August 28, 2015 [filed via www.regulations.gov]

Jack Housenger, Director
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: Comments of CropLife America on *EPA's Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products*. 80 FR 30644. May 29, 2015. Docket No. EPA-HQ-OPP-2014-0818

Dear Mr. Housenger:

CropLife America ("CLA") appreciates the opportunity to review and provide the attached comments on the *Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products* (the "Proposal") promulgated by the United States Environmental Protection Agency ("EPA" or the "Agency"). Established in 1933, CLA represents the developers, manufacturers, formulators and distributors of crop protection chemicals and plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers.

CLA represents the interests of its member companies by, among other things, monitoring legislation, federal agency regulations and actions and litigation that impact the crop protection and pest control industries, and participating in such actions when appropriate. CLA is committed to working with EPA, as the primary federal agency responsible for the regulation of pesticides, to encourage practical, science-based regulation of its members' products.

CLA would welcome the opportunity to discuss these comments in greater detail. Feel free to contact me at 202-872-3874 or rmcallister@croplifeamerica.org.

Sincerely,

Ray S. McAllister
Senior Director, Regulatory Policy

Cc: Michael Goodis
Marietta Echevarria

Attachment: CLA's comments to Docket No. EPA-HQ-OPP-2014-0818

Comments of CropLife America on *EPA's Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products*. 80 FR 30644. May 29, 2015. Docket No. EPA-HQ-OPP-2014-0818

August 28, 2015

CropLife America ("CLA") appreciates the opportunity to review and comment on the *Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products* (the "Proposal") promulgated by the United States Environmental Protection Agency ("EPA" or the "Agency"). Established in 1933, CLA represents the developers, manufacturers, formulators and distributors of crop protection chemicals and plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers.

CLA represents the interests of its member companies by, among other things, monitoring legislation, federal agency regulations and actions and litigation that impact the crop protection and pest control industries, and participating in such actions when appropriate. CLA is committed to working with EPA, as the primary federal agency responsible for the regulation of pesticides, to encourage practical, science-based regulation of its members' products.

EPA has requested input on its Proposal, which proposes additional mandatory pesticide label restrictions to protect managed bees under contract pollination services from foliar applications of certain pesticides that the Agency has categorized as acutely toxic to bees on a contact exposure basis. CLA strongly objects to the Agency's rationale for these proposed additional pesticide label restrictions, and urges the Agency to instead allow growers and beekeepers to balance the risks assumed by growers and providers of pollination services through privately negotiated contracts. Due to a lack of justification and scientific basis explained below, EPA should retract this Proposal.

EXECUTIVE SUMMARY

CLA recognizes the importance of honey bees to American agriculture and supports collaborative efforts that promote honey bee health. CLA's member companies provide safe and effective tools to protect farmers' crops and help feed the world's growing population. The goals of improving the nation's agricultural productivity AND ensuring the health of honey bees are not mutually exclusive. CLA is committed to a strategy that ensures that growers can efficiently grow and protect their crops from pests, while beekeepers can raise their livestock, produce honey and other products, and provide pollination services in an optimized environment.

CLA is, however, concerned that EPA's Proposal incorporates strategies around honey bees that are inconsistent with the underlying science and do not follow appropriate and required assessment procedures.

This Proposal is based on a one-size-fits-all approach that is arbitrary and inflexible, and does not follow EPA's own procedures for risk-based decision making. Strictly on a hazard basis, EPA has listed 76 active ingredients, components of more than 3,600 registered pesticide products, which EPA itself states cover most registered insecticides and a few herbicides. This blanket approach will lead to unnecessary restrictions and in some cases could prevent the use of

pest control tools that may pose less risk to honey bees, as well as negatively impact resistance management approaches.

CLA's main concerns focus on:

1) Risk assessment

Although CLA supports a consistent process to evaluate the need for mitigation language on pesticide labels, the Agency should follow its risk assessment procedures and not simply rely on hazard data to establish restrictive mitigation language. The application of existing risk assessment methods developed by EPA and currently being employed during registration review and for new active ingredients will provide more useful assessment information for evaluating appropriate label language to protect honey bees.

2) Lack of justification

EPA must follow the appropriate process in implementing changes to labels to address honey bee health. Active ingredients must be evaluated individually as part of the registration and registration review processes. EPA should follow its usual risk-benefit approach to pesticide regulation rather than using the hazard-based cut-off criteria proposed here. EPA has failed to make any showing to justify this stark departure from the risk-based approach to environmental protection required by law.

EPA has also failed to adequately consider the significant costs of this Proposal in comparison to its potential but unproven benefits, particularly the costs associated with EPA's proposed label amendments to a significant number of products. To the best of CLA's knowledge, EPA has not been able to identify with certainty how many and which products would be impacted by its proposed label change, currently making cost-benefit analysis impossible.

3) Needed flexibility-avoid unnecessary restrictions

Hazard is not necessarily a reliable predictor of risk. For this reason, relying simply on a single hazard value may result in products that do not present a high risk to honey bees having unwarranted at-bloom label restrictions. For example, if a product has low residual toxicity (*e.g.*, RT25 < 8 hours), night-time applications could mitigate the risk. CLA recommends that the Agency use the results of a risk assessment for the specific formulation of product, rather than a hazard value, to develop label restrictions that are not a "one size fits all" approach to protect honey bees and to avoid unnecessary restrictions for products that present a low real-world risk to honey bees.

The Proposal's inflexibility could needlessly prohibit pesticide applications sometimes needed by agricultural producers, including organic farmers. The state officials in charge of pesticide programs (State-FIFRA Issues Research and Evaluation Group; "SFIREG") have suggested that label language allow application of pesticides that are toxic to honey bees during bloom to crops with contracted honey bees if a key pest must be controlled during bloom and the pesticide has a short residual toxicity (RT25 < 8 hours).

CLA is also commenting on:

a) Incidents

The record that EPA has made available indicates an average incident rate of 12 incidents per year for 40 years, a timeframe during which many of the compounds on EPA's list for use restrictions have been in use. This low incident rate does not support a finding of imminent risk. While any incidents should be cause for concern, this does not warrant a mitigation approach which ignores the principles of science-based risk assessment. Further, many of the incident records are of questionable source and accuracy, appear to include duplicate records for many incidents, occurred outside the U.S., have limited details or no verification, etc. In addition, the Proposal does not outline how EPA will measure the remedial effects of the Proposal.

b) Improved label language

CLA recommends that there should be a common location on all pesticide labels under the "Directions for Use" that contains the instructions and precautions related to honey bee protection.

c) State plans

CLA supports the use of state Managed Pollinator Protection Plans ("MP3s"). Their effectiveness should be measured based on criteria demonstrating the success of communications among beekeepers, applicators and growers, rather than by bee death or hive health measurements, as these can be more likely affected by other factors, such as hive predation, disease infection or forage availability.

d) Indeterminate Bloom

The lack of exceptions to the blanket prohibition of using products on EPA's list during bloom, where contract pollination is used, presents a serious risk of excessive crop loss and economic damage to growers. There are a number of crop and pest complexes where managed pollination is frequently employed and treatment is required for control of major economic pests present during bloom. EPA's approach must be sufficiently flexible to avoid unnecessary impacts on both beekeepers and agricultural crop producers.

DETAILED COMMENTS (organized according to headings of the Proposal)

1. Overview

CLA recognizes the importance of honey bees to American agriculture and fully supports collaborative efforts that promote honey bee health, sustainable agricultural practices, as well as policies and processes that improve stewardship and promote the safe use of the industry's products. CLA's members provide safe and effective tools to farmers to help feed the world's growing population. The goals of improving the nation's agricultural productivity while ensuring the health of honey bees are not mutually exclusive. CLA and its members are committed to a strategy that ensures that growers can efficiently grow and protect their crops from destructive pests while beekeepers can raise their livestock and provide pollination services in a mutually supportive agricultural environment.

