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

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MEMORANDUM

SUBJECT: EFED Problem Formulation for the Registration Review of Imidacloprid

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Attached is the EFED problem formulation for imidacloprid. Under previous assessments, it was suggested that imidacloprid has the potential to cause acute risk to small seed-eating endangered avian species as well as to endangered and non-endangered small mammals. There seems to be evidence of avian repellency to imidacloprid treated seed which may mitigate some risk to seed-eating avian species. However, to what extent risk would be mitigated is still an uncertainty. Mammalian chronic levels of concern were also exceeded for small mammals that consume shortgrass. Exposure of this compound to an aquatic area can result in direct acute and chronic risk to endangered and non-target aquatic invertebrates (freshwater and estuarine/marine). Slope estimated chance of individual mortality following imidacloprid exposure is 1 in 71.7 for freshwater invertebrates. Although direct toxic risk to fish (freshwater and estuarine/marine) appears to be low, there is the possibility of secondary risk to fish through alterations in food chains that involve aquatic invertebrates.

A major ecological issue is the potential hazard to bees exposed to imidacloprid in treated crops. This problem first came to light in 1999 when incidents of bee death and disorientation were reported in France as being linked to bees foraging on sunflowers grown from treated seed. As a result of these incidents, France banned the use of imidacloprid as a seed treatment for sunflowers and maize. In the years since then, a number of studies have been conducted in Europe and Canada which show residues in pollen and nectar from canola grown from treated seed, as well as residues in blossoms and leaves of ornamental plants as long as 540 days after treatment of the surrounding soil.

In addition, The Agency is currently in collaboration with other Agencies and researchers regarding the issue of pesticides, particularly the neonicotinoids, and their adverse effects on honeybees. The Agency is exploring all possible causes of Colony Collapse Disorder in bees, including the possible impact of pesticides, including imidacloprid.

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OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

Problem Formulation For The Imidacloprid Environmental Fate And Ecological Risk Assessment

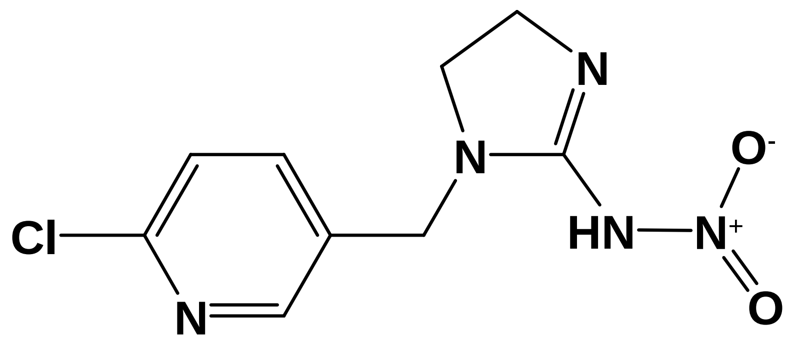

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Table of Contents

Problem Formulation

The purpose of this problem formulation is to provide the foundation for the ecological risk assessment being conducted for Imidacloprid. As such, it articulates the purpose and objectives of the risk assessment, evaluates the nature of the problem, and provides a plan for analyzing the data and characterizing the risk (EPA, 1998).

Nature of Regulatory Action

This document covers the Environmental Fate and Effects Division's (EFED) Registration Review of Imidacloprid. Previously, Section 3 risk assessments were completed for this chemical. Those reviews serve as the basis for this document.

Stressor Sources and Distribution

Nature of the Chemical Stressor

In this assessment, Imidacloprid is considered to be the only stressor as it is the active ingredient of the insecticide under consideration. The chemical is a systemic chloronicotinyl insecticide with long residual effects. Imidacloprid shares a common mechanism of toxicity with other systemic chloronicotinyl pesticides, such as the toxicity expressed through a common biochemical pathway.

Imidacloprid {1-((6-chloro-3-pyridinyl)methyl)-4,5-dihydro-N-nitro-N-nitro-1H-imidazol-2-amine} is a systemic neural toxic insecticide of the chemical class, nitroguanidines (chlorinated derivative of nicotine). As a neuron effector, this compound attacks the cholinergic receptors, especially the nicotinic receptors, by out-competing acetylcholine for available binding sites, thereby rendering acetylcholine dysfunctional.

The stressor is expected to reach terrestrial and aquatic receptors from application spray drift, runoff, and from translocation into plant products (e.g., pollen and nectar) from treated seed. This is discussed in more detail in the Environmental Fate section below.

Overview of Pesticide Usage

Imidacloprid is a systemic, chloro-nicotinyl insecticide with soil, seed and foliar uses for the control of sucking insects. It is commonly used on vegetable crops, tree nuts, tree fruits, stone fruits, cotton, tobacco, grapes, citrus, turf, and ornamentals. Target pests include aphids, thrips, whiteflies, termites, turf insects, soil insects and some beetles. Imidacloprid-based insecticide formulations are available as wettable powder, granular, seed dressing (flowable slurry concentrate), and soluble concentrate.

1. Environmental Fate

A summary of key environmental fate parameters (as determined for aquatic exposure modeling) is provided in Table 1, page 8. Note that exposure modeling of imidacloprid parent versus imidacloprid parent + degradates (in a total residue approach) yields essentially the same exposure estimates because of the high environmental persistence of parent imidacloprid. The major routes of dissipation for imidacloprid appear to be photolysis and anaerobic aquatic metabolism. Imidacloprid appears to be stable to aerobic soil metabolism. The chemical is mobile and is a major concern for ground waters, where there have been detections. Imidacloprid may readily runoff dissolved in water and reach adjacent bodies of water. Since the chemical appears to be persistent under aerobic soil metabolism, imidacloprid may be available for runoff for periods exceeding one season. Potentially important environmental degradates include:

1) imidacloprid guanidine, 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidinimine {Alias NTN 38014, NTN 33823}
2) imidacloprid olefin, 1-[(6-chloro-3-pyridin1yl)methyl]-1,3-dihydro-2H-imidazol-2-imine
3) imidacloprid urea, 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidinone.{NTN 33519}.

Since parent imidacloprid is environmentally persistent, these degradates are more likely to be found in ground water than surface water because of the usually much longer travel times to ground water.

It appears that photolysis plays an important role in the dissipation of imidacloprid (if, of course, exposure to sunlight occurs), both in aqueous solution (half-life 0.2 days) and on soil (half-life 39 days). Another route of transformation that appears to be important for imidacloprid is anaerobic aquatic metabolism (half-life 27 days), with the formation of imidacloprid guanidine (66% at 249 days; 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidinimine {Alias NTN 38014, NTN 33823}), a compound that appeared to be very persistent. Imidacloprid is very persistent under aerobic soil metabolism conditions (half-lives were 660, 188, 248 and 341 days in four soils).

