U.S. ENVIRONMENTAL PROTECTION AGENCY'S POLICY TO MITIGATE THE ACUTE RISK TO BEES FROM PESTICIDE PRODUCTS

U.S. Environmental Protection Agency

Office of Pesticide Programs

January 12, 2017

DISCLAIMER

This policy represents the EPA's recommended labeling statements to mitigate acute risks to bees from pesticide products. This policy is not a regulation or an order and, therefore, does not legally compel changes to pesticide product registrations. Absent voluntary action from pesticide registrants to adopt the labeling language recommended in this policy, the EPA can only compel changes to pesticide product labeling through the procedures specified in the Federal Insecticide, Fungicide and Rodenticide Act. Accordingly, this document is not intended, nor can it be relied on, to create any obligations or rights enforceable by any party in litigation with the United States. The EPA may decide to follow the policy provided in this document, or to act at variance with the policy, based on analysis of specific circumstances when reviewing specific pesticide products.

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1 Executive Summary

On May 29, 2015, the U.S. Environmental Protection Agency (EPA) published its *Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products* (hereafter referred to as the Proposed Acute Risk Mitigation Strategy). In the Proposed Acute Risk Mitigation Strategy, the EPA described additional pesticide label restrictions to protect managed bees under contract pollination services from foliar applications of pesticides that are acutely toxic to bees on a contact exposure basis[1]. The proposed restrictions would prohibit applications of pesticide products that are acutely toxic to bees, during bloom where honey bees (*Apis mellifera*) are known to be present under contract for pollination services. The EPA also encouraged the efforts by states and tribes to reduce pesticide exposures through development of locally-based measures, such as through Managed Pollinator Protection Plans (MP3s). The EPA requested comment on the label restrictions, MP3s, and areas of uncertainty described in the proposal.

The EPA received and reviewed numerous comments submitted on the Proposed Acute Risk Mitigation Strategy and also conducted an analysis of potential impacts to growers. Based upon public comments and its analysis, the EPA has made modifications to its approach with the goal of better targeting compounds that pose an acute risk, and with the goal of reducing potential impact of this effort on growers. The EPA is now finalizing its approach to mitigate acute risk to bees. In general, the EPA will use its Tier 1 acute risk assessment to, in part, determine the products that trigger concerns about pollinator risk that the label restrictions are intended to address. The EPA's Tier 1 acute risk assessment is a quantitative analysis that relies upon conservative exposure values and chemical specific hazard information (the adult acute contact LD_{50} in this case) to estimate risk. Using the Tier 1 acute risk assessment methodology will more accurately identify, through a quantitative process, compounds of potential acute risk to bees. Recognizing that some pesticides may have a demonstrated low residual toxicity and that certain crops that have extended blooming periods, EPA has developed some exceptions to the label restrictions intended to allow greater flexibility in these instances but still provide protection for bees. In this document, *Policy to Mitigate the Acute Risk to Bees from Pesticide Products* (hereafter referred to, as the Policy), the EPA provides an exception for products with short residual toxicity times to allow for their use during hours that will reduce the likelihood of acute effects from exposure to residues of these products. This Policy also provides an exception for crops with extended bloom periods to allow applications during hours when bees are less likely to be foraging in order to ensure that acute risk to pollinators is reduced while providing options for grower to meet their pest management needs.

The EPA continues to support the development of managed pollinator protection plans (MP3s) by states and tribal nations. The EPA will continue to monitor the progress and effectiveness of MP3s and other Pollinator Protection Plans in reducing pesticide exposure to bees. The EPA has

[1] Acutely toxic is defined as a pesticide with a 48 – 96-hr median lethal contact dose to 50% of the bees tested (LD_{50}) of less than 11 micrograms per bee (LD_{50}<11 μg/bee).

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established a workgroup under its Pesticide Program Dialogue Committee (PPDC)[2] to develop performance metrics to gauge the efficacy of MP3s.

This Policy describes the EPA's approach to mitigate acute risk from pesticides to bees. A summary of the Policy is presented below.

- The EPA will generally use its Tier 1[3] acute risk assessment process as a means to identify pesticide products and specific labeled uses which fall within the scope of this Policy. The EPA will generally use the honey bee acute risk level of concern (LOC) based on contact exposure of 0.4[4] (risk quotient (RQ) >0.4) to determine whether a product application rate falls within the scope of this Policy. The following are used to determine the applicability of this Policy for uses of pesticide products:
  (1) liquid or dust formulations as applied;
  (2) outdoor foliar application on agricultural crop(s) that may utilize contract pollination services; and,
  (3) maximum application rate(s).

- See Appendix C for a list of crops that may utilize contract pollination services[5].

- The EPA generally intends that the labels for all products applied as either a liquid or dust, with outdoor foliar use(s) on crops that may utilize commercial pollination services at application rates that result in acute contact RQs that exceed the acute risk LOC of 0.4 for bees, be amended to include the acute risk mitigation restriction as follows:

  FOR FOLIAR APPLICATIONS OF THIS PRODUCT TO A CROP WHERE BEES ARE UNDER CONTRACT TO POLLINATE THAT CROP: Foliar application of this product is prohibited to a crop from onset of flowering until flowering is complete when bees are under contract for pollination services to that crop unless the application is made to prevent or control a threat to public and/or

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[2] The Pesticide Program Dialogue Committee is an EPA Federal Advisory Committee Act (FACA) group of EPA's Office of Pesticide Programs.

[3] For more information on EPA's Tier I acute risk analysis, please see, EPA's *Guidance for Assessing Pesticide Risks to Bees*

[4] The acute risk level of concern (LOC) is exceeded when the ratio (referred to as the risk quotient [RQ]) of exposure dose to the LD_{50} value exceeds 0.4. (the exposure level at which 50% of exposed bees die) exceeds 0.4. In other words, when bees may be exposed to a pesticide at or above a level that is 40% of the dose that caused one half of bees to die in relevant acute toxicology studies, EPA believes such exposures present a risk of concern and it evaluates the need for additional risk mitigation. Additional information on acute risk LOC for bees can also be found in EPA's *Guidance for Assessing Pesticide Risks to Bees*, see: https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

[5] EPA uses multiple lines of information to understand the potential for a crop to rely upon, or be attractive to bees, and therefore may utilize commercial pollination services including the USDA document, *Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen*.

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animal health as determined by a state, tribal, authorized local health department or vector control agency.

- In order to increase flexibility for growers to meet their pest control needs while still protecting bees, the EPA will generally allow the acute risk mitigation restriction (above) to be amended for products subject to this Policy, if product-specific toxicity of residues on foliage data (OCSPP 850.3030)[6] are submitted, found acceptable, and indicate a residue toxicity (RT_{25})[7] time of 6 hours or less ($RT_{25} \leq 6$ hrs.). In these situations, the EPA believes that it is generally appropriate to amend the acute risk mitigation restriction to the following:

  FOR FOLIAR APPLICATIONS OF THIS PRODUCT TO A CROP WHERE BEES ARE UNDER CONTRACT TO POLLINATE THAT CROP: This product has been determined to have a short residual toxicity (RT_{25}) time. Foliar application of this product is prohibited to a crop from onset of flowering until flowering is complete when bees are under contract for pollination services to that crop unless:

  (i) The application is made to prevent or control a threat to public and/or animal health as determined by a state, tribal, authorized local health department or vector control agency; OR,

  (ii) The application is made in the time period between 2-hours prior to sunset and 8 hours prior to sunrise.

- Based upon its analysis examining the potential economic impacts of the acute risk mitigation measures, *Impact Estimates from Proposed and Revised Pollinator Labeling for Representative Blooming Agricultural Crops Utilizing Commercial Pollination Services*, (USEPA, January 2017), the EPA will generally permit modification of the label restriction for crops that utilize commercial pollination services **and** have an indeterminate[8] blooming period. Pesticide applications to such crops may be made during specified time windows or under certain temperatures conditions. The indeterminate blooming crops for which the modification to the acute risk mitigation language applies are identified in Appendix C and includes but is not limited to crop such as:
  - Crops grown for seed, such as groundcovers, forages, oilseed, and fruit/vegetable crops.
  - Strawberries

[6] USEPA 2012. Ecological Effects Test Guidelines OCSPP 850.3030: Honey Bee Toxicity of Residues on Foliage. Office of Chemical Safety and Pollution Prevention (7101). EPA 712-C-018. January 2012.

[7] The RT_{25} is defined as the exposure time required to result in 25% mortality to bees exposed via contact to weathered residues on foliage.

[8] EPA uses the term "indeterminate bloom" to indicate crops that bloom either continuously or intermittently for multiple weeks and/or for most of the crop's growing season that bloom for longer than four consecutive weeks.

