Process for Requiring Exposure and Effects Testing for Assessing Risks to Bees during Registration and Registration Review

Office of Pesticide Programs
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Table of Contents

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1. Purpose

The intent of this document (referred to as *Process* document) is to provide interim guidance to the public and staff within the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) for determining when honey bee exposure and effects (toxicity) data identified in the EPA's 2014 risk assessment framework *Guidance for Assessing Pesticide Risks to Bees*[1] (hereafter referred to as the 2014 *Guidance*) and the 2016 *Guidance on Exposure and Effects Testing for Assessing Risks To Bees* are required. This document is being made available to describe OPP's plans for requiring these data to assess chemical risks to bees. This document focuses on conventional pesticides; the agency discusses its current approach for other types of pesticides in section 4 of the companion document, 2016 *Guidance on Exposure and Effects Testing for Assessing Risks To Bees*.

2. Background

Assessing risks to bees is a complex matter. The scientific community is in general agreement that a multitude of factors contribute to potential adverse impacts on bees, including lack of nutritional resources, pests and pathogens, and pesticides, among others. To better understand the potential impacts that pesticides might have on bee health, EPA has determined that additional bee toxicity and exposure information are necessary to conduct its evaluations as part of its registration and registration review programs.

In general, pesticides can only be sold and distributed in the United States if they have been registered by the EPA. Prior to the agency granting a registration, each applicant must establish that its product meets the standards set forth in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(5) and/or 3(c)(7). These standards include finding that when a pesticide is used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment. FIFRA also provides for regular review of existing pesticide registrations. FIFRA section 3(g) and its implementing regulations at 40 CFR Part 155 set forth the process for the reevaluation of currently-registered pesticides (*i.e.*, registration review).

FIFRA's implementing regulations at 40 CFR Part 158 set forth the data requirements for pesticide registration. Additionally, these regulations discuss the flexibility the EPA has when requiring data for pesticide registrations. Under 40 CFR 158.30, the EPA may determine to modify the data requirements on an individual or case-by-case basis to fully characterize the effects of a pesticide product. Additionally, these regulations make clear the data routinely required under Part 158 may not always be sufficient to assess whether there are unreasonable adverse effects on the environment. Under 40 CFR 158.30(b) and 40 CFR 158.75, the EPA may require additional information to better characterize the potential risks.

Consistent with the EPA's process for evaluating risk to various taxa, assessing risk relies on multiple studies identified in Title 40 (Protection of the Environment) of the Code of Federal Regulations, Part 158 (Data Requirements for Pesticides; abbreviated as 40 CFR Part 158). However, where necessary, the EPA has the authority to require data which may extend beyond the suite of exposure and effect data identified in the 40 CFR Part 158. Pesticide registrants (*i.e.*, the regulated community) are required by

[1] USEPA, PMRA, CDPR. 2014. Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency (PMRA), California Department of Pesticide Regulation (CDPR). June 19, 2014. http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf (last accessed 06/27/2016).

law to provide the data needed to assess the potential for adverse effects from exposure to pesticides. To meet the data requirements, registrants will, in large part, depend on contract research organizations (CROs) to conduct these studies since CROs have experience in conducting the studies and can provide consistent and reliable data that meet the specification identified in the 40 CFR Part 158. The EPA recognizes that the capacity of CROs to conduct new studies on behalf of the regulated community depends on the nature of the studies and the laboratory's familiarity with the test species and/or study conditions.

In the absence of these data, risk assessors may not be able to fully determine the potential for exposure and effects to bees. However, where the EPA determines that a pesticide use is not likely to expose bees or in situations where acute and/or chronic toxicity is not expected based on other lines of evidence, additional data may not be warranted to support regulatory decisions.

The EPA has developed guidance documents[2] for risk assessors that identify additional, relevant data in evaluating exposure and effects of pesticides on honey bees. The agency is in the process of revising the existing insect pollinator data requirements in 40 CFR Part 158 to codify the data necessary to complete risk assessments consistent with the risk assessment framework. Having all required studies available to the EPA at the time of application should reduce the potential for delays in the registration process.

Table 1 identifies the current data requirements for conventional pesticides codified at 40 CFR Part 158, Subpart G for toxicity and exposure testing for insect pollinators. **Tables 2** and **3** list the additional types of studies the EPA has determined are necessary to more fully evaluate the potential exposure and effects to bees for various pesticide use patterns.

[2] *Ibid* USEPA 2014.

Table 1. Toxicity Testing Requirements for Insect Pollinators as Specified in 40 CFR Part 158, Subpart G.

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Green-house	Indoor		
Insect Pollinator Testing									
850.3020	Honey bee adult acute contact toxicity	R	CR	R	R	NR	NR	TGAI	1
850.3030	Honey bee toxicity of residues on foliage	CR	CR	CR	CR	NR	NR	TEP	2
850.3040	Field testing for pollinators	CR	CR	CR	CR	NR	NR	TEP	3

Definitions: R = Required; CR = Conditionally Required; NR = Not Required; TGAI = Technical Grade of the Active Ingredient; TEP = Typical End-Use Product

Test Notes:

1. Data using the TGAI are required to support all outdoor end-use product uses. Data are generally not required to support end-use products in the form of a gas, a highly volatile liquid, a highly reactive solid, or a highly corrosive material.
2. Data are required only when the formulation contains one or more active ingredients having an acute LD_{50} of <11 micrograms per bee as determined in the honey bee acute contact study and the use pattern(s) indicate(s) that honey bees may be exposed to the pesticide. (Note that in the regulatory text this is actually Test Note 24.)
3. Required if any of the following conditions are met: (Note that in the regulatory text this is actually Test Note 25.)
   i. Data from other sources (Experimental Use Permit program, university research, registrant submittals, *etc*.) indicate potential adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, *etc*.);
   ii. Data from residual toxicity studies indicate extended residual toxicity;
   iii. Data derived from studies with terrestrial arthropods other than bees indicate potential chronic, reproductive or behavioral effects.

Table 2. Additional Requirements [a, b] for Bee Exposure and Effects Testing

Study	Study Type	Test substance	Test Note No.
Non-Guideline Study (Tier 1) [c]	Honey bee adult acute oral toxicity	TGAI	1
Non-Guideline Study (Tier 1) [d]	Honey bee larvae acute oral toxicity	TGAI	1
Non-Guideline Study (Tier 1) [c] [g]	Honey bee adult chronic oral toxicity	TGAI	1
Non-Guideline Study (Tier 1) [e] [g]	Honey bee larvae chronic oral toxicity	TGAI	1
Non-Guideline Study (Tier 2) [f] [g]	Semi-field testing for pollinators (tunnel or colony feeding studies)	TEP (tunnel) or TGAI (feeding)	2

Definitions: TGAI = Technical Grade of the Active Ingredient; TEP = Typical End-Use Product

[a] Recommendations for bee toxicity data may be modified for certain types of outdoor residential uses for which exposure is considered extremely limited (*e.g.*, crack and crevice treatment, spot treatment, *etc*). In such cases, acute toxicity data may still be warranted but chronic toxicity data may be of limited value in the risk assessment.

[b] For greenhouse uses that involve bee pollination, Tier 1 and Tier 2 bee exposure and effects data may be required.