Based on its K_{oc} values, imidacloprid would have medium mobility, with K_{oc}s ranging from 161 to 256 (based on nine soils, five domestic and four foreign). However, based on its K_{ads} values, it appears that imidacloprid is mobile and has the potential to leach to subsurfaces. The K_{ads} range is 0.96-4.76 for the same nine soils. On the other hand, imidacloprid guanidine appears to be less mobile than the parent imidacloprid (K_{oc} range 327-942; K_{ads} range 0.76-14.20).

Due to the very low octanol/water partition coefficient of imidacloprid, it is not expected to bioaccumulate in fish (the data requirement was previously waived).

Five terrestrial field dissipation studies confirm the laboratory findings, that under aerobic soil metabolism conditions, imidacloprid persists substantially. The half-lives were as follows: >365, >>365, 146, 107, and >120 days.

Small scale prospective ground water monitoring (PGW)studies in Michigan and California have been conducted, and while not necessarily representing field conditions under which ground water recharge and imidacloprid leaching would be greatest, the studies do provide some information on imidacloprid leaching and ground-water contamination potential. Imidacloprid and some of its degradates were shown to leach in soil during water infiltration periods at both study sites.

The California PGW study (planted to broccoli) appears to include some effects of nearby applications of imidacloprid in years prior to the initiation of the study, with control samples bearing imidacloprid residues. At the California site a few ground-water detections of imidacloprid and its degradates were reported at concentrations between 0.05 and 0.10 ppb. However, very little ground water recharge occurred during the course of this study so there was very little potential for any contaminant to leach to ground water during the course of the study.

In the Michigan PGW study (planted to potatoes), imidacloprid was found to be leaching at a variable rate and concentration. Detectable residues of imidacloprid occurred in all six, and in four out of six on-site lysimeters at the three and six foot depths, respectively, by 319 days after treatment (DAT 319), at concentrations up to 3.35 ppb. At the Michigan study site, imidacloprid parent was consistently detected in one of six monitoring well clusters in the treated field beginning about 500 days after application and continuing through the close of the study some 5 years after application. No degradation products were detected in ground water during this period. The maximum concentration of imidacloprid parent detected in ground water in any one sample at the Michigan study site was 0.24 ppb. An EPA review concluded that the 0.24 ppb level might increase slightly over time as imidacloprid continues to leach into groundwater; however, the level was not expected to increase dramatically given that the levels seen at the three and twelve foot soil depths was 1.63 ppb and 1.31 ppb, respectively.

Overall, in the two PGW study sites, the degradates imidacloprid urea, imidacloprid guanidine, and imidacloprid guanidine olefin were each a very minor component of the <u>detected</u> residues. However, it is important to understand that total residues detected were almost always less than 0.5 ppb (ug/L) and usually less than 0.1 ppb whereas the minimum detection limit for imidacloprid and each of its degradates in these studies was 0.03 ppb. The implication of this is that theoretically, degradation products, if they were present at slightly less than 0.03 ppb would be the dominant residues present in many samples.

Other significant ground-water monitoring data include evidence of leaching of parent imidacloprid from New York state monitoring. Suffolk County Department of Health Services reports that there were 27 detections of imidacloprid above a detection limit of 0.2 ppb in about 5,000 samples. [1]

More recently, imidacloprid has been detected in several domestic drinking water wells in New York state:

> "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)." (Imidacloprid NYS DEC Letter - Registration of New Imidacloprid Products in New York State as Restricted-Use Products 10/04)

There was evidence that some (but not all) of the above imidacloprid detections in drinking water wells did not represent normal leaching from an imidacloprid-treated field

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[1] See Imidacloprid Section 3 Review dated 5/1/07 (DP Barcode 334030 et al.) for further details.

Imidacloprid has been detected in surface water surveys conducted in Florida (Pfeuffer and Matson, 2001) and New York (Phillips and Bode, 2002). However, surface water monitoring data are generally sparse and there have been both few analyses and few detections reported to date. No surface water monitoring data for imidacloprid degradates have been identified.

EFED concludes that the available data on imidacloprid show that the compound is mobile and persistent, has potential to leach to ground water and presents concerns for transport to surface water by runoff. More definitive prospective ground-water monitoring studies could more precisely document the circumstance leading to leaching to ground water and the level of residues in ground water, however, the currently available PGW and outside ground water monitoring studies do provide a general picture that imidacloprid and its degradates can leach to ground water under some real world conditions in which the pesticide is used.

Table 1. Imidacloprid environmental fate parameters (as used for aquatic exposure modeling input).

Parameter	Input	Source
Solubility (ppm)	580	Product chemistry submissions
Molecular weight	255.66	http://chemfinder.cambridgesoft.com and Product Chemistry submissions.
Vapor Pressure (mm Hg or torr), 20 C	1.5E-09	Product chemistry submissions; Miles Technical & Safety Information sheet, March, 1992.
Henry's Law Constant (atm m3 mol -1)	4.0E-12	Registrant. Unable to locate original submission. SRC PhysProp Database lists as 1.65E-15 atm-m3/mole at 25 C as an estimated value apparently calculated from the vapor pressure and water solubility.
Hydrolysis $t_{1/2}$ @ pH 7 (days)	Stable	MRID 42055337
Aerobic soil $t_{1/2}$ (days)	520	MRIDs 452393-01, 02, 42073501; 90% upper bound confidence limit of mean
Aerobic aquatic $t_{1/2}$ (days)	1040	2x the aerobic soil input value, per EFED guidance document
Photolysis $t_{1/2}$ in water (days)	0.2 to 39	Input guidance & MRIDs 42256376; 42256377; with consideration of persistence in irradiated water in ecotoxicity studies.
Organic carbon partition coefficient - K_{oc} (mL/g)	178	MRIDs 425208-01 and 420553-38

The above table was used for GENEEC or PRZM-EXAMS in a previous risk assessment (See DP Barcode D313218, review dated 6/9/2005; also DP Barcodes D334030 et al., review dated 3/8/2007). Parameter values selected conservatively as noted in table comments.

Receptors

2. Aquatic and Terrestrial Effects

The receptor is the biological entity that is exposed to the stressor (EPA, 1998). Due to the outdoor uses of imidacloprid, exposure and effects to non-target aquatic and terrestrial organisms are expected. As outlined below the toxicity of imidacloprid varies widely depending on the type of organism that is the receptor.

Toxicity studies on aquatic invertebrates (freshwater and estuarine/marine) show that these organisms are highly sensitive to imidacloprid, which is classified to be acutely very highly toxic to these organisms (EC_{50} = 0.037 to 0.115 ppm). Chronic effects (growth and movement) were noted in daphnids (NOAEC/LOAEC = 1.8/3.6 ppm), midge (Chironomus tentans) (NOAEC = 0.001) and in mysid shrimp (NOAEC/LOAEC = 0.0006/0.0013 ppm). Refer to the section below on ecological incidents for a summary of several reports of adverse impacts on non-target species such as crayfish and bees.

