March 25, 2024

Caleb Hawkins
Pesticide Re-Evaluation Division
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 204600-0001

Submitted to Docket **EPA-HQ-OPP-2023-0428:**

Re: Request for Comment: Petition Seeking Rulemaking for Registration of Neonicotinoid Insecticides and Other Systemic Insecticides. 88 FR 82286. November 24, 2023

Dear Mr. Hawkins:

On November 24, 2023, the U.S. Environmental Protection Agency's (EPA or the Agency) published a Notice of Availability and Request for Comment on a petition received from the Public Employees for Environmental Responsibility (PEER), the American Bird Conservancy (ABC), and 63 co-petitioners (the "Petition"), requesting that the Agency initiate a rulemaking for neonicotinoid insecticides and other systemic insecticides. PEER and ABC believe the Agency should amend the existing regulations under the Federal Insecticide, Rodenticide, and Fungicide Act (FIFRA) to require all applicants and registrants of neonicotinoid and other systemic insecticides to provide performance (efficacy) data to the Agency in applications for registration and during registration review.

Crop Life America (CLA)[1] and RISE (Responsible Industry for a Sound Environment)[2] appreciate the opportunity to comment on this Petition, which specifically requests amendment of 40 CFR §158.400(e)(1) to:

[1] Established in 1933, CropLife America (CLA) represents the developers, manufacturers, formulators, and distributors of pesticides for agriculture and pest management in the United States. CLA's member companies produce, sell, and distribute nearly all the pesticide and biotechnology products used by American farmers. CLA represents the interests of its registrant 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.

[2] RISE is a national not-for-profit trade association representing more than 220 producers and suppliers of specialty pesticide and fertilizer products to both the professional and consumer markets. RISE member companies manufacture more than 90 percent of domestically produced specialty pesticides used in the United States, including a wide range of products used on lawns, gardens, sport fields, and golf courses and to protect public health.

- Exclude neonicotinoid and other systemic insecticides from the product performance data submission waiver;
- Require submission of efficacy data within 180 days of promulgation of a final rule for each already registered product containing neonicotinoid or other systemic insecticides;
- Deny or revoke registration of any product containing neonicotinoid or other systemic insecticides that "lacks a demonstration that its benefits exceed its environmental and overall costs."

CLA and RISE oppose the proposed actions above and contend that submission of efficacy data will not improve the Agency's ability to protect human health and the environment from potential adverse effects of pesticide use. If amended, this additional review requirement could place an unnecessary burden on the Agency which is already under-resourced.

CLA and RISE's comments are divided into 4 categories:

I. Background and Summary of Statutory and regulatory authority for the efficacy data submission waiver;
II. Lack of added benefit to human health or the environment for the Agency to review efficacy data;
III. Current efficacy data generation and review process; and
IV. Benefits of neonicotinoid and other systemic insecticides.

CLA and RISE appreciate the opportunity to comment on this petition and the extension that the agency granted, allowing for additional stakeholder analysis and input. Should you have any questions or comments, please feel free to contact us at mbasu@croplifeamerica.org, kspotz@pestfacts.org, or (202) 296-1585.

Sincerely,

Manojit Basu, PhD
Vice President, Science Policy
CropLife America

Kristen Spotz
Senior Director of Regulatory Affairs
RISE

CC: Ed Messina Director, OPP
Kimberly Nesci, Director, USDA OPMP

I. Background and Summary of Statutory and Regulatory Authority for the Efficacy Data Submission Waiver

The Petition seeks to modify the 1984 efficacy data submission waiver at 40 CFR § 158.400(e)(1) by adding the italicized language in the quote below:[3]