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- Cucurbits (such as melons, cucumbers, squash, pumpkins)
- Oilseed crops (including sunflower)
- Avocado

- If the stated criteria of this Policy are met, and the use of the subject product is to one of the crops listed above, the EPA believes that it is generally appropriate to amend the acute risk mitigation restriction to the following:

  FOR FOLIAR APPLICATIONS OF THIS PRODUCT TO A CROP WHERE BEES ARE UNDER CONTRACT TO POLLINATE THAT CROP: Foliar application of this product is prohibited to a crop from onset of flowering until flowering is complete when bees are under contract for pollination services to that crop unless:

  (i) the application is being made to prevent or control a threat to public and/or animal health as determined by a state, tribal, authorized local health department or vector control agency; OR,
  (ii) the application is being made in the time period between 2-hours prior to sunset until sunrise; OR,
  (iii) the application is being made at a time when the temperature at the application site is 50°F or less.

- This Policy provides a brief discussion of several of the key terms of the acute risk mitigation restriction.

- To implement this Policy, the EPA has identified the active ingredients for which there are products that (i) are applied as either a liquid or a dust; and (ii) have foliar applications to an agricultural site that may utilize managed bees for contract pollination services. Because this list is large, the EPA intends to issue this list in three groups. Appendix A to this Policy identifies the Group 1 active ingredients that are subject to this Policy, and identifies the application rate for each of those active ingredients above which the Tier 1 acute risk LOC is exceeded.

- Environmental Hazards Language for Pollinating Insects. The EPA did not discuss environmental hazards language in its Proposed Acute Risk Mitigation Strategy. However, considering comments the EPA has received in the past and in response to the Proposed Acute Risk Mitigation Strategy, to ensure that labels being revised pursuant to this Policy are clear and consistent, the EPA is modifying the environmental hazards language pertaining to non-target organisms[9]. The EPA intends that product labels submitted in accordance with this Policy are also revised to reflect updated *Environmental Hazards - pollinating insect hazards* language. The EPA will update its

[9] See Chapter 8 of the EPA Label Review Manual

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Label Review manual and will implement this new language, through both its registration and registration review programs:

> Environmental Hazards Language for Pollinating Insects. *This product is [moderately/highly] toxic to bees and other pollinating insects exposed to direct treatment, or to residues in/on blooming crops or weeds. Protect pollinating insects by following label directions intended to minimize drift and to reduce risk to these organisms.*

- For other pesticide exposure scenarios where bees are within the forage area or pollinating adjacent crops, the EPA will continue to monitor the progress and effectiveness of MP3s and other Pollinator Protection Plans in reducing pesticide exposure to bees.

2 Background

On May 29, 2015, the EPA published its Proposed Acute Risk Mitigation Strategy. In that notice, the EPA proposed label language that would prohibit foliar applications of liquid or dust formulations of moderately to highly toxic pesticides, where the acute contact LD_{50} [10] is less than 11 micrograms per bee (LD_{50} <11 µg ai/bee), during bloom for sites with bees onsite under contract, unless the application is made in accordance with a government-declared public health response. Additionally, the proposal encouraged the development of MP3s by states and tribes to foster communication between growers/applicators and beekeepers to further reduce the likelihood of exposure for all other uses. The EPA requested comment on the proposed label restrictions, MP3s, and areas of uncertainty described in the Proposed Acute Risk Mitigation Strategy.

The EPA received roughly 113,000 responses following a 90-day comment period, which closed on August 28, 2015. In drafting the final policy to mitigate acute risk to bees, the EPA has considered public comments it received and other lines of information, including its economic impacts analysis, *Impact Estimates from Proposed and Revised Pollinator Labeling for Representative Blooming Agricultural Crops Utilizing Commercial Pollination Services* (USEPA, January 2017). The EPA's impact analysis considers comments in response to the Proposed Acute Risk Mitigation Strategy, and also contains information and analysis on some crops for which public comments were not received. The Policy reflects input from public comments, but does not include a discussion of all the comments it received. For a discussion of all comments and the EPA's response please see, *Response to Public Comments Submitted on The Environmental Protection Agency's Proposal to Mitigate Exposure to Bees from Acutely*

[10] LD_{50} is the median lethal dose of a product to 50% of the adult bees tested.

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Toxic Pesticide Products. EPA is now presenting its final Policy to Mitigate Exposure to Bees from Acute Risk from Pesticide Products.

3 Label restriction for applications to crops with bees present under contract for pollination services

Based on the comments received and the impact assessment, EPA has revised the language of the acute risk mitigation restriction and the criteria that trigger this restriction. The revised language is intended to be clearer, and the revised criteria are intended to reduce the potential economic costs to growers from this Policy. EPA has also developed alternative label language in order to provide greater flexibility for growers to protect crops while mitigating acute risk to bees for certain pesticides or crops. The EPA believes that through this Policy pesticide exposure to bees under the conditions most likely to lead to acute risk will be reduced. The EPA believes that the adjustments made to the proposal that are contained in this final Policy will reduce potential economic impact from these efforts. While the mitigation outlined in this policy focuses on managed bees under contract pollination services, EPA believes that in protecting managed bees, these measures would also protect native solitary and social bees that are also in and around treatment areas. This Policy, as well as EPA's support for development of state and tribal MP^3s, is consistent with the President's directive and the National Strategy to Promote the Health of Honey Bees and Other Pollinators[11], which addresses the multiple factors affecting honey bees and pollinator health.

3.1 Scope and Criteria for Acute Risk Mitigation Language

This Policy generally applies to all products (Section 3, 24(c) Special Local Need registrations and where applicable, Section 18 emergency exemption petitions[12]) that meet all of the following criteria:

(1) liquid or dust formulations as applied; and

(2) outdoor foliar use directions on agricultural crop(s) that may utilize contract pollination services[13] ; and,

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[11] See: https://www.whitehouse.gov/sites/default/files/microsites/ostp/Pollinator%20Health%20Strategy%202015.pdf

[12] Depending on the nature of the emergency for which a Section 18 petition has been submitted, the at-bloom restriction may not apply. This determination will be made on a case-by-case basis.

[13] EPA may use multiple lines of information, including the USDA document, *Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen*, to determine whether a labeled use site may or may not utilize contract pollination services. The USDA list of pollinator-attractive crops is built upon an effort that

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(3) maximum application rate(s) that result in risk estimates that exceed the acute risk LOC for bees of 0.4 (based on contact exposure).

For this Policy, the EPA has identified the active ingredients for which there are products that (i) are applied as either a liquid or a dust; and (ii) have foliar applications on agricultural crops that may utilize contract pollination services. Because this list of compound is long, and to help manage the work of amending pesticide labels the EPA has divided this list into t three groups. For each active ingredient in Group 1, the EPA has identified the application rate above which the Tier 1 acute risk LOC is exceeded. The acute risk LOC of 0.4 is based on the maximum label application rate (as discussed in EPA's *Guidance for Assessing Pesticide Risk to Bees*) and the chemical-specific acute contact toxicity value (*i.e.*, LD_{50}). The acute risk LOC analysis for Group 1 conventional active ingredients used in support of this Policy is presented in Appendix A. In the future, as it continues to implement this Policy, the EPA will identify the active ingredients of Group 2 and Group 3.

The label restrictions outlined in this Policy would not replace more restrictive chemical-specific, bee-protective provisions (*e.g.*, pre-bloom restrictions) that may already be included on a product label. For example, based on a chemical-specific assessment, the EPA may have determined that the residues of a pesticide measured in pollen and nectar warrant that an application be prohibited for a crop or crops for a period of time prior to bloom (*i.e.*, a pre-bloom restriction) in addition to prohibitions during bloom, to mitigate the potential risk to bees. The EPA generally intends to carry out this Policy by seeking to have pesticide registrants with products that meet the three criterion identified in this Policy submit revised labels. EPA will review all labels and make a determination, on a case-by-case basis, whether the acute risk mitigation restriction is needed or not for that label and whether, in cases where specific pollinator-protection language exists on a label (*i.e.*, pollinator protection language predicated on a chemical-specific risk assessment), such language should be retained in favor of the label language outlined in this policy.

In this Policy, the EPA refers to honey bees as the bee most associated with commercial pollination services. However, the EPA is aware that other species, such as the orchard mason bee (*Osmia lignaria*), the leafcutter bee (*Megachile rotundata*), and the bumble bee (*Bombus impatiens*), may also be employed for contracted pollination services. This Policy applies to any bee species that is contracted for pollination services.

The EPA's intent of this Policy is to protect bees that provide pollination services from acute risks of pesticide products. The EPA intends that through chemical-specific analyses, and not this Policy, it will assess other potential pesticide risks to bees (such as chronic risk through the dietary route of exposure). The EPA will conduct comprehensive chemical-specific risk

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was initially developed by the European Food Safety Administration (EFSA) as an Appendix to their *Guidance Document on the Risk Assessment of Plant Protection Products on Bees (Apis mellifers, Bombus spp. and solitary bees)*

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assessments and take appropriate action to mitigate risks through the registration and registration review programs based on the best available science. In this Policy, the EPA has identified measures intended to allow flexibility so growers protect bees from acute contact risks while meeting their pest management needs. As in the past, the EPA is open to, and will work with stakeholders to identify or develop other options that mitigate potential risks from pesticide products while maintaining these tools in order to protect crops.