Imidacloprid is considered to be practically non-toxic to fish (freshwater and estuarine/marine) on an acute basis (LC_{50} = 83 to 163 ppm). Chronic NOAEC/LOAEC values were calculated at 1.2/2.5 ppm with growth being the major endpoint affected.

Imidacloprid appears to be moderately toxic to avian species on an acute level (152.3 mg/kg) and slightly to practically non-toxic to birds on a subacute level (Bobwhite quail LC_{50} = 1,536 ppm; Mallard duck LC_{50} > 4,797 ppm). However, exposure to the granular product (2.5G) could result in high toxicity to small birds (house sparrow LD_{50} = 41 mg/kg). Chronic toxicity data show that imidacloprid exposure can result in egg shell thinning and a decrease in adult weight (NOAEC/LOAEC = 36/>61 ppm).

Mammalian toxicity data suggest that this compound is moderately toxic on an acute basis (LD_{50}= 424 mg/kg) to small mammals. Reproductive effects were noted at 250 ppm.

Acute toxicity studies with honeybees show that imidacloprid is very highly toxic to nontarget insects (LD_{50} = 0.0039 - 0.078 µg/bee). This is a concern for pollinators because imidacloprid is a systemic pesticide which has been shown to translocate into the nectar and pollen of crop plants grown from treated seed. Studies with ornamental plants have shown that imidacloprid may also translocate into plant parts when the chemical is applied to the soil around the base of the plants. In these studies with ornamentals, detectable residues were found in flowers and leaves as long as 540 days after application to the soil.

Consistent with the process described in the Overview Document (EPA, 2004), risk assessments use a surrogate species approach in its evaluation of a pesticide. Toxicological data generated from surrogate test species, which are intended to be representative of broad taxonomic groups, are used to extrapolate to potential effects on a variety of species (receptors) included under these taxonomic groupings. In the case of Imidacloprid, the requirements for ecological studies have mostly been fulfilled for its current use patterns. Additionally, any open literature studies would be identified through EPA's ECOTOX database (http://cfpub.epa.gov/ecotox/), which employs a literature search engine for locating chemical toxicity data for aquatic life, terrestrial plants, and wildlife.

Table II-1 provides a summary of the taxonomic groups and the surrogate species that are usually tested to help understand potential ecological effects of pesticides to these non-target taxonomic groups.

Table II-1 Test species evaluated for assessing potential ecological effects of Imidacloprid and the associated toxicity endpoint classification

Taxonomic Group	*Example(s) of Surrogate Species*	*Toxicity endpoint*
Birds[1]	Mallard (*Anas platyrhynchos*) Bobwhite (*Colinus virginianus*)	Acute Dietary: LC_{50} Chronic: NOAEC
Mammals	Laboratory rat (*Rattus norvegicus*)	Acute Oral: LD_{50} Chronic 2-Generation: NOAEL
Insects	Honey bee (*Apis mellifera L.*)	Acute contact*:* *u*g/bee
Freshwater fish[2]	Bluegill sunfish (*Lepomis macrochirus*) Rainbow trout (*Oncorhynchus mykiss*)	Acute: LC_{50} Chronic: NOAEC
Freshwater invertebrates	Water flea (*Daphnia magna*)	Acute: LC_{50} Chronic : NOAEC
Estuarine/marine fish	Sheepshead minnow *(Cyprinodon variegates)*	Acute: LC_{50} Chronic: NOAEC
Estuarine/marine invertebrates	Mysid shrimp *(Americamysis bahia)* Eastern oyster (*Crassostrea virginica)*	Acute: LC_{50} Chronic: NOAEC
Terrestrial plants[3]	Monocots – corn (*Zea mays*) Dicots – soybean (*Glycine max*)	lbs ai/A
Aquatic plants and algae	Duckweed (*Lemna gibba*) Green algae (*Selenastrum capricornutum*)	Acute: EC_{50}

[1] Birds represent surrogates for terrestrial-phase amphibians and reptiles.
[2] Freshwater fish may be surrogates for aquatic-phase amphibians.
[3] Four species of two families of monocots, of which one is corn; six species of at least four dicot families, of which one is soybeans.

3. Incident Reports

The Agency's Ecological Incident Information System (EIIS) does contain reports of damage or adverse effects to non-target organisms attributed to the use of imidacloprid.
There are four incidents involving imidacloprid that have been noted reflecting lawn use and effects to non-target organisms: 1) surfaced dead grubs appeared to have been eaten by birds, resulting in the death of several young and adult robins; 2) possible runoff event from a lawn resulted in the death of 3,000 crayfish in a near-by stream; 3) "mad bee" disease in France; and 4 & 5) lawn grass chemically burned by the application of the compound.

#1007257-001 A private citizen of Myerstown, Pa. reported watering in pesticide (GrubEx) and then found that grubs had surfaced a couple of days later. He was very concerned to see that the birds that fed on the grubs died.

#1007892-007 Turf application resulted in possible runoff into McKenna Creek (Columbus, Ohio) killing about 3,000 crawfish. Pesticide application was made on 7/22, slight rain event occurred on 7/22 (0.01 inches) and on 7/23 (0.09 inches). On July 23 dead crawfish were found. Water samples taken two days after the incident showed imidacloprid residues at 0.17, 0.11, and

1.3 ppb. In all likelihood the initial concentration was much higher. Water samples also detected metolachlor residues.

#1010775-001 Protests by the National Union of French Beekeepers have targeted GAUCHO, made by Bayer AC. This product along with REGENT TS (fipronil) was used to coat sunflower seeds for protection against insects. The French Farm Ministry suspended use of GAUCHO over the concerns about the aberrant disorientated behavior ("mad bee disease") of honey bees that had been associated with the sunflower crop that had originated from the coated seeds. Imidacloprid residues were found in the nectar.

#1009445-035 September 1999, complaint from resident in Assonet, MA. Home owner applied GrubEx Season-Long Grub Control to his lawn in June. He claims that 50% of the lawn burned.

#1009445-036 Resident in Brooklyn, NY applied GrubEx Season-Long Grub Control to his lawn and the entire lawn turned brown.

A lack of reported incidents does not necessarily mean that such incidents have not occurred. In addition, incident reports for non-target plants and animals typically provide information on mortality events only. Reports for other adverse effects, such as reduced growth or impaired reproduction, are rarely received.

4. Ecosystems potentially at Risk

The ecosystems at risk are often extensive in scope, and as a result it may not be possible to identify specific ecosystems during the development of a baseline risk assessment. Relative to the proposed use patterns of imidacloprid, terrestrial and aquatic ecosystems are expected to be at risk as a result of its current uses.

