Department of Pesticide Regulation

Mary-Ann Warmerdam
Director

Arnold Schwarzenegger
Governor

September 15, 2009

<Registrant Contact>
<Company Name>
<Company Address>
<City, State Zip>

Dear <Salutation>:

Data Requirements Regarding Reevaluation
of Certain Neonicotinoid Products

On February 27, 2009, pursuant to Article 8, Subchapter 1, Chapter 2, Division 6 of Title 3 of the California Code of Regulations, the Department of Pesticide Regulation (DPR) placed certain pesticide products within the nitroguanidine insecticide class of neonicotinoids containing the following active ingredients: imidacloprid, **clothianidin**, dinotefuran, and thiamethoxam into reevaluation.

Under the reevaluation, you were notified of a meeting on April 1, 2009 and provided an opportunity to comment on DPR's proposed data requirements for products containing clothianidin. DPR received a number of comments on the proposed data requirements which were considered before DPR finalized its reevaluation data requirements.

To determine the crops of focus for data requirements, DPR utilized California's Pesticide Use Reporting (PUR) database. This information is available electronically through the California Pesticide Information Portal (CalPIP) on DPR's Web site at <http://calpip.cdpr.ca.gov/main.cfm>. DPR staff attended the U.S. Department of Agriculture workshop, regarding honey bee toxicity testing and study protocols. This workshop reviewed and evaluated the latest study protocols for toxicity testing to all honey bee life stages.

REEVALUATION DATA REQUIREMENTS

Pursuant to this reevaluation <Company Name> is required to submit the following:

I. Compliance Proposal and Existing Information

Within **60 days** from the date of this letter, submit a written response that includes (1) a statement of how you intend to comply with the data requirements for products containing **clothianidin** (i.e., as a sole entity or through the formation of a Task Force); (2) identification of existing data to which you have access that meets the data

requirements as outlined in items III and IV of this letter; and, (3) any questions or clarifying information you need to comply with these data requirements.

When identifying data pursuant to item (2) above, please provide a summary of the data, including:

a. Study title, purpose, and explanation of applicability to the data requirement;
b. An abstract;
c. Summary of study results:
d. Description of methodologies; and,
e. Information on the availability of the raw data.

II. Submission of Existing Data

Within **90 days** from the date of this letter, submit copies of existing studies identified above that DPR has determined may be relevant to its clothianidin reevaluation data requirements.

III. Field Based Study with Clothianidin: Residue Analysis of Nectar and Pollen in Flowering Plants

A. Unless informed otherwise by DPR, within **120 days** from the date of this letter, submit a study protocol for conducting a residue analysis study of flowering plants from a representative crop grown in various soil texture categories.

General Design: Conduct a study that analyzes for clothianidin residues in the nectar and pollen of a representative crop grown in various regions within California. DPR is requiring registrants to collect nectar and pollen (see **"sampling"**) from a certain flowering plant and analyze the samples for residues of clothianidin. Based on data from DPR's PUR, it appears that while labeled for use on pome fruits, clothianidin has not been used on pome fruits. If correct, clothianidin registrants must conduct the study using a surrogate neonicotinoid.

As an alternative, DPR will accept the data from nectar and pollen analyzed for residues of imidacloprid, dinotefuran, or thiamethoxam and their major metabolites as a surrogate neonicotinoid. An acceptable protocol must be submitted to DPR before the study is initiated.

Study Protocol Specifics:

Crop/Crop Groups to be Sampled:

- Pome fruits

Sampling:

- Collect residue data from pollen and nectar utilizing direct or indirect sampling regimes. Study protocol shall include sampling methodology capable of providing data that are representative of concentrations of clothianidin or surrogate neonicotinoid in nectar and pollen at maximum label rates. For example, a direct sampling regime includes collecting pollen and nectar directly from the plant or, in the case of low pollen and nectar producing flowers, collecting bees observed to be foraging on the target crop. Obtain the pollen from bee pollen baskets and nectar from bee honey stomach. If collected from bees, the pollen must be analyzed to verify that it is from the target crop. Alternatively, an indirect sampling regime would include collecting blossoms from representative crops and extrapolating the pollen and nectar content. Refer to item III B below.

