



## PROJECT SHEET

**SUBCOMMITTEE:** Joint Review of Conventional Chemical Pesticides

**PROJECT TITLE:** **Joint Review:**  
**Group 1A - Reduced Risk Joint Review Chemicals**  
**Group 1B - Reduced Risk Joint Review Chemicals**  
**Group 2 - Non-Reduced Risk Chemicals: NAFTA Priorities**  
**Group 3 - Negotiated Joint Review Chemicals**  
**Workshare Reviews**  
**Pilot Projects**

**PROJECT TEAM:** Canada: Mark Brohm, PMRA  
Mexico: Rocío Allatore, SALUD  
US: Anthony Gilbert, EPA

**INITIATION:** June 2000

**UPDATE:** August 2003

**GOAL:** **Group 1A and 1B:** To conduct the Joint Review of Reduced Risk Chemicals;  
**Group 2:** To conduct the Joint Review of Non-Reduced Risk Chemicals including organophosphate (OP) alternatives and other NAFTA priorities (e.g., methyl bromide alternatives);  
**Group 3:** To conduct the Joint Review of chemicals with negotiated time lines;  
**Workshare Review:** To share information, reviews, risk assessments, etc. on chemicals/products of interest to the NAFTA countries.  
**Pilot Projects:** To explore the potential for pilot projects under the joint review program.

### BACKGROUND/RATIONALE:

Joint reviews and work sharing are fundamental elements in the harmonization of pesticide regulatory programs, increasing the efficiency of the registration process, providing more equal access to pest management tools, strengthening the regulatory process and facilitating the registration of alternative pest control tools. The program is continuing to evolve as agencies and applicants build upon their experiences.

The joint review program was started in 1996 for new reduced risk chemicals with one technical and one end-use product and contained 1-2 uses within the same use pattern which were submitted simultaneously to the reviewing countries. This group has now been subdivided into two groups, Group 1A Joint Reviews and Group 1B Joint Reviews, which will be described later in this document. The program was expanded in 1999 to include a second group for certain non-reduced risk chemicals, including alternatives to organophosphate (OP) chemicals or NAFTA priority chemicals (e.g., methyl bromide alternatives). In 2000, a third group was added for negotiated joint reviews for chemicals that don't meet the specific criteria for the first two groups, but meet the basic criteria for a joint review, e.g., have identical submission/data packages that will be submitted to the agencies within the same timeframe.

The procedures for the Joint Review process have been amended to reflect this expansion. A critical necessity for successful joint reviews is early pre-submission consultation among the applicant and agencies involved. In addition to these three formal groups, considerable chemical-specific *ad hoc* information/work sharing also occurs amongst the NAFTA agencies. A copy of the expanded joint review process document, *Procedures for Joint Review Applications for Chemical Pesticides*, may be found on both the EPA website (<http://www.epa.gov/oppfead1/international/naftatwg>) and the PMRA website (<http://www.hc-sc.gc.ca/pmra-arla/>).

The Agencies continue to receive imaginative and constructive proposals from industry that go beyond current boundaries and provide opportunities to further expand and build upon joint review/work sharing experiences to date. While these new frontiers may initially entail challenges that preclude a totally synchronized outcome, they also provide the practical experience and learning opportunity for all partners that are essential to expanding the formal JR process.

## **DESCRIPTION OF JOINT REVIEW AND WORKSHARE REVIEW GROUPS:**

Group 1A Joint Reviews (Reduced Risk Chemicals\*) contain products with only one active ingredient and a maximum of two end-use products. Chemicals in this group will usually have a 12-month time line for evaluation and decision after passing the PMRA and EPA screens. (\*In order to be considered a Group 1 Joint Review, the proposed new active ingredient and the uses of the proposed formulated product must meet the US's criteria for a reduced-risk pesticide. EPA's reduced-risk program encourages the development, registration and use of lower risk pesticide products which would result in reduced risks to human health and the environment when compared to the existing pesticide alternatives.)

Group 1B Joint Reviews (Reduced Risk Chemicals) contain products with more than one active ingredient and/or two or more end-use products. Chemicals in this group will have time lines of 18 to 24 months for evaluation and decision after passing the PMRA and EPA screens.

Group 2 Non-Reduced Risk Chemicals: NAFTA Priorities contains non-reduced risk chemicals that are considered NAFTA priorities, e.g., organophosphate (OP) and methyl bromide alternatives. Chemicals in this group will usually have an 18-24 month schedule for evaluation and decision after passing the PMRA and EPA screens.

Group 3 Negotiated Joint Review Chemicals contains chemicals which do not meet the criteria for Group 1 or 2. Chemical submissions eligible for consideration at this time include those with electronic data submission components, OECD formats, multiple active ingredients and/or uses. Chemicals in this group will have negotiated time lines of 24 months or longer for evaluation and decision after passing the PMRA and EPA screens.

Workshare Reviews include the sharing of information, reviews, risk assessments, etc. (with the registrant's permission), e.g., for imported uses/tolerances, coordination of reviews/risk assessments for chemicals/uses that have different target decision dates for each country, etc.

Pilot Projects allow the exploration of new programs that may further the harmonization of the Joint Review process, such as joint review of minor uses and second entry joint reviews. Timelines for chemicals accepted into this Joint Review group will have negotiated review schedules for evaluation and decision after passing the PMRA and EPA screens.