Assessment Endpoints

Assessment endpoints are defined as "explicit expressions of the actual environmental value that is to be protected". Defining an assessment endpoint involves two steps: (1) identifying the valued attributes of the environment that are considered to be at risk; and (2) operationally defining the assessment endpoint in terms of an ecological entity (i.e., a community of fish and aquatic invertebrates) and its attributes (i.e., survival and reproduction). Therefore, selection of the assessment endpoints is based on valued entities (i.e., ecological receptors), the ecosystems potentially at risk, the migration pathways of pesticides, and the routes by which ecological receptors are exposed to pesticide-related contamination. The selection of clearly defined assessment endpoints is important because they provide direction and boundaries in the risk assessment for addressing risk management issues of concern. Changes to assessment endpoints are typically estimated from the available toxicity studies, which are used as the measures of effects to characterize potential ecological risks associated with exposure to pesticides.

To estimate exposure concentrations, the ecological risk assessment typically considers a single application at the maximum application rate to fields that have vulnerable soils. The most sensitive toxicity endpoints are used from surrogate test species to estimate treatment-related direct effects on acute mortality and chronic reproductive, growth and survival assessment endpoints. Toxicity tests are intended to determine effects of pesticide exposure on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, sub-acute, and reproduction studies and are typically arranged in a hierarchical or tiered system that progresses from basic laboratory tests to applied field studies. The toxicity studies are used to evaluate the potential of a pesticide to cause adverse effects, to determine whether further testing is required, and to determine the need for precautionary label statements to minimize the potential adverse effects to non-target animals and plants.

Conceptual Model

For a pesticide to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a pesticide moves in the environment from a source to an ecological receptor. For an ecological pathway to be complete, it must have a source, a release mechanism, an environmental transport medium, a point of exposure for ecological receptors, and a feasible route of exposure.

A conceptual model provides a written description and visual representation of the predicted relationships between imidacloprid, potential routes of exposure, and the predicted effects for the assessment endpoint. A conceptual model consists of two major components: risk hypothesis and a conceptual diagram (EPA, 1998).

1. Risk Hypotheses

For imidacloprid, the following ecological risk hypothesis is being employed for this baseline risk assessment:

Imidacloprid, when used in accordance with the label, is expected to result in potential adverse effects upon the survival, growth, and reproduction of non-target insects and terrestrial and aquatic organisms.

2. Conceptual Diagram

A conceptual diagram/model is established for the likely outdoor environmental exposure pathways from imidacloprid uses is provided in Figure 1.

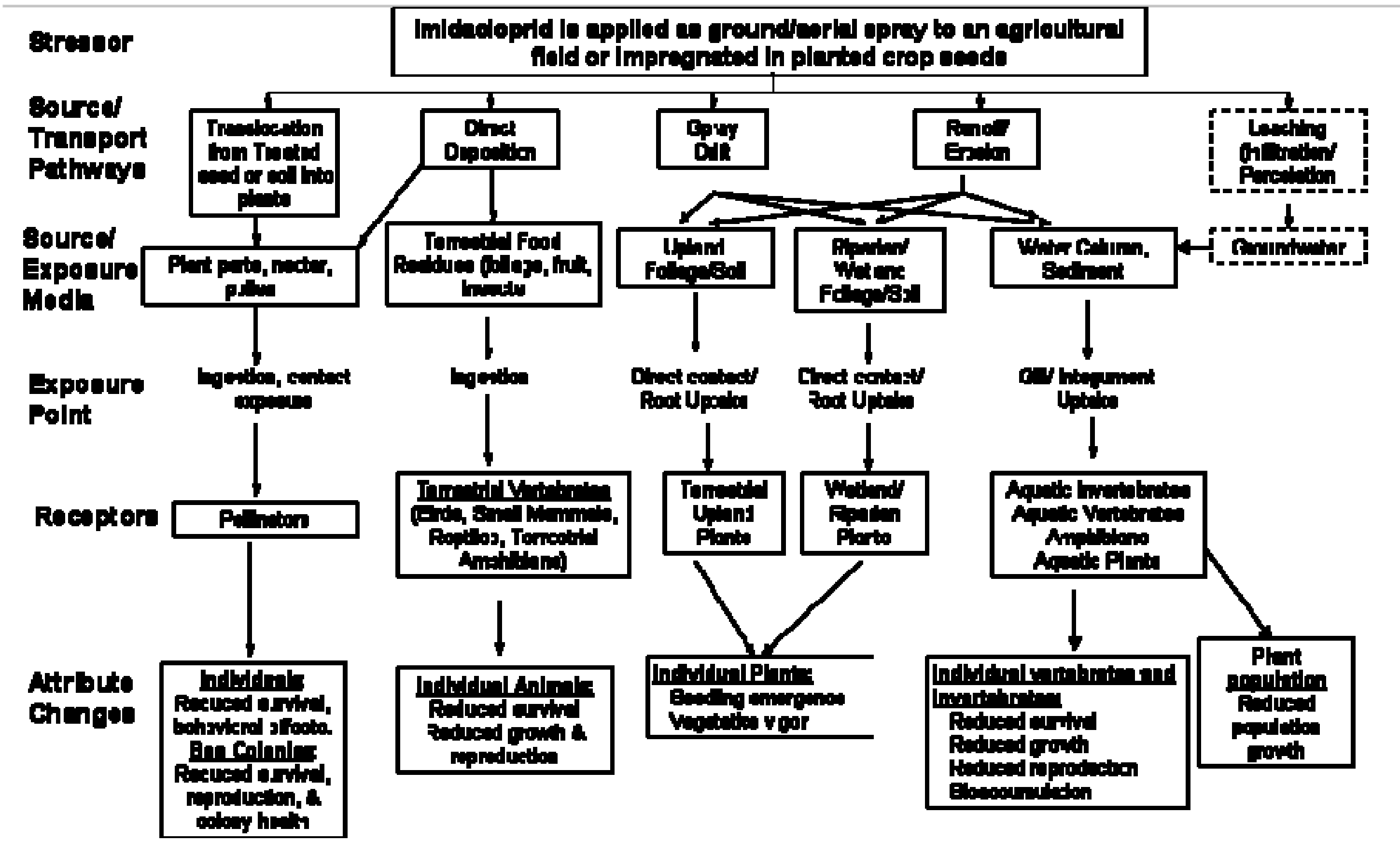

Figure 1. Ecological Conceptual Exposure Model for Screening-Level Risk Assessment of Imidacloprid.

Analysis Plan

1. Conclusions from Previous Risk Assessments

In light of the high toxicity of imidacloprid towards aquatic organisms and bees, EFED focused its past assessments on agricultural uses and the potential harm to aquatic organisms and beneficial insects.

