CENTER FOR FOOD SAFETY

March 25, 2024

Environmental Protection Agency
Office of Pesticide Programs
1200 Pennsylvania Ave., NW
Washington, DC 20460

RE: **Docket EPA-HQ-OPP-2023-0428**: Petition Seeking Rulemaking for Registration of Neonicotinoid Insecticides and Other Systemic Insecticides

Center for Food Safety (CFS) appreciates the opportunity to comment, on behalf of itself and its 970,000 members and supporters, on the petition from the Public Employees for Environmental Responsibility (PEER) and the American Bird Conservancy (ABC) requesting that EPA require applicants seeking registration of neonicotinoid and other systemic insecticides submit performance (efficacy) data to enable FIFRA-compliant assessment of the risks, costs and benefits of these insecticides.

CFS believes that EPA's default position should be to require data on and assessment of product performance of pesticides generally, to enable the Agency to make sound "regulatory judgements under FIFRA" (40 CFR 158.1), which requires the fullest possible information on the risks, costs and benefits of a pesticide and its various uses. In contrast to the 1984 rule that exempted nearly all agricultural pesticides from performance data requirements, with a provision empowering EPA to require such data on a case-by-case basis, CFS believes that FIFRA-compliant decisions demand that the situation should be reversed: a general rule requiring product performance data, with exemptions only in extraordinary circumstances on a case-by-case basis.

As explained in the Petition and discussed in these comments, performance data is particularly urgent in the case of neonicotinoid and other systemic insecticides – and above all for their uses as seed treatments.

CFS will first discuss the concept of product performance, and the factors it needs to encompass in order to enable sound registration decisions. Next, we address the overwhelming evidence of the poor performance of neonicotinoid seed treatments on corn and soybeans, followed by reasons product performance data are needed for systemic seed treatments more generally. Finally, we share thoughts and recommendations on best practices for collection of performance data.

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Product Performance

Evaluating how well a pesticide does its job of pest management naturally requires attention to more than simply its effects on the pest itself. One would not describe a pesticide as performing well if its use is associated with harms to human health or the environment, or substantial economic, environmental and/or social costs, even it were very efficacious at managing the target pest(s). However, in waiving the requirement of product performance data for most pesticides in 1984,[1] EPA was thinking of performance in these narrow terms as how well the product kills the target pest(s), and conflated efficacy in this sense with overall product "benefits," untethered from possible costs. This conflation is seen in EPA's rationale for the data waiver – "rather than require efficacy data the Agency presumes that benefits exceed risks"[2] – as if pest-killing prowess is the full measure of "benefits" rather than only one aspect of a pesticide's performance, and costs did not exist. This same reductive view of performance is seen in USDA's comment on the data waiver proposal, urging EPA to continue to collect "efficacy/benefit data."[3]

Fortunately, EPA elsewhere offers a fuller conception of performance that the Agency should re-embrace in considering the petition that is the subject of these comments. EPA's Test Guidelines pair effectiveness and usefulness as the two primary but distinct aspects of "product performance," which is understood as "all aspects of a product's effectiveness and usefulness."[4] Likewise, EPA defines "performance data" in like terms as "any data pertaining to pesticide effectiveness and usefulness."[5] Moreover, EPA cites numerous background factors that require consideration in an evaluation of product performance, among them "dosage rates," "nature and level of pest control," "duration of pest control," and "benefits and/or adverse effects of product use."[6] Another critical reason to demand product performance data is found in EPA regulations, under a section entitled *Purposes of the registration data requirements.* Product Performance data are needed as "a mechanism to ensure that pesticide products will perform as intended and that *unnecessary pesticide exposure to the environment will not occur* as a result of the use of ineffective products" (40 CFS 158.130(c), emphasis added).