## **STATUS REPORTS OF PRODUCTS:**

<b>COMPLETED (REGISTERED) JOINT REVIEWS</b>				
<b>ACTIVE INGREDIENT</b>	<b>REGISTRANT</b>	<b>PESTICIDE TYPE</b>	<b>USES</b>	<b>COMPLETION DATE</b>
Cyprodinil	Novartis	fungicide	fruit/nut crops	April 1998
Diflufenzopyr	BASF	herbicide	corn, non-agricultural sites	February 1999
Fenhexamid	Tomen Agro/ Bayer	fungicide	grapes, strawberry, ornamentals	May 1999
Zoxamide	Rohm & Haas/ Dow AgroSciences	fungicide	grapes, potato	March 2001-EPA May 2001-PMRA July 2001-Mexico
Acetamiprid	Novartis/Bayer	insecticide	cole/fruited/leafy vegetables, pome fruit, grapes, ornamentals	March 2002-EPA June 2003-PMRA
			canola/mustard seed treatment	Dec. 2003-PMRA Sept. 2003-EPA
Pyraclostrobin	BASF	fungicide	barley, blueberry, fruiting/ bulb/cucurbit/root vegetables, chickpea, grapes, lentil field bean & pea, potato, rye, stone fruit, strawberry, sugarbeet, wheat	Sept. 2002-EPA March 2003-PMRA
Mustard Seed Sodium Olefin Sulfonate	Exit Holdings, LLC	rodenticide	Control of Richardson's ground squirrels	March 2003-EPA April 2003-PMRA
Clothianidin	Bayer	insecticide	corn/canola seed treatment	May 2003
Famoxadone w/Cymoxanil	DuPont	fungicide	potato, tomato	May 2003-PMRA July/Aug. 2003-EPA
Boscalid	BASF	fungicide	beans, bulb/fruited vegetables, canola, carrots, grapes, lettuce, potato, stone fruit, strawberry, turf	June 2003-PMRA July 2003-EPA

ACTIVE INGREDIENT	REGISTRANT	PESTICIDE TYPE	USES	COMPLETION DATE
<b>COMPLETED NEW USES/SECOND ENTRY</b>				
Fenhexamid	Bayer/IR-4	fungicide	raspberry	April 2002-EPA April 2002-PMRA
<b>COMPLETED (REGISTERED) WORKSHARE REVIEWS (WSRs)</b>				
Sulfosulfuron	Monsanto	herbicide	wheat	March 1999-PMRA May 1999-EPA
Flucarbazone Sodium	Bayer	herbicide	wheat	March 2000-PMRA Sept. 2000-EPA
Thiamethoxam Seed Trt. Uses	Novartis	insecticide with fungicides	canola /mustard/sorghum seed treatment	Nov. 2000-PMRA Dec. 2000-EPA June 2003-PMRA (sorghum)
Helix/Helix Xtra w/ difenoconazole metalaxyl-M, and fludioxonil fungicides			cucurbit/fruited/tuberous & corn vegetables, pome fruit - foliar treatment	May 2001-EPA May 2001-PMRA Negative reg. decision
Foramsulfuron + Safener	Aventis/Bayer	herbicide	corn	March 2002-EPA April 2003-PMRA
Iodosulfuron - Methyl Sodium	Aventis/Bayer	herbicide	corn	Sept. 2002-EPA April 2003- PMRA
<b>COMPLETED IMPORT MRL/TOLERANCE WORKSHARE REVIEWS</b>				
Iprovalicarb	Bayer	Fungicide	imported grapes, raisin, wine	July 2002-PMRA Aug. 2002-EPA
Tolyfluanid	Bayer	Fungicide	imported apples, grapes, hops, tomato	Sept. 2002-EPA March 2003-PMRA
<b>CURRENTLY UNDER JOINT REVIEW</b>				
ACTIVE INGREDIENT	REGISTRANT	PESTICIDE TYPE	USES	TARGET REG. DECISION DATE
Spirodiclofen	Bayer	insecticide	pome/stone fruit, imported grapes	January 2005
<b>CURRENTLY UNDER WORKSHARE REVIEW</b>				
Novaluron (RIMON)	Makhteshim	insect growth regulator	pome fruit, potato	July 2004-EPA TBD-PMRA
Cyazofamid	ISK	fungicide	potato, imported grapes	Jan. 2004-EPA TBD-PMRA
<b>CURRENT SECOND ENTRY WORKSHARE REVIEWS</b>				
Propamocarb: potential tri-lateral w/Mexico	Bayer	fungicide	field & greenhouse cucurbits, lettuce, peppers, tomatoes	June 2004-EPA TBD-PMRA TBD-Mexico

<b>POTENTIAL JOINT REVIEWS</b>		
<b>PESTICIDE TYPE</b>	<b>USES</b>	<b>SUBMISSION DUE</b>
herbicide	corn	March 2003-EPA April 2003-PMRA
herbicide	barley, wheat	January 2004
herbicide	rangeland, pastureland, rights-of-way, cereal grains	March 2004
fungicide	barley, canola, wheat	May 2004
<b>POTENTIAL SECOND ENTRY/NEW USES WORKSHARE REVIEWS</b>		
fungicide	imported tomato-US; domestic tomato-MX	April 2003-EPA TBD-Mexico