IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

JEFF ANDERSON, BRET ADEE, DAVID HACKENBERG, LUCAS CRISWELL, GAIL FULLER, CENTER FOR FOOD SAFETY, AMERICAN BIRD CONSERVANCY, PESTICIDE ACTION NETWORK NORTH AMERICA, and POLLINATOR STEWARDSHIP COUNCIL,

Plaintiffs,

v.

GINA MCCARTHY and ENVIRONMENTAL PROTECTION AGENCY,

Defendants,

and

CROPLIFE AMERICA, AMERICAN SEED TRADE ASSOCIATION, AGRICULTURAL RETAILERS ASSOCIATION, AMERICAN SOYBEAN ASSOCIATION, NATIONAL COTTON COUNCIL OF AMERICA, NATIONAL ASSOCIATION OF WHEAT GROWERS, and NATIONAL CORN GROWERS ASSOCIATION,

Defendant-Intervenors.
_____/

No. C 16-00068 WHA

ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT, DENYING AS MOOT DEFENDANT-INTERVENORS' MOTION FOR SUMMARY JUDGMENT, AND DENYING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

In this challenge to federal agency action, all parties move for summary judgment. For the reasons discussed below, the agency's motion is **GRANTED**, defendant-intervenors' motion is **DENIED AS MOOT**, and plaintiffs' motion is **DENIED**.

STATEMENT

Plaintiffs are beekeepers, farmers, and organizations concerned about the effect of pesticide-treated seeds on bees and other pollinators. They brought this action to challenge the alleged failure of the Environmental Protection Agency and its Administrator, Gina McCarthy, to enforce the Federal Insecticide, Fungicide, and Rodenticide Act with respect to such seeds. According to plaintiffs, many seeds planted in the United States are coated with neonicotinoids, a type of pesticide that distributes throughout the resultant plant and thus kills insects both by direct contact and via the plants they ingest. Additionally, these seeds, when planted, can release pesticidal "dust-off" that further spreads neonicotinoids beyond the seeds themselves (Dkt. No. 90-1 at 4). Thus, plaintiffs allege, the practice of coating seeds with neonicotinoids has had a systematic and catastrophic impact on bees and the beekeeping industry throughout the United States (*id.* at 1).

Under FIFRA, pesticides must be registered with the EPA prior to use. 7 U.S.C. 136a. The Administrator, however, may exempt from registration requirements "any pesticide which the Administrator determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this subchapter in order to carry out the purposes of this subchapter." 7 U.S.C. 136w(b). In 1988, pursuant to this authority, the EPA created an exemption from FIFRA registration requirements for "articles or substances . . . treated with, or containing, a pesticide to protect the article or substance itself . . . if the pesticide is registered for such use." 40 C.F.R. 152.25(a).

In 2003, in a publication titled "Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States" (Dkt. No. 88-3), the EPA clarified the 1988 "treated articles or substances" exemption applied to "pesticide-treated seeds" as long as the pesticide is registered for such use under FIFRA and "the pesticidal protection imparted to the treated seed does not extend beyond the seed itself to offer pesticidal benefits or value attributable to the treated seed." Subject to those two conditions, "[s]eeds for planting which are treated with pesticides registered in the U.S. are exempt from registration as pesticides" (*id.* at 1–2).

In 2013, the EPA issued to FIFRA compliance and enforcement managers a document titled "Guidance for Inspecting Alleged Cases of Pesticide-Related Bee Incidents." The cover memorandum stated, "This guidance is a supplement to the [FIFRA] Inspection Manual . . . I request that you distribute this guidance to your state lead agencies and tribal pesticide programs and encourage you to discuss implementation of this guidance with them." A disclaimer at the beginning of the document cautioned (Dkt. No. 88-2):

> This guidance represents EPA's recommended procedures for [FIFRA] inspectors when they are conducting FIFRA inspections as a result of an incident involving bee deaths. This guidance is not a regulation and, therefore, does not add, eliminate or change any existing regulatory requirements. The statements in this document are intended solely as guidance. This document is not intended, nor can it be relied on, to create any rights enforceable by any party in litigation with the United States. EPA, state and tribal officials may decide to follow the guidance provided in this document, or to act at variance with the guidance, based on analysis of site-specific circumstances.

The focal point of our lawsuit is a single passage within the guidance itself, which stated (*id.* at 7–8 & n.17):

> Note: Treated seed (and any resulting dust-off from treated seed) may be exempted from registration under FIFRA [pursuant to 40 C.F.R. 152.25(a)] as a treated article and as such its planting is not considered a "pesticide use." However, if the inspector suspects or has reason to believe a treated seed is subject to registration (*i.e.*, the seed is not in compliance with the treated article exemption), plantings of that treated seed may nonetheless be investigated.

Plaintiffs filed this lawsuit in 2016, claiming the 2013 Guidance is reviewable under the Administrative Procedure Act. Their complaint asserted four claims for relief. The first, third, and fourth claims for relief asserted that the 2013 Guidance exceeded the EPA's statutory authority, failed to comply with the APA's rulemaking requirements, and was arbitrary and capricious (Dkt. No. 1 at 22–29). The second claim for relief asserted that the EPA's "non-enforcement policy" regarding neonicotinoid-coated seeds, as embodied in the 2013 Guidance, was an unlawful "abdication" of its responsibilities under FIFRA (*id.* at 25–26).

The EPA moved to dismiss for lack of subject-matter jurisdiction (Dkt. No. 21) and several trade organizations that would be affected by the outcome of this case moved to intervene (Dkt. No. 26). A previous order granted the motion to intervene and denied the EPA's

motion to dismiss, finding that "the factual dispute between the parties — whether the 2013 Guidance constituted final agency action — is 'so intertwined' with the merits that a 'jurisdictional finding of genuinely disputed facts is inappropriate.'" The order acknowledged the EPA "put forth a strong argument in support of dismissal of the lawsuit at the Rule 12 stage" but noted that, in our circuit, "essentially all environmental cases concerning subject-matter jurisdiction are decided only after reviewing the administrative record, typically at the summary judgment stage" (Dkt. No. 62 at 4–6).

The EPA now moves for summary judgment on plaintiffs' first, third, and fourth claims for relief on the basis that the 2013 Guidance was not a reviewable final agency action, and on plaintiffs' second claim for relief on the basis that plaintiffs have failed to identify any nondiscretionary action that has been unlawfully withheld (Dkt. No. 88). Defendant-intervenors join in the motion and separately move for summary judgment on the basis that plaintiffs' lawsuit constitutes an improper programmatic challenge to the EPA's regulation of pesticides (Dkt. No. 89). Plaintiffs also move for summary judgment on their first, third, and fourth claims for relief on the basis that the 2013 Guidance was a reviewable final agency action, and on their second claim for relief on the basis that the EPA's policy of non-enforcement as to neonicotinoid-coated seeds is an unlawful "abdication" of its responsibilities under FIFRA subject to judicial review (Dkt. No. 90-1).