2 Background

In the background to the Proposal (Section 2, p. 4), EPA has detailed how it has undertaken the development of improved scientific tools to assess risks and to manage potential risks from pesticides to honey bees. It describes how it has formalized its scientific process for quantifying potential risks to honey bees, integrated this framework into registration and registration review programs, and how it is developing laboratory and field-based tests for additional species of solitary and social bees. CLA has been very supportive of these efforts and is proactively working to ensure that the additional tests are feasible and reproducible. CLA, however, is very concerned that EPA is following an unpredictable and non-transparent path of regulation that is ostensibly in the interest of honey bee protection, but is precipitous and poorly justified, does not rely on best available science, and bypasses EPA's risk assessment process. Recent examples include:

- July 2013: In a letter to registrants, the Agency demanded that alleged pollinator incidents be reported to EPA within 10 days, for registrants of neonicotinoids only (requirement is 15 days for human fatalities). EPA issued this demand – at odds with the Agency's own adverse effect reporting regulations – in response to a highly publicized misuse incident in Oregon.[1]
- August 2013: EPA issued a letter to registrants of neonic insecticides mandating significant label changes, allowing barely 48 hours for stakeholders to react, and then ignored the significant inconsistencies identified by the commenters.[2]
- October 2014: The Agency published an incomplete assessment on *Benefits of Neonicotinoid Seed Treatments to Soybean Production*, drawing inappropriate conclusions despite strong objections from economic experts within USDA.[3]
- April 2015: Without citing any authority or precedent, EPA issued letters to registrants, arbitrarily demanding withdrawal of pending neonic registration applications until sometime in the future, when the Agency completes Registration Review for the neonic active ingredient that is the subject of a pending application .[4]

---

[1] Bradbury, S (Jul 22, 2013) Letter to Registrants of Nitroguanidine Neonicotinoid Products. Subj: Registered products containing imidacloprid, dinotefuran, clothianidin or thiamethozam, USEPA Office of Pesticide Programs. Retrieved from http://www2.epa.gov/sites/production/files/2013-11/documents/bee-july2013-letter.pdf. Accessed on Aug 25, 2015

[2] Bradbury, S (Aug 15, 2013) Letter to Registrants of Nitroguanidine Neonicotinoid Products. Subj: Pollinator protection labeling for nitroguanidine neonicotinoid products. USEPA Office of Pesticide Program. Retrieved from http://www2.epa.gov/sites/production/files/2013-11/documents/bee-label-info-ltr.pdf. Accessed on Aug 25, 2015

[3] Johansson R (April 6, 2015) Letter to Richard Keigwin re: USDA Public Comments on the EPA's Benefits of Neonicotinoid Seed Treatments to Soybean Production document published in the October 22, 2014 Federal Register; EPA docket identification (ID) number EPA-HQ-OPP-2014-0737. 10 pp. USDA Office of the Chief Economist. Federal Docket No. HQ-OPP-2014-0737-0942. Retrieved from http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2014-0737-0942 (accessed August 26, 2015).

[4] Housenger J (Apr 2, 2015) Memo to Registrants of Nitroguanidine Neonicontinoid Products re: New and Pending submissions for outdoor uses of products containing the nitroguanidine neonicotinoids imidacloprid, dinotefuran, clothianidin or thiamethoxam. 3 pp. U.S. EPA Office of Pesticide Programs. http://www2.epa.gov/sites/production/files/2015-04/documents/neonicotinoid-new-use.pdf (accessed August 26, 2015)

The current Proposal goes beyond these examples. The Proposal is based on a one-size-fits-all approach that is arbitrary and inflexible and does not follow either the standard for registration under the Federal, Insecticide, Fungicide, and Rodenticide Act ("FIFRA") or EPA's own *Guidance for Assessing Pesticide Risks to Bees* ("*Guidance*").[5] EPA has listed 76 active ingredients, which are components of more than 3,600 registered insecticidal and herbicidal products. The Agency itself acknowledges that most insecticides are included, along with a few herbicides. EPA is proposing a hazard-based cut-off criterion for the active ingredient of 11 µg/bee contact LD50 to impose the prohibition. This criterion for evaluating bee toxicity emerged in work by E.L. Atkins and various colleagues at the University of California-Riverside, reported in a number of publications from the 1950s through the 1980s.[6] Typical pesticide use rates of that time period were often more than 10 times the typical use rates of modern crop protection products. Again we wish to highlight that this Proposal does not even follow EPA's risk assessment *Guidance,* which begins with a Tier 1 risk assessment to characterize acute risk to bees. Applying this risk assessment should be the first step in determining if a product's use warrants additional mitigation. If mitigation *is* warranted it should be concise, practical, consistent with FIFRA's risk/benefit safety standard, and consider external stakeholder input.

EPA's Proposal cites no validated scientific data demonstrating that the agricultural uses of the listed pesticides, when applied according to their labels and labeling, cause adverse effects on bees. Instead, this Proposal references allegations, anecdotes and incomplete incident reports to justify arbitrary restrictions on 76 active ingredients. It references reported bee kill incidents contained within the EPA Incident Data System ("IDS") and the Ecological Incident Information System ("EIIS") databases as a justification with no analysis of how these data support the proposed action. CLA submitted a FOIA request to obtain these data from EPA. Preliminary review of this information (under Section 3 below) demonstrates clearly that the reports do not support this inappropriate and arbitrary label Proposal, and the action is indefensible. The appropriate way to utilize incident information is a well-administered incident investigation process that directs hypothesis-driven experiments to identify causes. Without doing a thorough assessment of each crop / pest scenario, the imposition of a blanket prohibition with no flexibility for a grower to protect his crop will significantly increase tensions between grower and beekeeper. It will also discourage research and investment into urgently needed new modes of insecticidal action, as even low use rate candidate products, posing no risk to bees under approved use conditions, may not be developed if they exceed the arbitrary hazard-based cut-off.

EPA further justifies the action based on the statement "Pesticides have also been identified as one among multiple factors negatively impacting honey bee health, including declines in honey bees specifically". This statement is incorrect.

Over the last two decades, a period that more than covers current honey bee practices and relevant pesticide concerns, the number of US honey bee colonies has been stable at around 2.5

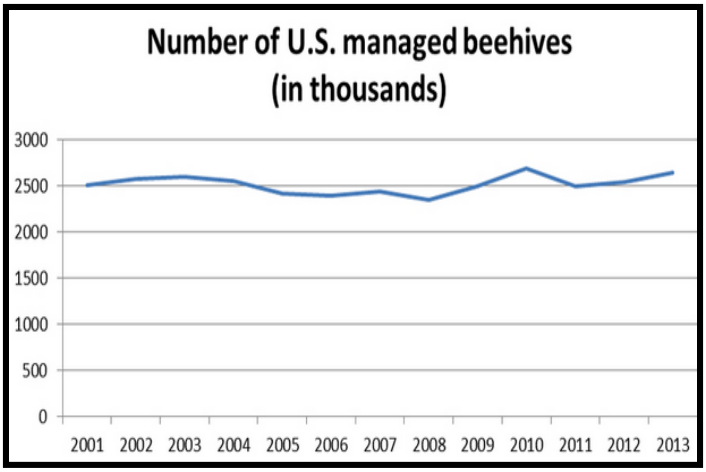
---

[5] USEPA Office of Pesticide Programs, Health Canada Pest Management Regulatory Agency, California Department of Regulation. (Jun 19, 2014) Guidance for assessing pesticide risks to bees. 59 pp. Retrieved from http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf. Accessed Aug 25, 2015

[6] Atkins EL, Kellum D, Atkins KW (1981) Reducing pesticide hazards to honey bees: mortality prediction techniques and integrated management strategies. Leafl. 2883 Division of Agriculture, University of California, Riverside.

million colonies, and has actually increased four out of the past five years. The number is up 13% in the U.S. since 2008 (see Figure 1). While it is true that honey bee colonies declined from a high of 5.9 million colonies just after World War II, numerous papers have described the key political and socioeconomic factors (*e.g.*, sugar prices, cheap honey imports, ageing beekeeper population) plus the process of data collection leading to this decline.[7] Overwintering hive losses have been trending downwards since the Bee Informed Partnership started its survey following the winter of 2006/2007 (see Figure 2). USDA's National Agricultural Statistics Service ("NASS"), in its most recent honey report[8], notes that from 2013 to 2014 honey production in the U.S. was up 19%, yield per colony was up 15%, and the total colony number was up 4% to 2.74 million. More recently summer/seasonal losses have been recorded but there is no clear interpretation as to the meaning of these data as beekeepers are splitting, combining and building up their colonies during this period. CLA is aware of anecdotal reports that the Bee Informed Partnership survey process is somewhat confusing for beekeepers, calling into question some of the reported results. A recent review putting losses in historical context indicates that recent colony loss rates are not unprecedented[9]. As outlined in the *National Strategy to Promote the Health of Honey Bees and other Pollinators*[10], NASS will be conducting more rigorous assessments of honey bee colony losses, which are urgently needed to ensure that the appropriate concerns are being addressed. CLA supports this NASS effort for more accurate information collection.