[c] Honey bee acute oral toxicity test protocol available through OECD TG 213. For aquatic uses, acute oral toxicity data are needed to evaluate exposure of bees through drinking water and in evaporative cooling of the hive and for exposure through systemic transport into food items (pollen/nectar).

[d] Honey bee acute larval toxicity test protocol available through OECD TG 237.

[e] Draft test protocols are currently being finalized through the OECD.

[f] Semi-field tunnel study protocol available through OECD Guidance 75.

[g] Study protocol should be submitted for review prior to conduct of the study.

Test Notes:

1. Data using the TGAI are required to support all outdoor end-use product uses. Data are generally not required to support end-use products in the form of a gas, a highly volatile liquid, a highly reactive solid, or a highly corrosive material. For greenhouse use patterns, data are required for crops that require pollination (*e.g.*, tomatoes); for aquatic use patterns, data are required if bees are likely to be exposed as a result of the proposed use.
2. Tier 2 studies may be required pending the results and evaluation of Tier 1 studies. Tier 2 studies may be required if the ratio of the EEC and larval or adult bee acute LD_{50} >0.4 or the ratio of the EEC and chronic NOAEC >1. Tier 2 may be required if data from other sources (Experimental Use Permit program, university research, open literature, registrant submittals, adverse effect incident reports, *etc.*) indicate the potential to adversely affect bee colonies, especially effects other than acute mortality (*e.g.*, reproductive, behavioral, *etc.*). Tier 2 studies may also be required if data derived from studies with terrestrial arthropods other than honeybees indicate potential chronic, reproductive, or behavioral effects.

Table 3. Additional Requirements for Residue Data Measured in Pollen and Nectar.

Study	Study Type	Test substance	Test Note No.
Non-Guideline Study (Tier 3)	Field trial of residues in pollen and nectar	TEP	1, 2

Definitions: TEP = Typical End-Use Product

1. Field studies that quantify pesticide residues in pollen/nectar may be required to refine screening level exposure estimates, depending on the results and evaluation of Tier 1 studies. Pollen and nectar residue studies may be required if the ratio of the EEC and larval or adult bee acute LD_{50} >0.4 or the ratio of the EEC and chronic NOAEC >1. Incident data and/or compelling open literature studies can also serve as rationale for requiring pollen and nectar residue studies. These data can be collected at any point during the tiered process; prior consultation with the Agency is recommended to determine when to collect the data, and test protocols must be submitted for Agency review prior to initiation of the study. For greenhouse use patterns, data are required for crops that require pollination (*e.g.*, tomatoes); for aquatic use patterns, data are required if bees are likely to be exposed as a result of the proposed use (*e.g.,* riparian vegetation).
2. Protocol should be submitted for EPA review prior to initiating study.

The EPA initiated the rulemaking process in 2015 to codify all of the data required to support each tier of the risk assessment process for bees in 40 CFR Part 158. Depending on the timing of the proposed rule and the number and complexity of the comments received, as well as other external factors, the EPA projects the new rule to be effective by mid-late 2017. In the meantime (before promulgation of the new data requirements), the agency will on a case-by-case basis determine whether these data are needed for individual registration actions.

The EPA's data requirements are established to provide the information needed to determine whether a new pesticide product and new uses on currently registered products meet the standard for registration. In general, registrants must address the established data requirements in 40 CFR Part 158. However, the EPA sometimes determines that special studies or additional data beyond those codified in 40 CFR Part 158 are required to make a finding of no unreasonable adverse effects finding under FIFRA.

As part of the re-evaluation of pesticides, the EPA may determine that additional data are needed to support the continued registration of a pesticide. In such cases, the EPA first issues a Preliminary Work Plan (PWP) that outlines the expected timeline for the registration review, the likely risk assessments that will need to be conducted, and the data the agency expects to be necessary to fully evaluate the pesticide during the re-evaluation process. Subsequent to taking comment on the PWP, the EPA issues a Final Work Plan (FWP). If additional data are needed as part of the registration review, the EPA issues a Data Call-In Notice (DCI) under FIFRA section 3(c)(2)(B). The DCI requires each affected registrant to provide evidence within 90 days that the affected registrant is taking appropriate steps to respond to the DCI. Additionally, the DCI sets deadlines for data submission and may specify interim deadlines. In accordance with the terms of clearance for the information collection request (ICR) approved by the Office of Management and Budget (OMB) under OMB Control Number 2070-0174, the EPA must provide OMB with prior notice and opportunity to review each DCI before issuance. Once OMB has approved the DCI, OPP may issue the order. As noted earlier, the DCI may include studies which are not codified in 40 CFR Part 158, and these studies are subject to the same authorities covered by the ICR. In some circumstances, subsequent to issuing a DCI as part of the registration review program, the agency may identify the need for additional data to support the continued registration of a pesticide. In these circumstances, the EPA, after receiving approval from OMB, will issue a follow-up DCI to require the submission of these additional data.

The next sections discuss what additional data are needed, the timing of when the EPA may request additional data, and describe how the EPA will integrate the pollinator risk assessment methods into its overall regulatory approaches for both registration and registration review.

3. Implementation

As previously discussed, the EPA has initiated the rulemaking process to codify the pollinator toxicity and exposure testing in 40 CFR Part 158. In the interim, OPP has developed a plan for evaluating when these data may be required on a case-by-case basis, consistent with the 2014 *Guidance* and the 2016 *Guidance on Exposure and Effects Testing for Assessing Risks to Bees*. Specifically, this plan summarizes OPP's approach for addressing the new bee testing needs in the context of three types of regulatory actions for conventional pesticides:

- Registration Review of existing pesticides;
- Registration of pesticides containing new active ingredients and first outdoor uses; and
- Registration of new additional outdoor pesticide uses.

Appendix 1 contains a flowchart depicting the general process the Agency will follow in determining whether additional pollinator data will be necessary for different registration and registration review actions.

When the data described in the 2016 *Guidance on Exposure and Effects Testing for Assessing Risks to Bees* are not available, there will likely be aspects of the potential for exposure and effects to bees which are not known. In these situations, registration and registration review decisions will consider:

- the nature of the uncertainties (*e.g.*, which data are not available);
- the extent to which mitigation measures can reduce exposure/effects from the pesticide undergoing the action;
- the benefits associated with the use; and,
- whether there are alternatives and the potential comparative risks associated with those alternatives.

3.1 Conventional Pesticides in Registration Review

FIFRA Section 3(g) mandates that the EPA periodically review the registrations of all pesticides to ensure that they do not pose unreasonable adverse effects to human health and the environment. This periodic review is necessary in light of scientific advancements, changes in policy, and changes in use patterns that may alter the conditions underpinning previous registration decisions. In determining whether the likelihood and magnitude of adverse effects (*i.e.*, risk) to taxa from exposure to pesticides are unreasonable, FIFRA requires that the Agency consider the risks and benefits of any use of the pesticide.

During registration review, OPP may determine that data from the types of studies discussed in this document are necessary before a final decision is issued pursuant to 40 CFR Part 155. The way in which the pollinator data may be required during registration review will depend on the stage of the agency's review of the chemical in the review process. The EPA's approach will depend on when the initial registration review DCI was issued and whether the agency may have required the submission of additional pollinator data. The DCI is generally issued early on in the registration review process after the EPA has reviewed and summarized existing data and considered anticipated data needs (*e.g*., acute and/or chronic bee toxicity data) necessary to conduct a risk assessment and formulate a registration review decision.

