**What is the normal process for registering a pesticide with regards to pollinator safety?**

To support the registration of a pesticide, the registrant is required to submit a data package that provides information on the constituents of the pesticide, its product chemistry, the environmental fate, the ecological effects, human toxicity, proposed use information, and for chemicals with food uses, residue studies and rotational crop field studies. The Title 40 of the Code of Federal Regulation (aka 40CFR) defines the data required to support registered and/or proposed uses. Data are specified according to the use (*e.g.*, outdoor).

With respect to evaluating potential for adverse effects to pollinators from the exposure as a result of specific uses of a pesticide, these data have historically consisted of both laboratory-based studies of individual adult bees and field-based colony-level studies. In 2011, EPA issued interim guidance on additional studies used to assess exposure and effects to bees, and in 2014, EPA issued final guidance on these additional tests which include acute adult oral toxicity, acute larval toxicity, and both adult and larval chronic toxicity tests. These additional tests are typically conducted according to OECD test guidelines and guidance documents. These test designs have undergone extensive testing by multiple labs (referred to as "ring testing"), both domestically and internationally to ensure that the studies are fit-for-purpose (*i.e.*, they measure what they are intended to measure) and can provide robust, reproducible data. Depending on the outcome of the laboratory-based studies of individual bees, higher-tier semi-field colony-level studies may be required (*e.g.*, enclosure studies, colony feeding studies, and/or studies of residues in pollen and nectar). Again, depending on the outcome of those tests, full-field, colony-level studies may then be required.

It is important to keep in mind that the law requires that companies applying for registration (*aka* applicants) and companies who may be applying for new uses of existing chemicals or for those whose products are in registration review (*aka* registrants), must generate the data themselves (*i.e.*, it is not the financial responsibility of the public) to generate these data. The data must be generated consistent with the standards identified in the 40CFR160 under "good laboratory practice (GLP)". While there was a time when registrants used to generate much of the data to fulfill testing requirements in-house, now most registrants/applicants typically utilize contract research organizations (*aka* CROs) who specialize in specific studies and who are trained in complying with GLP standards.

**What are the categories for pollinator safety and how are they determined?**

I'm not sure water are meant by categories for pollinator safety. There are only toxicity categories [of which I am aware] and these categories are based on acute toxicity studies. The categories are often specified in the Environmental Hazard section of the label. With respect to bees, if a compound has an acute $LD_{50}$>11 µg ai/bee, then it is classified as practically non-toxic to bees; if a compound has an $LD_{50}$ between 2 and 10.99 µg ai/bee, it is classified as moderately toxic to bees. If a compound has an $LD_{50}$ of <2 µg ai/bee, it is classified as highly toxic to bees on an acute exposure basis. Environmental hazard statements regarding bees may be further modified based on data from the Toxicity of Residues on Foliage study and what is referred to as the RT25, *i.e.*, the time required for weathered residues on treated foliage to kill 25% of the adult bees in contact with the residues on foliage. Therefore, bee acute toxicity data and data on the RT25 are used to develop label Environmental Hazard statements. Risk managers may use the EPA Label Review Manual (Chapter 8 Environmental Hazards) to develop Environmental Hazard statements. Also, both acute and chronic toxicity data, use information and



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environmental fate information are used to develop restrictions specified in the Directions for Use section of the label.

**What pollinator species are normally assessed?**

The current suite of laboratory-based studies, semi-field and full-field studies are typically conducted with the Western (European) honey bee (*Apis mellifera*). OECD recently released acute contact and acute oral toxicity test guidelines for bumble bees (*Bombus* spp). Draft protocols have been developed for mason bees (*Osmia* spp). The EPA Office of Research and Development has participated in some of the ring tests with bumble bee and mason bees and has been working with researchers in the International Commission for Plant-Pollinator Relationships (ICP-PR) to develop chronic toxicity tests for bumble bees using microcolonies.

As with other taxa and as a characteristic of toxicity testing in general, surrogate species are frequently relied upon. For example, freshwater fish are used as surrogates for aquatic-phase amphibians and birds are used as surrogates for reptiles and terrestrial-phase amphibians. These test species are selected based on their commercial availability, their ability to thrive under laboratory conditions, and the ease in which they can be handled. EPA relies on *Apis mellifera* as a surrogate for solitary and social non-*Apis* bees. Work by Arena and Sgolastra 2014, Thompson, and more recently by Parminger have suggested that honey bees are relatively reasonable representatives of bee sensitivity to pesticides falling within factors of 2 – 5x.