The contributing reasons for a presumption of risk include imidacloprid's relatively high solubility in water, resistance to hydrolytic and metabolic degradation in water and soil, and ability to translocate in plants.

2. Preliminary Identification of Data Gaps

Environmental Fate:
The environmental fate database for imidacloprid is largely complete. There is a data gap for an aerobic aquatic metabolism study.

Aquatic Metabolism. Acceptable data have not been provided to quantify the metabolism of imidacloprid under aerobic aquatic conditions. According to Code of Federal Regulations 40 (CFR40 2007) Part 158 Subpart D (data requirements for pesticides) aerobic aquatic metabolism are required for pesticides with terrestrial uses. Since imidacloprid has uses on many terrestrial crops, aerobic aquatic metabolism data for imidacloprid should be submitted to fulfill OPPTS Guideline 835.4300. These data are used to estimate the degradation of imidacloprid in aquatic systems and ultimately to derive aquatic EECs using PRZM/EXAMS. In the case that these data are unavailable at the time risk assessments are conducted, PRZM/EXAMS input parameter guidance default values will be employed to account for aerobic aquatic metabolism (See Table 1).

Ecological Effects:
The following are ecotoxicity data gaps for imidacloprid:

Field Test for Pollinators (141-5): Based on potential risk to bees from imidacloprid treated plants, specifically via translocation to pollen and nectar, EFED has indicated a need for pollinator field testing in a number of risk assessments. Although the Agency has not received a study conducted according to OPP protocols, we have reviewed information from a number of studies. A registrant-submitted study conducted in 2001 in Canada, in which bees were exposed to canola grown from treated seed, showed a potential for effects on foraging behavior and colony health. However, the results were inconclusive. Another study conducted in Europe, this one from the published literature, showed residues in canola grown from treated seed more than 2 months after planting. Finally, studies submitted under (6)(a)(2) showed residues in blossoms and leaves of ornamental plants as long as 540 days after treatment of the surrounding soil.

EFED recently received a number of European studies from the published literature. These studies examine the potential effects of imidacloprid on bee memory and foraging activity, metabolism, learning, and coordination, and investigate areas of differential toxicity and metabolite toxicity. These studies are currently in review. In addition to this information, EFED has learned that an imidacloprid field study is being conducted by the University of Maryland, in conjunction with the USDA, to examine potential effects on mortality, behavior, and susceptibility to disease.

EFED still believes that a field study on bees with imidacloprid, based on protocols developed with Agency input, will be needed. One particular area of uncertainty is the potential for adverse impacts on pollinators following repeat applications to orchard crops. However, at this time it would be appropriate to review the information soon to be made available (published literature and the U of MD/USDA study) before making a decision regarding additional field testing with pollinators.

Tier I Seedling Emergence (122-1) and Aquatic Plant Growth (122-2): These test are required for all pesticides having outdoor uses. In addition, there have been phytotoxicity incidents reported (lawn effects) that raise a concern for toxicity to plants.

Seed Leaching Study: EFED believes that a seed leaching study would greatly increase certainty regarding a more realistic estimate of groundwater leaching and runoff. This in turn would allow a refinement of exposure estimates and environmental concentration values (EECs). EFED has issued guidance for this study (Memo from Denise Keehner re: Standard Method for Determining the Leachability of Pesticides from Treated Seeds, 7/6/2000).

3. Measures of Effects and Exposure

For a chemical, a number of measures of exposure are used, which are the measures of stressor existence and movement in the environment and their contact or co-occurrence with the assessment endpoint. Measures of exposure are potentially estimated using models. Aquatic exposure usually consists of aquatic EECs based on a total residue approach and derived using a water-body that is vulnerable and representative of static ponds and first order waterways. Terrestrial exposure is usually estimated using a model that assumes a direct application to a variety of avian, mammal and reptilian food items. Exposure to terrestrial plants is typically estimated using a model that assumes the chemical drifts or moves with runoff to adjacent habitats. Models require quantitative measurements for endpoints to evaluate the effects of the chemicals on the various species. Table II-2 provides a summary of the assessment endpoints previously identified as survival, growth and reproduction along with the measure of effects and exposure.

Table II-2 Measures of ecological effects and exposure for Imidacloprid.

Assessment Endpoint		*Surrogate Species and Measures of Ecological Effect*[1]	*Measures of Exposure*
Birds[2]	Survival	House sparrow acute oral LD_{50} = 41.0 mg/kg (2.5G) (MRID 420553-09) Quail acute oral LD_{50} = 152.3 mg/kg (MRID 420553-08) Mallard duck acute oral LC_{50} >4797 ppm (MRID 420553-11) Bobwhite acute dietary LC_{50} = 1536 ppm (MRID 420553-10)	Maximum residues on food items
	Reproduction and growth	Bobwhite chronic reproduction NOAEC= 36 ppm (MRID 420553-12) Mallard chronic reproduction NOAEC= 47 ppm (MRID 434665-01)	Maximum residues on food items
Mammals	Survival	Laboratory rat acute oral LD_{50} = 424 mg/kg (MRID 420553-31)	Maximum residues on food items
	Reproduction and growth	Laboratory rat oral reproduction chronic NOAEC = 250 ppm (MRID 422563-40)	Maximum residues on food items
Freshwater fish[3]	Survival	Bluegill sunfish acute LC_{50} >105 ppm (MRID 420553-14) Rainbow trout acute LC_{50} >83 ppm (MRID 420553-15)	Peak EEC[4]
	Reproduction and growth	Rainbow trout chronic (early life-stage) NOAEC=1.2 ppm and LOAEC=2.5 ppm (MRID 420553-20)	60-day average EEC[4]
Freshwater Invertebrates	Survival	Midge acute EC_{50} = 0.069 ppm (MRID 422563-04)	Peak EEC[4]
	Reproduction and growth	Water flea chronic (life cycle) NOAEC= 1.3 ppm LOAEC= 3.6 ppm (MRID 420553-21)	21-day average EEC[4]
Estuarine/ Marine fish	Survival	Sheepshead minnow acute LC_{50} = 163 ppm (MRID 420553-18)	Peak EEC[4]
	Reproduction and growth	(no data)	60-day average EEC[4]
Estuarine/ Marine Invertebrates	Survival	Eastern oyster acute EC_{50} >145 ppm (MRID 422563-05) Mysid shrimp acute LC_{50} = 0.037 ppm (MRID 420553-19)	Peak EEC[4]
	Reproduction and growth	Mysid chronic NOAEL > 0.0006 ppm and LOAEC = 0.0013 (MRID 420553-22)	21-day average EEC[4]
Terrestrial Plants[5]	Survival and growth	(no data)	Estimates of runoff and spray drift to non-target areas
Insects	Survival	Honeybee acute contact LD_{50}= 0.0039 ug/bee (MRID 422730-03)	Maximum application rate
Aquatic Plants and Algae	Survival	Green algae EC_{50} > 10 ppm (MRID 422563-74)	Peak EEC

[1] If species listed in this table represent most commonly encountered species from registrant-submitted studies, risk assessment guidance indicates most sensitive species tested within taxonomic group are to be used for baseline risk assessments.
[2] Birds represent surrogates for amphibians (terrestrial phase) and reptiles.
[3] Freshwater fish may be surrogates for amphibians (aquatic phase).
[4] One in 10-year return frequency.
[5] Four species of two families of monocots - one is corn, six species of at least four dicot families, of which one is soybeans.
LD_{50} = Lethal dose to 50% of the test population; NOAEC = No observed adverse effect concentration; LOAEC = Lowest observed adverse effect concentration; LC_{50} = Lethal concentration to 50% of the test population; EC_{50}/EC_{25} = Effect concentration to 50%/25% of the test population.

