UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

PC Code: 122806
DP Barcodes: D397515
Chemical: Emamectin benzoate
Date: January 23, 2012

MEMORANDUM

SUBJECT: Addendum to the Emamectin benzoate Problem Formulation (June 23, 2011; DP Barcode D385989): Additional data needs

TO: Katherine St. Clair, Chemical Review Manager
Risk Management and Implementation Branch 2
Pesticide Re-evaluation Division (7508P)

FROM: Tanja Crk, Biologist Tanja Crk 1.23.2012
Environmental Risk Branch 3
Environmental Fate and Effects Division (7507P)

THROUGH: Rosanna Louie-Juzwiak, Risk Assessment Process Leader
Dana Spatz, Branch Chief 23 JAN 2012 1-23-12
Environmental Risk Branch 3
Environmental Fate and Effects Division (7507P)

Since the Preliminary Problem Formulation was finalized (June 23, 2011) for the Environmental Fate, Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments for Emamectin Benzoate, EFED's understanding of pollinator data needs relating to systemic insecticides has evolved after continued evaluation of available honeybee field study results and available terrestrial invertebrate acute data. As stated in the Preliminary Problem Formulation, emamectin benzoate is highly toxic to honeybees on an acute contact basis. Based on available acute toxicity data for honeybees, emamectin benzoate residues on foliage, resulting from a foliar application at 0.015 lb a.i./A, can remain toxic to honeybees for 8-24 hours. Given its systemic properties, there is also the potential that honeybees may be exposed to emamectin benzoate that has

translocated to the nectar and pollen as a result of a spray or tree injection application. Finally, there are uncertainties associated with the potential impacts to the developmental stages of beneficial insects (e.g., larval stage), and from any chronic exposures. As a result, the following studies are included as additional data needs in support of the ecological risk assessment for emamectin benzoate under Registration Review:

OPPTS 850.3040 Field Testing for Pollinators

A honey bee field study that provides relevant and reliable toxicity information on the performance of the colonies after exposure to emamectin benzoate is recommended. Additional semi-or full-field studies may be requested pending review of lower tier studies (*i.e.*, non-guideline studies: larval toxicity; chronic feeding study; and, residues in pollen and nectar – *i.e.*, magnitude of residue study). A study protocol for the field test should be submitted for Agency review prior to study initiation.

Emamectin benzoate is highly toxic to bees on an acute contact basis (0.0035 µg a.i./bee; MRID 42851530) and when applied as a foliar spray at a rate of 0.015 lbs a.i./A it will remain toxic to bees on foliage for 8-24 hours after application (MRID 43393006). Because of this, EFED recommends that emamectin benzoate not be applied to blooming, pollen-shedding or nectar-producing parts of plants; but the test crop should be one on which bees will actively forage for both nectar and pollen (e.g., cotton, melon, alfalfa). EFED expects the study design will include maximum emamectin benzoate application rates, at minimum intervals, and maximum number of applications. EFED does not know how much emamectin benzoate can be expected to be translocated to the nectar and pollen when applied as a foliar, soil, or tree injection application to plants before nectar or pollen production. If emamectin benzoate is being translocated to the nectar and pollen, there is uncertainty as to whether there is any adverse effect to foragers or to the hive over time.

Non-Guideline Pollinator Larval Toxicity Study

Emamectin benzoate is highly toxic to bees on an acute contact exposure basis; however, because the acute contact study is conducted with young adult honeybees, there is uncertainty regarding the potential effects of emamectin benzoate on larval bees. Therefore, EFED recommends that the registrant conduct a larval toxicity study. The registrant should consult with the Agency prior to initiation of this study.

Non-Guideline Lab Pollinator Chronic Feeding Study

A chronic adult laboratory feeding study should be conducted to determine if chronic, repeated exposure leads to mortality or sublethal effects. This study would provide an endpoint for comparison with acute oral data and a comparison of effects from acute to sustained exposure over longer periods of time. The registrant should consult with the Agency prior to initiation of this study.