Figure 1.



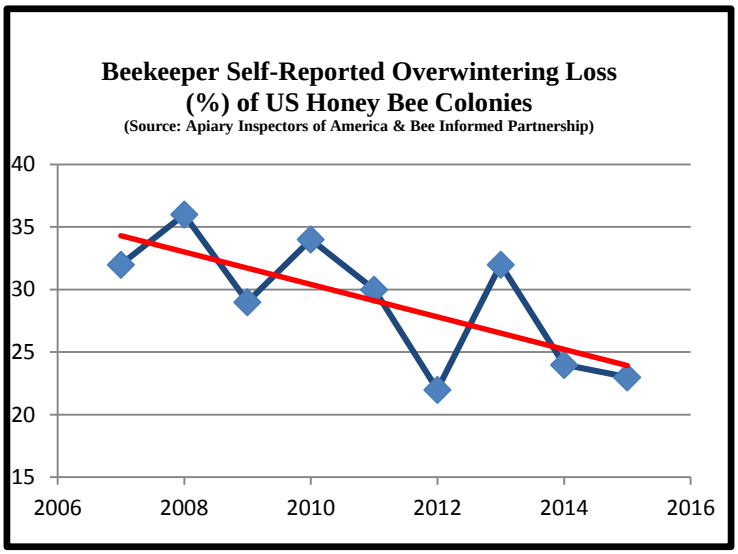
[7] Smith KM, Loh EH, Rostal MK, Zambrana-Torrelio CM, Mendiola L, and Daszak P. (2014) Pathogens, pests, and economics: drivers of honey bee colony declines and losses. EcoHealth 11:DOI: 10.1007/s10393-013-0870-2. Retrieved from http://www3.syngenta.com/country/ca/en/corporate-responsibility/stewardship/beehealth/Documents/Smith_etal_EcoHealth_Alliance_publication_on_HB_Health.pdf. Accessed Aug 25, 2015

[8] Anonymous (Mar 20, 2015) Honey. USDA, National Agriculture Statistics Service, Report 1949-1492. Retrieved from http://usda.mannlib.cornell.edu/usda/current/Hone/Hone-03-20-2015.pdf. Accessed Aug 25, 2015

9 Borst PL (2015) The fall and rise of the honey bee. American Bee Journal. (March 2015): 315. Retrieved from http://apisenterprises.com/The%20Fall%20and%20Rise%20of%20The%20Honey%20Bee-2.pdf. Accessed on Aug 25, 2015

[10] Pollinator Health Task Force (May 19, 2015) National strategy to promote the health of honey bees and other pollinators. The White House. Retrieved from https://www.whitehouse.gov/sites/default/files/microsites/ostp/Pollinator%20Health%20Strategy%202015.pdf. Accessed Aug 25, 2015

Figure 2.



Also incorrect is the conclusion EPA has drawn from USDA's 2013 *Report on the National Stakeholders Conference on Honey Bee Health*[11], which makes no mention of foliar uses of pesticides, the subject of the current proposed action, but instead focuses on systemic insecticides (particularly neonicotinoids) and the need to determine potential effects at field relevant doses. Since the issuance of that USDA report, significant data have been published, demonstrating that at field relevant doses, systemic uses of neonicotinoids do not cause adverse effects on honey bee colonies[12,13,14]. The last of these reports is an extensive 3-year studied funded in part by USDA and co-authored by USDA and EPA scientists.

VanEngelsdorp D., *et al.*, [15] actually reach a conclusion opposite to that stated by EPA in the Proposal [p. 6]. The study found no single causative agent for bee mortality and concluded that "CCD colonies generally had higher virus loads and were co-infected with a greater number of

[11] National Honey Bee Health Stakeholder Conference Steering Committee (2013) Report on the national stakeholders conference on honey bee health, October 15-17, 2012. Retrieved from http://www.usda.gov/documents/ReportHoneyBeeHealth.pdf. Accessed Aug 25, 2015

[12] Godfray HCJ, Blacquière T, Field LM, Hails RS, Petrokofsky G, Potts SG, Raine NE, Vanbergen AJ, McLean AR (2014) A restatement of the natural science evidence base concerning neonicotinoid insecticides and insect pollinators. Proceedings of the Royal Society B 281:20140558. Retrieved from http://rspb.royalsocietypublishing.org/content/281/1786/20140558. Accessed Aug 25, 2015

[13] Carreck NL, Ratnieks FLW (2014) The dose makes the poison: Have "field realistic" rates of exposure of bees to neonicotinoid insecticides been overestimated in laboratory studies? Journal of Apicultural Research 53:607. Retrieved from http://www.ibra.org.uk/articles/Neonicotinoids-has-laboratory-field-realistic-exposure-been-overestimated Accessed on Aug 25, 2015

[14] Dively GP, Embrey MS, Kamel A, Hawthorne DJ, and Pettis JS. (2015) Assessment of chronic sublethal effects of imidacloprid on honey bee colony health. Plos One 10(3):(e0126043) Retrieved from http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0118748. Accessed Aug 25, 2015

[15] vanEngelsdorp D, Evans JD, Saegerman C, Mullin C, Haubruge E, Nguyen BK, Frazier M, Frazier J, Cox-Foster D, Chen Y, Underwood R, Tarpy DR, Pettis JS (2009) Colony collapse disorder: a descriptive study. PLoS ONE 4: e6481. doi:10.1371/journal.pone.0006481. Retrieved from http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0006481. Accessed on Aug 28, 2015.

disease agents than control colonies" and "… found no evidence that the presence or amount of any individual pesticide occurred more frequently or abundantly in CCD-affected apiaries or colonies." In fact, the opposite was true; two products, esfenvalerate in wax, and coumaphos in wax, brood, and adult bees were found more frequently and at higher levels in control colonies than in CCD colonies.

Bee experts agree that many factors affect honey bee health, including parasites; diseases; weather extremes; loss of forage and habitat; and stresses resulting from crop or hive management practices, which are becoming increasingly burdensome on the practice of beekeeping, particularly commercial pollination services. Perhaps no factor is more important than the *Varroa* mite, an invasive parasite that has wreaked havoc on bees since its introduction into the U.S. in the 1980s[16]. The USDA has identified *Varroa* as "the single most detrimental pest of honey bees" and noted it is closely associated with colony decline. Studies show that poor bee health correlates well with the presence of mites and diseases, but not with the use of pesticides[17,18,19,20,21,22]. Many of CLA's member companies have products or are developing products to combat *Varroa* and are supporting efforts to improve bee forage and habitat, supporting the *National Strategy*.