**Some pesticides are known to be more toxic when mixed with other chemicals. How is that determined?**

Laboratory-based toxicity studies are typically conducted with technical grade product (typically, >95% active ingredient); however, formulated product testing with individual bees may be required if there is evidence to suggest that the formulated product may be more toxic than TGAI. Formulated product testing may also be conducted if the solubility limit of the TGAI limits the extent to which the laboratory-based studies can provide definitive endpoints. Most colony-level studies except colony feeding studies are conducted with formulated end-product. Therefore, if there are multiple active ingredients co-formulated, then that is when they would be evaluated.

There is research (*e.g.* Johnson and Percel; Johnson *et al.* 2013, 2014) demonstrating that some chemicals that might be tank mixed at the time of application can result in greater than additive effects; typically, these potential relationships are documented in open literature or through incident reports.

Open literature studies (*e.g.*, Mullin *et al.* 2010; Ostiguy *et al.* 2019) demonstrate that there can be a large number of pesticides in colonies, particularly in wax, that represent "environmental mixtures". Some of the pesticides detected in the highest quantity and frequency in various hive matrices have been those with in-hive uses to control varroa mites (*e.g.*, coumaphos, *tau*-fluvalinate, thymol). Other compounds detected in colonies have included chemicals that have limited water solubility and that may preferentially partition into wax.

With respect to tank mixes, there are a large number of potential chemical combinations; the extent to which a grower may utilize such combinations varies at the field level with environmental conditions, costs, and pest pressure. With respect to environmental mixtures, they are dependent on the chemical/physical properties of the product, environmental conditions (*e.g.*, weather) and the area over

which the bee may be foraging across seasons. Attempting to require such diverse data across registrants to account for all of the combinations would be logistically challenging.

In 2016, EPA in collaboration with the California Department of Pesticide Regulation conducted a pilot study to look at common tank mixes used in almonds during bloom. That study indicated that in almonds, the most frequently applied chemicals during bloom tended to be fungicides and that insecticides tended to be applied before and after the peak bloom period. The study also showed that tank mixing of insect growth regulators (IGRs) had declined by roughly 60% from 2014 – 2016. This reduction in the use of IGRs may be grower response to best management practices recommended by the Almond Board of California based on data generated by Reed Johnson at Ohio State University with respect to the IGR diflubenzuron.

**What do you know about pesticide treated seeds? (This is a general question we've been asking a lot of people because no one seems to know much.)**

For some pesticides, seed treatments have been one of the dominant forms of application (*e.g.*, neonicotinoids) as they can reduce the need for foliar applications and can provide more targeted applications.

In 2008, there was an incident in Germany where large numbers of honey bee colonies were affected by drift of abraded maize seed coatings onto oilseed rape that was in bloom in adjacent fields. In that particular case, a suitable sticking agent was not used to treat the seed and conditions during planting were dry and windy.

Several years later, there were incidents in provinces of Ontario and Quebec, Canada, that were attributed to the drift of abraded corn seed coatings during planting. These incidents were primarily associated with pneumatic planting equipment.

Because of what is referred to as a treated article exemption and because of the number of factors that can potentially affect the extent to which treated seed coatings can result in what is referred to as fugitive dust of "dust-off", EPA encouraged the regulated community to work with stakeholders to develop processes that could reduce the potential for dust-off. In response, registrants, seed-treatment companies and equipment manufacturers have worked to develop seeding equipment fluency agents, improve seed sticking technologies and improve equipment design to reduce potential dust-off. EPA also worked with NGOs such as the Pollinator Partnership to conduct research examining factors associated with corn dust and to identify potential mitigation factors. Seed companies have also utilized metrics for determining the extent to which treated seeds may be vulnerable to dust-off using what is referred to as Heubach test (2008).

> The term "treated article" typically refers to items that are treated with a pesticide to protect the item itself and are typically added to the item (*e.g.*, wood, seed, shower curtains) during manufacture or before use. EPA may grant exemptions for registering such a non-public health uses as a pesticide.

In 2013, EPA hosted a summit on reducing exposure from seed treatments. This summit highlighted EPA's efforts to engage stakeholder to reduce exposure from drift of abraded seed coatings during planting.



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Contrary to the notion that EPA doesn't evaluate seed treatments, the fact is that EPA evaluates risk to non-target organisms from seed treatments by considering the amount of active ingredient used to treat seed, the number of seeds per acre, and the seeding rate to convert those values into an equivalent application rate in terms of lbs active ingredient applied per acre. Because of the number of factors that can influence the extent of dust off, EPA does not quantify potential risks to bees from fugitive dust; however, as can been seen in the recent pollinator risk assessments for the neonicotinoids, potential risks from exposure to dust-off was qualitatively characterized.

