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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 8, 2020

**PC Code: 129099**
**DP Barcode: 447632**

**MEMORANDUM**

**SUBJECT:** **Imidacloprid**: Response to Public Comments Related to the Preliminary Risk Assessments and Addendum to the Non-Pollinator Risk Assessments in Support of Registration Review (Docket No. EPA-HQ-OPP-2008-0844)

**TO:** Steven Snyderman, Chemical Review Manager
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**FROM:** Keith Sappington, Senior Science Advisor
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Keith Sappington Digitally signed by Keith Sappington Date: 2020.01.08 09:40:14 -05'00'
Digitally signed by MEGHANN NIESEN Date: 2020.01.08 07:52:37 -05'00'
MOHAMMED RUHMAN Digitally signed by MOHAMMED RUHMAN Date: 2020.01.08 08:14:00 -05'00'

**THRU:** Justin Housenger, Branch Chief
Ryan Mroz, Risk Assessment Process Leader
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JUSTIN HOUSENGER 2020.01.08 12:39:50 -05'00'
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The Registration Review for the neonicotinoid insecticide imidacloprid (PC Code 129099) has been a phased process with the release of aquatic, terrestrial, and pollinator preliminary risk assessments at different times with individual public comment periods. Additionally, the registration review of imidacloprid has been closely aligned, in timing and risk assessment approaches and methodology, with the three other nitroguanidine-substituted neonicotinoids clothianidin, thiamethoxam, and dinotefuran. Appendix 1 provides a summary table of the risk assessment documents and docket numbers associated with each of the four neonicotinoids.

The purpose of this document is to collectively respond to imidacloprid-specific public comments received on the aquatic, terrestrial, and pollinator preliminary risk assessments. Also, this document serves as an addendum to the preliminary aquatic and terrestrial risk assessments, where additional modeling or corrections were needed based on public comments, or where additional characterization or impacts to risk conclusions are discussed.



ED_006569N_00009042-00001

Updates and responses to imidacloprid-specific comments on the preliminary pollinator risk assessment have been incorporated into the "Final Bee Risk Assessment to Support the Registration Review of Imidacloprid (DP 443668, Jan/2020)".

For responses to public comments that were common across all four neonicotinoid active ingredients for the aquatic, terrestrial, and pollinator preliminary risk assessments, a common response to comments document was written. See the document, "EFED Response to Public Comments Common to the Preliminary Pollinator and Preliminary Non-Pollinator Registration Review Risk Assessments Across the Four Neonicotinoid Pesticides (Imidacloprid, Thiamethoxam, Clothianidin, and Dinotefuran) (DP 447635, Jan/2020)".

This document is divided into several sections. Section 1 responds to imidacloprid-specific public comments on the preliminary aquatic (DP435477; 2016) and terrestrial (DP 442930; 2017) risk assessments. Section 2 responds to imidacloprid-specific public comments on the preliminary pollinator risk assessment (DP 429937; 2016). Finally, section 3 is an addendum for addressing any updated modeling or risk conclusion discussions for non-pollinator taxa.

EFED generally uses an outline format to address the comments (comment summary followed by EFED response). Full text of the public comment submissions can be found in the imidacloprid docket at https://www.regulations.gov/docket?D=EPA-HQ-OPP-2008-0844.

# 1. Imidacloprid Non-pollinator Comments

## 1.1. Bayer Crop Science, American Bird Conservancy, Northwest Center for Alternatives to Pesticides:

*Bayer Crop Science (Docket ID No.: EPA-HQ-OPP-2008-0844-1163): Indirect effects predictions should not be made based on current EPA Assessment.*

*American Bird Conservancy (Docket ID No.: EPA-HQ-OPP-2008-0844-1163): Agency's findings in aquatic assessment of concern because aquatic inverts are important dietary component for birds, bats, fishes, and other wildlife. Loss of aquatic inverts can be devastating to certain bird species.*

*Northwest Center for Alternatives to Pesticides (Docket ID No.: EPA-HQ-OPP-2008-0844-1218): The risk assessment demonstrates immediate and striking concern for primary food items of salmon and steelhead.*

**EPA Response:** Indirect effects are not quantitively evaluated as part of the EFED risk assessment process but generally addressed in risk characterization, specifically in the aquatic risk assessment. The language included is as follows "As indicated below, the potential exists for risks to fish indirectly through reductions in aquatic invertebrates that comprise their prey base". This statement recognizes how aquatic invertebrate impacts could potentially affect high trophic levels that rely on these organisms as a food source. EFED does not conduct analysis to determine the degree to which indirect effects could occur and there are a lot of factors that influence whether an indirect effect may or may not occur.

## 1.2. Bayer Crop Science, CropLife America, Pesticide Policy Coalition:

*Bayer Crop Science: Thirty-one (31) studies relying on higher tier approaches (e.g., outdoor mesocosm studies) to assess potential effects of imidacloprid are available. These higher tier data reduce uncertainty associated with extrapolating effects and exposures observed in the laboratory to the environment. Further, these studies allow for direct assessment and endpoint derivation for potential effects on populations, communities, and ecosystem functions.*

*Crop Life America: Rather than use the wealth of higher-tier data available to evaluate the risks of imidacloprid registered uses, EPA's draft aquatic ecological risk assessment relies on base-line screening-level assessments. EPA has acknowledged the availability of relevant higher-tier data and has incorporated summaries of conclusions of higher- tier studies by the European Food Safety Authority and the Canadian Pest Management Regulatory Agency. EPA has also summarized conclusions of higher-tier assessments from the published literature as reported by its authors but has not independently reviewed the studies. In fact, EPA states in its assessment (page 114) "due to resource and time constraints, an independent review of the higher tier aquatic toxicity data for imidacloprid was not conducted as part of this preliminary ecological risk assessment (...). However, the Agency expects to revise the preliminary ecological risk assessment to reflect public comment and any additional refinements deemed necessary to support risk management decisions." EPA should conduct an independent evaluation of all available higher-tier studies including those from other regulatory agencies and should commit to an independent review of the microcosm data to ensure that its final assessment is based on all available data.*

*Pesticide policy coalition (PPC): At present, EPA's preliminary aquatic risk assessment for imidacloprid relies only on lower tier laboratory studies and does not account for relevant, field-based studies. EPA has acknowledged the availability of higher tier data but has not committed to complete its review of the data and make any corresponding refinements to the current assessment. The PPC is aware that registrants have provided EPA with an abundance of higher tier studies, including wildlife field studies and water residue monitoring analyses. The PPC encourages EPA to follow through with its improved risk assessment framework and dedicate the resources necessary to review these higher tier studies to ensure that its final assessment is based on the best available science.*

**EPA Response:** EFED's summary of the available higher tier aquatic effects studies is presented on pages 114-116 of the aquatic assessment (DP435477; 2016). Numerous independent reviews of these data have been conducted (PMRA 2016, EFSA 2014, Morrissey 2015, Pisa 2015, Smit 2015) in addition to registrant review (BCS 2016). The available studies varied widely in design (continuous vs. short-term pulse exposure) and several did not include the most sensitive insect groups (*e.g.,* Ephemeroptera), that EPA's assessment identified in its extensive review of available registrant submitted and open literature data. Despite these limitations, reviews by PMRA, EFSA and Pisa all indicate the threshold of effects occuring at 0.1 ug a.i./L or lower for the higher tier studies. Smit estimated a higher tier effects threshold at 0.17 ug a.i./L. Bayer Crop Science (BCS) estimated effects threshold at 0.24 ug a.i./L.

Therefore, the limitations in these higher tier studies notwithstanding, the effects thresholds appear to be within an order of magnitude of the chronic NOAEC determined for mayflies based on lower tier effects data. As a result, EFED does not believe the higher tier effects data alter the overall conclusions of the aquatic risk assessment that identified acute and chronic risk above the respective levels of concern for multiple registered use patterns. Further, because the overall conclusions would not be altered, the decision was made to not further refine the aquatic assessment.