Because the need for additional pollinator data was determined subsequent to the initiation of registration review program in 2007, the registration review process for many conventional pesticide active ingredients is already well underway. With a few exceptions, registration review DCIs issued after January 1, 2015, generally required the submission of all of the pollinator testing identified in the 2014 *Guidance,* unless the agency made a determination that a subset of these data would not be needed to complete the re-evaluation of that specific pesticide. The agency has reviewed all conventional pesticide active ingredient cases and categorized them based on where they are in the registration review process. We have categorized registration review cases into 3 Bins:

Bin #1: Cases that may need a subsequent pollinator DCI because the initial registration review DCI was issued before January 1, 2015 or the chemical was first registered with the agency between 2008 and the time of issuance of this *Process* document

Bin #2: Cases in the first 15-year cycle of registration review where EPA either considered or will consider whether the pollinator data identified in the 2014 *Guidance* are needed to complete registration review. The registration review DCI for these cases was/will be issued after January 1, 2015.

Bin #3: Cases in the first 15-year cycle of registration review that have either been cancelled or have or registered use patterns that do not result in exposure to bees

For those pesticide cases where the EPA determines that the pollinator data identified in the 2014 *Guidance* are necessary for the registration review, a DCI will be issued requiring the appropriate pollinator studies. Generally, Tier 1, 2 and 3 studies will be required in the DCI, but the need for Tier 2 and 3 data and study protocols will be determined based on the results from Tier 1 studies and other lines of evidence. **Appendix 2** contains footnotes that can be used to support DCI tables for registration review.

Except for the pesticides imidacloprid, clothianidin, dinotefuran, and thiamethoxam[3], if the registration review DCI was issued before January 1, 2015, it did not contain a request for the suite of new pollinator data identified in Tables 2 and 3 because the EPA first established the need for these studies in the risk assessment framework *Guidance for Assessing Pesticide Risks to Bees,* published in June 2014. EPA has determined that there are 298 conventional pesticide registration review cases that may need a subsequent pollinator DCI because the initial registration review DCI was issued before January 1, 2015 (255 cases) or the chemical was first registered with the agency between 2008 and the time of issuance of this *Process* document (43 cases). The specific chemicals are listed in **Appendix 3, Table 1**.

Therefore, if exposure to bees is considered relevant based on the pesticide's use pattern, and the registration review DCI was issued before January 1, 2015, then EPA will complete the risk assessment consistent with the existing schedule and available data. Specifically, agency risk assessors will calculate a risk quotient (RQ) for honey bees based on all available data, including pollinator data that may have been submitted in the absence of a DCI, according to the 2014 *Guidance*, even if the additional data summarized in **Tables 2 and 3** have not yet been submitted.

If risks of concern are identified, various factors will be considered to determine the most appropriate regulatory determination. First, the EPA will evaluate the likelihood of exposure to bees considering whether the registered uses involve bee-attractive crops (based on the USDA list[4]), whether the directions for use allow application when bees may be present (*e.g.*, application at bloom), whether expected usage in agriculture is likely to lead to problematic pollinator exposure scenarios, and whether suitable measures can be identified to mitigate exposure. As in every other registration decision, the EPA will also consider the benefits associated with the registration action to determine whether those benefits outweigh the risks of adverse effects. In order to facilitate the review and the FIFRA "no unreasonable adverse effects" determination, the EPA may request that the registrant submit additional information including efficacy data on key pest management claims, benefits and user alternatives assessments, and/or hazard comparison data to other registered pesticide alternatives.

When all of the Tier 1 data are not available to evaluate potential exposure and effects to bees, it may be difficult to develop suitable mitigation measures for some compounds (*e.g.*, systemic insecticides) especially when the use is on an indeterminate blooming plant (*e.g.*, cotton, cucurbits) which is attractive to pollinators.

After taking public comment on its proposed interim registration review decision, the EPA will consider the comments received and then issue an interim registration review decision that, after consideration of all risks and benefits, may include mitigation measures to address potential risks to pollinators. Depending upon the nature and extent of any required mitigation, the EPA may require, through a separate DCI, the additional pollinator data identified in the 2014 *Guidance* to adequately inform a useful refinement of risk estimates in the final registration review decision. If the risks can be appropriately mitigated, additional data may not be necessary.

[3] Registration Review DCIs were issued for imidacloprid, clothianidin, dinotefuran and thiamethoxam with requirements to submit pollinator effects and exposure data consistent with the suite of studies listed in the 2014 *Guidance*. DCIs were issued on the following dates: imidacloprid, November 10, 2010; dinotefuran, March 1, 2013; clothianidin, March 13, 2013; and thiamethoxam, March 14, 2013.
[4] USDA 2015. Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen. http://www.ree.usda.gov/ree/news/Attractiveness_of_Agriculture_crops_to_pollinating_bees_Report-FINAL.pdf (last accessed 06/28/2016).

Registration Review DCI Issued After January 1, 2015

If the registration review DCI was, or will be, issued after January 1, 2015 then the EPA considered (or will consider) if exposure to bees is relevant to the registration review determination based on the pesticide's use pattern and the appropriate pollinator studies based on the 2014 *Guidance*. Registration review DCIs issued after January 1, 2015, generally required the submission of all of the pollinator studies identified in the 2014 *Guidance,* unless the agency made a determination that a subset of these data would not be needed to complete the re-evaluation of that specific pesticide. As a result, assessments for these chemicals will be based on the pollinator studies and the risk assessment framework as described in the 2016 *Guidance on Exposure and Effects Testing for Assessing Risks to Bees*. EPA has determined that there are 134 conventional pesticide registration review cases that have considered or will consider the need for pollinator data at the time of the initial registration review DCI. The specific chemicals are listed in **Appendix 3, Table 2.**

The EPA expects to complete the first round of registration review docket openings (completing Preliminary Work Plans and Final Work Plans) and issuing registration review DCIs (which will include, as appropriate, additional data necessary to address pollinator risks) for all conventional pesticide cases subject to registration review in 2017.

Cancelled Pesticides and Pesticides with Use Patterns that do not result in exposure to bees

At the time of issuance of this *Process* document, the EPA has determined that there are 70 conventional pesticide registration review cases that have either been cancelled since registration review started or have registered use patterns that do not result in exposure to bees. For these chemicals, the new suite of pollinator data will not be necessary. The specific chemicals are listed in **Appendix 3, Table 3** because they have been voluntarily cancelled by their manufacturer or the use pattern of the chemical clearly would not result in potential exposure to pollinators.

Laboratory Capacity Considerations

The EPA is aware that there may be practical constraints on laboratory capacity for conducting all of these tests simultaneously given the large number of chemicals in Bin #1 and Bin #2. As a result, the agency believes that it is appropriate to prioritize the submission of studies for those pesticides with the greatest potential for bee exposure and adverse effects on bees. Decisions on when to issue subsequent DCIs for pesticides in Bin #1 will be determined based on a consideration of the following factors:

- The toxicity of the pesticide to bees and/or related taxa;
- The mode of action of the pesticide (*i.e.,* some pesticides are not acutely toxic to adult bees but may be chronically toxic to larval bees based on their mode of action);
- Information regarding bee kill incidents for the pesticide;

- Information indicating the pesticide has been detected in honey bee colonies (*e.g.*, Mullin *et al*. 2010[5], Stoner and Eitzer 2012[6] and USDA 2012[7]);
- Pesticide use patterns with a high potential for contact exposure of bees (*e.g.,* applications at bloom of bee-attractive crops identified through the USDA list[8]);
- Pesticide use patterns that lead to a high potential for oral exposure of bees (*e.g.,* applications at or prior to bloom for systemic pesticides); and
- Pesticide uses on crops that require commercial pollination with managed bees.

