #6)

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(3) Residue Chemistry Assessment Detailed residue chemistry assessment. Prepared by the residue chemist.	Residue Chemistry Memo for: Chemical Name	Contains summary DER information; analysis and determination of the nature of the residues, the residues to be included in the tolerance expression, residues to be considered in the risk assessment, and the environmental degradates of concern.	As above	As above	As above		(**NOTE:** Documents #1-5 which are the basis of the preliminary HED risk assessment (Document #6) may be posted on the internet with document #6—in which case the status, availability etc. would correspond to Document #6)

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(4) Dietary Risk Assessment Memo Summary of input and results from the dietary risk assessment. Prepared by the dietary exposure modeler.	(DEEM Memo) or Dietary Exposure Analysis for: Chemical Name	Summary of the input and results from the dietary risk assessment run with DEEM or Lifeline	As above	As above	As above		Potential residues in drinking water are now included directly in the dietary exposure calculation (i.e. food and water residues combined). (**NOTE:** Documents #1-5 which are the basis of the preliminary HED risk assessment (Document #6) may be posted on the internet with document #6—in which case the status, availability etc. would correspond to Document #6)

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(5) Occupational and Residential Exposure (ORE) Assessment Risk assessment for occupational and residential exposure preprared by ORE reviewer.	Occupational and Residential Exposure Assessment for: Chemical Name	Contains summary DER information; analysis of relevant expsoaure scenarios and estimates of exposure; derivation of risk estimates (MOEs).	As above	As above	As above		(**NOTE:** Documents #1-5 which are the basis of the preliminary HED risk assessment (Document #6) may be posted on the internet with document #6—in which case the status, availability etc. would correspond to Document #6)

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(6) Preliminary Health Effects Division (HED) Risk Assessment Document A new, but still draft, version of (1) above that now contains the summary risk assessment for all aspects of the chemical—it integrates all of the documents 1-5 above. Prepared by the HED lead risk assessor.	Preliminary Human Health Risk Assessment for: Chemical Name	Preliminary integrated risk assessment—summary document which combines the above assessments on toxicology, residue chemistry, dietary expsoure and occupational and residential expsoure into a complete assessment of the human health risk.	Preliminary	Public; after posting on website	No, not after posting on website	www.epa.gov/pesticides/reregistration/status.htm	

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	(7) Final Health Effects Division integrated risk assessment. Final version of human health risk assessment (6) above. Prepared by the HED lead risk assessor.	Final Human Health Risk Assessment for: Chemical Name	Same document as (6) above that contains all changes resulting from review by risk managers, public comment, or rebuttals by registrant in risk management/ risk mitigation phase.	Final; published	Public	No	www.epa.gov/pesticides/reregistration/status.htm	

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Regulatory /decision making	(1) Reregistration Eligibility Decision ***(RED)*** **OR** Interim Reregistration Eligibility Decision ***(IRED)*** for chemicals that have been identified as having a common mechanism of toxicity with other pesticides but for which the cumulative risk assessment required by FQPA has not been completed **OR** Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision ***(TRED)*** for chemicals which only require a reassessment of the	Reregistration Eligibility Decision for: Chemical Name **OR** Interim Reregistration Eligibility Decision for: Chemical Name **OR** Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for: Chemical Name	REDs and IREDs provide a detailed summary of EFED and HED risk assessments and the risk management decision. Includes bibliography for the chemical. TREDs provide a detailed summary of the HED risk assessment for tolerances only and the risk management decision. This is an assessment of aggregate risk—	Final; published	Public	No	www.epa.gov/pesticides/reregistration/status.htm	

Major steps / phases of the evaluation process and monograph preparation	**Brief description of this step (*who, what, when*)**	**Name of document produced and available for worksharing**	**Brief description of document(s) (*what does it cover*)**	**Status of document(s) (*internal memo; draft, final; published*)**	**If not published: Available to whom? (*governments only; public*)**	**Clearance needed before release?**	**Where to get the document? (contact name, website)**	**Remarks /Other**
	tolerances. Detailed summary of risk assessments and risk management decision. Prepared by Special Review and Reregistration Division (SRRD) risk manager		from food, water, and residential exposures. Occupational and ecological risks are not included. These are the documents that are signed by management to make the decisions official.					
	(2) Fact Sheet--brief summary of risk assessment and risk management decision. Prepared by Special Review and Reregistration Division (SRRD) risk manager.	R.E.D. Facts Chemical Name **OR** Chemical Name Facts	Brief summary of the risk assessment and risk management decisions.	Final	Published	No	www.epa.gov/pesticides/reregistration/status.htm	
Remarks/Other								