### 1.3. Bayer Crop Science (BCS) on behalf of the Imidacloprid EPA DCI cost-sharing consortium members (Bayer, Nufarm, Ensystex, Helena, UPI, and Albaugh) (Docket ID No.: EPA-HQ-OPP-2008-0844-1186 and 1187):

***Imidacloprid Labeled Use Information (page 3):*** *BCS stated that "There are errors in the use patterns EPA used for the modeling scenarios (Table 3-6 of the preliminary EPA assessment). Specifically:*

*1.) The max seedling rate for carrots is 0.0336 kg a.i./ha not 0.115 kg a.i./ha.*
*2.) There is no registered use for citrus seed treatment but the table includes a seedling rate of 0.270 kg a.i./ha.*
*3.) The maximum foliar rate on citrus is 0.28 kg a.i./ha, not 0.291 kg a.i./ha.*
*4.) The max seasonal rate for hops is 0.336 kg a.i./ha, not 0.561 kg a.i./ha.*
*5.) The max seasonal rate for leafy greens is 0.4256 kg a.i./ha, not 0.561 kg a.i./ha.*
*6.) The max seed treatment rate for leak is 0.168 kg a.i./ha, not 0.204 kg a.i./ha.*
*7.) The max seed treatment rate for potato is 0.28 kg a.i./ha, not 0.561 kg a.i./ha.*
*8.) The max seed treatment rate for sugarbeet is 0.328 kg a.i./ha, not 0.481 kg a.i./ha.*
*9.) The foliar rate for tobacco (0.561 kg a.i./ha) is incorrectly listed in the seed treatment column.*
*10.) A maximum of 3 foliar applications for tree nuts, resulting in an annual max of 3.36 kg a.i./ha, not 6 apps resulting in an annual max. of 0.561 kg a.i./ha as indicated in the table.*

*11.) All non-agricultural uses have a maximum annual application of 0.448 kg a.i./ha.*

**EPA Response:** Hereunder Table 1 summarizes EFED response to these comments

*Table 1. Summary of responses to rate questions.*

<table>
<tr><th>BCS Comment</th><th>EFED Response</th></tr>
<tr><td>1.) The max seedling rate for carrots is 0.0336 kg a.i./ha not 0.115 kg a.i./ha.</td><td>A change to 0.0336 is acceptable. A slight increase in EECs is expected for this corrected combined application because the difference in application (0.115- 0.0336= 0.0814 kg/ha) will be added to the soil rate. The maximum application rate of 0.561 kg/ha will be as follows: 0.0336 kg/hac for seed; plus 0.3974 kg/hac for soil (0.298 + 0.0814); plus 0.147 kg/ha for foliar. The aquatic assessment determined risk to aquatic invertebrates only from use on carrots and risk conclusions would not change with an updated seed application rate.</td></tr>
<tr><td>2.) There is no registered use for citrus seed treatment, but the table includes a seedling rate of 0.270 kg a.i./ha.</td><td>As shown in the Table “item 3 below” the 0.270 rate is as per page 29 of the label containing direction for newly planted citrus trees.</td></tr>
<tr><td>3.) The maximum foliar rate on citrus is 0.28 kg a.i./ha, not 0.291 kg a.i./ha.</td><td>Based on the label which indicates a Maximum rate of 0.561 kg/ha (refer to label language below) *, EFED modeled combined applications as follows:
<table>
<tr><th>Seeds/ Seedling</th><th>Soil</th><th>Foliar</th><th>Total</th><th>Notes</th></tr>
<tr><td>0</td><td>0</td><td>0.2805 x 2 @ 10 d.</td><td>0.561</td><td>Foliar rate</td></tr>
<tr><td>0</td><td>0.561</td><td>0</td><td>0.561</td><td>Soil rate</td></tr>
<tr><td>0.270</td><td>0.291</td><td>0</td><td>0.561</td><td>Seedling rate + Reduced Soil rate</td></tr>
<tr><td>0.270</td><td>0</td><td>0.291 x 1</td><td>0.561</td><td>Seedling rate + Reduced Foliar rate</td></tr>
</table>
In the Table above (rates in kg/ha), the foliar rate = 0.2805 “as indicated by the Registrants comment” with two applications. In order to arrive at a maximum combined rate of 0.561 for the last two runs, in the table above, it was assumed the slightly higher foliar rate of 0.291with one, not two applications.<br><br>* Page 29 of GAUCHO 550 SC (EPA Reg. No. 264-827): Maximum GAUCHO 550 SC INSECTICIDE allowed per year: 14.0 fluid ounces/Acre (0.5 lb AI/Acre). Regardless of formulation or method of application, apply no more than 0.5 lb active ingredient per acre per year, including soil and foliar uses.</td></tr>
<tr><td>4.) The max seasonal rate for hops is 0.336 kg a.i./ha, not 0.561 kg a.i./ha.</td><td>The assessment modeled the combined rate* as follows:
<table>
<tr><th>Seeds/ Seedling</th><th>Soil</th><th>Foliar</th><th>Total</th><th>Notes</th></tr>
<tr><td>0</td><td>0.225</td><td>0.112 x 3 @ 21 d.</td><td>0.561</td><td>Reduced Soil rate + Foliar rate</td></tr>
</table>
* Page 33 of GAUCHO 550 SC: Regardless of formulation or method of application, apply no more than 0.5 lb active ingredient per acre per year, including soil and foliar uses.</td></tr>
<tr><td>5.) The max seasonal rate for leafy greens is 0.4256 kg a.i./ha, not 0.561 kg a.i./ha.</td><td>What was modeled is the combined rate* as follows:
<table>
<tr><th>Seeds/ Seedling</th><th>Soil</th><th>Foliar</th><th>Total</th><th>Notes</th></tr>
<tr><td>0</td><td>0.296</td><td>0.053 x 5 @ 5 d.</td><td>0.561*</td><td>Reduced Soil rate + Foliar rate</td></tr>
</table>
* Page 19 of GAUCHO 550 SC: Regardless of formulation or method of application, apply no more than 0.5 lb active ingredient per acre per crop season, including soil and foliar uses.</td></tr>
<tr><td>6.) The max seed treatment rate for leak is</td><td>EFED disagrees with this comment; the rate of 0.182 lb. a.i/ha (0.204 kg/ha) was calculated by EFED (Refer to Table A-12 page 150 of the risk assessment based on the number of seeds needed to plant one acre).</td></tr>
</table>