3.2 Using EPA's Tier 1 Acute Risk Assessment as a Criterion to Determine Pesticide Products with Potential Acute Risk to Bees

In the proposal, one of the criteria for determining whether a pesticide product would be subject to the Policy was its hazard classification as either "highly" or "moderately" toxic to bees based on acute contact exposure, *i.e.,* those pesticides with an LD_{50} <11 µg/bee, based on either the acute contact toxicity test following OCSPP Guideline 850.3020 or its equivalent test in Europe (*i.e.*, OECD 214[14]). During the public comment period, the EPA received a number of comments regarding the use of hazard category (of a compound) as one of three criteria to identify which pesticide compounds would or would not be subject to the acute risk mitigation restrictions (*i.e.*, whether or not an active ingredient has an acute contact LD_{50} <11 µg/bee). A number of commenters argued that the EPA based its proposed action on hazard (*i.e.*, toxicity) rather than a quantified risk approach, where both hazard and exposure are taken into consideration, and noted that such an approach would be inconsistent with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which is a risk-based statute. These commenters therefore urged the EPA to consider a quantitative risk-based approach that considered both hazard and exposure.

While the proposed approach did not involve a quantitative risk analysis, it did consider both hazard (*i.e.*, active ingredients that are acutely toxic) and exposure as the proposed approach applied to use scenarios where exposure to managed bees is almost certain since large numbers of bees are intentionally brought into the application site. Nonetheless, the EPA recognizes the merits of this comment. A more quantitative risk-based approach could more accurately target risk by capturing risk scenarios which may have been missed by the EPA's initial proposal (*e.g.*, for an active ingredient that is of low toxicity but high application rate) and by not presuming risk where it may not exist (*e.g.*, for an active ingredient of high toxicity but low application rate). The EPA agrees that a quantitative risk-based approach would be more consistent with its intent by better targeting pollinator protection while minimizing impacts on growers to protect crops.

Therefore, for this Policy, the EPA will use its Tier 1 acute risk LOC as one of the criteria for applicability of this Policy to a pesticide product. The EPA will identify a threshold application rate above which the acute risk mitigation label restriction, identified in this Policy, will

[14] Organization for Economic Cooperation and Development (OECD) 1998. OECD Guidelines for the Testing of Chemicals. Test Number 214, Acute Contact Toxicity Test.

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generally apply. The EPA's Tier 1 acute risk assessment process relies on chemical-specific adult honey bee acute contact toxicity data (LD_{50} data) and conservative contact exposure estimates for foliar applications. The EPA relied upon its Tier 1 acute contact risk assessment approach to determine the threshold application rate for each active ingredient, applied either as a liquid or dust, that includes foliar application instructions for use on an agricultural crop that may utilize contract pollination services. Discussion of the Tier 1 exposure assumptions can be found in the EPA's EPA's *Guidance for Assessing Pesticide Risks to Bees*.

Since this revised approach (using the Tier 1 acute risk assessment) more accurately reflects potential risk based on both hazard and quantified exposure, the Policy is no longer limited in scope to just those conventional pesticide products that are "highly toxic" and "moderately toxic". Rather, the Policy applies to all conventional pesticide active ingredients that are applied as either a liquid or a dust and that are foliar applied to a crop that may utilize commercial pollination services. This is because an active ingredient of low acute contact toxicity may be applied at an application rate that results in an estimated acute RQ greater than 0.4, and conversely, an active ingredient of high acute contact toxicity may be applied at a rate that results in an estimated acute RQ less than 0.4.

Based upon chemical-specific adult honey bee acute contact toxicity data and the EPA's Tier 1 default exposure assumptions, a maximum application rate for each conventional pesticide active ingredient will be identified, above which the Tier 1 acute risk estimate would exceed the acute LOC of 0.4 for adult bees. Therefore, labeled use(s) of a pesticide product to a crop that may use bees under contract for pollination, at a rate above the identified threshold would exceed the EPA's acute risk threshold of 0.4 are subject to the acute risk mitigation language identified in this Policy (below). See Appendix A for the threshold analysis and inputs to that analysis, and see Appendix B for a list of crop groups and example crops that may use bees under contract for pollination.

The Acute Risk Mitigation Label Language:

> The EPA intends that all labels for products that (1) are applied as either a liquid or a dust; (2) are foliar applied outdoors to agricultural crop(s) that may utilize contract pollination services; and (3) have an application rate(s) that result in risk estimates exceeding the acute risk LOC of 0.4 for bees, be amended to reflect the acute risk mitigation language below.
>
> > FOR FOLIAR APPLICATIONS OF THIS PRODUCT TO A CROP WHERE BEES ARE UNDER CONTRACT TO POLLINATE THAT CROP: Foliar application of this product is prohibited to a crop from onset of flowering until flowering is complete when bees are under contract for pollination services to that crop unless the application is made to prevent or control a threat to public and/or animal health as determined by a state, tribal, authorized local health department or vector control agency.

3.3 Flexibility in the Acute Risk Mitigation Policy

In the EPA's Proposed Acute Risk Mitigation Strategy, the only exception included in the acute risk mitigation language was for the application of a product under a government-declared public health response. During the comment period, a number of comments were received from a wide range of stakeholders, including both beekeepers and growers, urging the EPA to provide greater flexibility in the strategy.

It is the EPA's goal to mitigate acute risk to bees while limiting impacts to agriculture in terms of either decreased yields or increased production costs, where appropriate. Therefore, in consideration of comments received and to better account for the variability in pollinator risks and impacts on crop production, the EPA has revised its approach to be more flexible by providing specific exceptions to the acute risk mitigation label restriction. In addition to the exception for applications for public health, the EPA has identified two types of exceptions to the label restriction that it believes will still mitigate potential exposure to bees while providing flexibility to growers. One type of exception is product-based and is predicated on acceptable residual toxicity time (RT_{25}) that is short. The second type of exception is predicated on the use site to which an active ingredient is being applied. The specific exceptions are discussed below.

3.3.1 Applications with Products of Low Residual Toxicity

A number of comments were received, from both beekeepers and growers, regarding the use of residual toxicity information to help identify pesticides that could be used during bloom and not pose a significant risk to bees. Residual toxicity data are generated through the Toxicity of Residues on Foliage Test (OCSPP Guideline 850.3030[15]) and are referred to as RT_{25} data. The RT_{25} is the time needed to reduce the toxicity of a pesticide product's residues and to bring mortality down to 25 percent (25%) for adult bees exposed by contact to field-weathered residues on the surfaces of the treated plants. The RT_{25} is intended to be a measure of the time that the pesticide product is expected to remain toxic to bees in the field when bees are exposed to residues on plants treated at a specific application rate. Based on the EPA's regulations for requiring data related to impacts on non-target organisms (40 CFR 158.630), the EPA has typically determined whether RT_{25} data are needed based on the results of acute contact toxicity test (OCSPP Guideline 850.3020[16]) with young adult bees; the toxicity of residues on foliage study is triggered if the median lethal dose to 50% of the bees tested (LD_{50}) is less than eleven micrograms per bee (≤ 11 μg/bee).

[15] USEPA 2012. Ecological Effects Test Guidelines OCSPP 850.3030: Honey Bee Toxicity of Residues on Foliage. Office of Chemical Safety and Pollution Prevention (7101). EPA 712-C-018. January 2012.
[16] USEPA. 2012. Ecological Effects Test Guidelines OCSPP 850.3020: Honey Bee Acute Contact Toxicity Test. Office of Chemical Safety and Pollution Prevention (7101). EPA-712-C-019. January 2012.

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Commenters to the Proposed Acute Risk Mitigation Strategy indicated that RT_{25} information is useful to growers and beekeepers as it can help guide their product selection by informing them on which product(s) may have less toxicity to bees on an acute exposure basis if the product was applied after dusk. In 2012, the potential utility of these data were previously suggested by the Pesticide Program Dialogue Committee (PPDC) Workgroup on Pollinator Protection[17]. In response to recommendations by the PPDC Workgroup to make RT_{25} data more available for growers and beekeepers, EPA posted the RT_{25} values from available accepted studies to an on-line database. During the review process of these studies, the EPA noted that RT_{25} values vary between formulated products of the same pesticide active ingredient and do not appear to be correlated with chemical/physical characteristics of the pesticide active ingredient. It is likely that since the weathering component of the test is performed outdoors, environmental conditions and inert ingredients within formulated products may affect the length of time residues remain toxic to bees. As a consequence, an RT_{25} value for one formulation may vary, and further, may not be representative of another formulation of the same pesticide active ingredient.

