



May 26, 2016

Pest Management Regulatory Agency Publications Section
Pest Management Regulatory Agency (PMRA)
Health Canada
2720 Riverside Drive
Ottawa, Ontario
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Via E-mail: PMRA.publications@hc-sc.gc.ca

Re: Proposed Re-evaluation Decision PRVD2016-07, Thiram

To Whom It May Concern:

The American Seed Trade Association (ASTA) wishes to raise strong concerns about the announcement made by the Canadian Pest Management Regulatory Agency (PMRA) regarding its intention to cancel the registration for Thiram for use as a seed treatment. Founded in 1883, ASTA's mission is to enhance the development and movement of quality seed worldwide. ASTA's diverse membership consists of over 700 companies involved in seed production, distribution, plant breeding and related industries in North America. ASTA represents all varieties of seeds, including grasses, forages, flowers, vegetables, row crops and cereals. The cancellation of the registration for Thiram will have a significant impact on U.S. seed suppliers, Canadian seed dealers and commercial vegetable growers in Canada. Our analysis of PMRA's risk assessment uncovered a number of assumptions that are incorrect based on our knowledge of the seed production and seed treatment industries and usage patterns for Thiram in Canada. We believe the risk assessment greatly over-estimated the amount of Thiram used as seed treatment in Canada and the potential exposure from Thiram-treated seed.

Thiram is widely used as a seed treatment on vegetable seed that is treated in the U.S. and then exported to Canada. It is important to note that nearly all of the vegetables that are grown in Canada are raised from seed that is imported into the country from the U.S, Europe and Asia. The Canadian climate is inhospitable to vegetable seed production which requires dry, full year growing conditions. U.S. sales of vegetable seeds to Canada have been valued at approximately \$40 million **annually** since 2011¹ The vast majority of that seed is treated with Thiram, so our member companies have significant interest in the regulation of Thiram in Canada. (Our own informal polling of our member companies did

¹ USDA Foreign Agricultural Service Global Agricultural Trade System
<http://apps.fas.usda.gov/GATS/default.aspx>

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not reveal the use of Thiram as a seed treatment for canola, dry beans, rye, flax or wheat seed exported to Canada despite the focus on these crops in the risk assessment.)

Given the substantial amount of exports from the U.S. to Canada, it is unfortunate that the registration review process for Thiram in Canada is far out of step with the U.S. Environmental Protection Agency (EPA) and the European Food Safety Authority (EFSA). EPA published its reregistration eligibility decision for Thiram in September 2004, and Thiram continues to be registered and sold in the U.S. PMRA utilized a 1000 fold risk factor in preparing its risk assessment. This was not used by the European Food Safety Authority, and Thiram continues to be allowed to be sold and used in the E.U. We also note that the current procedures used by PMRA to announce the results of the risk assessment prior to accessing data from the registrant have placed an unfortunate cloud of concern over Thiram, which has been safely used for decades. In fact, Thiram has been used as a seed treatment since the 1930's² and has been registered in Canada since 1960.

Thiram is the preferred choice as a seed treatment for vegetable seed exporters because of its broad functionality, low cost, and the extensive list of countries where it is registered. In many cases there are not equivalent substitutes available. Thiram is one of the few broad spectrum seed treatment fungicides remaining on the market. It controls a wide range of fungi and has multi-site contact activity to protect the seed and seedling from decay. Fungi do not build up resistance to Thiram so it is an essential part of a resistance management program, particularly in combination with other fungicides. Newer fungicides are very narrowly targeted to specific pests. Without the ability to use Thiram in combination with these more targeted fungicides, there may be a greater risk of development of resistance to certain fungicides. Thiram is considered a valuable tool in many other countries to address phytosanitary concerns related to imported seed. Both Chile and Mexico require certain seeds to be treated and Thiram is a widely-used option for this purpose.

Due to the small volume of product needed to treat vegetable seed and the high cost of registering a pesticide for use on a single crop, the economics of providing seed treatments for vegetable seed can be challenging. Certain alternatives to Thiram are known to be 300% more expensive. Furthermore, alternative products, where they exist, would need to be registered in Canada and the country of origin. As a net importer of vegetable seed, Canadian farmers will be put at a disadvantage to producers in other countries if approved fungicides are not available or if seed suppliers must use higher cost alternatives.