> The Agency has waived the requirement to submit product performance data unless (a) the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or (b) a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans; or (c) *is a neonicotinoid or other systemic insecticide.* However, each registrant must ensure through testing that his or her product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case by-case basis, submission of product performance data for any pesticide product registered or proposed for registration. *Each existing registrant of a neonicotinoid or other systemic insecticide who has not already submitted efficacy data must submit data on whether its product is efficacious within 180 days of the promulgation of this Rule, whereupon the Agency will consider the product's foreseeable benefits and costs to the environment. The Agency shall not register, and shall revoke any existing registration for, any neonicotinoid or other systemic insecticide that lacks a demonstration that its benefits exceed its environmental and overall costs.*

CLA and RISE oppose the modification proposed in the Petition and offer the historical context below, which led to the EPA establishing the exemption. The concept of this exemption, or efficacy data submission waiver, is rooted in statute and has had considerable input from Congress, the United States Department of Agriculture (USDA), and other stakeholders over many years, who often voiced concerns or differing opinions. The result, as described below, is an efficacy data submission waiver for nearly all agricultural pesticides, with provisions to help ensure that FIFRA's safety standard of "no unreasonable adverse effects on the environment" is met, while effectively managing EPA's resource commitments.

History

The Federal Environmental Pesticide Control Act of 1972 (FEPCA)[4] completely rewrote FIFRA, transforming what had originated as a consumer protection law into one firmly grounded in the protection of human health and the environment. That act also initiated the "reregistration" of pesticide products to ensure that pesticides then on the market met these enhanced health and environmental requirements (at p. 998-999). By the late 1970s, to address EPA budget limitations in the face of expanded regulatory authority, the Agency's review of human health and environmental protection data was prioritized over review of pesticide efficacy data for consumer protection purposes.

[3] https://www.ecfr.gov/current/title-40/part-158/section-158.400#p-158.400(e)
[4] https://www.congress.gov/bill/92nd-congress/house-bill/10729/text/statute?s=1&r=1

The Agency proposed to Congress better ways to manage the workload.[5] In a statement presented to a Subcommittee of the House Agriculture Committee on April 27, 1977, EPA Administrator David Costle explained:

> "… we feel that far too much Agency time is currently being spent in reviewing efficacy data while shortages abound in the reregistration data validation areas. Since the registrant, the USDA, and pesticide users are generally in a better position to judge efficacy, particularly of agricultural pesticides, we are proposing that the Agency should have explicit authority to waive the efficacy data requirement when appropriate..."[6]

Senate Report 95-334 of July 1, 1977, added several details to the rationale for an efficacy data submission waiver, beyond the enormity of the reregistration task. In the context of new reregistration requirements, the report concluded that public resources could be better used in hazard rather than efficacy evaluation of products (other than public health/disinfectant uses).[7]

In an interim final rule implementing certain provisions of FEPCA, published on May 11, 1979,[8] the Agency further explained the rationale for the "Waiver of Efficacy Data Requirement." In particular, the authority of the Administrator to take corrective action, including withdrawal of any or all waivers of efficacy data submissions, is described. The Agency details a standard by which to judge if the efficacy data submission waiver is being abused: "…a significant increase in complaints from the agricultural community, other user groups, or the general public about ineffective products," and "… a pattern of inadequate performance has been reported."

The interim final rule also demonstrated that the Agency's viewpoint concerning efficacy data submissions waivers was also aligned with key stakeholders in pesticide industry, including USDA, that agricultural pesticide efficacy could be effectively regulated by the marketplace (in conjunction with extension services and university research personnel). The interim final rule described the Agency's concerns and reason for requiring efficacy data for, "health-related use patterns and new and added uses of chemicals which have been identified as posing a risk of unreasonable adverse effects". The Agency conceded, however, that it must have sufficient information about the proposed use patterns to assess hazards to human health and the environment. Because efficacy data had been useful in providing this supplemental information, the Agency reserved the right to request this additional information if the submitted label was not sufficiently detailed.