4. Endangered Species Considerations

Pesticide ecological risk assessments for registration review will address Endangered Species Act Section 7(a)(2) obligations. Due to the registered outdoor uses for imidacloprid, endangered species are expected to be affected. Also, incident reports are available that indicate possible risk to endangered species.

Probit Slope Analysis

The probit slope response relationship is evaluated to calculate the chance of an individual event corresponding to the listed species acute LOCs. If information is unavailable to estimate a slope for a particular study, a default slope assumption of 4.5 is used as per original Agency assumptions of typical slope cited in Urban and Cook (1986).

a. Terrestrial Species

Terrestrial acute toxicity studies for imidacloprid did provide raw data and estimates of slopes for birds (2.48) and for small mammals (4.5). Based on these slopes, the corresponding estimate chance of individual mortality following imidacloprid exposure is 1 in 1.52×10^{2} for birds and 1 in 2.94×10^{5} for mammals.

b. Aquatic Species

Acute toxicity studies for imidacloprid did provide raw data and estimates of slopes for most fish and invertebrate species. A default slope of 4.5 was used for freshwater fish. Based on this slope, the corresponding estimate chance of individual mortality following exposure is 1 in 4.17×10^{8}. Analysis of raw data from the aquatic acute toxicity studies provided slopes of 1.69 for freshwater invertebrates, 4.21 for estuarine/marine invertebrates and 6.82 for estuarine/marine fish. Based on these slopes, the corresponding estimate chance of individual mortality following imidacloprid exposure is 1 in 71.7 for freshwater invertebrates, 1 in 4.62×10^{7} for estuarine/marine invertebrates and 1 in 1×10^{16} for estuarine/marine fish. Given the potentially high environmental persistence of imidacloprid invertebrate species exposure in particular may be a concern.

5. Path Forward

The planned ecological risk assessment will evaluate the lines of evidence and make a determination of potential effects to endangered species. If the planned ecological risk assessment indicates that imidacloprid may affect, either directly or indirectly, listed species or affect critical habitat, the Agency will take steps to refine the assessment to determine whether this pesticide's uses are likely to adversely affect, or are not likely to adversely affect the species. In the case of critical habitat, the Agency will assess whether use of the pesticide may destroy or adversely modify any principle constituent elements for the critical habitat.

If the Agency's assessment results in a determination that the pesticide may affect but is not likely to adversely affect a listed species or designated critical habitat, the Agency will request concurrence by the USFWS and NMFS (Services) on that determination. If the Services do not concur, the Agency will enter into Formal Consultation with them under the Endangered Species Act. If the Agency's assessment results in a determination that the pesticide is likely to adversely affect a listed species or designated critical habitat, the Agency will initiate Formal Consultation with the Services. Formal Consultation concludes with issuance of a Biological Opinion to the Agency. The Agency may seek to change the terms of registration to address unacceptable risks to a listed species should EPA determine such risks exist.

In addition, The Agency is currently in collaboration with other Agencies and researchers regarding the issue of pesticides, particularly the neonicotinoids, and their adverse effects on honeybees. The Agency is exploring all possible causes of Colony Collapse Disorder in bees, including the possible impact of pesticides, including imidacloprid.

6. Other Information Needs

Information is requested for confirmation on the following information:

1. Use history
2. State or local use restrictions
3. Ecological incidents not already reported to the Agency
4. Review of ECOTOX database

The analysis plan will be revisited and may be revised depending upon the information submitted by the public in response to the opening of the Registration Review docket.

7. Summary

- Imidacloprid is a neonicotinoid nitroguanidine insecticide, these compounds tend to be environmentally persistent, thereby increasing the probability of exposure by non-target organisms.
- The stressor is expected to reach terrestrial and aquatic receptors from application spray drift, runoff, and translocation from treated soil or seed into plant products.
- Relative to the outdoor use pattern of imidacloprid, terrestrial and aquatic ecosystems are expected to be at risk as a result of its current uses.
- The Agency's Ecological Incident Information System (EIIS) contains reports of damage or adverse effects to non-target organisms attributed to the use of imidacloprid.
- Ecological toxicity data were available for risk assessment purposes.
- A review of open literature will need to be completed.

Possible risk concerns from the use of imidacloprid:

- Direct effects to fish and aquatic invertebrates in the water column via acute toxicity.

- Direct effects to aquatic invertebrates dwelling in the sediment and/or pore water via acute and/or chronic toxicity.

- Direct acute and chronic effects to bees and other beneficial insects.

- Indirect effects to plants that rely on bees for pollination.

- Indirect effects to fish dwelling in the sediment and/or pore-water via food chain alteration.

Imidacloprid is toxic to upland game birds. The LD_{50} is 152 mg/kg for bobwhite quail, and 31 mg/kg in Japanese quail. In studies with red-winged blackbirds and brown-headed cowbirds, it was observed that birds learned to avoid imidacloprid treated seeds after experiencing transitory gastrointestinal distress (retching) and ataxia (loss of coordination). It was concluded that the risk of dietary exposure to birds via treated seeds was minimal. Based on these studies, imidacloprid appears to have potential as a bird repellent seed treatment (Avery et al. 1993 & 1994).

