

Response to Public Comments Received on
Draft Biological Evaluations for
Imidacloprid, Thiamethoxam, and Clothianidin

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1 Introduction

This response to comments (RTC) document provides the response of the Environmental Protection Agency (EPA) to public comments received regarding the draft national-level listed species biological evaluations (BE) for three neonicotinoid insecticides: imidacloprid (IMI), thiamethoxam (THIA), and clothianidin (CLO). This document includes responses from the Office of Pesticide Programs' (OPP) Environmental Fate and Effects Division (EFED), Biological and Economic Analysis Division (BEAD), and Pesticide Re-evaluation Division (PRD) to division-relevant comments.

This RTC document has five sections. **Section 1** is the introduction. **Section 2** responds to public comments that are common across all three neonicotinoid active ingredients (a.i.). These comments are more general in nature and either apply across all a.i.s or did not require an in-depth scientific analysis or response. **Sections 3 – 5** are chemical-specific sections for each of the three active ingredients imidacloprid, thiamethoxam, and clothianidin. A list of all commenters is provided in **Appendix A**. **Appendix B** addresses monitoring data associated with wastewater treatment plant discharge and how the levels compare to estimated environmental concentrations (EEC) reported in the BEs.

A total of 473 comment documents were submitted to the docket in www.regulations.gov pertaining to the draft BEs for the three neonicotinoids (docket ID: EPA-HQ-OPP-2021-0575). These included approximately 350 comments from individuals and 7 mass mail campaigns with a total of approximately 67,000 signatures. Comments were also submitted by various stakeholder organizations, including environmental and other non-governmental organizations; pesticide registrants and registrant groups,

affiliates, and consultants; commercial associations; farm bureaus; growers; academic organizations; and local, state, and federal government agencies. A list of all commenters is provided in **Appendix A** (note that individual citizen commenters are not listed individually). Since many of the comments had similar themes and subjects, the responses below are grouped by common subject area, rather than individual commenters.

Commenters noted that since there were such a large number of Likely to Adversely Affect (LAA) determinations made, EPA should begin the cancellation process for neonicotinoids. It is important to note that the LAA threshold for a BE is very conservative as the likely “take” of even one individual of a species triggers an LAA determination. An LAA determination in the BE should not be interpreted to mean that EPA has made a determination that neonicotinoids are putting listed species in jeopardy. Those determinations are made by the Services in their biological opinions. EPA will make a determination on the state of the registration of the neonicotinoids after the biological opinions have been finalized.

A common theme throughout the comments was that EPA should do more to evaluate risks to listed species based on what is commonly occurring on the landscape (*e.g.*, the use of average application rates, common agricultural practices, and updated spray drift technologies) and consider risks associated with individual uses. EPA has considered some of these practices in its weight of evidence analysis. EPA evaluated, according to the labeled use directions, whether an individual of a listed species may be affected according to the maximum use rates and methods of application on the labels, even if the majority of actual applications could result in lower exposures (*e.g.*, from lower application rates and/or spray drift reduction technology). In turn, the action area is then determined based on the full spatial footprint of the labeled use sites. When determining the likelihood of adverse effects to an individual and the strength of the evidence supporting effects conclusions, EPA considered the labeled use directions in the context of available usage data and common agronomic practices as well as alternative assumptions regarding toxicity and potential exposure.

In regard to addressing public comments and initiating consultation with the Services under Section 7 of the Endangered Species Act, EPA carefully considered the comments to determine if any updates to the BEs were necessary, particularly in context with implementing mitigation measures that would reduce the potential for jeopardy. In many cases the information or data submitted in the comments would have little to no bearing on the likelihood of impacting one individual, considering the conservative nature of the effect determinations (*i.e.*, No Effect (NE), Not Likely to Adversely Affect (NLAA), and Likely to Adversely Affect (LAA) determinations).

EPA will continue to work with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (collectively referred to as the “Services”) during consultation to update any analyses and/or effects determinations that are needed to predict or determine if the Action would likely rise to the level of jeopardy (J) of a species or adverse modification (AM) of its critical habitat. As needed, EPA will work with the Services to incorporate into these updates any mitigation measures that may have been proposed or implemented since publication of the BEs. EPA may also identify species that need additional data refinements when considering mitigation options. As relevant, the Agency will consider any public comments received on the draft BEs and any other relevant data during consultation with the Services. In summary, as is typical during the consultation process, EPA will be working with the Services throughout the consultation to clarify how the effects determinations included in the final BEs and comments received on the draft BEs can best inform the Services’ biological opinions, following the publication of the final BEs for thiamethoxam, clothianidin, and imidacloprid, which consist of this RTC

document and the final BE chapters, appendices, and attachments that are based on those of the draft BEs for these pesticides.

2 Responses to Public Comments Common Across the Three Neonicotinoids (Imidacloprid, Thiamethoxam, and Clothianidin)

EPA received many comments that were not specific to the BEs (e.g., on the Revised Method, on biological opinions, programmatic consultation). Many of these comments have been addressed in previous RTC documents that can be referenced for further information¹. EPA provides responses to some of those comments again here for emphasis.

2.1 EPA Processes

Comment: Two commenters (CropLife America and Golf Course Superintendents Association of America) stated that the public comment period for the biological evaluations was too short for the length and technicality of the documents.

EPA Response: *Given the Agency's current workload and limited resources, as well as the June 2022 deadline for completion of the final BEs for clothianidin, imidacloprid and thiamethoxam, the Agency determined that the public comment period was adequate for these actions. EPA considered the requests to extend the comment period and determined that an extension was not necessary.*

Comment: Many commenters reiterated their concerns with mitigation proposed in the proposed interim decisions (PID), and, in some cases, provided suggestions for the mitigation. The majority of these comments were duplicates of comments submitted to the PIDs.

EPA Response: *The initial public comment period for the PIDs was 60 days, which was extended for 30 days and then re-opened for an additional 30 days. During the combined 120-day public comment period, the Agency received approximately 224,000 comments. Over 8,000 unique submissions were received from various stakeholders, including the neonicotinoids' registrants, grower groups, non-governmental organizations, pesticide industry groups, and local, state and federal government agencies. The Agency is currently reviewing these comments for consideration in the amended neonicotinoids' PIDs, which are anticipated for early 2023. The amended neonicotinoids' PIDs will be available for a 60-day public comment period.*

Comment: The Agency received numerous comments from individuals and non-profit organizations requesting a ban or suspension on all neonicotinoids.

EPA Response: *The BE includes an effects determination focused on potential effects to threatened and endangered species ("listed species"), following the procedures outlined in the Revised Method.² Substantive comments of a scientific nature, and that are related to the BEs are addressed below. Decisions regarding the overall registration of the neonicotinoids are beyond the scope of the BE and will be addressed through registration review.*

¹ Available at: <https://www3.epa.gov/pesticides/nas/revised/response-to-public-comments.pdf>

² <https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional>

2.2 Benefits of Neonicotinoids in Row Crops

This section groups comments on the benefits of neonicotinoids for large area row and field crops by the crop discussed. After the comment summaries, EPA provides a consolidated response.

Commenters: National Potato Council (NPC) (-0056); Washington Potatoes (-0038); American Soybean Association (ASA) (-0341); Sugarbeet stakeholders (-0334); American Peanut Council (APC) (-0047); Mid-South Entomology Working Group (MSEWG) (-0021)

Summary of Comments:

Potato

Both commenters (NPC and Washington Potatoes) stated that neonicotinoids are the most important class of insecticides for potato growers to control Colorado potato beetle, flea beetles and disease-transmitting insects (*e.g.*, aphids, psyllids). The neonicotinoids are also important for resistance management, especially for Colorado potato beetle and for controlling soil pests such as white grubs and wireworms. Depending on the target pest, alternatives include flonicamid, pymetrozine, spirotetramat, ethoprophos, fipronil, bifenthrin and 1,3-D.

Commenters stated that it is common grower practice to treat tubers with neonicotinoids before planting or use in-furrow applications to protect the “seed” and young plants. The NPC stated that 90% or more of all neonicotinoids are applied at planting. Individuals also indicated that in the absence of neonicotinoids, alternatives would include synthetic pyrethroids, carbamates (methomyl, oxamyl, or carbaryl), an organophosphate (phosmet), and insecticides with newer modes of action that are significantly more expensive and may lead to secondary pest outbreaks.

Soybean

ASA provided comments about the benefits of neonicotinoids as a seed treatment and their importance to soybean production.

Sugarbeet

The primary pests targeted by neonicotinoids in sugarbeets are the beet leafhopper as a seed treatment (vector of curly top virus) and sugarbeet root maggot (seed treatment or as an in-furrow application). Secondary pests controlled by neonicotinoids include cutworm, wireworm, flea beetle, black bean aphid and springtails. There are no alternative seed treatments available for control of these insect pests. Given that sugarbeets are biennial, it is unlikely pollinators would be exposed to neonicotinoid residues since the fields are unattractive to pollinators.

Peanuts

The APC supports the continued use and availability of imidacloprid in the production of peanut. In the comment, APC stated that a single, in-furrow application of imidacloprid at-plant is critically important for the management of thrips feeding on seedlings. APC further stated that imidacloprid is an economically viable option for growers as it is an inexpensive chemical control relative to alternatives. APC stated that imidacloprid is commonly used on approximately 15% of peanut acres across six states

(Alabama, Florida, Georgia, North Carolina, South Carolina, and Virginia). Lastly, APC stated that with the cancellation of chlorpyrifos, maintaining the availability of imidacloprid at current application rates in peanut was critically important.

Comment Covering Multiple Crops

MSEWG's comment applied to a variety of agronomically important crops in the region, particularly corn, cotton, grain sorghum, rice, soybean, and wheat and emphasizes the benefits that neonicotinoids provide in terms of the management of key insect pests and improvement of crop profitability, particularly when they are used as seed treatments. They noted that some important pests have begun showing reduced susceptibility to some neonicotinoids, as is the case with the tarnished plant bug and thiamethoxam use in cotton. They also pointed out that loss of neonicotinoids would probably drastically increase the use of older chemistries such as carbamates and organophosphates that pose serious acute human health risks.

EPA Response: *Although not part of the effects determinations, EPA agrees that neonicotinoids provide important benefits to growers of these crops; the stakeholder claims largely agree with the benefits assessments conducted by the Agency that are available in the neonicotinoid PID regulatory dockets at www.regulations.gov. These memos include:*

- *Benefits and Impacts of Potential Mitigation for Neonicotinoid Seed Treatments on Small Grains, Vegetables, and Sugarbeet Crops;*
- *Benefits of Neonicotinoid Use and Impacts of Potential Risk Mitigation in Vegetables, Legumes, Tree Nuts, Herbs, and Tropical and Subtropical Fruit;*
- *Biological and Economic Analysis Division (BEAD) Response to Public Comments Submitted in Response to BEAD's Assessment entitled "Benefits of Neonicotinoid Seed Treatments to Soybean Production" Dated October 15, 2014, OPP Docket: EPA-HQ-OPP-2014-0737, and Benefits of Neonicotinoid Seed Treatments to Soybean Production. U.S. Environmental Protection Agency*

2.3 Benefits of Neonicotinoids in Specialty Fruits and Vegetables

This section groups comments on the benefits of neonicotinoids for agricultural crops other than large area row and field crops on the basis of the regions or states in the U.S. that commenters focused on. After the comment summaries, EPA provides a consolidated response.

Arizona

Commenter: The Arizona Farm Bureau Federation. (-0339)

Summary of Comment: The Arizona Farm Bureau Federation strongly supports the continued use and availability of clothianidin, imidacloprid and thiamethoxam and urges the Agency not to prohibit or restrict their availability and use. Neonicotinoids play an important role, and in some cases a critical role, in the production of Arizona's staple crops, including leafy greens, vegetables (cole crops), melons, cotton, and citrus. Imidacloprid is used on over 50 different crops in Arizona and accounts for about 40% of all reported neonicotinoid use in Arizona agriculture. Additionally, the use of imidacloprid is also critical in the movement of citrus nursery stock. The Arizona Farm Bureau and the Arizona Pest Management Center has also previously submitted comments regarding the importance of clothianidin,

imidacloprid, and thiamethoxam in the production of Arizona's crops (Docket ID #EPA-HQ-OPP-2008-0844-1255; EPA-HQ-OPP-2008-0844; EPA-HQ-OPP-2011-0581; Docket ID: EPA-HQ-OPP-2011-0865).

California

Commenter: California Specialty Crops Council (CSCC). (-0048)

Summary of Comment: The California Specialty Crop Council commented on their continued support for the registration and availability of clothianidin, imidacloprid, and thiamethoxam in the production of onion, pepper, and melon. Additionally, CSCC commented on the important role neonicotinoids play in integrated pest management and insecticide resistance management.

Florida

Commenter: Florida Fruit and Vegetable Association (FFVA) (-0018)

Summary of Comment: FFVA submitted comments on behalf of growers of a variety of crops, including vegetables, citrus, and small fruit such as blueberries. FFVA expressed its support for the continued use of all neonicotinoids in these crops. They described key target pests, the damage they can cause, and details of how various neonicotinoids are used in these crops. They particularly emphasized the need for neonicotinoids as part of the insecticide tools they need to reduce populations of the Asian citrus psyllid in order to suppress the spread of the incurable citrus greening disease ("Huanglongbing" or HLB), which inevitably results in the slow decline of yield from infected citrus trees and results in the replacement of those trees.

Georgia

Commenters: Chill C Farms LLC (-0359), Lewis Taylor Farms, Inc. (-0358), Minor Brothers Farm (-0356), Southern Valley (-0357), Clark Crop Consultant (-0354), Dr. Alton Sparks, Jr. University of Georgia Department of Entomology (-0028)

Summary of Comments: The commenters above provided similar comments for specialty crops grown in Georgia (e.g., bell pepper, cucumber, eggplant, squash, green bean, cabbage, melons); therefore, they were grouped together. Generally, these commenters discussed pollinator friendly practices they use to reduce exposure to pollinators. They also stated that there is little clothianidin use in vegetable crops in Georgia, but imidacloprid and thiamethoxam are not only important for whitefly and pepper weevil control but are also important for resistance management. They indicated that there are two other insecticides that are used in rotation with neonicotinoids for each pest and that resistance could develop rapidly in the absence of neonicotinoids given that these are season-long pests that require multiple applications in the Southern U.S. They also emphasized the importance of the short pre-harvest interval (PHI) of neonicotinoids as compared to alternatives; shorter PHIs allow for use of the insecticides to protect vegetables nearing harvest from damage by the pepper weevil, which needs season-long control in the southern United States. Commenters also noted that most of their applications of imidacloprid are soil treatments. Additionally, Dr. Sparks provided details about the timing of applications of each neonicotinoid, noting that for whiteflies, the important application timing is in the fall and winter due to the late season start of infestations.

Michigan

Commenter: Dr. Zsafia Szendrei, Vegetable Extension Entomologist, Department of Entomology, Michigan State University (-0037)

Summary of Comment: Dr. Szendrei provided several details of crop phenology, types of bees that visit vegetable crops, and typical uses of neonicotinoids in potatoes, cucurbits, and leguminous vegetables (mainly snap beans and green peas) that are widely grown in Michigan. She stated that while neonicotinoids are recommended and used in a variety of ways in these crops, the most critical uses of neonicotinoids (as indicated by an informal survey) are the at-planting and seed coat applications that provide about a month of protection from initial insect pest infestations in numerous vegetable crops. She also emphasized that lowering rates would undermine resistance management.

Texas

Commenter: Texas Citrus Mutual (-0022)

Summary of Comment: Texas Citrus Mutual attached the 2021-2022 Texas Citrus Pesticide Guide which provides growers with product information including comparative performance against a range of citrus pests. The Guide includes the product name, active ingredient, labeled rate/acre, reentry interval, pre-harvest interval, maximum allowable rate/ year; efficacy control rating for 13 different pest types, and qualitatively described effects on predatory and parasitic natural control agents for pests.

The Pacific Northwest

Commenter: Dr. David Epstein, Vice President for Scientific Affairs, Northwest Horticultural Council (-0343)

Summary of Comment: Dr. Epstein provided a general description of pest management benefits of two neonicotinoids, imidacloprid and thiamethoxam, in the production of tree fruit by growers in Idaho, Oregon, and Washington who are represented by the Northwest Horticultural Council on pesticide regulatory matters. The comment described the major target pests for which these neonicotinoids are typically used, with an emphasis on the aphids, leafhoppers, the pear psylla, and the Western cherry fruit fly. Dr. Epstein noted that in the past few years the need for these insecticides to suppress leafhoppers and mealybugs has taken on much more importance because these insects transmit a plant disease called Little Cherry Disease, which results in unmarketable fruit; infected trees cannot be cured. He also emphasized the lower cost of imidacloprid as compared to many alternatives, stating that these cost four to nine times more (per acre) than imidacloprid.

EPA Response: *Although not part of the effects determinations, EPA agrees that neonicotinoids provide important pest management benefits to growers of many vegetable and fruit crops. For example, the Agency highlighted the importance of thiamethoxam in controlling the pepper weevil in the usage and benefits assessments for vegetables that were conducted for the PIDs for the neonicotinoids. Novel information provided by the Northwest Horticultural Council highlights the importance of neonicotinoids in managing Little Cherry Disease, a problem that was not captured by the Agency in its registration review assessments.*

These comments provided information on the importance of neonicotinoids and how they are applied, especially regarding pests and bloom time. As appropriate, EPA will provide relevant information on usage that is included in these comments in its consultations with the Services.

For additional information see the Agency's benefits analyses for such crops, that are available in the neonicotinoid PID regulatory dockets at www.regulations.gov. These memos include:

- *Benefits of Neonicotinoids Insecticide Use in Pre-Bloom and Bloom Periods of Citrus. U.S. Environmental Protection Agency.*
- *Benefits of Neonicotinoid Insecticide Use in Cucurbit Production and Impacts of Potential Risk Mitigation.*
- *Benefits of Neonicotinoid Insecticides in Berries (Strawberry, Caneberry, Cranberry, and Blueberry) and Impacts of Potential Mitigation.*
- *Benefits of Neonicotinoid Insecticides Usage in Grapes and Impacts of Potential Mitigation.*
- *Usage, Pest Management Benefits, and Possible Impacts of the Potential Mitigation of the Use of the Four Nitroguanidine Neonicotinoids in Pome Fruits (Apple, Pear).*
- *Assessment of Usage, Benefits and Impacts of Potential Mitigation in Stone Fruit Production for Four Nitroguanidine Neonicotinoid Insecticides (Clothianidin, Dinotefuran, Imidacloprid, and Thiamethoxam).*
- *Benefits of Neonicotinoid Use and Impacts of Potential Risk Mitigation in Vegetables, Legumes, Tree Nuts, Herbs, and Tropical and Subtropical Fruit.*

2.4 Benefits of Neonicotinoids in Nursery and Floriculture

Commenter: The IR-4 Project (-0327); Society of American Florists (SAF) (-0335)

Summary of Comments: The IR-4 Project supports the continued use of sustainable pest management tools that benefit the growers of specialty crops including environmental horticultural (also referred to as ornamental) crops. The IR-4 Project stated that neonicotinoids are effective for managing numerous pests of these ornamental crops such as beetles, plant bugs, scales, thrips, or whiteflies. Neonicotinoid insecticides are one set of tools used to manage insect pests to economically acceptable levels so that growers can produce high quality crops in sufficient quantities for the marketplace.