The EPA agrees that the use of a pesticide product with a low RT_{25} could mitigate the acute contact risk to bees if the pesticide is applied within sufficient time to allow the residues to dry/dissipate before bees forage on that crop. As such, the EPA understands that RT_{25} data can represent a valuable tool for both beekeepers and growers, and therefore, EPA is incorporating flexibility in the Policy around RT_{25} data.

In developing an RT_{25} option, the EPA considered what a RT_{25} value would be such that a product could be applied and sufficient time remained after the application so that residues could dry before bees were likely to forage on that crop. Based both on empirical information and anecdotal comments from beekeepers, forage activity of honey bees increases with daylight and temperature[22]. Therefore, the window for use of a product with a low RT_{25} value would generally be the time between sunset and sunrise at a use site. Commenters to the Proposed Acute Risk Mitigation Strategy, including beekeepers, growers, and state lead agencies suggested that a product with an 8-hour RT_{25} value [or less] could be used safely during certain hours after primary foraging activity decreases.

If the EPA only permitted applications after sunset, then a short period of daylight would exist before applicators would be compelled to make applications in the dark. However, the EPA has learned from various commodity groups and from aerial applicators that, depending upon the topography and other variables, night-time applications (particularly aerial applications) are not possible at all sites and may present safety issues for applicators. To work around this limitation for safe application, the EPA reasons that a longer application window (around dusk) would increase benefits to growers and applicators by providing more daylight hours during which to make an application, but not greatly reduce protection for bees (as bees generally return to the colony as the sun begins to set). Therefore, in creating flexibility around the RT_{25} data, the EPA

[17] See: https://www.epa.gov/sites/production/files/2014-05/documents/next-steps-pp-nov-2012.pdf, and https://www.epa.gov/sites/production/files/2014-05/documents/session8-pollinator.pdf

will generally lengthen the application window by adding 2 hours, prior to sunset, when bee foraging activity is reduced.

As discussed above, the EPA is also concerned about the potential variability that may be inherent in RT_{25} values. Depending upon the location, such as northern tier states, the time between sunset and sunrise may be short at certain times of the year, (even less than 8 hours). Such a short time between sunset and sunrise leaves little time for an application to be made and for residues to dry prior to sunrise. In addition to the 2-hour pre-sunset interval discussed above, the EPA reasons that having a differential between the RT_{25} value and the amount of time allotted for residues to dry would provide a margin of time to account for potential variability in an RT_{25} value. For example, if a product with an RT_{25} value of 6 hours was applied 8 hours prior to sunrise, then an additional two hours would be available to account for any site-specific variability that may cause the RT_{25} to be greater than the recorded 6-hour value. In this case, the 2-hour differential between the RT_{25} value and the amount of time required for the residues to dry provides greater protection for bees.

The EPA considered whether the application window for products should vary product-by-product based upon specific RT_{25} values; for example, a product with an RT_{25} of 4 hours could perhaps be applied 2-hours prior to sunset, but not less than 6 hours (rather than 8 hours) prior to sunrise. The EPA does not believe that trying to fine tune this exception, or using the data to comparatively (*i.e.*, one product is "safer" than another) is supported by RT_{25} data. The EPA believes that products with an RT_{25} equal to or less than 6 hours, applied 2-hours prior to sunset but not less than 8 hours prior to sunrise, is consistent with this Policy by mitigating potential risk to bees, while providing flexibility for growers to protect crops. Consequently, at this time the EPA intends to generally treat consistently all products with an RT_{25} equal to or less than 6 hours.

The EPA believes that, in general, a product with an RT_{25} value of 6 hours or less ($RT_{25} \leq 6$ hrs.) could be used during bloom in a manner that is consistent with the intent of this Policy by mitigating acute risk to bees but allowing flexibility for growers. With the provision for an application window that starts 2-hour prior to sunset, and the provision for a 2-hour differential between the RT_{25} value and the amount of time required for residues to dry, the EPA believes it can: (*i*) create a wider window for applications to be made prior to night-time for all application methods; (*ii*) provide options for safer aerial applications to be made, (*iii*) provide more time for pesticide residues to dry prior to sunrise when bee activity may begin at a target site; and, (*iv*) provide a margin of protection (for bees) by accounting for any variability (in the RT_{25}) that may arise due to site-to-site conditions.

To ensure that RT_{25} data can be relied upon by the EPA, growers and beekeepers to reasonably reduce the likelihood of pesticide exposure, the test design used to generate RT_{25} data must be reviewed to ensure the reliability and predictive nature of RT_{25} data across active ingredients and formulations. Therefore, the EPA will work with stakeholders to enhance the RT_{25} study methods and ensure that RT_{25} values are suitably predictive for acutely toxic products used at bloom on pollinator-attractive crops. Through such efforts, the EPA hopes to address the uncertainty regarding the extent to which the RT_{25} value can be extrapolated across formulations

and environmental conditions. With the availability of suitable RT_{25} information on a product, the EPA believes that in general, the proper use of such a product with a low RT_{25} value would mitigate acute risk to bees.

Therefore, if acceptable product-specific toxicity of residues on foliage data (OCSPP 850.3030[18]) are submitted and indicate an RT_{25} value of 6 hours or less ($RT_{25} \leq 6$ hrs.), then the EPA will generally allow the acute risk mitigation language to be amended to indicate that the subject product may be applied during bloom if it is applied between 2-hours prior to sunset but not less than 8 hours prior to sunrise at the application site.

With respect to existing data, the EPA will determine, on a case-by-case basis, whether residues on foliage data (OCSPP 850.3030) previously submitted by a pesticide registrant on specific formulations are acceptable and sufficient to permit the RT_{25} exception. Registrants with existing product-specific RT_{25} data may cite these data and request this exception be applied to their specific product.

Acute Risk Mitigation Label Language for Products with Demonstrated Low Residual Toxicity

If acceptable product-specific toxicity of residues on foliage data (OCSPP 850.3030[19]) are submitted and indicate an RT_{25} value of 6 hours or less ($RT_{25} \leq 6$ hrs.), then the acute risk mitigation language can be amended to the following:

> FOR FOLIAR APPLICATIONS OF THIS PRODUCT TO A CROP WHERE BEES ARE UNDER CONTRACT TO POLLINATE THAT CROP: This product has a Residual Toxicity time of ≤ 6 hours ($RT_{25} \leq 6$ hrs.). Foliar application of this product is prohibited to a crop from onset of flowering until flowering is complete when bees are under contract for pollination services to that crop unless:
>
> (i) The application is made to prevent or control a threat to public and/or animal health as determined by a state, tribal, authorized local health department or vector control agency; OR,
>
> (ii) The application is made in the time period between 2 hours prior to sunset and 8 hours prior to sunrise.

3.3.2 Analysis of Impacts and Flexibility for Applications to Certain Crop Types

The EPA received numerous comments on the potential adverse economic impacts to certain crops from the Proposed Acute Mitigation Strategy. To understand the potential economic impacts from this effort, the EPA conducted its own analysis, *Impacts Estimates from Proposed*

[18] USEPA 2012. Ecological Effects Test Guidelines OCSPP 850.3030: Honey Bee Toxicity of Residues on Foliage. Office of Chemical Safety and Pollution Prevention (7101). EPA 712-C-018. January 2012.
[19] USEPA 2012. Ecological Effects Test Guidelines OCSPP 850.3030: Honey Bee Toxicity of Residues on Foliage. Office of Chemical Safety and Pollution Prevention (7101). EPA 712-C-018. January 2012.

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and Revised Pollinator Labeling for Representative Blooming Agricultural Crops Utilizing Commercial Pollination Services, (USEPA, January 2017). The EPA examined the potential impacts (i.e., cost to growers and potential yield impacts) of its acute risk mitigation effort under two general scenarios: Scenario # 1: if all acutely toxic active ingredients (*i.e.*, those with an $LD_{50} < 11$ µg/bee, the hazard criterion of the Proposed Acute Risk Mitigation Strategy) were unavailable during bloom; and Scenario # 2: if pesticide uses exceeding the acute risk LOC 0.4 (i.e., the criterion as revised in this Policy) were unavailable during bloom.

While comments submitted to the EPA were crop-specific, the EPA conducted its analysis by identifying representative crops from different crop groups, which served as surrogates for the larger number of crops within that group. For example, the EPA examined apples (East Coast and West Coast) as a surrogate for pome and stone fruits due to the general similarities of target pest groups and substitution choices. For the cucurbit crops, the EPA examined several crops including cantaloupes, cucumbers, pumpkins, and squash. In general, it is expected that under any new pest management scenario, growers may incur impacts in yield reductions, reduced quality, or increased costs if pest control is compromised by switching to different pest management systems. By taking an approach of looking at representative crops, the EPA attempted to understand the broad economic implications of this effort.