Treated Fields:

- Each field must have been previously treated with clothianidin or surrogate neonicotinoid by soil or foliar application at least once per year in the previous two years.
- Sample nine (9) treated fields for the representative crop/crop group.
- Collect two composite samples per field.
- The locations selected for the nine treated fields must represent each of three soil texture categories (three fields per type):
  a. Coarse-textured: Sands and Loamy Sands;
  b. Medium-textured: Loam, Silt Loam, and Silt; and,
  c. Fine-textured: Clay, Clay Loam, and Silty Clay.
  If there is a problem locating crops grown in one of the soil textures, then five fields are to be selected with each of the two remaining soil texture categories.
- The locations selected must be of sufficient size to provide appropriate experimental design.

Analysis:

- Utilize an appropriate analytical method to determine residue concentrations of clothianidin or surrogate neonicotinoid in pollen and nectar.
- The method should receive the following for clothianidin or surrogate neonicotinoid:

neonicotinoid and its major metabolite	limit of quantification (LOQ) in ppb	limit of detection (LOD) in ppb
clothianidin	10	2.5
imidacloprid and hydroxyl-metabolite	5	1.5
olefin-metabolite	10	3.0
dinotefuran and DN and UF metabolites[1]	10	3.0
thiamethoxam and CGA-322704[2]	10	2.5

[1] DN [*N*-methyl-*N'*-nitro-*N"*-(tetrahydro-3-furanyl)methyl)guanidine] and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea]

[2] CGA-322704 [*N*-(2-chloro-thiazol-5-ylmethyl)-*N'*-methyl-*N'*-nitro-guanidine]

Quality Control:

- Utilize good laboratory practices and adequate quality assurance/quality control measures, including validation and concurrent recoveries.

DPR will establish a date for submission of the final study report once the protocol is approved.

B. If you choose to collect residue data from blossoms, you must also conduct a study indicating that the levels of clothianidin or surrogate neonicotinoid residues in pome fruit blossoms are equal to or greater than residues in pollen and nectar. Within **120 days** from the date of this letter, submit a study protocol for conducting a blossom versus nectar/pollen residue comparison study.

DPR will establish a date for submission of the final study report once the protocol is approved.

IV. Acute Toxicity Studies on Honey Bee Life Stages

Based upon data on file, DPR estimates the lethal concentration of clothianidin needed to kill 50 percent of a test population (LC_{50}) of adult honey bees is 190 ppb. The LC_{50} was estimated by converting the acute oral LD_{50} to a concentration in nectar using the standard consumption model used in bee feeding studies.

Within **one year** from the date of this letter submit the results of an LC_{50} study on honey bees starting with the larval stage through emergence. A protocol for the study is available on DPR's Web site at <http://www.cdpr.ca.gov/docs/registration/reevaluation/chemicals/neonicotinoids.htm>.

If you choose to use an alternate protocol for conducting this study, the study protocol must be submitted to DPR within **120 days** from the date of this letter. The protocol must be accepted by DPR before the study is initiated. DPR will establish a date for submission of the final study report once the protocol is approved.

All studies and protocols submitted to DPR must be formatted in accordance with CA Notice 2006-06, Format Guidelines for Data Submitted to Support Pesticide Product Registrations in California. This Notice is located on DPR's Web site at <http://www.cdpr.ca.gov/docs/canot/CA2006-06.pdf>.

Depending upon the results of the above studies, DPR may require additional studies, including but not limited to: a honey residue analysis study, and green house and/or field toxicity studies.

GENERAL INFORMATION

DPR plans to work closely with U.S. Environmental Protection Agency's (U.S. EPA's) Office of Pesticide Programs and Pest Management Regulatory Agency (PMRA) Health Canada throughout the reevaluation process.

Upon request, DPR staff will meet with data generators to discuss the conduct of the above required studies.

Please note that pursuant to Food and Agricultural Code section 12811.5, as revised January 1, 2006, any registrant that does not submit its own data to fulfill a data requirement imposed by the Director to maintain the registration of its pesticide product, and instead relies upon data owned by another company, should be aware that they may have certain obligations, in specifically defined situations, to the owner of the data. For further information, please refer to

DPR's AB 1011 – Consolidated Resources Web site at <http://www.cdpr.ca.gov/docs/legbills/ab1011/resource.htm>.