Appendix A: Data Justification Tables

Study Title: Field Test For Pollinators **Guideline Number: 850.3040 (141-5)** **Test substance: Emamectin benzoate**
Rationale for Requiring the Data
Given the potential for exposure to pollinators to toxic levels of emamectin benzoate translocated in treated crops, the Agency has indicated the need for pollinator field testing. This exposure to honey bees and other non-target terrestrial invertebrates could be manifested through the presence of emamectin benzoate from various routes of exposure, including, but not limited to, nectar and pollen. In order to have a better understanding of emamectin benzoate exposure routes and potential impact on pollinators, more information is needed from carefully designed field studies. The registrant should consult the Agency on the design of the protocol prior to the initiation of the study.
Practical Utility of the Data
How will the data be used? To assess risk to non-target listed and non-listed terrestrial invertebrate species. This study would allow the Agency to refine the screening level risk assessment for beneficial terrestrial invertebrates. The effects data would be used to determine the potential for risk to beneficial terrestrial invertebrates from specific routes of exposure. **How could the data impact the Agency's future decision-making?** EPA is required by section 7(a)(2) of the Endangered Species Act (ESA) to ensure that any action it authorizes or takes "…is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of critical habitat" and "to use the best scientific data available" in carrying out this obligation. The data EPA intends to call in are necessary to inform the determination required by ESA as to whether continued registration of a pesticide is or is not likely to jeopardize the species or its critical habitat. The lack of these data will limit the flexibility that the Agency and registrants have in coming into compliance with ESA and could result in use restrictions that are unnecessarily severe. In addition, the lack of these data may result in assumed risk and potential mitigation of emamectin benzoate formulations under FIFRA.

Study Title: Pollinator Larval Toxicity Study **Guideline Number: Non-guideline** **Test Substance: Emamectin benzoate**
Rationale for Requiring the Data
Environmental fate and toxicological data indicate that emamectin benzoate is a persistent and systemic insecticide and is highly toxic to adult honey bees on an acute exposure basis. Because of the potential for pollen and nectar to be contaminated with emamectin benzoate it is important to determine the toxicity of this compound to pollinator larvae. The registrant should consult the Agency on the design of the protocol prior to the initiation of the study.
Practical Utility of the Data

How will the data be used?
To assess risk to non-target listed and non-listed terrestrial invertebrate species. This study would allow the Agency to refine the screening level risk assessment for beneficial terrestrial invertebrates. The effects data will be used to determine the potential for risk to beneficial terrestrial invertebrates through direct effects on larval bees.
How could the data impact the Agency's future decision-making?
EPA is required by section 7(a)(2) of the Endangered Species Act (ESA) to ensure that any action it authorizes or takes "…is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of critical habitat" and "to use the best scientific data available" in carrying out this obligation. The data EPA intends to call in are necessary to inform the determination required by ESA as to whether continued registration of a pesticide is or is not likely to jeopardize the species or its critical habitat. The lack of these data will limit the flexibility that the Agency and registrants have in coming into compliance with ESA and could result in use restrictions that are unnecessarily severe. In addition, the lack of these data may result in assumed risk and potential mitigation of emamectin benzoate formulations under FIFRA.

Study Title: Pollinator Laboratory Chronic Feeding Study
Guideline Number: Non-guideline
Test Substance: Emamectin benzoate

Rationale for Requiring the Data

Environmental fate and toxicological data indicate that emamectin benzoate is a persistent and systemic insecticide and is highly toxic to adult honey bees on an acute exposure basis. Because of the potential for pollen and nectar to be contaminated with emamectin benzoate it is important to determine the toxicity of this compound to adult pollinators on a chronic basis. It is possible for emamectin benzoate to cause sublethal effects, which may affect the ability of the pollinator to forage for food, communicate, and rear young. The registrant should consult the Agency on the design of the protocol prior to the initiation of the study.

Practical Utility of the Data

How will the data be used?
To assess risk to non-target listed and non-listed terrestrial invertebrate species. This study would allow the Agency to refine the screening level risk assessment for beneficial terrestrial invertebrates. The effects data will be used to determine the potential for risk to beneficial terrestrial invertebrates through direct effects on bees over time.
How could the data impact the Agency's future decision-making?
EPA is required by section 7(a)(2) of the Endangered Species Act (ESA) to ensure that any action it authorizes or takes "…is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of critical habitat" and "to use the best scientific data available" in carrying out this obligation. The data EPA intends to call in are necessary to inform the determination required by ESA as to whether continued registration of a pesticide is or is not likely to jeopardize the species or its critical habitat. The lack of these data will limit the flexibility that the Agency and registrants have in coming into compliance with ESA and could result in use restrictions that are unnecessarily severe. In addition, the lack of these data may result in assumed risk and potential mitigation of emamectin benzoate formulations under FIFRA.