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Division of Solid & Hazardous Materials
Bureau of Pesticides Management
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Alexander B. Grannis
Commissioner

July 17, 2007

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Doina Bujor
Regulatory Manager
Arysta LifeScience North America Corporation
15401 Weston Parkway, Suite 150
Cary, North Carolina 27513

Dear Ms. Bujor:

Re: **Denial of Application for Registration of Four New Pesticide Products, ARENA 50 WDG Insecticide (EPA Reg. No. 66330-40), CLUTCH 50 WDG Insecticide (EPA Reg. No. 66330-40), CELERO 16 WSG Insecticide (EPA Reg. No. 66330-52), and ARENA 0.5 G Insecticide (EPA Reg. No. 66330-53), Which Contain the New Active Ingredient Clothianidin**

The Department has reviewed your application, received July 26, 2005, and additional information, received October 12, 2005, October 2, 2006, and March 13, 2007, to register ARENA 50 WDG Insecticide (EPA Reg. No. 66330-40), CLUTCH 50 WDG Insecticide (EPA Reg. No. 66330-40), CELERO 16 WSG Insecticide (EPA Reg. No. 66330-52), and ARENA 0.5 G Insecticide (EPA Reg. No. 66330-53) in New York State. The four products contain the new active ingredient clothianidin (chemical code 044309).

ARENA 50 WDG Insecticide (EPA Reg. No. 66330-40) is a foliarly applied insecticide for control of a wide spectrum of insects infesting turfgrass. The maximum application rate for this product is 0.4 lb. active ingredient per acre per season (12.8 ounces of product).

CLUTCH 50 WDG Insecticide (EPA Reg. No. 66330-40) is a foliarly applied insecticide for control of a wide spectrum of insects infesting apples and pears. The maximum application rate for this product is 0.2 lb. active ingredient per acre per season (6.4 ounces of product).

CELERO 16 WSG Insecticide (EPA Reg. No. 66330-52) is an insecticide for broad spectrum control of aphids, whiteflies and mealybugs infesting ornamentals. The maximum application rate is 0.4 lb. active ingredient per acre per season (40 ounces of product).

ARENA 0.5 G Insecticide (EPA Reg. No. 66330-53) is a foliarly applied insecticide for broad spectrum control of white grubs, billbugs, sod webworms, chinch bugs, and suppression of mole crickets and cutworms infesting turfgrass. The maximum application rate for this product is 0.4 lb. active ingredient per acre per season (80 pounds of product).

The Department sent Arysta LifeScience a letter, dated February 13, 2007, intending to deny the registration of the above-mentioned products unless a rather lengthy list of information was submitted to the Department. The requested information was needed in order for the Department to continue it's review. The following is the list of information previously requested by the Department:

- United States Environmental Protection Agency (U.S. EPA) Data Evaluation Record (DER) report, or if unavailable, a copy of the U.S. EPA's detailed review of the following outstanding data required as a condition of U.S. EPA registration:
    - Developmental Immunotoxicity Study on Clothianidin
    - Whole Sediment Acute (Freshwater) Study
    - Whole Sediment Acute (Estuarine and Marine) Study
    - Field Test for Pollinators (seed treatment uses on corn and canola)
    - Field Test for Pollinators (pre-bloom foliar and/or granular application to Pome fruit to determine clothianidin concentrations in nectar and pollen)
    - A new Aerobic Aquatic Metabolism Study
    - Small Scale Prospective Groundwater Study
- Additional information regarding the chronic toxicity to bird species more sensitive than Bobwhite Quail and Mallard ducks.
- Any available data which quantifies residue levels in ornamental plant foliage, pollen, or nectar.
- Any additional available data that exists for aquatic habitats.
- Any additional available toxicity data that exists for invertebrate taxa including pollinators.

The following is your company's response which was submitted in response to the Department's request:

"1. Developmental immunotoxity study with comparative measures between pups and the parents

Response: Bayer CropScience submitted a waiver request on April 2006. EPA did not review or comment on this waiver yet.

2. Aerobic aquatic metabolism study

Response: The study was completed and submitted by Bayer CropScience in May 2006. The DER is not available yet.

3. Protocol for small-scale prospective groundwater monitoring study
Response: Arysta LifeScience submitted a waiver request in June 2006 with additional supporting data. A copy is included in the Volume 1 of this submission - "Additional Data". EPA did not review or decide on the waiver request.