<table>
<tr><th>BCS Comment</th><th>EFED Response</th></tr>
<tr><td>0.168 kg a.i./ha, not 0.204 kg a.i./ha.</td><td>Data for the active ingredient is taken from the label while that for the seeding rate (No. of seeds/Acre) given by BEAD (Acres Planted per Day and Seeding Rates of Crops Grown in the United States; US EPA, March 24, 2011).</td></tr>
<tr><td>7.) The max seed treatment rate for potato is 0.28 kg a.i./ha, not 0.561 kg a.i./ha.</td><td>EFED disagrees with this comment; this rate of 0.28 kg a.i/ha is determined, by the registrant, based on seeding rate of 2,000 lbs./A. However, the rate is 34,848 lbs. seeds as per BEAD (Acres Planted per Day and Seeding Rates of Crops Grown in the United States; US EPA, March 24, 2011). Based on this seeding rate the application rate will be higher than the maximum rate therefore, EFED used the maximum rate of 0.561 kg a.i/ha in modeling for the assessment.</td></tr>
<tr><td>8.) The max seed treatment rate for sugarbeet is 0.328 kg a.i./ha, not 0.481 kg a.i./ha.</td><td>EFED disagrees with this comment; the rate of 0.481 kg a.i/ha was calculated (Refer to Table A-12 page 150).<br>Data for the active ingredient is taken from the label while that for the seeding rate (lbs. of seed/Acre) given by BEAD (Acres Planted per Day and Seeding Rates of Crops Grown in the United States; US EPA, March 24, 2011).</td></tr>
<tr><td>9.) The foliar rate for tobacco (0.561 kg a.i./ha) is incorrectly listed in the seed treatment column.</td><td>The registrant is correct in that this rate should have been listed under soil application. This change will be updated for the final pollinator assessment, but it is noted that it was modeled as soil application. See correction, below:
<table>
<tr><th>Seeds/ Seedling</th><th>Soil</th><th>Foliar</th><th>Total</th><th>Notes</th></tr>
<tr><td><s>0.561</s> 0</td><td>0.561</td><td>0</td><td>0.561*</td><td>Soil rate</td></tr>
<tr><td>0</td><td>0.249</td><td>0.053 x 5 @ 5 d.</td><td></td><td>Reduced Soil rate + Foliar rate</td></tr>
</table></td></tr>
<tr><td>10.) A maximum of 3 foliar applications for tree nuts, resulting in an annual max of 0.336 kg a.i./ha, not 6 apps resulting in an annual max. of 0.561 kg a.i./ha as indicated in the table.</td><td>EFED's inspection of the label indicated that:<br>(1) Single rate ranges from 1.2 to 2.8 fl. oz./A= 0.0431 to 0.1006 lb./A or 0.0483 to 0.1127 kg/ha;<br>(2) The "Maximum GAUCHO 550 SC INSECTICIDE allowed per year: 10.0 fluid ounces/Acre (0.36 lb AI/A or 0.425 kg/ha). Regardless of formulation or method of application, apply no more than 0.5 lb active ingredient per acre per year, including soil and foliar uses.";<br>(3) The number of applications was not stated in the label and if calculated it will be 3.7 applications<br><br>EFED assumes 4 foliar applications of 2.5 fl. oz./A (NOT six) = 0.0898 lb./A=0.100 kg/ha this will give a maximum yearly rate of 0.359 lb /A/Year or 0.40 kg/ha/Y in addition to a reduced soil rate of 0.161 kg/ha/Y A total of 0.561 kg/ha/year for a combined application as per the label. Therefore, EFED modeled the following:
<table>
<tr><th>Seeds/ Seedling</th><th>Soil</th><th>Foliar</th><th>Total</th><th>Notes</th></tr>
<tr><td>0</td><td>0.561</td><td>0</td><td>0.561*</td><td>Soil rate</td></tr>
<tr><td>0</td><td>0.161</td><td>0.100 x 4 @ 5 d.</td><td>0.561*</td><td>Reduced Soil rate + Foliar rate</td></tr>
</table>
* As per the label (EPA Reg. No. 264-827)</td></tr>
<tr><td>11.) All non-agricultural uses have a maximum annual application of 0.448 kg a.i./ha.</td><td>According to all labels, not just GAUCHO (EPA Reg. No. 264-827, only nurseries specify this rate; for all other uses, the rate = 0.5 lb a.i/A on multiple labels. Please refer to Table A-15, page 155 of the Risk Assessment.</td></tr>
</table>

***A Flawed Study (Sanchez-Bayo et al. 2006) was included in EPA Non-Insect Effects Characterization:*** *EPA included results from this study, which the Agency rated as "qualitative", in the preliminary risk assessment document to characterize the sensitivity of ostracoda to imidacloprid exposure. This study is*

*not robust with 9-11% mortality reported in the controls for the ostrocod toxicity testing with imidacloprid over the 48 hr exposure period. Figure 3 in the manuscript demonstrates that control immobility was even greater than the 11% mortality observed for Cypridopsis vidua; however, the percent control immobility is not reported in the manuscript for any of the tests performed. Given the poor control performance and lack of further information to evaluate the performance of the study system, this study should be excluded from any quantitative or qualitative use. Further, EPA summarized the findings of the study's acute ostrocod tests as providing EC50 values of 1.0 to 3.0 µg ai/L. The actual publication reports acute EC50 values of 1.0 to 10 µg ai/L.*

**EPA Response**: EFED acknowledges that a supplemental qualitative classification recognizes some deficiencies in a study with a fit for purpose goal. From the referenced study, the 48 h $EC_{50}$ based on immobilization ranges from 1-10 ug/L for the three ostracod species conducted in the dark. Under normal light conditions, the range in 48-h $EC_{50}$ values is 3-16 ug/L. However, the most sensitive 48-h $EC_{50}$ values among the three species regardless of light conditions ranges from 1 to 3 ug/L. EFED determined that control mortality of 9-11% is not unreasonable when considering this test was for a non-standard test species. The large difference between the mortality $LC_{50}$ and the immobility $EC_{50}$ observed in this study is consistent with results published for other aquatic invertebrates. As far as the immobility results in the study manuscript Figure 3, there does appear to be elevated immobility (~30%) for one of the test species (*Ilyocypris dentifera);* although within the open literature figure there is uncertainty in the symbol appearances. However, without the raw data available, it is not clear what the control immobility was under normal light conditions or for other species tested.

***Exposure Assessment:*** *EPA should refine their standard Tier II screening level modeling approach and consider Bayer's higher tier spatially and temporally explicit refined assessment (MRID 49835801). EECs obtained from standard EPA/EECs obtained from Bayer's refined assessment are as follows: FL citrus: peak 15.6/0.14; 21-d 9.88/0.10; and 60-d 5.61/0.06 and for CA citrus: peak 1.26/0.09; 21-d 0.82/0.06; and 60-d 0.51/0.04.*

**EPA Response:** The EPA appreciates Bayer's submission of their refined aquatic assessment. With Bayer's refined aquatic assessment there were still many exceedances of the Level of Concern for aquatic taxa. EPA also noted that the calculation of the EECs used in that refined assessment differed from how EFED calculates EECs. Specifically, Bayer's assessment relied on 90$^{th}$ percentiles without consideration of a return interval, while EFED's EECs incorporate a 1-in-10 year return interval. Further, the decision to conduct refinements to an aquatic risk assessment involves both science and risk management considerations. Based on consultation with risk managers in the Pesticide Reevaluation Division, additional refinement beyond those conducted in the EFED aquatic risk assessment were not considered necessary to support the risk management decisions involving aquatic risk of imidacloprid.

***Comparing Modeled EECs with Monitoring Data:*** *EPA compared modeled peak EECs to the detected concentrations in surface water monitoring data (Figure 5-1, page 102 of the EPA assessment) and concluded that model-based EECs are environmentally realistic. This comparison is biased to the detectable residue and is not a correct representation of the entire monitoring data (detects and non-detects). Therefore, the conclusion drawn from this comparison is inappropriate.*

**EPA Response:** EPA Figure 5-1 clearly states that the monitoring data depicted are detected concentrations only. Elsewhere in Section 3 of the assessment the entire data set of monitoring data, detects and non-detects, are comprehensively summarized. As far as the validity of comparing detected concentrations with peak EECs, EFED believes this comparison is appropriate since both the detected

concentrations and the EECs represent infrequent, high end values of their respective distributions. In fact, aquatic EECs represent a much higher percentile (e.g., >99th percentile) compared to the frequency of detected concentrations from the United States Geological Survey (USGS) and California Department of Pesticide Regulation (CDPR) databases (5-67% depending on waterbody type). Contrary to the registrant's suggestion, it would be inappropriate to compare aquatic EECs which represent an upper percentile among 30 years of daily concentrations to a median value or other central tendency of all detected and non-detected monitored concentrations.