3. Problem statement – IDS and EIIS

In order to comment effectively on the various aspects of EPA's Proposal, CLA asked EPA for access to the reports of allegations of incidents, cited in this Proposal, via a request under the Freedom of Information Act ("FOIA") on June 29, 2015. EPA responded in part on July 16, 2015, and belatedly posted that response in the public docket on August 13, 2014 (Docket no. EPA-HQ-OPP-2014-0818-0218). Given EPA's significant reliance on these reports in its rationale for issuing this Proposal, CLA respectfully submits that informed stakeholder comments would have been facilitated if the Agency had made these reports publicly available in

[16] Report on the National Stakeholders Conference on Honey Bee Health. National Honey Bee Health Stakeholder Conference Steering Committee. October 17 – 17, 2012. http://www.usda.gov/documents/ReportHoneyBeeHealth.pdf

[17] *Ibid* vanEngelsdorp D., et al. (2009)

[18] VanEngelsdorp, D, N Speybroeck, J D Evans, B K Nguyen, C Mullin, M Frazier, J Frazier, Cox-Foster D, Chen Y, Tarpy DR, Haubruge E, Pettis JS, Saegerman C (2010) Weighing risk factors associated with bee colony collapse disorder by classification and regression tree analysis. Journal of Economic Entomology 103:1517. Retrieved from http://jee.oxfordjournals.org/content/103/5/1517. Accessed Aug 25, 2015

[19] Rogers, REL, Kemp JR (Oct 15, 2004) Assessing bee health in the maritimes: A survey of pesticide residues in honey bee, Apis mellifera, colonies. PEI ADAPT Council Project 319.02.

[20] Nguyen BK, Saegerman C, Pirard C, Mignon J, Widart J, Thirionet B, Verheggen FJ, Berkvens D, De Pauw E, Haubruge E (2009) Does imidacloprid seed-treated maize have an impact on honey bee mortality? Journal of Economic Entomology 102:616. Retrieved from http://dx.doi.org/10.1603/029.102.0220. Accessed Aug 28, 2015

[21] Chauzat, MP, Carpentier P, Martel AC, Bougeard S, Cougoule N, Porta P, Lachaize J, Madec F, Aubert M, and Faucon JP. (2009) Influence of pesticide residues on honey bee (hymenoptera: Apidae) colony health in France. Environmental Entomology 38:514-523. Retrieved from http://www.bij-zeeuwsvlaanderen.nl/scientific_pesticide/Chauzat_et_al_2009_pesticide_residues_honey_bee%20colony_health_FR.pdf. Accessed on Aug 25, 2015

[22] Genersch E, Von Der Ohe W, Kaatz H, Schroeder A, Otten C, Buchler R, Berg S, Ritter W, Muhlen W, Gisder S, Meixner M, Liebig G, Rosenkranz P (2010) The German bee monitoring project: A long term study to understand periodically high winter losses of honey bee colonies. Apidologie 41:332 Retrieved from http://link.springer.com/article/10.1051%2Fapido%2F2010014. Accessed Aug 28, 2015.

the docket at the opening of the comment period. Given the broad implications of this action on growers, registrants and the Agency, EPA should have done so.[23]

Apparent errors, incompleteness, and repetition in the EIIS reports make interpretation of the information a challenge. Use sites associated with alleged incidents are not consistently reported and identified. The Abstracts for individual reports give some information hinting at investigation, but seldom give conclusions or details or information regarding who conducted the investigation. Many if not most of the incident reports do not indicate whether any investigation was pursued. Details on the criteria and rating system leading to conclusions of Highly Probably, Probable, Possible, or Unlikely are not provided.

The information provided from the EIIS database identifies some 530 unique incidents reported from the 1970s through 2015, from a variety of sources. CLA would assert that reports relevant to the current Proposal are limited to the alleged incidents occurring (a) in the United States, (b) after 1995 (more likely associated with currently relevant agricultural practices), and (c) judged to be "Probable" or "Highly Probable". This reduces the relevant number to approximately 115 reports, over 10 years.

The Proposal specifically cites EIIS reports from 2014 regarding incidents affecting approximately 20,000 colonies in almond pollination and 2,000 colonies in blueberry pollination, as primary causes for concern in justifying the proposed prohibitions and restrictions on use of 76 specific active ingredients. CLA finds no mention of blueberries in the information provided from EIIS. Nine reports were associated with almond pollination in California in 2014, reportedly affecting a total of 13,300 hives. None of those reports indicated that alleged pesticide effects were either Probable or Highly Probable. Four of the reports (3000 hives total) did not mention a specific pesticide. For the other five reports, a total of 11 active ingredients are alleged as "Possible" sources of effects, only one of which occurs on the Proposal's list of 76 active ingredients. For five of the incident reports (5,840 hives), the Abstracts indicate that some form of investigation may yet be in progress, or some report forthcoming.

Clearly, the limited and incomplete information provided from the EIIS database is not significant evidence and not adequate (a) to support or justify the Agency's Proposal to make sweeping prohibitions on labels of hundreds of products containing the 76 active ingredients, with far-reaching economic consequences, and (b) to effectively deny pending applications until Registration Review is complete. CLA is continuing a dialogue with the Agency to seek clarification and additional information on the incident reports from EIIS, IDS, and FIFRA §6(a)(2) sources, as well the supporting background information on additional reasons that EPA states in the Proposal for seeking the label restrictions. This additional information must likewise be subject to public scrutiny and comment before decisions are made regarding proposed label restrictions that EPA asserts are supported by it.

CLA is aware that the California Department of Pesticide Regulation ("CalDPR") has conducted investigations on some ten incident reports associated with the 2014 almond pollination season that were received through California government channels. It is not clear if and how the CalDPR reports overlap with those appearing in EPA's EIIS database. It would be premature for EPA to make decisions on the proposed label restrictions for the 76 active ingredients before reports of those CalDPR investigations are likewise subject to public scrutiny and comment.

[23] *See, e.g.*, 5 U.S.C. §552

4. Desired state

Labels

CLA members are deeply committed to the proper stewardship of the industry's products. Many years of research and development and millions of dollars of pre- and post-registration testing support the safe and effective use of crop protection products when used according to their labels. This stewardship certainly includes honey bees as well as a wide range of other potentially non-target organisms. The various risk assessments are the scientific tools used to understand how to construct pesticide labels to ensure appropriate mitigations are included to minimize any risks or potential risks.

CLA recommends that labels have one place to provide clear, consistent and enforceable instructions for honey bee protection. As the risk assessment and management process considers the agricultural practices for each use separately, CLA recommends that the best place is under the "Directions for Use". If specific honey bee protection instructions apply to all crop uses of the product, then placement at the beginning of the "Directions for Use" section is appropriate. All other use-site-specific statements could be included with the use instructions for each crop or crop grouping. Inserting honey bee protection information in many places throughout the label will lead to confusion and potentially undesirable consequences. Label language should minimize complexity to promote consistent interpretation and thus better protection for honey bees. Inconsistencies in label instructions leading to conflicting and contradictory instructions only make the label less effective. Current environmental hazard statements of many products already contain language like "Do not apply this product or allow it to drift to blooming crops or weeds on which bees are actively foraging." CLA supports the position that has been put forward in comments submitted to this docket by SFIREG:

> *"…move all bee protection language from the Environmental Hazard Statement section of the label to the Directions For Use section. This policy should be incorporated into the EPA Pesticide Label Review Manual*."[24]

There is also the potential that repetition of honey bee protection instructions throughout the label could obscure other very important instructions. Having concise, science based and appropriately placed honey bee protection label language will lead to a label that best protects honey bees, while providing much needed crop protection solutions for growers.

Another concern with the Proposal is lack of flexibility for growers to manage pest outbreaks that may cause significant loss. CLA concurs with the recommendation of the SFIREG comments in this regard:

> *"… provide flexibility in the proposed label language by allowing application of pesticides that are toxic to bees during bloom to crops with contracted pollinators if there is a key pest that must be controlled during bloom and the pesticide has a short RT25 (less than 8 hours). The pesticide would have to be applied when the bees are not foraging and when they would not be foraging within 8 hours (e.g.,*

[24] Giguere, C. (2015?) SFIREG comments to OPP docket EPA-HQ-OPP-2014-0818. Retrieved from https://aapcotest.files.wordpress.com/2015/08/epa-pollinator-policy-sfireg-docket-comments-2015.pdf. Accessed Aug 25, 2015

after blooms close in afternoon as is case with many cucurbits or late evening for other crops in which blooms do not close).”