4. Whole sediment acute toxicity invertebrates, freshwater
Response: The study was completed by Bayer and submitted to EPA in May 2006. The DER is not available yet. A summary of the study is included in Volume 1 of the present submission.

5. Whole sediment acute toxicity invertebrates, estuarine and marine
Response: Due to the company move and changes in the Regulatory Department, Arysta requested an extension for submitting this data. The study was initiated and is ongoing at Wildlife International, LTD. We expect the finalization in May 2007. At that time we will submit a summary of the findings.

6. Field testing for pollinators (seed treatment)
Response: Arysta does not have seed treatment rights for this active ingredient.

7. Field test for pollinators (pre-bloom foliar and/or granular application to pome fruit to determine clothianidin concentration in nectar and pollen)
Response: Arysta submitted a waiver request together with label language mitigation. Copies of the waiver request and the last approved label for Arena 50 WDG are included in Volume 1 of this submission."

The Department has repeatedly asked for additional information which would mitigate our concerns. This most current submission consists primarily of waiver requests and some new summary data which is pending U.S. EPA review.

The Department has numerous unmitigated concerns regarding the use of clothianidin in New York State.

HEALTH EFFECTS:

The New York State Department of Health (DOH) stated that Arena 50 WDG and Clutch 50 WDG were not very acutely toxic to laboratory animals by the oral, dermal or inhalation routes of exposure. These two pesticide products, which are identical in formulation, were mildly irritating to the skin, but were moderately irritating to the eyes (tested on rabbits). The products were not skin sensitizers (tested on guinea pigs). The U.S. EPA permitted the bridging of the above noted acute toxicity data for Arena 50 WDG and Clutch 50 WDG to support the registration of the formulated products Arena 0.5G and Celero 16 WSG. The reason given by the U.S. EPA for this action was that the latter three products were found to be "substantially similar" to Arena 50 WDG and Clutch 50 WDG. The DOH previously reviewed the active ingredient clothianidin in the pesticide product Poncho 600, which was subsequently withdrawn by the registrant. In that review, the DOH noted that clothianidin was not very acutely toxic to laboratory animals via the oral, dermal or inhalation exposure routes. Also, the active ingredient was neither very irritating to the eyes or skin (tested on rabbits), nor was it a skin sensitizer (tested on guinea pigs). Clothianidin did not cause oncogenic effects in chronic feeding studies

in rats and mice, and the U.S. EPA classified the chemical as "not likely to be a human carcinogen." However, data from chronic and developmental/reproductive studies showed that clothianidin has the potential to cause some toxicity. The U.S. EPA Office of Pesticide Programs calculated an oral reference dose (RfD) of 0.0098 milligrams per kilogram body weight per day (mg/kg/day) based on a no-observed-effect level (NOEL) of 9.8 mg/kg/day from a rat multi-generation reproduction study (decrease in absolute thymus weights, delay in sexual maturity) and an uncertainty factor of 1,000 (10x to account for intraspecies differences, 10x to account for interspecies differences and an additional 10x to account for a lack of a developmental immunotoxicity study). A current search of the toxicological literature did not find any significant new information on the toxicity of clothianidin. Please note, as previously stated, as a condition of federal registration of these formulated products, the U.S. EPA required that the registrant submit a "Developmental Immunotoxicity study with comparative measures between pups and the parents (OPPTS 870.7800)" by December 31, 2006. This is still an outstanding requirement.