***Surface Water Monitoring Data:*** *Bayer presented an overview of monitoring data compiled from various sources up to July 2017. The overview was presented to address several concerns with the Agency's evaluation of monitoring data, in particular, the Agency's following statement in the Executive Summary (p. 9): "It is evident, however, that concentrations of imidacloprid detected in streams, rivers, lakes and drainage canals routinely exceed acute and chronic toxicity endpoints derived for freshwater invertebrates". This conclusion relies on the inappropriate comparison of individual sample concentrations to highly conservative endpoints, and in particular comparison of these acute single-sample concentrations to chronic endpoints. It is important when comparing monitored concentrations to risk indicators or exposure modeling, that acute and chronic exposures are differentiated, and compared with appropriate endpoints. For purposes of evaluating chronic exposures and risks, it is proposed that the annual average concentrations be used as the indicator of chronic exposure to aquatic invertebrates. The majority of the surface water monitoring data is from flowing water, so it is expected that observed 14 concentrations are short term resulting from precipitation and irrigation events, and are not representative of chronic concentrations which remain relatively constant over time.*

**EPA Response:** EFED believes that its statement on page 9 is correct, as evidenced by Figures 5-2 and 5-8, whereby detected concentrations of imidacloprid in aquatic ecosystems frequently exceeded toxicity reference values for multiple species of aquatic invertebrates. Regarding the perceived conservatism in the toxicity endpoints chosen, even if they increased by 1 or 2 orders of magnitude to reflect less sensitive taxa, detected concentrations would still exceed such values, if at a lesser frequency. In the assessment, EFED notes that the vast majority of monitoring data are based on grab samples representing non-targeted study designs (*i.e.,* not targeted both temporally nor spatially). Therefore, EFED believes it is highly unlikely that a single grab sample taken under such study designs would represent a peak (acute) exposure concentration since it would likely not be captured based on probability. On the basis of probability, such grab samples more likely represent longer-term averages instead of peak (acute) concentrations due to the high degree of temporal variability expected in aquatic concentrations from hour to hour and from day to day.

Such temporal variability is illustrated by EFED's use of the Pesticide in Water Calculator (PWC) model output of daily concentrations over a 30-year time series for characterizing risk to aquatic organisms. In its standard risk characterization, the Expected Environmental Concentration (EEC) is <u>not</u> selected based on an annual average since doing so would largely ignore higher concentrations that occur over shorter time periods which have the potential to adversely impact aquatic organisms. Rather, EFED calculates the EEC to reflect two important principles: 1) an averaging period that approximates the time required to elicit chronic effects and 2) a return frequency that allows for time for populations to recover in between concentration excursions. For acute and chronic effects on aquatic invertebrates, EFED's standard averaging period is 1 day and 21 days, respectively. These averaging periods are roughly approximate the duration of chronic tests, although EFED acknowledges that shorter exposure durations could result in chronic effects depending on the critical exposure period necessary to illicit such effects. Importantly, EFED selects a 1-in-10-year return interval for its return frequency. Compared to a 30-yr

time series of daily average concentrations, this return interval corresponds to very high percentile on the cumulative frequency distribution (*e.g.,* 99.9% or higher). Therefore, in contrast to the registrant's comment, EFED's comparison of monitoring data to acute and chronic toxicity endpoints for imidacloprid is likely to be substantially less conservative (less protective) when compared to its comparison of aquatic EECs to toxicity endpoints, even without considering that these monitoring data largely do not reflect temporally-targeted study designs. Had sufficient monitoring data been available to construct reliable long-term time series, then a much higher percentile of these data would likely be appropriate for comparing to toxicity endpoints. Since sufficient monitoring data were not available to estimate reliable time series, EFED simply chose to overlay the available monitoring data with toxicity endpoints as an additional line of evidence considered in the risk assessment process. In contrast to the registrant's comment, EFED recognizes that such comparisons are likely to be less conservative compared to EFEDs aquatic risk characterization.

***Types of Water Bodies:*** *EPA must thoroughly evaluate a system's desired function and attributes to ensure meaningful and achievable protection goals are established and to prevent data (i.e., monitoring data) obtained from the aquatic system being used for waterbodies it does not represent. EPA's current assessment does not do this adequately. The Agency cites imidacloprid concentrations in drainage ditches as a line of evidence that acute and chronic toxicity endpoints for freshwater invertebrates [mayflies] are routinely exceeded. However, these aquatic systems are not suitable habitat for most mayfly species due to hydrology, temperature, dissolved oxygen, turbidity and other non-pesticide related factors. We agree with the Agency's observation that concentrations in rivers are an order of magnitude lower than concentrations in streams. Using Google Earth to view many of the monitoring locations in areas with higher concentrations of imidacloprid shows that in agricultural areas, the highest concentrations are in drainage ditches and creeks in close proximity to agricultural fields and concentrations decrease in larger downstream streams and rivers. Higher concentrations in some areas and certain waterbodies should not be considered as representative of waterbodies across the nation, or to represent all uses (agricultural, residential, etc.) of imidacloprid.*

**EPA Response:** The noted exceedances do not pertain to just drainage ditches; they also occur for streams, waterbodies experiencing storm events and to a lesser extent, rivers and lakes. EFED agrees that concentrations in water bodies in close proximity to agricultural areas are generally higher than those further from agricultural areas. However, this does not mean that water bodies near agricultural areas are not "important" ecologically. Such water bodies support many types of wildlife and have become increasingly important habitat in agriculturally intensive ares with less abundant natural areas. These can also be used to represent other natural waterbodies not sampled near agricultural areas. Further, these monitoring data are not being used to represent an unbiased nation-wide representation of surface water concentrations. There are undoubtedly biases related to non-random selection of sites and timing of sampling. Rather, they are simply being used as an additional line of evidence to support EFED's risk conclusions that registered uses of imidacloprid can lead to concentrations in surface waters that pose risk to aquatic invertebrates

***Management Goal:*** *The management goals of the assessment are not clearly established in the problem formulation. "Section 2.4 Ecosystems at Risk" EPA does not mention drainage canals or ditches in the list of aquatic ecosystems at potential risk – presumably because the Agency recognizes these systems are not constructed to serve as aquatic habitat and does not plan to establish a level of protection unattainable for the system given its function and design – however, EPA includes water monitoring data from ditches and drainage canals in the monitoring section as a line of evidence that acute and chronic*

*toxicity endpoints are exceeded. In future assessments the Agency should exclude monitoring data from ditches and drainage canals from the assessment.*

**EPA Response:** EFED appreciates this comment; however, current risk assessment methods use what scientific toxicity information is available in combination with the label use rates and standard exposure models to assess risk to aquatic species. The EFED risk assessment process does not distinguish between waterbody types but evaluates conservative water bodies that are protective of water bodies in general. Additionally, the specific water systems mentioned, drainage canals or ditches, can be analogous to near field small streams. These small streams are often not monitored, cannot be monitored, or are ephemeral. The nature of the waterbody does not preclude risk to aquatic species or in other similar areas that happen to not have monitoring data available and therefore data from ditches and drainage canals should not be excluded.

***Concentration Trends:*** *Bayer included a figure for Surface water monitoring data (imidacloprid detects only), and annual 90th percentile concentrations (detects only), compared with imidacloprid use (1999-2017). The analysis showed that the significant increase in imidacloprid use since 2009 does not result in corresponding increases in the surface water maximum concentrations, the frequency of detections at higher concentrations (e.g. >1.0 µg/L), or the 90th percentile concentrations of imidacloprid.*

**EPA Response:** Relating changes in usage data, from year to year, to observed increase or decrease in monitored concentrations is difficult. This is because detected concentrations are highly dependent on many uncertain factors such as: intensity of the monitoring effort (*i.e.*, number of sites/samples taken corresponding to year for which usage is estimated) and shifts in usage patterns (Increase in usage may correlate with lower concentrations if there was a shift into incorporated/watered-in soil and seed applications from foliar application).

***Error:*** *The "Commercial (Perimeter Treatment): (0.5 lbs a.i./A, CA)" scenario in Table 5-3 on page 89, incorrectly indicates a LOC exceedance for freshwater chronic risk.*

**EPA Response** EFED appreciates this correction and agrees a chronic RQ of 0.9 is below the chronic risk LOC of 1.0

***Avian Population Trends:*** The avian guild of aerial insectivores is a good bioindicator of damaged aquatic invertebrate communities since the species that comprise the guild rely on emerging aquatic invertebrates for food. Analysis of population trends for the aerial insectivore guild across North America and regions of high imidacloprid use demonstrate there is no association with imidacloprid use and the 19 population trends for this guild, thus strongly suggesting the aquatic invertebrate communities are not adversely impacted as well.

**EPA Response:** EFED appreciates the submission of this information, but notes multiple factors likely influence avian population dynamics in North America and elsewhere which renders such general associations with pesticide use difficult to establish. EFED further notes that numerous studies have associated declines in global insect populations to multiple factors including (but not limited to) habitat loss, pathogens, invasive species, climate change and synthetic pesticides use (for review, see Sanchez-Bayo and Wyckhuys, 2019).