3.2 Registration Applications for New Active Ingredients and First Outdoor Uses for Conventional Pesticides

Although the primary mechanism for collecting the bee exposure and effects data needed to develop an updated risk assessment will involve the registration review program, the EPA has also begun to evaluate potential risks to pollinators in an enhanced manner within the context of its registration programs (*i.e.*, registering new active ingredient and new uses of existing chemicals). This transition will occur in two phases. The first phase involves an initial period prior to the codification of the new data requirements, where the EPA will determine whether to require these data on a case-by-case basis as the agency reviews applications for new active ingredients/new uses or will wait to require these data until registration review. The second phase involves the period after which enhanced pollinator data requirements have been codified. In this latter phase, applicants/registrants will be required to submit with applications for registration for a new active/new use which include outdoor uses or the first outdoor use for an existing registration the full suite of laboratory-based pollinator data and pending the outcome of the screening-level assessment possible semi-field and full-field data on bee colonies. Since the EPA is providing early notice through this guidance, and several other means, about its approach to implementing the updated data requirements for pollinators, after promulgation of the final rule, new applications must address all required bee data, without an extended phase in or start-up period.

Registrants have already begun to develop and submit data which are consistent with the *Guidance on Exposure and Effects Testing for Assessing Risks to Bees.* Prior to codification of the data rule, the EPA strongly encourages registrants who submit applications for new conventional active ingredients or first outdoor uses of conventional active ingredients to submit the full suite of studies identified in the 2014 *Guidance*.

If an application for registration of a new conventional pesticide or the first outdoor use for an existing chemical is or has been submitted to the agency prior to the codification of the data requirements, the EPA will review the submission package and consider it for registration. In that circumstance and relative to the risk assessment for pollinators, the EPA will calculate risk quotients (RQs) for honey bees based on the available honey bee data according to the 2014 *Guidance.*

[5]Mullin, C. A., M. Frazier, J. L. Frazier, S. Ashcraft, R. Simonds, D. vanEngelsdorp, and J. S. Pettis. 2010. High Levels of Miticides and Agrochemicals in North American Apiaries: Implications for Honey Bee Health. PLoSONE 5(3): e9754.doi:10.1371/journal.pone.0009754. http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0009754

[6] Stoner, K. A. and B. D. Eitzer. 2013. Using a Hazard Quotient to Evaluate Pesticide Residues Detected in Pollen Trapped from Honey Bees (*Apis mellifera*) in Connecticut. PLoS ONE 8(1): e77550.doi: 10.1371/journal.pone.0077550.

[7]USDA. 2012. APHIS 2011 – 2012 National Honey Bee Pests and Diseases Survey Report. http://www.aphis.usda.gov/plant_health/plant_pest_info/honey_bees/downloads/2011_National_Survey_Report.pdf

[8] *Ibid* USDA 2015.

If risks of concern are identified, various factors will be considered to determine the most appropriate regulatory determination. First, the EPA will evaluate the likelihood of exposure to bees considering whether the proposed uses of the registration action involve bee-attractive crops (based on the USDA list[9]), whether the directions for use allow application when bees may be present (*e.g.*, application at bloom), whether expected usage in agriculture is likely to lead to problematic pollinator exposure scenarios, and whether suitable measures can be identified to mitigate exposure. The EPA will also consider the benefits associated with the registration action to determine whether those benefits outweigh the risks of adverse effects. The burden to support an application for registration is always on the registrant. Therefore, registrants are required to provide enough information on the registration action to support a finding of no unreasonable adverse effects. In order to facilitate the review and any no unreasonable adverse effects determinations, the EPA may request that the registrant submit a Public Interest Finding, efficacy data on key pest management claims, benefits and user alternatives assessments, and/or hazard comparison data, on the proposed chemical compared to registered pesticide alternatives.

When all of the Tier 1 data are not available to evaluate potential exposure and effects to bees, it may be difficult to develop suitable mitigation measures for some compounds (*e.g.*, systemic insecticides) especially when the use is on an indeterminate blooming plant (*e.g.*, cotton, cucurbits) which is attractive to pollinators. If the EPA cannot evaluate the potential exposure and effects to bees, EPA may not be able to make the necessary determination under FIFRA to register the pesticide or the new use.

For new chemical submissions and first outdoor uses where the EPA determines that the benefits outweigh the predicted risks and registration can therefore occur, new bee data might be requested as a condition of registration if it is deemed likely that additional data could adequately inform a useful refinement of risk estimates. For new active ingredients, the EPA may determine it is appropriate to register under FIFRA 3(c)(7)(C) authority, in part, because EPA had not previously determined these data were necessary and the applicant would not have had time to generate the data. For approval of first outdoor new uses and in consultation with the Office of General Counsel, the EPA may determine it is appropriate to require the bee data conditionally under FIFRA 3(c)(7)(B). In determining whether to grant a conditional registration, the risks to pollinators and the potential to mitigate those risks will be considered. Identified risks, uncertainties resulting from any missing data and the anticipated benefits of the new pesticide will be considered in making any conditional registration decision.

As with all new active ingredients, as well as other significant use expansion requests, the EPA will also engage the public about its regulatory decisions as described in http://www2.epa.gov/pesticide-registration/public-participation-process-registration-actions. In this process, the EPA takes public comments on a pre-decisional basis about regulatory positions for new chemicals and other significant actions. The EPA will consider the comments received before making final determinations on these actions. This will enable the EPA to engage the public on its approaches and progress in this area.

Applications submitted after the codification of the data rule will immediately be subject to the new data requirements. Applications for new pesticide ingredients and/or a first outdoor use that are submitted after codification of the final rule without a full set of the Tier 1 data (or alternatively an acceptable waiver request) will be deemed to be incomplete and would fail the screens the EPA conducts for completeness under the Pesticide Registration Improvement Act (PRIA) to determine whether the package meets the necessary data requirements specified in 40 CFR Part 158.

[9] *Ibid* USDA 2015.

PRIA contains both an Initial Content Screen and a Preliminary Technical Screen provision that enables the agency to ensure that registration applications are complete and adequately address the data and labeling requirements such that the EPA review teams would be expected to proceed with its regulatory evaluation on that action. If the Technical Screen for a PRIA action identifies missing data which are necessary and required, the EPA will provide that information to the registrant along with a 10-day deadline for resolving that specific defect(s) or missing data. In the event that the registrant does not adequately address the deficiency in the allotted time, the application would be rejected.