The U.S. EPA established a tolerance for clothianidin residues in or on pome fruit at 1.0 part per million (ppm). The chronic population adjusted dose (cPAD) for clothianidin is 0.0098 mg/kg/day and has the same basis as the RfD. The U.S. EPA estimated that chronic dietary exposure to clothianidin residues would be 6 percent of the cPAD for the general U.S. population, 13 percent for all infants less than one year old, 15 percent for children one to two years old and 5 percent for females 13-49 years old and all adults 50 years and older. This chronic exposure analysis is based on the conservative assumptions that all treated crops for which there are tolerances had clothianidin residues at the respective tolerance level, with the exception of anticipated residues being used for apples and pears, and that 100 percent of the crops would be treated with clothianidin. The U.S. EPA conducted a risk assessment for both occupational exposure and residential/recreational exposures to clothianidin. For workers handling clothianidin at the maximum labeled application rate of 0.4 pounds per acre, the combined estimated margins of exposure (MOEs) for dermal and inhalation exposures ranged from 8,300 to 73,000. For these MOE estimates, it was assumed that workers wore a single layer of clothing, but did not wear gloves (the clothianidin-containing product labels require long-sleeved shirt, long pants, shoes plus socks and chemical-resistant gloves). The U.S. EPA used a dermal absorption factor of one percent (based on study data in monkeys) and assumed 100 percent absorption for inhalation exposure. The NOEL used for estimating these MOEs was 9.8 mg/kg/day from the rat multi-generation reproduction study. Generally, the U.S. EPA considers MOEs of 100-fold or greater to provide adequate worker protection. For post-application exposures (harvesting, golf course maintenance) of workers, the respective MOEs were about 1,200 and 2,300. With regard to residential/recreational exposures to clothianidin, especially from post-application exposure to turf treated with this active ingredient, estimated MOEs for children, adults and golfers were 1,300, 8,900 and 77,000/130,000 (child golfer/adult golfer), respectively. The U.S. EPA considered MOEs of 1,000-fold or greater (due to the 1,000-fold uncertainty factor used for the RfD and cPAD) to provide adequate protection to children and adults from post-application exposures to clothianidin.

There are no chemical specific federal or New York State drinking water/groundwater standards for clothianidin. Based on its chemical structure, clothianidin falls under the 50 microgram per liter New York State drinking water standard for "unspecified organic contaminants" (10 NYCRR Part 5, Public Water Systems). The available information on clothianidin and the Arena, Celero and Clutch products indicates that overall neither the active ingredient nor the formulated products were very acutely toxic in laboratory animal studies.

While the formulated products caused moderate eye irritation, these products are granular formulations and are unlikely to "splash" into the eyes of workers. In addition, the product label contains the precautionary statement "Causes moderate eye irritation." Although data from chronic and developmental/reproductive studies showed that clothianidin has the potential to cause some toxicity, the expected exposures from the labeled uses of these clothianidin-containing products should not pose a significant health risk to workers.

Furthermore, dietary exposure of the general public to clothianidin from treated crops is also not expected to pose significant health risks. Given the above, the DOH does not object to the registration of Arena 0.5G Insecticide, Arena 50 WDG Insecticide, Celero 16 WSG Insecticide and Clutch 50 WDG Insecticide in New York State as labeled.

ECOLOGICAL EFFECTS:

The Department's Division of Fish, Wildlife & Marine Resources' Bureau of Habitat (BOH) has completed an ecological risk assessment of the active ingredient clothianidin and the formulated products, Arena 50 WDG, Clutch 50 WDG, Celero 16 WSG, and Arena 0.5 G insecticides, which all contain clothianidin as the sole active ingredient. The BOH objects to their registration.

The BOH stated that clothianidin is a new active ingredient in the nitroguanidine subgroup of the Nicotinoid family. As with other chlorinated nicotine analogs, clothianidin is a neurotoxin that targets post-synaptic receptors of the neurotransmitter acetylcholine. Clothianidin is persistent in the environment, mobile, and systemic in plants. Residues will carry over from year to year, increasing with repeated applications. BOH's primary concerns are that clothianidin is likely to reach surface waters contributing to contaminant loading and potentially impacting non-target aquatic species, and that nontarget pollinators attracted to pollen or nectar in treated areas will be exposed to potentially toxic residues in those resources. Of slightly less concern is the potential for repeated or continuous avian and mammalian exposure.

Numerous additional studies were required for clothianidin as a condition of continued federal registration. Their purpose is to reduce the level of uncertainty associated with predicted impacts to nontarget pollinator and aquatic organisms. With a compound as persistent as clothianidin, outstanding issues regarding impacts to resources should be resolved before registration is considered.

In addition, Arena 50 WDG, Clutch 50 WDG, and Celero 16 WSG contain the following warning in the Environmental Hazards section: "This product is toxic to bees exposed to treatment and for more than 5 days following treatment. Do not apply this product to blooming, pollen-shedding or nectar-producing parts of plants if bees may forage on the plants during this time period, unless the application is made in response to a public health emergency declared by appropriate state or federal authorities."

The BOH stated that clothianidin has a water solubility of 327 mg/L. Clothianidin will have little tendency to bioaccumulate due to its low octanol/water partitioning coefficient, $K_{OW,}$ of 5.0. It has very low vapor pressure, 9.8×10^{-13} mmHg, and volatilization from soil or water will not contribute significantly to its dissipation. Clothianidin soil organic carbon partitioning coefficients, K_{OC}s, range from 84 to 345 ml/g with a mean of 140.5. Chemicals with K_{OC}s in this range are predicted to be highly mobile in soil.