CLA believes the EPA has not adequately considered the time and resources required by EPA staff, State Lead Agencies or registrants to implement the Proposal.

Crops employing contract pollination services

Growers and beekeepers are in the best position to determine the appropriate practices that they need to ensure that the crop can be protected from destructive pests while ensuring the contracted bees are protected while on-site. USDA’s Economic Research Service reports that 10 crops accounted for more than 95% of fees received by U.S. beekeepers for pollination services provided to growers in 2012: almonds, apples, avocados, canola seed, cherries, cultivated blueberries, dried prunes, grapes, sunflowers, and watermelons.[25] USDA’s Agricultural Research Service lists a total of some 145 crops that “use managed pollinators”.[26] With the large number and diversity of crops that require managed pollination services, EPA’s Proposal may have far-reaching effects on U.S. agriculture.

For these reasons, CLA believes that privately negotiated contracts are the best way to effectively balance the risks assumed by growers and providers of commercial pollination services. If EPA agrees, it will be important for EPA to fully vet this Proposal with a broad cross-section of beekeepers and growers to verify the practicality and burden of imposing this Proposal on farmers using contracted pollination services.

To assist the parties with such contracts, EPA could provide to them via a website a list of product/crop combinations with potential for acute risk to honey bees, according to EPA’s established risk assessment methods based on application rates needed to control specified pests present during bloom and the acute toxicity values. Growers and beekeepers could reference such a list in their contracts to include clauses restricting those uses, for example, to night-time applications for short-residual toxicity products, or requiring advance notice. Input from stakeholders on the design and management of such a website would be essential. Current example contracts from various sources already include language regarding the use of bee-toxic pesticides.[27]

---

[25] Bond J, Plattner K, Hunt K (Sep 26, 2014) Fruit and Tree Nuts Outlook: Economic Insight. U.S. Pollination-Services Market. USDA Economic Research Service. FTS-357SA. 6 PP. Retrieved from http://www.ers.usda.gov/media/1679173/special-article-september_-pollinator-service-market-4-.pdf. Accessed Aug 28, 2015. Note: While ERS lists grapes as generating significant fees for pollination services, growers and beekeepers alike have confirmed that grape are not commercially pollinated.

[26] USDA (2015) Attractiveness of agricultural crops to pollinating bees for the collection of nectar and/or pollen. 42 pp. Retrieved from http://www.ree.usda.gov/ree/news/Attractiveness_of_Agriculture_crops_to_pollinating_bees_Report-FINAL.pdf. Accessed Aug 25, 2015

[27] Sample Beekeeper/Grower Contract, The University of Georgia College of Agricultural and Environmental Sciences, *available at* http://www.ent.uga.edu/bees/pollination/sampleContract.pdf (accessed Aug. 27, 2015); Sample Almond Pollination Agreement, Project Apis m., *available at* http://projectapism.org/wp-content/uploads/2013/10/Pollination-Contract-Template.pdf (accessed Aug. 27, 2015); Pollination Contracts, Mid-Atlantic Apicultural Research & Extension Consortium, *available at* https://agdev.anr.udel.edu/maarec/wp-content/uploads/2010/03/Pollination_Contract.pdf (Feb. 2000); Sample Pollination Contract, The Merrimack Valley Beekeepers Association, *available at* http://mvbee.org/wp-content/uploads/2012/02/Pollination-Contract.pdf (accessed Aug. 27, 2015);

5.2 Application to sites with bees present under contract pollination services

Application restrictions based on hazard rather than risk

CLA supports a consistent process to develop clear mitigation language on pesticide product labels but is concerned that the Proposal by the Agency relies exclusively on honey bee acute hazard data to establish restrictive mitigation language. As detailed below, the application of existing risk-assessment methods developed by EPA, and currently being employed during registration review and for new active ingredients entering the market, will provide more useful and valuable information regarding potential mitigations needed to protect honey bees.

LD50 < 11 µg/bee

For crops requiring contracted pollination services, the Agency's Proposal is to use the honey bee acute contact LD50 value of < 11 µg/bee as the threshold or hazard cut-off value for requiring label language to restrict any applications during crop bloom while contracted honey bees are present in the field. In Figure 3, the horizontal line represents the pass-fail cutoff; compounds that fall below the line would require new labeling and those above would not. CLA believes that any application restrictions on pesticide product labels should be based on the results of a risk assessment, as opposed to a hazard value. The Agency has established *Guidance* for risk assessment for pesticides and bees which can be used to determine if application restrictions during crop bloom are warranted. In Figure 4, the diagonal line represents the Level of Concern. Active ingredients whose combination of application rate and LD50 fall above the line present low risk, while those whose combination of application rate and LD50 fall below the line suggest the need for risk refinement or mitigation.

Figure 3.

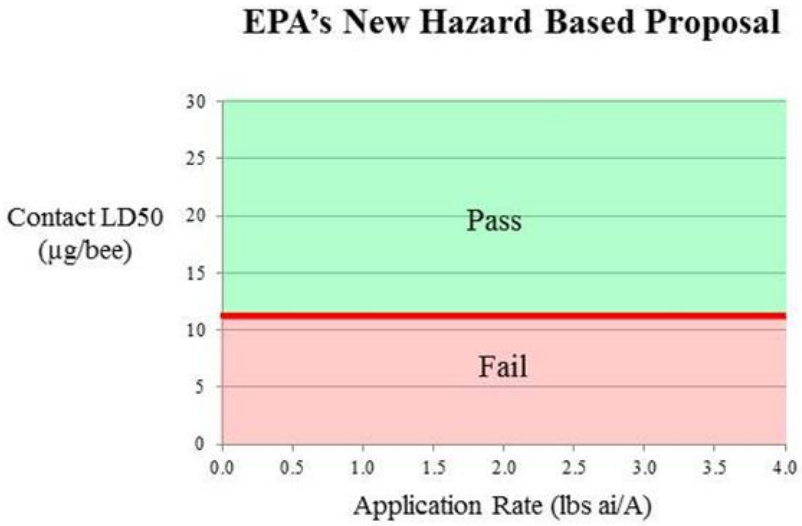
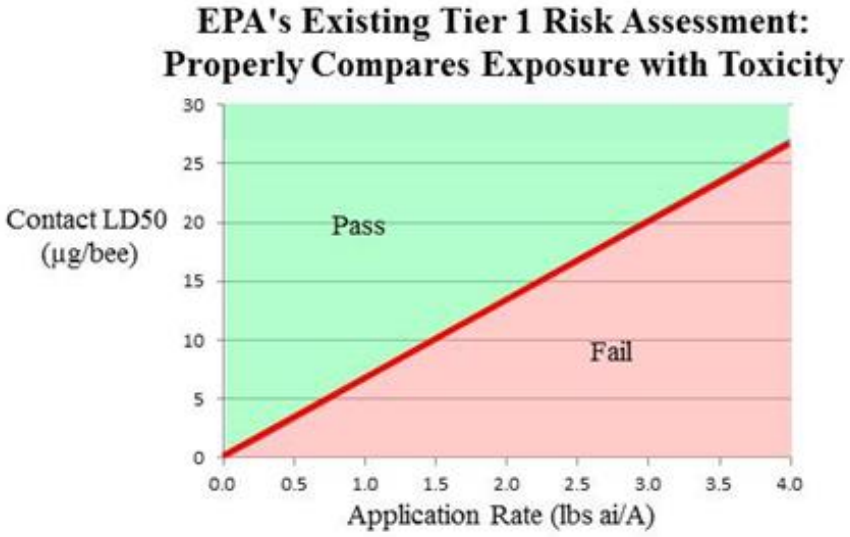
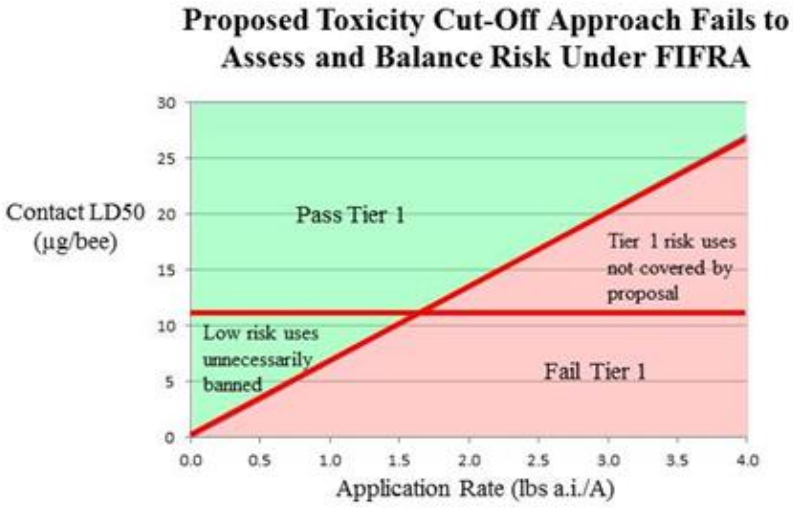


Figure 4.