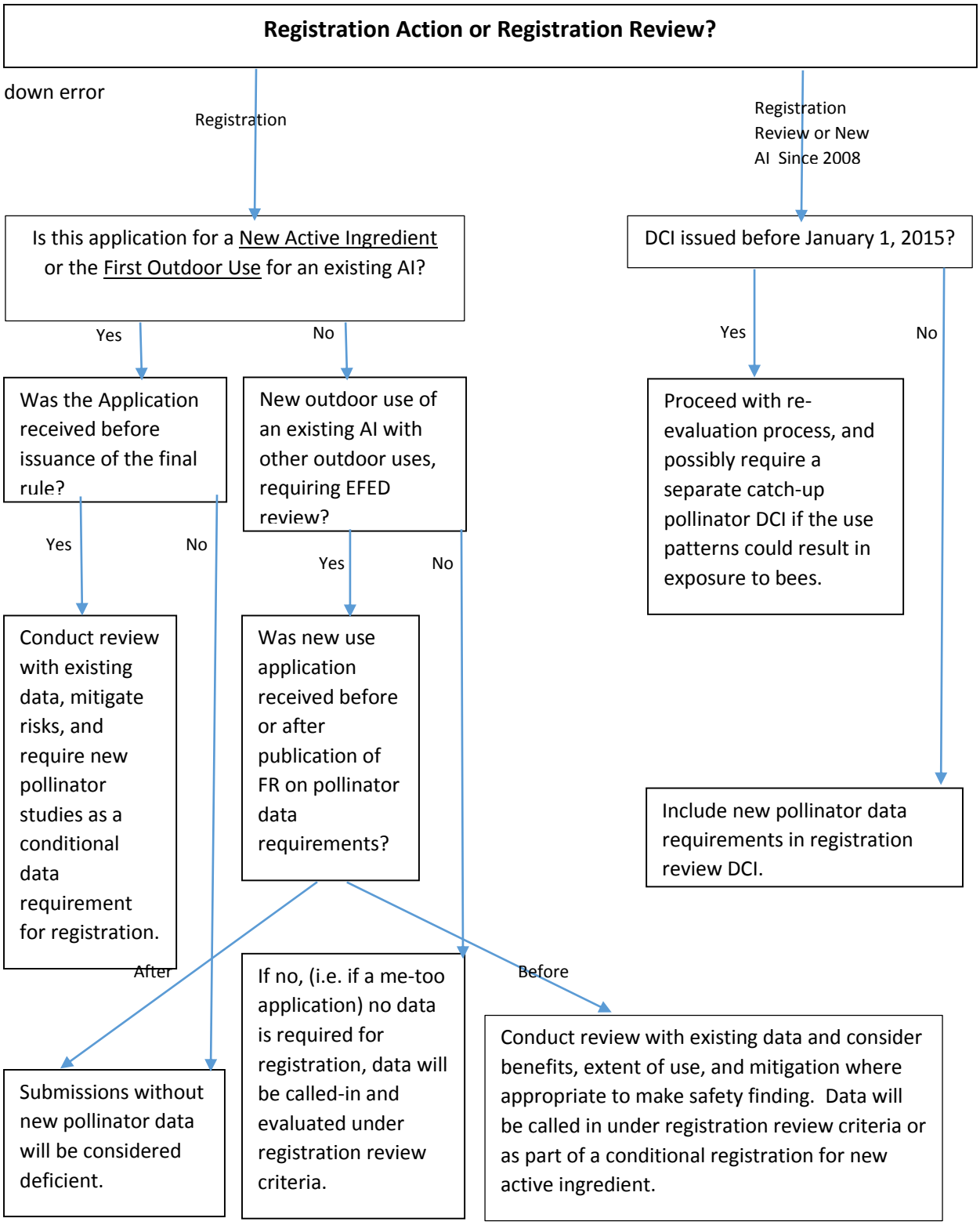
3.3 New Additional Outdoor Uses for Conventional Pesticides

Once the new data requirements are codified in 40 CFR Part 158, registration applications for a pesticide which is already labeled for an outdoor use must contain the Tier 1 bee data, or provide an appropriate waiver rationale as a way of addressing this requirement. Applications that are submitted after codification of the new data requirements without the Tier 1 data will be deemed to be incomplete and fail the completeness screen as previously described in Section 3.2.

If the application for an additional outdoor use is submitted before the issuance of the final rule amending 40 CFR Part 158, the EPA will review the submission package and consider it for registration. Similar to the process described above for new chemicals and first outdoor uses in the preceding section, the EPA will calculate RQs for honey bees based on the available honey bee data. If risks of concern are identified based on the available data, the nature of the missing data, the benefits, alternatives, mitigation options, and decision standards under FIFRA will be considered as previously described in Section 3.2. In the interim period before the final rule is issued, registration applications for existing chemicals will be considered under the current data scheme for pollinators. For existing pesticides, which already have an outdoor use, it is anticipated that additional bee data will be, or will have already been required as part of an existing or new registration review DCI or as part of the conditional registration for the new active ingredient.

Label changes or mitigation measures can occur at any point during an application review or as part of registration review. Implementing changes through the registration review program may avoid users shifting to products that have either not yet adopted mitigation measures or that have not yet been fully evaluated under registration review using the new pollinator data requirements. Notwithstanding the EPA's preference to use registration review to facilitate an orderly review of these data, if the EPA learns of effects to bees that require more immediate attention, the EPA will take appropriate regulatory action.

Appendix 1. Flow-Chart for Assessing the Need for Additional Pollinator Data for New Uses/Chemicals and Registration Review.



Appendix 2. Data Call-in Table Footnotes for Exposure and Effects Studies with Bees

The following list of footnotes should be considered by OPP risk managers for inclusion in data call-in tables for each of the exposure and effect studies identified below. Estimated time frames for study submission are 12 months for all Tier 1 (laboratory-based) studies and 24 months for colony-level Tier 2 and Tier 3 (semi-field and full field colony-level) studies which include an overwintering component in addition to field residue studies.

Tier 1 (Laboratory-based Studies)

850.3020 Acute Contact Toxicity Study with Adult Honey Bees

- USEPA. 2012*a*. "Honey Bee Acute Contact Toxicity" Ecological Effects Test Guidelines OCSPP 850.3020. EPA 712-C-019
- See also OECD 214: OECD.1998*b*. OECD Guidelines for the Testing of Chemicals. Test Number 214, Acute Contact Toxicity Test. http://www.oecd-ilibrary.org/environment/test-no-214-honeybees-acute-contact-toxicity-test_9789264070189-en;jsessionid=43gvto47wnue9.delta

Honey Bee Adult Acute Oral Toxicity

- See the OECD 213: OECD Guidelines for the Testing of Chemicals. Honeybees, Acute Oral Toxicity Test. 213. http://www.oecd-ilibrary.org/environment/test-no-213-honeybees-acute-oral-toxicity-test_9789264070165-en

Honey Bee Larvae Acute Oral Toxicity

- OECD Test Guideline 237 may be used to develop a protocol for this study (OECD. 2013 Guidelines for Testing Chemicals. Honey bee (*Apis mellifera*) larval toxicity test, single exposure.) See: http://www.oecd-ilibrary.org/environment/test-no-237-honey-bee-apis-mellifera-larval-toxicity-test-single-exposure_9789264203723-en

Honey Bee Adult Chronic Oral Toxicity

- OECD has not yet finalized test guidelines for chronic studies, and efforts are underway to develop standardized guidelines for assessing the effects from chronic exposure to adult and larvae in the laboratory. Discussion of the study design elements for the 10-day adult toxicity test can be found in Appendix O of the European Food Safety Authority (EFSA) guidance document: EFSA. 2013. Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees. EFSA Journal 2013;11(7):3295, 266 pp. doi:10.2903/j.efsa.2013.3295.
  Available online at:
  http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2668.pdf
- A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.