ANALYSIS

1. LEGAL STANDARD.

Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. F.R.C.P. 56(a); *Conservation Congress v. Finley*, 774 F.3d 611, 617 (9th Cir. 2014). When a court reviews a government agency's action, however, the standard for summary judgment is amplified by the APA, which provides the applicable standard of review. *Finley*, *supra*, at 617; *Good Samaritan Hosp., Corvallis v. Matthews*, 609 F.2d 949, 951 (9th Cir. 1979). The APA requires the reviewing court to "decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action." The reviewing court shall "compel

agency action unlawfully withheld or unreasonably delayed" and "hold unlawful and set aside agency action, findings, and conclusions" found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "without observance of procedure required by law." 5 U.S.C. 706(1)–(2). Thus, in considering motions for summary judgment, "the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Occidental Eng'g Co. v. I.N.S.*, 753 F.2d 766, 769–70 (9th Cir. 1985).

2. NATURE OF PLAINTIFFS' CLAIMS.

As a preliminary matter, this order clarifies the current status of plaintiffs' four claims for relief. Plaintiffs' theory underlying their first, third, and fourth claims is that the 2013 Guidance constituted an unlawful "final agency action" under Section 706(2) (*e.g.*, Dkt. Nos. 90-1 at 16–25, 95 at 2–8). Plaintiffs' second claim for relief started out as a claim for "failure to act" under Section 706(1) (*see, e.g.*, Dkt. No. 81 at 4–5) but then evolved into claim under Section 706(2) instead. *See Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 62 (2004) (Section 706(1) provides relief for an agency's failure to act). Plaintiffs commit to this change in their opposition brief where they say their second claim for relief "should properly be regarded as a claim under § 706(2), *not § 706(1)*, despite Plaintiffs having cited both in their Complaint and in briefing" (Dkt. No. 95 at 9) (emphasis added).

In attempting to defuse various arguments leveled by the EPA and defendant-intervenors against their second claim for relief, plaintiffs repeatedly emphasize that they are *not* bringing any claim under Section 706(1) (Dkt. No. 103 at 7, 11–12). Plaintiffs' counsel also reaffirmed this position at oral argument. Thus, despite plaintiffs' repeated use of the phrase "failure to act," this order construes all four of plaintiffs' claims for relief as challenging, *under Section 706(2) only*, the 2013 Guidance's alleged promulgation of a new policy applying the "treated articles and substances" exemption to pesticide-treated seeds and their dust-off. This order first addresses plaintiffs' first, third, and fourth claims for relief within the framework of final agency

action analysis, reserving for later the nettlesome question of whether plaintiffs' "failure to act" claim can survive summary judgment.

3. FINAL AGENCY ACTION?

The APA permits judicial review of "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court." 5 U.S.C. 704. Since plaintiffs seek review under the general provisions of the APA, they must challenge a "final agency action." *Ibid.*; *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 882 (1990); *Or. Nat. Desert Ass'n v. U.S. Forest Serv.*, 465 F.3d 977, 982 (9th Cir. 2006). An "agency action" includes "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." 5 U.S.C. 551(13); *Norton*, *supra*, at 62. Moreover, to be final, an agency action must satisfy two conditions. *First*, "the action must mark the consummation of the agency's decisionmaking process — it must not be of a merely tentative or interlocutory nature." *Second*, "the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (quotations omitted); *Fairbanks North Star Borough v. U.S. Army Corps of Eng'rs.*, 543 F.3d 586, 591 (9th Cir. 2008).[1]

A. Agency Action.

Having ruled out the possibility that plaintiffs claim a "failure to act" under Section 706(1), the next step of the inquiry is to determine whether the challenged 2013 Guidance is "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof" so as to constitute "agency action." 5 U.S.C. 551(13); *Norton*, *supra*, at 62. To repeat, the relevant passage from the Guidance reads in its entirety (Dkt. No. 88-2 at 7–8):

> Inspectors may also take into account any locations of treated seed planting when identifying locations of potential pesticide sources. Note: Treated seed (and any resulting dust-off from treated seed)

[1] In their complaint and opposition to defendants' motion to dismiss, plaintiffs had previously argued that FIFRA, 7 U.S.C. 136n(a), also authorizes judicial review (Dkt. Nos. 1 at 1–2, 57 at 24–25). In their motion for summary judgment, defendants contend "a cause of action may exist under either the APA or another judicial review provision, but not both" (Dkt. No. 88 at 10). Plaintiffs' briefs on summary judgment do not revive their contention that 7 U.S.C. 136n(a) authorizes judicial review.

> may be exempted from registration under FIFRA [pursuant to 40 C.F.R. 152.25(a)] as a treated article and as such its planting is not considered a "pesticide use." However, if the inspector suspects or has reason to believe a treated seed is subject to registration (*i.e.*, the seed is not in compliance with the treated article exemption), plantings of that treated seed may nonetheless be investigated.

The EPA characterizes this passage, and the 2013 Guidance as a whole, as "a set of non-binding recommendations for the use of federal, state, and tribal inspectors" rather than an agency action (Dkt. Nos. 88 at 11, 96 at 3, 100 at 5–6). The plain language of the 2013 Guidance supports the EPA's position in three ways.

First, the key passage quoted above reads like a recommendation, not a mandate. The first sentence discusses what inspectors "may" take into account during investigations. The customary meaning of "may" is permissive. *Sierra Club v. Johnson*, 614 F. Supp. 2d 998, 1003 (N.D. Cal. July 23, 2008). The "Note" about pesticide-treated seed states that both the seeds and resultant dust-off "*may* be exempted from registration under FIFRA," indicating that applicability of the "treated articles and substances" exemption is not a foregone conclusion but a mere possibility, *i.e.*, the exemption *may or may not apply*. This interpretation fits with the rest of the passage, which sets forth a corresponding scenario for each possibility: *If* the inspector finds pesticide-treated seed (and resultant dust-off) exempt, *then* "as [a treated article] its planting is not considered a 'pesticide use.'" But *if* "the inspector suspects or has reason to believe a treated seed is subject to registration (*i.e.*, the seed is not in compliance with the treated article exemption), plantings of that treated seed may nonetheless be investigated."