The Society of American Florists strongly supports the continued registration of neonicotinoid insecticides. Clothianidin, imidacloprid and thiamethoxam are necessary for controlling a broad range of floriculture pests including mites, aphids, whiteflies and thrips. The use of thiamethoxam and imidacloprid in rotation with other crop protection tools, when necessary, is vital in preventing or delaying the development of insecticide resistance.

EPA Response: *Comments made by the IR-4 Project and SAF are largely in agreement with the Agency's analysis for the PIDs that found neonicotinoids to be an important tool for pesticide applicators in the turfgrass and ornamental pest control industries. For more information, see BEAD's Review of "The Value of Neonicotinoids in Turf and Ornamentals" prepared by AgInfomatics, LLC for Bayer CropScience, Syngenta, and Valent, available in the neonicotinoid PID regulatory dockets at www.regulations.gov.*

2.5 Poultry Litter

Commenters: Mid-South Entomology Working Group (MSEWG) (-0021), Elanco US Inc. (-0040), CropLife America (CLA) (-0330 and -0345), and United States Department of Agriculture (USDA) (-0331)

Summary of Comments:

The commenters highlighted that poultry litter is one of the main causes of LAA determinations in the BEs. The poultry litter assessment suffers from flaws in the assumed usage footprint as well as application rate and frequency. Rather than develop a new use data layer (UDL) for the poultry litter assessment, EPA combined existing UDLs. As a result of the breadth of crops in these pre-existing UDLs that are not expected to receive a poultry litter amendment, the spatial footprint of the poultry litter UDL is overestimated. EPA acknowledges the over-estimation associated with inclusion of counties with no-reported data stating, “Counties with no data probably contain developed area and have a lesser chance to have poultry production.” The issues with the spatial footprint of poultry litter assessment are further exacerbated with EPA’s assertion 100% of the defined spatial footprint is treated (*i.e.*, 100% percent crop treated). As a result of this compounding conservatism, the assessment predicts application to a land area in many cases that is unreasonable. It is recommended that EPA develop an independent UDL for the poultry litter assessment which better reflects the possible usage footprint and revises the application estimates considered realistic practices.

EPA Response: *In an attempt to refine the spatial footprint, EPA considered the maximum distance traveled for poultry litter to inform the geographic range considered by EPA such that any regional areas of the U.S. or a percent of the U.S. could be removed from exposure consideration. EPA reviewed the poultry litter practices of the top states for poultry production in the U.S.. Poultry operations in the U.S. are concentrated in AL, AR, DE, FL, GA, KY, MD, MN, MO, MS, NC, OH, OK, PA, SC, TN, TX, VA, WI, and WV, with additional poultry operations in CA, IA, IL, IN, LA, MI, NE, NY, OR, and WA. Overall, there do not appear to be any restrictions on moving poultry litter from one state to another. Based on the information EPA found about state incentive programs, poultry litter can move as little as 5 to 10 miles from the originating farm and as far as 100 to 300 miles. Since poultry litter can be moved from state to state and over long distances, EPA cannot exclude the possibility of poultry litter application in any areas of the country. Additionally, even areas without major poultry production may still have smaller poultry operations nearby that may be treating litter with neonicotinoids. EPA acknowledges that the poultry litter UDL is conservative and probably overpredicts the extent to where poultry litter containing neonicotinoid residues may be applied. However, in order to be protective of the listed species, EPA believes this to be a conservative method to identify if an individual of a listed species has been potentially affected. These issues will be further considered during consultation with the Services, as relevant.*

2.6 Usage Data

Commenter: Washington State Department of Agriculture (-0328)

Summary of Comment: Washington State Department of Agriculture (WSDA) provided information on neonicotinoids usage for certain crops during the growing season in Washington State. WSDA recommended that pesticide usage estimates be used to help refine risk estimates. WSDA also suggested that their information could be used for identifying opportunities for targeted outreach, education, technical assistance, and monitoring efforts. Further, WSDA recommended that usage data be paired with agricultural land use data and other geospatial data to produce usage intensity maps and other products that can be used for risk assessment purposes including assessing risks to threatened and endangered species.

EPA Response: *The usage data for clothianidin, imidacloprid, and thiamethoxam submitted by WSDA was considered and, as appropriate, used to enhance our understanding of the usage of these active ingredients in Washington state in a qualitative manner. Additionally, as appropriate and needed, EPA will provide relevant information on usage that is included in these comments in its consultations with the Services.*

Commenters: Bayer US LLC *et al.* (-0049), Florida Fruit and Vegetable Association (FFVA) (-0018), United States Department of Agriculture (USDA) (-0331), Valent U.S.A. LLC (-0051), Western Growers (-0353), Russell L. Groves (-0019)

Summary of Comment: Five comments discussed the geographic scale of usage data incorporated in the BEs, which is typically at the state level. Commenters indicated that state-level usage data do not necessarily provide a realistic picture of how pesticides are being applied on the finer geographic scale often associated with species ranges, and that finer scale data is needed to make a real determination of the actual impacts. Furthermore, several commenters suggested that the assumption that an entire state's usage occurs within the species range is unrealistic and overly conservative. Several commenters suggested that EPA seek out sub-state level usage data (including county or farm scale data) from existing sources or through cooperation with stakeholders in the grower community to further refine the BE assessments.

EPA Response: *Many comments on the geographic resolution of usage data used in the BEs have been addressed in other chemical BE RTC documents³. EPA agrees that the distribution of pesticide usage on a crop within a state is likely uneven. In addition to pest pressures noted by commenters, this occurs simply as a result of the pest management decisions made by different growers/applicators, including selection of alternative pesticide(s) or other pest management decisions, that are based on factors beyond pest pressure. The Agency also acknowledges the difficulty of reconciling usage data at a state, regional, or national level with species ranges, which while uncertain, are often provided at the sub-state level, and agrees with Dr. Grove's assertion that "to address the difference in scale, several assumptions will need to be made with respect to where pesticide-treated acres could co-occur relative to a species' habitat (e.g., all treated acres occur within the habitat, evenly dispersed throughout the state, or primarily outside of a species habitat)." EPA would also like to note that utilizing state level usage data in step 2, in addition to the maximum labeled parameters in step 1, presents a significant refinement to risk assessments, while still being protective.*

One way EPA has sought to reconcile these different spatial scales is through use of UDLs and Census of Agriculture data. To the extent possible, methods that utilize the available usage data in a scientifically defensible way are being applied. For example, the usage on a crop is mapped to the UDL, which is where the crops within the UDL were grown within the state based on geospatial data. Additionally, as described in the Revised Method⁴, the Census of Agriculture is used to identify counties where no registered crops occur for a given UDL. To do this, all crops found in each UDL are linked to the Census of Agriculture and the number of registered crops found in each county identified. As part of the spatial analysis, the overlap is removed for counties with no registered crops prior to the use as an input for the MAGtool. If a single registered crop occurs in the county the overlap remains unaltered. When

³ <https://www3.epa.gov/pesticides/nas/methomyl/response-to-draft-bes.pdf>

⁴ <https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional>

conducting the Step 2 spatial analysis, UDLs are limited to just those counties where registered crops for each UDL occur.

Refining biological evaluations to incorporate the location of pesticide usage for a crop at the “sub-state level,” is more complicated than simply understanding the location and number of acres of crops grown within a state and the fraction of those acres that are treated with an active ingredient based on historical pest pressure. The availability of reliable and spatially refined historical pesticide usage estimates is only one of two primary considerations for implementation of a more refined probabilistic methodology for allocation of pesticide usage at the sub-state level. The other consideration is the ability of historical usage data to adequately estimate future usage at the sub-state level. One major concern with county-level usage estimates is the impact that individual growers’ decisions in the future will have on the usage for that county. Data from the USDA NASS 2017 Census of Agriculture indicate that for many of the crops surveyed by Kynetec and NASS, the number of operations growing the commodity within individual counties is often quite small.

While a small number of operations does not affect usage statistics for mandatory reporting programs and can be accounted for in the statistical design of surveys of grower usage to ensure reliable estimates of historical usage, the utility of those data for predicting future applications is limited because the choice of a single individual to use or not use a pesticide in the future has a large impact on the accuracy of the predicted usage. Therefore, while data and/or methods may be available to estimate historical usage at the county-level, the reliability of those data for estimating future usage at the county-level require further validation before they can be incorporated into assessments. If sub-state sources are identified that are deemed reliable for estimating historical usage, EPA will need to evaluate the ability of those sub-state estimates of historical usage to estimate future usage and the extent to which they could potentially replace models relying on the existing state-level usage estimates.

Commenters: American Soybean Association (ASA) (-0341), Bayer US LLC et al. (-0049), Florida Fruit and Vegetable Association (FFVA) (-0018), National Potato Council (NPC) (-0056), United States Department of Agriculture (USDA) (-0331), Valent U.S.A. LLC (-0051), and Russell L. Groves (-0019)

Summary of Comment: Several individuals commented on the manner in which use and usage data were incorporated into the BEs, including questions about the use of maximum label rates and high exposure application methods in the determination of the action area (step 1) leading to overly conservative assumptions. Commenters indicated that lower application rates and lower exposure application methods are often far more common in practice than the higher risk parameters incorporated in the BEs. Commenters asked that “both EPA and the services” utilize real world usage data in their assessments of the biological impacts of application. Several commenters provided information from a variety of sources (including Kynetec AgroTrak, NASS QuickStats, and more anecdotal grower information) on how neonicotinoids are “typically” applied.

EPA Response: *Many comments on the incorporation of use data in step 1 and usage data in step 2 of the BEs have been addressed in other chemical BE RTC documents⁵. The Agency agrees that neonicotinoid applications are made using a variety of methods including foliar, soil, and seed treatment and that the maximum label rate is a conservative assumption. However, some growers may apply at the maximum application rate with higher exposure application methods. Therefore, the Agency assesses risks using these parameters in the determination of the action area (step 1) to be protective. Average*

⁵ <https://www3.epa.gov/pesticides/nas/methomyl/response-to-draft-bes.pdf>

usage rates and other application methods are also incorporated into the BEs in step 2 to inform the likelihood of potential risk. EPA decided that data on pesticide usage represent critical information for determining whether an individual of a listed species is likely to be exposed and adversely impacted, which is the goal of Step 2. EPA also decided that the data on pesticide usage is the best available data with which to forecast future use. The alternative assumption is that all potential use sites are treated simultaneously, which is not realistic or representative of what occurs in the field. Incorporation of usage data in Step 2 allows the EPA to use “real world” data to determine whether a pesticide is LAA or NLAA for a listed species or its critical habitat, and if LAA, which uses are of greatest concern. EPA decided that use of available usage data as described in the Revised Method are consistent with the ESA standard for use of the “best scientific and commercial data available.” The EPA currently uses historical usage data to forecast future pesticide usage at the national level for dietary risk assessments. The forecast method being used was publicly vetted through a FIFRA Scientific Advisory Panel (SAP) in 2002. This method forecasts national pesticide usage for an active ingredient on individual crops. EPA also notes that utilizing state level usage data in step 2, in addition to the than maximum label parameters in step 1, presents a significant refinement to risk assessments, while still being protective. This was acknowledged by several commenters on these BEs.

The Agency appreciates commenters who submitted usage data, offered to submit usage data, or provided potential contacts that may be able to fill usage data gaps. EPA also notes that several of the usage sources cited by commenters (including Kynetec AgroTrak, NASS QuickStats, and California Department of Pesticide Registration PUR dataset) are the same sources or usage data employed by EPA in the BE. Other commenters provided more qualitative “typical” grower information, or quantitative usage from unclear sources. In both cases, EPA notes that the usage data provided was largely in line with the usage data provided in the SUUMs and utilized in the BEs. The additional usage data submitted and sources suggested by commenters will be considered and, as appropriate and relevant, EPA will provide relevant information on usage that is included in these comments in its consultations with the Services.

Commenters: Bayer US LLC *et al.* (-0049), Valent U.S.A. LLC (-0051)

Summary of Comment: Key points from these comments, as interpreted by the Agency, are summarized as follows:

- “The acreage used in calculating treated acres does not account for acres treated more than once in a season, leading to overly conservative percent crop treated (PCT) estimates”,
- “The methodology used in calculating a PCT is inconsistent with the exposure modeling which assumes applications to use sites at maximum annual label rates”,
- “Agricultural PCTs: a UDL minimum PCT of 2.5% results in excessive overestimation of usage for some crops and states”, and
- Expressed concerns about the surrogate usage data assumptions made by EPA when usage data were unavailable.
- Agricultural PCTs: a UDL minimum PCT of 2.5% results in excessive overestimation of usage for some crops and states,

EPA Response: *Many comments on the calculation and rounding of percent crop treated (PCT) estimates in the BEs have been addressed in other chemical BE RTC documents⁶. PCT values used in the BEs are obtained from usage data surveys, not calculated by EPA, and represent estimates of actual observed*

⁶ <https://www3.epa.gov/pesticides/nas/methomyl/response-to-draft-bes.pdf>

usage. For our primary agricultural data sources, the PCT is the base acres treated (BAT) (i.e., the number of unique acres treated one or more times in given survey year for a use site) divided by the crop acres grown (CAG) (i.e., the acres of a given use site that occur within a given survey year) ($PCT = BAT / CAG$). BAT is directly reported in the agricultural usage data, not calculated based on label rates. Reported BAT accounts for multiple treatments per year and counts treated acres only once, regardless of the number of applications received. Commenters suggested that rather than using this reported BAT value, EPA should calculate the number of total acres treated based on the reported pounds applied and the maximum annual label rate used in exposure analysis. This suggestion was based on the assertion that:

“[EPA’s] approach to PCT calculations does not consider multiple applications on the same land or actual application rates. As noted in Section 2.1 of Appendix 1-7 of the draft BEs, this represents a conservative assumption, as the same land may be treated multiple times in a year, thus inflating the acres treated and PCT. The absence of an application rate in the consideration of a PCT estimation implicitly assumes that the acres treated are in alignment with the application rate and number of applications assumed in any exposure magnitude calculations.”

EPA would like to clarify that while magnitude of exposure and likelihood of exposure are both assessed by EPA in the BEs, they are not the same analysis and have different inputs. Further, the reported BAT values used in the PCT calculation account for multiple applications to the same piece of land and actual application rates, in that for each survey respondent BAT is reported as the number of acres treated at least once (i.e., does not double count acres treated more than once). Although BAT is directly reported, one way to calculate BAT would be to take the total acres treated (TAT) annually and divide it by the observed annual application rate. This seems to be akin to what the commenters are suggesting, except that rather than using the observed annual application rate they suggest using the labeled annual application rate used in the magnitude of exposure analysis. Using this labeled annual application rate in conjunction with the observed pounds applied would inherently result in a lower calculated BAT value than growers report in the usage data. This is because users often treat at rates below the maximum application rate. As noted in the responses above, label rates and observed rates are utilized in the BE analysis for different reasons. Therefore, there is not an inherent disconnect, and the reported PCT used in the BE is not overestimated.

Some confusion may have resulted from the statement in section 2.1 of Appendix 1-7 noted above. When this statement referred to “inflating the acres treated and PCT” because “the same land may be treated multiple times in a year” it is actually referencing the estimated treated acres from the UDL after applying the PCT, not the calculation of the crop PCT. The agriculture UDLs represent 5 years of field locations and therefore any estimated treated acres based on the PCT would be greater than the expected treated area for a given year. In addition, a field found in multiple UDLs due to rotation could be found in the estimated treated acres twice. Potential double-counting of acres across UDLs is addressed in the “redundancy” calculations in the WoE.

When considering the calculation of the PCT, utilizing the maximum labeled annual application rate to calculate BAT from TAT would inherently result in a lower BAT (and thus lower PCT) if actual applications were made below the labeled rates, although EPA points out that the sample calculations provided by the commenters using the labeled annual application rates resulted in remarkably similar PCTs when values were rounded utilizing the minimums used by EPA. The differences seen in the BE Factors (BE PCT/calculated “PCT”) were largely due to differences in very small PCTs that EPA rounded to <2.5%.

As addressed in previous RTC documents⁷, pesticide usage data available are based on surveys of growers and/or other user groups and is not exhaustive of all usage. For this reason, an update made for the final BE set the lowest possible PCTs at 2.5%. PCTs below this value are rounded up to 2.5% to buffer against uncertainty associated with these surveys and low usage estimates. The surveys utilized by EPA are designed to be statistically robust, but by definition sample the target populations rather than provide a complete accounting of all pesticide usage. Therefore, PCT estimates resulting in values below 2.5% are generally a good indicator of limited usage of an active ingredient, but by using 2.5% the PCT accounts for possible usage not captured by the survey data.

Commenter: United States Department of Agriculture (USDA) Office of Pest Management Policy (-0331)

Summary of Comment: “There are significant differences in agricultural application rates across regions and states due to variation in pest pressure, crop varieties, soil types, environmental conditions, and agronomic practices. Accordingly, USDA encourages EPA to consider available state-level usage data, such as from the National Agricultural Statistics Service (NASS), Agricultural Market Research Data (AMRD), the California Pesticide Information Portal Pesticide Use Reporting (CalPUR) database, and other data from individual states whenever possible to determine likely exposure more accurately to listed species and critical habitat.”

EPA Response: *EPA currently uses state level PCT in step 2 to determine the likelihood of exposure. This step also incorporates national level average application rates to help inform the magnitude of exposure. EPA will investigate the impact of incorporating state level average rate information as appropriate and necessary during consultation with the Services. State level average application rates are available to the Agency.*

Commenters: Bayer US LLC *et al.* (-0049), Valent U.S.A. LLC (-0051), United States Department of Agriculture (USDA) Office of Pest Management Policy (-0331)

Comment: Multiple commenters expressed concern about the assumptions made in step two for application rates and PCT when no usage data are available for a site. Commenter’s concerns are especially acute for non-crop use sites, as data on the “typical” usage of pesticides are mainly available for major row and specialty crops. “Typical” usage data are unavailable for other use sites, including residential, forestry, poultry litter, and others. Usage data are also lacking for crop seed treatments. For these sites, EPA – in the absence of available “typical” usage data – essentially relied on maximum label use information for all exposure modeling, resulting in exposure estimates (and risks to species and critical habitats) for these use sites that are much higher than what would occur given realistic application assumptions.

EPA Response: *EPA strives to utilize the best available data. Currently, EPA incorporates available state-level PCT usage data to help determine likely exposure to listed species and critical habitat. In the absence of sufficient data of an acceptable quality for the use site in the state of interest, EPA may develop a usage estimate based on surrogate data (i.e., similar crops in the same state, the same crop in a nearby location with similar agronomic conditions, use of the national maximum in lieu of state data, etc.). When identifying a surrogacy method, the EPA takes a conservative approach intended to refine the usage estimate, and also avoid underestimation. In very few cases is a default assumption of 100 PCT a reasonable approximation of the likely usage of a pesticide. An example of 100 PCT being a relatively*

⁷ <https://www3.epa.gov/pesticides/nas/methomyl/response-to-draft-bes.pdf>

reasonable approximation of usage includes some herbicides where herbicide-tolerant crops are planted almost exclusively. However, that scenario is not representative of most pesticide usage.