Honey Bee Larvae Chronic Oral Toxicity

- OECD has not yet finalized test guidelines for chronic studies with honey bee larvae. OECD draft guidance has is being developed, see OECD 2013*b*. OECD Draft Guidance Document Honey Bee (*Apis mellifera*) Larval Toxicity Test, Repeated Exposure. http://www.oecd.org/env/ehs/testing/Draft_GD_honeybees_rep_exp_for_2nd_CR_25_November_2013.pdf
- A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.

850.3030 Honey Bee Toxicity of Residues on Foliage

- USEPA. 2012*b*. "Honey Bee Toxicity of Residues on Foliage." Ecological Effects Test Guidelines OCSPP 850.3030. EPA 712-C-018.

Tiers 2 and 3 (Semi-field and Full Field Colony-level Studies)

Semi-field testing for pollinators (tunnel or colony feeding studies)

- The need for a semi-field test for pollinators (*i.e.*, either a field-feeding test or a tunnel test) will be determined based upon lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment.
- Formal guidelines for semi-field tests do not yet exist; however, information that can help guide the development of either a semi-field tunnel test protocol can be found at OECD 75, see: OECD. 2007. Series on Testing and Assessment Number 75. Guidance document on the honey bee (*Apis mellifera* L.) brood test under semi-field conditions. Environmental Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. ENV/JM/MONO(2007)22. 31-Aug-2007. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)22&doclanguage=en.
- For field-feeding studies see: Oomen *et al*. 1992: Oomen, P. A. A. DeRuijter and J. Van der Steen. 1992. Method for honey bee brood feeding tests with insect growth-regulating insecticides. Bul OEPP/EPPO Bulletin 22: 613 – 616.
- A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.

850.3040 Field Testing for Pollinators

- The need for a field test for pollinators will be determined based upon lower-tiered tests and/or other lines of data and the need for a refined pollinator risk assessment.
- See information and guidance identified in the EPA documents, (*i*) USEPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment September 11 – 14, 2012. Office of Chemical Safety and Pollution Prevention Office of Pesticide Programs Environmental Fate and Effects Division, Environmental Protection Agency, Washington DC; Environmental Assessment Directorate, Pest Management Regulatory Agency, Health Canada, Ottawa, CN; California Department of Pesticide Regulation; (*ii*) 2014 Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency, California Department of Pesticide Regulation. June 19, 2014. http://www2.epa.gov/sites/production/files/201406/documents/pollinator_risk_assessment_guidance_06_19_14.pdf.
- USEPA. 2012*c*. "Field Testing for Pollinators." Ecological Effects Test Guidelines OCSPP 850.3040. EPA 712-C-017.
- A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.

Residues in Pollen and Nectar/Field Residue Analysis

- Measurements of residues in the pollen/nectar are needed based upon lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment.
- A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. The following elements could be considered when developing study protocol(s) for the monitoring of residues in pollen/nectar.
  - Consideration of the range of application methods and environmental conditions (*e.g.*, soil and hydric regimes) that the target crop(s) may be under.
  - Consideration of the attractiveness of the selected crop to pollinators
  - Consideration of a collection schedule sufficient to allow for an understanding of the character of residues, in the pollen/nectar and/or plant tissues, over time.
  - Consideration of data sufficient to determine whether residues of the active ingredient and/or degradation product(s) accumulates in soil and is/are bioavailable for plant to uptake in a following planting, and therefore result in potential exposure to pollinators.
  - Consideration of the market proportion of the selected target crop(s).
- A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.

Appendix 3. Conventional Chemical Cases Potentially Subject to the Need for Additional Pollinator Data.

Table 1. Conventional Chemicals Likely to Receive Follow-Up Pollinator Data Call-In (DCI) (case name, case #)

Chemicals in this table are subject to a DCI that will require the suite of pollinator data identified in the EPA's 2014 risk assessment framework *Guidance for Assessing Pesticide Risks to Bees*.

- Shaded chemicals have already begun registration review but did not receive a registration review DCI for various reasons. These cases will be reviewed to determine if use patterns would result in exposure to bees and be subject to the subsequent pollinator DCI.
- Highlighted chemicals are those conventional cases that were first registered between 2008 and the time this *Process* document was issued and will be reviewed to determine if use patterns would result in exposure to bees and be subject to the subsequent pollinator DCI.
- Based on currently registered use(s) for some chemicals, the likelihood of exposure to bees may be considered low and additional pollinator toxicity testing may not be triggered.

1,3-Dichoropropene (1,3-D or Telone), 0328	Imazosulfuron, 7281
2,4-D, 0073	Imidacloprid, 7605
2,4-DB, 0196	Imiprothrin, 7426
2,4-DP-p, 0294	Indaziflam, 7278
2-EEEBC (Debacarb), 4031	Indoxacarb, 7613
Abamectin, 7430	Inorganic nitrate/nitrite, 4052
Acephate, 0042	Inorganic sulfites (sulfur dioxide), 4056
Acetaminophen, 7610	Iodosulfuron-methyl-sodium, 7253
Acetamiprid, 7617	Iprodione, 2335
Acetic acid, & salts, 4001	Iron salts, 4058
Acibenzolar-S-methyl, 7031	Isofetamid, 7071
Aldicarb, 0140	Isoxaben, 7219
Allethrin stereoisomers, 0437	Isoxaflutole, 7242
Aluminum phosphide, 0025	Kasugamycin, 7045
Ametoctradin, 7066	Kresoxim-methyl, 7026
Ametryn, 7036	Lactofen, 7210
Aminocyclopyrachlor, 7279	Lambda-Cyhalothrin, 7408
Amitraz, 0234	Linuron, 0047
Antimycin A, 4121	Lufenuron, 7627
Asulam, 0265	Macleaya extract, 7024
Atrazine, 0062	Magnesium phosphide, 0645
Azoxystrobin, 7020	Malathion, 0248
Benfluralin, 2030	Maleic hydrazide, 0381
Bensulfuron-methyl, 7216	Mandipropamid, 7058
Bensulide, 2035	Mepiquat/mepiquat chloride, 2375
Bentazon, 0182	Meptyldinocap, 7061
Benzovindiflupyr, 7072	Mesosulfuron-methyl, 7277