As an example, using EPA's screening-level risk assessment approach, a compound with a contact LD50 of 11 µg/bee would require an application rate of $\geq$ 1.62 lb ai/A to exceed EPA's level of concern (RQ = 0.4) for high risk due to contact exposure. Relying simply on a single hazard value may require products that do not present a high risk to bees having unwarranted at-bloom label restrictions. This would represent a Type 1 error, a failure to balance risk with benefits of pesticide use (see Figure 5). Using publically-available data, CLA performed screening-level risk assessments for several compounds on the list of 76 active ingredients and found several Type 1 errors. This should be confirmed by EPA with the most up-to-date toxicity and use data for all 76 active ingredients.

Figure 5.



On the other hand, there may be compounds with lower acute toxicity (*i.e.*, LD50 ≥ 11 µg/bee) that actually present a greater theoretical risk to honey bees, due to higher application rates. Approval of these uses would represent a Type 2 error (also a failure to balance risk with benefits of pesticide use; Figure 5) in which no risk mitigation is imposed, even though a Tier 1 risk assessment would indicate the need for risk refinement or mitigation.

Figure 4 represents a simple, interim approach to risk assessment based on the honey bee acute toxicity data for active ingredients. A straightforward calculation of the application rate that would result in a toxic acute dose to a honey bee directly sprayed with a product having a given acute toxicity value could be compared with application rates actually used in crop production. The results could reliably indicate whether such a use would or would not need any mitigation or restrictions.

Residual toxicity

In considering pesticide use restrictions during crop bloom, CLA encourages the Agency to also consider all relevant scientific data such as residual foliar toxicity (or confirmed lack of residual toxicity) of the pesticidal product, as well as results from semi-field tunnel and field studies. If a product does not pass Tier 1 risk assessment but has low residual toxicity (*i.e.*, RT25 < 8 hours), night-time applications offer a practical, reliable means to mitigate risk. In addition, if higher-tier data obtained from semi-field and field studies or other publically-available data that meet the Agency's data quality standards should help inform risk mitigation labeling. Finally, if practical experience of growers and beekeepers have demonstrated that at-bloom applications do not present an unacceptable risk to honey bees, the Agency should not impose further risk mitigation. CLA believes that flexibility needs to be retained for growers and beekeepers to work together to find practical solutions to insect pest control issues, while minimizing exposure and risk to honey bees.

Risk assessment

CLA supports the Agency's pragmatic, science-based, tiered risk assessment approach in all areas of pesticide registration and registration review, in particular to develop mitigation measures for products containing active ingredients that are not acutely toxic to honey bees (the *Guidance*). Potential risks to honey bees should be reviewed under the same thorough risk assessment that properly balances other potential risks and benefits of pesticide use under FIFRA.

In summary, CLA believes that EPA's proposed approach could ultimately be counterproductive and contrary to the principles of the Agency's risk assessment paradigm, as well as its duty under FIFRA to properly balance the range of potential risks and benefits of pesticide use. This could become especially critical for new product innovations, which will likely have a comprehensive package of exposure and effects studies with honey bees, and may ultimately offer reduced risk alternatives to products currently on the market. Using risk assessment results would be consistent with the development of other environmental mitigation measures on U.S. pesticide labels (*e.g.*, spray drift or runoff buffers). This would also be consistent with recent statements by the U.S. Government on the use of risk assessment in chemical regulation:

> *Risk Assessment is the scientific gold standard as set forth by all three WTO SPS organizations (OIE, IPPC, CODEX). To abandon this standard weakens scientific credibility, creates confusion, makes regulatory harmonization and risk*

> *communication very difficult, and in the end produces an inferior product. The simplest solution to the broad range of policy and regulatory options is to standardize the use of risk assessment in all cases. … Risk assessments present results that are more complete and informative. Conversely, hazard based assessments may result in decision-making that neglects relevant science and results in poor outcomes from a variety of perspectives including public health, environmental protection, and socio-economic interests.*[28]

CLA recommends that the Agency use the results of a risk assessment, rather than a hazard value, to develop label restrictions that are not a "one size fits all" approach to protect honey bees, in order to avoid unwarranted application restrictions for products that present a low risk to honey bees. CLA also recommends that the Agency allow growers and beekeepers flexibility to develop or maintain local risk mitigation practices such as applying short-residual products at night that are effective in mitigating risk to honey bees but which still allow some application during the bloom period to control problematic pest infestations in the crop. Finally, as noted, we urge the Agency to revise its Proposal to reflect the first-round stakeholder comments and issue and invite comments on a reconsidered and refined proposal, to also address implementation issues.

5.3 Application to sites that are not under contracted pollination services

The Proposal describes the use of state and tribal MP3s in mitigating exposure to bees that may be present in fields to be treated, but not under contract for pollination services. CLA and its members supports this use of MP3s, which can provide and promote communications channels between growers and beekeepers that would allow exchange of information on hive locations and timing of pesticide application. If growers can know where bees are located near their fields and beekeepers can be made aware of nearby applications, actions can be taken to protect the bees while allowing growers to use the tools they need for healthy and abundant crop yields. Judgement on how best to protect managed honey bees is best left to expert growers and bee keepers who understand the local situation, crop needs, and available exposure mitigation options. MP3s have the potential to provide the flexibility needed by both parties.

EPA's Proposal states that the Agency "… will be evaluating on an ongoing basis the effectiveness of these plans at reducing exposure of bees to pesticides. After state or tribal MP3s have been in place for several years, EPA will then determine whether additional label revisions are appropriate." (Section 8, p. 15) CLA believes this is a wise path. All stakeholders directly involved at the local level should participate in deciding on the measures of success for MP3s. The effectiveness of MP3s should be measured based on criteria demonstrating the success of those communications and the satisfaction of the parties involved. Increase or decrease in reports of honey bee health concerns may not be a reliable measure of MP3 success for a variety of reasons.

[28] Anonymous (Jan 16, 2015) European Commission's public consultation on defining criteria for identifying endocrine disruptors (EDs) in the context of the implementation of the plant protection product regulation and biocidal products regulation. Comments of the U.S. Government. Retrieved from http://www.usda-eu.org/wp-content/uploads/2015/01/United-States-Submission-Endocrine-Disrupters-2015-01-20.pdf. Accessed Aug 25, 2015

Exceptions to EPA label prohibition

The proposed prohibitions on application of the 76 active ingredients during bloom would allow no exceptions "… unless the application is made in association with a government-declared public health response." CLA shares the concerns of RISE (Responsible Industry for a Sound Environment) expressed in its comments to this docket under the subheading, "Public health and invasive species exemptions." CLA incorporates RISE's comments on this issue by reference.

CLA also recommends that EPA allow exceptions from the prohibitions where the grower and the beekeeper have specifically addressed the scenario. Adding this exception to the label or otherwise would allow growers and beekeepers the flexibility they require to continue their operations, encourage voluntary risk mitigation and provide an avenue for reconciliation if an adverse incident occurs. This flexibility is particularly important for crops that have indeterminate bloom, and for other uncertainties recognized in these comments.