For many non-agricultural use sites, however, state-level and often national-level usage data are not available, and a suitable surrogate cannot be identified. In the absence of usage data, EPA has relied upon maximum label use information to avoid underestimating exposure. EPA welcomes reliable information on un-surveyed crops or surveyed crops in un-surveyed states that might be used to inform more realistic application assumptions. If available and deemed relevant, additional information may be included as part of the consultation with the Services.

2.7 Seed Treatment

Commenters: American Soybean Association (ASA) (-0341), BASF Corporation and Valent U.S.A. LLC (-0053), CropLife America (CLA) (-0330), CropLife America (CLA) (-0345), CropLife America (CLA) (-0345), National Sorghum Producers (NSP) (-0351); United States Department of Agriculture (USDA) (-0331)

Summary of Comments: The commenters noted that seed treatments are important for pest management and for IPM programs. The commenters suggested for the Agency to integrate quantitative seed treatment usage within assessments. The commenters expressed that the current assumptions for seed treatment usage are too conservative when assuming 100% of seed is treated, or when using foliar PCT data as a surrogate. The commenters provided seed treatment quantitative usage data and various data source suggestions: Context, Benjamin Kirk, seed sales data, NASS or a combination of usage data sources. It was suggested that in the absence of quantifiable data, qualitative data, such as the species biology, could be used to identify when a species would be eating seed, and apply this information to the time of the planted treated seed to identify exposure to species from eating treated seeds. One commenter, ASA, cited previous BEAD assessments, the screening level usage analyses (SLUAs) which previously, but no longer, incorporated seed treatment usage data.

EPA Response: *The Agency appreciates the additional information provided, including seed treatment use and usage information and additional options for the Agency to look into seed treatment data sources.*

The Agency recognizes the important role that seed treatments fill and that seed treatment usage can be substantial. However, the Agency currently has no seed treatment usage data upon which to make reliable estimates of usage. Therefore, EPA made conservative assumptions or utilized surrogate usage information to account for this lack of quantitative information. While verifiable quantitative usage data that indicate the total pounds active ingredient used to treat seed or the location and the number of acres planted with treated seed are not currently available, nor has the Agency been able to verify the quality of the usage data provided by the commenter, applications of neonicotinoids to seed and seed pieces may be generally characterized as commonly used on a wide variety of crop seeds and seed pieces for planting based on extension recommendations and other information. The Agency has actively been seeking out and meeting with data sources for seed treatment usage information. The Agency is pursuing options to purchase additional seed treatment usage information and if available will consider the newly identified usage data source as part of the consultation with the Services.

ASA has referenced previous SLUAs prepared by BEAD for clothianidin (2015), thiamethoxam (2016) and imidacloprid (2017) which referenced seed treatment usage data. Unfortunately, Kynetec USA, Inc., the primary source of agricultural usage data including the historical (2005-2014) seed treatment data used

by EPA, no longer provides seed treatment usage data. Kynetec USA, Inc., ceased providing data in 2015 due to concerns that they had about the reliability of the data that stemmed primarily from farmers inability to identify what seed treatment was on their seed. Seed treatment brand names often transcend seed type (e.g., Cruiser Maxx Brand Soybeans, Cruiser Maxx Brand Corn, Cruiser Maxx Brand Wheat, Cruiser Maxx Brand Rice) and there may be multiple products with different coatings under the same brand name within a seed, further complicating understanding of the coatings applied to the seed that the grower is planting. For these reasons, Kynetec USA, Inc. has stated they no longer support the seed treatment data that they offered previously. These SLUAs were utilizing usage data from prior to and leading up to 2015. The Agency is committed to using the most current sound science and adapting methodology based on new information available. Therefore, because the data source has indicated the seed treatment data are no longer reliable, the Agency no longer relies on these data. As such, the Agency has released updated SLUAs for clothianidin (2020), thiamethoxam (2020), imidacloprid (2020) which included a note that seed treatment data were no longer available and not reported in the SLUAs.

Commenter: Center for Food Safety (CFS) (-0465)

Summary of Comment: CFS commented on various aspects of the characterization and usage of seed treatment usage data. CFS noted that the wording surrounding what defines total agricultural usage is misleading. CFS also indicated other seed treatment usage data sources (Kynetec USA Inc) whom is being used by USGS. CFS noted that previous assessments provided by BEAD (the SLUA) utilized seed treatment usage information.

EPA Response: *The Agency agrees that the characterization of ‘total agricultural use minus seed treatment’ could have been made more clearly in the biological evaluation. Any forthcoming analyses in support of consultation with the Services, if needed, may more clearly present agricultural pesticide usage estimates as summarized reports of usage of pesticides applied via foliar and soil applications to surveyed crops.*

BEAD recognizes the important role that seed treatments fill and that seed treatment usage can be substantial. Unfortunately, Kynetec USA, Inc., the primary source of agricultural usage data including the historical (2005-2014) seed treatment data to the EPA and the data cited in the USGS Pesticide National Synthesis Project, no longer provides seed treatment usage data. USGS states on their website, “Beginning 2015, the provider of the surveyed pesticide data used to derive the county-level use estimates discontinued making estimates for seed treatment application of pesticides because of complexity and uncertainty. Pesticide use estimates prior to 2015 include estimates with seed treatment application” (USGS 2017).

More specifically, Kynetec USA, Inc., ceased providing data in 2015 due to concerns that they had about the reliability of the data that stemmed primarily from farmers inability to identify what seed treatment was on their seed, as was addressed in the EPA response to American Soybean Association (ASA) (-0341), BASF Corporation and Valent U.S.A. LLC (-0053), CropLife America (CLA) (-0330), CropLife America (CLA) (-0345), CropLife America (CLA) (-0345), United States Department of Agriculture (USDA) (-0331) comments in this document.

CFS has noted potentially misleading/confusing language regarding “where the seed treatment typically occurs” (Thiamethoxam BE, App. 4-5, p.20). While verifiable quantitative usage data that indicate the total pounds active ingredient used to treat seed or the location and the number of acres planted with treated seed are not currently available, applications of neonicotinoids to seed and seed pieces may be

generally characterized as commonly used on a wide variety of crop seeds and seed pieces for planting based on extension recommendations and other information such as stakeholder feedback.

Commenter: Center for Food Safety (CFS) (-0465)

Summary of Comment: Center for Food Safety noted confusion around the use of calculated poultry litter geographic extent as representative for neonicotinoid treated seed throughout the U.S.

EPA Response: *There are rare occurrences where a seed treatment use is not registered for foliar and/or soil use as well (e.g., thiamethoxam use on rice seed). This does not impact the geographic extent of the action area in Step 1 because these seed treatment-only uses are also found in the poultry litter layer. In Step 2, analyses separately consider poultry litter and seed treatment. The geographic extent of the poultry litter layer represents all agricultural area where poultry litter may be applied and is independent from the geographic extent of the seed treatment crops. The geographic extent for the corresponding UDL is used for seed treatment crops. The seed treatment-only modelling was considered separately if a species hadn't reached LAA from the foliar and soil treatments. In many cases, a pesticide is registered for application as both a seed treatment and a foliar and/or soil application. In such cases, the EECs from the foliar and soil treatments are considered to be protective when evaluating the impact to one or more individuals of a species.*

2.8 Assessment Methodology

Comment: EPA should undertake substantial efforts to refine the methodology and reduce the “compounding conservatism” and use of “worst case scenarios.” EPA should consider other weight of evidence frameworks and use actual data instead of less accurate modeling and employ the “reasonably certain to occur” standard. The Agency needs to better communicate uncertainty in the analysis associated with conservative assumptions made in the analysis.

EPA Response: *Many comments on the methodology and perceived conservatism of the methodology have been addressed in previous RTC documents⁸. EPA's responsibility in meeting its obligations to make effects determinations under the ESA as the action agency is to evaluate if an individual of a listed species may be affected. As a result, the process must be protective and evaluate circumstances where the maximum potential exposure could occur. EPA also considered a number of lines of evidence (e.g., usage data, average rates and common application methods, exposure for treated areas versus offsite transport, species-specific information) in its evaluation.*

Regarding the “reasonably certain to occur” standard, when conducting effects determinations, EPA made conservative assumptions to address identified uncertainties to ensure protection of the assessed species. The influences of those conservative assumptions are considered as part of the MAGtool (Magnitude of Effect Tool⁹) analysis, where alternative parameters are selected and estimates of the likelihood of individual effects are calculated based on these alternative parameters. The alternative analysis considered more average usage data, including common application methods and practices, as well as other toxicity endpoints. EPA believes that this approach is consistent with the current “reasonably certain to occur” standard. If both the conservative and alternative assumptions arrive at

⁸ <https://www3.epa.gov/pesticides/nas/revised/response-to-public-comments.pdf>

⁹ <https://www.epa.gov/endangered-species/models-and-tools-national-level-listed-species-biological-evaluations#magtool>

the conclusion that one or more individuals of a listed species may be impacted, there is a greater degree of confidence in the LAA determination. If there is a difference in conclusions when using conservative and less conservative assumptions, EPA has less evidence to support the LAA determination; however, there is still the potential for impacts to an individual under some circumstances.

The “worst-case” scenario, as referred to in comments, utilized the maximum PCT and upper distribution of acres, and includes many factors that refine the screening level approach, such as:

- *Basing the EECs on a variety of dietary items or a species-preferred dietary item in the terrestrial environment,*
- *Applying on/off field assumptions about the species,*
- *Using application methods that are associated with the most likely type of application (ground vs aerial) instead of the most conservative method,*
- *In the probabilistic analysis, basing EECs on a distribution of values:*
 - *For terrestrial exposure, based on the mean Kenaga and standard deviation;*
 - *For aquatic exposure, based on consideration of a range of daily EECs from multiple scenarios, varying curve numbers and varying applications dates.*

Based on these refinements, the weight of evidence (WoE) is not considered a “worst-case” analysis.

Regarding uncertainty in the analyses, detailed descriptions of these uncertainties and how they are addressed were provided in the response to public comments on the revised methods¹⁰.

Comment: Commenters have criticized the methods used in the aquatic modeling. In particular: (1) a flowing water and watershed model should be developed for assessing different configurations of Bin 2 flowing water bodies rather than use the edge-of-field concentrations; (2) a variable volume static water body, similar to the wetland habitat conceptual model used in PAT, could be designed and serve as a reasonable screening level model for Bin 5 habitat; (3) a watershed scale model, capable of representing the heterogeneity in landscape characteristics, environmental processes, and agronomic practices should be developed and implemented for the evaluation of exposure in the moderate and high flow habitat bins (Bin 3 and Bin 4); (4) a modeling approach for aquatic habitat that accounts for application timing variability, PCA variability, and PCT variability should be implemented in the Step 2 probabilistic aquatic exposure modeling; and, (5) the spatial resolution of exposure scenarios at the HUC2 scale is insufficient to characterize species-specific exposure.

EPA Response: *The aquatic modeling methods are designed to estimate exposure and determine if an individual of a species is likely to be adversely affected. As such, EPA believes the modeling used in the BEs performs this function.*

The aquatic modeling depends on not only the volume and flow of the waterbody receiving it, but also on the watershed discharging to it. Unlike EPA’s pond and index reservoir conceptual models, which have fully characterized watershed sizes, Bins 2 and 5 are very small and the estimation of the watershed contributing to these waterbodies is not easily determined from available data sources. As the volume of these waterbodies can easily be overwhelmed by a field discharge, EPA believes the use of the edge-of-field concentrations to represent exposure concentrations in these waterbodies to be appropriate.

¹⁰ *Ibid.*

EPA agrees that the use of a watershed model to evaluate the medium and high flowing waterbodies is the proper means for aquatic modeling these waterbodies. EPA's Spatial Aquatic Model (SAM) is being developed to do such modeling. However, EPA has not finalized the development of this model. Stakeholders have commented that EPA should use the Soil and Water Assessment Tool (SWAT) for these waterbodies. However, EPA has not evaluated the tool or the appropriate parameters for use in the tool such that it can be used on a national basis for listed species. Until EPA can develop or evaluate a watershed model, EPA will continue to explore the best way to use PWC to evaluate medium and high flowing waterbodies.

EPA agrees that the best way to do probabilistic exposure modeling for the aquatic habitats in Step 2 would be to account for application timing variability, PCA variability, and PCT variability in the actual modeling and use the results in the MAGtool. However, EPA currently has conducted thousands of PWC runs to model the various uses, application methods, and aquatic habitats without this type of probabilistic approach. Proper probabilistic modeling would generate upwards of a million results, which is not feasible. EPA developed scaling factors to account for the variability in application date and hydrologic soil conditions as a simple probabilistic approach for aquatic modeling. This allows EPA the ability to evaluate the impact of these factors to the listed aquatic species.

Lastly, given the general but protective nature of the waterbodies and fields being assessed, the use of HUC 2 meteorology to distinguish regional differences in precipitation is sufficient for use in the BEs.

Comment: Several commenters provided case studies employing method refinements that they believe EPA should employ in the development of their BEs.

EPA Response: *EPA appreciates the proposed methods suggested by the commenters but is unable to fully consider and evaluate the methods before releasing the final neonicotinoid BEs and considers that the proposed methods are unlikely to impact NLAA or LAA effects determinations based on the conservative nature of these determinations. As needed and deemed appropriate, EPA will consider higher tier analyses or method refinements further during consultation discussions with the Services.*

Comment: Several commenters questioned the conservative nature of the endpoints used in the BE and the criteria used for study evaluation. Specific detailed comments were provided regarding specific endpoints.

EPA Response: *Extensive discussion on the methodology for selecting endpoints and responses to comments on these methods have been previously published.¹¹ EPA utilized the most sensitive scientifically valid and reliable endpoints. When evaluating unpublished studies submitted by registrants, EPA utilized the standard test guidelines that were most representative of the studies (e.g., OCSP 850 test guidelines, OECD test guidelines). For studies available in the scientific literature (identified using the ECOTOX database), EPA used its open literature guidance¹². As part of the weight of evidence, EPA also considered alternative endpoints, which represent less conservative assumptions. This alternative analysis was used to evaluate the impact of using the most sensitive endpoints in the effects analysis.*

¹¹ *Ibid.*

¹² Available online at: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluation-guidelines-ecotoxicity-data-open>

EPA agrees that the thresholds are conservative representations of the available data. Values selected as thresholds represent the most sensitive available data. Therefore, the threshold is expected to be more conservative than the broader range of toxicity within a taxon – it is meant to be a protective value. Also, HC₀₅ values determined from species sensitivity distributions (SSD) were used to determine acute thresholds. SSDs are composed of all available acute toxicity data for a given taxon, and thus reflect a wide range of toxicity. For acute toxicity data, EPA also uses the LC₅₀/LD₅₀ data and associated slope to account for variability among individuals. Some factors could overstate exposure or toxicity; however, there are also environmental factors and stressors that increase the vulnerability and sensitivity of species to toxic effects to pesticides in natural environments.

Regarding impacts to prey, pollination, habitat and dispersal (PPHD), EPA agrees that several conservative assumptions are made related to exposure of PPHD and that an effect to PPHD will lead to an impact to an individual of a listed species. EPA utilizes a conservative endpoint (e.g., HC₀₅ or most sensitive tested species) to represent potential impacts on an individual of a listed species due to declines in PPHD. EPA agrees that it is relevant to consider endpoints that represent a mid-point of sensitivities among tested species within a taxon. Since the relationship is unknown between the most sensitive tested species responses and those of species representing PPHD of listed species, EPA determined that a conservative approach was appropriate. It is unknown if the most sensitive tested species are conservative when considering the large number of untested species. As stated above, to evaluate the impact of EPA's assumptions regarding use of the most sensitive endpoint, EPA considered other endpoints in an alternative analysis. The purpose of this analysis was to evaluate whether EPA's conservative assumptions influenced the effects determination for a given species.

Regarding study quality comments raised about specific chemicals and endpoints, these comments are addressed in the chemical-specific comments below.

Comment: There is a lack of transparency as well as potential errors in the Magnitude of Effect Tool (MAGtool). There are no quality control (QC) and quality assurance (QA) processes designed specifically for the MAGtool in any of the documentation.

EPA Response: *The MAGtool has been through internal peer and QA/QC review in EPA. In addition, the MAGtool is built upon many of the standard models that have already been through a robust internal/external QC process, including PWC, PFAM, T-REX and AgDRIFT, and utilizes the results and/or equations from those tools. EPA appreciates the identification of any errors or inconsistencies in the model through public review. Review of the commenter's cited errors indicates many were not critical to the performance of the model nor do they significantly impact the effects determinations. The errors have been corrected and updated in the current version of the MAGtool. These changes do not preclude initiation of the consultation process with the Services, where additional considerations regarding tools may be considered, as needed.*

Regarding the transparency of the tool, both the User's guide for the MAGtool as well as the Revised Method provided with the draft BEs include discussions about the assumptions that were made and how the lines of evidence are applied in the BEs. The MAGtool was developed in Excel and uses visual basic to provide transparency in how assumptions were applied. In order to keep the tool at a manageable size, some data are copied and pasted without the links to where they were derived. However, as the code is developed using visual basic, a user can evaluate where the data are coming from by stepping through the code. Like most tools, the MAGtool was initially built for functionality, for use in BEs. As methods are

revised and updated, tools will be refined and upgraded as necessary and EPA will continue to work with the Services to explore the utility of the MAGtool outputs to best inform the biological opinions.

Comment: Commenters noted the Terrestrial Plant Exposure Zone (T-PEZ) conceptual model failed to account for variability in the fractions of sheet flow and channelized flow impacting the T-PEZ, over-estimating the amount of pesticide captured within the exposure zone. The Wetland Plant Exposure Zone (W-PEZ) conceptual model should only consider terrestrial EECs when the water table is less than 0.5 cm and only consider aquatic EECs when the water table is greater than or equal to 0.5 cm. PAT and especially the terrestrial module should go through a Scientific Advisory Panel (SAP) review. In addition, the scientific community and all stakeholders should get the opportunity to review and test PAT before it is used in biological evaluations supported by the EPA. Conference/workshop presentations are wholly inadequate to validate the scientific integrity of a new model.