Clothianidin is persistent in soil, systemic in plants, and is expected to be mobile post-application with the potential to leach into ground water and be transported with runoff into surface waters. On an acute basis, it is slightly toxic to mammals and ranges from practically nontoxic to moderately toxic in the three bird species for which data was submitted. It can produce adverse effects with chronic exposures. It is practically nontoxic to both freshwater and marine/estuarine fish on an acute basis, but can produce toxicity with chronic exposure. Invertebrate sensitivity ranges widely, clothianidin is practically nontoxic to daphnia and the eastern oyster, but is very highly toxic to marine mysid shrimp and the freshwater midge *Chironomus riparius*. It is also highly toxic to honey bees from both contact and oral administration.

Clothianidin is persistent in the environment, parent compound residues will carry over into subsequent growing seasons and will increase with continued use. It is stable to hydrolysis but does degrade via photolysis. In a sterile aqueous buffer clothianidin degraded with a predicted environmental half-life, $T_{1/2}$, of 14.4 hours. In natural river water its mean $T_{1/2}$ was 26.4 hours. Soil surface photolysis proceeds at a much slower rate with a $T_{1/2}$ of 34 days. Results from ten aerobic soil metabolism studies were reported between the two clothianidin data packages. $T_{1/2}$s ranged from 148 to 6,932 days with a geometric mean of 660 days. One partially acceptable aerobic aquatic study yielded a $T_{1/2}$ of 181 days. The study was conducted with pond water according to Canadian guidelines and did not include aerobic sediments as required by U.S. guidelines. An acceptable anaerobic study conducted in a sediment/pond water system yielded $T_{1/2}$s of 14.2, 37, and, 26.7 days in the water column, sediment, and total system, respectively.

Results from a total of eight clothianidin terrestrial field dissipation studies have been submitted. In two of the studies, it was not possible to calculate a dissipation $T_{1/2}$. In a study conducted in California, clothianidin concentrations varied widely with no consistent pattern of decline. The U.S. EPA reviewer did report, however, that 71.6% of the applied material remained as parent compound after 982 days. Since 28% of the parent compound dissipated in 2.7 years, or 10.4% per year, for the purpose of this review a rough estimate of a 50% dissipation time, DT_{50}, of 4.8 years or 1,755 days was used. Similarly, in a study conducted in the Canadian province of Saskatchewan, too little dissipation occurred over the course of the study to calculate a $T_{1/2}$. After 775 days, 80% of the applied material remained as parent compound. A rough estimate DT_{50} in this case is 5 years or 1898 days. $T_{1/2}$s in the remaining studies range from 257 to 1386 days. The geometric mean of all values is 701 days. Parent clothianidin was detected in the 15-30 cm deep soil layer in all studies, as soon as 3 or 5 days post-application in four cases. In two studies it reached the 30-45 cm layer in 15 and 31 days, and, reached the 45-60 cm layer in the last two studies, within 28 days at the Wisconsin site. Once detected, the parent compound tended to remain in the soil at the maximum detected depth until study termination. Non-extractable soil residue concentrations were not determined in any of the studies.

Modeling was conducted to estimate non-target organism clothianidin exposures from labeled use of the products. Two levels of avian and mammalian food item residues resulting from clothianidin applications are used in the avian and mammalian exposure models. The first is the “Upper limit” residues which are concentrations on a range of food items that occur immediately following application at a given rate. The second set are the “Typical” or average residues observed following application.

Food item residue levels are compared to toxicity values for birds and mammals in the avian and mammalian toxicity modules. It should be noted that no chronic or reproductive data was submitted for the Japanese Quail which, based on the acute data, is at least 4.7 times more sensitive to clothianidin than the Bobwhite Quail.

Another criterion for birds and mammals specific to granular products is whether the amount of exposed granules per square foot exceeds toxicity thresholds. The U.S. EPA Environmental Fate and Effects Division (EFED) presumption of unacceptable risk thresholds using this approach are, greater than 1/2 of the LD_{50}/ft^2 for non-endangered species, and greater than 1/10 of the LD_{50}/ft^2 for endangered species.

