

## PROJECT SHEET

**SUBCOMMITTEE:** Joint Review

**PROJECT TITLES:** **Joint Reviews:**  
**Group 1A—Joint Review of Reduced Risk Chemicals**  
**Group 1B—Joint Review of Reduced Risk Chemicals**  
**Group 2—Joint Review of Non-reduced Risk Chemicals: NAFTA Priorities**  
**Group 3—Joint Review of Chemicals with Negotiated Timelines**  
**Workshare Reviews**  
**Pilot Projects**

**PROJECT ID:** JR07-00-1005

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**INITIATION:** June 2000

**UPDATE:** May 2006

**GOAL:** **Group 1A and 1B:** To conduct the Joint Reviews of Reduced Risk Chemicals.  
**Group 2:** To conduct the Joint Reviews of Non-reduced Risk Chemicals including organophosphate alternatives and other NAFTA priorities (e.g., methyl bromide alternatives).  
**Group 3:** To conduct the Joint Reviews of Chemicals with Negotiated Timelines.  
**Workshare Reviews:** 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; they increase the efficiency of the registration process, provide more equal access to pest management tools, strengthen the regulatory process and facilitate the registration of alternative pest control tools. The program is continuing to evolve as agencies and applicants build upon their experiences.

In 1996, the joint review program was launched for new reduced-risk chemicals. At that time, one technical and one end-use product with 1–2 uses within the same use pattern were submitted simultaneously to the reviewing countries. This group has now been subdivided into two joint review groups, which will be described hereafter in this document: Group 1A and Group 1B. The program was expanded in 1999 to include a second group for certain non-reduced risk chemicals, including alternatives

to organophosphate chemicals or NAFTA priority chemicals (e.g., methyl bromide alternatives). In 2000, a third group was added for joint reviews of chemicals with negotiated timelines, which do not meet the specific criteria for the first two groups but meet the basic criteria for a joint review, i.e., 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 presubmission 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*, is available on both the United States Environmental Protection Agency (EPA) website (<http://www.epa.gov/oppfead1/international/naftatwg>) and Health Canada's Pest Management Regulatory Agency (PMRA) website ([http://www.pmr-arla.gc.ca/english/pubs/jnt\\_rev-e.html](http://www.pmr-arla.gc.ca/english/pubs/jnt_rev-e.html)).

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 joint review process.

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

Group 1A Joint Reviews of Reduced Risk Chemicals<sup>1</sup> contains 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.

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

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

Group 3 Joint Review of Chemicals with Negotiated Timelines contains chemicals that 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 timelines of 24 months or longer for evaluation and decision after passing the PMRA and EPA screens.

The Workshare Review Group includes 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.

The Pilot Project Group allows the exploration of new programs that may further the harmonization of the

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<sup>1</sup> To be considered in the Group 1 Joint Review, the proposed new active ingredient and the uses of the proposed formulated product must meet the EPA's criteria for a reduced risk pesticide. The EPA's reduced risk program encourages the development, registration and use of lower risk pesticide products that would result in reduced risks to human health and the environment when compared to the existing pesticide alternatives.

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—SSA <sup>2</sup>
Acetamiprid	Novartis/Bayer	Insecticide	Cole/fruitleafy 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	September 2002— EPA March 2003—PMRA
Mustard seed and sodium alfa-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 (with cymoxanil fungicide)	DuPont	Fungicide	Potato, tomato	May 2003—PMRA July/Aug. 2003—EPA
Boscalid	BASF	Fungicide	Beans, bulb/fruitleafy vegetables, canola, carrots, grapes, lettuce, potato, stone fruit, strawberry, turf	June 2003—PMRA July 2003—EPA
Spirodiclofen	Bayer	Insecticide	Pome fruit, stone fruit, grapes, citrus fruits and tree nuts	Feb. 2005—PMRA May 2005—EPA
Pinoxaden	Syngenta	Herbicide	Wheat and barley	July 2005—PMRA July 2005—EPA