Failure of a registrant to comply with the requirements of this reevaluation, may subject that registrant's product(s) to cancellation pursuant to Food and Agricultural Code section 12825(h).

Mailing Address

Please address all correspondence regarding this reevaluation as follows:

Neonicotinoid Reevaluation
Attn: Denise Alder
Department of Pesticide Regulation
1001 I Street, P.O. Box 4015
Sacramento, California 95812-4015

CONTACTS

If you have any questions regarding the reevaluation process, please contact Ms. Denise Alder by e-mail at <dalder@cdpr.ca.gov> or by telephone at 916-324-3522. If you have any questions regarding the required residue study protocols, please contact Dr. John Troiano by e-mail at <jtroiano@cdpr.ca.gov> or telephone at 916-324-4115. If you have any questions regarding honey bee toxicity study protocol, please contact Mr. Rich Bireley by e-mail at <rbireley@cdpr.ca.gov> or by telephone at 916-324-3930.

Sincerely,

Original signed by

Ann M. Prichard, Chief
Pesticide Registration Branch
916-324-3931

cc: Mr. Tom Moriarty, U.S. EPA, Pesticide Re-evaluation Division, Team Leader
Mr. Al Ramputh, PMRA Canada, Reevaluation Coordination Section II
Dr. John Troiano, DPR, Research Scientist II
Mr. Rich Bireley, DPR, Senior Environmental Research Scientist
Ms. Denise Alder, DPR, Program Specialist

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Under the reevaluation, you were notified of a meeting on April 1, 2009 and provided an opportunity to comment on DPR's proposed data requirements for products containing dinotefuran. DPR received a number of comments on the proposed data requirements which were considered before DPR finalized its reevaluation data requirements.

To determine the crops of focus for data requirements, DPR utilized California's Pesticide Use Reporting (PUR) database. This information is available electronically through the California Pesticide Information Portal (CalPIP) on DPR's Web site at <http://calpip.cdpr.ca.gov/main.cfm>. DPR staff attended the U.S. Department of Agriculture workshop, regarding honey bee toxicity testing and study protocols. This workshop reviewed and evaluated the latest study protocols for toxicity testing to all honey bee life stages.

REEVALUATION DATA REQUIREMENTS

Pursuant to this reevaluation <Company Name> is required to submit the following:

I. Compliance Proposal and Existing Information

Within **60 days** from the date of this letter, submit a written response that includes (1) a statement of how you intend to comply with the data requirements for products containing **dinotefuran** (i.e., as a sole entity or through the formation of a Task Force); (2) identification of existing data to which you have access that meets the data

requirements as outlined in items III and IV of this letter; and, (3) any questions or clarifying information you need to comply with these data requirements.

When identifying data pursuant to item (2) above, please provide a summary of the data, including:

a. Study title, purpose, and explanation of applicability to the data requirement;
b. An abstract;
c. Summary of study results:
d. Description of methodologies; and,
e. Information on the availability of the raw data.

II. Submission of Existing Data

Within **90 days** from the date of this letter, submit copies of existing studies identified above that DPR has determined may be relevant to its dinotefuran reevaluation data requirements.

III. Field Based Study with Dinotefuran: Residue Analysis of Nectar and Pollen in Flowering Plants

A. Unless informed otherwise by DPR, within **120 days** from the date of this letter, submit a study protocol for conducting a residue analysis study of flowering plants from representative crops grown in various soil texture categories.

General Design: Conduct a study that analyzes for dinotefuran residues in the nectar and pollen of representative crops grown in various regions within California. DPR is requiring registrants to collect nectar and pollen (see **"sampling"**) from the three crops/crop groups listed below and analyze the samples for residues of dinotefuran and its major metabolites, DN [*N*-methyl-*N'*-nitro-*N"*-(tetrahydro-3-furanyl)methyl)guanidine] and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea].

As an alternative, DPR will accept the data from nectar and pollen analyzed for residues of imidacloprid, thiamethoxam, or clothianidin and their major metabolites as a surrogate neonicotinoid. An acceptable protocol must be submitted to DPR before the study is initiated.