The potential for, and the implications of, aquatic non-target organism exposure were evaluated in order to estimate active ingredient concentrations in aquatic habitat from both direct application to the surface of a water body and from transport to surface waters with precipitation runoff. The direct application to surface water modeling is primarily designed to evaluate hazard from inadvertent overspray during aerial application and is not included here since none of these products may be applied by aircraft.

When multiple applications of a product are allowed, modeling is used to calculate soil residue concentrations at various points in a use season. These concentrations are then used in a subsequent modeling program as application rate inputs. When evaluating a compound as persistent as clothianidin, so little dissipation occurs between applications that the single application rate, simple additive accumulation, or the seasonal maximum rate are used as program inputs. The Pesticide Multiple Application Report illustrates the multi-year progressive increase in clothianidin soil residue concentrations that will occur with repeated use.

The results of the modeling show that risks to birds and mammals appear to be low from clothianidin use with the caveats that BOH modeling programs do not calculate exposures to mammals smaller than rabbits, and, there is significant uncertainty with respect to chronic toxicity to bird species more sensitive than Bobwhite Quail and Mallard Ducks. Aquatic systems are more likely to be impacted by labeled use of these products. The extent and degree of impacts is uncertain, outstanding registration requirements imposed at the federal level will resolve some of this uncertainty. Another area of significant uncertainty is that clothianidin is systemic in plants and is expressed in pollen and nectar. While there is some data from seed treatment studies and the U.S. EPA EFED has required pre-bloom apple treatment studies to assess concentrations in pome fruit pollen and nectar, there appears to be no similar work addressing the residues in ornamental plants which receive exaggerated application rates.

The avian toxicity modeling results show that residues on short grass immediately following application may exceed avian acute NOEC concentrations. There were no toxicity thresholds exceeded in the remaining food item categories. The mammalian toxicity modeling showed no thresholds being exceeded.

Application of the Arena 0.5 G granular product exceeds the U.S. EPA criteria for 15g and 35g mammals, and 20g birds when the full seasonal rate is applied. At that rate, the risk quotients, LD_{50}/ft^2, for the three groups are 0.71, 0.31, and 0.49, respectively. To achieve an LD_{50} dose, however, the 15g mammal would have to consume 67 granules, the 35g mammal 156 granules, and the 20g bird 97 granules. Since the granules are clay, it is unlikely that mammals would consume them in these quantities. The birds may pick them up as grit while foraging but

not likely in sufficient numbers to receive an acutely toxic dose. Since there is no chronic data for the more sensitive Japanese Quail or any data on smaller passerine species it is not possible to rule out chronic or reproductive effects for such species when exposed to multiple applications in a single season. The most sensitive parameter in the Bobwhite Quail reproductive study was eggshell thickness.

Following the single seasonal application to pome fruits, the modeling shows that the mysid shrimp acute and chronic NOECs may be exceeded in shallow near-shore areas from runoff. The first run includes results for all aquatic species evaluated. Subsequent run results only include those species for which a toxicity threshold was exceeded. Run II illustrates potential runoff following a second application to pome fruits the following season. It shows shallow-depth NOECs for freshwater and marine/estuarine invertebrates being exceeded and a chronic LOEC being exceeded for the marine/estuarine mysid.

Results from runs III-V show that applications to turf will result in increasing impacts to aquatic invertebrates in use areas with long term use, run V uses soil residue levels reached during the second use season. Runs VI-X show that applications at the seasonal maximum rate may exceed aquatic invertebrate toxicity thresholds in the first season of use and that these impacts will be relatively insensitive to mitigation attempts like runoff control measures.

The supporting study base for these clothianidin products while substantially complete is best described as a work in progress. The multiple studies required as conditions of federal registration will resolve some but not all of the questions that remain unanswered at this point. The most concern BOH has with these products is for the potential impacts to aquatic habitat and pollinators. As conditions of continued registration the U.S. EPA has required the following:

- A new Aerobic Aquatic Metabolism Study
- Small Scale Prospective Groundwater Study
- Whole Sediment Acute, Freshwater
- Whole sediment Acute, Estuarine and Marine
- Field Test for Pollinators (seed treatment uses on corn and canola)
- Field Test for Pollinators (pre-bloom foliar and/or granular application to Pome fruit to determine clothianidin concentrations in nectar and pollen)
- Developmental Immunotoxicity Study
- Rotational Field Crop Residues (mature soybeans)
- Seed Leaching Study

The largest concern BOH has with these products is for the potential impacts to aquatic habitat and pollinators. However, there is significant uncertainty with respect to chronic toxicity to bird species more sensitive than Bobwhite Quail and Mallard Ducks.