When conducting its analysis, the EPA identified, for the representative crops, the bloom-time applications and target pests associated with those applications. To estimate impacts from the Proposed Acute Risk Mitigation Strategy (scenario # 1), the EPA assumed that products that were either moderately or highly toxic to bees on an acute contact exposure basis were not available and that alternative compounds (that were not moderately-highly toxic to bees) would be used. With this information, the EPA estimated any changes in pest management costs, and estimated impacts to yields. To estimate impacts from its revised quantitative risk-based approach (scenario # 2), the EPA went back to the list of compounds applied at bloom and determined which or whether any would not be available based on exceeding the acute risk LOC of 0.4. If the identified compounds all exceeded the acute risk LOC of 0.4, the EPA then looked for alternative products that did not exceed the acute risk LOC of 0.4. Again, with this information, the EPA estimated any changes in pest management costs, and estimated impacts to yields. The EPA employed proprietary market research data, U.S Department of Agriculture's National Agricultural Statistics Service data, state agricultural extension guides, and where necessary, other publically available information. While the EPA is aware of scenarios where growers may use their own bees or rely, in part or in whole, upon native bees for pollination, the EPA's analysis only focused on scenarios where managed bees are contracted for pollination services.

Under Scenario #1, the EPA estimated that increased costs to growers could potentially be significant and potential yield losses could also be expected. Increased pest management costs ranged from unknown to approximately $100/acre. While yield losses were not estimated quantitatively for all crops, the EPA was able to determine whether expected impacts on yield was *low*, *medium*, or *high*. Based on this analysis, the EPA determined that most crops/crop

groups examined under the Proposed Acute Risk Mitigation Strategy were likely to see high impacts if all moderately to highly toxic active ingredients were prohibited during bloom.

Under Scenario #2, the EPA determined that some alternative effective active ingredients would remain available to growers during bloom. With the availability of certain moderately or highly toxic alternatives, the expected increased pest management costs for all crops/crop groups are lower. While estimates still range from unknown to approximately $100/acre, under the revised Tier 1 acute risk-based approach, expected yield losses are anticipated to be much lower than under the Proposed Acute Risk Mitigation Strategy. The EPA found, however, that even under the revised quantitative risk-based approach, uncertainty in yield loss and therefore potential significant impacts persist for cucurbit crops, strawberries, sunflowers, avocado, and crops grown for seed, which are crops that have indeterminate blooming periods. On the whole, the EPA's analysis revealed that the magnitude of projected impacts is driven by the likelihood of yield losses. While pesticide substitution costs can be significant for some crops, these impacts are dwarfed by any potential loss of crop yield (or significant reductions in crop quality) that would result from the inability to control specific pests during bloom. The EPA's analysis concluded that yield losses under both scenarios are likely for the crops with long periods of indeterminate bloom, and on the whole, extended bloom times are the best predictor of high impacts driven by yield losses.

Given the greater potential impacts of this effort on certain crops, (*i.e.*, those crops the EPA examined with indeterminate bloom periods), the EPA reasons that greater flexibility for growers to manage pests, in the form of exceptions to the acute risk mitigation language may be appropriate for crops with indeterminate bloom periods and for crops grown for seed. Indeterminate blooming crops include crops that bloom either continuously or intermittently for multiple weeks and/or for most of the crop's growing season. See Appendix C for a list of crop groups and example crops that have indeterminate bloom and may use bees under contract for pollination. Appendix C also notes crops that may be grown for seed and therefore typically use bees under contract for pollination. Examples of these crops include:

- Crops grown for seed, such as groundcovers, forages, oilseed, and fruit/vegetable crops.
- Strawberries
- Cucurbits (such as melons, cucumbers, squash, pumpkins)
- Oilseed crops (including sunflower)
- Avocado

The EPA has attempted to capture the wide range of commercial agriculture in its impacts analysis and this Policy. The EPA acknowledges that there may be crops it has not considered in its analysis that may fit the characteristics of an indeterminate blooming crop, and/or crops that may experience unforeseen yield losses that are disproportionately adverse to their production system due to this Policy. The EPA will consider, on a case-by-case basis, extending the greater flexibility (*e.g.*, time and temperature) discussed in this Policy to those crops as well. The EPA also recognizes that the specific scenarios that result in high impacts to growers could change as new pest pressures emerge and the availability of alternatives change. As new scenarios emerge,

the EPA will consider those on a case-by-case basis as well as whether any modifications in this Policy are appropriate.

Exception for Evening Applications

While bees may forage over a broad range of temperatures and environmental conditions, honey bees tend to forage during specific times when flowers are prone to releasing pollen and/or nectar; foraging for pollen or nectar generally does not begin until temperatures reach 12 – 14 °C (54 – 57°F), and forage flights are generally correlated with greater light intensity[20]. While not always the case, such conditions tend to occur during the day but after the early morning hours and before the late evening hours.

In previous efforts to mitigate pollinator risk from the nitroguanidine neonicotinoids (2013)[21], the EPA also used application timing as a way to protect pollinators while ensuring that farmers have tools for crop protection. In that effort, the EPA permitted application of the nitroguanidine neonicotinoids if the application was made after sunset. In response to this mitigation strategy, as noted above, aerial applicators and others informed the EPA that depending upon the topography of an area, night-time applications can be dangerous and therefore not a feasible option for growers to protect their crops. The EPA's rationale to widen that application window, by permitting applications to begin 2 hours prior to sunset, addresses this point and EPA believes that a 2-hour pre-sunset provision is applicable for scenarios involving indeterminate blooming crops. Therefore, for indeterminate blooming crops only, the EPA will allow application of acute risk pesticide products from two hours prior to sunset until sunrise at the target site.

Exception for Applications in Cool Weather

When the EPA worked to reduce potential risk from to the neonicotinoids, it also identified an option of permitting applications under cool temperatures, specifically when the temperature at the application site was 55° F or less. The EPA based this temperature cut-off on both anecdotal information, but also on empirical information that indicates that 55°F was an approximate temperature below which bee activity began to decrease[22]. However, comments from beekeepers (on the 2014 neonicotinoid language), indicated that a 55° F cut-off may be too high as bees will forage at temperatures at or around this temperature. Therefore, to increase protection for pollinators, but to continue to provide flexibility to growers, the EPA will continue to use a temperature threshold but will lower it to 50°F. Therefore, for indeterminate blooming crops, the EPA will allow application of acute risk pesticide products when the temperature at the application site is 50°F or less.

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[20] Winston, M. L. 1987. The Biology of the Honey Bee. Harvard University Press, Cambridge, MA ISBN 0-674-07409-2

[21] Nitroguanidine neonicotinoids include: imidacloprid, thiamethoxam, clothianidin and dinotefuran

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Acute Risk Mitigation Label Language for Crops That Have Extended or Indeterminate Bloom, Or Crops That Are Grown for Seed

The EPA intends that all labels for products that (1) are applied as either a liquid or a dust; (2) are foliar applied outdoors to agricultural crop(s) that may utilize contract pollination services; and (3) have an application rate(s) that result in risk estimates exceeding the acute risk LOC of 0.4 for bees, be amended to reflect the acute risk mitigation language.

If that product is registered for use on a crop(s) that have extended or indeterminate bloom or crop(s) that are grown for seed (See Appendix C), the acute risk mitigation language may be modified to the following:

> FOR FOLIAR APPLICATIONS OF THIS PRODUCT TO A CROP WHERE BEES ARE UNDER CONTRACT TO POLLINATE THAT CROP: Foliar application of this product is prohibited to a crop from onset of flowering until flowering is complete when bees are under contract for pollination services to that crop unless:
>
> (i) the application is being made to prevent or control a threat to public and/or animal health as determined by a state, tribal, authorized local health department or vector control agency; OR
> (ii) the application is being made to from 2-hours prior to sunset until sunrise; OR,
> (iii) the application is being made at a time when the temperature at the application site is 50°F or less.

3.3.3 Applications to Protect Public Health

Public comments on the Proposed Acute Risk Mitigation Strategy and the public health exemption did not contest the EPA's intent to allow such an exemption, but rather urged the EPA to reword the exemption so as to avoid confusion or any misunderstanding of the exemption. The EPA believes that the protection of public health is of paramount importance and will retain this exemption, but has revised the label language based upon comments received (see text in italics).

> FOR FOLIAR APPLICATIONS OF THIS PRODUCT TO A CROP WHERE BEES ARE UNDER CONTRACT TO POLLINATE THAT CROP: Foliar application of this product is prohibited to [*crop*] from onset of flowering until flowering is complete when bees are under contract for pollination services to [*crop*] *unless the application is made to prevent or control a threat to public and/or animal health as determined by a state, tribal, authorized local health department or vector control agency.*

Vector control is an important role of local governments, who also understand the concerns around protecting pollinators. In light of efforts to control the Zika virus, local governments have begun to focus on ways to minimize adverse effects of mosquito control efforts on bee. Several counties in Florida, for example, have created websites with information on measures that can protect bees, such as locating bees away from populated areas where mosquito spraying is targeted, or locating them in no-spray areas.[22] Above all, local governments encourage beekeepers to communicate with the authorities of their mosquito control district to discuss concerns and solutions to protecting public health and protecting bees. For concerns regarding bees and public or animal health emergencies, individuals should contact their local authorities.