Study Protocol Specifics:

Crop/Crop Groups to be Sampled:

- Cotton
- Cucurbits
- Fruiting vegetables

Sampling:

- Collect residue data from pollen and nectar utilizing direct or indirect sampling regimes. Study protocol shall include sampling methodology capable of providing data that are representative of concentrations of dinotefuran or surrogate neonicotinoid in nectar and pollen at maximum label rates. For example, a direct sampling regime includes collecting pollen and nectar directly from the plant or, in the case of low pollen and nectar producing flowers, collecting bees observed to be foraging on the target crop. Obtain the pollen from bee pollen baskets and nectar from bee honey stomach. If collected from bees, the pollen must be analyzed to verify that it is from the target crop. Alternatively, an indirect sampling regime would include collecting blossoms from representative crops and extrapolating the pollen and nectar content. Refer to item III B below.

Treated Fields:

- Each crop/crop group, or field in the case of an annual crop/crop group, must have been previously treated with dinotefuran or surrogate neonicotinoid by soil or foliar application at least once per year in the previous two years.
- Sample nine (9) treated fields for each representative crop/crop group.
- Collect two composite samples per field.
- The locations selected for the nine treated fields per crop/crop group must represent each of three soil texture categories (three fields per type):
  a. Coarse-textured: Sands and Loamy Sands;
  b. Medium-textured: Loam, Silt Loam, and Silt; and,
  c. Fine-textured: Clay, Clay Loam, and Silty Clay.
  If there is a problem locating crops grown in one of the soil textures, then five fields are to be selected with each of the two remaining soil texture categories.
- The locations selected must be of sufficient size to provide appropriate experimental design.

Analysis:

- Utilize an appropriate analytical method to determine residue concentrations of dinotefuran and its DN and UF metabolites or surrogate neonicotinoid in pollen and nectar.
- The method should receive the following for dinotefuran and the DN and UF metabolites or surrogate neonicotinoid:

neonicotinoid and its major metabolite	limit of quantification (LOQ) in ppb	limit of detection (LOD) in ppb
dinotefuran and DN and UF metabolites[1]	10	3.0
imidacloprid and hydroxyl-metabolite	5	1.5
olefin-metabolite	10	3.0
thiamethoxam and CGA-322704[2]	10	2.5
clothianidin	10	2.5

[1] DN [*N*-methyl-*N'*-nitro-*N"*-(tetrahydro-3-furanyl)methyl)guanidine] and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea]

[2] CGA-322704 [*N*-(2-chloro-thiazol-5-ylmethyl)-*N'*-methyl-*N'*-nitro-guanidine]

Quality Control:

- Utilize good laboratory practices and adequate quality assurance/quality control measures, including validation and concurrent recoveries.

DPR will establish a date for submission of the final study report once the protocol is approved.

B. If you choose to collect residue data from blossoms, you must also conduct a study indicating that the levels of dinotefuran or surrogate neonicotinoid residues in blossoms are equal to or greater than residues in pollen and nectar. Within **120 days** from the date of this letter, submit a study protocol for conducting a blossom versus nectar/pollen residue comparison study. The study design shall include and be relevant to all of the crop/crop groups for which you are using an indirect sampling regime. In the case of crop groups, the individual crop selected shall represent the entire group as identified above.

DPR will establish a date for submission of the final study report once the protocol is approved.

IV. Acute Toxicity Studies on Honey Bee Life Stages

Based upon data on file, DPR estimates the lethal concentration of dinotefuran needed to kill 50 percent of a test population (LC_{50}) of adult honey bees is 380 ppb. The LC_{50} was estimated by converting the acute oral LD_{50} to a concentration in nectar using the standard consumption model used in bee feeding studies.

Within **one year** from the date of this letter submit the results of an LC_{50} study on honey bees starting with the larval stage through emergence. A protocol for the study is available on DPR's Web site at <http://www.cdpr.ca.gov/docs/registration/reevaluation/chemicals/neonicotinoids.htm>.