<sup>2</sup>

SSA: Secretaría de Salud

<b>COMPLETED (REGISTERED) JOINT REVIEWS</b>				
Aminopyralid	Dow	Herbicide	Wheat, rangeland, pastureland and industrial vegetation management	June 2005—PMRA August 2005—EPA
Topramezone	BASF (Canada) AMVAC (U.S.)	Herbicide	Corn (field, sweet, and popcorn)	July 2005—PMRA August 2005—EPA
<b>COMPLETED NEW USES/SECOND ENTRY</b>				
Fenhexamid	Bayer/IR-4	Fungicide	Raspberry	April 2002—PMRA April 2002—EPA
Fenhexamid (minor use pilot project)	Bayer/IR-4	Fungicide	Ginseng	August 2005—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 September 2000—EPA
Thiamethoxam Seed Treatment Uses	Novartis	Insecticide with fungicides	Canola /mustard/sorghum Seed treatment	Nov. 2000—PMRA December 2000—EPA June 2003—PMRA (sorghum)
Helix/Helix Xtra with difenoconazole metalaxyl-M, and fludioxonil fungicides			Cucurbit/fruited/tuberous and 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
Cyazofamid	ISK	Fungicide	Potato, tomato, wine grapes and cucurbits	Nov. 2004—EPA March 2005—PMRA
Paraquat (new safer formulation)	Syngenta	Herbicide	Several registered uses	September 2005—EPA and CICOPLAFEST <sup>3</sup>

<sup>3</sup> CICOPLAFEST: Comisión Intersecretarial para el Control del Proceso y Uso de Plaguicidas, Fertilizantes y Sustancias Tóxicas

<b>COMPLETED IMPORT MRL/TOLERANCE WORKSHARE REVIEWS</b>				
Iprovalicarb	Bayer	Fungicide	Imported grapes, raisins and wine grapes	July 2002—PMRA August 2002—EPA
Iprovalicarb	Bayer	Fungicide	Tomatoes	September 2005— EPA and CICOPLAFEST
<b>CURRENTLY UNDER JOINT REVIEW</b>				
<b>ACTIVE INGREDIENT</b>	<b>REGISTRANT</b>	<b>PESTICIDE TYPE</b>	<b>USES</b>	<b>TARGET REG. DECISION DATE</b>
Polymeric betaine	Reutgers	Antimicrobial	Heavy duty wood preservative	Winter 2007
Prothioconazole	Bayer	Fungicide	Wheat, oats, barley, pulse	Summer 2006
XDE-175	Dow	Insecticide	Pome Fruit, Stone Fruit, Bulb Vegetables, Blueberries, Cole Crops, Fruiting Vegetables and Okra, Herbs, Leafy Vegetables, Caneberries, Potatoes, Tuberous, Corn Vegetables, Corn, Grape, Strawberries, Asparagus, Cucurbits, Cereals, Soybean	Fall 2007
BAY-309	Bayer	Herbicide	Spring wheat, durum wheat, winter wheat, spring barley, oats, triticale and timothy (for seed production only)	Summer 2007
<b>CURRENTLY UNDER WORKSHARE REVIEW</b>				
Novaluron	Makhteshim	Insect growth regulator	Pome fruit and potato	July 2004—EPA Winter 2006— PMRA
<b>CURRENT SECOND ENTRY WORKSHARE REVIEWS</b>				
NONE				
<b>POTENTIAL JOINT REVIEWS</b>				
<b>PESTICIDE TYPE</b>	<b>USES</b>			<b>SUBMISSION DUE</b>
Insecticide	Several uses			2005
Herbicide	Corn and wheat			2006
Insecticide	Wheat, oats, cucurbits, stone fruit, pome fruit			2007

<b>POTENTIAL SECOND ENTRY/NEW USES WORKSHARE REVIEWS</b>		
<b>PESTICIDE TYPE</b>	<b>USES</b>	<b>SUBMISSION DUE</b>
Herbicide	Wheat, barley and oats	2007