### 1.4. Northwest Center for Alternatives to Pesticides

**(Docket ID No.: EPA-HQ-OPP-2008-0844-1218):** *Seed treatment modeling does not take into account the potential contamination from deposition of abraded seed coat dust onto the treated field or adjacent areas (p. 8) and therefore, may underestimate aquatic exposure from the planting of treated seeds. EPA states that it lacks standardized methods for quantitatively modeling dust off of abraded coating from treated seeds and "the Agency is working with different stakeholders to identify best management practices and to promote technology-based solutions that reduce this potential route -- 4 of exposure." Respectfully, we believe that the agency should work immediately to model this exposure route. Risk assessment should not ignore potential exposure routes simply because voluntary BMPs are in development.*

**EFED Response:** There are some routes of possible exposure, like seed dust drifting off field into adjacent water bodies, that EFED does not currently have a quantitative method to estimate. Additionally, this exposure would be extremely variable depending on the type of crop being planted. EFED is working with risk managers and with stewardship opportunities to better work on this route of exposure with best management practices to reduce risk to non-target organisms.

### 1.5. San Francisco Estuary Institute

**(Docket ID No.: EPA-HQ-OPP-2008-0844-1220):** *We urge the US EPA to update its Preliminary Aquatic Risk Assessment to include consideration of pet spot-on flea control products and the potential environmental impacts of their release to the environment via municipal wastewater treatment plants.*

**EPA Response:** The Agency appreciates these comments and greatly values the work in addressing the contribution to imidacloprid surface water contamination from pet/residential uses and effluent from municipal wastewater treatment plants. For this type of use we use Down the drain model " part of E-FAST2 model" (URL: https://www.epa.gov/tsca-screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014) which requires two major input values: the amount of chemical released to wastewater and the estimated removal from wastewater treatment. The first input value is provided by the registrant and the second value is estimated by EPI suite (URL: https://www.epa.gov/tsca-screening-tools/download-epi-suitetm-estimation-program-interface-v411). References included in your comments provide valuable information that could be used as inputs. However, the Agency prefers to obtain the active ingredient amount related to indoor uses from the registrant. Monitoring is another source of data concerning imidacloprid surface water contamination from pet/residential uses.

EFED recognizes that pet/residential uses were not considered in the draft aquatic risk assessment of imidacloprid. EFED risk conclusions depend on modeled estimated environmental concentrations (EECs) along with monitoring data which are used as another line of evidence to support these conclusions. In the draft aquatic risk assessment, EPA identified level of concern exceedances for freshwater invertebrates and It was evident that concentrations of imidacloprid detected in streams, rivers, lakes and drainage canals routinely exceed acute and chronic toxicity endpoints derived for freshwater invertebrates.

### 1.6. Southern cotton growers

**(Docket ID No.: EPA-HQ-OPP-2008-0844-1425)**: *Regarding seed drop rates, southeast cotton acres plant on average 40-50,000 plants per acre instead of the EPA assumption of 85,000 seed per acre belt wide.*

**EFED Response:** EFED appreciates the comment on the seeding rate for cotton in Texas. However, the Agency assessment is nationwide and therefore, the highest seeding rate was used from Table 2 nationwide data as a screen. Regionally based values are used as needed to support risk management decisions.

Table 2. Summary of nationwide cotton seeding rates.

| State | Seeding Rate (number of seeds needed for planting one cotton acre) | |
|---|---|---|
| | Minimum | Maximum |
| Georgia | 36,300 | 39,930 |
| Texas[1] | **50,000** | **52,800** |
| Louisiana | 52,500 | 52,800 |
| Mississippi | 39,204 | 55,023 |
| Tennessee | 29,000 | 60,000 |
| California | 35,000 | 85,000 |
| [1]**Note:** EPA estimates for Texas is in the range of 50,000 to 52,800 seeds/A. The value that could be used for Texas is 52,800 which is not far from the maximum rate of 50,000 you indicated. | | |

# 2. Imidacloprid Pollinator Comments

### 2.1. Bayer CropScience

***Persistence data:*** *The Consortium strongly disagrees with several unsupported and unwarranted comments on the persistence and potential accumulation of imidacloprid in soil. A complete analysis of all the submitted data, results in a more accurate characterization of the degradation of imidacloprid. The EPA estimated half-lives do not represent the field data available to the Agency, and is based on an incorrect selection of the kinetics model. The Consortium is providing specific data and analysis to support more appropriate conclusions about the environmental fate of imidacloprid.*

**EPA Response:** Considering information provided after the publication of the preliminary pollinator assessment the half-lives used were refined in subsequent risk assessments. The refined half-life ranges from 139 days to 608 days (305 days to >2,000 days reported in the pollinator assessment) with the upper 90th confidence level of the mean half-life of 254 days, which is used as modeling input.

***Toxicity endpoint selection****: The Consortium believes the Agency should reconsider their decision to classify the Boily et al. 2013 study as reliable for use in quantitative risk assessment and should review all available evidence which includes several additional relevant studies apparently not considered so far.*

**EPA Response:** EFED recognizes the deficiencies with the selected Boily study and maintains the previously determined study classification. An additional adult chronic oral toxicity study was submitted

after publication of the preliminary pollinator risk assessment. This study (MRID 50399101) was evaluated and incorporated to reflect the new chronic adult endpoint, and the resultant RQs still indicate a chronic risk level above the LOC for most uses.

***Exposure estimates:*** *Imidacloprid has one of the most extensive data sets ever developed from which to derive bee exposure estimates. When robust data are available, the Consortium believes that acute and chronic EECs should be derived from 90th and 50th percentile levels of available measurements of field trials biased toward worst-case conditions. EPA's approach was to use the maximum measurement in the entire data set as the acute EEC, and the maximum daily mean measurement as the chronic EEC. This approach is overly conservative and, in some cases, resulted in EECs that were more than 10 times greater than would have been calculated following Bayer's approach.*

**EPA Response:** The Agency acknowledges that the Tier I refined exposure estimates used to calculated RQs for risk determination are the maximum single and maximum daily average residue values for acute and chronic exposure, respectively. Within the preliminary and final pollinator assessment, RQs are calculated with all residue data available to show a full characterization of risk.

***Tier II risk:*** *In the Tier II approach for characterizing risks, the Agency used the Bayer-submitted colony feeding study (MRID 49510001) to establish a NOEC for use at the Tier II level when comparing to nectar residues. In addition, the Agency compares results from one trial as reported in Dively et al. (2015) for comparisons to pollen residues. For this study the Agency states that "the findings were restricted to a significant ($p<0.05$) reduction in overwintering survival at the 100 ppb treatment group in one trial" (p. 208). The Consortium disagrees with the significance finding in this endpoint as presented by the Agency.*

**EFED Response:** EPA agrees with the assertion that the Dively study had uncertainties and limitations as EPA makes those known in its preliminary assessment. Following comments in the preliminary assessments, EFED worked to develop a method that utilizes a factor accounting for the differential pollen consumption of a hive relative to the nectar as well as registrant submitted colony feeding studies utilizing pollen patties.

***Bridging data between crop groups:*** *EPA should have bridged to crop groups listed as uncertain with other crops for which data are available based on similarities in taxonomy.*

**EPA Response:** In the final pollinator risk assessment, EFED did bridge from crops with data available to other crop groups based on similarities in taxonomy and across other neonicotinoid chemicals. This approach is detailed in an attachment to be posted alongside the assessments and response to public comment document to the public docket.

***Incident reports:*** *More than half (8 of 15) of the reported incident are no longer permitted on current labels. This includes applications to linden, basswood and other Tilia species trees.*

**EPA Response:** EFED recognizes that applications to linden trees are no longer permitted on some labels and these species represent many of the reported incidents. However, this is not the case for all registrations or locations. The assessment therefore reflects all incidences as reported to the EPA that had an acceptable likelihood of certainty.