As mentioned previously, Thiram is registered broadly around the globe allowing companies to efficiently manage trade of Thiram-treated seed. If Thiram is not allowed in Canada, seed companies will be required to establish separate inventories of seed to address Canada's specific restrictions or choose to stop supplying the market. The net result would be fewer options for Canadian growers. Companies would be forced to sell a limited number of varieties that were either untreated or treated with more expensive fungicides.

² The Role of Seed Treatment in Modern U.S. Crop Production. Washington, DC: CropLife Foundation, 2013. Print.

Selling untreated seed to Canada would not be a desirable outcome as it would potentially result in more worker and environmental exposure to pesticides. Farmers may choose to do the treatment themselves in a planter box or Canadian seed dealers may start to do their own small batch seed treatments. Farmers may also need to apply additional foliar fungicide sprays in the field to control disease, adding to the amount of pesticides in the environment.

The benefit of seed treatment is that it allows a very small and precise application of an active ingredient to protect against early season pests to protect seeds and seedlings at a critical stage in their development. This provides both an economic and environmental benefit in comparison to foliar or soil applications. Vegetable seed is very small. The number of pounds of seed that are actually being planted throughout the entire horticultural sector of Canada is quite small and the amount of Thiram being used is a small fraction of that weight. The horticulture industry is concentrated on approximately 250,000 acres in Canada compared to wheat plantings of about 24 million acres. Based on an analysis of proprietary industry data and CANSIM data from Statistics Canada, we estimate that approximately 3,400 pounds of Thiram total are used annually as seed treatment on vegetable crops in field production in Canada (Table 1).³ Greenhouse production, primarily of cucumbers and tomatoes, increases that figure by less than 5 pounds. This usage equates to less than half an ounce of Thiram per acre of production in Canada.

Again, it is important to note that the treatment of vegetable seed is taking place outside of Canada, usually in specialized seed treatment facilities. There are no known commercial vegetable seed treatment facilities in Canada. The seed treatment industry is constantly evolving to improve seed treatment processes and minimize risk. Potential worker and environmental exposure is reduced through the addition of polymer film coatings that are added at the time of seed treatment to create a shell around the treated seed that controls dust off during planting. In addition, ASTA as well as our counterpart, the Canadian Seed Trade Association, have developed and distributed guides for farmers and seed treaters for proper handling of treated seed. An important part of those recommendations is the use of Personal Protective Equipment (PPE) including gloves, long-sleeves and pants when treating or planting treated seed.^{4,5}

Because treatment of vegetable seed using Thiram is occurring in the U.S. and the amount of vegetable seed planted in Canada is low, we believe the assumptions related to occupational exposure in the risk assessment are incorrect. The risk assessment also does not appear to have taken the use of PPE into account when calculating exposure. We note that PMRA used a Dermal Absorption value of 50% since no studies were on file to estimate the potential dermal absorption. We understand the registrant for

³ Statistics Canada. *Table 004-0215 - Census of Agriculture, vegetables (excluding greenhouse vegetables), every 5 years*, CANSIM (database). (accessed:) <http://www5.statcan.gc.ca/cansim/a26?lang=eng&id=40215>

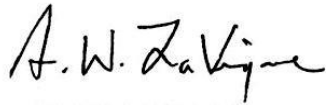
⁴The Guide to Seed Treatment Stewardship
<http://seed-treatment-guide.com/>

⁵ Guide to Treated Seed Stewardship <http://cdnseed.org/wp-content/uploads/2015/05/Guide-to-Treated-Seed-Stewardship-May-20151.pdf>

Thiram has data on dermal exposure, which they will present to PMRA, and also that there is a wide gap between what is seen toxicologically following dermal exposure and the 50% dermal absorption value.

We support the continued registration of Thiram for use as a seed treatment in Canada. Thiram as a seed treatment for vegetables has significant economic benefits for Canadian farmers and consumers. We hope that PMRA will take into consideration new information presented by the registrant and also the small amount of Thiram that is used on vegetable seed grown in Canada, prior to making a final determination on its registration as a seed treatment.

Sincerely,

A handwritten signature in black ink that reads "A.W. LaVigne". The signature is written in a cursive style with a large, stylized initial "A".

Andrew W. LaVigne
President & CEO

Table 1.