4. Label Language Description

4.1 Defining Terms of the Mitigation Language

The EPA received numerous comments requesting clear definitions of the terms used in the Proposed Acute Risk Mitigation Strategy label restriction. The EPA understands that the interaction of honey bees with commercial agriculture is complex and incorporates variables that reflect professional and personal preferences and practices. To develop language that fits the complex nature of pollination services and mitigates acute risk to bees, the EPA focused on key conditions it believes define the scenario this Policy aims to protect. These conditions are:

- The target crop is flowering.
- The target crop of the application is also the target crop of pollination services contract; and,
- A contract for pollination services exists between the grower and beekeeper(s).

The EPA believes that these three aspects can differ between every pollination scenario and so it has attempted to develop mitigation language to address these various aspects and mitigates risk to bees. The EPA explains its intentions with respect to the terminology used to facilitate a collective understanding of these terms in order to identify the conditions where a pesticide application is prohibited.

The EPA also clarifies that as a general matter, the prohibitions for applications specified in the label language of this Policy are intended to apply when all three conditions, listed above, are met at the same time. That is, as long as the target crop is flowering and is the crop for which pollination services have been contracted, the restrictions for foliar applications to that target

[22] See for example, University of Florida IFAS Extension information about Mosquito Control and Beekeepers , or Indian River Mosquito Control District information about Mosquito Control and Beekeepers, or Seminole County information about Mosquito Control and Beekeepers.

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crop apply. Where bees are under contract to pollinate a target crop but the target crop is not yet flowering (or has completed flowering), the restrictions of this label language would not apply. Conversely, when a target crop is flowering but a pollination contract does not exist between the grower and beekeeper for pollination services for that target crop (at the time of the intended application), the restriction of this label language would not apply. Below is the final acute risk mitigation restriction EPA generally intends to use, followed by a discussion of several key terms of the restriction language.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

> **FOR FOLIAR APPLICATIONS OF THIS PRODUCT TO A CROP WHERE BEES ARE UNDER CONTRACT TO POLLINATE THAT CROP: Foliar application of this product is prohibited to a crop from onset of flowering until flowering is complete when bees are under contract for pollination services to that crop unless the application is made to prevent or control a threat to public and/or animal health as determined by a state, tribal, authorized local health department or vector control agency.**

4.1.2 Characterizing the Terms "Onset of Flowering" and "Until Flowering is Complete"

The EPA's intent in using the terms "onset of flowering" and "until flowering is complete" is to characterize the time and condition of the target crop that result in an increased number of pollinating bees foraging in the target crop. This time will generally correspond to the time when bees will be foraging in the target crop and most likely receive the greatest exposure, if pesticides are used on that crop. The terms "onset of flowering" and "until flowering is complete" characterize the conditions necessary for potential exposure to occur; as well as the duration of potential exposure and therefore the application prohibition. The EPA understands that there are crop types that pose a challenge to defining the onset of flowering or defining when flowering is complete, such as indeterminate blooming crops. However, the EPA believes that potential acute risk to bees can be mitigated for indeterminate blooming crops (see Section 3.3.2).

The EPA acknowledges that crop type, cropping system, environmental conditions, and other factors all impact the timing and duration of when a crop flowers. Over time, growers across the U.S. have developed and use many operational definitions, including terms of crop phenology in order to produce crops. For example, tools such as growing degree-day calculators have been developed for a number of crops and are used to predict plant phenology, including predicting when a crop will flower. In the context of protecting bees from pesticide exposures, some states such as California and Florida have gone further by articulating the specific criteria to determine

when a crop is either in bloom or out of bloom. California has codified a definition of bloom for citrus (3 CA ADC Section 6656 Citrus/Bee Protection Area), and Florida has created a guidance document for determining citrus bloom.

The EPA believes that even where a state/tribe lead agency has not defined the onset of, or completion of, flowering in a quantitative manner or otherwise, there exists sufficient knowledge and operational understanding among growers and beekeepers alike as to when a crop is flowering. Such a period is likely to be reflected or inherently expressed in the terms of the pollination contract where such a contract is likely to be entered for the period during which bees can provide valuable pollination services (*i.e.*, the time during which the target crop is flowering). Indeed, it is the EPA's understanding that many private pollination contracts include dates which define the period of the pollination service. Therefore, since onset and completion of flowering is likely to be specific to each field scenario, and the EPA believes that there are sufficient lines of information from which parties (such as growers, beekeepers, and state lead agencies) can draw to determine when a crop has begun, or has completed flowering, the EPA does not believe it would be helpful to provide a specific definition for "onset of flowering" or for "completion of flowering."

4.1.3 Characterizing When Contracted Bees are "On Site"

Commenters to the Proposed Acute Risk Mitigation Strategy asked about the term "on site" and inquired whether the bees needed to be within some pre-defined proximity to the application site for the label language to be enforceable. The EPA presumes that there is spatial proximity between the colonies that are providing pollination services and the crop that is the target of the pollination service. However, exactly where the contracted bee colonies are located with respect to the crop for which they are contracted to pollinate is of less importance than an understanding that: "*application of pesticides to crop X is affected because at that moment there are managed bees under contract to pollinate crop X, irrespective of whether those colonies are located in crop X, adjacent to crop X, or some distance from crop X*". Therefore, the established link (*i.e.*, the contract) between the crop that is the pollination target and the pollinating colonies is more important than the physical location of the colonies performing the pollination service. Because the phrase "on site" is not critical to the spirit or implementation of the acute risk mitigation language, the EPA has modified the acute risk mitigation label language to remove the term "on site."

4.1.4 Characterizing "Bees Under Contract"

At the time of the Proposed Acute Risk Mitigation Strategy, the EPA understood that the term "under contract" could be complex in the context of grower-beekeeper relationships for pollination services, as pollination contracts can vary from verbal to written and may or may not

involve fee-for-service. While the form of pollination contracts can vary greatly, it is reasonable for the EPA to believe that all such contracts capture the most basic element that indicates the particular crop that is the target of the pollination service. Therefore, for this Policy, the EPA intends that a pollination contract be understood in a broad manner, as written or oral, formal or informal. As noted above, it is the EPA's understanding that many pollination contracts include dates of the service indicating that the grower and beekeeper have a shared understanding of both a target crop for the service and a time frame during which pollination services is most in need and therefore when potential exposure (to the honey bee) is greatest.

It is the EPA's intent that the acute risk mitigation label language extends only to the crop(s) identified in the pollination contract (written or oral). Because agricultural cropping areas can be complex, pesticide exposure to managed bees may still exist even if this Policy is implemented correctly. For example, different varieties of the same crop, or different crops - all which may be in different stages of flowering - may be in close proximity to one another, but the contract for pollination service only identifies one of those crops. As a consequence, only the application to the crop for which the pollination contract exists is affected. The EPA acknowledges that in scenarios such as these, all potential risk is not mitigated through this Policy; however, the EPA reasons that the presumed highest exposure potential would be mitigated in such scenarios. Further, under its registration review program, the EPA will conduct a more thorough assessment of potential pollinator risks from a particular compound and determine whether risks to pollinators merit further mitigation beyond those outlined in this Policy.

5 Modifications to the *Environmental Hazards* Section of Pesticide Labels

The EPA has typically required products labeled for use outdoors to have Environmental Hazards statements (40 CFR 156.80 – 156.85). The Environmental Hazards language is located under the general heading of "Precautionary Statements" on pesticide labels and provides precautionary language informing users of the potential hazards to the environment from transport, use, storage, or spillage of the product. One of the topic areas of environmental hazard statements pertains to non-target organisms, and to pollinating insects in particular (*i.e.*, *Pollinating Insect Hazard Statement*; see chapter 8, section IV, B of the EPA Label Review Manual.

In a letter dated June 27, 2014, the State FIFRA Issues Research and Evaluation Group (SFIREG) pointed out that language identified in the *Environmental Hazards – pollinating insect hazards* section, created potential confusion with other label language intended to protect pollinators. SFIREG was referring to an action by the EPA in August 2013, where the EPA required specific pollinator protection language for all products containing one of the four nitroguanidine neonicotinoid insecticides (*i.e.*, imidacloprid, clothianidin, thiamethoxam, and dinotefuran). This pollinator protection language prohibited the application of neonicotinoid

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products to bee-attractive crops during bloom, unless certain conditions were met. SFIREG noted that since environmental hazards language is intended to provide general information, it is often broad. SFIREG also noted that the language of the *Environmental Hazards – pollinating insect hazards* section contradicted the pollinator protection language required for neonicotinoid products because the environmental hazard wording was broader than the language in the use directions. As written, the broad and directive nature of the existing *Environmental Hazards – pollinating insect hazards* language appeared to supersede the [neonicotinoid] pollinator protection language. In order to reduce confusion between the *Environmental Hazards – pollinating insect hazards* statement and the neonicotinoid pollinator protection language, SFIREG recommended that the EPA modify the environmental hazard language so that it is not more restrictive than the specific neonicotinoid pollinator protection language. The Environmental Hazards language that creates the potential confusion is the following:

> "Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area."