## 2.2. Center for Food Safety

**(EPA-HQ-OPP-2008-0844-0883) Consideration of additional data:** *In January 2016, IMD was reported on in a full GreenScreen prepared by ToxServices of Washington, DC, for the Natural Resources Defense Council. The report is attached to this comment and incorporated herein by this reference. EPA should fully consider it in the final PPA. The GreenScreen chemical hazard assessment method was chosen because of its widespread acceptance by governments, industry, and non-governmental organizations alike. GreenScreen integrates aspects of EPA's Design for Environment Alternatives Assessment and the Globally Harmonized System of Classification and Labelling of Chemicals. GreenScreen is routinely used by governments and industry and is increasingly being incorporated into environmental scorecards and standards.*

**EPA Response**: This publication was reviewed and showed endpoints selected that were not more sensitive than those used for risk assessment by EFED. Additionally, the risk estimation process in this publication is different than that used in the Agency's general risk quotient process.

## 2.3. National Cotton Council (EPA-HQ-OPP-2008-0844-0855)

**Exposure assumptions:** *In all cases, EPA has assumed the highest consumer to represent other stages and castes. The underlying assumption is that all "nectar" or "pollen" fed upon contains the pesticide treatment and that the maximum amount possible to consume. Tier I takes such an extreme approach, its only value is quick dismissal of extremely harmless materials. EPA notes "empirical data can be used to refine conservative exposure estimates and reduce uncertainties associated with the Tier I exposure estimates by providing direct measurements of pesticide concentration resulting from actual use settings" (p. 71, paragraph 2). However, the NCC points out invalid assumptions of exposure are not addressed by quantitative measurement of pesticide on plant parts. EPA continues to place emphasis on toxicity assuming exposure.*

**EPA Response**: With data submitted since the time of the preliminary pollinator assessment, there are studies for all three tiers of the Agency's bee risk assessment process. EFED recognizes that Tier I is a high end estimate of exposure. Further refinements are made in refined Tier I assessment which utilizes field measured residue data. For imidacloprid colony level Tier II (semi-field) and Tier III (full field) data were also available to further characterize the potential impacts to this higher level of biological organization.

**Availability to honey bees:** *The NCC is aware previous research has demonstrated the flower nectaries are not easily utilized and exposure related to the flower nectaries lacks sufficient verification. Studies indicate the short tongue of pollinators limits the utilization of floral nectar. Cotton residue study and real exposure, floral nectaries difficult to reach for honey bee species.*

**EPA Response**: As part of the determination of exposure, EFED consulted the USDA attractiveness guide that indicate cotton flowers contain pollinator attractive nectar. Furthermore, EFED is unable to independently confirm the claim that honey bees have limited use of cotton nectar. Particularly because cotton is frequented by beekeepers for honey production.

## 2.4. California fresh fruit association

**(Docket ID No.: EPA-HQ-OPP-2008-0844-0890) Crop attractiveness:** *Crop attractiveness information over-estimates exposure. Provides example of table grapes not requiring pollination along with certain varieties of nectarines and peaches planted for commercial production. Cautions against applying attractiveness across broad crop groupings as it over-estimates exposure from pollen-nectar.*

**EPA Response**: The USDA crop attractiveness information is the best available data for qualitatively evaluating the potential exposure of bees to agricultural crops. Where possible, different types of crops are differentiated in terms of exposure (*e.g.,* mandarins and tenting). As explained by USDA (https://www.ars.usda.gov/office-of-pest-management-policy/office-of-pest-management-policy-home-page/), a formal process exists for stakeholders to submit data to support an evaluation that would potentially culminate in amending the current crop attractiveness designations. This has been done multiple times over the past several years resulting in updates. It is recommended that the commenter provide such data per the USDA guidance, in order for EPA and USDA to consider differentiating different varieties of crops within a broader crop group. In the updated final bee risk assessment, EFED used the USDA 2017 guidance.

## 2.5. Florida fruit and vegetable association

**(Docket ID No.: EPA-HQ-OPP-2008-0844-1023) Chemical buildup in the soil:** *Florida soils perform differently than the soils used in the assessment. EPA should consider the regional differences in soil and how it may impact uptake.*

**EPA Response:** EFED appreciates the comments concerning imidacloprid persistence and the potential for soil buildup at the regional scale. The Agency measure of persistence is based on laboratory aerobic soil metabolism data for soils varied in texture, organic matter content, pH, and cation exchange capacity. Aerobic soil data are used as a measure of the degradation processes affecting the pesticide dissipation. Another measure of pesticide dissipation is the terrestrial field dissipation studies (TFD) in which the combined degradation and transport (*e.g.,* leaching, plant uptake and others) are measured. The potential pesticide soil buildup is one of the results obtained from TFD studies. Unfortunately, the submitted TFD studies for imidacloprid were not acceptable and an attempt to characterize potential soil buildup was performed based on available aerobic soil studies. However, it was stated that this analysis is conservative because it is based on degradation alone and does not consider pesticide movement in the field which involve important processes in pesticide dissipation. For characterizing persistence and potential buildup, the document is modified in response to your comment and new studies submitted following issuance of the first draft. Hereunder is the referenced text:

*"Aerobic soil transformation of imidacloprid is expected to be relatively slow with degradation half-lives ranging from 172 to 608 days and upper 90th confidence limit on the mean t½ of 254 days (n=8). Based on this route of degradation alone, imidacloprid is expected to be highly persistent in the soil system. This persistence in soils may lead to accumulation over the years with repeated applications. However, the magnitude of soil accumulation is expected to be highly affected by other important routs of dissipation including: leaching, run-off and plant up-take which are expected to reduce this accumulation".*

## 2.6. Natural Resources Defense Council

**Other stressors:** *EPA failed to explain the dramatic differences in Nosema infection rates across treatment groups in the key study that EPA used to set the colony risk estimate (see discussion below). Failure to address the impacts of combinations of pathogens with pesticides is a significant uncertainty with this assessment, particularly with regards to bumblebees, solitary bees, and other vulnerable native species that have a smaller colony size and may therefore have less ability to survive a pathogen-pesticide combined assault. These real-world scenarios are not represented in EPA's assessment. This supports the use of a Database Uncertainty Factor.*

**EPA Response:** The higher tier studies (Colony Feeding Study) available for review included measures of pathogen infection (Nosema, Varroa) and found no relationship between imidacloprid concentration and infection rates. The Agency's current bee risk assessment process only considers the impact to bees at the individual and colony levels resulting from pesticide exposure only. While the Agency recognizes a growing body of data in the open literature that investigates the impacts of imidacloprid with other stressors, such as pathogen infection, and even included such studies in its suite of data evaluated, there was generally equivocal results on the nature of effects. Furthermore, other independent reviews (*e.g.,* Collinson et al 2015) have similarly indicated conflicting evidence on the impact of neonicotinoids and immune function.

**Strength of evidence approach:** *The assessment fails to include critical elements of a systematic review process for evaluating and integrating multiple streams of data. Systematic reviews integrate information from human epidemiologic data, in vivo toxicologic data, in vitro cellular and mechanistic data, and in silico computational information. The NRC recommended that a systematic evidence-integration process be developed that considers all lines of evidence (i.e., human, animal, and mechanistic), systematically determine the strength of evidence (not weight of evidence) considering such aspects as consistency of exposure and evaluates study bias.*

**EPA Response:** The Agency has an established, systematic process for identifying, evaluating, and incorporating data into our risk assessment that was followed. Specifically, the 2014 pollinator framework outlines the process for assessing risk to bees. Additionally, in the *Final Bee Risk Assessment to Support the Registration Review of Imidacloprid,* more information is provided in a weight of evidence approach for risk assessment. This includes consideration of further residue data in pollen and nectar, additional colony level field studies, and additional open literature study relative to what was evaluated to support the preliminary assessment.

**Literature search:** *The literature search was not systematic, did not include clear exclusion criteria, and failed to identify sponsorship.*

**EPA Response:** The literature review presented in the draft pollinator risk assessment was conducted in conjunction with multiple governmental agencies. This review also includes open literature studies within the Agency ECOTOX database. EFED open literature review guidance is also available (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluation-guidelines-ecological-toxicity-data-open) and was followed for the imidacloprid literature review. Included in conjunction with the final pollinator risk assessment includes data evaluation records and open literature study reviews supporting the risk assessment.

