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## **Minor Use Joint Review Procedures Document – Project ID #: JR04-04- 0809**

Initiated 2004. Updated September 2009

**Canada** 



Project Leads

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### Goal/Objective

To develop a registration process that will permit a regulatory decision of pesticide uses for the minor use grower communities in both countries simultaneously in an eight-month timeframe. All candidates will be chosen from projects conducted jointly by Interregional Research Project No. 4 (IR-4) and Agriculture and Agri-Food Canada (AAFC) using the NAFTA Field Trial Region map.

The first pilot candidates were successfully registered following the draft Standard Operating Procedure (SOP) developed for the new process for registering minor uses. The draft SOP was finalized based on the experiences gained while reviewing the pilot candidates. However, with the goal of accommodating a greater number of simultaneous joint review regulatory decisions the SOP was revised in November of 2008 to address issues that arose during 2007 and 2008 review cycle. PMRA and EPA have also implemented a work-share process for those chemicals/crops that can not be completed as a joint review but data were developed by both AAFC and IR-4. A work-share process has been developed to review the residue chemistry data and ensure both EPA and PMRA agree on the level for MRLs.

The United States Environmental Protection Agency (EPA) and Health Canada Pest Management Regulatory Agency (PMRA) have completed review for eleven joint review projects, have nine projects pending and have identified the next candidates for review in 2009 and 2010 cycle.

### Project Description/Procedure

Since 1996, IR-4 and AAFC have cooperatively conducted joint residue trials for minor use projects identified by the minor use grower communities in both countries as pest solution priorities. Previously, the submission, review and registration of the petitions using this jointly developed residue data occurred independently in each country. Often, these new minor uses would be registered in the United States before they received registration in Canada, resulting in trade irritant issues. To address this issue and benefit from the efficiencies of conducting joint projects, it was proposed that the EPA and the PMRA develop a registration process to permit the joint review of these cooperatively conducted projects such that registration



would occur simultaneously in both countries. The goal was to develop an SOP to reach a regulatory decision in eight months.

### **Background/Rationale**

Conducting joint minor use residue trials using the NAFTA field residue trial map has reduced the number of trials required in both countries while at the same time satisfying the data requirements of both countries. To maximize these gains in efficiencies, the next logical step is to ensure that the registration of these new minor uses provides minor use growers in both countries with concurrent access to the products. A process has been developed such that the PMRA and the EPA working cooperatively will be able to reach a simultaneous regulatory decision in eight months for these joint minor uses.



## Workplan

GOAL	ACTIVITIES	TIME FRAME
Draft joint review SOP	Based on PMRA and EPA established review procedures, cooperatively develop a draft SOP that permits the review of minor use petitions within an eight-month timeframe.	April 2005
Conduct joint review of pilot candidate	The first candidate, fenhexamid for use on ginseng, was identified and reviewed using the draft SOP. The EPA took the lead in conducting the review of the food residue and dietary risk assessment of the pilot candidate. The product was successfully registered meeting the proposed goal of a regulatory decision in eight months.	September 2005
Conduct joint review of second pilot candidate	The second candidate, s-metolachlor for use on winter squash / pumpkin, was successfully registered in the fall of 2006 and was received by both agencies in January 2006.	November 2006
Revisit draft SOP	Any proposed changes resulting from the experiences gained will be discussed and the draft SOP revised.	December 2006
Conduct joint minor use reviews using accepted SOP	Please see the attached tables EPA and PMRA will meet to determine the lead review agency for review of these projects. In cooperation with IR-4 and AAFC, discussions to identify possible candidates for submission in 2010 were held at the Food Use Workshop in Cleveland	2007 and ongoing



	September 2009.	
EPA and PMRA revised SOP	The SOP was revised to address issues that have arose with the joint reviews in 2007 and 2008 with the goal of accommodating a greater number of simultaneous joint review regulatory decisions in the future. The two agencies also implemented a work-share process for those chemicals/crops that can not be completed as a joint review.	November 2008
AAFA and IR-4 will draft SOP	AAFC and IR-4 will draft a SOP to ensure both EPA and PMRA receive the same data set for review and to provide updates when the expected submission date is going to change.	2010

**Registered Pesticides**

Active Ingredient	Pesticide Type	Product	Registrant	Crop	Registration Date CANADA	Registration Date UNITED STATES
Fenhexamid	Fungicide	Elevate 50WDG	Arysta	Ginseng	August, 2005	February, 2007
S-Metolachlor	Herbicide	Dual Magnum	Syngenta	Winter squash, pumkin	December, 2006	March 21, 2008
Cymoxanil Famoxadone	Fungicide	Tanos	Du Pont	Caneberry	September, 2007	September, 2007
Imidacloprid	Insecticide	Admire 240	Bayer	Caneberry	October, 2007	October, 2007
Cyazofamid	Fungicide	Ranman 400SC	ISK	Carrot	July, 2008	August, 2008
Fluazinam	Fungicide	Allegro 500F	ISK	Blueberry	June, 2008	June, 2008
Fluazinam	Fungicide	Allegro	ISK	Brassica	June, 2008	June, 2008



		500F		cg5		
Fluazinam	Fungicide	Allegro 500F	ISK	Edible-podded legume vegetables	September, 2008	March, 2008
Acetamiprid	Insecticide	Assail 70 WP	Nippon	Strawberry	November, 2009	January, 2008
Fenamidone	Fungicide	Reason 500SC	Bayer	Carrot	Rejected in Canada due to efficacy	October, 2007
Cymoxanil Famoxadone	Fungicide	Tanos	Syngenta	Celery	Rejected in Canada due to occupational exposure issues	April 2009

**Completed WORKSHARE**

Active Ingredient	Pesticide Type	Product	Registrant	Crop	Registration Date CANADA	Registration Date UNITED STATES
Thiamethoxam	Insecticide	Platinum Insecticide, Actara, Cruiser	Syngenta	Sugar Beet	Label Review	

**Active Joint Review Submissions**

Active Ingredient	Pesticide Type	Product	Registrant	Crop
Novaluron	Insect Growth Regulator	Rimon 10EC	Makhteshim	Mustard Greens and Stone Fruits
Novaluron	Insect Growth Regulator	Rimon 10EC	Makhteshim	Stone Fruits
Novaluron	Insect Growth Regulator	Rimon 10EC	Makhteshim	Snap Bean
Novaluron	Insect Growth Regulator	Rimon 10EC	Makhteshim	Bell and Non Bell Pepper
Novaluron	Insect Growth Regulator	Rimon 10EC	Makhteshim	Strawberry
Fluazinam	Fungicide	Allegro 500F	ISK Biosciences	Apple
Fluazinam	Fungicide	Allegro	ISK Biosciences	Carrot



		500F		
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**Active Workshare**

<b>Active Ingredient</b>	<b>Pesticide Type</b>	<b>Product</b>	<b>Registrant</b>	<b>Crop</b>
Clethodim	Herbicide	Select EC	Arysta	Blueberry
S-Metolaclor	Herbicide	Dual Magnum	Syngenta	Carrot
Acetamiprid	Insecticide	Assail	Nippon Soda	Grape
Triflusulfuron Methyl	Herbicide	Upbeet	DuPont	Garden Beet
Lamda-Cyhalothrin	Insecticide	Matador 120EC	Syngenta	Carrot
S-Metolaclor	Herbicide	Dual Magnum	Syngenta	Mustard Green
S-Metolaclor	Herbicide	Dual Magnum	Syngenta	High Bush Blueberry
Acetamiprid	Insecticide	Tristar 70 WSP	Nippon Soda	ghTomato