EPA Response: *The Plant Assessment Tool (PAT) is a replacement for EPA's TerrPlant model and employs mechanistic representations of fate (e.g., degradation) and transport (e.g., runoff) processes, using data that are typically available for pesticides, to model runoff and spray drift exposure to terrestrial and wetland environments. For terrestrial plants, runoff and erosion are modeled using PRZM and spray drift is modeled using AgDRIFT deposition values. The model uses a mixing cell approach to represent water within the active root zone area of soil, and accounts for flow through the terrestrial plant exposure zone (T-PEZ) caused by both treated field runoff and direct precipitation onto the T-PEZ. Pesticide losses from the T-PEZ occur from transport (i.e., washout and infiltration below the active root zone) and degradation. The conceptual model for the T-PEZ receiving runoff is simplistic, assuming the runoff and pesticide mass is evenly distributed across the T-PEZ. EPA will consider specific improvements provided by the stakeholders (consideration of slope, surface roughness, flow path length, the fraction of flow entering the T-PEZ as sheet flow, etc.), as relevant, in future revisions of the tool.*

The W-PEZ is used to assess terrestrial and aquatic plants that can exist in wetland environments. Both types of plants can exist in a wetland, regardless of the depth of the wetland. The comparison of terrestrial plant endpoints in the wetland occurs regardless of the depth of the wetland because there are submerged and emergent rooted wetland species of plants and many of them are not dependent on the depth (wetland depths) or presence of surface water (i.e., the wetland can dry out and the plants will still survive). Whereas aquatic plants require there to be some water available, EPA determined that any depth less than 0.5 cm would likely trigger senescence and dormancy and is not sufficient to maintain a stable or growing population of aquatic plants.

EECs in PAT rely upon the Pesticide Water Calculator (PWC) model-generated runoff volume and EECs. PWC and the APEZ conceptual model have been through internal peer and QA/QC review in EPA as well as external peer review. Aspects of the PAT model that have not been through external peer review are limited to the conceptual models defining the area and depth of the TPEZ and WPEZ modules. Regardless of the level of review of each conceptual model in PAT, for the purposes of the neonic BEs, PAT is the best available tool for estimating exposures to plants.

Comment: In **Appendix 4-5**, EPA notes that aquatic Estimated Environmental Concentrations (EEC) for foliar and soil treatments are orders of magnitude greater than corresponding seed treatments. It is further noted that foliar or soil treatments can thus be considered protective of seed treatment uses. We believe that it is unrealistically conservative to present foliar or soil treatment EECs as surrogates for seed treatment EECs in the BE. Instead, EECs based on seed treatment uses should be quantitatively

assessed alongside the foliar and soil treatment uses, resulting in a more transparent risk picture across the neonicotinoid uses.

To conduct a quantitative risk assessment for seed treatment uses, best-available data should be utilized regarding seed treatment usage statistics, which inform the PCT refinements at Step 2 of the BE. Context Market Research (Context) is an authoritative source of seed treatment information that can be used to estimate seed treatment PCTs.

EPA Response: *As foliar and soil uses are permitted on the neonicotinoid labels, the EECs are considered protective in evaluating the impact of the uses to one or more individuals of a species. As needed, EPA has quantitatively derived EECs for seed treatments that can be considered during consultation with the Services to inform the Services' biological opinions and potential mitigation measures.*

Comment: The blanket no effect (NE) determinations the Agency gave to aquatic mollusks (which are the majority of all listed aquatic invertebrates) are plainly contrary to the best available science and must be remedied in the final BE for all three chemicals. EPA chose to assess acute mortality risk to all listed aquatic mollusks using a grand total of three toxicity studies on only two different species between the three pesticides. For acute toxicity, one study (Prosser *et al.* 2016) was used quantitatively in the imidacloprid BE, but only used the 7-day LC₅₀, not the 28 day, and these endpoints were not used in the clothianidin and thiamethoxam BEs despite the data being there. For the sublethal, chronic endpoint for aquatic mussels, EPA identified a maximum acceptable toxicant concentration (MATC) of 15,811 ppb, 129,100 ppb and 99,999 ppb for imidacloprid, clothianidin and thiamethoxam, respectively. Yet in the Prosser *et al.* study (ECOTOX Record Number: 173464), the authors identified a 28-day LC₅₀ (mortality) threshold of 645.6 ppb, 182.6 ppb and 983.2 ppb, respectively. At the very least, EPA must use these lower values in the Prosser study in place of the current thresholds.

EPA Response: *EPA appreciates the registrant for raising the Prosser et al. 2016 study and its inconsistent use across the assessments to our attention. After further review, the acute mollusk toxicity endpoint (7-day LC₅₀) will no longer be derived from this study for the imidacloprid assessment. A new acute mollusk toxicity endpoint was selected for imidacloprid that is consistent with the 2-4-day exposure duration employed by thiamethoxam and clothianidin endpoints, and which is consistent with OCSPP acute toxicity testing guidelines for aquatic invertebrates.*

Regarding the sublethal data contained in the Prosser et al. (2016) study, the endpoints were screened out in the draft BEs because of lack of standard regulatory endpoints (i.e., EC₁₀ values were available instead of NOAEC/LOAEC values). In response to this comment, EPA re-analyzed the raw data to derive NOAEC/LOAEC values for consideration as the most sensitive sublethal mollusk endpoints. EPA has determined that the 28-day ramshorn snail mortality NOAEC of 10 µg/L (LOAEC = 50 µg/L) for clothianidin and NOAEC of 100 µg/L (LOAEC = 500 µg/L) for imidacloprid are suitable for use as the most sensitive sublethal endpoint for mollusks. For thiamethoxam, no mortality effects were noted. Therefore, staying consistent with the draft BEs, thiamethoxam will use the clothianidin endpoint given that it is more sensitive. NE and NLAA determinations for mollusks for all three chemicals may be reviewed with consideration given to the variation in sensitivity across aquatic invertebrates. All potential updates to the biological assessment for mollusks, including new endpoints and effect calls, will be considered, as relevant, during consultation with the Services.

Comment: EPA needs to consult on all species listed under the ESA, including newly listed species, experimental populations, candidate and proposed species. EPA should also include the American

bumble bee (*Bombus pensylvanicus*) in its revised biological evaluations for the neonicotinoid insecticides. Although this insect is not a currently listed species, the Fish and Wildlife Service has recently determined a petition including substantial scientific and commercial information indicating that listing the American bumble bee as an endangered or threatened species may be warranted. Bumble bee species are highly susceptible to neonicotinoid exposures and are likely jeopardized by continued use of these insecticides.

EPA Response: *For this action, EPA's obligation under ESA is to consult on federally listed endangered and threatened species that may be affected. EPA will continue to work with the Services regarding the most appropriate species list to use during the consultation process, including those species that are proposed for listing or candidates and experimental populations. For these BEs, EPA chose to include proposed and candidate species and experimental populations in case they are formally listed between the time when the BE is completed and the biological opinion is finalized. EPA clearly makes separate calls for each of the species, so it is possible to distinguish determinations for endangered and threatened species from those that are proposed, candidates, and experimental populations. Because the specific species that are considered listed changes over time, EPA identifies a "cutoff date" for the list of species that are considered in the BE.*

Comment: EPA has inconsistently considered species that are presumed extinct or having highly restricted ranges in their risk assessments and biological evaluations. For example, the Eskimo curlew (*Numenius borealis*) is assigned a MA/LAA in all three of the neonic BEs. However, in the 2020 Ecological Assessment of Dicamba Use on Dicamba-Tolerant (DT) Cotton and Soybean Including Effects Determinations for Federally Listed Threatened and Endangered Species, **Appendix L** includes concurrence information from USFWS that the Eskimo curlew is presumed extinct and that the proposed action is not likely to adversely affect this species (see EPA-HQ-OPP-2020-0492-0002). The information from USFWS confirming this species is presumed extinct should be used for subsequent assessments unless information to the contrary is available. This determination is still applicable and should be applied to this and all subsequent evaluations.

EPA Response: *EPA agrees with the commenter that species that are presumed extinct or have highly restricted ranges should be similarly assessed in pesticide biological evaluations (after accounting for any relevant differences in the use and usage of each pesticide). These species considerations will be considered, as relevant, in the forthcoming consultation with the Services.*

Comment: Registrants have outlined several conservation measures for avoidance, minimization and mitigation that include product label information and timing, equipment practices to minimize off-target movement, stewardship practices and conservation off-sets. These need to be considered during the formal consultation.

EPA Response: *EPA appreciates that the registrants have documented the stewardship measures in their comments for the neonicotinoids. As needed and relevant, EPA will consider these measures, as well as others that are identified, during consultation discussions with the Services.*

Comment: For listed bird species that are granivores or omnivores and potentially exposed to seed treatment pesticides, the US EPA does not currently have a refined seed treatment assessment model. Their current screening-level model for assessing risks of seed treatments to birds (*i.e.*, T-REX) is inadequate for an endangered species assessment. T-REX is a generic model that does not include species-specific inputs for diet or body weight and assumes that generic bird species consume only

treated seeds in their diet, an unrealistic assumption for listed bird species. Moore and Priest (2021) developed a refined model to assess the risk of seed treatments to listed bird species referred to as the ESASeedPARAM (Endangered Species Assessment Seed Treatment Probabilistic Avian Risk Assessment Model). This model should be used to provide more realistic risk estimates for listed species.

EPA Response: *EPA has not fully evaluated ESASeedPARAM. Because of the complexity of the model (i.e., the probabilistic nature of the model and the distributions for the various parameters), the need to evaluate the underlying sources of data, and the winnowing of the listed species to a subset of birds and mammals believed to consume seeds, EPA will need time to go through the model and its assumptions. Until EPA has fully evaluated the model and discussed its use with the Services, particularly the limited number of species assumed to consume seeds, the current methods employed in the BEs will be used to evaluate potential effects to listed granivorous and omnivorous birds and mammals, as relevant, during consultation with the Services.*

Comment: While the EPA has made some effort to assess the exposure to non-target wildlife through neonic-treated seeds, the agency's methods ultimately fail to adequately assess the impacts to listed species and must be remedied in the final BEs. Many studies in the literature identify seed treatments as one of the most consequential methods for exposure to wildlife. Much of this likely has to do with abraded seed dust and the timing of application, which often happens much earlier than foliar spraying. The ESA does not allow for significant impacts to be waved away with promises of voluntary measures or technology certain to solve problems. The ESA demands that the EPA look at the effects of its action in registering and reregistering these neonicotinoids and all their uses, including the impacts of abraded seed dust that occur as a result of EPA's action.

EPA Response: *Exposure from abraded seed dust from pesticide-treated seeds is considered as part of exposure estimates for seed treatments. The "linearly increasing with depth" (Δ) option in PWC v2.0 is used to represent the potential distribution of treated seeds and seed dust in the soil profile. The method provides a reasonably conservative estimation of potential pesticide exposure that accounts for residues on seeds that are placed at depths and at depths less than specified, and also assumes abraded seed dust will be deposited on the soil surface. Weather conditions, type of seeding equipment and typical operation of seeding equipment, soil type, roughness of the soil surface, and incomplete incorporation result in unequal seeding depth and potentially higher exposure than if the pesticide were entirely applied at the specified depth.*

Comment: The National Agricultural Aviation Association (NAAA) commented that the Tier 1 model in AgDRIFT and associated assumptions should not be used to assess the risk of drift from aerial applications of atrazine or other pesticides. NAAA provided details and proposed the use of the Tier 3 AgDRIFT model.

EPA Response: *AgDRIFT is the currently approved model for evaluating potential spray drift from a pesticide application. The agency appreciates the additional suggestions provided by NAAA for revising the AgDRIFT modeling inputs and continues to work with industry to update and improve modeling methods to better reflect common application practices. At the recent December 2020 Center of Excellence in Regulatory Science in Agriculture (CERSA) workshop, EPA, NAAA, and other stakeholders discussed these potential refinements for AgDRIFT modeling. EPA is currently reviewing these suggestions and will consider, as needed, whether they are appropriate for future actions. It is important to note that modeling for a national-level assessment is first conducted using maximum application rates, limitations, and instructions listed on pesticide labels and is further refined as the analysis*

progresses with any reliable usage data that may inform on the most common application methods and/or typical application rates. In the absence of specific use directions and application restrictions implemented across all product labels, default assumptions (based on empirical data) are used.

Comment: EPA should use the most up-to-date, best scientific and commercial data available for listed species ranges, including using data from NatureServe for species attribute data. Species attribute data should be used to better inform where the species might be in relation to use sites and describe more precise species ranges limited to habitat factors.

EPA Response: *EPA relies on the Services (who are the species experts) when identifying the species location data. Species location data for both the range and designated critical habitats are managed by the Services and made publicly available on their websites. As species location information is updated, refined, or secondary source is identified for a species by a Service, it will be incorporated into the BE process. These data are updated routinely for use in the BE. EPA will work with the Services during consultation to identify whether other information is available to refine the species' ranges.*

Comment: In response to the EPA's evaluation of the potential risks to listed species from exposure to neonicotinoid seed treatments, several commenters have provided their own qualitative assessments of the likelihood that various listed species would be exposed via consumption of neonicotinoid-treated seeds in agricultural fields. These assessments included specific life history information in a weight-of-evidence approach, including habitat use and diet, for over a dozen listed bird, reptile, and mammal species.

EPA Response: *EPA appreciates the commenters' submission of life history information for these listed species. EPA relies on the Services (who are the species experts) when identifying the species life history data. Much of this species-specific life history information is applicable when considering potential effects at the population level and will be taken into account during the consultation with the Services, as needed and relevant. Any corrections for species that have been presumed extinct (including the Eskimo curlew) and/or have highly restricted ranges will be addressed, as needed and relevant, in EPA's forthcoming consultation with the Services.*

Comment: Effects determinations for any one or a combination of the neonicotinoids are incorrect for the following species; Gopher Tortoise, Piping Plover, Alabama Red Belly Turtle, Rio Grande Silver Minnow, Giant Garter Snake, Cape Fear Shiner, California Least Tern, Least Tern, Knowlton's Cactus, Wood Stork, and Hawaiian pollinators and insects such as the Hawaiian Yellow-Faced Bee and Hilaris Yellow Bee, based on incorrect habitat, population abundance, typographical error, or listing status.

EPA Response: *EPA appreciates the commenter for this detailed species-specific analysis regarding the effects determinations for each of these species. Much of this species-specific life history information is applicable when considering potential effects at the population level and will be taken into account during the consultation with the Services, as needed and relevant.*

Comment: Spatial analysis tools provided by EPA include a series of scripts and documentation to enable stakeholders to generate pesticide "Use Site" (UDL) information, and then perform co-occurrence analysis with the species range or critical habitat data layers. These layers should be more readily available to the public.

EPA Response: *Due to the complexity of sharing the large spatial dataset used in the BE, EPA only provides the tools and documentation used to generate the spatial data. EPA will continue to explore ways to efficiently make the spatial data and analysis available, without regeneration.*

Comment: Grouping crops into UDLs may obscure the use of these application rates.

EPA Response: *Regarding the UDL crop grouping, the USDA NASS (2013-2017) accuracy assessments show that, on a state-by-state basis, the Cropland Data layer (CDL) is relatively accurate (90% or greater) for states that are major producers of major commodity crops. These crops such as corn, soybeans, wheat, and cotton are grown over extensive contiguous areas, and USDA has independent data for training and quality assurance analysis. However, as indicated on the USDA error matrices for the CDL, the high frequency of error for other crops suggests that CDL may not be suitable for representing non-commodity minor crops. To address this, EPA aggregates minor crops into broader crop groupings to reduce the likelihood that EPA misses significant areas of a species' range that could overlap with labeled use sites. EPA considers all application rates that may be associated with the use sites in any of the UDL groupings and will continue to work with the Services on the best method for making assumptions about application rates and possible EECs for these areas, based on the range of uses within a particular UDL. EPA evaluates all uses on the label at the maximum label rates when making an NLAA/LAA determination; for the group UDLs, the maximum label rate across crops in the UDL is evaluated. This is done even if the majority of applications may be made using a scenario (e.g. application rate, technology) that could result in lower exposure. Other application rates and less conservative assumptions may be taken into account during the consultation with the Services, when applicable.*

Additionally, EPA appreciates the individual species analyses conducted by USDA and, as needed, may use them when moving forward with tool and data refinements during consultation with the Services.

Comment: We request that EPA and the Services lay out a specific plan that addresses the primary source of neonicotinoids in municipal wastewater – topically applied pet treatments (pet “spot-ons” and sprays). In multiple enclosed scientific papers, we again share the scientific evidence (see Sandaria *et al.* 2017¹³ and Sandaria *et al.* 2016¹⁴, enclosed) around neonicotinoids in municipal wastewater, highlighting the concentrations in municipal wastewater effluent. As the effects of climate change impact available water supplies, municipalities around the country must pursue other sources of drinking water, including indirect and direct potable reuse. Pesticides in wastewater effluent pose a serious challenge to the feasibility of potable reuse. Treated wastewater effluent continuously discharged into surface waters represents an ongoing source of contaminants recalcitrant to removal.

EPA Response: *EPA has acknowledged in Chapter 3 of the BEs the indoor uses that can contribute to concentrations in aquatic environments. EPA has also acknowledged that it does not have the information sufficient to model these uses and is using the aquatic concentrations derived for residential uses as a surrogate for indoor uses. EPA has included a summary of the Sandaria et al. papers (2016; 2017) in Appendix B, as well as a comparison of the modeled concentrations to those in municipal*

¹³ Sadaria, A.M., Sutton, R., Moran, K.D., Teerlink, J., Brown, J.V., Halden, R.U. 2017. Passage of Fiproles and Imidacloprid from Urban Pest Control Uses through Wastewater Treatment Plants in Northern California, USA. *Environ Toxicol Chem* 36:1473-1482

¹⁴ Sadaria, A.M., Supowit, S.D., Halden, R.U. 2016. Mass Balance Assessment for Six Neonicotinoid Insecticides During Conventional Wastewater and Wetland Treatment: Nationwide Reconnaissance in United States Wastewater. *Environ. Sci. Technol.* 50:6199–6206

wastewater. EPA will work with the Services, as necessary, on finding ways to mitigate impacts of neonicotinoids in municipal wastewater on listed species.

3 Responses to Public Comments Specific to Imidacloprid

Commenter: Nufarm Americas Inc. (-0054)

Summary of Comment: Nufarm compared the foliar maximum annual rates used in the imidacloprid BE Appendix 1-3 to the labeled rates. Nufarm stated that the annual maximum rates for foliar applications to Christmas trees modeled in the BE (0.49 lbs AI/A/year) are not the maximum annual rate labeled (0.4 lbs AI/A/year). Nufarm also stated that the annual maximum rates for foliar applications of turf- sod and turf- golf courses modeled (0.5 lbs AI/A/Yr) are not the maximum annual rates labeled (0.4 lbs AI/A/Yr). Nufarm noted that there are no aerial application methods currently on imidacloprid labels for turf and ornamental uses, though these uses were assessed in the BE. The commenter has offered to share sales data to refine the risk assessments. Nufarm stated that the application rates used in the BE modeling are not suited to fit the worst case scenario, but rather we should consider temporal data regarding certain species to better characterize risks.

EPA Response: *The Agency appreciates Nufarm's willingness to share sales data with the Agency to refine the risk assessments. However, sales data are not indicative of where and how a pesticide is applied.*

EPA has identified several imidacloprid registrations for Christmas trees which have an annual application rate of 0.5 lbs AI/A/year (91234-139, 264-758, 264-827, 264-823, etc.). Therefore, EPA has concluded that the imidacloprid annual foliar maximum application rate used in the BE for Christmas trees is correct.