## 2.7. Pollinator Stewardship Council

**Tier III studies:** *Field studies should be conducted on all plants foraged by bees including a pollen analysis, including soybeans, cotton, and canola.*

**EPA Response:** Included in the final pollinator risk assessment are several new studies submitted since the time of the preliminary pollinator assessment that were evaluated for imidacloprid. Two full field studies (Tier III) are available for imidacloprid on cotton and pumpkins. These are very research extensive and have historically not been informative for risk assessment. The final risk assessment relies more on the Tier II data, primarily residues in pollen and nectar and the associated low and no adverse effect levels as determined from colony feeding studies. In addition, conducting full field studies on all bee attractive crops is resource intensive and would potentially not alter current colony level conclusions for these use patterns. Tier II colony feeding studies and field residue studies provide a means to evaluate the potential for colony level impacts resulting from the use of imidacloprid on attractive crops. It also addresses variability in exposure and incorporates some level of conservatism.

## 2.8. USDA

**Recommended refinements:** *For Stone Fruit and Tree Nuts and Tuberous and Corm Vegetables, extremely conservative assumptions of 100% aerial applications and 10-15 mph wind speeds were used for AgDRIFT modeling. First, from the CALPIP database, there were no aerial applications applied in any of these crops in 2014. Secondly, a review of agricultural extension service recommendations in each state for spray applications would reveal consistent agreement that spray applications be made in winds under 10 mph, and generally within 3-8mph.*

**EPA Response:** The application parameters used in the pollinator off field drift assessment are consistent with the label. Specifically, the droplet size, wind speed, and boom height used are the max allowable on the label. When conducting off field assessments, EFED policy is to use this enforceable language, and not necessarily the general practice.

## 2.9. Xerces Society for Invertebrate Conservation

**EPA-HQ-OPP-2008-0844-1016 Colony feeding study:** *The risk findings in the Preliminary Assessment are heavily dependent upon a single honey bee colony level study (MRID 49510001). We have significant concern with EPA's choice to weigh so heavily on this single study. EPA must take steps to strengthen its population level analysis. If EPA continues to rely upon MRID 49510001 an uncertainty factor must be added to respond to the data gaps and problems noted with the study. Clearly, MRID 49510001 has extensive problems including data gaps, questionable methodology and numerous other concerns. If EPA persists in using this study to set the bar for determining risk, as it has in the Preliminary Assessment, a margin of safety must be included by applying uncertainty factors.*

**EPA Response:** The use of colony-level endpoints and consideration of full field studies does address, to some extent, impacts on bee populations. The apical endpoints related to survival, growth, and reproduction are considered closely aligned with the potential for population level impacts. Additionally, it is not within EFED policy as stated in the Agency's 2014 *Guidance for Assessing Pesticide Risks to Bees* (USEPA *et al.* 2014) to apply uncertainty factors in ecological risk assessment.

**Exposure estimates:** *The Preliminary Assessment uses average residue levels to assess exposure. This method fails to look at high end exposure scenarios. EPA must better represent the range of potential exposures that native and managed bees face. The importance of understanding the range of exposures (especially high-end exposures) is exemplified by the fact that the rusty patched bumble bee under consideration for listing under the Endangered Species Act and that a recent status review found more than one quarter of bumble bee species in North America at risk of extinction. Another reason to include high end exposure assessments is because EPA disregards numerous exposure routes. Therefore, EPA's methodology already fails to assess the overall exposure a bee may receive.*

**EPA Response:** The Agency acknowledges that the Tier I refined exposure estimates are the maximum single and maximum daily average residue values. Within the preliminary and final pollinator assessment tier I RQs are calculated with all residue data available to show a full characterization of risk. For the Tier II assessments all average daily residue values were compared against the colony level NOAEC and LOAEC values. If one measured residue exceeded the no effect level a risk determination was made.

**Landscape assessment:** *IMD is widely used throughout the United States. If we are to understand the impacts of this large-scale use EPA must undertake a landscape wide approach to evaluate its environmental contamination and the impacts this contamination has on human health and the environment. The Preliminary Assessment evaluates IMD's risk by crop, and application method. While these narrow assessments can be useful to understand priority risks to target mitigation, it fails to provide a broader view of the ecological risks posed by overarching IMD use in the landscape. This recommendation is not pollinator specific and should be considered in the design of a broad-reaching ecological risk assessment.*

**EPA Response:** It is Agency policy to assess a chemical by registered use. For imidacloprid the risk assessment was undertaken by crop group and were applicable risk was able to be assessed for combined foliar and soil applications within a growing season. we evaluate all registered uses, which is a matter of policy, and the degree to which larger scale effects might occur over any given area depends on a lot of factors including the degree which uses are located in that area and what those risk profiles are for those uses - landscapes are extremely variable and that type of assessment would be very complex.

## 2.10. CropLife America

**Endpoint selection:** *Of greater impact is the decision by EPA to use a flawed bee chronic oral toxicity endpoint. This endpoint comes from a study that has significant methodological deficiencies and that reported results which are contradicted by a number of higher-quality studies.*

**EPA Response:** The Agency recognizes the deficiencies of the original open literature study and maintains the selected study classification. An additional adult chronic oral toxicity study was submitted after publication of the preliminary pollinator risk assessment. This study (MRID 50399101) was evaluated and incorporated to reflect the new chronic adult endpoint, and the resultant RQs still indicate a chronic risk level above the LOC for most uses.

### 2.11. Washington state university

**Direct to water application:** *When reviewing all the use patterns of imidacloprid and their potential impacts on pollinators, I assume that you will also consider the recent registration obtained by the shellfish industry in Willapa Bay, WA (EPA. REG. No 88867-1 and No. 88867-2). This use of imidacloprid is to control burrowing shrimp, a pest of oysters in the tideflats of Willapa Bay and Grays Harbor.*

**EPA Response:** This direct to water application is not likely to impact pollinators. EFED worked extensively with WA previously on this issue.

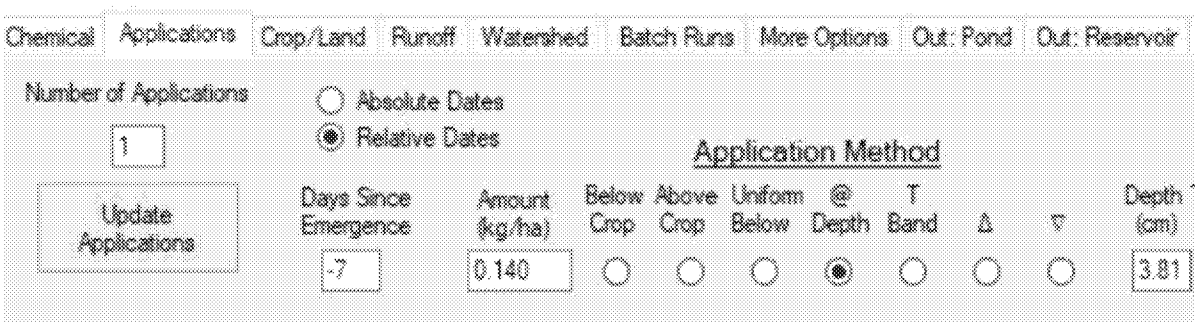
# 3. Addendum

**INTRODUCTION**

In 2019, EFED finalized guidance for aquatic modeling of granular and treated seed applications, to standardize EFED's surface water modeling approach. The guidance recommends using the "linearly increasing with depth" option (a.k.a. the triangle method) in the Pesticide Water Calculator (PWC) model, to account for seeds or granules placed at depths shallower than the incorporation depth specified on the labels. Prior to the 2019 guidance, the assumption in the PWC model (*i.e.* the "at depth" option) was that residues from treated seeds or pesticide granules placed below 2 cm were not available for runoff. Huff Hartz et al[1] and Young and Fry[2] have demonstrated that when pesticide is incorporated below 2 cm, as is the case with some treated seeds, runoff of pesticide can still occur.

