

Imidacloprid - Registration of New Imidacloprid Products in New York State as Restricted-Use Products 10/04

New York State Department of Environmental Conservation

Division of Solid & Hazardous Materials

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October 29, 2004

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Ms. Margaret Cherny
Vice President, Government Relations and Communications
Bayer CropScience, LP
Research Triangle Park
P.O. Box 12014
Research Triangle Park, North Carolina 27709

Dear Ms. Cherny:

Re: Registration of New Imidacloprid Products in New York State as Restricted Use Products:

Merit 75 WP Insecticide (EPA Reg. No. 432-1314)

Merit 75 WSP Insecticide (EPA Reg. No. 432-1318)

Prokoz Zenith 75 WSP Insecticide (EPA Reg. No. 432-1318)

Lesco Bandit 75 WSP Insecticide (EPA Reg. No. 432-1318)

Touchstone 75 WSP Insecticide (EPA Reg. No. 432-1318)

Merit 0.5 G Insecticide (EPA Reg. No. 432-1328)

Merit 2.5 G (EPA Reg. No. 432-1376)

The New York State Department of Environmental Conservation (Department) registered the active ingredient imidacloprid in March 1995. The professional nursery, turf, ornamental and agricultural uses were registered in the spring of 1995, while the consumer turf use was registered in January 1996. As indicated in our registration decision letter dated March 24, 1995, after review of the technical studies submitted, the Department had concerns regarding the long-term environmental fate and environmental persistence of the active ingredient imidacloprid and degradates when used over sole source aquifers. Groundwater modeling performed by the Department prior to the registration of imidacloprid indicated the potential for accumulation and persistence of imidacloprid and its degradates in groundwater after repeated annual applications. The Department was especially concerned about the use of imidacloprid on Long Island which has been identified as a sole-source aquifer. The letter also stated that the continued registration of all imidacloprid products within New York State will be dependent upon the annual review of groundwater monitoring data collected within the Long Island aquifer.

In a registration letter dated October 24, 1996, the Department again expressed its concerns. Imidacloprid is

persistent and potentially mobile. Soil degradation is slow, with half-lives ranging from 120-365 days. While photolysis in water is very rapid, with a half-life of 4.2 hours, imidacloprid is stable to hydrolysis. Field dissipation studies performed by the registrant for the Merit products indicate that imidacloprid can dissipate fairly quickly from the soil application zone. Due to the leaching potential, combined with its persistence, the potential distribution and widespread use of imidacloprid in New York State, both the Department's Division of Water and the New York State Department of Health expressed concerns regarding the potential for multi-year residue build-up in groundwater.

The Department has been working closely with the Suffolk County Department of Health Services (SCDHS) and has provided funding to the county for groundwater monitoring in Nassau and Suffolk Counties. When the Quality Assurance Project Sampling Plan (QAPP) entitled "Imidacloprid Groundwater Monitoring Project Plan" was signed by representatives from Bayer CropScience and the Department in 1996, an "action threshold" of 25 ppb (half of the New York State drinking water standard) was discussed and agreed upon. The intent of the monitoring was to detect levels of imidacloprid in the groundwater directly beneath the site specified and being used at maximum label rates in conjunction with the groundwater monitoring project. In a Bayer CropScience letter dated May 22, 1998, Bayer stated that if multiple groundwater detections occurred at or above 10 ppb, mitigation steps would be taken. These "action thresholds" were intended for groundwater samples taken from the monitoring wells established for the imidacloprid groundwater monitoring project. While the Department expected to find imidacloprid in the groundwater monitoring wells immediately under and adjacent to test sites, the Department was surprised to find that imidacloprid had rapidly migrated down gradient to private homeowner wells. The first detection of imidacloprid in a private homeowner well (far removed from the intended monitoring zone) was in April 2000. To date, imidacloprid has been detected at concentrations (0.2 to 7 ppb) in 12 monitoring wells and 16 down gradient private homeowner wells. Imidacloprid has also been recently detected at 0.24 ppb in two Suffolk County community water supply wells (85 feet and 90 feet deep). Additionally, imidacloprid has now been detected at a golf course monitoring well (0.43 ppb) and at monitoring wells near trees (0.2 to 5.1 ppb) that have been treated with imidacloprid by trunk injection for the Asian Longhorned Beetle (ALB).

