



**Joint Reviews – Conventional
Agricultural Chemicals
Work-share Reviews – Conventional
Agricultural Chemicals
Pilot Projects – Conventional
Agricultural Chemicals – Project
ID #: JR07-00-1005**

Initiated June 2000. Updated October 2009.

NOTE: This is the last update which will be made to this project sheet as the project has been completed and a NAFTA Joint Review Program for Conventional chemicals has been established.



Project Leads

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Goal/Objective

Joint Reviews: To conduct joint reviews of conventional agricultural chemicals for new active ingredients with the goal of a harmonized and simultaneous registration decision by all participating regulatory authorities.

Work-share Reviews: To share information, reviews, risk assessments, etc. as they become available on chemicals/products under review by the participating regulatory authorities.

Pilot Projects: To explore the potential for pilot projects under the Joint Review Program.

Project Description/Procedure

Joint Reviews (Conventional Chemicals)

The Joint Review program is a formal process with negotiated timelines, where the workload is split among participating regulatory authorities and the reviews of data are exchanged and peer-reviewed. The scope of the current Joint Review program that is the subject of this project sheet now includes all conventional agricultural chemicals

Work-Share Reviews

The Work-Share Review program is a formal process where the active ingredient(s) and associated end-use product(s) are not yet registered in any of the participating countries at the time that the dossier is submitted. (Note: As domestic timelines are followed, there may be different target decision dates within each participating jurisdiction). This allows (with the applicant's permission) for the sharing of information, reviews, and risk assessments, e.g., for imported uses/tolerances, coordination of reviews, etc.



Pilot Projects

The Pilot Project initiative allows the exploration of new programs that may further the harmonization of the joint review process, such as the joint review of minor uses and “second entry” joint reviews (i.e., the joint review of use expansions for active ingredients where the active ingredient(s) is already registered in participating countries).

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 evolving as regulatory authorities and applicants build upon their experiences.

In 1996, the joint review program was launched for new reduced-risk¹ chemicals. At that time, one technical and one end-use product with one to two uses within the same use pattern were submitted simultaneously to the reviewing countries. This program has now been expanded to include all conventional agricultural chemicals. 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 the participating regulatory authorities.

Regulatory authorities 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. While these situations 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 international regulatory cooperation.

Recent expansions of this NAFTA program have included trilateral joint reviews (e.g., involving Australia or a rapporteur state from the European Union) and “global” joint reviews involving a number of regulatory authorities (e.g., chlorantraniliprole). In addition, “second entry” joint reviews to accommodate use expansions are also being accepted.

¹ The proposed new active ingredient and the uses of the proposed formulated product must meet the EPA's criteria for a reduced-risk pesticide.



Status Report

Table 1: Completed Joint Reviews for New Active Ingredients and Associated End-Use Products				
Active ingredient	Registrant	Pesticide Type	Uses	Review Completion date
Cyprodinil (NAFTA)	Novartis	Fungicide	Apples and stone fruit.	April 1998 March 1998 -PMRA
Diflufenzopyr (NAFTA)	BASF	Herbicide	Corn, non-agricultural sites	February 1999 January 1999 – PMRA
Fenhexamid (NAFTA)	Tomen Agro / Bayer	Fungicide	Grapes, strawberry, ornamentals	May 1999
Zoxamide (NAFTA)	Rohm & Haas / Dow AgroSciences	Fungicide	Grapes, potato	March 2001—EPA May 2001—PMRA July 2001—SSA ²
Acetamiprid (NAFTA)	Aventis/Bayer	Insecticide	Cole/leafy vegetables, pome fruit, grapes, ornamentals, field	March 2002—EPA May 2002 —PMRA
			Canola/mustard seed treatment	Oct. 2002 —PMRA Sept. 2003—EPA
Pyraclostrobin (NAFTA)	BASF	Fungicide	Barley, blueberry, fruiting/ bulb/cucurbit/root vegetables, chickpea, grapes, lentil field bean & pea, potato, rye, stone fruit, strawberry, sugarbeet, wheat, faba bean, bluegrass/ fescues/ ryegrass grown for seed	Sept. 2002—EPA December 2002—PMRA
Mustard seed and sodium alfa-olefin sulfonate (NAFTA)	Exit Holdings, LLC	Rodenticide	Control of Richardson's ground squirrels	March 2003—EPA April 2003—PMRA