If you choose to use an alternate protocol for conducting this study, the study protocol must be submitted to DPR within **120 days** from the date of this letter. The protocol must be accepted by DPR before the study is initiated. DPR will establish a date for submission of the final study report once the protocol is approved.

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Depending upon the results of the above studies, DPR may require additional studies, including but not limited to: a honey residue analysis study, and green house and/or field toxicity studies.

GENERAL INFORMATION

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Please note that pursuant to Food and Agricultural Code section 12811.5, as revised January 1, 2006, any registrant that does not submit its own data to fulfill a data requirement imposed by the Director to maintain the registration of its pesticide product, and instead relies upon data owned by another company, should be aware that they may have certain obligations,

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Failure of a registrant to comply with the requirements of this reevaluation, may subject that registrant's product(s) to cancellation pursuant to Food and Agricultural Code section 12825(h).

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Under the reevaluation, you were notified of a meeting on April 1, 2009 and provided an opportunity to comment on DPR's proposed data requirements for products containing imidacloprid. DPR received a number of comments on the proposed data requirements which were considered before DPR finalized its reevaluation data requirements.

To determine the crops of focus for data requirements, DPR utilized California's Pesticide Use Reporting (PUR) database. This information is available electronically through the California Pesticide Information Portal (CalPIP) on DPR's Web site at <http://calpip.cdpr.ca.gov/main.cfm>. DPR staff attended the U.S. Department of Agriculture workshop, regarding honey bee toxicity testing and study protocols. This workshop reviewed and evaluated the latest study protocols for toxicity testing to all honey bee life stages.

REEVALUATION DATA REQUIREMENTS

Pursuant to this reevaluation <Company Name> is required to submit the following:

I. Compliance Proposal and Existing Information

Within **60 days** from the date of this letter, submit a written response that includes (1) a statement of how you intend to comply with the data requirements for products containing **imidacloprid** (i.e., as a sole entity or through the formation of a Task Force); (2) identification of existing data to which you have access that meets the data

requirements as outlined in items III and IV of this letter; and, (3) any questions or clarifying information you need to comply with these data requirements.

When identifying data pursuant to item (2) above, please provide a summary of the data, including:

a. Study title, purpose, and explanation of applicability to the data requirement;
b. An abstract;
c. Summary of study results:
d. Description of methodologies; and,
e. Information on the availability of the raw data.

II. Submission of Existing Data

Within **90 days** from the date of this letter, submit copies of existing studies identified above that DPR has determined may be relevant to its imidacloprid reevaluation data requirements.

III. Field Based Study with Imidacloprid: Residue Analysis of Nectar and Pollen in Flowering Plants

A. Unless informed otherwise by DPR, within **120 days** from the date of this letter, submit a study protocol for conducting a residue analysis study of flowering plants from representative crops grown in various soil texture categories.

General Design: Conduct a study that analyzes for imidacloprid residues in the nectar and pollen of representative crops grown in various regions within California. DPR is requiring registrants to collect nectar and pollen (see **"sampling"**) from the seven crops/crop groups listed below and analyze the samples for residues of imidacloprid and its major metabolites. An acceptable protocol must be submitted to DPR before the study is initiated.

Study Protocol Specifics:

Crop/Crop Groups to be Sampled:

- Almonds
- Citrus
- Cotton
- Cucurbits
- Fruiting vegetables
- Pome fruits
- Strawberries

Sampling:

- Collect residue data from pollen and nectar utilizing direct or indirect sampling regimes. Study protocol shall include sampling methodology capable of providing data that are representative of concentrations of imidacloprid in nectar and pollen at maximum label rates. For example, a direct sampling regime includes collecting pollen and nectar directly from the plant or, in the case of low pollen and nectar producing flowers, collecting bees observed to be foraging on the target crop. Obtain the pollen from bee pollen baskets and nectar from bee honey stomach. If collected from bees, the pollen must be analyzed to verify that it is from the target crop. Alternatively, an indirect sampling regime would include collecting blossoms from representative crops and extrapolating the pollen and nectar content. Refer to item III B below.