The New York State Department of Health is concerned about the presence of any pesticides in private or community drinking water supplies. Impact to community supply wells at depths of 85 and 90 feet is of particular concern to the Department of Health. Additionally, imidacloprid is fairly resistant to breakdown once it moves into groundwater. So far, monitoring has only shown the presence of the parent imidacloprid compound. It is unknown if any degradates are present in the groundwater. This concern is heightened by the fact that imidacloprid pesticide products have been registered for a short period of time (nine years).

Given the above, both the Department and the New York State Department of Health are concerned about the continued unrestricted use of all nursery, turf, ornamental, agricultural and consumer registered use patterns. Consistent with the United States Environmental Protection Agency's (USEPA) philosophy of developing Best Management Plans (BMPs), when impacts to groundwater/drinking water are detected, the Department intends to be proactive and ensure the responsible use of the affected products. While the detected level of imidacloprid in groundwater samples has not reached the action thresholds, the Department is troubled by the increasing frequency of detections of the parent compound with respect to the short duration of registration and its use at less than maximum labeled rates in New York State. The Department is particularly concerned about the increasing number of detections in samples from public and private drinking water wells.

In cooperation with Bayer CropScience, Cornell Cooperative Extension, representatives of regulated users and the Department, targeted BMPs for imidacloprid have been developed. The Department must take steps to evaluate the impact of various use patterns on groundwater. The Department's goal is to manage the current labeled uses of all imidacloprid products in order to protect the groundwater resources of Long Island and, at the same time, preserve its use for crops and other use patterns where no alternatives for insect control exist. The Department intends to maintain the registration of the critical uses (in conjunction with the BMPs) of

imidacloprid on Long Island while also gathering more information so that we may resolve our groundwater concerns.

The Department first met with Bayer CropScience on July 30, 2002 to discuss our concerns, and possible use pattern modifications. Bayer CropScience was also informed in a letter dated July 11, 2002 that until this issue is resolved, the Department will not register any additional imidacloprid products (basic or supplemental distributor). Subsequent meetings and conference calls have taken place on October 1, 2002; November 4, 2002; July 28, 2003; May 18, 2004; July 15, 2004 and July 22, 2004.

The Department received a letter dated October 21, 2004 from Bayer CropScience expressing dissatisfaction with the Department's technical position. We interpret this letter as Bayer's final positions on the various imidacloprid product related registration matters that we have been negotiating for some time. We find Bayer's positions inconsistent with many of our previous discussions. Our discussions on the "trigger" related concentration agreement thoroughly highlighted the difference between such concentrations being present in near surface waters versus deeper aquifer zones. The New York State Health Department was present to aid in understanding the concerns associated with the sampling results from the drinking water wells. Such data is not representative of the agreed upon "mitigation triggers" as your letter suggests.

You also stated in your October 21, 2004 letter that only 1% of the samples collected by Suffolk County have detected imidacloprid. However, the detections that the Department is most concerned about are not from the monitoring wells established for the imidacloprid groundwater monitoring project. As noted above, there has been an increasing number of detections in private homeowner wells which are far removed from the intended monitoring zone.

We further shared the sound scientific reasoning behind our intentions to limit the application of imidacloprid products to professional and agricultural use by classifying the products as "restricted use" while we further evaluated the means by which this compound migrates through the soil matrix. As we discussed, limiting the application of this product to those persons who are certified applicators would also ensure that we would receive annual reporting information on use location and amounts.

To provide further explanation, products which are classified as "restricted use" in New York State are restricted in their purchase, distribution, sale, use and possession in New York State. Furthermore, restricted products may only be purchased, sold and used by a certified applicator in New York State.

According to New York State Department of Environmental Conservation Regulations 6 NYCRR 326.3(a): "It shall be unlawful for any person to distribute, sell, offer for sale, purchase for the purpose of resale, or possess for the purpose of resale, any restricted pesticide unless said person shall have applied for, and been issued a commercial permit."

Also, the Pesticide Reporting Law (PRL) in Article 33 Title 12 of the Environmental Conservation Law requires all certified commercial pesticide applicators to report information annually to the Department regarding each pesticide application they make. Commercial pesticide retailers are required to report all sales of restricted pesticide products. If no sales are made within New York State, a report must still be filed with the Department indicating this is the case.