² SSA: Secretaria de Salud



Table 1: Completed Joint Reviews for New Active Ingredients and Associated End-Use Products

Active ingredient	Registrant	Pesticide Type	Uses	Review Completion date
Clothianidin (NAFTA)	Sumitomo Chemical Takeda Agro Company, Ltd./Bayer/Gustafson Partnership	Insecticide	Corn and canola/ rapeseed seed treatment	May 2003
Famoxadone (with cymoxanil fungicide) (NAFTA)	DuPont	Fungicide	Potato, field tomato	May 2003—PMRA July/Aug. 2003—EPA
Spirodiclofen (NAFTA)	Bayer	Insecticide	Pome fruit, stone fruit, grapes, citrus fruits and tree nuts	April 2005—PMRA May 2005—EPA
Pinoxaden (NAFTA)	Syngenta	Herbicide	Spring/Duram wheat and barley	July 2005—PMRA July 2005—EPA
Aminopyralid (NAFTA)	Dow	Herbicide	Wheat, rangeland, pastures, industrial and non-crop areas.	June 2005 —PMRA August 2005—EPA
Topramezone (NAFTA)	BASF/ AMVAC	Herbicide	Field	June 2005—PMRA August 2005—EPA
Prothioconazole (NAFTA)	Bayer	Fungicide	Barley, canola, chickpeas, lentils, rapeseed, oriental mustard and wheat	May 2006 – PMRA March 2007 - EPA
Pyrasulfotole (Canada, US and Australia)	Bayer	Herbicide	Spring wheat, durum wheat, winter wheat, barley, oats, triticale, and timothy (for seed production only)	August 2007 - EPA July 2007 - PMRA
Spinetoram (NAFTA)	Dow	Insecticide	Pome fruit, stone fruit, cole crops, fruiting vegetables, okra, leafy vegetables, caneberries, strawberries, asparagus, bushberries, root vegetables, cereals, leaves of root/tuber vegetables, grapes, and soybean	September 2007 – EPA October 2007 – PMRA
Pyroxulam (Canada, US and Australia)	Dow	Herbicide	Wheat	January 2008 – PMRA February 2008 -EPA



Table 1: Completed Joint Reviews for New Active Ingredients and Associated End-Use Products				
Active ingredient	Registrant	Pesticide Type	Uses	Review Completion date
Spirotetramat (Canada, US and EU/Austria)	Bayer	Insecticide	Pome fruit, grape, tree nuts, stone fruit, hops, cucurbit vegetables, fruiting vegetables, brassica and non-brassica leafy vegetables, potato and other tuberous and corm crops	June 2008 – PMRA EPA?
Chlorantraniliprole (Canada, US and several other countries)	Dupont	Insecticide	Pome fruits, stone fruits, grapes, potatoes, fruiting vegetables, <i>Brassica</i> vegetables, leafy vegetables, and turf.	April 2008 – PMRA EPA?
Thiencarbazone-methyl (done in conjunction with Joint Review of the safener cyprosulfamid) (Canada, US, EU/United Kingdom)	Bayer	Insecticide	Corn and sorghum	July 2008 – PMRA October 2008 - EPA
Saflufenacil (Global)	BASF	Herbicide	General purpose herbicide, for field and row crops, orchards, groves and vineyards crops, harvest aid (dessicant) and non-crop uses	July 2009 – PMRA ? - EPA

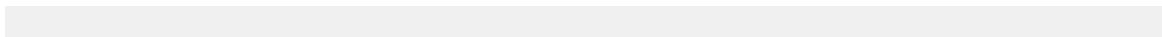


Status Report (Cont'd)

Table 2: Completed Minor Uses for Already Registered Active Ingredients				
Active ingredient	Registrant	Pesticide Type	Uses	Review Completion date
Fenhexamid (minor use pilot project)	Arysta	Fungicide	Raspberry	April 2002—PMRA (represents reg. date) April 2002—EPA
Fenhexamid (minor use pilot project)	Arysta	Fungicide	Ginseng	March 2006 – EPA August 2005— PMRA (represents reg. date)
S-metolachlor	Syngenta	Herbicide	Pumpkin and winter squash	EPA – tolerance established August 30, 2006 and use registered September 28, 2006 PMRA – December 2006 (represents reg. date)
Imidacloprid	Bayer	Insecticide	Caneberry	August 2006 – EPA October 2006- PMRA(represents reg. date)
Cymoxanil and famoxadone	Dupont	Fungicide	Caneberry	September 2007 – EPA September 2007 – PMRA(represents reg. date)
Fenamidone	Bayer	Fungicide	Carrot	September 2007 – EPA. PMRA-Screened out due to inadequate efficacy data