Treated Fields:

- Each crop/crop group, or field in the case of an annual crop/crop group, must have been previously treated with imidacloprid by soil or foliar application at least once per year in the previous two years.
- Sample nine (9) treated fields for each representative crop/crop group.
- Collect two composite samples per field.
- The locations selected for the nine treated fields per crop/crop group must represent each of three soil texture categories (three fields per type):
  a. Coarse-textured: Sands and Loamy Sands;
  b. Medium-textured: Loam, Silt Loam, and Silt; and,
  c. Fine-textured: Clay, Clay Loam, and Silty Clay.
  If there is a problem locating crops grown in one of the soil textures, then five fields are to be selected with each of the two remaining soil texture categories.
- The locations selected must be of sufficient size to provide appropriate experimental design.

Analysis:

- Utilize an appropriate analytical method to determine residue concentrations of imidacloprid and its hydroxy and olefin metabolites.
- The method should receive a limit of quantification (LOQ) of 5 ppb and limit of detection (LOD) of 1.5 ppb for imidacloprid and the hydroxy-metabolite and a LOQ of 10 ppb and a LOD of 3 ppb for the olefin-metabolite.

Quality Control:

- Utilize good laboratory practices and adequate quality assurance/quality control measures, including validation and concurrent recoveries.

DPR will establish a date for submission of the final study report once the protocol is approved.

B. If you choose to collect residue data from blossoms, you must also conduct a study indicating that the levels of imidacloprid residues in blossoms are equal to or greater than residues in pollen and nectar. Within **120 days** from the date of this letter, submit a study protocol for conducting a blossom versus nectar/pollen residue comparison study. The study design shall include and be relevant to all of the crop/crop groups for which you are using an indirect sampling regime. In the case of crop groups, the individual crop selected shall represent the entire group as identified above.

DPR will establish a date for submission of the final study report once the protocol is approved.

IV. Acute Toxicity Studies on Honey Bee Life Stages

Based upon data on file, DPR estimates the lethal concentration of imidacloprid needed to kill 50 percent of a test population (LC_{50}) of adult honey bees is 185 ppb. The LC_{50} was estimated by converting the acute oral LD_{50} to a concentration in nectar using the standard consumption model used in bee feeding studies.

Within **one year** from the date of this letter submit the results of an LC_{50} study on honey bees starting with the larval stage through emergence. A protocol for the study is available on DPR's Web site at <http://www.cdpr.ca.gov/docs/registration/reevaluation/chemicals/neonicotinoids.htm>.

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Upon request, DPR staff will meet with data generators to discuss the conduct of the above required studies.

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<Company Address>
<City, State Zip>

Dear <Salutation>:

Data Requirements Regarding Reevaluation
of Certain Neonicotinoid Products

On February 27, 2009, pursuant to Article 8, Subchapter 1, Chapter 2, Division 6 of Title 3 of the California Code of Regulations, the Department of Pesticide Regulation (DPR) placed certain pesticide products within the nitroguanidine insecticide class of neonicotinoids containing the following active ingredients: imidacloprid, clothianidin, dinotefuran, and **thiamethoxam** into reevaluation.

Under the reevaluation, you were notified of a meeting on April 1, 2009 and provided an opportunity to comment on DPR's proposed data requirements for products containing thiamethoxam. DPR received a number of comments on the proposed data requirements which were considered before DPR finalized its reevaluation data requirements.

To determine the crops of focus for data requirements, DPR utilized California's Pesticide Use Reporting (PUR) database. This information is available electronically through the California Pesticide Information Portal (CalPIP) on DPR's Web site at <http://calpip.cdpr.ca.gov/main.cfm>. DPR staff attended the U.S. Department of Agriculture workshop, regarding honey bee toxicity testing and study protocols. This workshop reviewed and evaluated the latest study protocols for toxicity testing to all honey bee life stages.

REEVALUATION DATA REQUIREMENTS

Pursuant to this reevaluation <Company Name> is required to submit the following:

I. Compliance Proposal and Existing Information

Within **60 days** from the date of this letter, submit a written response that includes (1) a statement of how you intend to comply with the data requirements for product containing **thiamethoxam** (i.e., as a sole entity or through the formation of a Task Force);

(2) identification of existing data to which you have access that meets the data requirements as outlined in items III and IV of this letter; and, (3) any questions or clarifying information you need to comply with these data requirements.