		Field Production of Fresh Vegetables												
Source	Application Rate 75-WP Thiram	Thiram Load of Rate 75-WP	CANSIM Table-004- 004-0215	CANSIM Table-004- 0215	Farms Reporting	Seed Count	Commercial Planting Rates	Seeds required to sow total Acres in Canada	MS	Quince will treat How Many Seed	Crop Usage of Thiram based on Industry Knowledge	Total Quinces to Treat Canadian Acres	Commercial Plantings	Predominate Treatment
	Quinces/100LB	Quinces/100LB	Acres	Acres		MS/LB	MS/Acre	MS	MS/Quince	%	Quinces			
Beets	PMBA	5.76	3,841	2,294	2,294	33.5	300.0	1,153,200.0	775.5	90%	1,338.4 Direct Seed	Thiram		
Broccoli	PMBA	5.76	10,266	1,265	1,265	100.0	20.0	205,320.0	2,314.8	90%	79.8 Transplant	Thiram		
Brussel Sprouts	PMBA	5.76	1,673	488	488	82.0	15.0	25,095.0	1,898.1	90%	11.9 Transplant	Thiram		
Cabbage	PMBA	5.76	4,32	10,269	1,583	111.0	15.0	154,055.0	2,569.4	90%	54.8 Transplant	Thiram		
Carrots	PMBA	5.76	23,426	2,486	2,486	250.0	500.0	11,713,000.0	5,787.0	70%	1,416.8 Direct Seed	Thiram, Thiram, Royal (PRODUCTION)		
Cauliflower	PMBA	5.76	4.32	1,829	971	95.0	15.0	27,435.0	2,199.1	90%	11.2 Transplant	Thiram		
Cauliflowers	PMBA	3.2	2.4	5,781	2,427	16.0	8.0	46,248.0	666.7	50%	34.2 Direct Seed	Thiram and F400		
Edible Beans	PMBA	4.16	1,000	0	0	105.0	6.0	6,000.0	3,365.4	90%	1.6 Transplant	Thiram & F300		
Green and Wax Beans	PMBA	1.6	1.2	20,996	2,599	2.0	100.0	2,099,600.0	166.7	50%	6,298.8 Direct Seed	Mostly Capran, Some - MEFENOXAM, FLUDIOXONIL, THIRAM		
Green Peas	PMBA	1.6	29,565	2,066	2,066	1.5	1,500.0	44,347,500.0	125.0	10%	35,478.0 Direct Seed	Mostly Capran, Some Thiram		
Lettuce	PMBA	5.76	4.32	8,358	1,753	320.0	52.0	434,616.0	7,407.4	10%	5.9 Direct Seed	Thiram, F300		
Melon	PMBA	3.2	2.4	1,000	0	14.0	3.0	3,000.0	583.3	90%	4.8 Transplant	Thiram & F300		
Melons Cuckling	PMBA	5.12	3,84	14,647	1,871	95.0	300.0	4,394,100.0	2,474.0	90%	1,598.5 Direct Seed	Thiram		
Onions Shallots and Green	PMBA	4.16	3.12	2,070	1,082	200.0	500.0	1,035,000.0	6,410.3	90%	145.3 Direct Seed	Thiram		
Peppers	PMBA	5.76	4.32	8,503	2,239	60.0	4.0	87,360.0	69.4	50%	56.6 Transplant	F400 and Thiram		
Pumpkins	PMBA	5.76	4.32	2,012	937	45.0	450.0	905,400.0	1,041.7	90%	78.2 Direct Seed	Thiram		
Radishes	PMBA	5.76	4.32	4,470	992	100.0	100.0	447,000.0	2,314.8	90%	173.8 Direct Seed	Thiram		
Rutabagas & Turnips	PMBA	5.76	4.32	1,670	1,035	45.2	300.0	501,000.0	1,046.3	90%	430.9 Direct Seed	Thiram		
Squash & Zucchini	PMBA	3.2	2.4	7,154	2,806	3.9	3.0	21,462.0	120.8	50%	88.8 BOTH	F400 and Thiram		
Sweet Corn	PMBA	3.52	2.64	57,262	2,997	3.2	20.0	1,145,240.0	1,212	70%	6,613.8 Direct Seed	Mostly Capran and Thiram, Apron, Dividend		
Tomatoes	PMBA	4.16	3.12	18,344	3,704	180.0	8.0	146,752.0	5,769.2	90%	22.9 Transplant	Thiram		
Watermelon	PMBA	3.2	2.4	2,000	0	8.0	2.0	4,000.0	333.3	90%	10.8 Transplant	Thiram & F300		
MS = 1,000 seeds														
Commercial Seeding rate - per member experience in the field														
Seed Count - Industry information														
CANSIM - Statistics Canada http://www5.statcan.gc.ca/cansim/2467lang-eng&rentlang-eng&id=0040215&tabMode=dataTable&clan=1&p1=1&p2=9														