Aquatic systems are more likely to be impacted by labeled use of these products. The extent and degree of impacts is uncertain, outstanding registration requirements imposed at the federal level will resolve some of this uncertainty.

The focus of the U.S. EPA pollinator concern is for effects to honey bees from agricultural crops. While important, these concerns should extend to all pollinators and should include the ornamental plant use patterns as well. Ornamental plants receive exaggerated application rates and, to date, the BOH has not seen any data quantifying residue levels in these plants foliage, pollen, or nectar. Any such data that exists should be submitted for consideration along with any additional data that exists for aquatic habitats, avian species, and any additional toxicity data that exists for invertebrate taxa that include pollinators.

Although the U.S. EPA has required additional studies to address their concerns regarding adverse effects on pollinators, the registrant has submitted a waiver request along with adding mitigative label language. The Department still has unanswered questions regarding pollinators and a waiver request to not do the required study does not address the questions the Department has regarding the potential adverse effects on pollinators. Due to the numerous concerns, data gaps and unanswered questions, the BOH objects to the registration of any clothianidin product at this time.

ENVIRONMENTAL FATE AND GROUNDWATER IMPACTS:

The following is groundwater staff's technical review:

Degradates:

ACT	2-chlorothiazol-5-ylmethylamine
CTCA	2-chlorothiazol-5-lymethanol
FA	formamide
HMIO	4-hydroxy-2-methylamino-2-imidazolin-5-one
MAI	3-methylamino-1H-imidazop1,5-c]imidazole
MG	Methylguanidine
MIT	7-methylamino-4H-imidazol[5,1-b] [1,2,5]thiadiazin-4-one
MNG	*N*-methyl-*N*'-nitroguanidine
MU	methylurea
TMG	*N*-(2-clorothiazol-5-ylmethyl)-*N*'-methylguanidine
TZMU	*N*-(2-chlorothiazol-5-ylmethyl)-*N*'-methylurea

Solubility: Clothianidin has a solubility of 327 mg/L.

Hydrolysis: U.S. EPA found this study acceptable (MRID 45422317). Clothianidin is stable to hydrolysis at pHs 5 and 7. At pH 9, the half life was 3.7 days at 62°C and 0.7 days at 74°C. Two major degradates were formed at pH 9. There were no major degradates at environmental temperatures.

Soil Photolysis: U.S. EPA found this study acceptable (MRID 45422323). Clothianidin degraded with a half-life of 8.2 days in a sandy loam soil at 20°C. No major degradates occurred.

Aqueous Photolysis: In studies the U.S. EPA found to be acceptable (MRIDs 45422318, 45422320 and 45422322), nitroimino- and thiazolyl- [^{14}C] clothianidin degraded rapidly in sterile, pH 7 buffer at 25^{o}C; the half-lives were 3.4 and 3.1 hours, respectively. Four major degradates were found in the nitroimino-^{14}C study. MG, TZMU, HMIO and MU were found with maximum concentrations of 34.7% (432 hours), 29.3% (24 hours), 26.6% (24 hours) and 11% (432 hours), respectively. In the thiazolyl-^{14}C study, clothianidin degraded mainly to TZMU, FA, MIT and CO_2 with maximum concentrations of 39.7% (24 hours), 16.1% (120 hours), 11.8% (24 hours) and 34.1% (432 hours), respectively.

In studies that the U.S. EPA found to be supplemental (MRIDs 45422319, 45422321) in non-sterile river water pH 7 to 9.6, nitroimino- and thiazolyl- [^{14}C] clothianidin degraded with half-lives of 25.1 and 27.7 hours, respectively. The temperature range was 21.5 to 31.3^{o}C. In the nitroimino-^{14}C study, clothianidin degraded to MG, HMIO and MU with concentrations of 46.5% (696 hours), 28.0% (120 hours) and 12.0% (432 hours), respectively. In the thiazolyl-^{14}C study, clothianidin degraded mainly to CO_2 at 28.5% (696 hours), Urea, TMG, MAI, and CTCA with maximum concentrations of 18.1% (264 hours), 17.2% (120 hours), 13.6% (120 hours), and 13.3% (432 hours), respectively.

Anaerobic Aquatic Metabolism: The U.S. EPA found this study to be acceptable (MRID 45422330). In a silt loam sediment flooded with pond water, clothianidin degraded with half-lives of 4 days in the water phase, 37 days in the sediment phase, and 27 days overall. No major degradates were found.