Plaintiffs reply that this passage represents a "definitive statement" despite its permissive language because the phrase "its planting is not considered a 'pesticide use'" is "definitive" (Dkt. No. 95 at 4). That phrase would be definitive if it were its own sentence, but it is not. It is merely a fragment within a sentence. Plaintiffs' interpretation would completely omit not only the surrounding permissive language in the rest of that sentence and the rest of the passage, but also the *two immediately preceding words*, namely, "*as such* its planting is not considered a 'pesticide use'" (emphasis added) — with "as such" meaning "as a treated article." In other words, the planting of a seed is not considered a pesticide use *if* the seed is a treated article covered by the "treated articles or substances" exemption (*see* Dkt. No. 96 at 14–15). This order

declines to interpret a single incomplete phrase inconsistently with the plain meaning of the rest of the relevant passage.

Plaintiffs further reply that it would make "no sense" to interpret this passage as making permissive and conditional statements because "a treated seed that has resulting dust-off" can *never* qualify for the "treated articles or substances" exemption, since "'[r]esulting dust-off from treated seed' necessarily includes the pesticidal coating and necessarily has pesticidal effects that extend beyond the seed itself" (Dkt. Nos. 95 at 4, 103 at 14–15). The premise is plaintiffs' interpretation of the 2003 Harmonization Document as applying the "treated articles or substances" exemption only to pesticide-treated seeds that cause no pesticidal effect beyond the seed itself. This argument would carry some weight if the 2003 Harmonization Document had interpreted the exemption to be inapplicable whenever a pesticide-treated seed's pesticidal effect extends in *any* way beyond the seed itself. The 2003 Harmonization Document, however, did not impose such a strict limitation. That document set forth two conditions for exemption, the second of which is that "the treatment is for the protection of the article or substance itself" (Dkt. No. 88-3 at 1).

Plaintiffs point out that the 2003 Harmonization Document explained the second condition for exemption as follows: "The term 'for the protection of the [seed] itself' means that the pesticidal protection imparted to the pesticide-treated seed does not extend beyond the seed itself to offer pesticidal benefits or value attributable to the treated seed" (*id.* at 2). Plaintiffs read this sentence as rendering ineligible for exemption any "treated seed that has resulting dust-off" (Dkt. No. 103 at 14). Again, plaintiffs gloss over informing context and fail to read the phrase as a whole, *i.e.*, "*the treatment is for* the protection of the article or substance itself" (emphasis added) — wherein the words "the treatment is for" contemplate the pesticidal treatment's intended purpose rather than its entire range of potential but unintended effects. The plain meaning of these excerpts from the 2003 Harmonization Document, read together, is that the pesticidal treatment used on the seed must be for — *i.e.*, intended for — the protection of the seed itself as opposed to protection that extends beyond the seed to offer other pesticidal benefits or value.

This interpretation is consistent with the 2003 Harmonization Document's use of the phrase "pesticidal *benefits or value*" — as opposed to, *e.g.*, "pesticidal *effects*" — and with the immediately following sentence, which states, "Unless claims of pesticidal benefit or value attributable to the treated seed and extending beyond the treated seed are made in conjunction with the distribution or sale of the treated seed within the U.S., the EPA will presume that the seed will have been treated 'for the protection of the seed itself'" (Dkt. No. 88-3 at 2). This sentence highlights the distinction contemplated by the 2003 Harmonization Document between exempt pesticide-treated seeds and non-exempt pesticide-treated seeds — the latter would be distributed or sold with "claims of pesticidal benefit or value attributable to the treated seed and extending beyond the treated seed," while the former would ostensibly be distributed or sold with claims of pesticidal benefit or value *only* for the seed itself. In other words, the focus of the second condition for exemption described in the 2003 Harmonization Document is on the pesticidal treatment's intended purpose rather than on all its potential effects.

Nothing in the plain language of the 2003 Harmonization Document strictly limits the "treated articles and substances" exemption to pesticide-treated seeds that can never cause a pesticidal effect beyond the seed itself. Plaintiffs' claim that "treated seed that has resulting dust-off *cannot be exempted*" (Dkt. No. 103 at 14) (emphasis in original) is thus unsupported and fails to rebut the EPA's position that, as described by the plain language of the 2013 Guidance, "[t]reated seed (and any resulting dust-off from treated seed)" may or may not be exempt from FIFRA registration requirements (*e.g.*, Dkt. No. 96 at 15). *See Sierra Club*, *supra*, at 1003 (customary meaning of "may" is permissive).

Second, the EPA's position that the 2013 Guidance is "a set of non-binding recommendations for the use of federal, state, and tribal inspectors" is consistent with its cover memorandum. The cover memorandum, addressed to FIFRA Compliance and Enforcement Managers by the Office of Compliance, described the 2013 Guidance as a "guidance for inspecting alleged cases of pesticide-related bee incidents." Moreover, the cover memorandum stated, "I *request* that you distribute this guidance to your state lead agencies and tribal pesticide programs and *encourage* you to discuss implementation of this guidance with them" (Dkt. No.

88-2) (emphasis added). This sort of permissive language is consistent with the EPA's position, but inconsistent with plaintiffs' claim that the 2013 Guidance was a "rule" or equivalent thereof with the force of law (*e.g.*, Dkt. No. 103 at 13–15).

Third, the 2013 Guidance included an explicit disclaimer that stated in relevant part (Dkt. No. 88-2) (emphasis added):

> This guidance is an *inspection support tool* provided by the U.S. Environmental Protection Agency (EPA), for use by EPA regions, states and tribes conducting inspections under [FIFRA]. This guidance represents EPA's *recommended* procedures for these inspectors when they are conducting FIFRA inspections as a result of an incident involving bee deaths. *This guidance is not a regulation and, therefore, does not add, eliminate or change any existing regulatory requirements. The statements in this document are intended solely as guidance.* This document is not intended, nor can it be relied on, to create any rights enforceable by any party in litigation with the United States. EPA, state and tribal officials may decide to follow the guidance provided in this document, *or to act at variance with the guidance*, based on analysis of site-specific circumstances. This guidance may be revised without public notice to reflect changes in EPA's policy.

Plaintiffs offer two responses to this disclaimer. The first is that the disclaimer is "boilerplate" language, and the Court is not obliged to accept it at face value (Dkt. No. 90-1 at 23). As this order explains, however, the disclaimer — boilerplate or not — is consistent with the EPA's position and with the rest of the 2013 Guidance. Plaintiffs are correct that the disclaimer is not *dispositive* of the true nature of the 2013 Guidance, but that does not mean the disclaimer is not *relevant*.