The Agency agrees with Nufarm that their label for imidacloprid has a maximum foliar labeled rate for turf-sod and turf-golf courses of 0.4 lbs AI/A/Yr. The modeled rate at 0.5 lbs a.i/A reflects the stated use information for turf on label use directions from another registrant.

The Agency has reviewed labels associated with turf and ornamental uses with respect to aerial application method information. While some labels indicate that aerial applications are prohibited, other labels leave it open for interpretation whether aerial may be used, such as indicating that the product may be applied in a broadcast method. Due to aerial applications not being explicitly prohibited on the labels, the Agency determined it was necessary to assess these use sites for aerial application methods as well.

Comment: The draft BE does not account for regional-specific use restrictions, inflating the Action Area. In excess of 7 million acres of state-owned lands have implemented use restrictions that are not considered in the draft BE. EPA should obtain this information from appropriate state organizations and make the proper adjustments for the final BE.

EPA Response: *EPA is always interested in refinements based on the best available data. However, it is resource intensive and not necessarily practical to obtain all current state-specific labels during the development of the biological evaluation. It would be welcomed if the commenter provides more specific information regarding the use restrictions on state-owned lands, to be potentially considered in consultation with the Services as deemed relevant.*

Comment: The non-agricultural UDL spatial footprint and usage assumptions lead to unreliable results. The spatial footprint associated with the six non-agricultural UDLs (Christmas Trees, Developed, Open Developed, Field Nurseries, Manager Forest, and Poultry Litter) in the draft BE is extensive, due in part to the conservative approach taken when selecting land use data layers considered relevant for uses in each UDL. Since EPA was unable to quantify the amount of imidacloprid usage for the use sites associated with these UDLs, it was assumed in the draft BE that 100% of the use site for all UDLs (*i.e.*, 100% PCT for all UDLs) is treated. Based on the total acreage associated with these UDLs in the CONUS and the annual application rate assumed in the draft BE exposure modeling scenario associated with each UDL, the total annual imidacloprid usage considered in the draft BE for the non-agricultural uses alone is >545 million pounds. This is multiple orders of magnitude greater than the total imidacloprid allocated for production of agricultural and nonagricultural products in the CONUS annually, and drastically overpredicts actual usage.

EPA Response: *EPA agrees that when the totality of the non-agricultural area and the annual application rate are combined, the potential amount of imidacloprid applied exceeds the production amount by several orders of magnitude. But EPA believes this is not a fair comparison, as the BEs must focus on local use of the product in non-agricultural areas and the impact of that use on an individual of a listed species. For agricultural applications, EPA has been able to use State-level usage data to help refine their estimates. But as the commenter has indicated, this information is often not available for non-agricultural uses. Spatial information is not available to help refine the footprint of where the non-agricultural uses occur. Therefore, EPA has used the best available data it has on non-agricultural uses to make its effects determination. As needed, EPA will discuss this information with the Services during consultation.*

Comment: The draft BE does not consider EPA’s own conclusions regarding dissipation. For the terrestrial exposure evaluation, the draft BE relies on the default assumption that the foliar half-life of imidacloprid is 35 days. The reliance on this default is a lack of consideration of the best available data and EPA’s own evaluations. In Attachment 3-2 EPA states, “there is an opportunity for risk assessors to refine the default T-REX EECs using chemical-specific foliar dissipation rates in order to more realistically estimate residues...” Within Attachment 3-2, the Agency references three residue studies that EPA concluded satisfy the requirements for refining foliar dissipation half-lives (MRIDs 50357101, 50025901, and 50025902). The EPA Data Evaluation Record (DER) contains imidacloprid specific DT₅₀ values calculated by EPA. To meet the requirement for using the best available science, the final BE should use a 1.4-day DT₅₀ in place of the default 35-day foliar half-life.

Table 3-1. Summary of Foliar DT₅₀s Calculated by EPA not Considered in Draft BE for Imidacloprid

MRID	Crop/foliar treatment	DT ₅₀ calculated by EPA (days) ^a
50357101	Watermelon; 3 foliar apps @ 140 g ai/ha with 4-7d interval	1.34
50025901	Soybean; 2 foliar apps @ 100 g ai/ha with 10d interval	1.34
50025902	Soybean; 2 foliar apps @ 100 g ai/ha with 10d interval	1.43

^aBased on total imidacloprid residues (parent, imidacloprid-5-hydroxy, and imidacloprid-olefine) and single first order rate model

In addition to a refined DT₅₀ for foliage, EPA has studies available that refine the DT₅₀ for arthropods and seeds. MRID 47699440 evaluated the magnitude and decline of residues on arthropods. Arthropods

were directly over sprayed and maintained in cages. Two replicate cages were maintained in the lab and two additional replicates were maintained outdoors in an orchard subject to environmental conditions. Residues were analyzed on day 0, 1, 2, 3, 4, 5, 7, 10, 13, 17, and 21 after application. Residue decline was similar between lab and field samples. Kinetic analysis performed with PestDF on the laboratory-maintained samples, taken as a more conservative approach, results in a DT₅₀ of 0.431 days when considering total imidacloprid residues (imidacloprid, imidacloprid 5-hydroxy, and imidacloprid olefin). Using this refinement of the default 35-day half-life based on the available and robust data has a large impact on the predicted arthropod residues for uses with multiple applications and should be incorporated into the final BE.

DT₅₀ refinements are also possible for seeds based on Roy 2019 and MRID 50354944 who evaluated residue decline on treated seeds. Roy 2019 reports a DT₅₀ of ~4.7 days while MRID 50354944 reports a < 1-day DT₅₀.

EPA Response: *EPA acknowledges the submission of the leaf residue data. An adjustment of the DT₅₀ will not impact any of the LAA determinations due to impacts being predicted with only one application. However, if needed EPA may discuss this information with the Services during consultation.*

Comment: The fraction of retained residues in birds does not consider all relevant information. EPA appropriately derived an estimate for the fraction of chemical retained from day to day in exposed birds based on a hen metabolism study (MRID 42556116) but failed to consider data from Bean 2019. Bean evaluated the ADME of imidacloprid in Japanese Quail and reported clearance to less than the limit of detection (<LOD) for all tissues by 24 hours post exposure. The average elimination half-life across all doses and samples was ~3.8 hours, equivalent to a retained fraction of 0.0126. The retained fraction calculated by EPA based on the hen metabolism study was 0.527. Both values reflect efficient clearance of imidacloprid, but the value derived from Bean 2019 represents a 51% greater clearance in 24 hours. In the final BE it is recommended alternative assessments be performed with the retained fraction of 0.0126 and results be considered within the weight of evidence.

EPA Response: *Based on the large spatial extent of imidacloprid usage as indicated by its numerous registered uses, and the currently available toxicity data for birds, EPA does not expect the estimated fraction of imidacloprid retained in birds will change the LAA determinations in the BEs, but if needed will discuss with the Services during consultation the potential relevancy of this information to the Services' biological opinions.*

Comment: Avian food intake rates in the draft BE do not rely on the best available data. The allometric relationships used in the draft BE to estimate avian food intake are not specific to the gross energies and assimilation efficiencies of different dietary items. Relying on publicly available data six taxonomic order specific allometric equations and one equation based on all data, to serve as a surrogate for the remaining taxa, have been derived. As the best available data, these equations should replace the default currently incorporated in the MAGtool for the final BE. Details on data sources and derivation of allometric equations are available in **Section 4.3** and **Appendix C** of "ESASEEDPARAM: A Seed Treatment Model For Listed Bird Species" (**Chapter 6**).

EPA Response: *As noted in Section 2, EPA has not fully evaluated ESASeedPARAM. Because of the complexity of the model (i.e., the probabilistic nature of the model and the distributions for the various parameters), the need to evaluate the underlying sources of data, and the winnowing of the listed species to a subset of birds and mammals believed to consume seeds, EPA will need time to go through*

the model and its assumptions. Until EPA has fully evaluated the model and discussed its use with the Services, particularly the limited number of species assumed to consume seeds, the current methods employed in the BEs will be used to evaluate potential effects to listed granivorous and omnivorous birds and mammals, as relevant, during consultation with the Services.

Comment: The residential scenarios in the BE incorrectly assume the entire house lot is treated with imidacloprid. **Chapter 3 Section 3.5.7** of the BE discusses the scenarios chosen for simulating non-agricultural uses, including residential uses. In the BE, the “ResidentialESA” scenario was used, with the assumption that 100% of the house lot is treated with imidacloprid. While it is true that imidacloprid has multiple different residential use sites described on its labels, it is not possible for the entirety of each house lot to be treated. Areas such as the house footprint itself cannot be treated. In addition, impervious areas such as driveways and sidewalks are not listed as use sites for imidacloprid. For the remaining landscape units on a residential lot, it remains highly implausible that 100% of those areas would be treated. Thus, the resulting application mass per house lot is inflated, leading to over-prediction of aquatic EECs.

A careful assessment of the use sites specifically identified the imidacloprid label should be conducted and treated area fractions of a typical house lot estimated. In addition, the Residential Exposure Joint Venture (REJV) database provides a wealth of information concerning outdoor residential pesticide usage (REJV, 2014), which could be used to better quantify actual residential application practices of homeowners, including imidacloprid treated use sites.

EPA Response: *EPA accounted for untreated residential areas by adjusting the application rate used in the modeling for the area of the residence treated (0.88) and the fraction of the lots treated (0.587). While the REJV data was designed for and may have utility in terms of understanding general consumer pesticide use patterns, the robustness of those data for determining usage of individual active ingredients has not been fully evaluated. In particular, the imidacloprid usage data within the REJV dataset have not been determined to be statistically robust for the purposes of estimating usage at the national, regional, or state levels.*

Comment: Spray drift modeling with AgDRIFT was based on outdated droplet size assumptions. The spray drift contributions to aquatic exposure were based on incorrect AgDRIFT Tier 1 model droplet size assumptions. The ground spray model assumed very fine to fine droplets. For aerial, the fine to medium droplet size was assumed. In practice, imidacloprid is applied with medium droplet size or coarser, and this practice will be required on all labels in the future. This droplet size distribution corresponds with the AgDRIFT fine to medium/coarse droplet size option for ground boom and the medium to coarse droplet size option for aerial. At distances of 50 meters from the application site, these changes correspond to reductions in deposition of 68% and 45%, respectively for ground and aerial applications (see **Figure 3-2**). These Tier 1 curves still maintain multiple conservative elements, such as high boom, 90th percentile predictions for ground, and aerial predictions based on conservative meteorological conditions and spray practices. Also note that imidacloprid requires a 25 ft (7.62 m) surface water buffer for ground applications and a 150 ft (45.7 m) surface water buffer for aerial applications.

Drift modeling should be updated with the appropriate droplet size assumptions that will be required on all imidacloprid label’s following EPA’s PID and which are supported by imidacloprid’s primary registrant, Bayer.

EPA Response: *In assigning the drift fractions, EPA considered buffers specified on the labels but used default values, for droplet size, referenced in USEPA 2013 to determine the reduced drift values used in modeling. This is because the criteria for choosing the application droplet size is not clearly defined in the labels. Most label states to choose the “largest droplet spectrum that provides sufficient control and coverage”. The largest droplet spectrum that “provides sufficient control and coverage” may not be, as suggested in the comment: “fine to medium/coarse” for ground application and “medium/coarse” for aerial application. Additionally, some of the labels did not clearly address the droplet size spectrum to be used and even did not specify the requirement for the 25-ft buffer for ground application nor the 150-ft buffer for aerial application. In applying corrections to drift, EPA policy is to rely on current (not future) labels and AgDRIFT Tier I modules for aerial and ground application.*

Comment: The 10-ft Vegetative Filter Strip (VFS) required on imidacloprid labels was not accounted for in the aquatic modeling. Imidacloprid labels for outdoor agricultural use require a 10-ft vegetative filter strip (VFS) between the downstream edge of a treated field and any surface water body. A VFS is a recommended practice by the USDA NRCS (NRCS, 2000), and has been shown to reduce off site pesticide losses by over 50%. Recently published data have also shown that mechanistic models, such as the Vegetative Filter Strip Model (VFSSMOD) are capable of accurately predicting pesticide off-site transport reductions measured in the field (Reichenberger *et al.*, 2019). The Reichenberger *et al.* (2019) study collated 244 measurements of pesticide reductions from VFSs, spanning a range of chemical sorption classes and VFS widths, and found that reductions in pesticide mass were higher than 40% in more than 90% of the field experiments.

A regulatory exposure modeling methodology adopted in the European Union (EU) to account for pesticide off-site transport reductions from VFS implementation led to a simple “reduction factor” approach. This “reduction factor” approach is applied to other practices and mitigations in the EU and is detailed in the MAGPIE report (MAGPIE, 2017). The MAGPIE approach to VFS reduction factors considered experimental data and identified the 10th percentile reduction for different classes of pesticides and different VFS widths. For pesticides with a K_{oc} of <1000 L/kg, a reduction of 40% was identified for filter strips of 5 m width (see **Table A2.2** in MAGPIE, 2017). Although the 5 m width associated with this reduction factor is wider than the imidacloprid VFS requirement of 10 ft (3.05 m), the MAGPIE report indicates that 3 m buffers perform similarly to 5 m buffers, with the 25th percentile reduction from the 3 m buffer and the 5 m buffer both at 45%.

The label required VFS should be accounted for in the aquatic exposure modeling. Either a mechanistic approach to quantifying the buffer effectiveness (such as with VFSSMOD) or a reduction factor approach (such as the MAGPIE approach) could be applied.

EPA Response: *EPA is aware that maintained vegetative filter strips can reduce off-site movement of pesticides to aquatic systems especially where there is high affinity to soil constituents (high K_{oc}) and/or plant /interception/uptake. At this time, EPA is considering information and approaches, as relevant, that could be used to estimate reduction of pesticides loading to aquatic systems resulting from maintained vegetative filter strips (e.g., modeling/studies).*

Comment: The study cited Perez-Iglesias 2014 (E168449) was classified as qualitative for use in 2017 and classified as quantitative in 2021 for use in the biological evaluation.

EPA Response: *The Agency acknowledges this discrepancy and notes the endpoint was not used to quantitatively evaluate effects as the most sensitive endpoint. A review and addendum for the study may*

be performed and an updated study classification may be issued to resolve the discrepancy. EPA may discuss this information with the Services during consultation when relevant.

Comment: The following study was reviewed and classified as quantitative; however, the commenter notes this study should be invalid. This study was used as the most sensitive endpoint to derive mortality thresholds for TEP in the biological evaluation.

Table 3-2. Ecotox Study Classification

Study	Ecotox	Classification	Reasons should be invalid
Ocampo 2006	E166820	Quantitative	No control survival reported No analytical confirmation Exposure period and data reported only 24-hours

EPA Response: *No direct mortality effects to fish are expected from imidacloprid exposure, using this endpoint, and it is expected this would not change based on reviews of additional studies with similar endpoints. The review notes, even though analytical verification was not performed, the test substance typically is stable under test conditions. EPA may discuss this information with the Services during consultation when relevant.*

Comment: The following studies were classified for use in the BE as either qualitative or quantitative; however, Bayer notes they should be invalid and removed from effects arrays for reasons listed. Additionally, there are studies in effects arrays that lack evaluations and classifications.

Table 3-3. Additional Ecotox Study Classifications

Study	Ecotox	Classification	Reasons should be invalid
Naiei 2020	E184004	Qualitative	LC ₅₀ extrapolated >100X below lowest test concentration No analytical confirmation
Frew 2013	E169170	Quantitative	Single replicate/treatment with only 5 individuals/replicate No analytical confirmation No ability to verify statistics

EPA Response: *The two studies noted above were not used to quantitatively estimate effects in EPA's assessment, rather they were only included within the effects arrays. Studies specifically reported in effects arrays are not necessarily reviewed and classified. Arrays are built from any effects data available in the public ECOTOX database which are included based on meeting minimum criteria. Studies reviewed and classified are a subset of those in the ECOTOX database which may present more sensitive endpoints than established toxicity studies. The Agency may review and, if needed, update the study classifications for these studies for future assessments and consultation with the Services.*

Comment: The following studies were used in either in SSDs or noted in the biological evaluation but not reviewed and given formal classifications: E166568, E171489, E175427, E178290, E183047, E183503, E183458, E102186 E184007, E184011, E184033, E184567, E184283, E184087 (commenter notes E184007 should be invalid due to close dose spacing and no analytical verification).

EPA Response: *Where enough data are available to compile an SSD, for efficiency and time constraints not every study in the distribution is reviewed and classified. Studies close to certain percentiles used to orient the data (e.g., data near the 5th, 25th, 50th, 75th percentiles) are reviewed and classified for use in the biological evaluation. Regarding E184407, if this study were to be used quantitatively to estimate potential effects to listed species, the Agency would further review and provide a classification for it.*

Comment: The commenter notes in the study Roessink 2013 (E166772): “if immobility and mortality data are available from same test, the endpoint should be based on mortality.”

EPA Response: *In the BE, these data were not used quantitatively to estimate potential effects to listed species. Additionally, these data are from a formulation and TGA1 data from Raby were available and used as the most sensitive endpoints. Finally, correspondence with the study author, although not specifically used for an endpoint, indicated immobility was followed by mortality and the Agency believes the endpoint reported in the BE is appropriate as it captures what is considered to be an apical level endpoint.*

Comment: EPA study evaluations and classifications are missing for 14 studies presented in **Chapter 2** effects arrays, seven of which were used in the establishment of aquatic invertebrate effects thresholds. To ensure scientific credibility and comply with Agency commitments to transparency, EPA must address these missing study evaluations.

Table 3-4. Missing Ecotox Study Evaluations

Study	Included in Appendix 2-2	Included in Chapter 2 effects array	Evaluated in Appendix 2-3	Evaluated in EPA 2011
Aquatic Amphibian				
E102186	Yes	Yes	No	No
Fish				
E184007	Yes	Yes	No	No
E184011	Yes	Yes	No	No
E184033	Yes	Yes	No	No
E184567	Yes	Yes	No	No
E184283	Yes	Yes	No	No
E184087	Yes	Yes	No	No
Aquatic Invertebrates				
E166568	Yes	Yes	No	No
E171489	Yes	Yes	No	No
E175427	Yes	Yes	No	No
E178290	Yes	Yes	No	No
E183047	Yes	Yes	No	No
E183503	Yes	Yes	No	No
E183458	Yes	Yes	No	No

E184007 is expected to be classified as invalid and example of how critical it is for EPA to make the data evaluations transparent. In the study, *C. gariepinus* are exposed to a formulation containing 30.5% imidacloprid at levels equivalent to 1.52, 3.05, 3.35, 3.66, and 3.96 µg ai/L. Analytical verification of test levels is not provided in the publication. Considering the proximity of each test level a small deviation from nominal would prevent the test levels from being independent (*i.e.*, the test level concentrations

could overlap) preventing a reliable relationship of exposure and effect from being established. This uncertainty should invalidate the study in the absence of additional data.