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MRID	Citation Reference
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161-3 Photodegradation-soil

MRID	Citation Reference
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MRID	Citation Reference
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MRID	Citation Reference
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Appendix: Data Requirement Tables and Data Needs Justifications

Data Requirements Table						
Chemical No: 129099	IMIDACLOPRID DATA REQUIREMENTS FOR THE ENVIRONMENTAL FATE AND EFFECTS DIVISION					
Data Requirements	**Composition[i]**	**Use Pattern**	Does EPA have Data to Satisfy this Requirement? (Yes, No, Partially)	**Bibliographic Citation**	**Study Classification**	**Additional Data Required Under FIFRA 3(c)(2)(B)?**
§158.490 WILDLIFE AND AQUATIC ORGANISMS (6 Basic Studies in Bold)						
71-1(a) Acute Avian Oral, Quail/Duck	TGAI	1 and 2	Yes	42055308	Core	No
71-1(b) Acute Avian Oral, Quail/Duck	(TEP)	1 and 2	No	Not applicable		No
71-2(a) Acute Avian Diet, Quail	TGAI	1 and 2	Yes	42055310	Core	No
71-2(b) Acute Avian Diet, Duck	TGAI	1 and 2	Yes	42055311	Core	No
71-3 Wild Mammal Toxicity		1 and 2	No	Not applicable		No
71-4(a) Avian Reproduction Quail	TGAI	1 and 2	Yes	42055312	Core	No
71-4(b) Avian Reproduction Duck	TGAI	1 and 2	Yes	42055313 43466501	Supplemental	No
71-5(a) Simulated Terrestrial Field Study		1 and 2	No	Not applicable		No
71-5(b) Actual Terrestrial Field Study		1 and 2	No	Not applicable		No
72-1(a) Acute Fish Toxicity Bluegill	TGAI	1 and 2	Yes	42055315	Core	No
72-1(b) Acute Fish Toxicity Bluegill	(TEP)	1 and 2	No	Not applicable		No
72-1(c) Acute Fish Toxicity Rainbow Trout	TGAI	1 and 2	Yes	42055320	Core	No
72-1(d) Acute Fish Toxicity Rainbow Trout	(TEP)	1 and 2	No	Not applicable		No
72-2(a) Acute Aquatic Invertebrate Toxicity	TGAI	1 and 2	Yes	42256304	Core	No
72-2(b) Acute Aquatic Invertebrate Toxicity	(TEP)	1 and 2	No	Not applicable		No
72-3(a) Acute Estu/Mari Tox Fish	TGAI	1 and 2	Yes	42055318	Core	No
72-3(b) Acute Estu/Mari Tox Mollusk	TGAI	1 and 2	Yes	42256305	Supplemental	No
72-3(c) Acute Estu.Mari Tox Shrimp	TGAI	1 and 2	Yes	42055319	Core	No
72-3(d) Acute Estu/Mari Tox Fish	(TEP)	1 and 2	No	Not applicable		No
72-3(e) Acute Estu/Mari Tox Mollusk	(TEP)	1 and 2	No	Not applicable		No
72-3(f) Acute Estu/Mari Tox Shrimp	(TEP)	1 and 2	No	Not applicable		No
72-4(a) Early Life-Stage Fish	TGAI	1 and 2	Yes	42055320	Supplemental	No
72-4(b) Life-Cycle Aquatic Invertebrate	TGAI	1 and 2	Yes	42055321	Supplemental	Yes[3]
72-5 Life-Cycle Fish (Freshwater Fish)	TGAI	1 and 2	No			No
72-6 Aquatic Org. Accumulation	TGAI	1 and 2	No	Not applicable		No
72-7(a) Simulated Aquatic Field Study	(TEP)	1 and 2	No	Not applicable		No
72-7(b) Actual Aquatic Field Study		1 and 2	No	Not applicable		No
§158.540 PLANT PROTECTION						
122-1(a) Seed Germ./Seedling Emerg.-Tier I	(TEP)	1 and 2	No			Yes
122-1(b) Vegetative Vigor-Tier I	(TEP)	1 and 2	No			Yes
122-2 Aquatic Plant Growth-Tier I	(TGAI)	1 and 2	No	42256374	Supplemental	Yes
123-1(a) Seed Germ./Seedling Emerg.-Tier II	(TEP)	1 and 2	No			Pending[5]
123-1(b) Vegetative Vigor-Tier II	(TEP)	1 and 2	No			Pending[5]
123-2 Aquatic Plant Growth-Tier II	(TGAI)	1 and 2	No	42256375	Invalid	No
124-1 Terrestrial Field Study		1 and 2	No	Not applicable		No
124-2 Aquatic Field Study		1 and 2	No	Not applicable		No
§158.490 INSECT TESTING						
141-1 Honey Bee Acute Contact	TGAI	1 and 2	Yes	42273003 (oral-TGAI) 42273003 (acute contact - TGAI)	Core Core	No

Data Requirements Table						
Chemical No: 129099	IMIDACLOPRID DATA REQUIREMENTS FOR THE ENVIRONMENTAL FATE AND EFFECTS DIVISION					
Data Requirements	**Composition**[i]	**Use Pattern**	Does EPA have Data to Satisfy this Requirement? (Yes, No, Partially)	**Bibliographic Citation**	**Study Classification**	**Additional Data Required Under FIFRA 3(c)(2)(B)?**
141-2 Honey Bee Residue on Foliage	(TEP)	1 and 2	Yes	42480503 42632901	Core	No
141-5 Field Test for Pollinators		1 and 2	No			Yes
§158.290 ENVIRONMENTAL FATE by Study Type – with current guideline numbers [previous guideline numbers are in brackets]						
Degradation Studies-Lab:						
835.2120 [161-1] Hydrolysis	TGAI	1 and 2	Yes	42055337	Core	No
835.2240 [161-2] Photolysis in Water	TGAI	1 and 2	Yes	4225637 6		No
835.2410 [161-3] Photolysis on Soil	TGAI	1 and 2	Yes	42256377	Core	No
Metabolism Studies-Lab:						
835.4100 [162-1] Aerobic Soil Metabolism	TGAI	1 and 2	Yes	42073501, 45239302, 45239303, 45239301	Core	No
835.4200 [162-2] Anaerobic Soil Metabolism	TGAI	1 and 2	No			Reserved
835.4400 [162-3] Anaerobic Aquatic Metabolism	TGAI	1 and 2	Yes	42256378	Core	No
835.4300 [162-4] Aerobic Aquatic Metabolism	TGAI	1 and 2	No			Yes
Mobility Studies:						
835.1230 835.1240[163-1] Mobility (unaged)	TGAI	1 and 2	Yes	42520801, 42520802, 42055338	Supplemental	No
835.1230 835.1240 [163-1] Mobility (aged)	TGAI	1 and 2	Yes	42055338	Core	No
835.1410 [163-2] Laboratory Volatility	TGAI	1 and 2	No	not applicable		No
163-3 Field volatility	TEP	1 and 2	No	not applicable		No
Dissipation Studies-Field:						