Table 2: Completed Minor Uses for Already Registered Active Ingredients				
Active ingredient	Registrant	Pesticide Type	Uses	Review Completion date
Cymoxanil Famoxadone	E.I. DuPont Canada	Fungicide	Celery	May 2008 – PMRA Rejected
Fluazinam	ISK Biosciences Corp.	Fungicide	Blueberry	June 2008- PMRA(represents reg. date) EPA – March 2008
Fluazinam	ISK Biosciences Corp.	Fungicide	Brassica (Cole) Leafy Vegetables	June 2008-PMRA (represents reg. date). EPA – March 2008
Cyazofamid	ISK Biosciences Corp.	Fungicide	Carrot	July 2008-PMRA (represents reg. date). EPA August 2008
Fluazinam	ISK Biosciences Corp.	Fungicide	Snap Beans	Sept. 2008-PMRA (represents reg. date). EPA March 2008
Acetamiprid	Nippon Soda Company Ltd.	Insecticide	Strawberry	Aug 2009 – PMRA Registered EPA ?





Status Report (Cont'd)

Active ingredient	Registrant	Pesticide Type	Uses	Review Completion date
Iodocarb (NAFTA)	ISP Canada Corp.	Fungicide – Material preservative	New source of active ingredient	Dec 2007—PMRA EPA ? CIOCPLAFEST ³ ?

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



Status Report (Cont'd)

Table 4: Completed (registered) Workshare Reviews				
Active ingredient	Registrant	Pesticide Type	Uses	Review Completion date
Sulfosulfuron	Monsanto	Herbicide	Wheat	February 1999-PMRA May 1999—EPA
Flucarbazone Sodium	Bayer	Herbicide	Wheat	February 2000-PMRA September 2000—EPA
Thiamethoxam Seed Treatment Uses	Novartis	Insecticide with fungicides	Canola /mustard/sorghum seed treatment	Nov. 2000—PMRA December 2000—EPA Mar 2002 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	Herbicide	Corn	March 2002—EPA April 2003—PMRA
Iodosulfuron—Methyl Sodium	Aventis	Herbicide	Corn	Sept. 2002—EPA April 2003—PMRA
Clothianidin , carbathiin, metalaxyl, thiram	Bayer	Insecticide, fungicide	Canola, rapeseed	Sept. 2003 – PMRA EPA?
Cyazofamid	ISK	Fungicide	Potato	Nov. 2004—EPA March 2005—PMRA
Novaluron	Makhteshim	Insecticide	Apple and potato	July 2004 – EPA November 2006-PMRA
Paraquat (new safer formulation)	Syngenta	Herbicide	Several registered uses	September 2005—EPA and CICOPLAFEST



Table 4: Completed (registered) Workshare Reviews				
Active ingredient	Registrant	Pesticide Type	Uses	Review Completion date
Mandipropamid	Syngenta	Fungicide	Brassica, bulb vegetables, curcurbits, peppers, tomatoes, potatoes, leafy vegetables and grapes	August 2008 – PMRA EPA?

Status Report (Cont'd)

Table 5: Completed import MRL / Tolerance Workshare Reviews				
Active ingredient	Registrant	Pesticide Type	Uses	Review Completion date
Iprovalicarb	Bayer	Fungicide	Imported grapes, raisins and wine grapes	July 2001 PMRA August 2002—EPA
Iprovalicarb	Bayer	Fungicide	Tomatoes	September 2005—EPA and CICOPLAFEST
Boscalid	BASF	Fungicide	Pistachios, almonds, pecans, tropical fruits, coffee	July 2003 PMRA EPA?
Thiencarbazone -methyl	Bayer	Herbicide	Popcorn, sweet corn, field corn, wheat, soybean seed, milk, animal commodities	May 2009 PMRA EPA ? UK PSD ?