When identifying data pursuant to item (2) above, please provide a summary of the data, including:

a. Study title, purpose, and explanation of applicability to the data requirement;
b. An abstract;
c. Summary of study results:
d. Description of methodologies; and,
e. Information on the availability of the raw data.

II. Submission of Existing Data

Within **90 days** from the date of this letter, submit copies of existing studies identified above that DPR has determined may be relevant to its thiamethoxam reevaluation data requirements.

III. Field Based Study with Thiamethoxam: Residue Analysis of Nectar and Pollen in Flowering Plants

A. Unless informed otherwise, within **120 days** from the date of this letter, submit a study protocol for conducting a residue analysis study of flowering plants from representative crops grown in various soil texture categories.

General Design: Conduct a study that analyzes for thiamethoxam residues in the nectar and pollen of representative crops grown in various regions within California. DPR is requiring registrants to collect nectar and pollen (see **"sampling"**) from the five crops/crop groups listed below and analyze the samples for residues of thiamethoxam and its major metabolite, CGA-322704 [*N*-(2-chloro-thiazol-5-ylmethyl)-*N'*-methyl-*N'*-nitro-guanidine].

As an alternative, DPR will accept the data from nectar and pollen analyzed for residues of imidacloprid, clothianidin, or dinotefuran and their major metabolites as a surrogate neonicotinoid. An acceptable protocol must be submitted to DPR before the study is initiated.

Study Protocol Specifics:

Crop/Crop Groups to be Sampled:

- Cucurbits
- Fruiting vegetables
- Pome fruits
- Strawberries

Sampling:

- Collect residue data from pollen and nectar utilizing direct or indirect sampling regimes. Study protocol shall include sampling methodology capable of providing data that are representative of concentrations of thiamethoxam or surrogate neonicotinoid in nectar and pollen at maximum label rates. For example, a direct sampling regime includes collecting pollen and nectar directly from the plant or, in the case of low pollen and nectar producing flowers, collecting bees observed to be foraging on the target crop. Obtain the pollen from bee pollen baskets and nectar from bee honey stomach. If collected from bees, the pollen must be analyzed to verify that it is from the target crop. Alternatively, an indirect sampling regime would include collecting blossoms from representative crops and extrapolating the pollen and nectar content. Refer to item III B below.

Treated Fields:

- Each crop/crop group, or field in the case of an annual crop/crop group, must have been previously treated with thiamethoxam or surrogate neonicotinoid by soil or foliar application at least once per year in the previous two years.
- Sample nine (9) treated fields for each representative crop/crop group.
- Collect two composite samples per field.
- The locations selected for the nine treated fields per crop/crop group must represent each of three soil texture categories (three fields per type):
  a. Coarse-textured: Sands and Loamy Sands;
  b. Medium-textured: Loam, Silt Loam, and Silt; and,
  c. Fine-textured: Clay, Clay Loam, and Silty Clay.
  If there is a problem locating crops grown in one of the soil textures, then five fields are to be selected with each of the two remaining soil texture categories.
- The locations selected must be of sufficient size to provide appropriate experimental design.

Analysis:

- Utilize an appropriate analytical method to determine residue concentrations of thiamethoxam and the CGA-322704 metabolite or surrogate neonicotinoid in pollen and nectar.
- The method should receive the following for thiamethoxam and the CGA-322704 metabolite or surrogate neonicotinoid:

neonicotinoid and its major metabolite	limit of quantification (LOQ) in ppb	limit of detection (LOD) in ppb
thiamethoxam and CGA-322704[1]	10	2.5
imidacloprid and hydroxyl-metabolite	5	1.5
olefin-metabolite	10	3.0
clothianidin	10	2.5
dinotefuran and DN and UF metabolites[2]	10	3.0

[1] CGA-322704 [*N*-(2-chloro-thiazol-5-ylmethyl)-*N'*-methyl-*N'*-nitro-guanidine]

[2] DN [*N*-methyl-*N'*-nitro-*N"*-(tetrahydro-3-furanyl)methyl)guanidine] and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea]

Quality Control:

- Utilize good laboratory practices and adequate quality assurance/quality control measures, including validation and concurrent recoveries.