The preamble to the 1979 regulation noted objection to the data submission waiver, in USDA's April 6, 1979, response to the request submitted by EPA as required by FIFRA §25(a)(2)(B) (at p. 27943). Specifically, USDA was concerned that that EPA's failure to review efficacy data submitted in support of the registration of new uses, or the reregistration of old uses of pesticides, could result in less than

---

[5] https://www.congress.gov/94/statute/STATUTE-89/STATUTE-89-Pg751.pdf

[6] Senate Report 95-334 (to accompany S. 1678). Extension of the Federal, Insecticide, Fungicide, and Rodenticide Act. July 6 (legislative day, MAY 18), 1977.—Ordered to be printed Reported under authority of the order of the Senate of (July 1 (legislative day, May 18), 1977. at p. 73.

[7] Ibid., at p. 47.

[8] https://www.govinfo.gov/content/pkg/FR-1979-05-11/pdf/FR-1979-05-11.pdf#page=306

desirable formulations (i.e. products that are ineffective and/or cause unintended phytotoxicity) being available to users. EPA responded to USDA's objection noting that the efficacy data waiver was experimental in nature and that if abuses were identified the Agency could rescind any or all efficacy waivers to correct the situation. The response also noted that the USDA was an active partner in the development of the Administration's legislative proposal to amend FIFRA in early 1977 to incorporate the efficacy data waiver provision of FIFRA § 3(c)(5). In hearings on the FIFRA amendments before Congressional committees, USDA supported the Agency in the concept of an efficacy data waiver and recognized the effective force of the pesticide market in regulating non-efficacious products.

That 1979 Interim Final Rule implemented the efficacy data submission waiver essentially by "omission," that is, the products *not covered* in the efficacy data requirements, spelled out at 40 CFR §§160.18-2(d)(2) and (3), would have efficacy data waived.[9] Those data requirements and the data submission waiver were specific to *conditional registrations* of pesticide products.

In subsequently proposing a comprehensive update to all "Data Requirements for Registration" (47 FR 53192),[10] EPA noted USDA's response to an earlier draft of the regulation (at p. 53198). USDA believed waivers for efficacy data should only be granted on a case-by-case basis. EPA had stated its rationale for granting the initial efficacy data waiver in the Federal Register of May 11, 1979 (44 FR 27932) and its position that the marketplace could function effectively to remove ineffective products. EPA was aware of no serious problems with its existing efficacy data waiver, retains the right to require submission of efficacy data at its discretion, and therefore saw no persuasive reason to forgo further regulatory relief in this area.

Elsewhere in the preamble to that proposed rule, the Agency explained (at p. 53196) its reasoning for extending the efficacy data waiver to additional use patterns, including include all registration actions, both conditional and unconditional.

In the preamble to the final Part 158 regulation (49 FR 42856),[11] EPA responded to USDA's comments on the draft final regulation (at p. 42880). USDA noted that the regulation refers to the registration process as an evaluation of risks and benefits and suggested it be referred to as a risk analysis process or, alternatively, efficacy/benefit data should be required at the time of registration. EPA responded that while it agreed with USDA that the focus of the regulation and the data requirements is largely on the risk analysis process, the need for efficacy/benefit data is often based on *results* of the risk analysis. For most pesticides, the risk criteria (40 CFR Part 162) are not met or exceeded and therefore, rather than require efficacy data, the Agency presumes that benefits exceed risks. However, for a relatively few pesticides, submission of product performance data will be required for the evaluation of product benefits when product risks are potentially substantial, as set forth in § 158.160(b)(1) of the regulation.

---

[9] See 47 FR 53192 (November 24, 1982), section V.I, at 53196 (https://www.govinfo.gov/content/pkg/FR-1982-11-24/pdf/FR-1982-11-24.pdf#page=238):

> The Agency defined in § 162.18-2(D) the circumstances when efficacy data were required to be submitted as a matter of course. Other requirements that efficacy data be submitted were generally waived.

[10] https://www.govinfo.gov/content/pkg/FR-1982-11-24/pdf/FR-1982-11-24.pdf#page=238

[11] https://www.govinfo.gov/content/pkg/FR-1984-10-24/pdf/FR-1984-10-24.pdf#page=173

That final regulation expressed the efficacy data submission waiver in a test note to the product performance data requirements table (at p. 42897). EPA waived all requirements to submit efficacy data except if use of the pesticide bears a claim to control pests that pose a threat to human health. However, all registrants must be able to ensure that their products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration when necessary.