In their reply brief, plaintiffs raise a second argument against the disclaimer, claiming it is "directly contradict[ed]" by the following page in the 2013 Guidance (Dkt. No. 103 at 3–4). That page stated in relevant part (Dkt. No. 88-2 at 1): "This guidance will aid in standardizing bee incident inspections across federal, state and tribal agencies when trying to determine if the deaths are related to the use of a pesticide in violation of FIFRA. The data gathered in these types of inspections will help determine if the death of the bees was associated with the legal or illegal use of a pesticide." Plaintiffs point out that if "the purpose of the 2013 Guidance is to help determine whether the particular use of a pesticide was legal or illegal under FIFRA," then it also helps determine "whether EPA should take enforcement action or not." Thus, plaintiffs

argue, this language "reveal[ed] the true purpose of the document to be something much more substantive" than the disclaimer would suggest (Dkt. No. 103 at 3–4).

It does not follow that the disclaimer is "directly contradict[ed]" by the language quoted above. A disclaimer that essentially states the 2013 Guidance is non-binding does not contradict an acknowledgment that it will nonetheless be *helpful* to inspectors in conducting investigations and making determinations that may lead to discrete agency action. Moreover, plaintiffs' reasoning would lead to the untenable conclusion that virtually any guidance — no matter how non-binding or advisory — could be subject to judicial review on the vague theory that it informs some day-to-day activity that may somehow affect discrete agency action somewhere down the line. At best, plaintiffs possibly have shown a speculative degree of tension between the EPA's characterization of the 2013 Guidance's overall significance and the practical reality of its influence on the EPA's FIFRA enforcement efforts — but this falls well short of a direct contradiction that would completely discredit the disclaimer.

In summary, considering together the disclaimer, cover memorandum, and key passage that is the subject of plaintiffs' challenge, this order concludes the plain language of the 2013 Guidance supports the EPA's position that it was not an agency action.

Plaintiffs attempt to discredit the EPA's position by pointing out that "[a] reviewing court does not have to rubber stamp an agency's own characterization of its action (Dkt. No. 90-1 at 17). The foregoing analysis, however, is not a rubber stamp.

Plaintiffs cite *CropLife Am. v. E.P.A.*, 329 F.3d 876, 883 (D.C. Cir. 2003), for the proposition that "the agency's characterization of its own action is not controlling if it self-servingly disclaims any intention to create a rule with the 'force of law,' but the record indicates otherwise." *CropLife*, however, is distinguishable from this case. In *CropLife*, the EPA issued a press release stating "the Agency will not consider or rely on [third-party] human studies in its regulatory decision making, whether previously or newly submitted." *CropLife*, *supra*, at 878. The EPA claimed the statement was "nothing more than a 'policy statement,' and thus [was] not subject to judicial review." The reviewing court rejected the EPA's self-serving characterization of its own action as "not controlling" because "there [was] little

doubt that the . . . Press Release [bound] private parties and the agency itself with the force of law, and thus constitute[d] a regulation rather than a policy statement. The directive clearly establishe[d] a substantive rule declaring that third-party human studies [were] deemed immaterial in EPA regulatory decisionmaking." *Id.* at 883. In other words, in *CropLife* the record clearly contradicted the agency's characterization of its own action.

No comparable facts present in this case. Here, as discussed above, the plain language of the 2013 Guidance supports the EPA's position that it is "a set of non-binding recommendations for the use of federal, state, and tribal inspectors" (Dkt. Nos. 88 at 11, 96 at 3, 100 at 5–6), not a rule with the force of law.

Plaintiffs also cite *Siskiyou Reg'l Educ. Project v. U.S. Forest Serv.*, 565 F.3d 545, 553–54 (9th Cir. 2009), as an example of when "[t]he Ninth Circuit has found that statements within memoranda are final agency actions actionable under the APA." *Siskiyou* is also distinguishable from this case. In *Siskiyou*, the agency memorandum at issue interpreted "*binding* standards and guidelines [restricting] certain activities within areas designated as riparian reserves or key watersheds." *Siskiyou*, *supra*, at 551–53. The jurisdictional question addressed by the court was whether the lawsuit constituted an improper "programmatic attack." The court found the plaintiff's allegations challenged "specific instances of the [agency's] actions taken pursuant to its interpretation of [the memorandum], and therefore constitute[d] more than a programmatic attack or a vague reference to [agency] action or inaction." *Id.* at 554. There was no dispute as to whether the memorandum was a non-binding recommendation or a binding document with the force of law. *Siskiyou* is thus unhelpful to plaintiffs' position that mere issuance of a non-binding guidance is agency action for purposes of APA review.

Plaintiffs further contend the 2013 Guidance is an agency action because it effectively amended the "treated articles or substances" exemption as interpreted by the 2003 Harmonization Document (Dkt. No. 103 at 13). Specifically, plaintiffs claim the 2013 Guidance (1) "expand[ed] the . . . exemption from seeds to dust-off," (2) "stat[ed] definitively that the planting of treated seeds and dust-off is not considered a pesticide use," and (3) omitted the condition that "the pesticidal protection imparted to the treated seed does not extend beyond the

seed itself to offer pesticidal benefits or value attributable to the treated seed" (*e.g.*, Dkt. Nos. 90-1 at 13–14, 95 at 4–5, 103 at 14). Plaintiffs cite *Hemp Indus. Ass'n v. D.E.A.*, 333 F.3d 1082, 1087 (9th Cir. 2003), as the "key Ninth Circuit precedent" (Dkt. No. 103 at 13) for the proposition that an agency guidance has the "force of law" when it "effectively amends a prior legislative rule."

It is important to note that *Hemp* is distinguishable from this case because the challenged agency in *Hemp* had actually issued a *rule* banning naturally occurring THC. *Hemp*, *supra*, at 1084. The issue before that court was whether that rule was "legislative," in which case the agency needed to follow certain procedures described in the APA, or "interpretive," in which case the agency did not. Within that context, the court concluded "a rule has the 'force of law' [*i.e.*, is legislative] . . . when [it] effectively amends a prior legislative rule." *Id.* at 1087.

Here, in contrast, the challenged 2013 Guidance was not a rule (*see* Dkt. No. 100 at 5). A "rule," as defined by the APA, is "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency." 5 U.S.C. 551(4). Here, as discussed above, the 2013 Guidance did not "implement, interpret, or prescribe law or policy," nor did it describe any *requirements* of the EPA, since it comprised of recommendations with which compliance is permissive, not mandatory. There is thus no reason to conclude the 2013 Guidance was a "rule" — or rule "equivalent," as plaintiffs suggest (Dkt. No. 1 at 23) — of the sort contemplated by *Hemp*.