**How does the EPA protect pollinators?**

Multiple factors are known to affect pollinator health. With respect to the potential effects of pesticides and similar to the process used for other wildlife taxa, EPA evaluates risk based on the best available science using data that have been generated using internationally recognized methods and which meet the standard prescribed under the Data Quality Act. As with other taxa, potential risks to pollinators can be mitigated through a combination of label advisory statements (Environmental Hazard statements) and specific restrictions in the Directions for Use (DFU) section of the label. EPA also works with state/tribal lead agencies and stakeholders to reduce exposure of bees to pesticides by providing Cooperative Grant Agreement funds for those states/ Tribal Nations that elect pollinator protection as an option. EPA has also encouraged lead agencies to engage with stakeholders at the local level to develop Pollinator Protection Programs where stakeholders can determine the scope of those plans.

**How does EPA evaluate the potential risk to pollinators?**

As with other taxa, EPA relies on a tiered process to evaluate the potential risk of pesticides to bees. EPA has been evaluating potential risks to bees for well over 30 years; however, when colony losses began to increase in the mid-2000s, EPA and a broad range of other stakeholders participated in a global SETAC Pellston Workshop to develop a quantitative process for estimating risk to bees. In 2012, EPA working in collaboration with Health Canada's Pest Management Regulatory Agency and the California Department of Pesticide Regulation, presented a conceptual framework for assessing risk to bees to EPA's Federal Advisory Committee, the FIFRA Scientific Advisory Panel. In 2014 EPA, PMRA and CDPR published a harmonized guidance on assessing risk of pesticides to bees. The guidance describes a three-tiered process. The initial screen (Tier 1) relies on point estimates of acute and chronic toxicity to adult and larval bees and model-derived or default estimates of exposure. These point estimates of risk are then compared to regulatory thresholds or levels of concern (LOCs). For acute risk, the LOC is 0.4; for chronic risk, the LOC is 1.0. The decision to consider requiring additional data to refine risk estimates depends on whether Tier 1 risks can be mitigated and/or whether the FIFRA standard of no unreasonable risk can be met. Higher-tier data may include measured residues in pollen and nectar that can be used to refine risk estimates. Or, colony-level studies may be required under relatively controlled exposure conditions (*e.g.*, tunnel studies or colony feeding studies) and are referred to as Tier 2 semi-field studies. These studies are used to determine whether effects seen on individual bees translate into effects at the whole colony level and if so, whether the colony is able to recover from those effects. If further characterization is needed, full-field colony-level studies may be required. At this level, all of the factors influencing colony health are in play.

**What steps are EPA taking to improve pollinator health?**



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As noted earlier, in 2013, EPA hosted a pesticide summit focused on dust-off and measures to mitigate such exposure. Also, in 2013 EPA and USDA co-hosted a National Stakeholder Conference on Colony Collapse Disorder and declines in bee health. That conference highlighted each of the factors affecting pollinator health. In 2014, EPA and USDA co-hosted summits on varroa mites and on bee forage and nutrition.

In response to a White House directive in 2014, EPA and USDA co-chaired a Federal Task Force and in 2015, the White House released the National Strategy to Promote the Health of Honey Bees and Other Pollinators. As part of that plan, federal agencies committed to a number of actions to enhance the health of bees and other pollinators. The strategy included a Pollinator Research Action Plan (PRAP) to address uncertainties. Also, the strategy included a Public-Private Partnership Plan.

As with other taxa, EPA is ensuring that the best available science is brought to bear on assessing the potential role that pesticides may play on bees. Recognizing though that there are multiple factors influencing bee health, EPA has also been working with researchers to explore additional tools that can be used to control varroa mites and other colony pests. EPA has committed to fast-tracking the registration of varroacides (*e.g.*, oxalic acid). EPA has also encouraged states and Tribal Nations to develop pollinator protection plans where state and tribal lead agencies work with a wide range of stakeholders to reduce bee/pollinator exposure to pesticides. However, these plans are also an opportunity to develop pollinator habitat and expand education/training on pollinator protection at a local level.

EPA is currently working with USDA to host a National workshop on Pollinator Protection scheduled for early September 2020; this workshop will build on the PRAP and identify areas where research is currently being funded and to identify additional research needs.

**How can stakeholders engage in the regulatory process?**

Each ecological risk assessment and regulatory decision is posted on the EPA docket through regulations.gov for public comment. Also, states and tribal nations have pollinator protection plans where stakeholders can be engaged at a local level on protecting pollinators. Also, stakeholders can report incidents to their state/tribal lead agencies, to EPA or to the National Pesticide Information Center. EPA risk assessors use incident data as a line of evidence in assessing risk of pesticide use to non-target organisms such as bee and pollinators.