EPA Response: *Where enough data are available to compile an SSD, for efficiency and time constraints not every study in the distribution is necessarily reviewed and classified. Studies close to certain percentiles used to orient the data are reviewed and classified for use in the biological evaluation (e.g., data near the 5th, 25th, 50th, 75th percentiles). For the above referenced studies, while they were used in the SSD, previously reviewed and available open literature summaries represented the determinate percentiles used for the biological evaluation.*

Comment: Extensive higher-tier (mesocosm) data are available for imidacloprid. These studies provide benefits over laboratory studies as they evaluate potential lethal and sublethal impacts under realistic field conditions and consider the influence of community interactions. Consideration of these studies should result in refinement of the draft BE leading to a less burdensome and relevant consultation process.

Whitfield-Aslund 2017 and MRID 49835801, available to EPA, evaluate mesocosm studies for relevance and reliability with a data quality evaluation scheme similar to the scheme defined in the EPA 2011 memo. Data rated as quantitative was used to define a chronic threshold where no observable effects on abundance, emergence, and mortality of aquatic invertebrates occurs at the taxonomic level of family, subfamily, or class. The threshold reported in the studies is 1.01 µg ai/L and is highly relevant for the BE. The threshold is based on the generally more environmentally realistic study design of mesocosms, the threshold accounts for direct and indirect effects, and the establishment of a threshold at the family or higher level of organization is particularly relevant for PPHD evaluations where an obligate relationship does not exist.

EPA Response: *These studies are not appropriate for consideration of effects to a single individual because of historical challenges in interpreting these types of studies and the ability to discern a potential effect as chemically-mediated or by some other variable. These studies and results may be considered in community-level effects determinations, and therefore may be discussed with the Services during consultation, if appropriate.*

Comment: Acute oral toxicity data on imidacloprid for six species of birds, representing five taxonomic orders, is available which the Agency considers acceptable for quantitative use in an assessment (**Table 3-5**). The breadth of data allows for dose-based mortality thresholds for some listed species to be derived from LD₅₀ values of surrogate species in the same taxonomic order. This approach is comparable to EPA's approach to use reptile data for evaluation of listed reptiles, when available, instead of avian data, in an effort to rely on data from the most representative surrogate, and should be considered by EPA in the final BE.

Table 3-5. Acute Bird Mortality Endpoints Grouped for Surrogacy per Taxonomic Order

Taxonomic	Test Species	LD ₅₀ (mg a.i./kg bw)	Slope ^a	Study Classification (EPA 2017)	Reference
Galliformes	Japanese quail (<i>Coturnix japonica</i>)	17	4.5 ^b	Quantitative	MRID 44457401
		33	2.40	Quantitative	MRID 43310401
	Northern bobwhite (<i>Colinus virginianus</i>)	152	2.656	Quantitative	MRID 42055308
Anseriformes	Mallard (<i>Anas platyrhynchos</i>)	283	6.63	Quantitative	MRID 44059401
Passeriformes	House sparrow (<i>Passer domesticus</i>)	41.0	2.48	Quantitative	MRID 42055309
Columbiformes	Eared dove (<i>Zenaida auriculata</i>)	59	6.80	Quantitative	E183555
Icteridae	Grayish baywing (<i>Agelaioides badius</i>)	57.11	4.12	Not reviewed	Poliserpi <i>et al.</i> , 2021

a. Slopes not reported by EPA, calculated using probit analysis in R using drc package (Ritz *et al.*, 2015) on data provided in report or publication.

b. Slope reported by EPA in draft BE.

In addition to revising the quantitative approach, EPA must consider additional lines of evidence currently omitted in the draft BE. Imidacloprid induces a strong learned avoidance – documented in >38 lab, flight cage and field studies – which reduces the risk of mortality events and should be considered in the Weight of Evidence. In addition, there are >11 avian field studies with imidacloprid that investigate the potential for adverse effects under typical agronomic practices. These studies are summarized in MRID 50216001 and should be considered by EPA in the final BE.

EPA Response: *By design, laboratory test animals and species are obviously able to be reared in laboratory conditions and generally maintain good control performance. Additionally, these diet preference/avoidance studies are not anticipated to alter determinations at the individual level given the large spatial extent of usage for imidacloprid, the empirically derived toxicity of imidacloprid to birds across several species, and the unknown relevance of these studies for vulnerable and listed species in the field. Where relevant, these studies may be discussed with the Services during consultation.*

Comment: Appendix 2-6 of the draft BE describes the derivation of species sensitivity distributions (SSD) for terrestrial acute hazard. Generally, the Consortium is supportive of the Agency's use of SSDs in these scenarios, as the data set is of sufficient size. Greater transparency in how the Agency is interpreting the studies and the underlying assumptions that are being made in converting hazard values from the literature is warranted. No evaluations of any of the studies used in constructing the SSDs were provided which contrasts with documentation that was provided with the aquatic invertebrate SSD document. One of the challenges with using literature studies is that endpoints can be presented in a variety of units (e.g., mass ai/individual, lb ai/Acre) and enough information to convert these into a common unit for the SSD (i.e., mg/kg) must be available for use. The assumptions that EPA is using to make these conversions should be included in the documentation (e.g., body mass of *Apis cerana*).

EPA Response: *The Agency acknowledges the lack of evaluations for certain studies but notes that not all studies used in the construction of an SSD receive a full evaluation. Rather, and as has been consistent in previous assessments where they were utilized, studies that represent certain thresholds on the larger array of data receive a review, which have previously been made available.*

Comment: Only one dietary acute LC₅₀ is used for *Bombyx mori* from ECOTOX #162856 (Sun et al. 2012) with a value of 0.13 mg/kg. There are 8 LC₅₀ values reported in this reference each from separate studies ranging from 0.13 to 0.25 mg/kg. It is not clear why only the study with the lowest endpoint was utilized in the SSD when it is indicated in **Section 2** of this appendix that all endpoints would be used when multiple tests were conducted.

For *Culex quinquefasciatus*, the acute LC₅₀ value is listed as 0.31 mg/kg from ECOTOX #175414 (Shah et al 2016). It's not exactly evident where this value comes from. In **Table 2** of this reference, the LC₅₀ for clothianidin is listed as 0.31 µg/mL. Adjusting for density of the 10% sugar solution using 1.038 g/mL would yield a value of 0.30 mg/kg. Therefore, it seems the most likely source of the value used in the SSD was from a clothianidin study which was not adjusted for the density of the food item. An imidacloprid study is reported in this reference with an LC₅₀ of 1.59 µg/mL (slope of 3.99) which would be 1.53 mg/kg adjusted for density.

A literature review produced additional studies that should be considered in the acute dietary SSD that are summarized below:

Table 3-6. Available studies that should be considered in the terrestrial invertebrate acute dietary SSD

Species	Acute LC ₅₀ (mg/kg food)	Slope	Reference
<i>Spodoptera litura</i>	240.1, 57.7, 63.1, 49.9	1.36, 1.68, 1.62, 1.68	Rehan 2014
<i>Leptopilina boulardi</i>	10.17	2.68	Delpuech 2020
<i>Leptinotarsa decemlineata</i>	0.7425 (geomean of 124 values with a range of 0.27-8.41)	1.68 (mean, 0.9-2.8)	Olson 2000
<i>Musca domestica</i>	0.27	-	Farooq 2016
<i>Apis mellifera</i>	18.52	1.63	Jacob 2019
<i>Scaptotrigona postica</i>	72.45	1.91	Jacob 2019
<i>Heliothis virescens</i>	821	0.81	Lagadic 1993
<i>Spodoptera littoralis</i>	17.7	0.92	Lagadic 1993
<i>Apis mellifera</i>	195.2	5.0	Tome 2017
<i>Partamona helleri</i>	466.1	3.3	Tome 2017
<i>Danaus plexippus</i>	5.1, 17, 9.4		Krishnan 2020

EPA Response: Inclusion of the referenced studies in the acute dietary SSD used for the draft BE would not significantly alter the results in terms of the individual level NE/NLAA/LAA determinations due to the extensive spatial extent of the usage and currently available toxicity information for imidacloprid.

Comment: There are two separate LC₅₀ values for *Apis mellifera* ssp. *mellifera* used from ECOTOX #46261 (Suchail et al. 2000). These values are 0.052 and 0.19 mg/kg. Both values were calculated within the manuscript; however, both originate from the same experiment. The higher reported value (24.3 ng/bee) corresponding to 0.19 mg/kg utilizes the full data set. The lower reported value (6.7 ng/bee) corresponding to 0.052 mg/kg was derived by only fitting the three lowest test levels and excluding the other 14 test levels. Only the higher value should be utilized in the SSD as it uses the full data set.

Two LC₅₀ values are listed from ECOTOX #168903 (Biddinger et al. 2013). One is for *Apis mellifera* at 0.2 mg/kg. However, in this reference, the LD₅₀ is reported at 0.2 µg/bee, which using an adult female bee

mass of 128 mg, would be 1.56 mg/kg. The supplemental material lists this as 0.15 µg/bee (differences likely due to rounding), which when adjusted for body mass would be 1.19 mg/kg. The second listed LC₅₀ value is 7.60 mg/kg for *Osmia cornifrons*. In the referenced paper, this is listed as 3.8 µg/bee. It appears that EPA used a body mass of 0.5 g for this species (e.g., 3.8/0.5 = 7.6). This is not an appropriate assumption, as this species is typically much smaller. Measurements from the same lab as the referenced paper are mean body masses of 105.2 mg for females and 68.99 mg for males (supplemental material, Phan *et al.* 2020).

There is a value of 0.33 mg/kg listed for *Apis mellifera* from ECOTOX #82007. There is no corresponding entry for this reference number in **Appendix 2-2** “Accepted ECOTOX Database”. A search within the ECOTOX Knowledgebase website yielded no hits for this reference number.

Recently EPA conducted a bee risk assessment for the registration review of imidacloprid (USEPA, 2020b). In **Table 5-2** of EPA’s bee risk assessment, the Agency summarizes six acute contact honey bee studies that were submitted by the registrant and rated as acceptable. None of these studies were used in the derivation of the terrestrial invertebrate acute contact SSD.

A literature review produced additional studies that should be considered in the acute contact SSD and are summarized below:

Table 3-7. Available studies that should be considered in the terrestrial invertebrate acute contact SSD

Species	Acute LC ₅₀ (mg/kg bw)	Slope	Reference
<i>Podisus maculiventris</i>	0.002333	1.8	De Cock 1996
<i>Melanoplus sanguinipes</i>	86.12	0.4	Tharp 2000
<i>Spodoptera littoralis</i>	653.0	0.92	Lagadic 1993
<i>Heliothis virescens</i>	348.4	0.89	Lagadic 1993
<i>Danaus plexippus</i>	6.7, 8.4, 3.0		Krishnan 2020

EPA Response: Inclusion of the referenced studies in the acute dietary SSD used for the draft BE would not significantly alter the results in terms of the individual level NE/NLAA/LAA determinations due to the extensive spatial extent of the usage and currently available toxicity information for imidacloprid.

4 Responses to Public Comments Specific to Thiamethoxam

Comment: It was recommended that the Agency use thiamethoxam-specific foliar dissipation rates (DT₅₀) instead of the default 35-day value - foliar DT₅₀ to be used 3.3 ± 2.5 days. Using studies containing leaf residue data where foliar applications of thiamethoxam were made to crops that were previously submitted to the Agency and six additional studies being submitted in support of this analysis, the mean foliar DT₅₀ was determined to be 3.3 ± 2.5 days.

EPA Response: *EPA acknowledges the submission of the leaf residue data. An adjustment of the DT₅₀ will not impact any of the LAA determinations due to impacts being predicted with only one application. If appropriate, this may be further considered during consultation with the Services.*

Comment: Although foliar application scenarios were primarily used in the draft Thiamethoxam BE to cover seed treatment uses, seed treatment decline studies have been submitted. While there is currently not an input for seed treatment DT₅₀ values in T-REX, these studies can be used to determine a DT₅₀ for treated seeds for use as weight of evidence that long term exposure to residues on treated seeds is not consistent over time.

EPA Response: *As foliar and soil uses are permitted on the thiamethoxam labels, the EECs are considered protective in evaluating the impact of the uses to one or more individuals of a species. To the extent that this information is determinative for the biological opinion, EPA may further consider the seed EECs in evaluating mitigation and the impact of thiamethoxam uses to listed species during consultation with the Services.*

Comment: The Agency uses the AgDRIFT model as a component of the MAGtool and PAT to estimate the contribution of exposure from spray drift of foliar applications. It has been shown that AgDRIFT tends to overpredict deposition especially in the far field. Therefore, it was recommended that the Agency consider published drift deposition data for thiamethoxam as an alternative to the AgDRIFT estimates to further refine environmental exposure predictions.

EPA Response: *EPA appreciates Syngenta referencing the thiamethoxam open literature study on field drift. This study is specific to the Actara® 25WG formulation with the specific nozzle types identified. As other combinations of thiamethoxam formulations and nozzle types are possible, using the results from this study for exposure modeling in a national-level assessment, conducted using maximum application rates, limitations, and instructions listed on pesticide labels, would be inappropriate. In the absence of specific use directions and application restrictions implemented across all registered product labels, default assumptions (based on empirical data) and the AgDRIFT model are used to estimate spray drift.*

Comment: The Agency identified both thiamethoxam and its primary degradant clothianidin as residues of concern for terrestrial and aquatic organisms and used the lowest effects endpoints from either clothianidin or thiamethoxam studies as input values to the MAGtool. Clothianidin is more toxic than thiamethoxam to several terrestrial and aquatic taxa, leading to an overestimation of effects to listed species. Although clothianidin can be considered a degradate of concern, the contribution of clothianidin from a thiamethoxam application for exposure to terrestrial and aquatic wildlife is relatively low, especially at the time of application. Therefore, it was recommended that only thiamethoxam effects endpoints be used as input values to the MAGtool.

EPA Response: *Chapters 2 and 3 of the thiamethoxam BE provided the reasoning for relying upon thiamethoxam and clothianidin endpoints interchangeably. To summarize, several of the main points are:*

- *Both thiamethoxam and clothianidin are considered residues of concern for terrestrial and aquatic organisms in the thiamethoxam BE. This was based upon the fate and transport of the chemicals:*
 - o *Thiamethoxam degrades to clothianidin, and both active ingredients share similar environmental fate characteristics and show similar behavior in the environment.*
 - o *Available fate and residue data of thiamethoxam indicate that the major route of formation of clothianidin (as a degradate) is from metabolism of thiamethoxam within plants.*
 - o *Clothianidin is also a major degradate in three of eight aerobic soil metabolism studies and one of two anaerobic soil metabolism studies.*
 - o *Clothianidin is also formed under field conditions as it is detected in terrestrial field dissipation studies.*
- *EPA does not have a threshold for what factor difference in toxicity would represent a significant difference in toxicity; however, the weight of evidence presented in the BE indicates that the toxicity of the two chemicals is similar.*
- *As part of the weight of evidence, EPA also considered alternative endpoints, which represent less conservative assumptions. In particular, for endpoints where clothianidin was the most sensitive, the thiamethoxam-based endpoint was used as the alternative endpoint.*

Comment: Aquatic invertebrates outside the class Insecta are less sensitive to thiamethoxam than aquatic insects. Sufficient data are available to generate a species sensitivity distribution (SSD). The HC₀₅ for aquatic invertebrates outside the class Insecta was determined to be 106.1 µg/L. Adverse effects to listed aquatic invertebrates outside the class Insecta are not likely to occur and requests that the Agency re-evaluates how these species are assessed in the MAGtool with consideration of the HC₀₅ for aquatic invertebrates outside the class Insecta and exposure concentrations more reflective of those observed in available monitoring data.

EPA Response: *EPA agrees that aquatic invertebrates outside the class Insecta are less sensitive to thiamethoxam compared to aquatic insects. However, EPA disagrees that sufficient data are available to generate a species sensitivity distribution (SSD). EPA uses data to derive SSDs from literature that passed the ECOTOX quality screen and data from unpublished, registrant-submitted studies. There was a total of five aquatic invertebrate species outside of the class Insecta tested, resulting in nine toxicity endpoints. While there are no minimum sample sizes required by the SSD Toolbox and it is understood that in most cases SSDs will be fit with small sample sizes, attempting to fit distributions to such limiting cases (sample size barely exceeding the number of estimated parameters) will almost certainly result in unreliable estimates of toxicity concentrations. Therefore, EPA determined there were not sufficient data to generate an SSD for aquatic invertebrates outside the class Insecta. Ultimately, the thresholds are conservative representations of the available data. Values selected as thresholds represent the most sensitive available data. Therefore, the threshold is expected to be more conservative than the broader range of toxicity within a taxa, and is meant to be a protective value.*

Comment: It was requested that EPA include the latest aquatic toxicity data, particularly that for chronic toxicity. The EPA noted that there are significant data gaps with regards to acute and chronic toxicity data on thiamethoxam's effect on invertebrates. The following recently published studies were submitted that were not included in the RA:

- Maloney *et al.* (2017) measured acute toxicity of thiamethoxam to *C. dilutus*.
- Raby *et al.* (2018) measured acute toxicity of thiamethoxam to 21 different aquatic invertebrates.

While these papers provide additional acute toxicity data, it was requested that EPA seek to obtain chronic toxicity data to incorporate into the findings in the proposed decision in order to ensure that any associated mitigation measures are sufficient to prevent POTW effluent toxicity. Chronic toxicity data are recommended for two reasons:

- 1) POTWs continuously discharge to surface waters.
- 2) Use of acute toxicity data and the common default assumption that the acute-to-chronic toxicity ratio is 10 might significantly underestimate chronic toxicity given that some neonicotinoids are known to have chronic toxicity values that are more than 300-fold lower than the lowest acute toxicity value.

EPA Response: EPA appreciates the submission of both acute and chronic toxicity data to be included in the BE. Acute toxicity data from Maloney *et al.* (2017; ECOTOX reference 183458) and Raby *et al.* (2018; ECOTOX reference 178290) were utilized in the aquatic insect species sensitivity distribution (SSD) in the thiamethoxam BE (**Appendix 2-5**). As for chronic toxicity data, EPA has reviewed and incorporated all available chronic toxicity data that were deemed appropriate for use into the thiamethoxam BE. When evaluating unpublished studies submitted by registrants, EPA utilized the standard test guidelines that were most representative of the studies (e.g., OCSP 850 test guidelines, OECD test guidelines). For studies available in the scientific literature (identified using the ECOTOX database), EPA used its open literature guidance. Additionally, EPA has acknowledged that it does not have the information sufficient to model POTW effluent toxicity and is using the aquatic concentrations derived for residential uses as a surrogate for indoor uses. EPA has included a summary of the Sandaria *et al.* papers (2016; 2017) in **Appendix B**, as well as a comparison of the modeled concentrations to those in municipal wastewater. EPA will work with the Services, as necessary, on finding ways to mitigate the impact of neonicotinoids in municipal wastewater on listed species.