In a 2007 revision, 40 CFR Part 158 achieved is current organization and format, including placement of data requirements for experimental use products in a separate Subpart.[12] The statutory authority to waive the efficacy data requirement for registration of agricultural pesticides occurs in FIFRA §3(c)(5) [7 USC §136a(c)(5).

Based on that authority, EPA's current data requirement regulation for pesticide regulation lists only those product categories for which product performance data are required to be submitted (40 CFR §158.220(c) for experimental use permits (EUPs), and 40 CFR §158.400(d) for other pesticides). The requirement to submit product performance (efficacy) data is waived for all other pesticide products, including essentially all agricultural pesticides. The identical text occurs in both places, except that the EUP subpart retains the term "efficacy" in place of "product performance".

While the statute states that the Administrator "*may waive data requirements pertaining to efficacy*," the Agency has implemented a positive, definite waiver. On the other hand, actual application of the product performance data requirement is only on a case-by-case basis. In Pesticide Registration Notice 96-4, the Agency succinctly outlined the legal framework, legislative history, regulatory development, and practical rationale for the submission waiver.[13]

The Agency's expectation is that all registrants will perform the tasks necessary to assure themselves that the products they market will perform their intended functions when applied in accordance with label directions and commonly accepted pest control practices. Given the constraints on EPA's resources in 2024, the focus on review of highest priority data is more important than ever. The diversion of effort to review data of minimal value to regulatory decisions would leave more important tasks undone.

II. No Additional Public Health and Environmental Protection Benefit from the Submission and Review of Efficacy Data

There is no added benefit to human health or the environment from the proposed amendment(s) that would require the Agency to review efficacy data for neonicotinoid and other systemic insecticides. FIFRA sets an overall risk-benefit standard and requires pesticides to perform their intended function (i.e., is efficacious), when used according to label instructions. The petitioners claim that EPA cannot "make regulatory judgements" regarding the "risks and benefits of pesticide products". Under FIFRA, the current human health and environmental risk assessment framework is robust and addresses EPA's

[12] https://www.govinfo.gov/content/pkg/FR-2007-10-26/pdf/E7-20826.pdf
[13] https://www.epa.gov/pesticide-registration/prn-96-4-label-statements-involving-product-efficacy-and-potential-harm

responsibility to determine whether adverse effects are reasonably expected to result from a pesticide's use. EPA conducts these risk assessments during registration and registration review, which is currently on-going for the neonicotinoid insecticides.[14] Furthermore, EPA's Biological Economic and Analysis Division (BEAD) reviews pesticides' risks and benefits and provides use-related information and economic analyses for consideration in pesticide registration decisions, including the neonicotinoids and other systemic insecticides.[15]

As detailed by the regulatory authority described above, the Administrator may waive, at their discretion, data requirements pertaining to the efficacy of a pesticide.[16] However, the Administrator could invoke efficacy requirements if they believed that they were necessary to assure the quality of product or to protect consumers. Pursuant to this amendment, whenever the Administrator found that some other procedure for assuring the efficacy of pesticide products appeared to be sufficient, the Administrator could register or reregister products without requiring submission or citation of some or all the efficacy data that otherwise would be required under FIFRA.

III. Current Efficacy Data Generation and Review Process

As detailed above, EPA reviewing efficacy data is not the best use of resources since a pesticide manufacturer is not likely to expend the substantial investment in time and money needed to obtain registration of a pesticide on a non-efficacious product. Before a registrant launches a pesticide, extensive field efficacy trials are conducted across a wide range of geographies to determine activity against target pests in numerous climatic and farming conditions. These trials are conducted in cooperation with both private and public organizations. In general, pesticides which are commercially successful have gained acceptance based on their efficacy. Furthermore, FIFRA requires applicants for pesticide registration to provide to EPA, if requested, "a full description of the tests made and the results thereof upon which the claims are based." [17] It is therefore implicit that such tests are conducted and available for submission if requested.