The EPA agrees with SFIREG's comment that the referenced language of the Environmental Hazards section of pesticide labels can be confusing when compared with the neonicotinoid pollinator protection language. Further, this Policy is similar to the 2013 effort in that the EPA is developing label language that generally is intended to protect bees from pesticide exposure while providing flexibility for growers to protect crops. Therefore, the EPA believes that Environmental Hazards language issue raised by SFIREG is relevant to the current policy and wants to resolve this label language inconsistency as it may impede the application of, or enforcement of, the current Policy which pertains to a far larger number of pesticide products compared to the 2013 effort. Based upon the above reasoning, the EPA is revising the *Environmental Hazards - pollinating insect hazard statement*, to be consistent with labeling language intended to protect pollinators identified elsewhere on the label. The EPA intends to update the Label Review Manual with this revised *Environmental Hazards - pollinating insect hazard statement* language so that all label amendments, whether through this Policy or other Pesticide Program actions, are consistent.

<u>The Label Language</u>

The EPA intends that with this Policy, pesticide registrants with labels for products registered for foliar application to a crop(s) with an application rate that exceeds the honey bee acute risk trigger of 0.4, submit amended labels to reflect the acute risk mitigation language. Labels submitted to incorporate the acute risk mitigation label language should also revise the *Environmental Hazards - pollinating insect hazard statement* consistent with the following:

> <u>Environmental Hazard Language for Pollinating Insects</u>. *This product is [moderately/highly] toxic to bees and other pollinating insects exposed to direct treatment or to residues in/on blooming crops or weeds. Protect pollinating insects by following label directions intended to minimize drift and reduce pesticide risk to these organisms.*

6 State and Tribal (Managed) Pollinator Protection Plans

In the Proposed Acute Risk Mitigation Strategy, the EPA discussed the development of managed pollinator protection plans (MP3s). Several states (*e.g.*, California[23], Colorado[24], Florida[25], Mississippi[26], and North Dakota[27]) initially developed MP3s by productively engaging stakeholders within their respective states. These plans serve as examples of collaboration between stakeholders at the local level that can lead to broader awareness of needs and increased cooperation between stakeholders to reduce pesticide exposure for bees while maintaining the flexibility to protect crops. The common element in these plans has been the increased communication between stakeholders, and anecdotal reports from the stakeholder groups suggest that the plans are effective at increasing communication and cooperation.

The EPA is generally promoting the development of state and tribal MP3s that cover use of acutely toxic pesticides at sites where bees are located at or near the target crop but not under contract pollination services to the target site. However, the scope of such plans is not limited to a specific scenario but may be broader to include other elements that support the health of bees. States and tribes have the flexibility to determine the scope of an MP3 that best responds to pollinator issues in their region. For example, the scope could include applications to crops, and commercial applications to ornamentals in commercial, public, and residential settings, and other scenarios. In response to the Proposed Acute Risk Mitigation Strategy, the EPA received several comments with respect to MP3s, nearly all of which were supportive of the effort and of different states and tribes developing these plans.

The Association of American Pesticide Control Officials (AAPCO) is maintaining an inventory of the development of MP3s by state. The inventory is updated quarterly and includes information on the lead agency, point of contact, status of plan development, stakeholder engagement process, apiary registry, mapping service, target groups for BMPs, types of BMPs, evaluation measures, inclusion of non-managed pollinator, and link to published plans. In general, approximately 48 states have either completed or are in the process of developing an MP3. The EPA has formed a workgroup under the Pesticide Program Dialogue Committee to develop metrics that the EPA can use to evaluate the effectiveness of MP3s as a mechanism for reducing pesticide exposure to bees and promoting pollinator health.

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[23] California Department of Food and Agriculture. 2014. Bee and Beehive Information. http://www.cdfa.ca.gov/plant/pollinators/index.html ; California Food and Agricultural Code Section 29040-29056 http://www.beesource.com/forums/archive/index.php/t-321720.html

[24] Colorado Environmental Pesticide Education Program. Pollinator Protection 2013. http://www.cepep.colostate.edu/Pollinator%20Protection/index.html

[25] *Ibid* Florida Department of Agriculture and Consumer Services. 2014.

[26] *Ibid* Mississippi Honeybee Stewardship Program. 2014.

[27] *Ibid* North Dakota Department of Agriculture. 2014.

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The SFIREG has issued guidance for states to consider in developing MP3s, for states to consider in developing MP3s, which identifies several elements for establishing a framework for communication and cooperation between beekeepers and growers and reducing pesticide exposure for managed bees[28]. Tribes are also encouraged to consider this guidance in developing their own MP3s, as appropriate. In general, these elements include a public stakeholder participation process for the development of a MP3 to encourage local solutions based on improved communication and cooperation; a method for growers/applicators to know if there are managed bees near treatment sites, and to identify and contact beekeepers prior to application that will enable the grower/applicator to communicate about any planned treatments and how best to protect the colonies; inclusion of best management practices (BMPs) that both the grower/applicator and beekeeper can undertake to limit exposure of the managed bees to the proposed pesticide application; a clear defined plan for public outreach to promote robust adoption of the plan; and a process to periodically review and modify the plan as needed. The SFIREG guidance also identifies, as a component of MP3s, the need for a mechanism to measure the effectiveness of the managed pollinator protection plans. Since the issuance of the Proposed Acute Risk Mitigation Strategy, the SFIREG has issued guidance to identify performance measures to gauge the success of MP3s to gauge the success of MP3s for states that have adopted MP3s.

Also, since the issuance of the Proposal, the EPA, USDA, the National Association of State Departments of Agriculture (NASDA) and the Honey Bee Health Coalition (HBHC) hosted an MP3 symposium from March 10-11, 2016 to provide the tools, insights and relationships necessary for state, tribal and other stakeholders to pursue the development of MP3 plans effectively and efficiently. Approximately 130 individuals representing the EPA, USDA, states, tribes, pesticide manufacturers, beekeepers, agricultural organizations, and academia participated in the Symposium. Sessions at the Symposium included MP3 objectives and lessons learned; MP3 development primer; evaluating the effectiveness of MP3s; engaging stakeholders; developing best management practices; identifying and using tools for tracking and mapping; and forage and native pollinators. The result of the MP3 Symposium was enhanced relationships, access to resources and increased confidence that the utilization of MP3s is an effective process for addressing pollinator health concerns. This is evidenced through survey results which showed that the Symposium was successful in meeting its objectives. Specifically, 94% of survey responders agreed that the Symposium provided a high value experience through relationships, resources and approaches for improved MP3 plans. The majority (61%) of survey responders agreed that the MP3 process will address pollinator health concerns in their areas.

7 Implementation

The EPA has identified the active ingredients with at least one product labeled for either foliar liquid or dust application to a crop for which contracted bees may be used. Products that meet

[28] State FIFRA Issues, Research, and Evaluation Group Final Guidance for State Lead Agencies for the Development and Implementation of Managed Pollinator Protection Plans. June 2015. https://aapco.files.wordpress.com/2015/08/sfireg-mp3-guidance-final.pdf

both of these criteria are generally presumed to be subject to this Policy. As discussed briefly above, in section 3.1, this list of active ingredients subject to this Policy is somewhat large, and the number of pesticide products associated with these active ingredients is still larger. Therefore, to ease implementation of this Policy, the EPA has divided this list of active ingredients into three groups. Active ingredients placed into Group 1 are those active ingredients that are subject to this Policy, and that are acutely toxic to bees by contact (LD_{50} <11µg/bee). Active ingredients placed into Group 2 are those active ingredients that are subject to this Policy, are not acutely toxic to bees by contact (LD_{50}>11µg/bee), but that either have been implicated in bee kills and/or whose residues have been found on bees or in pollen or wax. Finally, Group 3 will contain all remaining active ingredients that are subject to this Policy. At this time, the EPA is providing a list of active ingredients in Group 1. At a later date, the EPA will provide a list of the active ingredients in Group 2 and Group 3.

For each active ingredient, the maximum active ingredient application rate that does not result in the exceedance of the acute risk LOC for bees is identified by the EPA (*i.e.*, any application rate above that specified would exceed the Tier 1 acute risk LOC of 0.4). Appendix A therefore, are the active ingredients in Group 1, along with their respective maximum active ingredient application rate. See Appendix B for a list of crops for which contracted bees may be used.