Comment: Habitats and proximity to use patterns

Table 2. Use of Habitat Requirements and Proximity to Use Patterns to Evaluate Indirect Effects		
Species	Habitat	Source(s)
Alameda whipsnake (<i>Masticophis lateralis euryxanthus</i>)	Local variations of chaparral, which have low nutrient levels and range from deep, weakly developed soils to shallow, rocky soils. Temperatures often exceed 100°F.	(FWS, 2021)
Salt marsh harvest mouse (<i>Masticophis lateralis euryxanthus</i>)	Emergent wetlands of San Francisco Bay and its tributaries. Generally restricted to saline or brackish marsh habitats around the San Francisco Bay Estuary.	(Bias & Morrison, 1999)
Fragrant prickly-apple (<i>Harrisia fragrans</i>)	Sand pine scrub habitat and in xeric hammock, coastal strand, and coastal hammocks along the Atlantic Coastal Ridge	(FWS, 2021)

For each of **Table 2** listed species, in the draft Thiamethoxam BE, the Agency assumed that the dietary items (for the animals), or pollinators (for the plant) were present on treated fields and other treated areas during thiamethoxam applications. However, based on proximity analyses for the agricultural use

patterns deemed LAA in the draft BE for indirect effects to these three listed species, none were found in close proximity to the species ranges. The Agency provided no scientific rationale in the Draft Neonics BEs for their assumption that dietary items or pollinators of listed species would be present on treated fields even though the habitat requirements of these receptor groups are generally similar to those where the listed species are found. Had the Agency accounted for the proximity of thiamethoxam use patterns to the habitats where listed species are found and adjusted exposure accordingly using a spray drift model, many LAA conclusions for indirect effects would have been NLAA.

EPA Response: *EPA appreciates the submission of this information. EPA relies on the Services' documents (e.g., Recovery plan, 5-year review) when identifying the species habitat requirements. If appropriate, the habitat requirement information will be further considered during consultation with the Services.*

Comment: The current implementation of the MAGtool only considers terrestrial insects in estimating the effects of pesticides, including thiamethoxam, on the prey of the Alameda whipsnake. Terrestrial insects are infrequently consumed by this species, and EPA provided no evidence that the reduced availability of insect prey would have any impact on even one individual snake.

In the case of the Everglade snail kite (*Rostrhamus sociabilis*), the model correctly considered aquatic invertebrates as the major receptor group upon which the kite species depends for food. However, the kite has an obligate dependency on apple snails, a unique dietary requirement that was not considered in the Draft Neonics BEs (Reichert et al., 2020). Although thiamethoxam is toxic to aquatic insects, it is non-toxic to aquatic snails including apple snails even at the upper bound concentrations estimated to occur by EPA in habitats of the Everglade snail kite.

The lack of species specificity regarding the dietary requirements of listed species led to EPA concluding that the use of thiamethoxam would adversely affect the availability of prey upon which listed species depend for numerous use patterns. Had the unique dietary requirements of listed animal species been considered, there likely would have been significantly fewer LAA conclusions. We recommend that EPA modify the MAGtool to estimate exposure and risk to the major dietary items upon which each listed species depends. We further recommend that EPA model typical diets for listed species that have multiple dietary items rather than modeling each dietary item assuming that it constitutes 100% of the diet.

EPA Response: *EPA relies on the Services (who are the species experts) when identifying the dietary requirements of listed species. If appropriate, the dietary item preferences and variation in dietary items consumed may be further considered during consultation with the Services.*

5 Responses to Public Comments Specific to Clothianidin

Comment: The commenter notes the terrestrial assessment of leafy vegetables used a retreatment interval of 7 days whereas labels specify an interval of 10 days. The commenter also notes foliar use on grapes allow only one application allowed per year, but two applications were evaluated.

EPA Response: *Terrestrial exposure modeling in the draft BE was conducted across all use patterns associated with a given UDL. For this reason, two applications were assumed for the CONUS Grapes UDL because two applications are allowed for ground applications. Similarly, some leafy vegetables labels do not specify a retreatment interval, so a 7-day interval was assumed.*

Comment: It is unclear if the proper droplet size distribution (medium to coarse, as specified on the labels) was used, as there was no mention of this in the modeling.

EPA Response: *Spray drift inputs for aquatic modeling of clothianidin were updated in the draft BE based on comments made to a previous assessment¹⁵. Accordingly, aerial applications are parameterized with a medium to coarse droplet spectra and ground applications are parameterized with fine to medium/coarse droplet spectra.*

EPA acknowledges that spray drift inputs for terrestrial modeling of clothianidin assumed finer droplet spectra but would be more accurate if they were consistent with spray drift assumptions in the aquatic inputs. However, this assumption does not impact the overall conclusions in the BE associated with terrestrial exposure off of the treated field.

Comment: The “Toxicity inputs” worksheet in the “Clothianidin WoE input parameters” workbook indicates that the mortality and slope values for mammals are LC₅₀ 99999 mg a.i./kg-diet and 4.5, respectively. However, **Table 2-1** in **Chapter 2** of the draft clothianidin BE indicates that “No Data” is available. It would appear the 99999 mg a.i./kg is a placeholder value in the model, but this should be specified and the reason for using this value (e.g., to prevent #DIV/0! errors in Excel) and a QC check to ensure these results are accounted for and do not contribute to the effect determinations.

EPA Response: *The commenter is correct that these are placeholder values. The value 99999 along with a default slope of 4.5 is used for an exposure/taxonomic input into the MAGtool in the case of non-definitive (>) values (no statistically significant effects at any tested concentration) or if no data is available. This is to prevent effects from being predicted to a species from the use of a non-definitive endpoint that may be exceeded by EECs when used in a dose response relationship or the generation of errors that are based on lack of an input to the model.*

Comment: The “Toxicity inputs” worksheet in the “Clothianidin WoE input parameters” workbook show empty values for the weight of the test animals used in the dietary based mortality for mammals, birds, reptiles and terrestrial amphibians and terrestrial invertebrates. However, **Table 2-1** in **Chapter 2** of the draft clothianidin BE shows data under the weight of the test animal heading for each of those organisms.

¹⁵ USEPA. 2020. Clothianidin Non-pollinator Addendum and Chemical-specific Response to Comments Document for Public Comments Received on the Registration Review Preliminary Pollinator and Preliminary Non-pollinator Risk Assessments. DP Barcode 447634. January 8, 2020

EPA Response: *Species body weights of the test animal is not utilized in the dietary based assessment, so there is no impact of the missing weight values on the dietary based conclusions.*

Comment: The slope for the terrestrial invertebrates whose effects metrics are presented in “lb a.i./A” units are assumed to be 4.5 in the “Toxicity inputs” worksheet within the “Clothianidin WoE input parameters” workbook. However, **Table 2-1 in Chapter 2** of the draft clothianidin BE shows the slope value is qualitatively assessed for these organisms and is 4.12.

EPA Response: *Generally, only quantitatively acceptable data are used for MAGtool inputs. The assessed slope for this taxon was based on available toxicity data which were evaluated qualitatively. The slope from the toxicity study was very similar to the default slope of 4.5, therefore the default slope was used. The use of the default value here does not impact effect determinations.*

Comment: There is a discrepancy in the test species used to derive the sublethal endpoint for mollusks. The “Toxicity inputs” worksheet in the “Clothianidin WoE input parameters” workbook show that the test animal used to derive the sublethal endpoint for the mollusk taxon is mysid shrimp (*i.e.*, cell G59). However, **Table 2-4** in the draft clothianidin BE indicates that the aquatic sublethal endpoints were based on the Eastern oyster. EPA needs to replace mysid shrimp with Eastern oyster in the comment cell in the MAGtool “Toxicity inputs” since **Chapter 2** in the draft clothianidin BE indicates that the threshold value used for mollusks (*i.e.*, 129,100 µg a.i./L) is based on the Eastern oyster. This error does not impact findings but is one example of a lack of general QC when reviewing the MAGtool before release to the public.

EPA Response: *EPA appreciates the commenter for bringing this typo to our attention. The correct species is indeed the Eastern oyster (*Crassostrea virginica*) from MRID 45422404. As noted by the commenter, this typo does not impact effect determinations.*

Comment: The “Toxicity inputs” worksheet in the “Clothianidin WoE input parameters” workbook show that the weight of the test animals used to derive the animal dose based sublethal endpoints for mammals, birds and reptiles/terrestrial amphibians are 350 g, 25 g and 25 g, respectively. However, **Table 2-2 in Chapter 2** of the draft clothianidin BE does not provide the weights of the tested animals nor is there any discussion provided in **Chapter 2** text body as to why these values were selected in the MAGtool. The weights of the tested animals are important since they are used to adjust the dose-based sublethal endpoint values in the MAGtool.

EPA Response: *The weights provided in Table 2-2 represent the mean weight of all test organisms used in the study from which the endpoint was derived. EPA recognizes that the column header, “Weight of test animal (g)”, could have been clearer. The endpoint for birds and reptiles/terrestrial amphibians was the same and was derived from an acute oral toxicity test with the house sparrow (*Passer domesticus*; MRID 49104802). For mammals, a chronic 2-generation study with the rat was used (MRID 45422714).*

Comment: The “Toxicity inputs” worksheet in the “Clothianidin WoE input parameters” workbook uses a value of 328 mg a.i./kg-diet as the animal dietary based MATC or LOAEC sublethal endpoint (eggshell thickness) for birds and based on the Bobwhite Quail. However, **Table 2-2 in Chapter 2** of the draft clothianidin BE uses a value of 329 mg a.i./kg-diet for the same bird species.

EPA Response: *EPA appreciates the commenter for bringing this typo to our attention. The correct MATC for this bobwhite quail study (MRID 45422421) is 328 mg a.i./kg-diet. The value entered into the*

MagTool as the sublethal dietary-based animal endpoint for birds was 329 mg a.i./kg-diet but should have been 328 mg a.i./kg-diet. Although this was a mistake, the small difference between these values would not result in any changes to effect determinations.

Comment: There is a discrepancy in the duration of study days used for aquatic mortality endpoints that are provided in **Table 2-2** of the draft clothianidin BE and the MAGtool “Toxicity inputs”. For instance, the “Toxicity inputs” worksheet in the “Clothianidin WoE input parameters” workbook displays 4 days as the duration of the study period but the values in the **Chapter 2** of the draft clothianidin BE range from 4 to 39 days for aquatic organisms. It is unlikely that this error will affect the MAGtool analysis in any significant way, however, this example furthers the point that proper QC practices need to be documented and implemented in the future iterations of the MAGtool.

EPA Response: *EPA appreciates the commenter for pointing out these typographical errors. The correct study duration for the acute toxicity study with *Mysidopsis bahia* (MRID 45422403) is 4 days, not 39 days. The correct 4-day duration value is listed in the Toxicity Inputs tab in **Appendix 4-2**. The HC₀₅ from the freshwater invertebrate SSD used for the freshwater invertebrate mortality endpoint is based on a dataset of 2- to 4-day toxicity values. The duration value provided in the “Clothianidin WoE input parameters” workbook is for informational purposes only and has no impact on the MAGtool analysis.*

Comment: The aquatic mortality endpoint used for all freshwater invertebrates (insect and non-insect) in the draft clothianidin BE is the HC₀₅ from a species sensitivity distribution (SSD) of 3.58 ug/L. The SSD in **Appendix 2-5** (EPA, 2021) is based on insect species only but is used for both insect and non-insect aquatic invertebrate species. A PMRA Special Review Decision on the risk of clothianidin to aquatic invertebrates (SRD2021-03) calculated different HC₀₅ and HC₂₅ values for non-insect aquatic invertebrates. We propose the use of the draft BE stated HC₀₅ based solely on insect species for the insect species; and an appropriate effects threshold based on non-insect aquatic invertebrate toxicity values for the non-insect species to derive the effects assessment for effects to PPHD where appropriate.

EPA Response: *EPA agrees that aquatic invertebrates outside the class Insecta are generally less sensitive to clothianidin compared to aquatic insects. Ultimately, the thresholds selected for analysis are conservative representations of the available data, and are selected as thresholds to represent the most sensitive available data. Therefore, the threshold is expected to be more conservative than the broader range of toxicity within a taxon and is meant to be a protective value. At the time of analysis for the clothianidin BE, the most sensitive threshold was chosen for all aquatic invertebrates. EPA recognizes that it is important to accurately characterize differing sensitivities among the classes of aquatic invertebrates. In this case, consideration of this variability is significant due to the mode of action of neonicotinoids and the important role that aquatic invertebrates serve as a prey base component of many aquatic communities. Therefore, to the extent that this information is determinative for the biological opinion, EPA may be revising its analysis of the aquatic invertebrate data and reporting the results of this re-analysis to the Services during consultation.*

Comment: Given the ability of higher tier/mesocosm studies to more closely account for indirect and community-related effects by reflecting natural conditions of exposure and biological processes, they are a critically important line of evidence to help the Agency evaluate whether their modeling lines of evidence are providing reasonable and realistic risk evaluations. There are several mesocosm studies available for clothianidin (e.g., Memmert, 2001; Hartgers and Roessink, 2015; Robinson *et al.* 2019 (Ecotox Ref No. 183407) and one field study (Kasai *et al.* 2016). An additional mesocosm study (Miles *et*

al., 2017) was deemed unacceptable due to contamination of control ponds. We note that EPA did document these studies in **Chapter 2** of the draft BE. Although EPA does extract data for inclusion into their R-Plots and SSDs, further use of the higher tier studies as part of a robust weight of evidence process to refute or support the modeling line of evidence is required.

EPA Response: *Higher tier full-field and mesocosm studies are often not used quantitatively because elements of their study designs often lower the confidence in the study results. In the case of the mesocosm studies available for clothianidin, two aquatic mesocosm (simulated pond system) studies have been submitted to the Agency by the registrant (MRID 47483004 and 50227907), and another study was found in ECOTOX (Miles et al. 2017; ECOTOX# 183651). Both of the registrant-submitted studies (MRIDs 47483004 and 50227907) did not analytically verify test concentrations and used Typical End Use Products (TEPs) rather than the Technical Grade Active Ingredient (TGAi). This is an important distinction because the aquatic exposure to TEPs is considered only through a direct application or spray drift of product to the aquatic environment. Similarly, Miles et al. 2017 has been classified as qualitative due to the use of a TEP as the test material, making it difficult to discern effects from clothianidin alone versus other ingredients in the formulation. Additionally, Miles et al. (2017), did not analytically verify the test concentrations. In particular, Robinson et al. 2019 (E183407) and Gavel et al. 2019 (E183401) were considered for aquatic-phase amphibian chronic and sublethal effects respectively (*Lithobates sylvaticus*) rather than true community-level mesocosm studies. Further, both of these studies were classified as qualitative due to several study design elements that lowered confidence in study results, including a lack of analytically verified test concentrations. Kasai et al. 2016 has not been formally reviewed by the EPA; however, it appears that this study would also be classified for qualitative use because of specific study design elements. One element in particular is the method of exposure, which was through treated plants which were transplanted into the mesocosms, an unlikely environmental exposure pathway for aquatic systems.*

Lastly, full-field and mesocosm studies are not appropriate for consideration of effects to a single individual or, indeed, even in some cases, to a species, but are rather measures of effects to a community of organisms. Mesocosm studies and their results may be considered (qualitatively) for characterization of community-level effects determinations, as relevant, during consultation with the Services.

Comment: The commenter identified various typographical errors and editorial issues in the Executive Summary, **Chapter 2**, and MAGtool worksheets.

EPA Response: *EPA appreciates the comments and agrees with these editorial corrections and comments. There are no changes to the effects determinations as a result of these corrections.*

Comment: Executive Summary - Page 3 – Toxicity Summary – There is no mention of herptiles (aquatic or terrestrial phase) in the Toxicity Summary provided.

EPA Response: *EPA appreciates the commenter pointing out this oversight in the Toxicity Summary (Executive Summary Section 2). No mortality was observed up to the highest concentration tested (327,000 µg/L) in the available open acute toxicity literature data (ECOTOX# 183651) in which three species of aquatic-phase amphibians were exposed to a clothianidin TEP. As noted above, use of a TEP as the test substance rather than TGAi is an important distinction because the aquatic exposure to TEPs is considered only through a direct application or spray drift of product to the aquatic environment. As a result this study has been classified as qualitative. In the assessment, the acute toxicity to aquatic-phase amphibians was conservatively represented by freshwater fish data. No mortality was observed in the*

available aquatic-phase amphibians or freshwater fish studies. Similarly, the available open literature study (ECOTOX# 183407) of chronic effects on aquatic-phase amphibians, classified as qualitative because it tested a clothianidin TEP, found no chronic effects up to the highest concentration tested (250 µg/L). Consequently, the most sensitive chronic freshwater fish endpoint was used as a surrogate.

No acute toxicity data are available for terrestrial-phase amphibians or reptiles exposed to clothianidin; therefore, the available acute toxicity data for birds was used as a surrogate. The open literature data available for chronic exposure of reptiles suggested that clothianidin exposure may influence some aspects of physiological biochemistry but these results are highly uncertain and no frank sublethal (e.g., growth, reproduction) effects were observed; therefore, the available chronic toxicity data for birds were also used as a surrogate for terrestrial-phase amphibians and reptiles.

Comment: Chapter 2 - Table 2-2 - It is unclear how a 200% increase in mortality is being described as a LOAEC for a sublethal endpoint.

EPA Response: *For the BEs, the most sensitive endpoint was selected from available sublethal studies by assessed taxonomic group. In the case of dose-based endpoints from sublethal bird studies, mortality was the most sensitive endpoint (MRID 49104802). In this dietary study with the House Sparrow, 0 birds died at the NOAEL (63 mg ai/kg-bw) and 2 birds died at the LOAEL (125 mg/kg-bw), thus the 200% increase in mortality. Mortality endpoints used in the analysis focused on the LD₅₀ whereas “sublethal” endpoints used the most sensitive endpoint overall, which could sometimes be associated with mortality or survival.*

Comment: Chapter 2 – Section 4.6 -Page 2-18 – This section is focused on Potential effects to aquatic vertebrates at the community-level using the Miles *et al.* (2017) and Robinson *et al.* (2019) mesocosm studies. The last sentence in this section appears to be incorrectly stated “Therefore, based on data for aquatic -phase amphibians, there may be indirect effects to aquatic vertebrate predators from clothianidin exposure”. In fact, the two mesocosm studies demonstrated no adverse effects to aquatic-phase amphibians. Rather, the authors findings indicated that direct effects to aquatic invertebrate predators (i.e., water bugs, backswimmer, dragonfly larvae, and crayfish) caused an increase in frog tadpole survival (~10% increase) due to a reduction in predation. Therefore, the final sentence should read “Therefore, based on the available mesocosm data, clothianidin exposure may result in direct effects to aquatic predatory invertebrates and no effects or beneficial effects to aquatic-phase amphibians due to a reduction in predation.” Ideally other lines of evidence could be used to support or refute these findings. For example, 1) using laboratory studies for aquatic invertebrate predators to demonstrate toxicity at similar thresholds to the measured mesocosm water EECs; and 2) using monitoring data to evaluate the range of concentrations in the mesocosm studies that resulted the adverse effects to aquatic invertebrate predators.