Additional insight into the broad scope of product performance is given in EPA directives regarding factors that must be addressed in tests of product performance, which include "adverse environmental effects such as bioaccumulation" and other environmental fate characteristics as well as "toxicity to beneficial nontarget organisms."[7] EPA recommends in particular that product performance test results should include "relevant information about possible increase in harmful nontarget organisms as a result of the pesticide use and

[1] EPA, Data Requirements for Pesticide Registration, 49 Fed. Reg. 42856-42905, October 24, 1984, at 42897, ft. 1.
[2] Id., at 42880.
[3] Id.
[4] EPA, Product Performance Test Guidelines: 810.1000 – Overview, Definitions, and General Considerations, EPA 712-C-98-001, March 1998, p. 1. https://www.regulations.gov/search?filter=EPA-HQ-OPPT-2009-0150-0002. Henceforth, "EPA 810.1000."
[5] EPA 810.1000, p. 5.
[6] EPA 810.1000, p. 1.
[7] Id.

application…."[8] Performance also includes a pesticide product's effects on yield, which may decrease or increase as a result of its use.[9]

Available Information Demonstrates That Neonicotinoid Seed Treatments Perform Poorly on Corn and Soybeans

Available information demonstrates clearly that neonicotinoids perform very poorly on major field crops like corn and soybeans, when judged by the full range of EPA product performance criteria described above.

However effectively a neonicotinoid might kill a target pest, it does so in the field only if that pest is present. In terms of major field crops, neonicotinoids are most effective on a handful of minor crop pests (e.g. seed corn maggot, white grub) that are seldom present in corn and soybean fields, and are still more rarely present at economically damaging levels (Sappington et al. 2018, Bailey et al. 2015). Recalling that performance encompasses efficacy and usefulness, neonicotinoids perform poorly here because although they are certainly *effective* at killing these minor pests, they are not *useful* and provide very little overall benefit because economic infestations are so rare in relation to their widespread use (Tooker et al. 2017). For instance, researchers in New York tested neonicotinoid seed treatments against untreated seed and alternative methods for control of seedcorn maggot in 2022. Their conclusion after one year was that there were no significant differences in any of the treatments, meaning that overall, seedcorn maggots did not affect corn establishment (Wise and Calixto 2022).

As regards major pests of corn and soybeans, neonicotinoid seed treatments perform poorly not because these pests are rare, but because they fail the efficacy side of the performance equation. Neonicotinoids have very little effect on corn rootworm in field tests (Tinsley et al. 2015), presumably because there is little overlap between the short window of time root concentrations are sufficiently high to kill corn rootworm and the pest's phenology, and root concentrations are generally quite low (Alford and Krupke 2017). In the case of soybean aphid, aphids tend to attack soybeans in economically significant numbers only after the insecticide has dissipated from above-ground tissues (Bailey et al. 2015, Krupke et al. 2017). Neonicotinoid seed treatments also have little effect on black cutworm, a minor pest (Kullik et al. 2011).

Systemic insecticides fail another performance test. Their lack of benefit on the vast majority of corn and soybean fields means that tens of millions of acres of farmland are being exposed to them unnecessarily, year after year. As noted above, EPA pesticide regulations on product performance are designed in part to protect against just such unnecessary exposure of the environment to ineffective pesticides (40 CFR 158.130). And avoidance of unnecessary pesticide use is also a cardinal principle of Integrated Pest Management, which EPA is enjoined to promote through regulatory policies and other means by Section 303 of the Food Quality Protection Act of 1996.

[8] Id. at 12.
[9] Id. at 11, 17.

Neonicotinoids also exhibit "toxicity to beneficial nontarget organisms," another aspect of product performance that is too often ignored (810.1000, p. 1). In laboratory and field studies, Douglas and Tooker (2005) demonstrated that slugs consuming thiamethoxam-treated soybean seeds/seedlings carried enough neonicotinoid in their tissues to poison and kill ground beetles attempting to prey on them; ground beetle activity-density was reduced, resulting in increased slug damage that reduced soybean yield by 5%. Researchers have also found that neonicotinoid seed treatment of soybean reduces parasitism of soybean aphid by a parasitic wasp relative to plants grown from untreated seed, potentially compromising the wasp's biocontrol services (Frewin et al. 2014). Another study found that soybean aphids were unaffected by feeding on plants grown from thiamethoxam-treated soybean seeds, but that consuming neonicotinoid-contaminated honeydew excreted by the aphids shortened the lives of a predatory midge and parasitoid wasp, which could reduce aphid predation and consequently soybean productivity (Calvo-Agudo et al. 2021).