There is no practical mechanism for obtaining annual reporting information on use location and amounts for imidacloprid products which are currently registered as "general use" in New York State and used by the general public. Therefore, in order to protect the groundwater and obtain accurate use data which can be tabulated and used in statistical analysis, the Department maintains that the consumer products should be prohibited from use on Long Island. In order for the affected consumer products to be registered, use modifications must be made. An example of label language that addresses these concerns is: "Not For Sale,

Use or Distribution In or Into Nassau, Suffolk, Kings or Queens Counties, New York." Affected currently registered consumer products will be placed into discontinued status. The island of Long Island is physically comprised of these four contiguous counties. The Department believes that due to the inherent difficulties of controlling the sale, distribution and use of "general use" consumer products, the prohibition should be extended to the natural physical boundaries of the island.

In all of our communications, our position has been shared openly with Bayer in the realm of sound environmental management based on the available scientific data. We find the notion that this was an "arbitrary decision" to be without basis.

The Department does not consider the use of imidacloprid consumer products to be critical on Long Island. Homeowner lawns, and ornamental flowers and shrubs will still be able to be treated with imidacloprid by licensed trained applicators. As New York State restricted use products, all professional use and commercial sales will be reported to the Department in accordance with the Pesticide Reporting Law. The dates, amounts and specific locations of imidacloprid applications will be provided to the Department annually. This information, along with eliminating the consumer use (of which the Department would have no application or reporting records), will allow the Department to evaluate the other use patterns and attempt to determine which uses are most problematic. This will allow further use decisions to be made if necessary.

Therefore, as a result of the Department's intention to continue registration for the critical uses to professional applicators and still be protective of human health and the environment, we register the aforementioned products as restricted use products, in accordance with 6 NYCRR 326.23(e), in New York State. The Department intends to protect the groundwater/drinking water of Long Island, while still preserving the use of imidacloprid where no viable alternatives exist.

Although the Department has received and reviewed your October 21, 2004 letter, our technical concerns remain and have not been adequately mitigated by Bayer CropScience's proposed registration conditions.

With regard to imidacloprid products, the Department will proceed to:

1. Classify as "restricted use" in New York State, as of January 1, 2005, all currently registered professional use products. Our authority for this action lies in 6 NYCRR Part 326.23(e). This includes all professional turf, ornamental, nursery and agricultural use products, except seed treatments and fly baits. These products include:

Merit 75% Concentrate Insecticide (EPA Reg. No. 3125-415)

Merit 2 Insecticide (EPA Reg. No. 3125-418)

Merit 75 WP Insecticide (EPA Reg. No. 3125-421)

Merit 75 WSP Insecticide (EPA Reg. No. 3125-439)

Merit 0.5 G Insecticide (EPA Reg. No. 3125-451)

Merit 2F Insecticide (EPA Reg. No. 432-1312)

Admire 2 Flowable Insecticide (EPA Reg. No. 3125-422)

Provado Solupak 75% Wettable Powder in Water Soluble Packets (EPA Reg. No. 3125-428)

Provado 1.6 Flowable Insecticide (EPA Reg. No. 3125-457)

Admire 2 Flowable Insecticide (EPA Reg. No. 264-758)

Provado Solupak 75% Wettable Powder Insecticide in WSP (EPA Reg. No. 264-761)

Provado 1.6 Flowable Insecticide (EPA Reg. No. 264-763)

These also include the following supplemental distributor products:

Marathon 1% Granular Greenhouse and Nursery Insecticide (EPA Reg. No. 3125-452-59807)