Data Requirements Table						
Chemical No: 129099	IMIDACLOPRID DATA REQUIREMENTS FOR THE ENVIRONMENTAL FATE AND EFFECTS DIVISION					
Data Requirements	**Composition**[i]	**Use Pattern**	Does EPA have Data to Satisfy this Requirement? (Yes, No, Partially)	**Bibliographic Citation**	**Study Classification**	**Additional Data Required Under FIFRA 3(c)(2)(B)?**
835.6100 [164-1] Terrestrial field dissipation	TEP	1 and 2	Yes	42256379, 42256380, 42256381, 42256382, 4225683,	Supplemental	No
Accumulation Studies:						
No longer classified as a fate study. [165-4] Fish bioaccumulation	TGAI	1 and 2	No	Waived		No
Ground Water Monitoring Studies:						
835.7100 [166-1] Small scale prospective groundwater study	TEP	1 and 2	Partially	44790102 44790103 45094701 45094702 45094703 45858201 45878701	Supplemental	Reserved
835.7200 [None] Large-Scale Retrospective Surface-Water Monitoring study	TEP	1 and 2	No	not applicable		No
835.7100 [166-2] Large-Scale Retrospective Ground-Water Monitoring study	TEP	1 and 2	No	not applicable		No

1. Composition: TGAI=Technical grade of the active ingredient; PAIRA=Pure active ingredient, radiolabeled; TEP=Typical end-use product
2. Use Patterns: 1=Terrestrial/Food; 2=Terrestrial/Feed; 3=Terrestrial Non-Food; 4=Aquatic Food; 5=Aquatic Non-Food (Outdoor); 6=Aquatic Non-Food (Industrial); 7=Aquatic Non-Food (Residential); 8=Greenhouse Food; 9=Greenhouse Non-Food; 10=Forestry; 11=Residential Outdoor; 12=Indoor Food; 13=Indoor Non-Food; 14=Indoor Medical; 15=Indoor Residential

3. This guideline requirement has been fulfilled for freshwater fish and invertebrates but has not been fulfilled for estuarine/marine fish or invertebrates.

4. Guideline study is recommended.

5. Requirement is pending results of Tier I testing or may be submitted in lieu of Tier I testing at Tier II level.

Ecological Effects Data Justifications for Imidacloprid

Guideline Number: 850.3040 (141-5) **Study Title: Field Test For Pollinators**
Rationale for Requiring the Data
Due to the potential for toxic exposure of pollinators from imidacloprid translocated in treated crops, EFED has indicated the need for pollinator field testing (141-5) in previous reviews. This exposure to honey bees and other nontarget insects could be manifested through the presence of imidacloprid in nectar and pollen. In order to have a better understanding of imidacloprid exposure routes and potential impact on pollinators, more information is needed from carefully designed field studies. However, as noted above in the Analysis plan, Preliminary Identification of Data Gaps, EFED believes that a thorough review of data currently on hand is needed prior to making a decision on additional field testing.
Practical Utility of the Data
How will the data be used? To assess risk to endangered and non-target insect species. This study would allow the Agency to refine the screening level risk assessment for beneficial insects. The effects data would be used to determine the likelihood that the risks could potentially impact beneficial insect communities, either by direct effects on bees or by indirect effects on other organisms by reducing their food sources. **How could the data impact the Agency's future decision-making?** If future endangered species risk assessments are performed without these data, the Agency would have to assume that the compound "may affect" endangered insects directly (and endangered species from other taxa indirectly), and use of it might need to be restricted in areas where endangered species could be exposed. The lack of these data will limit the flexibility the Agency and registrants have in coming into compliance with the Endangered Species Act and could result in use restrictions for the compound which are unnecessarily severe.

Guideline Number: 850.4100 & 850.4150; 850.4400 (122-1 a & b; 123-2) **Study Title: Tier I Seedling Emergence/Vegetative Vigor and Aquatic Plant Growth Studies**
Rationale for Requiring the Data
These tests are required for all pesticides having outdoor uses. In addition, phytotoxicity incidents have been reported (lawn effects) that raise a concern for toxicity to plants. Also, uses of Imidacloprid are registered Nationally and could have wide spread effects to plant species.
Practical Utility of the Data
How will the data be used? To assess risk to endangered and non-target plant species, these toxicity studies would allow the Agency to refine the screening level risk assessment. The effects data would be used to determine the likelihood that the risks can potentially impact plant communities, either by direct effects on plants or by indirect effects on other organisms by reducing their food sources. **How could the data impact the Agency's future decision-making?** If future endangered species risk assessments are performed without these data, the Agency would have to assume that Imidacloprid "may affect" endangered plants directly (and endangered species from other taxa indirectly), and use of imidacloprid might need to be restricted in areas where endangered species could be exposed. The lack of these data will limit the flexibility the Agency and registrants have in coming into compliance with the Endangered Species Act and could result in use restrictions for Imidacloprid which are unnecessarily severe.

Guideline Number: Non-guideline Study Title: Seed leaching Study
Rationale for Requiring the Data
EFED believes that a seed leaching study would greatly increase certainty regarding a more realistic estimate of groundwater leaching and runoff. This in turn would allow a refinement of exposure estimates and environmental concentration values (EECs). EFED has issued guidance for this study (Memo from Denise Keehner re: Standard Method for Determining the Leachability of Pesticides from Treated Seeds, 7/6/2000).
Practical Utility of the Data
How will the data be used? Data would allow a refinement of exposure estimates and environmental concentration values **How could the data impact the Agency's future decision-making?** If future endangered species risk assessments are performed without these data, the Agency would have to assume that Imidacloprid leeches 100% from the seed and use of imidacloprid might need to be restricted in areas where endangered species could be exposed. The lack of these data will limit the flexibility the Agency and registrants have in coming into compliance with the Endangered Species Act and could result in use restrictions for Imidacloprid which are unnecessarily severe.

Environmental Fate Data Justifications for Imidacloprid

Guideline Number: 835.4300 [162-4] Study Title: Tier Aerobic Aquatic Soil Metabolism Studies
Rationale for Requiring the Data
These tests are required for all pesticides having outdoor uses. Imidacloprid may reach aquatic environments through spray drift or runoff and it is important to understand the fate of imidacloprid in soil and water. The uses of Imidacloprid are registered nationally and could have wide spread effects on sensitive aquatic organisms.
Practical Utility of the Data
How will the data be used? These data are used to estimate the degradation of imidacloprid in aquatic systems and ultimately to derive aquatic EECs using PRZM/EXAMS.To assess risk to endangered and non-target plant species, these toxicity studies would allow the Agency to refine exposure assessments as part of the screening level risk assessment. The effects data would be used to determine the likelihood that the risks can potentially impact aquatic organisms or drinking water quality. **How could the data impact the Agency's future decision-making?** If future risk assessments are performed without these data, the Agency would have to use more conservative assumptions for exposure assessment with regards to imidacloprid persistence potentially then leading to an assumption that Imidacloprid "may affect" aquatic organisms directly, and use of imidacloprid might need to be restricted in areas where endangered species (for example) could be exposed. The lack of these data will limit the flexibility the Agency and registrants have in coming into compliance with the Endangered Species Act and could result in use restrictions for Imidacloprid which are unnecessarily severe.