The USDA, including its four regional Integrated Pest Management (IPM) centers and the Cooperative Extension System (CES), with a network of land-grant university experiment stations, conduct thorough evaluations of pesticide efficacy, potential phytotoxicity (crop injury), and, when appropriate, yield, in a variety of agricultural production systems, to provide unbiased information and advice to its farmer constituency. Over the decades, this fine-tuned expert system of research scientists and facilities has developed and maintained high credibility in the agricultural production community. The regional nature of the land grant university system is also inherently valuable to producing reliable, high-quality efficacy data, as crop production systems and environmental conditions vary on a regional basis. In contrast, EPA's small staff of biologists within the Office of Pesticide Programs (OPP), with limited agricultural

---

[14] Schedule for Review of Neonicotinoid Pesticides. https://www.epa.gov/pollinator-protection/schedule-review-neonicotinoid-pesticides

[15] Myers, C., Mallampalli, N., Wyatt, T.J. 2017. Biological and Economic Analysis Division (BEAD) Response to Public Comments Submitted in Response to BEAD's Assessment entitled "Benefits of Neonicotinoid Seed Treatments to Soybean Production" Dated October 15, 2014, OPP Docket: EPA-HQ-OPP-2014-0737. https://www.regulations.gov/document/EPA-HQ-OPP-2014-0737-0948

[16] Section 5 of S. 1678

[17] FIFRA SEC. 3. [7 U.S.C. 136a](F) Registration of Pesticides.

research expertise and lack of field and laboratory facilities, cannot expect to compete with USDA or CES in providing practical information on which growers can base economically and environmentally sound, practical pest management decisions.

Pest control is a considerable financial input in a farming operation. When selecting pesticides, growers most commonly ask about efficacy, economic return on investment, ease of handling, and safety.[18] Farmers commonly rely on USDA, CES publications and/or Certified Crop Advisors (CCA) when making these decisions. If a pesticide product does not meet efficacy standards, it will not be listed or recommended in that state by the CES, often in the form of IPM guides for individual crops, which are updated and published periodically.[19] Therefore, despite the enormous amount of performance data a pesticide registrant generates via internal or private contract research, registrants must still work with the land-grant extension service to verify performance before sales, and throughout the life of a pesticide.

It is also important to note, that while EPA does not routinely review efficacy data for agricultural pesticides in a formal capacity, EPA scientists routinely use performance data in their benefits assessments. Efficacy data can inform benefits assessments in support of registration review, FIFRA Section 18 Emergency Exemptions, and FIFRA 24 (c) Special Local Need applications. Sources of performance data for EPA scientists may include verbal consultations with experts, efficacy ratings published in crop commodity newsletters, CES newsletters, and short summaries in scientific journals (for example, the Entomology Society of America's Arthropod Management Tests journal).[20] In addition, registrants may include comparative efficacy data for EPA review in certain regulatory submissions, such as comparative performance data to support application for Reduced Risk Status.[21] Also, registrants will submit comparative product performance data to support extending exclusive use data protection for a pesticide product under FIFRA §3(c)(1)(F)(ii).

In "Product Performance Test Guidelines: OPPTS 810.1000 Overview, Definitions, and General Considerations,"[22] EPA states:

> Conditions under which the Agency may request efficacy data for any product, registered or proposed for registration, include but are not limited to the following:
>
> (1) A lack of efficacy has been reported for it.
>
> (2) The Agency needs such data to evaluate benefits of the pesticide (or of alternative pesticides) when substantial risks have been identified.
>
> (3) The Agency has reason to suspect that the product may not be efficacious.