Aerobic Aquatic Metabolism: The U.S. EPA found this study to be unacceptable. It was prepared in response to Canadian guidelines and does not fulfill Subdivision N Guidelines.

Aerobic Soil Metabolism Parent:

Soil Type	% OC	Soil pH	Aerobic Half-life	Degradates
silt[S]	2.66	7.8	147[1]	None
silt loam[S]	0.86	8.1	239[1]	10.7
loamy sand[A]	2.5	6.0	495[1]	None
sandy loam[A]	1.12	6.7	990[1]	None
loamy sand[S]	0.35	6.67	6932[2]	None
silt loam[A]	1.37	6.74	578[2]	CO_2
silt loam[S]	3.27	6.66	693[2]	None
loamy sand[S]	0.4	6.8	533[2]	None
sand[S]	0.73	6.22	533[2]	None
silt loam[S]	0.98	7.88	115[3]	Not identified

silt[S]	1.55	7.30	67[3]	Not identified
sandy loam[S]	1.02	7.17	65[3]	Not identified

[A]EPA found this study acceptable; [S]EPA found this study supplemental;
[1]MRID 45422325; [2]MRID 45422326; [3]MRID 45422327.

Aerobic Soil Metabolism Degradates: The half-life of MNG was 65-116 days and the U.S. EPA found the study to be supplemental (MRID 45422327). The half-life of TZNG was 53-122 days and the U.S. EPA found the study to be supplemental (MRID 45422328).

Adsorption/Desorption:

Soil Type	% OC	Soil pH	Ads/Des Koc Parent[1]	Ads/Des Koc MNG[S2]	Ads/Des Koc TZNG[S3]	Ads/Des Koc TZMU[S4]	Ads/Des Koc TMG[S5]
sand	2.5	6.0	119/170[A]	5.2/NC	204/270	46/68	641/782
sandy loam			345/382[A]	34/44	236/280	95/122	3620/4991
loamy sand	0.73	6.8	129/154[A]				
clay loam			123/139[A]				
sandy loam			84/95[A]	25/34	236/280	57/76	525/602
silt loam	1.37	6.74		16/13	242/276	56/71	641/782
loamy sand	0.4	6.8		21.4/NC	261/346	53.3/63	6159/9013

A - EPA found this study acceptable; S - EPA found these studies supplemental; [1]MRID 45422311; [2]MRID 45422313; [3]MRID 45422314 [4]MRID 45422315 [5]MRID 45422316; NC - not calculated.

Terrestrial Field Dissipation: The U.S. EPA found these studies acceptable. Clothianidin degraded in a sand soil with a half-life of 277 days (MRID 45422332), in a clay loam soil with a half-life of 1386 days (MRID 45422334), in a silt loam of 365 days (MRID 45422335), and in a silt loam of 315 days (MRID 45422333). In a silty clay loam in a semi-arid environment from Canada, the half-life could not be determined (MRID 45422336). No major degradates were found. Clothianidin was generally not detected below the 45 cm depth, and degradates were generally only detected in the 0-15 cm soil layer.

In lysimeter studies (MRIDs 45422331 and 45422508) in sandy loam, no parent was found in the leachate. Approximately 60% of applied was found in the soil. One minor degradate was found in the soil. In the second lysimeter study, no parent was found in the leachate, only minor degradates. Approximately 46% of applied was found in the soil. The U.S. EPA found these studies acceptable.

Modeling: Staff modeled clothianidin on Riverhead soil (to simulate upstate aquifers as well as Long Island) using a K_{oc} of 170 (sandy loam), a half-life of 495 days and the maximum application rate of 0.2 lb ai/a/yr. The model projected breakthrough in 4 months, and a consistent

concentration of between 9 and 13 ppb. Changing the application rate to 0.4 lb ai/a/yr, the model projected breakthrough in 4 months, and a consistent concentration of between 19 and 26 ppb. Modeling the degradate MNG at 10.7% of the applied rate of 0.2 lb ai/a/yr, a K_{oc} of 5.2 and a half-life of 116 days, the model projected breakthrough in 4 months and cyclic peaks ranging from 0 to 11 ppb. Changing the application rate to 10.7% of the applied rate of 0.4 lb ai/a/yr, the model projected breakthrough in 4 months and cyclic peaks ranging from 0 to 20 ppb.