***Example:*** Treated seeds are planted at a depth of 3.81 cm with a calculated application rate of 0.140 kg/ha with an assumed 7 days before the emergence date of the crop.

***Currently,*** the application tab is populated with the required parameters as shown in the figure, below.

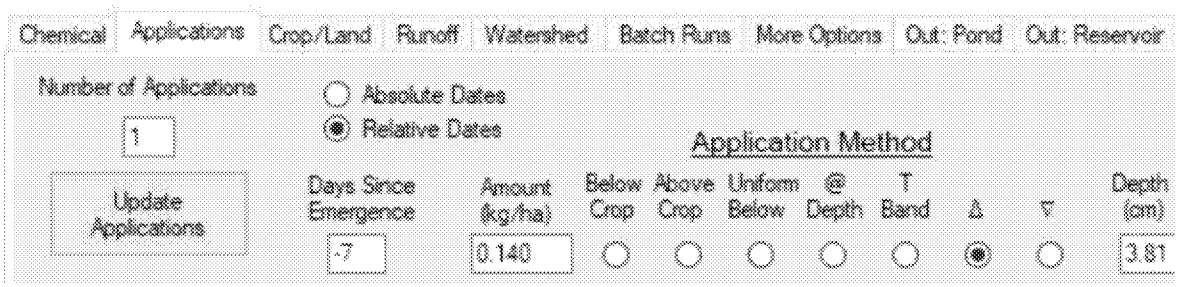



[1] Huff Hartz, K., Edwards, T., Lydy, M. 2017. Fate and transport of furrow-applied granular tefluthrin and seed-coated clothianidin insecticides: Comparison of field-scale observations and model estimates. Ecotoxicology (2017) 26:876–888

[2] Young, D., Fry, M. 2017. Field-scale evaluation of pesticide uptake into runoff using a mixing cell and a non-uniform uptake model. Environmental Modeling & Software 9/22/2017. https://doi.org/10.1016/j.envsoft.2017.09.007

In this case, the chemical mass will be placed at a depth of 3.81 cm below the run-off extraction zone of the EXAM model (0 to 2 cm). This will result in no chemical reaching the pond and EECs of zero because the only modeled exposure route, in seed treatment, is run-off.

***The new guidance method,*** calls for the application tab to be populated with the required parameters as shown in the figure, below (Choose "Pointing Up Triangle" application method instead of "@ Depth"; this is the only change).




In this case, the chemical mass will be distributed in a triangular shape between the depth of 3.81 cm (highest amount) and the surface of the soil (near zero amount). Portion of the chemical mass will be within the 2 cm run-off extraction zone of the EXAM model (0 to 2 cm). This will result in chemical reaching the pond and EECs will be >zero.

**EXPECTED CHANGES TO IMIDOCLOPRID AQUATIC EXPOSURE EECs RESULTING FROM SEED TREATMENT USES**

In the 2016 registration review aquatic risk assessment[1], modeling for seed treatment was executed as follows:

(1) By modeling combined applications with other permitted application methods including soil and/or foliar. Modeled crops included: Broccoli, Canola, Carrots, Crambe, Cotton, Flax, Fruiting vegetables, Leek, Mustard, Onions, Peanuts, and Soybeans. Resultant aquatic exposure EECs were from the combined application including seed application.

(2) By modeling seed treatment alone for some of the crops including: Beans, Canola, Flax/crambe, Potatoes and Sugar beet.

[1] Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid (D435477 dated December 22, 2016)

**Table 1** Inputs and outputs summary EECs

| Crop | Modeling Parameters | | | Aquatic EECs (ppb) For Application Method: | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | "@Depth" | | | "▲" | | |
| | Scenario | Rate Kg/ha | Depth (cm) | Peak | 21-d | 60-d | Peak | 21-d | 60-d |
| Beans | ILbeansNMC | 0.561 | 2.54 | 0.00 | 0.00 | 0.00 | 2.98 | 2.10 | 1.47 |
| Canola | NDcanolaSTD | 0.092 | 0.64 | 0.65 | 0.52 | 0.34 | 0.95 | 0.75 | 0.49 |
| Corn | MScornSTD | 0.140 | 3.81 | 0.00 | 0.00 | 0.00 | 0.79 | 0.56 | 0.31 |
| Potatoes | CAPotatoRLF_V2 | 0.561 | 7.62 | 0.00 | 0.00 | 0.00 | 0.02 | 0.01 | 0.01 |
| Sorghum | TXsorghumOP | 0.026 | 1.91 | 0.00 | 0.01 | 0.01 | 0.36 | 0.23 | 0.12 |
| Soybean | MSsoybeanSTD | 0.235 | 2.54 | 0.00 | 0.00 | 0.00 | 3.33 | 2.21 | 1.26 |
| Sugarbeet | CAsugarbeet_WirrigOP | 0.481 | 1.27 | 1.20 | 0.84 | 0.51 | 2.63 | 1.83 | 1.13 |
| Wheat | NDwheatSTD | 0.164 | 3.81 | 0.00 | 0.00 | 0.00 | 0.17 | 0.12 | 0.07 |

When using the updated method, the aquatic EECs for several seed treatment application scenarios increases. For the root and tuber (potato and sugarbeet) and oilseed (canola) crop groups the aquatic risk assessment calculated RQs above the acute and chronic LOCs and this conclusion would not change. The increases in EEC for cereal grains (corn, sorghum, and wheat) and legumes (soybean and beans) would result in RQs above the chronic LOC where these applications did not have RQs above the LOC identified before.

# References

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## Appendix 1. List of Neonicotinoid Pollinator and Non-pollinator Risk Assessments and Corresponding Docket ID Numbers

| | Pollinator / Bee Risk Assessment | Non-pollinator Risk Assessment(s) |
|---|---|---|
| Imidacloprid | Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid.<br>(DP 429937, 1/4/2016)<br>Docket ID: EPA-HQ-OPP-2008-0844-0140<br><br>Final Bee Risk Assessment to Support the Registration Review of Imidacloprid.<br>(DP 443668, 1/2020)<br>Docket ID: EPA-HQ-OPP-2008-0844-xxxx | Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid.<br>(DP 435477, 12/22/2016)<br>Docket ID: EPA-HQ-OPP-2008-0844-1086<br><br>Preliminary Terrestrial Risk Assessment to Support the Registration Review of Imidacloprid<br>(DP 442830, 11/28/2017)<br>Docket ID: EPA-HQ-OPP-2008-0844-1256 |
| Clothianidin | Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam.<br>(DP 437097, 1/5/2017)<br>Docket ID: EPA-HQ-OPP-2011-0865-0173<br><br>Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam.<br>(DP 455645, 1/2020)<br>Docket ID: EPA-HQ-OPP-2011-0865-xxxx | Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support the Registration Review of Clothianidin.<br>(DP 439290, 11/27/2017)<br>Docket ID: EPA-HQ-OPP-2011-0865-0242 |
| Thiamethoxam | Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam.<br>(DP 437097, 1/5/2017)<br>Docket ID: EPA-HQ-OPP-2011-0581-0034<br><br>Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam.<br>(DP 455645, 1/2020)<br>Docket ID: EPA-HQ-OPP-2011-0581-xxxx | Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support the Registration Review of Thiamethoxam.<br>(DP 439307, 11/29/2017)<br>Docket ID: EPA-HQ-OPP-2011-0581-0093 |
| Dinotefuran | Draft Assessment of the Potential Effects of Dinotefuran on Bees<br>(DP 437374, 1/3/2017)<br>Docket ID: EPA-HQ-OPP-2011-0920-0014<br><br>Final Bee Risk Assessment to Support the Registration Review of Dinotefuran.<br>(DP 451015, 1/2020)<br>Docket ID: EPA-HQ-OPP-2011-0920-xxxx | Preliminary Ecological Risk Assessment (excluding terrestrial invertebrates) for the Registration Review of Dinotefuran.<br>(DP 441527, 11/28/2017)<br>Docket ID: EPA-HQ-OPP-2011-0920-0616 |