Steps can be taken to use products determined to be acutely toxic by EPA in ways that protect both honey bees and the crop protected. Rather than excluding the use of a needed pesticide tool, a reasonable and effective management plan would be to include in the grower-beekeeper contract a provision requiring notification of the need to treat in time for the bees to be removed or otherwise protected from contact with the product. Such provisions are common in example pollination contracts that are readily available.

6. Uncertainties

6.1 Non-acutely toxic insecticides and insect growth regulators and **6.3 Systemic pesticides and prolonged residual toxicity**: CLA supports EPA's Proposal to continue to conduct comprehensive chemical-specific risk evaluations and take appropriate actions to address any risks through the registration and registration review programs, based on the available scientific evidence.

6.2 Insect growth regulators and fungicide tank mixes: In October 2014, the Almond Board of California released a comprehensive set of *Honey Bee Best Management Practices for California Almonds*[29] that effectively address concerns about fungicide use and tank mixtures of fungicides and insecticides during almond bloom, while ongoing research seeks the underlying causes of problems that have been observed in recent years. Success of these BMPs should be followed closely.

6.4 Indeterminate bloom: As stated earlier, the lack of exceptions to the prohibition of using products on EPA's list during bloom, in particular with crops of indeterminate bloom, where contract pollination is used, presents a serious risk of excessive crop loss and economic damage to growers. Such crops include cucurbits (watermelons, cucumbers, squash, melons, etc.) and caneberries (raspberries, blackberries, etc.).

6.5 Microbial pesticides

Any mitigation measures for microbial pesticides should follow established processes for determining data requirements and assessing risks to non-target organisms. As with

[29] Curtis B, Ludwig G, Veenstra D (eds.) (2014?) Honey bee best management practices for California almonds. 19 pp. Almond Board of California. Retrieved from http://www.almonds.com/sites/default/files/content/attachments/honey_bee_best_management_practices_for_ca_almonds.pdf. Accessed on Aug 25, 2015

conventional pesticides, microbial pesticides should be regulated based on risks rather than hazards, balanced with the benefits of pesticide use, as required by FIFRA.

Additional uncertainties

There are additional uncertainties associated with EPA's Proposal that the Agency has not recognized. For example, the lack of any other exceptions to the prohibitions would present serious risks of crop loss and economic damage to growers. A number of crop/pest complexes require treatment for control during bloom. Delay of even a few days in these applications could result in irreversible crop damage. Just a few examples are described briefly below.

Cucurbit crops, such as melons, are vulnerable to infestation by whiteflies (*Bemisia* spp.) during much of the growing season. Whiteflies vector plant diseases that cause serious yield loss, as well as damage to crops directly via feeding and honeydew production. Cucurbit crops bloom throughout the growing season, and growers may employ managed pollination services during much of the growing season. Many standard products that control whiteflies and thus prevent disease transmission are on EPA's list of 76 active ingredients. The inability to use these products during bloom presents a grave threat to cucurbit crops.[30]

Thrips (Thysanoptera) damage blooms and small developing fruit of many crops, such as blueberries. **Light brown apple moth** (*Epiphyas postvittana*) is a quarantine pest of caneberries in California; its detection can result in quarantine of fields by USDA and/or the California Department of Agriculture, only to be reopened following treatment and inspection for presence of the pest.[31] **Spotted-wing drosophila** (*Drosophila suzukii*) infests developing fruit of cherries, blueberries and caneberries much earlier in the season than other *Drosophila* species, when blooms may be present. The products necessary for control of these pests are all on EPA's list of active ingredients subject to this Proposal.

EPA's Proposal could also have adverse **consequences for organic agriculture**. Some pesticides recognized by USDA's National Organic Program[32] and certified by the Organic Materials Review Institute[33] for use in standard organic production are on EPA's list of 76 active ingredients, and would therefore be subject to the same restrictions as the conventional products.

Seed crops tend to be high-value, intensively managed crops, for which it is critical to have a variety of pest management tools. Many seed crops require managed pollination services, but are threatened by pests during bloom. Aphids infest Brassica crops such as broccoli and cabbage. Cucumber beetles are a problem on cucurbit crops such as melon and cucumber. Lygus bugs attach sunflowers and onions. Mr. Jim Errecart, an alfalfa seed producer for 35 years, commented in this docket that the alfalfa seed crop requires managed pollination, primarily by honey bees.[34] During the indeterminate bloom period that lasts up to 120 days, a

---

[30] Palumbo J (Apr 30, 2014) Whitefly Management on Spring Melons http://cals.arizona.edu/crop/vegetables/advisories/more/insect106.html. Accessed Aug 28, 2015

[31] Johnson MW, Pickel C, Strand LW, Varela LG, Wilen CA, Bolda MP, Flint ML, Frankie Lam WK, Zalom FG (2007) Light Brown Apple Moth in California: Quarantine, Management, and Potential Impacts. UC Statewide Integrated Pest Management Program. Sept 12, 2007. http://www.ipm.ucdavis.edu/EXOTIC/lightbrownapplemoth.html. (accessed Aug 24, 2015)

[32] http://www.ams.usda.gov/rules-regulations/organic/national-list

[33] https://www.omri.org/

[34] Federal Docket ID No. EPA-HQ-OPP-2014-0818-0163. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2014-0818-0163. (Accessed Aug 24, 2015)

variety of insect pests feed directly on the bloom, foliage and developing seed. Mr. Errecart discusses with the beekeeper which pesticides will be used during bloom and placement of the hives to reduce exposure. He informs the beekeeper during the season when pesticide application is needed and what steps are taken to minimize exposure to the bees.

In all of these situations, another means to protect both honey bees and crops would be to apply products at times when bees are not active, such as at night. Products which have acute toxicity on contact can be used in such situations as long as they do not exhibit extended residual toxicity.

Some crops such as blueberries may be grown in **plantings of multiple cultivars** that flower at different times, which would prolong the time that commercial pollinator services would be needed, as well as the vulnerability to pest problems requiring control during flowering.

The loss of acutely toxic products under any conditions also threatens the ability to **manage insecticide resistance**, which is a critical issue that the Agency has heretofore been working to address. Several insecticide Mode of Action groups[35] are represented on EPA's list of 76 active ingredients: Carbamates (Group 1A), Diamides (28), Indoxacarb (22A), Mectins (6), METI Acaricides and Insecticides (21A), Neonicotinoids (4A), Organophosphate (1B), Phenylpyrazoles (2B), Pyrethroids (3A), Spinosyn (5), and Sulfoximine (4C). These covers the major insecticide classes currently needed to control insect pests of crops.

If certain product classes are banned, there will be increased use of the remaining products, magnifying selection pressure for pest resistance. This is a particular concern in cases where the product is the market standard for effective control, as less effective products may require more frequent application, further increasing the risk of resistance.

7. Implementation

Administrative process

FIFRA and its implementing regulations provide for a systematic registration review process.[36] Through the registration review process, FIFRA grants EPA the authority to request relevant data to inform the Agency's risk assessments, allowing sufficient time for registrants and other stakeholders to generate and supply the data, for EPA to review the data, and for EPA to incorporate the data into its risk assessments. CLA maintains that registration review is the appropriate mechanism for identifying whether currently registered products are acutely toxic to bees. For the reasons stated elsewhere in these comments, hazard-based cut-off criteria would be inconsistent with FIFRA's risk-benefit safety standard, inappropriate as the basis for label mitigation, and a departure from EPA precedent. Hazard-based cutoff criteria fail to provide complete and appropriate analysis of the human health and environmental risks and benefits of the products that would be impacted by EPA's Proposal, compared to alternatives.