DPR will establish a date for submission of the final study report once the protocol is approved.

B. If you choose to collect residue data from blossoms, you must also conduct a study indicating that the levels of thiamethoxam or surrogate neonicotinoid residues in blossoms are equal to or greater than residues in pollen and nectar. Within **120 days** from the date of this letter, submit a study protocol for conducting a blossom versus nectar/pollen residue comparison study. The study design shall include and be relevant to all of the crop/crop groups for which you are using an indirect sampling regime. In the case of crop groups, the individual crop selected shall represent the entire group as identified above.

DPR will establish a date for submission of the final study report once the protocol is approved.

IV. Acute Toxicity Studies on Honey Bee Life Stages

Based upon data on file, DPR estimates the lethal concentration of dinotefuran needed to kill 50 percent of a test population (LC_{50}) of adult honey bees is 250 ppb. The LC_{50} was estimated by converting the acute oral LD_{50} to a concentration in nectar using the standard consumption model used in bee feeding studies.

Within **one year** from the date of this letter submit the results of an LC_{50} study on honey bees starting with the larval stage through emergence. A protocol for the study is available on DPR's Web site at <http://www.cdpr.ca.gov/docs/registration/reevaluation/chemicals/neonicotinoids.htm>.

If you choose to use an alternate protocol for conducting this study, the study protocol must be submitted to DPR within **120 days** from the date of this letter. The protocol must be accepted by DPR before the study is initiated. DPR will establish a date for submission of the final study report once the protocol is approved.

All studies and protocols submitted to DPR must be formatted in accordance with CA Notice 2006-06, Format Guidelines for Data Submitted to Support Pesticide Product Registrations in California. This Notice is located on DPR's Web site at <http://www.cdpr.ca.gov/docs/canot/CA2006-06.pdf>.

Depending upon the results of the above studies, DPR may require additional studies, including but not limited to: a honey residue analysis study, and green house and/or field toxicity studies.

GENERAL INFORMATION

DPR plans to work closely with U.S. Environmental Protection Agency's (U.S. EPA's) Office of Pesticide Programs and Pest Management Regulatory Agency (PMRA) Health Canada throughout the reevaluation process.

Upon request, DPR staff will meet with data generators to discuss the conduct of the above required studies.

Please note that pursuant to Food and Agricultural Code section 12811.5, as revised January 1, 2006, any registrant that does not submit its own data to fulfill a data requirement imposed by the Director to maintain the registration of its pesticide product, and instead relies upon data owned by another company, should be aware that they may have certain obligations,

in specifically defined situations, to the owner of the data. For further information, please refer to DPR's AB 1011 – Consolidated Resources Web site at <http://www.cdpr.ca.gov/docs/legbills/ab1011/resource.htm>.

Failure of a registrant to comply with the requirements of this reevaluation, may subject that registrant's product(s) to cancellation pursuant to Food and Agricultural Code section 12825(h).

Mailing Address

Please address all correspondence regarding this reevaluation as follows:

Neonicotinoid Reevaluation
Attn: Denise Alder
Department of Pesticide Regulation
1001 I Street, P.O. Box 4015
Sacramento, California 95812-4015

CONTACTS

If you have any questions regarding the reevaluation process, please contact Ms. Denise Alder by e-mail at <dalder@cdpr.ca.gov> or by telephone at 916-324-3522. If you have any questions regarding the required residue study protocols, please contact Dr. John Troiano by e-mail at <jtroiano@cdpr.ca.gov> or telephone at 916-324-4115. If you have any questions regarding honey bee toxicity study protocol, please contact Mr. Rich Bireley by e-mail at <rbireley@cdpr.ca.gov> or by telephone at 916-324-3930.

Sincerely,

Original signed by

Ann M. Prichard, Chief
Pesticide Registration Branch
916-324-3931

cc: Mr. Tom Moriarty, U.S. EPA, Pesticide Re-evaluation Division, Team Leader
Mr. Al Ramputh, PMRA Canada, Reevaluation Coordination Section II
Dr. John Troiano, DPR, Research Scientist II
Mr. Rich Bireley, DPR, Senior Environmental Research Scientist
Ms. Denise Alder, DPR, Program Specialist