Otherwise, the Agency has not established current, formal guidelines for conducting and reporting product performance studies for most agricultural and non-agricultural pesticides with the exception of

---

[18] The Pesticide Marketplace, Discovering and Developing New Products. Purdue University Extension. https://www.extension.purdue.edu/extmedia/ppp/ppp-71.pdf

[19] Example of crop-specific regional CES publication: Southeast Regional Strawberry Integrated Pest Management Guide for Plasticulture Production. 2021. University of Georgia Extension. AP 119-2_1.PDF (uga.edu)

[20] Entomological Society of America. Arthropod Management Tests. https://academic.oup.com/amt

[21] Applying for Reduced Risk Status Conventional Reduced Risk Pesticide Program | US EPA

[22] EPA 712–C–98–001. March 1998. https://downloads.regulations.gov/EPA-HQ-OPPT-2009-0150-0002/content.pdf

product performance guidelines for select invertebrate control agents (mosquito control treatments, treatments for imported fire ants, insect repellents applied to the skin, etc.).[23] To impose such a defined requirement now on registrants who are already undertaking their own efficacy testing as outlined above, would require the Agency to develop specific guidelines (a multi-year process), or would require registrants individually to develop such study protocols for each registration action and submit them to the Agency for review, in advance of conducting the studies. Petitioners have failed to establish that any perceived value of such an effort to protect from "unreasonable adverse effects on the environment" would justify the significant cost and diversion of agency resources that must accompany this effort.

Furthermore, a well-established and, in many cases, formal feedback loop exists among pesticide registrants, pesticide retailers, and the end-user. When claims of pesticide non-performance are reported to the retailer or registrant, a response is initiated that may include, but is not limited to, interviews to gather as much information as possible about the product(s) used, application specifics, field, and weather conditions; physical site visits; sample collection and analysis; and additional follow-up as needed. These responses to non-performance claims may also involve other experts to evaluate what led to the alleged non-performance (i.e., could pest resistance be developing? Were there confounding weather conditions? etc.) and identify corrective actions.

Finally, the Petitioners overlook a significant effect of their petition, should it be successful. Efficacy data of pesticide products can only be useful in comparison to alternative pesticide products and/or pest control strategies. By implication, those alternative products and strategies would also need efficacy data, to likewise be evaluated by the EPA staff in a significant expansion of the regulatory load for both the Agency and industry. Such a process would be largely duplicative of the efficient and well-organized efforts now conducted by the USDA, CES, land-grant universities, CCAs, and other field experts.

IV. Benefits of Systemic Neonicotinoid and other Systemic Insecticides.

The Petition expresses concern about the use of neonicotinoids and other systemic insecticides more generally and does not acknowledge the significant benefits they provide. Systemic pesticides, including neonicotinoids, represent a significant advancement in pesticide technology and when used in accordance with their labels, pose minimal risks for workers, applicators, and the environment. The systemic nature of a pesticide does not imply it is more toxic to pests or other organisms or that it is more persistent in the environment. Systemic pesticides are absorbed into the plant and move readily within it, either from roots to the leaves or leaves to roots. A systemic pesticide can be absorbed by the roots of a germinating seedling and move in the plant to control pests or diseases that affect the shoots and leaves. In general, this means that lower use rates are needed for effective pest control, and foliar spray applications can be reduced or eliminated. Requiring EPA review of efficacy data for neonicotinoid and other systemic insecticides would arbitrarily single out one subset to be treated differently than other pesticides.

The contention by the Petition that neonicotinoid and other systemic insecticides are frequently not effective is not consistent with peer-reviewed publications and recommendations, primarily from land-grant university studies. For example, since their introduction in the mid-1990s, neonicotinoids have become the most widely used class of insecticides due primarily to their effectiveness. An evaluation of

[23] https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-810-product-performance-test-guidelines