Plaintiffs attempt to overcome this distinction by claiming "an agency's interpretive rule or statement of policy can be a reviewable 'rule' within the meaning of the APA," citing *Appalachian Power Co. v. E.P.A.*, 208 F.3d 1015, 1021 (D.C. Cir. 2000), which stated:

> If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document, if it leads private parties or State permitting authorities to believe that it will declare permits invalid unless they comply with the terms of the document, then the agency's document is for all practical purposes "binding."

Plaintiffs provide no analysis as to why *Appalachian Power* applies in this case (Dkt. No. 90-1 at 19). Their bald statement that "an agency's interpretive rule or statement of policy *can* be a reviewable 'rule' within the meaning of the APA" (emphasis added) does not demonstrate that such is the situation here. As discussed above, the EPA did not act as if the 2013 Guidance was controlling in the field or a "legislative rule." In fact, an explicit disclaimer in the 2013 Guidance and the plain language of the document itself indicated otherwise. The EPA may base enforcement actions on the results of investigations conducted according to the 2013 Guidance, but nothing in the record indicates the EPA has taken discrete enforcement actions based directly on the 2013 Guidance itself. Finally, as discussed above, the 2013 Guidance would not lead its recipients to believe the EPA will "declare permits invalid," or take any action, "unless they comply with the terms of the document." In fact, the cover memorandum, disclaimer, and plain language of the 2013 Guidance all indicated compliance was voluntary because the document offered a set of recommendations, not rules or mandates. *Appalachian Power* is thus unhelpful to show that the 2013 Guidance "is for all practical purposes 'binding.'"

Even assuming for the sake of argument that *Hemp*'s reasoning applies, not only to actual rules issued by an agency, but also to non-binding guidance documents, *Hemp* would still not support plaintiffs' position. As discussed above, the 2013 Guidance did not amend the "treated articles or substances" exemption as interpreted by the 2003 Harmonization Document. The 2013 Guidance did not contradict the 2003 Harmonization Document, nor did the passage plaintiffs rely on definitively direct mandatory application or withholding of the "treated articles or substances" exemption.

B. Finality.

The 2013 Guidance, moreover, lacked the finality required for judicial review under the APA. To be "final" for purposes of the APA, an action must (1) "mark the 'consummation' of the agency's decisionmaking process," *i.e.*, "it must not be of a merely tentative or interlocutory nature," and (2) "be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett*, *supra*, at 177–78 (citations omitted). Neither requirement is satisfied here.

First, the 2013 Guidance did not mark the "consummation" of the EPA's decisionmaking process with respect to applying the "treated articles or substances" exemption to pesticide-treated seeds. As explained, the 2013 Guidance recommended that inspectors investigating bee deaths consider *if* the exemption should apply on a case-by-case basis. It did not mandate the investigations, much less direct their outcomes. Insofar as the resulting determinations from these investigations potentially influence the EPA's enforcement decisions further down the line, they are necessarily "tentative" or "interlocutory" in nature. Thus, the 2013 Guidance, which merely assisted investigations that are themselves only "tentative" or "interlocutory," could not be the "consummation" of the EPA's decisionmaking process.

Second, and for similar reasons, the 2013 Guidance could not have been an action "by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" Based on the 2013 Guidance alone it would be impossible to determine if a particular investigator would conclude a particular pesticide-treated seed qualifies for the "treated articles or substances" exemption, if the seed would therefore be subject to FIFRA's registration requirements, or if the EPA would take further enforcement action. Thus the 2013 Guidance — the alleged agency action in this case — was not a final agency action that determined rights or obligations, or triggered legal consequences.

Plaintiffs' other arguments that the 2013 Guidance was sufficiently final for purposes of APA review are similarly unpersuasive. *First*, plaintiffs claim the 2013 Guidance "represents the final word by EPA on its decision to exempt neonicotinoid-coated seeds and pesticidal dust-off from the requirements of FIFRA" (Dkt. No. 90-1 at 19). Thus, plaintiffs contend, the legal consequence flows that "planting of treated seeds and any resulting dust-off are not considered pesticidal uses under FIFRA" (*id.* at 21–22). But as stated, the 2013 Guidance conveyed no such decision. Contrary to plaintiffs' bald assertions that "sellers and users of . . . treated seed with associated pesticidal dust-off . . . do not have to comply with [FIFRA]," and that the "EPA does not and will not enforce FIFRA against the sale or use of neonicotinoid-coated seeds" (*id.* at 19–20), the 2013 Guidance expressly contemplated scenarios in which pesticide-treated seeds could be subject to FIFRA's registration requirements and necessitate enforcement (Dkt.

No. 88-2 at 7). The 2013 Guidance thus did not represent the EPA's "final word" as to any non-enforcement policy.

Second, plaintiffs claim the 2013 Guidance "is clearly the consummation of EPA's decisionmaking process" because "it is explicitly 'a supplement to the national [FIFRA] Inspection Manual,' . . . which is described as 'an important element of the [EPA's] Pollinator Protection Strategic Plan.'" Plaintiffs also point out the 2013 Guidance "is not a draft or preliminary document, but rather a final document published by the agency" (Dkt. No. 90-1 at 20). These are non sequiturs. A "supplement" to an inspection manual is not necessarily a "consummation" of the decisionmaking process aided by that manual. An "important element" of the EPA's plan to protect pollinators is not necessarily a "consummation" of its decisionmaking process as to a specific exemption relevant to that plan. And it would be absurd to conclude that a document is "final" for purposes of judicial review under the APA just because it is a final published document, as opposed to a preliminary draft. It is the document's nature, not the stage of its drafting, that is germane to the finality inquiry.[2]

4. FAILURE TO ACT?

As discussed, plaintiffs' second claim for relief is essentially a "failure to act" claim now brought under Section 706(2) instead of Section 706(1). At oral argument, plaintiffs focused solely on this claim, insisting they never abandoned their "failure to act" allegations and glossing over their previous flip-flopping from Section 706(1) to Section 706(2). Plaintiffs now stake their second claim for relief on an "exception" articulated in a footnote in *Heckler v. Chaney*, 470 U.S. 821 (1985).

A. *Heckler* Exception.

At oral argument, plaintiffs repeatedly emphasized that the "*Heckler* exception" authorizes judicial review of their second claim for relief. This begs the question: Exception to

[2] Plaintiffs also claim the 2013 Guidance "represents EPA's last word for the purposes of the *Bennett* test even though the agency *could* take some other action in the future" (Dkt. No. 90-1 at 20) (emphasis in original), ostensibly attempting to preempt an argument by the EPA that the 2013 Guidance lacked finality because the agency could take future action on the guidance's subject matter. Since neither the EPA nor this order relies on the possibility of future agency action in concluding the 2013 Guidance lacked finality, plaintiffs' point does not affect the analysis herein.

what? To answer this question, it is necessary to take a step back and clarify the context and holding of *Heckler*.