Status Report (Cont'd)

Table 6: Currently Under Joint Review for New Active Ingredients and Associated End-Use Products				
Active Ingredient	Registrant	Pesticide Type	Proposed Uses	Target Regulatory Decision Date
Thiencarbazon e-methyl + tembotrione (Global)	Bayer	Herbicide	Corn	July 2008
Fluopyram (Global)	Bayer	Fungicide	Strawberries, tomatoes and grapes, dried shelled pea and beans, rapeseed, brassica leafy vegetables (Crop Group 5), leafy green vegetables (Crop Subgroup 4A), leafy petiole vegetables (Crop Subgroup 4B), bulb vegetables, grapes, pome fruit (Crop Group 11), caneberries, bushberries, low-growing berries, strawberries (Crop Subgroups 13A, 13B, 13G), tomato	February 2010
Pyroxasulfone (Global)	K-I Chemical USA	Herbicide	Corn (field, pop and sweet), soybean and wheat	October 2010



Status Report (Cont'd)

Active Ingredient	Registrant	Pesticide Type	Proposed Uses
Novaluron	Makhteshim/IR-4	Insect growth regulator	Leafy Brassica Greens (Crop Group 5B), Stone Fruits (Crop Group 12), Bell And Non Bell Pepper, Snap Bean, Strawberry
Fluazinam IKF-1216	ISK Biosciences Corp.	Fungicide	Carrot, Apple



Status Report (Cont'd)

Table 8: Current New Uses / Second Entry for Already Registered Active Ingredients				
Active Ingredient	Registrant	Pesticide Type	Proposed Uses	Target Reg. Decision Date
Clothianidinimi dicloprid (NAFTA)	Bayer	Insecticide	Vegetable and cereal seeds, Potato seed piece treatment	November 2009
Spirotetramat (Global)	Bayer	Insecticide	Soybean, legume vegetables	December 2009
Azoxystrobin, Fludioxonil, Metalxyl-M, Thiabendazole (NAFTA)	Syngenta	Fungicide	Seed treatment for corn	March 2010



Status Report (Cont'd)

Table 9: Currently Under Work-Share Review				
Active Ingredient	Registrant	Pesticide Type	Proposed Uses	Target Reg. Decision Date
Metrafenone	BASF	Fungicide	Grapes	Spring 2010
Chlorantranili-prole (NAFTA)	Du Pont	Insecticide	<ul style="list-style-type: none"> • Tuberous and Corn Vegetables – Crop SubGroup 1C • Legume Vegetables – Crop Group 6 • Cucurbit Vegetables – Crop Group 9 • Corn – Field, Pop, and Seed • Grass, Forage, Fodder, and Hay Group – Crop Group 17 • Non-Grass Animal Feeds Group – Crop Group 18 • Herbs and Spices – Crop Group 19 • Oilseeds, including Crambe, Hare's ear mustard, Jojoba, Lesquerella, Lunaria, Milkweed, Mustard, Oil radish, Poppy seed, Rapeseed, Canola, Rose hip, Sesame, Tallowwood, Tea oil plant • Mint • Artichoke • Okra • Asparagus • Peanuts 	December 2009



			<ul style="list-style-type: none">• Hops• Tobacco Import MRLs for: <ul style="list-style-type: none">• Rice• Crop Group 10 – Citrus Fruit Group• Tropical Fruits - including atemoya, avocado, banana/plantain, biriba, black sapote, canistel, cherimoya, custard apple, feijoa, figs, guava, ilama, longan, Spanish lime, mango, marney sapote, persimmon, pomegranate, pulasan, rambutan, sapodilla, soursop, star apple, starfruit, sugar apple, wax jambu; grapefruit, pummelo and all grapefruit/pummelo citrus hybrids; white sapote (Casimiroa) and other cultivars and/or hybrids of white sapote, acerola, jaboticaba, lychee, papaya and passionfruit• Pineapple• Cacao• Sugarcane• Olive• Ti palm• Coffee• Prickly pear cactus	
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Status Report (Cont'd)

Table 10: Current Import MRL / Tolerance Joint Review or Work-Share Reviews				
Active Ingredient	Registrant	Pesticide Type	Proposed Uses	Target Regulatory Decision Date
Ethiprole (Global JR)	Bayer	Insecticide	Rice, dried tea, milk, egg, mammal and poultry commodities	October 2010
Fluopyram (Global JR)	Bayer	Fungicide	Almond, pistachio, banana, citrus, undelinted cotton seed	Summer 2010

Table 11: Potential Joint Reviews for New Active Ingredients and Second Entry New Uses
JR projects in the discussion stage for potential submission over the next 3 years include: 4 insecticides, 6 fungicides, 2 herbicides and 1 plant growth regulator.