Over the following 4 months, EPA will send letters to registrants, who have agricultural products containing active ingredients identified in Group 1, regarding (i) the acute risk mitigation labeling EPA believes is necessary to ensure that the product provides appropriate mitigation of acute risks to managed bees, and (ii) the revised Environmental Hazards labeling. These letters will reiterate the specific parameters used to determine if a product is subject to the mitigation, provide the specific mitigation language, and give directions on how to submit labeling amendments to add the mitigation. For the compounds identified by the EPA that are subject to this Policy, registrants should determine which of their own products are subject to the mitigation then submit revised labels accordingly. While EPA has attempted to ensure that the active ingredients listed in Appendix A account for all current products covered by this policy, EPA does not intend this list to serve as the exclusive list of active ingredients covered by the Policy. If EPA has missed active ingredients in Appendix A that meet the Policy criteria or if new pesticides are registered that meet these criteria, EPA expects such products to contain labeling necessary to address risks to managed bees and will therefore seek to ensure that applicants or registrants for such products submit labeling to address these risks.

Once EPA has completed processing the revised labels for pesticide products that contain active ingredients in Group 1, the EPA will then issue letters to registrants who have agricultural product(s) containing active ingredients identified in Group 2, and later, to those registrants who have agricultural products containing active ingredients identified in Group 3. Throughout this effort, the EPA will coordinate its efforts to implement this Policy with its efforts under the registration review program. As an example, and as discussed above in section 3.1 the EPA intends that risk management for pollinators based on a chemical specific analysis will supersede this Policy. Because the EPA is near to completing the chemical-specific pollinator assessment for the nitroguanidine neonicotinoids under registration review, it intends to implement pollinator risk management through under the registration review process and not through this Policy.

Changes to Application Rates

A pesticide registrant may choose to lower its application rate in order to avoid exceeding the acute risk LOC of 0.4 for a use(s) on it product label(s). EPA will evaluate such changes on a case-by-case basis, considering efficacy and potential impacts any changes may have.

Appendix A

List of Group 1 Active Ingredients, Acute Toxicity Value, and Threshold Application Rate

	PC Code	Chemical	Acute Contact Toxicity Value (µg/bee)	Acute Contact Toxicity Classification	Maximum Foliar Application Rate (in lbs. ai/A) that is Below the Tier 1 Acute Risk LOC of 0.4.
1	122804	Abamectin	0.54	Highly	0.0780
2	103301	Acephate	1.2	Highly	0.1733
3	209600	Alpha-cypermethrin	0.023	Highly	0.0033
4	118831	Beta Cyfluthrin	0.0120	Highly	0.0017
5	000586	Bifenazate	7.8	Moderately	1.1267
6	128825	Bifenthrin	0.0146	Highly	0.0021
7	056801	Carbaryl	1.1	Highly	0.1589
8	059101	Chlorpyrifos	0.059	Highly	0.0085
9	044309	Clothianidin	0.0275	Highly	0.0040
10	090098	Cyantraniliprole	0.058	Highly	0.0084
12	128831	Cyfluthrin	0.037	Highly	0.0053
13	109702	Cypermethrin	0.023	Highly	0.0033
14	097805	Deltamethrin	0.0015	Highly	0.0002
15	057801	Diazinon	0.052	Highly	0.0075
16	035001	Dimethoate	0.16	Highly	0.0231
17	044312	Dinotefuran	0.047	Highly	0.0068
18	122806	Emamectin benzoate	0.0035	Highly	0.0005
19	109303	Esfenvalerate	0.0172	Highly	0.0025
20	044501	Fenazaquin	1.12	Highly	0.1618
21	127901	Fenpropathrin	0.0015	Highly	0.0002
22	129098	Fluazinam	4.0	Moderately	0.5778
23	128807	Gamma cyhalothrin	0.0061	Highly	0.0009
24	129099	Imidacloprid	0.0439	Highly	0.0063
25	067710	Indoxacarb	0.1800	Highly	0.0260
26	128897	Lambda-Cyhalothrin	0.0380	Highly	0.0055
27	057701	Malathion	0.189	Highly	0.0273
28	090301	Methomyl	0.068	Highly	0.0098
29	034401	Naled	0.4800	Highly	0.0693
30	103801	Oxamyl	0.3100	Highly	0.0448
31	109701	Permethrin	0.024	Highly	0.0035
32	059201	Phosmet	1.06	Highly	0.1531
33	069001	Pyrethrins	0.022	Highly	0.0032
34	129105	Pyridaben	0.024	Highly	0.0035
35	121001	Sethoxydim	10	Moderately	1.4444

36	110007	Spinetoram (a mixture of spinetoram-J and spinetoram-L)	0.0240	Highly	0.0035
37	11008	Spinetoram (major component (4,5- dihydro))	0.024	Highly	0.0035
38	110009	Spinetoram (minor component (4-methyl)	0.0267	Highly	0.0039
39	110003	Spinosad	0.0029	Highly	0.0004
40	005210	Sulfoxaflor	0.13	Highly	0.0188
41	060109	Thiamethoxam	0.0240	Highly	0.0035
42	090111	Tolfenpyrad	0.47	Highly	0.0679
43	129064	Zeta-cypermethrin	0.023	Highly	0.0033

Appendix B

List of Crops for which Contracted Bees May Be Used*

The crop groups listed below are those that may use bees under contract for pollination services but may not have indeterminate bloom periods. The corresponding acute risk mitigation restrictions for these crops is described in section 3.2 above.

Crop Group	Example Crop
Pome fruit group (crop groups 11 and 11-10)	Apple, Asian pear, crabapple, pear
Stone fruit group (crop groups 12 and 12-12)	Apricot, cherry (sweet and tart), nectarine, peach, plum, plumcot, prune, sloe (12-12 only)
Berries group (crop group 13)	Blackberry, blueberry (highbush and lowbush), raspberry
Berry and small fruit group (crop group 13-07) except strawberry	Blackberry, blueberry (highbush and lowbush), cranberry, kiwifruit, raspberry
Tree nut group (crop groups 14 and 14-12)	Almond, chestnut

* EPA has developed this list based upon professional opinion and source material such as the USDA document, *Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen*. Other crops and/or crop groups that meet the subject criteria may exist that are not listed here. EPA expects that such products should also bear labeling necessary to address risks to managed bees and will therefore seek to ensure that applicants or registrants for such products submit labeling to address these risks.

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Appendix C

Crops that Have Indeterminate Bloom or That May Be Grown for Seed**

The crop groups listed below are those that may use bees under contract for pollination services and may have indeterminate bloom periods. Crop groups denoted with an asterisk (*) are crop groups that use bees under contract for pollination only when they are grown for seed. See Section 3.3.2 for a discussion of alternate acute risk mitigation language for use of products on indeterminate blooming crops.

Crop Group	Example crops
Cucurbit vegetables group (crop group 9)	Pumpkin, cucumber, gherkin, squash, gourd, Momordica spp. (balsam apple, balsam pear, bitter melon, Chinese cucumber), watermelon
Berry and small fruit (crop group 13-07), strawberry only	Strawberry
Tropical and subtropical fruit, inedible peel group (crop group 24)	Avocado
Root and tuber vegetables (crop group 1)* Leaves of root and tuber vegetables (crop group 2)*	Carrot, radish, rutabaga, turnip, beets, sugar beets
Bulb vegetable group (crop groups 3 and 3-07)*	Onion, garlic, leeks
Leafy vegetables (except Brassica) (crop group 4)*	Celery, lettuce, spinach
Leafy vegetable group (crop group 4-16)*	Celery, cilantro, collards, kohlrabi, lettuce, spinach
Brassica (cole) leafy vegetables (crop group 5)*	Broccoli, Brussel sprouts, cabbage, cauliflower, collards, kale, kohlrabi
Brassica head and stem vegetable (crop group 5-16)*	Broccoli, Brussel sprouts, cauliflower, cabbage
Legume vegetables (succulent or dried) (crop group 6)*	Bean, lentil, chickpea, peas, soybean
Fruiting vegetable group (crop groups 8 and 8-10)*	Pepper, tomato, eggplant
Cereal grains group (crop group 15)*	Buckwheat
Nongrass animal feeds (forage, fodder, straw, and hay) (crop group 18)*	Alfalfa, clover for forage and silage, vetch
Herbs and spices group (crop group 19)*	Borage

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Oilseed group (crop group 20)*	Borage, rapeseed, canola, safflower, sunflower
Stalk, stem and leaf petiole vegetable group (crop group 22)*	Asparagus, celery, kohlrabi

** EPA has developed this list based upon professional opinion and source material such as the USDA document, *Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen*. Other crops and/or crops or crop groups that meet the subject criteria may exist that are not listed here. EPA expects that such products should also bear labeling necessary to address risks to managed bees and will therefore seek to ensure that applicants or registrants for such products submit labeling to address these risks.