As stated, judicial review of claims like the ones in this case requires a "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. 704. Where there is no such final agency action, judicial review is not available and the inquiry ends. *If* final agency action exists, however, then such action is nonetheless unreviewable unless it *also* clears the hurdle imposed by Section 701(a)(2), *i.e.*, that it is not agency action "committed to agency discretion by law." *F.T.C. v. Standard Oil Co. of Cal.*, 449 U.S. 232, 238 & n.7, 246–47 (1980); *Aguayo v. Jewell*, 827 F.3d 1213, 1223 (9th Cir. 2016). In other words, Section 701 functions *in addition to*, but does not *replace*, Section 704. This is evident both in the case law applying these provisions and in the plain language of Section 701(a), which states, "This chapter applies, *according to the provisions thereof*, except to the extent that – (1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law." The *Heckler* decision, applying Section 701(a)(2), held that in situations where an agency "refus[es] to take enforcement steps . . . the presumption is that judicial review is not available" because "an agency's decision not to prosecute or enforce . . . is a decision generally committed to an agency's absolute discretion." *Heckler*, *supra*, at 831–33. In short, an agency's refusal to take enforcement action is generally unreviewable under Section 701(a)(2). The exception to this general rule — *i.e.*, the "*Heckler* exception" plaintiffs rely on — is in a footnote to the aforementioned analysis, wherein *Heckler* stated the Court "express[ed] no opinion" on whether an agency's decision to "consciously and expressly adopt[] a general policy that is so extreme as to amount to an abdication of its statutory responsibilities" would similarly be "unreviewable under § 701(a)(2)." *Id.* at 833 & n.4 (quotations omitted).

That expression of "no opinion" left open the possibility that "[a] decision that is committed to agency discretion by law may nonetheless be reviewable where the agency has consciously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities." *Garcia v. McCarthy*, 649 F. App'x 589, 592 (9th

Cir. 2016) (quotations omitted). Plaintiffs' application of this exception to their second claim for relief, however, suffers from two fatal flaws.

First, application of the *Heckler* exception requires an agency decision to "consciously and expressly" adopt a general policy. Plaintiffs claim the "EPA's failure to enforce FIFRA against neonicotinoid-coated seeds and pesticidal dust-off is a 'consciously and expressly adopted general policy,' which 'amounts to an abdication of [the EPA's] statutory responsibilities,'" but this is mere recitation of the *Heckler* exception coupled with a bald assertion that it is on point in this case. Plaintiffs have not identified a single document that contains such a decision. The administrative record and the Court's *in camera* review of additional documents submitted by the EPA also revealed nothing that would qualify as a decision "consciously and expressly" adopting any general policy, much less one "so extreme as to amount to an abdication of [the EPA's] statutory responsibilities." The bulk of those documents included multiple drafts, often attached to multiple email chains, of the 2013 Guidance as its contents were repeatedly and painstakingly discussed, reviewed, and edited in the long road to publication.

In their reply brief, plaintiffs argue judicial review is available for the EPA's "policy of non-enforcement [as to pesticide-treated seeds] . . . expressed in [the] EPA's 2013 Guidance" (Dkt. No. 103 at 8). This argument is unavailing. As stated, the 2013 Guidance — which plaintiffs characterize as the "focal point" that "expressed" the alleged policy — contained no language indicating the EPA took a definitive stand on the applicability of the "treated articles or substances" exemption to any pesticide-treated seeds. Indeed, the very fact that the relevant passage acknowledged two possibilities — either pesticide-treated seed qualifies for the exemption or it does not — indicated the EPA had no standing policy on the matter.

To this end, the 2013 Guidance specifically informed investigators "plantings of . . . treated seed may . . . be investigated" if the pesticide-treated seed "is subject to registration (*i.e.*, the seed is not in compliance with the treated article exemption)" (Dkt. No. 88-2 at 7). This language indicated that the EPA in issuing the 2013 Guidance expressly contemplated *potential enforcement* of FIFRA requirements as to pesticide-treated seeds, which directly

contradicts plaintiffs' allegations of a "policy of non-enforcement" and "abdication of duties." Thus, even assuming for the sake of argument that a blanket-exemption policy as to pesticide-treated seeds would constitute an abdication of the EPA's responsibilities under FIFRA as to such seeds, there is no basis for finding the EPA "consciously and expressly adopted a general policy" abdicating its statutory responsibilities here.

Second, plaintiffs' framing of their second claim for relief within the *Heckler* exception is predicated on flagrant mischaracterization of how the exception functions. At oral argument, plaintiffs' counsel repeatedly stated the *Heckler* exception dispenses with the APA's final agency action requirement for judicial review. That was and remains wrong. Plaintiffs could properly raise the *Heckler* exception to defend their second claim for relief *if* they had first alleged a final agency action that defendants had argued was nonetheless unreviewable because of the hurdle imposed by Section 701(a)(2). As explained, however, plaintiffs cannot even clear the initial Section 704 hurdle of identifying a final agency action. Thus, their claim cannot reach the additional requirements of Section 701(a)(2), let alone raise *Heckler* as a defense against said requirements. In short, the *Heckler* exception might save plaintiffs' claim from Section 701(a)(2) but does nothing to circumvent Section 704.[3]

What plaintiffs need here is not an exception to Section 701(a)(2), but an exception to the "final agency requirement" of Section 704. Such an exception exists — in Section 706(1). "A court's review of an agency's failure to act [under Section 706(1)] has been referred to as an exception to the final agency action requirement." *ONRC Action v. Bureau of Land Mgmt.*, 150 F.3d 1132, 1137 (9th Cir. 1998); *Indep. Min. Co., Inc. v. Babbitt*, 105 F.3d 502, 511 (9th Cir. 1997). Plaintiffs, however, have unequivocally foresworn any reliance on Section 706(1) (*e.g.*, Dkt. No. 95 at 9). The final agency action requirement for judicial review under the APA thus applies squarely to their second claim for relief under Section 706(2). As stated, plaintiffs

[3] Plaintiffs' briefing indicates they understood how to apply *Heckler* correctly, *i.e.*, to rebut the EPA's argument that any alleged decision to not enforce FIFRA would generally be unreviewable pursuant to Section 701(a)(2) as a decision committed to agency discretion (*see* Dkt. Nos. 95 at 8–13, 103 at 8). If so, plaintiffs' representation at oral argument that they relied on *Heckler* all along as an exception to the "final agency action" requirement of Section 704 was disingenuous.

cannot meet this requirement. Thus, their second claim for relief — like their first, third, and fourth claims — is unreviewable under the APA.