1,3-Dichoropropene (1,3-D or Telone), 0328	Imazosulfuron, 7281
Bicyclopyrone, 7284	Metalaxyl & Mefenoxam, 0081
Bifenazate, 7609	Methiocarb, 577
Bifenthrin, 7402	Methomyl, 0028
Boric acid & sodium borate salts, 0024	Methoxyfenozide, 7431
Bromacil, 0041	Methyl bromide,0335
Bromoxynil & esters, 2070	Methyldithiocarba... (metam-Na), 2390
Buprofezin, 7462	Metofluthrin, 7445
Butralin, 2075	Metrafenone, 7052
Butylate, 0071	Metribuzin, 0181
Captan, 0120	Metsulfuron, 7205
Carbaryl, 0080	MGK-264, 2430
Carbon, carbon dioxide, saw, 4019	MSMA, 2395
Carfentrazone-ethyl, 7422	Naled, 0092
Chlorantraniliprole, 7449	Niclosamide, 2455
Chlorethoxyfos, 7410	Nicosulfuron, 7227
Chlorfenapyr, 7419	Nithiazine (2H-1,3-Thiazine…,7415
Chlorimuron, 7403	Nitrapyrin, 0213
Chloropicrin, 0040	Norflurazon, 0229
Chlorothalonil, 0097	Orthosulfamuron, 7270
Chlorpropham, 271	Oryzalin, 0186
Chlorpyrifos, 0100	Oxalic acid, 7466
Chlorpyrifos-methyl, 8011	Oxamyl, 0253
Chlorsulfuron, 0631	Oxathiaipiprolin, 7073
Clethodim, 7226	Oxydemeton-methyl (ODM), 0258
Clodinafop-propargyl, 7250	Oxytetracycline, 0655
Clofentezine, 7602	Paclobutrazol, 7002
Clomazone, 7203	Paraquat dichloride, 0262
Cloransulam methyl, 7243	Pendimethalin, 0187
Clothianidin, 7620	Penflufen, 7065
Copper compounds, Group II, 0649	Penthiopyrad, 7063
Copper salts, 4026	Permethrin, 2510
Copper sulfate, 0636	Phorate, 0103
Coumaphos, 0018	Phosmet, 0242
Cyanamide, 7005	Phosphine, 7608
Cyantraniliprole, 7462	Phostebupirim, 7606
Cyclanilide, 7018	Picoxystrobin, 7283
Cyflufenamid, 7068	Piperalin, 3114
Cyflumetofen, 7463	Piperonyl butoxide, 2525
Cyfluthrins, 7405	Pirimiphos-methyl, 2535
Cymoxanil, 7023	Polybutene resins, 4076

1,3-Dichoropropene (1,3-D or Telone), 0328	Imazosulfuron, 7281
Cypermethrin, 2130	Prallethrin, 7418
Cyphenothrin, 7412	Primisulfuron-methyl, 7220
Cyprodinil, 7025	Prodiamine, 7201
Cyromazine, 7439	Profenofos, 2540
Daminozide (Alar), 0332	Prohexadione calcium, 7030
Dazomet, 2135	Prometon, 2545
DCPA (chlorthal dimethyl), 0270	Prometryn, 0467
DDVP (Dichlorvos), 0310	Pronamide (Propyzamide), 0082
Deltamethrin, 7414	Propamocarb, 3124
Demiditraz, 7461	Propazine, 7278
Denatonium saccharide (Benz…), 7625	Propetamphos, 2550
Desmedipham, 2150	Propionic acid & salts, 4078
Diazinon, 0238	Propoxur, 2555
Dichlobenil, 0263	Propylene oxide, (PPO) 2560
Dicrotophos, 0145	Prosulfuron, 7235
Diflubenzuron, 0144	Pymetrozine, 7474
Diflufenzopyr, 7246	Pyrethrins & derivs., 2580
Dimethoate, 0088	Pyridaben, 7417
Dimethomorph, 7021	Pyridalyl, 7451
Dimethyl disulfide (DMDS), 7454	Pyrifluquinazon, 7458
Dinotefuran, 7441	Pyrimethanil, 7059
Dioctyl sodium sulfosuccinate, (DSS) 4029	Pyrimidinone (Hydramethylnon),2585
Dipropyl isocinchomeronate, 2215 (MGK 326)	Pyriproxyfen, 7424
Diquat dibromide, 0288	Pyrithiobac sodium, 7239
Dithiopyr, 7225	Pyroxasulfone, 7282
d-Limonene, 3083	Pyroxsulam, 7275
Emamectin benzoate, 7607	Quinclorac, 7222
EPTC, 0064	Quinoxyfen, 7037
Esfenvalerate, 7406	Quizalofop, 7215
Ethaboxam, 7053	Rimsulfuron, 7218
Ethalfluralin, 2260	Saflufenacil, 7277
Ethephon, 0382	Sedaxane, 7070
Ethoprop, 0106	Silica & silicates, 4081 (silicon dioxide)
Etofenprox, 7407	Simazine, 7280
Fenarimol, 7001	Soap salts, 4083
Fenazaquin, 7447	Sodium acifluorfen, 2605
Fenbutatin oxide (Vendex), 245	Sodium cyanide, 8002
Fenhexamid, 7027	Sodium metabisulfite, 7019
Fenitrothion, 0445	Sodium tetrathiocarbonate, 7009
Fenoxaprop-p-ethyl, 7209	Spinetoram, 7448

1,3-Dichoropropene (1,3-D or Telone), 0328	Imazosulfuron, 7281
Fenoxycarb, 7401	Spinosad, 7421
Fenpropathrin, 7601	Spirotetramat, 7452
Fenpyrazamine, 7459	Starlicide, 2610
Fipronil, 7423	Streptomycin, 0169
Flazasulfuron, 7271	Sulfentrazone, 7231
Fluazinam, 7013	Sulfometuron-methyl, 3136
Flubendiamide, 7450	Sulfosulfuron, 7247
Flucarbazone-sodium, 7251	Sulfoxaflor, 7460
Fludioxonil, 7017	Sulfuryl fluoride, 0176
Fluensulfone, 7464	Sumithrin (phenothrin), 0426
Flufenacet, 7245	Tau-fluvalinate, 2295
Flumetsulam, 7229	Tebufenozide, 7416
Flumiclorac-pentyl, 7232	Tebuthiuron, 0054
Flumioxazin, 7244	Tefluthrin, 7409
Fluopicolide, 7055	Temephos, 0006
Fluopyram, 7067	Terbacil, 0039
Fluoroacetic acid derivatives, 3073	Terbufos, 0109
Flupyradifurone, 7465	Tetrachlorvinphos, 0321
Fluridone, 7200	Tetramethrin, 2660
Flurprimidol, 7000	TFM/lamprecide, 3082
Fluthiacet-methyl, 7245	Thiamethoxam, 7614
Flutolanil, 7010	Thidiazuron, 4092
Flutriafol, 7060	Thiencarbazone, 7276
Fluxapyroxad, 7064	Thifensulfuron, 7206
Folpet, 0630	Thiobencarb, 2665
Fomesafen, 7211	Thiodicarb, 2675
Foramsulfuron, 7252	Tolclofos-methyl, 7069
Formetanate HCl, 0091	Tolfenpyrad, 7453
Fosamine ammonium, 2355	TPTH (fentin hydroxide), 0099
Fosetyl-Al (Aliette), 0646	Triasulfuron, 7221
Fosthiazate, 7604	Tribenuron methyl, 7217
Gamma-Cyhalothrin, 7437	Tribufos (DEF), 2145
Glufosinate ammonium, 7224	Trichlorfon, 0104
Glyphosate, 0178	Trifloxystrobin, 7028
Gonadotropin releasing hormone, 7800	Trifloxysulfuron-sodium, 7260
Halosulfuron-methyl, 7233	Triflumizole, 7003
Hexaflumuron, 7413	Trifluralin, 0179
Hexazinone, 0266	Triflusulfuron, 7236
Hexythiazox, 7404	Trinexapac-ethyl, 7228
Hymexazol, 7016	Undecylenic acid, (UDA) 4095

1,3-Dichoropropene (1,3-D or Telone), 0328	Imazosulfuron, 7281
Imazalil & Imazalil sulfate, 2325	Urea sulfate (1:1), 7213
Imazapyr, 3078	Zonastat-H,7801

Table 2. Conventional Chemicals that Received or Will Receive a Registration Review Data Call-In (DCI) after January 1, 2015 (case name, case #)

Chemicals in this table have already received or will receive a registration review DCI that received consideration of the 2014 *Guidance* and contains the suite of pollinator data.