550 studies including peer-reviewed and extension publications that reported performance of neonicotinoid-based treatments allowed for 5,271 pairwise comparisons. This evaluation concluded that, compared to no-insecticide controls, neonicotinoid-based seed-treatment pesticides consistently produce better results for crop yield, crop damage, and pest control, and led to better net income and percent of income/hectare (ha) for the grower.[24] Meta-analysis of yield data can provide a broad view of the impact of seed treatments across varied conditions. Three meta-analyses compared yields of neonicotinoid-treated corn, cotton, and soybean seed to fungicide-only treated seed in trials across the Mid-South (Arkansas, Louisiana, Mississippi, and Tennessee). All three analyses showed that the use of neonicotinoid seed treatments can provide significant economic benefits to growers.[25, 26, 27]

Further, systemic neonicotinoid insecticides play a key role in IPM programs for agricultural pests and invasive species control, such as the Emerald Ash Borer and Spotted Lantern Fly. Registrants of these chemistries continue to invest in improved formulations, and stewardship efforts to minimize impacts to pollinators and non-target species. Growing Matters BeSure! Pollinator Stewardship Campaign is an excellent example of a stewardship program focused on delivering best management practices to growers for neonicotinoid treated seed handling or planting and for foliar applications to agricultural crops, ornamentals, and turf.[28] In addition, as the chemistries move through registration review or other opportunities for label review, additional precautionary and restrictive language aimed at pollinator protection has been included where applicable.

Conclusion

A deciding factor in the development of the efficacy data submission waiver concept was the Agency's desire to reduce the resources devoted to reviewing product performance so that additional resources could be devoted to the much more critical evaluation of health and safety data. CLA and RISE support the current regulatory framework and recognize the robust systems described above, which enable an objective and dynamic efficacy data review process for pesticides, including the neonicotinoid and other systemic insecticides. There would be no added benefit to human health, the environment, or end-users of pesticides should this Petition be successful and require EPA to expand its efficacy data review obligations. On the contrary, the additional resources required for EPA to develop a framework for efficacy data submission and review would negatively impact the Agency's ability to fulfill its other regulatory mandates and delay pesticide registration decisions. Delayed registration decisions may translate to delayed access to newer chemistries and/or innovative products important in controlling emerging pest threats or in resistance management. A new regulatory requirement for efficacy data

[24] Grout, Koenig, Kapuvair, McArt. 2020. Neonicotinoid Insecticides in New York State: economic benefits and risk to pollinators. Cornell University

[25] North, J.H., J. Gore, A.L. Catchot, S.D. Stewart, G.M. Lorenz, F.R. Musser, D.R. Cook, D.L. Kerns, and D.M. Dodds. 2018. Value of Neonicotinoid Insecticide Seed Treatments in Mid-South Cotton (Gossypium hirsutum [Malvales: Malvaceae]) Production Systems. Journal of Economic Entomology 111(1): 10-15.

[26] North, J.H., J. Gore, A.L. Catchot, S.D. Stewart, G.M. Lorenz, F.R. Musser, D.R. Cook, D.L. Kerns, and D.M. Dodds. Value of Neonicotinoid Insecticide Seed Treatments in Mid-South Soybean (Glycine max) Production Systems. Journal of Economic Entomology 109(3): 1156-1160. 2016.

[27] North, J.H., J. Gore, A.L. Catchot, S.D. Stewart, G.M. Lorenz, F.R. Musser, D.R. Cook, D.L. Kerns, B.R. Leonard, and D.M. Dodds. 2018. Value of Neonicotinoid Insecticide Seed Treatments in Mid-South Corn (Zea mays) Production Systems. Journal of Economic Entomology 111(1): 187-192.

[28] Growing Matters. BeSure! About Stewardship: Adopt best-management practices while planting https://growingmatters.org/besure.

submission may also present additional hurdles for new or small companies to bring novel chemistries to market.

CLA and RISE support the existing efficacy data submission waiver provision and recognize the system of experts that currently adequately evaluate pesticide efficacy. CLA and RISE also acknowledge the benefits to agriculture and non-agricultural use sites offered by neonicotinoid and other systemic insecticides and the complementary stewardship efforts of our company members in these markets. We welcome additional opportunities to discuss our points with the Agency and other stakeholders and appreciate this opportunity to comment.