EPA Must Incorporate Product Performance Data in Assessments of Systemic Insecticides

When the 1984 data waiver was promulgated, EPA presumed that benefits exceed risks for most pesticides based on the notion that farmers would not purchase and apply pesticides that were ineffective, which presupposes further that farmers are in a position to accurately evaluate efficacy. This would most often be true with spray applications where the effect of the pesticide on insect pests or weeds is observable. Thus, EPA continued to require efficacy data for pesticides in two situations where the user cannot ascertain performance: antimicrobials and termiticides. The former involves pest microorganisms "whose presence cannot be readily observed by the user," who is thus also unable to determine if the product has effectively eliminated them.[10] EPA requires efficacy data for termiticides for the same reason: "the user cannot determine if they have performed their intended function."[11]

Growers who use treated seeds are still more unable to evaluate efficacy than users of antimicrobials or termiticides. First, underground pests covered by the label and the effect of seed treatments on them are difficult to observe, like treatments for control of termites or microbes. Second, because neonicotinoids move systemically from seed into the tissues of the growing seedling, are invisible to the farmer, and dissipate at uncertain rates, it is extremely difficult for users to assess their efficacy against above-ground pests. Third, seeds often come with multiple active ingredients and/or plant-incorporated protectants (PIPs), making it impossible to separate the effects of the seed treatment, if any, from those of other active ingredients or PIPs that affect the target pest(s). Fourth, many growers do not have a clear idea of which product or active ingredients have been applied to their seeds (Hitaj et al. 2020), such that any pest control benefits or decrements cannot be traced back to the source.

All of these factors argue for collection of the full range of performance data for systemic, seed applied insecticides. Farmers empowered with knowledge of the performance (or lack thereof) of these products would then be in a better position to choose treated or untreated seed, as best fits their particular agronomic situations. Of course, seed-pesticide companies and their distributors often make treated seed the default option, with untreated

[10] EPA, Data Requirements for Pesticide Registration, 49 Fed. Reg. 42856-42905, October 24, 1984, at 42880.
[11] EPA 810.1000 at 2.

seed of the variety a farmer wants either impossible or difficult to access. EPA should explore regulatory avenues to make untreated seed more widely available.

Collection of Product Performance Data

As discussed above, the poor performance of neonicotinoid seed treatments on corn and soybean is already well established in the scientific literature. The harms they cause to non-target organisms are also widely acknowledged. Therefore, there may be little need for EPA to call-in registrant studies on performance of neonicotinoid seed treatments on these crops.

Otherwise, EPA should collect the full range of product performance data for any registration, re-registration or new use of a systemic insecticide. Advanced tests should "closely approximate actual use."[12] Tests should take place in different regions with different growing environments with typical target pest pressures. Tests should not be conducted in fields selected or artificially stocked for high pest pressure, since this may give a skewed sense of pest control benefit.

EPA should critically evaluate all test results for every pest listed on the label. It is not enough to determine that pesticide X kills 50% of a pest Y population at concentration Z in a laboratory test. Rather, as outlined in the Product Performance Test Guidelines 810.1000, full information on the pest's life cycle and phenology and the concentrations of systemic insecticide in various plant tissues over time is required to ascertain whether windows of pest phenology and efficacious systemic insecticide concentrations within plant tissues coincide sufficiently to ensure a target pest will actually be controlled under typical field conditions. As noted above, there is significant data indicating that corn rootworm and soybean aphid should be removed from the labels of neonicotinoid seed treatment products.

Beyond efficacy, EPA must collect performance data relating to the potential "costs" of systemic insecticides. This includes potential suppression of beneficial biocontrol organisms, which can occur through direct contact with the systemic, or contact via a pest organism, as described above. Yield declines that result from such impairment of biocontrol have been observed and must be assessed.

In short, a product's performance must be judged not only by its "efficacy" or "benefits," but also by its adverse effects and other costs. Systemic insecticides, and particularly when applied as seed treatments, are in particular need of performance data in order to enable EPA to make better, FIFRA-compliant registration decisions.

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[12] EPA 810.1000 at 1.

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