Marathon 60WP Greenhouse and Nursery Insecticide WSP (EPA Reg. No. 3125-492-59807)
Marathon II Greenhouse and Nursery Insecticide (EPA Reg. No. 3125-549-59807)
Lesco Systemic Insecticide Contains Merit (EPA Reg. No. 3125-421-10404)
Lesco Systemic Insecticide Contains Merit WSP (EPA Reg. No. 3125-439-10404)
Lebanon Merit 0.3G Lawn & Garden Insecticide (EPA Reg. No. 3125-464-961)
Turf Grub Control Contains Merit (EPA Reg. No. 3125-464-961)
Grofine Grub Preventer with Merit (EPA Reg. No. 3125-464-8378)
Fortify Season Long Grub Control with Merit Insecticide (EPA Reg. No. 3125-464-9198)
Trugreen by Chemlawn Grub Guard with Stress Relief (EPA Reg. No. 3125-471-71902)
Turf Fertilizer Plus Merit Insecticide, 14-0-14 (EPA Reg. No. 3125-474-538)
Lebanon Pro Fertilizer with Merit 0.2% (various fert. blends) (EPA Reg. No. 3125-474-961)
Lebanon Proscape Homog. Fert w/ Merit .2% Grub Preventer 11-3-20 (EPA Reg. No. 3125-474-961)
Pro-Mate Merit 0.2% Plus Turf Fertilizer (various fert. blends) (EPA Reg. No. 3125-474-5905)
Shaw's Turf Food with Grub Control 20/Merit (various fert. blends) (EPA Reg. No. 3125-474-8378)
Tee Time Fertilizer w/Merit Insecticide (various fert. blends) (EPA Reg. No. 3125-474-9198)
Andersons Prof Turf Products Fert with Merit (various fert. blends) (EPA Reg. No. 3125-474-9198)
15-3-15 with Merit Insecticide (EPA Reg. No. 3125-474-9198)
The Andersons Fertilizer w/Merit Insecticide (various fert. blends) (EPA Reg. No. 3125-474-9198)
Lesco Merit 0.2 Plus Fertilizer (various fertilizer blends) (EPA Reg. No. 3125-474-10404)
Lesco Merit 0.2 Plus Elite Fertilizer (EPA Reg. No. 3125-474-10404)
Lesco Merit 0.2 Plus Mini Fertilizer (various fert. blends) (EPA Reg. No. 3125-474-10404)
Howard Johnson's Merit 0.2 Plus (EPA Reg. No. 3125-474-32802)
Signature Fertilizer with 0.2% Merit (EPA Reg. No. 3125-474-65783)
Professional Turf Products Grub Away Plus Fertilizer 0-0-7 (EPA Reg. No. 3125-474-71902)
Lebanon Fertilizer with Merit 0.3% Insecticide (EPA Reg. No. 3125-475-961)
Shaw's Turf Food 15-2-5 with Grub Control 15/Merit (EPA Reg. No. 3125-478-8378)
Lebanon Pro Fert. w/Merit 0.25% Insecticide 28-3-10 (EPA Reg. No. 3125-479-961)
Shaw's Turf Food with Grub Control 25/Merit (various fert. blends) (EPA Reg. No. 3125-479-8378)

Classify as "restricted use" in New York State, all new professional use products which are registered effective the date of this letter. These products include:

Merit 75 WP Insecticide (EPA Reg. No. 432-1314)
Merit 75 WSP Insecticide (EPA Reg. No. 432-1318)
Prokoz Zenith 75 WSP Insecticide (EPA Reg. No. 432-1318)
Lesco Bandit 75 WSP Insecticide (EPA Reg. No. 432-1318)
Touchstone 75 WSP Insecticide (EPA Reg. No. 432-1318)
Merit 0.5 G Insecticide (EPA Reg. No. 432-1328)
Merit 2.5 G (EPA Reg. No. 432-1376)

The following supplemental distributor products are also included:

Golf Products Turf Fert. w/Merit (EPA Reg. No. 432-1349-9198)
Andersons Golf Products w/Merit (EPA Reg. No. 432-1349-9198)
Pointer II Insecticide (EPA Reg. No. 69117-6)
ProMate Merit 0.2% Plus Turf Fertilizer (EPA Reg. No. 432-1349-5905)
Merit 0.3G Grub Control (EPA Reg. No. 432-1340-32802)
Howard Johnson's Merit 0.2 Plus (EPA Reg. No. 432-1349-32802)
Shaw's Turf Food w/Grub Control 20/Merit (EPA Reg. No. 432-1349-8878)
Shaw's Turf Food with Grub Control 15/Merit (EPA Reg. No. 432-1353-8378)
Shaw's Turf Food with Grub Control 25/Merit (EPA Reg. No. 432-1354-8378)

Lebanon Pro. Turf Products Fertilizer w/Merit 0.2% Insect and Grub Control (EPA Reg. No. 432-1349-961)