B. Administrative Record.

Finally, this order must address the parties' fight over the administrative record. Plaintiffs had previously moved to compel "completion and supplementation" of the administrative record, and to conduct limited discovery in support of their second claim for relief (Dkt. No. 81). A prior order instructed the EPA to submit under seal for *in camera* review "documents that relate to the development of the guidance that are *not* a part of the administrative record, including pre-decisional and deliberative documents," instructed plaintiffs to "lay out any alleged shortfalls in the administrative record" in their summary judgment briefs, and denied plaintiffs' request for limited discovery without prejudice (Dkt. No. 86). Plaintiffs now renew their request for limited discovery relevant to their second claim for relief (Dkt. No. 90-1 at 11). The original basis for this request was that, unlike plaintiffs' other claims for relief, a claim for failure to act under Section 706(1) is not predicated on an agency action for which there can be a clearly demarcated administrative record. Thus, plaintiffs argued, they should be allowed to take extra-record discovery (Dkt. No. 81 at 4–5). As stated, plaintiffs have since abandoned their claim under Section 706(1) and are proceeding on the theory that all four claims for relief challenge a final agency action under Section 706(2). The premise of their request for limited discovery is now defunct (*see* Dkt. No. 100 at 8 & n.4). Accordingly, the request is **DENIED**.

Plaintiffs also renew their request to compel the EPA to supplement the administrative record with additional materials. The prior order directing the EPA to lodge the administrative record stated, "The administrative record shall include all emails and memoranda discussing whether the agency should proceed by guidance versus some other procedure and/or discussing whether the guidance would constitute final agency action" (Dkt. No. 62 at 8–9). In claiming the EPA has failed to comply with that order, plaintiffs highlight the importance of three documents: (1) "Pros and Cons of Issues Surrounding Review and Release of the Guidance," (2) an email

from the Chief Division of Plant Health, Ohio Department of Agriculture, and (3) a PowerPoint presentation titled "2012 Indiana Bee Kill Investigations" (Dkt. No. 90-1 at 14–15).

The Court's *in camera* review of these unredacted documents, and others submitted by the EPA, revealed nothing that would weigh in plaintiffs' favor on the issue of "whether the agency should proceed by guidance versus some other procedure" or "whether the guidance would constitute final agency action." Nor did any document submitted for *in camera* review support application of the *Heckler* exception to this case. There is thus no reason to compel additional production. Plaintiffs also seek documents that would be relevant to the *merits* of their claims (*e.g.*, *id.* at 16; Dkt. No. 103 at 1–2) but, as discussed, have not satisfied the requirements for judicial review under the APA. Their request to supplement the administrative record is therefore **DENIED**.

CONCLUSION

The Court is most sympathetic to the plight of our bee population and beekeepers. Perhaps the EPA should have done more to protect them, but such policy decisions are for the agency to make. A district judge's role is limited to judicial review of final agency actions, which do not include the type of guidance involved here.

For the foregoing reasons, defendants' motion for summary judgment, in which defendant-intervenors join, is **GRANTED**. Defendant-intervenors' separate motion for summary judgment is **DENIED AS MOOT**. Plaintiffs' motion for summary judgment is **DENIED**. Plaintiffs' request for judicial notice (Dkt. No. 93) of documents not relied upon in this order is **DENIED AS MOOT**.

IT IS SO ORDERED.

Dated: November 21, 2016.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE

CITIZEN PETITION TO THE
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BRET ADEE, AMERICAN BEEKEEPING FEDERATION, AMERICAN BIRD CONSERVANCY, AMERICAN HONEY PRODUCERS ASSOCIATION, JEFF ANDERSON, LUCAS CRISWELL, GAIL FULLER, DAVID HACKENBERG, PESTICIDE ACTION NETWORK OF NORTH AMERICA and POLLINATOR STEWARDSHIP COUNCIL including and represented by **CENTER FOR FOOD SAFETY** 660 Pennsylvania Ave., SE, Suite 302 Washington, D.C. 20003, *Petitioners,*	Docket Number _____
Filed With:	
SCOTT PRUITT, ADMINISTRATOR Environmental Protection Agency Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460**)**	

EXECUTIVE SUMMARY

This Citizen Petition seeks to end an existing regulatory loophole for seeds coated with systemic pesticides. The Environmental Protection Agency (EPA) is tasked with regulating pesticides in the United States, pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §136 et seq. However, a class of pesticides made up of crop seeds coated with systemic insecticides ("coated seeds") that are intended to kill pests of the plants are not regulated by EPA under FIFRA. Although these seeds fit the definition of "pesticide" and have devastating impacts to the environment and Petitioners' interests, EPA exempts the coated seeds

from FIFRA's registration and labeling requirements, improperly relying on the Treated Article Exemption, 40 C.F.R. §152.25(a).

Petitioners are commercial beekeepers, farmers, and environmental and agriculture public interest groups, all with a keen interest in ending this loophole for these pesticide-coated seeds. These seeds are used on nearly 150 million acres across the country, representing the vast majority of systemic insecticide use, where they cause both acute and chronic bee kills, contribute to pollinator decline, pollute soil and water, and harm wildlife, including threatened and endangered invertebrate and bird species. Excessive honey bee mortality and wild pollinator declines are a major crisis for American agriculture as so many of our food crops require pollination. Because the coated crop seeds are not treated primarily to protect the seed itself, but rather to protect the growing plant, and have vast adverse impacts beyond the seed, they cannot be properly exempted as "treated articles." Nor can EPA continue to allow the coated seeds to avoid compliance with FIFRA's mandatory safety standards and enforceable labeling requirements.

This Petition seeks an amendment to, or a formal re-interpretation of, the Treated Article Exemption, 40 C.F.R. §152.25(a), to clearly communicate to the regulated community that systemic pesticidal seeds intended to kill insect pests of the plants are not included under the Treated Article Exemption and are therefore subject to FIFRA's requirements. Petitioners also request that EPA aggressively enforce FIFRA's registration and labeling requirements for each separate seed product coated with a systemic insecticide.