It is imperative that EPA follow the appropriate process in implementing any changes in label language to address honey bee health. Active ingredients should be evaluated individually and fully as part of the processes for registration, registration review, or special review. EPA should perform a full evaluation of all of the evidence to determine whether additional mitigation is

[35] IRAC International MoA Working Group. (May 2015) IRAC mode of action classification scheme: Version 7.4. 26 pp. Insecticide Resistance Action Committee. Retrieved from http://www.irac-online.org/documents/moa-classification/?ext=pdf. Accessed Aug 28, 2015

[36] FIFRA §3(g); 40 CFR Part 155, Subpart C.

necessary. There should be a full investigation of the use patterns of each pesticide product, including at least a screening-level risk assessment. If it is shown that additional data are required to refine the risk assessment, such data should be requested under formal data call-in procedures. EPA has failed to make any showing to justify this stark departure from the risk-based approach to environmental protection required by law.

Part of following the appropriate processes is allowing sufficient time for an evaluation to be made and for changes to be implemented. The workload on the registrants and on the Agency to fully evaluate each active ingredient and allow for generation of any required additional data will be considerable. The proposed label mitigation cannot be expected to go into effect in the 2016 growing season.

Proposal implementation

Given EPA's reliance on bee kill incident reports as justification for this Proposal, EPA should have made this information available as supporting documentation at the time the docket was opened for public comments. Belated posting in the docket of partial information on reported bee kill incidents hampers the ability of stakeholders to comment effectively.

EPA has also failed to consider the significant costs of this Proposal. Given the significant economic implications of this Proposal, which would require changing of hundreds of product labels, this significant regulatory action should be subject to review by the Office of Information and Regulatory Affairs ("OIRA") within the Office of Management and Budget. Executive Order 12,866 requires agencies to conduct an analysis of the costs and benefits of significant proposed regulatory actions and, to the extent permitted by law, directs that such actions shall only proceed on the basis of a reasoned determination that the benefits of such action justify the costs.[37] OIRA should also review any related regulatory requirements for registration including, but not limited to, acute and chronic larval and acute and chronic adult honey bee studies.

Additionally, federal agencies faced with complex regulatory actions often offer multiple opportunities for public input to ensure that the final actions represent the best public policy. In such instances, agencies may provide multiple rounds of public comments, or host multiple stakeholder workshops. In this case, EPA's implementation of this action will have significant impacts on external stakeholders including pesticide registrants. Additional opportunities for stakeholder input and broader analysis of the Agency's justification for this Proposal would assist EPA in balancing the important role that America's farmers play in producing food and fiber while protecting human health and the environment (bees, in particular), through science-based policymaking.

If EPA pursues the proposed restrictions on these 76 active ingredients, CLA requests that EPA resubmit this Proposal for another round of comments along with all data, documents and cost-benefit analysis that the Agency claims as justification for such Proposal. The Agency should

---

[37] *See* Executive Order 12866 (Sep 30, 1993) Regulatory Planning and Review. 58 FR51735, October 4, 1993. Retrieved from http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf. Accessed Aug 28, 2015. *See also* Orszag, P R (Mar 4. 2009) Memorandum for the heads and acting heads of executive departments and agencies. Office of Mgmt. & Budget, Executive Office of The President. Retrieved from https://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_fy2009/m09-13.pdf. Accessed Aug 25, 2015

also consider hosting stakeholder workshops to facilitate collaboration between growers and beekeepers that may make these proposed restrictions unnecessary.

Cost/benefit analysis

EPA has decided that the mere possibility of exposure by honey bees to acutely toxic pesticides justifies a significant labeling mandate on a significant number of products, while failing to consider the significant agronomic and economic costs of this Proposal. In fact, the Proposal and associated Federal Register Notice do not even ask the question or request comment on such costs. In fact, EPA has not been able to identify with certainty how many and which products would be impacted by its proposed label change, making cost-benefit analysis impossible. In order to quantify such costs, if EPA requires information on the benefits of the pesticide uses that would be curtailed by this regulatory action, then it is incumbent on EPA to request this information from growers, registrants and other knowledgeable stakeholders. Furthermore, EPA assumes benefit from this proposed regulatory action without any proposal or plan to measure that benefit. Any future proposal must outline how EPA will establish performance metrics and measure the success of the proposed action. In summary, before undertaking any regulatory action following this Proposal, EPA must obtain and analyze data on costs and benefits associated with its implementation, including comments received from farm groups and other industry stakeholders in response to this Proposal.[38]

FIFRA's standard for registration requires EPA to taking into account the economic, social and environmental costs and benefits of the use of the pesticide[39], and EPA's failure to consider the costs of this Proposal also makes it impossible to be subject to OIRA review as required by Executive Order 12,866, and discussed more thoroughly above. EPA must not proceed with this Proposal without first completing a cost-benefit analysis.

EPA and registrants both have strong commitment to product stewardship. We fully support EPA's continued efforts to enhance the protection of honey bees in meaningful ways. However, this proposal prohibiting the foliar application of acutely toxic pesticide products during bloom in its current form is flawed and unworkable, and should be retracted. CLA encourages the Agency to thoroughly consider these and other posted comments to develop a practical and flexible guidance to manage risks to honey bees from acutely toxic compounds. The proposed one-size-fits-all, hazard-based approach disregards EPA's own established *Guidance* for honey bee risk assessment. CLA strongly urges EPA to adhere to established science-based risk assessment procedures for evaluating individual chemical compounds through registration and registration review. The rigorous and science based approach is the most effective way for EPA and all agricultural stakeholders to understand the risks appropriately and establish practical and effective measures that will lead to enhanced honey bee protection, while simultaneously protecting crops from pests.

Appendix A – List of registered active ingredients that meet the acute toxicity criteria

76 active ingredients and foliar applications

Of the 76 active ingredients on EPA's list, only 45 have registered uses on the 10 crops accounting for 95% of commercial pollination fees, according to a preliminary search of product

[38] *See e.g.,* FIFRA §2(bb).
[39] *See Id.*

labels. Thirty-two of those active ingredients are not used as foliar applications on crops (Table 1).

Table 1. Registered Active Ingredients – No Foliar Crop Uses

At Planting Application Only	No Foliar Crop Label	Homeowner or Restaurant Uses	Animal Parasite Application
Aldicarb Bensulide Chlorethoxyfos Ethoprop Fosthiazate Phorate Tefluthrin	Amitraz Arsenic acid Chlorfenapyr Chlorpyrifos methyl Metaflumizone Methiocarb Momfluorothrin Naled Phenothrin Rotenone Tetramethrin	D-trans-allethrin Fenitrothion Imiprothrin Prallethrin Propoxur	Cyphenothrin Dichlorvos Etofenprox Tetrachlorvinphos Amitraz Fluvalinate
Greenhouses and Ornamentals	**EPA Phase Out**	**Stored Grain**	
Fluvalinate	Endosulfan Resmethrin Carbofuranb	Pirimiphos-methyl	

Two of the active ingredients are herbicides. Bensulide is used either pre-plant or pre-emergent to the crop. Sethoxydim is used for post-emergent weed control applications on alfalfa but not for alfalfa grown for seed.

All of the remaining active ingredients from EPA's list are used on crops that require managed or contracted pollination services. The product labels currently have bee-protective language that limits the application of products or their drift to blooming crops or weeds while bees are foraging in/or adjacent to the treatment area. There are also label restrictions for applications during bloom, especially in the case of tree fruits such as pome and stone fruit. The new EPA label prohibition during bloom proposed by EPA would negates practical risk mitigation measures currently available to growers and beekeepers, such as nighttime applications.

Appendix B – Proposed labeling

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 SITES WITH BEES ON-SITE FOR COMMERICAL POLLINATION SERVICES: Foliar application of this product is prohibited from onset of flowering until flowering is complete when bees are on-site under contract, unless the application is made in association with a government-declared public health response. If site-specific pollinator protection/pre-bloom restrictions exist, then those restrictions must also be followed.

- CLA strongly recommends that EPA retain current mitigations for 48 hour notification that are present on neonic labels. Also, considering the broad range of products, additional mitigations would be appropriate to ensure crop protection (spray at night, etc.).
- EPA needs to clearly define and describe terms –
    - on site
    - contract
    - onset of flowering
    - completion of flowering