4-Aminopyridine, 0015	Ipconazole, 7041
Acequinocyl, 7621	Mancozeb, 0643
Acetochlor, 7230	MCPA, 0017
Acrolein, 2005	MCPB, and salts, 2365
Alachlor, 0063	Mecoprop-p (MCPP-p), 0377
Aliphatic alcohols C6-C16, 4004	Mefluidide, 2370
Aliphatic esters, 4005	Mesotrione, 7256
Aliphatic solvents, 3004	Metaflumizone, 7446
Amicarbazone, 7269	Metaldehyde, 0576
Aminopyralid, 7267	Metconazole, 7049
Anthraquinone, 6054 (122701)	Metiram, 0644
Bispyribac-sodium, 7258	Metolachlor & s-metolachlor, 0001
Boscalid, 7039	Momfluorothrin, 7457
Brodifacoum, 2755	Myclobutanil, 7006
Bromadiolone, 2760	Napropamide, 2450
Bromethalin, 2765	Naptalam, 0183
Bromuconazole, 7035	Napthalene, 0022
Butafenacil, 7261	Napthaleneacetic acid, 0379
Carbofuran	Nicarbazin, 7628
Carboxin, 0012	Novaluron, 7615
Chlorflurenol, 2095	Oxadiazon, 2485
Chlormequat chloride, 7069 (018101)	Oxyfluorfen, 2490
Chlorophacinone, 2100	PCNB, 0128
Cholecalciferol, 7600	p-Dichlorobenzene, 3058
Clopyralid, 7212	Penoxsulam, 7265
Cryolite, 0087	Phenmedipham, 0277
Cyazofamid, 7056	Picloram, 0096
Cycloate, 2125	Pinoxaden, 7266
Cyproconazole, 7011	Polyethoxylated alcohols, 3119
DCNA, 0113	Polypropylene glycol, 3123
Derivs. of benzoic acid, 4013	Propachlor, 0177
Dicamba, 0065	Propanil, 0226
Diclosulam, 7249	Propargite, 0243
Difenacoum, 7630	Propiconazole, 3125
Difenoconazole, 7014	Propoxycarbazone-sodium, 7264
Difethialone, 7603	Prothioconazole, 7054
Dikegulac sodium, 3061	Pyraclostrobin, 7034

4-Aminopyridine, 0015	Ipconazole, 7041
Dimethenamid, 7223	Pyraflufen-ethyl, 7259
Diphacinone, & salts, 2205	Pyrasulfotole, 7272
Diphenylamine, 2210	Rotenone, 0255
Diuron, 0046	Sabadilla alkaloids, 3128
Dodine, 0161	Sethoxydim, 2600
Endothall, & salts, 2245	Siduron, 3130
Ethofumesate, 2265	Spirodiclofen, 7443
Etoxazole, 7616	Spiromesifen, 7442
Etridiazole (Terrazole), 0009	Spiroxamine, 7040
Famoxadone,7038	Strychnine, 3133
Fenamidone, 7033	Sulfur, 0031
Fenbuconazole, 7012	Tebuconazole, 7004
Fenpyroximate, 7432	Tembotrione, 7273
Ferbam, 2180	Tetraconazole, 7043
Flonicamid, 7436	Thiabendazole, and salts, 2670
Florasulam, 7274	Thiophanate-methyl & carbendazim, 2680
Fluazifop-butyl, isomers, 2285	Thiram, 0122
Flumethrin, 7456	Topramezone (BAS 670H), 7268
Flumetralin, 4119	Triadimefon, 2700
Fluometuron, 0049	Triadimenol, 7008
Fluoxastrobin, 7044	Triallate, 2695
Fluroxypyr, 1-methylheptylester, 7248	Triclopyr, salts & esters, 2710
Forchlorfenuron, 7057	Triforine, 2720
Furfural, 7050	Triticonazole, 7036
Imazamox, 7238	Uniconazole, 7007
Imazapic, 7234	Warfarin & Na salt, 0011
Imazaquin, 7204	Xylene (aromatic solvents), 3020
Imazethapyr, 7208	Zinc phosphide, 0026
Inorg. chlorates (Na chlorate), 4049	Ziram, 8001
Inorganic polysulfides, 4054	Zoxamide, 7032

Table 3. Chemicals that will Not Receive a Data Call-In (DCI) Requiring Pollinator Data (case name, case #)

Chemicals in this table will not receive a subsequent DCI because they either have no exposure potential to bees, have no US registrations, or the pesticide case has been voluntarily cancelled.

1 RS, cis-permethrin, 7429	Maneb, 0642
2-Hydroxyethyl octyl sulfide, 8005	Mepanipyrim, 7042
4-CPA, and salts, 2115	Methamidophos, 0043
Aldoxycarb, 7624	Methidathion, 0034

1 RS, cis-permethrin, 7429	Maneb, 0642
alpha-Chlorohydrin, 7629	Methyl parathion, 0153
Amitrole, 0095	Mevinphos, 0250
Ancymidol, 3017	Milbemectin, 7623
Aquashade, 4010	Mitin FF, 3097
Azinphos-methyl (AZM), 0235	Molinate, 2435
Bitertanol, 8007	Neodecanamide, N-methyl, 7428
Bitrex, 8010	Noviflumuron, 7434
Cacodylic acid, & salts, 2080	Phosalone, 0027
Chloroneb, 0007	Picaridin, 7433
Clofencet, 7015	Pirimicarb, 7438
Cyhalofop-butyl, 7255	PT807-HCl (Diethyl-2-(4-meth..), 7029
Cyhexatin, 0237	Pyrazon, 2570
Deet, 0002	Pyridate, 7214
Diclofop-methyl, 2160	Resmethrin, 0421
Dicofol, 0021	Sulfluramid, 7411
Difenzoquat, 0223	Sulfonic acids, C14-16-al & C-14-16 al, 7618
Dimethepin, 3063	Sulfosate, 7202
Disulfoton, 0102	Tall oil fatty acids, K salts, 7612
Dithianon, 7048	Tanol derivs. (furanones), 3138
Endosulfan, 0014	Tebufenpyrad, 7435
Ethametsulfuron-methyl, 7254	Tepraloxydim, 7257
Ethoxyquin, 0003	Terpineols, 3139
Fenamiphos, 333	Thiacloprid, 7622
Fenvalerate, 2280	Thiazopyr, 7240
Flufenoxuron, 7444	Thiophanate-ethyl, 0378
Flufenpyr-ethyl, 7262	Tralkoxydim, 7237
Halofenozide, 7425	Tralomethrin, 7400
Imazamethabenz, 7207	Tridemorph, 8009
Inorg. thiosulfates (Ca thio..), 4057	Urea, 4096
Iodomethane (methyl iodide), 7321	Vinclozolin, 2740
Lindane, 0315	Yellow mustard seed, 7619