Lebanon Proscape Homogeneous Fertilizer with Merit 0.2% Grub Preventer (EPA Reg. No. 432-1349-961)

Lebanon Fertilizer w/Merit 0.3% Insecticide (EPA Reg. No. 432-1350-961)

Lesco Merit Plus Turf Fertilizer (EPA Reg. No. 432-1349-10404)

Discus (EPA Reg. No. 432-1392-59807)

Signature Fertilizer with Merit 0.2% (EPA Reg. No. 432-1349-65783)

2. Assist the professional applicator community to comply with the BMP documents to ensure product availability.

3. Decline to register consumer products, except pet products and potting soil mixes, unless the product uses are modified. "Not For Sale, Use or Distribution In or Into Nassau, Suffolk, Kings or Queens Counties, New York," is an example of label language that addresses the Department's concerns. Currently registered consumer products will be placed into discontinued status. These products include:

Bayer Advanced Lawn Complete Insect Killer for Soil & Turf R-T-Spray (EPA Reg. No. 72155-29)

Bayer Advanced Lawn Complete Insect Killer for Soil & Turf R-T-Spread (EPA Reg. No. 72155-31)

Bayer Advanced Lawn Season-Long Grub Control R-T-S Granules (EPA Reg. No. 72155-44)

The following supplemental distributor products are also included:

Spectracide Grub Stop Full Season Grub Killer (EPA Reg. No. 3125-593-8845) GRUBEX (EPA Reg. No. 432-1339-538)

4. Allow existing stocks of professional use products currently in the hands of distributors in New York State to be sold and used as restricted use products.

5. Share any additional groundwater data indicating the presence of imidacloprid with Bayer.

As a condition of continued registration in New York State, Bayer CropScience is required to:

1. Release and distribute the developed BMPs.

2. Stop shipment by November 1, 2004 of any of the older labeled consumer use imidacloprid products.

3. In conjunction with the Department, inform the affected users and dealers that the professional products are now restricted use products.

4. Continue to monitor the existing groundwater monitoring wells as identified in the 1996 QAPP and report data to the Department annually.

5. Provide the Department, by December 31, 2004, any available toxicity data on imidacloprid degradates, groundwater monitoring data for the degradates, and in-vivo metabolism data of imidacloprid in humans. The Department will use this information to help establish ambient groundwater and drinking water standards.

We trust that Bayer CropScience will practice good product stewardship and continue to make product available to professional applicators in New York State and Long Island.

Based on the information above, the Department believes that if no action is taken at this time, the

frequency and level of concentrations of imidacloprid and its degradates in public and private drinking water wells may increase. The Department is proposing a systemic approach of determining which use patterns are most problematic. These actions will maintain the critical uses on Long Island and allow the Department to track product use and coordinate groundwater monitoring. Information developed will allow the Best Management Plans for these uses to be modified while maintaining other critical use patterns.

The aforementioned actions taken by the Department will allow a proactive approach to reducing the environmental load of imidacloprid on Long Island's sole source drinking water aquifer, allow the Department to evaluate and study continued critical use and place the active ingredient only in the hands of trained applicators.

The Department reiterates that the continued registration of all imidacloprid products within New York State will be dependent upon the ongoing review of groundwater monitoring data collected within the Long Island sole source aquifer. The Department will continue to evaluate the various use patterns.

Bayer CropScience is reminded that if New York State registration is requested for any new product or currently registered product which contains imidacloprid with revised and/or limited use directions, the product will be considered a Major Change in Labeling and the Department will require an extensive review to determine the technical merits along with any and all available groundwater monitoring data.

This registration letter concludes the technical discussions and negotiations between Bayer CropScience and the Department. Should you have any further questions, please contact Samuel Jackling, Chief of our Pesticide Product Registration Section, at (518) 402-8768, or me, at (518) 402-8788.

Sincerely,

Maureen P. Serafini
Director
Bureau of Pesticides Management

cc: Karen Cain, Bayer CropScience
Meredith Laws, Chief, USEPA Insecticide-Rodenticide Branch
Nancy Kim, New York State Department of Health
Richard Zimmerman, New York State Department of Agriculture and Markets
Will Smith, Cornell University, PMEP

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For more information relative to pesticides and their use in New York State, please contact the PMEP staff at:

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