Small-Scale Prospective Groundwater Monitoring Study: In the November 24, 2004 EFED Environmental Risk Assessment memo, the U.S. EPA stated:

"Due to direct soil and foliar applications of clothianidin and concerns about the chemical leaching into ground water (see below) the Agency will request the registrant to submit a small-scale prospective groundwater monitoring study:

> Source: EPA review "EFED Risk Assessment for the Seed Treatment of Clothianidin 600 FS on Corn and Canola" dated February 20, 2003 (page 3):
>
> "Clothianidin has the properties of a chemical which could lead to widespread groundwater contamination, but no ground-water monitoring studies have been conducted to date. Should the registrant request field uses involving direct application of clothianidin to the land surface, Prospective Ground-Water Monitoring Studies may be needed to evaluate fully the potential impact of such uses." Due to the extreme mobility and persistence of clothianidin in the environment, a small-scale prospective groundwater monitoring study will provide additional fate information on the better understanding of this chemical in the environment and improve the certainty of the risk assessment."

U.S. EPA Comments: In the November 24, 2004 EFED Environmental Risk Assessment memo, U.S. EPA stated: The available environmental fate data for clothianidin indicates that the chemical is persistent, mobile, and systemic. It is stable to hydrolysis at all pHs at environmental temperatures, has the potential to leach to groundwater, be transported via runoff to surface water bodies and could accumulate in soils from year to year with repeated uses. The major route of dissipation for clothianidin would appear to be photolysis if exposure to sunlight occurs (e.g. the measured aqueous photolysis half-life was <1 day and aerobic half-lives were 148 to 1155 days). Major degradates include TMG, MNG and TZNG."

Groundwater Staff Summary:

Given the potential for this active ingredient to leach to groundwater, the U.S. EPA's comments, the lack of actual groundwater monitoring data, and the results of the computer simulations, groundwater staff are concerned about clothianidin leaching into groundwater in vulnerable areas. Therefore, groundwater staff objects to the registration of these four products in New York State.

The U.S. EPA Notices of Registration for all four products required that a small-scale prospective groundwater monitoring study be submitted by November 30, 2006. The U.S. EPA recommended that the registrant submit a protocol prior to the initiation of the study. Information and results obtained from the small-scale prospective groundwater monitoring study are essential in order to provide additional fate information on the better understanding of this

chemical in the environment and improve the certainty of the risk assessment. However, the registrant has submitted a waiver to the U.S. EPA and has requested that the U.S. EPA deem the study unnecessary.

CONCLUSION:

The Department has reviewed all information submitted to date in support of registration of ARENA 50 WDG Insecticide, CLUTCH 50 WDG Insecticide, CELERO 16 WSG Insecticide, and ARENA 0.5 G Insecticide in New York State and continues to have numerous unresolved concerns regarding the potential of clothianidin to impact groundwater and the fish and wildlife resources in New York State.

Therefore, based on the above-mentioned information, the Department hereby **denies** the application for registration of **ARENA 50 WDG Insecticide** (EPA Reg. No. 66330-40), **CLUTCH 50 WDG Insecticide** (EPA Reg. No. 66330-40), **CELERO 16 WSG Insecticide** (EPA Reg. No. 66330-52), and **ARENA 0.5 G Insecticide** (EPA Reg. No. 66330-53) in New York State.

You may pursue the options available under Article 33-0711 of the New York State Environmental Conservation Law.

Please be reminded that the application fee is **nonrefundable**. If you wish to reapply, you must submit a new application for registration as a New Active Ingredient, applicable application fee and all required documents. The application should only be resubmitted when additional information, such as the reviews of the studies required to be submitted to the U.S. EPA as conditions of continued federal registration, is available for submission. Any available information or new information and/or studies regarding impact to aquatic habitats and pollinators, as well as groundwater data, preferably from a small-scale prospective groundwater monitoring study, should be submitted. The status of the required Developmental Immunotoxicity Study should also be addressed.

Please be aware that any unregistered product may not be sold, offered for sale, distributed, or used in New York State.

If you have any questions, please contact Samuel Jackling, Chief of our Pesticide Product Registration Section, at (518) 402-8768.

Sincerely,

Maureen P Serafini

Maureen P. Serafini
Director
Bureau of Pesticides Management

cc: N. Kim/D. Luttinger - NYS Dept. of Health
R. Mungari - NYS Dept. of Ag. & Markets
W. Smith - Cornell University, PMEP