EPA Response: *EPA appreciates the commenter bringing this typographical error to our attention. Indeed, the concluding sentence here should have read, “Therefore, the available aquatic-phase amphibian community-level toxicity data suggest no effects on aquatic-phase amphibians at the community level with certain clothianidin TEPs at nominal tested concentrations (≥352 µg/L).” This potential revision did not have an impact on the effects determinations.*

Comment: Chapter 2 – Section 13.2 – Aquatic Incidents – EPA reported one aquatic incident from a drench application in a residential yard in Florida, but no details were provided, and the incident certainty was labelled “possible” due to the confounding presence of other pesticides. There are several

lines of evidence that suggest that clothianidin did not cause the one reported incident. These are: 1. Incidents involving fish (in particular) are more commonly noted and reported for most pesticides due to their visibility; 2. laboratory studies conducted on numerous fish species indicate fish are tolerant of clothianidin (see draft BE **Table 2-7**); 3. the reported incident was labelled “possible” and no details were provided. Therefore, the Agency should adjust draft BE **Table 2-24** to indicate no aquatic incidents that directly implicate clothianidin were reported.

EPA Response: *The Incident Reports section includes all ecological incidents involving clothianidin that are classified with certainty categories of possible, probable, or highly probable. No data other than details associated with the incident itself (toxicological/residue reports, record completeness, the presence/absence of other pesticides) are used to evaluate the likelihood of an incident in IDS. Therefore, this clothianidin incident retains its classification as “possible.”*

Comment: Table 2-27 – Page 2-53 the 99999 values in this table are presumably placeholders for endpoints that do not change in the alternative analysis “No change, non-definitive”. This should be better documented in a table footnote. The same issue was noted directly in the MAGtool which would benefit from additional clarity on the use of this value in special situations.

EPA Response: *The commenter is correct that the 99999 values are placeholders for non-definitive (>) values or in situations where toxicity data are not available. A description of this placeholder has been provided above in **Section 2** of this document.*

Comment: The BE assessment endpoint for sublethal effects for freshwater invertebrates is a NOAEC of 0.05 ug/L based on a 42% reduction in emergence in the study Cavallaro *et al.* 2017 (E175184). This endpoint does not meet basic scientific validity criteria for use in science-based risk management decisions because it is not repeatable by the same laboratory (Maloney *et al.* 2018), cannot be independently validated (Raby *et al.* 2018), and is not supported by higher tier studies (Hartgers and Roessink 2015). In addition, the endpoint from the Cavallaro study is more than an order of magnitude lower than endpoints derived for the same effect (*i.e.*, midge emergence) in four independent studies – performed at two independent laboratories and one performed within the same laboratory – resulting in an insupportably low NOEC value.

In summary, we believe that the Cavallaro *et al.* 2017 study is not scientifically valid and not suitable endpoint for the aquatic invertebrate risk assessment for clothianidin. There is an extensive data package on aquatic invertebrate species that is available for clothianidin, which has been summarized and evaluated by both US EPA (US EPA, 2017) and more recently by the Canadian Pest Management Regulatory Authority (PMRA, 2021). We concur with the recent decision of the Pest Management Regulatory Agency (PMRA) (PMRA, 2021 -SRD2021-03) to use the geometric mean of the EC₁₀/EC₂₀ for *C. dilutus* (n=3, Cavallaro *et al.*, 2017; Raby *et al.*, 2018a; Maloney *et al.*, 2018) of 0.12 ug/L for the most sensitive species, and a community level NOEC of 0.281 ug/L from the mesocosm study (Hartgers and Roessink, 2015). The mesocosm endpoint is consistent with other laboratory studies on the most sensitive taxa (*i.e.*, insects), and is also a more appropriate endpoint for aquatic invertebrate risk assessments.

EPA Response: *EPA revisited the study by Cavallaro et al. 2017 (MRID 50344701) and stands by the previous review and interpretation of the results. EPA acknowledges that the NOAEC for emergence in the Cavallaro et al. study is lower than that found by Raby et al. 2018 (MRID 50776201). However, a more sensitive endpoint, average adult lifespan, was observed in Raby et al. 2018. This and other points*

were summarized in the clothianidin Response to Comments on the Registration Review Preliminary Pollinator and Preliminary Non-pollinator Risk Assessments (DP 447634, 1/8/2020).

The results of the Cavallaro et al. and Raby et al. studies are relatively similar given that experimental variability is expected, especially with non-identical experimental conditions and design. There is concordance of the two studies in terms of the level of emergence at higher test concentrations and greater divergence at lower concentrations. Despite the Raby et al. study having greater replication than the Cavallaro et al. study for measurements of emergence, results were more variable in the Raby et al. study at concentrations below those showing 0% to 3% emergence (i.e., 0.63 µg a.i./L and lower). Further, the control performance in the Cavallaro et al. study was better than that in the Raby et al. study (95% vs 69% emergence, respectively). Both of those factors may contribute to the slightly different results. Greater variability in emergence at the lower test concentrations may simply represent greater variability in the sensitivity of individuals to the test material under the same (within study) and different (between study) conditions. There is no evidence that one study is more accurate than the other in terms of capturing this variability.

Furthermore, there is inherent uncertainty in the exposure concentrations in the Cavallaro et al. and Raby et al. studies. In these studies, exposure to the test material would be primarily in the porewater, not the overlying water, however pore water concentrations were not measured. In terms of the overlying water concentrations, there is greater confidence in those in the Cavallaro et al. study because they analyzed samples taken every three days throughout the study. In comparison, Raby et al. at best only analyzed samples every ~9-10 days during the exposure period depending on the test level, however there were some test levels that did not have analytical results presented.

Nonetheless, there should be caution when attempting to make precise comparisons between the two studies in terms of the percent emergence at specific exposure concentrations. Comparisons are potentially confounded by reliance on overlying water concentrations, and the assumption that the relationship between overlying water and porewater concentrations is invariable. Although the low Koc (119 L/kg-oc) of clothianidin and use of a sand substrate in both studies suggest that overlying water concentrations may reasonably approximate porewater concentrations, even relatively small deviations from this relationship (e.g., among test concentrations and between the two studies) could confound comparisons between the studies. This is especially concerning at lower concentrations where sensitivity among individuals may be inherently more variable, and small deviations in concentration may potentially be more impactful on the results.

Although EPA has not fully reviewed Maloney et al. 2018, the endpoints from this study are 28-day EC₅₀ values. EPA generally only uses NOAECs/NOAELs and LOAECs/LOAELs for chronic assessment.

Regarding the use of the mesocosm endpoint, as noted above, full-field and mesocosm studies are not appropriate for consideration of effects to a single individual or, indeed, even in some cases, to a species, but rather to a community of organisms. These studies and results may be considered (qualitatively), as needed and relevant, for characterization of community-level effects determinations during consultation with the Services.

Lastly, EPA and PMRA rely upon different policies, data evaluation and analysis practices, and overall risk assessment processes; therefore, while EPA appreciates the registrant's submission of PMRA's conclusions, the Agency does not concur with PMRA's conclusion in this instance.

Appendix A. List of Commenters for Neonicotinoid BEs

This appendix lists the submitters of public comments on the draft BEs for imidacloprid, thiamethoxam, and clothianidin. This list excludes submissions on unrelated topics. For example, comments sent to the wrong docket were forwarded to the correct docket and not listed here. Public comments can be found in the neonicotinoid docket EPA-HQ-OPP-2021-0575 on www.regulations.gov. Specific comment numbers associated with the commenters listed below are in brackets, *i.e.* [-XXXX], so the full comment address is EPA-HQ-OPP-2021-0575-XXXX.

Individual Citizens

- ~350 comments from individuals
- 7 mass mail campaigns (total signatures: ~67,000) requesting bans on active ingredients and/or protection of listed species

Environmental and Other Non-Governmental Organizations (NGO)

- CleanEarth4Kids.org [-0226]
- Westland Ecumenical Community Food Pantry [-0289]
- Pollinator Pathways NE [-0319]
- Ecology Party of Florida [-0314]
- Friends of Animals [-0335]
- Beyond Pesticides [-0361]
- Nextdoor, Inc. [-0363]
- Cine-Consults [-0366]
- Northern Michigan Environmental Action Council [-0368]
- Center for Biological Diversity (CBD) [-0460, -0461, -0462, -0463, -0464, -0470]
- Center for Food Safety (CFS) [-0465]
- United States Public Interest Research Group (U.S. PIRG) [-0469]
- Environmental Action [-0471]
- Environment America [-0474]

Pesticide Registrants and Consultants

- Syngenta Crop Protection, LLC [-0010, -0045, -0467]
- Bayer CropScience LP [-0008, -0466]
- Bayer US LLC *et al.* [-0049]
- Valent U.S.A. LLC [-0051, -0053]
- BASF Corporation [-0053]
- Nufarm Americas, Inc. [-0054]
- SBM Life Science Corp. [-0336]
- Elanco US Inc. [-0040]
- Humane Wildlife Control Inc. [-0320]
- Clark Crop Consulting, Inc. [-0354]
- FIFRA Endangered Species Task Force (FESTF) [-0350]

Commercial Associations

- CropLife America (CLA) [-0011, -0330, -0345]
- National Sunflower Association (NSA) [-0013]
- Agricultural Retailers Association *et al.* [-0017]
- Florida Fruit and Vegetable Association (FFVA) [-0018]
- The Michigan Vegetable Council, Inc. [-0020]
- Mid-South Entomology Working Group (MSEWG) [-0021]
- Texas Citrus Mutual (TCM) [-0022]
- National Corn Growers Association (NCGA) [-0023]
- Georgia Fruit and Vegetable Growers Association (GFVGA) [-0024]
- Iowa Corn Growers Association (ICGA) [-0025]
- National Barley Growers Association (NBGA) [-0041]
- National Association of State Foresters (NASF) [-0042]
- National Association of Wheat Growers (NAWG) [-0043]
- California League of Food Producers (CLFP) [-0044]
- American Peanut Council (APC) [-0047]
- California Specialty Crops Council (CSCC) [-0048]
- California Citrus Quality Council (CCQC) and California Citrus Mutual (CCM) [-0050]
- National Potato Council (NPC) [-0056]
- U.S. Canola Association (USCA) [-0058]
- Cranberry Institute (CI) [-0059]
- South Dakota Agri-Business Association (SDABA) [-0316]
- American Seed Trade Association (ASTA) [-0332]
- U.S. Beet Sugar Association *et al.* [-0034]
- National Pest Management Association (NPMA) [-0337]
- California Fresh Fruit Association (CFFA) [-0338]
- Agricultural Retailers Association (ARA) [-0340]
- American Soybean Association (ASA) [-0341]
- Northwest Horticultural Council [-0343]
- California Walnut Commission (CWC) [-0344]
- Golf Course Superintendents Association of America (GCSAA) [-0346]
- Responsible Industry for a Sound Environment (RISE) [-0347]
- California Tomato Research Institute (CTRI) and California Tomato Growers Association (CTGA) [-0348]
- National Cotton Council (NCC) [-0349]
- National Sorghum Producers (NSP) [-0351]
- AmericanHort [-0352]
- Western Growers [-0353]
- Society of American Florists (SAF) [-0355]
- California Seed Association (CSA) [-0362]
- National Agricultural Aviation Association (NAAA) [-0459]
- Washington State Potato Commission [-0038]

Farm Bureaus

- New York Farm Bureau (NYFB) [-0026]
- American Farm Bureau Federation (AFBF) [-0039]
- Michigan Farm Bureau [-0052]
- Arizona Farm Bureau Federation (AZFB) [-0339]
- Pennsylvania Farm Bureau (PFB) [-0360]

Growers

- Minor Brothers Farm [-0356]
- Southern Valley [-0357]
- Lewis Taylor Farms, Inc. [-0358]
- Chill C Farms LLC [-0359]

Academic Organizations

- Department of Entomology, University of Wisconsin [-0019]
- Department of Entomology, Michigan State University [-0037]

Local, State, and Federal Government Agencies

- Washington State Department of Agriculture (WSDA) [-0328]
- Ohio Department of Natural Resources [-0016]
- City of South Miami [-0458]
- San Francisco Bay Regional Water Quality Control Board [-0036]
- Bay Area Clean Water Agencies (BACWA) [-0030]
- National Association of Clean Water Agencies (NACWA) [-0046]
- IR-4 Project [-0057, -0327]
- United States Department of Agriculture (USDA) [-0331]

Appendix B. Monitoring Data Analysis for Neonicotinoids in Wastewater Treatment Plants (WWTPs)

Two open literature studies were submitted to the Agency providing measurements of neonicotinoids in WWTPs. The following discussion provides a summary of the concentrations reported in the studies and the concentrations used in the BEs to characterize release concentrations from WWTPs.

Sadaria, A.M., Supowit, S.D., Halden, R.U. 2016. Mass Balance Assessment for Six Neonicotinoid Insecticides During Conventional Wastewater and Wetland Treatment: Nationwide Reconnaissance in United States Wastewater. *Environ. Sci. Technol.* 50:6199–6206

In early December 2014, a large activated-sludge sewage treatment plant with an engineered wetland downstream was sampled by the study authors. Influent and effluent samples for the wetland were collected over a period of 24 hours for 5 consecutive days (Thursday through Monday). The plant was located in the southwestern region of the United States and designed to serve a population of up to 2.5 million people with a design capacity of 870 million liters/day (MLD), or approximately 348 L/person/d, receiving sewage comprised of 94% domestic wastewater and 6% industrial wastewater. The wastewater processes at the WWTPs included screening, grit removal, primary sedimentation, activated sludge biological treatment, secondary clarification, disinfection treatment by chlorination, thickening of primary sludge, waste-activated sludge by centrifugation, anaerobic sludge digestion, and dewatering of digested sludge by centrifugation. The hydraulic retention time (HRT) of the wetland was about 4.7 days and the wetland had an average water depth of about 1.5 m. Additionally, in 2015, 12 additional United States WWTPs voluntarily collected 24-hour flow-adjusted samples, which were provided to the study team as composited samples. The WWTPs were located in the western (n = 4), southern (n = 6), and midwestern (n = 2) regions of the United States. Typically, only one 24-hour composite sample for each WWTP was provided of raw influent and treated effluent collected simultaneously on a random workday. Four facilities provided effluent only. Three facilities performed tertiary treatment by filtration. Three facilities performed UV disinfection instead of chlorination. All other facilities performed conventional treatment (secondary treatment followed by chlorine disinfection).

For the sampling collected in 2014, detections of imidacloprid (45–55 ng/L; 100% detection frequency), acetamiprid (3–5 ng/L; 100% detection frequency), and clothianidin (<1–666 ng/L; 80% detection) were reported. Average concentrations of imidacloprid and clothianidin in secondary effluent were 48.6 ± 7.8 and 131.3 ± 170.8 ng/L, respectively. During the sampling period average daily concentrations of imidacloprid entering and leaving the engineered wetland were 48.2 ± 4.8 and 41.5 ± 11.5 ng/L, respectively. On the first day of sampling, the average daily imidacloprid concentration entering the engineered wetland were 54.4 ± 3.4 ng/L. After 5 days, the average daily imidacloprid concentration leaving the engineered wetland was 49.9 ± 14.6 ng/L, indicating that no significant removal of imidacloprid was observed. During the sampling period (5 days), average daily concentrations of clothianidin entering and leaving the engineered wetland were 124.8 ± 121.8 and 69.3 ± 53.9 ng/L, respectively. However, study authors indicated that notable changes in loading of clothianidin (*i.e.*, instances where the effluent was higher than the influent) made it impossible to draw any firm conclusions about potential losses in the wetland.

For the 12 WWTPs sampled in 2015, the average concentrations discharged (minimum, maximum, median values in ng/L, and detection frequency) were 62.6 ng/L (18.5, 146.4, 52.7, 100%) for imidacloprid, 1.9 ng/L (0.6, 5.7, 1.3, 67%) for acetamiprid, and 12.1 ng/L (9.9, 13.4, 12.5, 33%) for

clothianidin. Thiamethoxam, thiacloprid, and dinotefuran were not detected in any of the samples examined, with minimum detection limits (MDLs) of 0.3, 0.1, and 32.6 ng/L, respectively. During this one-time sampling event at each facility (see discussion above pertaining to the sampling), study authors observed that relatively higher concentrations were discharged in the period of June to November when compared to the December to May time frame; however, they concluded that regional time series analysis was required to confirm and elucidate this phenomenon.

Sadaria, A.M., Sutton, R., Moran, K.D., Teerlink, J., Brown, J.V., Halden, R.U. 2017. Passage of Fiproles and Imidacloprid from Urban Pest Control Uses through Wastewater Treatment Plants in Northern California, USA. *Environ Toxicol Chem* 36:1473-1482

Imidacloprid, an urban pest control insecticide, was monitored during drought conditions in 8 San Francisco Bay (San Francisco, CA, USA) WWTPs. One facility sampled served only a large airport and the associated operations. The remaining 7 locations, representative of more typical municipal WWTPs, had per capita daily influent flows of 235 L/person/d to 302 L/person/d. Single 24-hour flow-weighted composite samples of influent and effluent were collected from each WWTP, except for one facility that used an influent composite (flow-weighted composite of 6 subsamples collected regularly throughout the 24-hour day). In influent, imidacloprid was detected in the range of 58–306 ng/L. In effluent, imidacloprid was detected in the range of 84–305 ng/L. Partitioning was also investigated; in influent, 100% of imidacloprid was present in the dissolved state. Imidacloprid persisted during wastewater treatment, regardless of treatment technology utilized (93±17%). At the airport WWTP, imidacloprid concentrations in effluent were approximately 3 times higher than influent levels, suggesting inconsistent loading into this facility that provided sanitary services to a major US airport.

BE Modeling

For comparison purposes, the EECs for Bins 4 and 7 (**Chapter 3**) presented in the BEs (**Appendix 3-1**) for the three neonicotinoids, residential outdoor uses (**Table B-1** below) are on the same order of magnitude or higher than the values reported in the WWTPs open literature. While Bins 2 (edge of field estimates) and 10 (wetland) tend to have higher modeled EECs than Bins 4 and 7, Bins 4 and 7 are similar in context to the types of waterbodies that may represent waterbodies receiving effluent from WWTPs. It should also be noted that the effluents discussed in the above open literature documents are not waterbody concentrations, except for perhaps those leaving the wetland (Sadaria *et al*, 2016), and do not account for any dilution that may occur when the effluent enters a waterbody.

Table B-1. Residential EECs for Bins 4 and 7 (Appendix 3-1)

Value	Clothianidin (ng/L)	Imidacloprid (ng/L)	Thiamethoxam (ng/L)
Sadaria <i>et al.</i> 2016, secondary effluent	131.3 ± 170.8	48.6 ± 7.8	N/A
Sadaria <i>et al.</i> 2016, wetland effluent	69.3 ± 53.9	49.9 ± 14.6	N/A
Sadaria <i>et al.</i> 2016, effluent from 12 WWTPs	9.9 - 13.4	18.5 - 146.4	N/A
Sadaria <i>et al.</i> 2017, effluent	N/A	84 – 305	N/A
Minimum	960	454	252
10th%	1,551	622	607
Median	3,064	1,609	1,907
Average	3,277	2,135	2,135
90th%	5,113	3,913	3,423
Maximum	8,362	9,690	5,956