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CITIZEN PETITION TO THE U.S. ENVIRONMENTAL PROTECTION AGENCY SEEKING RULEMAKING OR A FORMAL AGENCY INTERPRETATION FOR PLANT SEEDS COATED WITH SYSTEMIC INSECTICIDES

INTRODUCTION

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §136 *et seq.*, the Environmental Protection Agency (EPA) regulates pesticide use in the United States. Currently, EPA does not enforce FIFRA's requirements as to a class of pesticides that includes crop seeds coated with systemic insecticides intended to kill pests of the plants. EPA improperly interprets the Treated Article Exemption, 40 C.F.R. §152.25(a), to exempt these pesticidal seeds from FIFRA's registration and labeling requirements. However, this class of pesticides causes widespread adverse effects on the environment and its exemption violates FIFRA for the reasons detailed herein. This Petition seeks an amendment to, or a formal re-interpretation of, that EPA regulation, 40 C.F.R. §152.25(a), to clearly communicate to the regulated community that systemic pestidical seeds intended to kill pests of the plants are not included under the Treated Article Exemption and are therefore subject to FIFRA's requirements for registration and labeling. To continue this unlawful exemption would be severely detrimental to Petitioners' interests. Petitioners also request that EPA aggressively enforce FIFRA's registration and labeling requirements for each separate seed product coated in systemic insecticides.

EPA has allowed millions of pounds of crop seeds, such as corn, soybean, and sunflower seeds, planted on almost 150 million acres each year, to be coated with four systemic insecticide active ingredients: acetamiprid, clothianidin, imidacloprid, and thiamethoxam (hereinafter "neonicotinoids").[1] These seeds coated with neonicotinoids and other systemic insecticides

[1] Brassard, D. 2012. Memorandum - Estimated Incremental Increase in Clothianidin Usage from Pending Registrations. EPA Biological Analysis Branch, Biological and Economic Analysis Division, Office of Chemical Safety and Pollution Prevention; *See* Answer ¶ 2, *Anderson v. McCarthy,* No. 3:16-cv-00068-WHA, ECF No.67 (N.D. Cal. May 27, 2016) ("between 2010 and 2014, approximately 142 million acres on average were planted with

intended to protect the plant will be referred to throughout as "coated seeds." Approximately ninety-five percent of the land area in the United States that is treated with any neonicotinoid insecticide is treated via planting coated seeds.[2] In the vast majority of cases, the coatings are not intended to protect the seed itself from any disease, pest, or predator. Rather, the coating chemicals are *systemic*, meaning they are absorbed into the plant's circulatory system as the plant grows and are predominately intended to have an external pesticidal effect on pests and predators of the growing plant. That effect is exerted not only on plant pests, but also on beneficial insects, valuable pollinators, and birds, including threatened and endangered species protected under the Endangered Species Act (ESA).[3] For many coated crop seeds, the coatings are abraded off of the seed as dust or are sloughed off the seed into the surrounding soil. Indeed, more than eighty to ninety percent of the chemical coating can move off of the seed to contaminate the air, soil, marginal vegetation, and waters.[4]

Over the past decade the increasing use of seeds coated with neonicotinoid insecticides has coincided with mass die-offs of honey bees and wild native bees. If left unchecked, these losses could precipitate an economic and ecological disaster impacting the Petitioners and the United States as a whole at a time when the nation can ill afford it. Honey bees not only produce nutritious honey, but are also of enormous economic importance to American agriculture as pollinators. About ninety percent of all flowering plants require pollinators to reproduce and nearly a third of pollination is performed by bees in American agriculture.[5] Honey bee

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seeds treated with [neonicotinoid] pesticides."). Note: after the initial filing of this Petition, copies of the footnoted supporting documents will be subsequently provided or their location will be indicated to EPA.

[2] Thomas Steeger, Environmental Fate and Effects Division, Office of Pesticide Programs, EPA. *Bee health in the USA and the debate about Neonicotinoids*. Powerpoint dated April 11, 2014. Slide 8.

[3] 16 U.S.C. 1531 *et seq.*

[4] Goulson, D., 2014. Pesticides linked to bird declines. *Nature* 511:295-296; doi:10.1038/nature13642.

[5] United Nations, Food and Agriculture Organization. *Global Action on Pollination Services for Sustainable Agriculture*. Undated background report, *at* http://www.fao.org/pollination/background/en/; Johnson, R. and Corn,

pollination adds tens of billions of dollars annually in crop value. Healthy populations of all pollinators are essential for the future of American agriculture.

EPA has allowed this threat to pollinators to transpire without requiring the seeds to be registered under FIFRA or for the seed bags or tags to bear mandatory or enforceable labeling under FIFRA. The Agency has failed to adequately assess the risks of the unregulated seeds, instead exempting them from registration or labeling requirements and only registering the liquid coating products. EPA has never provided the public with any justification for its exemption. EPA's actions and inactions have led to excess bee colony mortality, declines in native bees, increased bird mortality, nationwide soil and water contamination, contaminated marginal vegetation and other environmental and economic harms, thereby severely damaging the Beekeeper Petitioners' businesses, while also damaging the land and welfare of the Farmer Petitioners and damaging the interests of the Public Interest Organization Petitioners.

EPA has approved other non-neonicotinoid systemic insecticides and appears poised to register additional systemic seed coatings. If additional systemic seed coatings are registered, the resulting seeds will present the same potential damage to Petitioners as the unregulated and unlabeled neonicotinoid-coated seeds. Thus, they also are subject to Petitioners' requests herein.

PETITION REQUESTS

Pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution[6] and the Administrative Procedure Act (APA),[7] Petitioners

L. 2015 *Bee Health: Background and Issues for Congress.* Congressional Research Service, No. 7-5700, at https://fas.org/sgp/crs/misc/R43191.pdf.

[6] U.S. CONST. amend. I.

[7] 5 U.S.C. § 553(e).

request the Administrator of EPA to take the following actions (please note Requests No. 1 and 2 are in the alternative):[8]

1. **Amend 40 C.F.R. § 152.25(a) to clarify that it does not apply to seeds for planting coated with systemic pesticides, such as the neonicotinoids, that are intended to kill pests of the plant instead of pests of the seed itself (shown in red):**

> **Treated articles or substances**. An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation, but excluding seeds for planting coated with a systemic pesticide intended to kill pests of the plant) if the pesticide is registered for such use.

2. ***Alternatively*, publish a final, formal, agency interpretation in the Federal Register stating that EPA interprets the exemption in 40 C.F.R. § 152.25(a) not to apply to seeds for planting coated with systemic pesticides, such as the neonicotinoids, that are intended to kill pests of the plant instead of pests of the seed itself.**

3. **Aggressively enforce FIFRA's numerous pesticide registration and labeling requirements for each separate crop seed product that is coated with a neonicotinoid or other systemic insecticidal chemical.**

Failure by the Administrator to take the requested actions would severely harm Petitioners' interests. It also would violate the mandates of FIFRA and would be arbitrary and capricious. In view of the severity of the impacts the Petitioners are suffering and EPA's excessive delays in resolving the concerns over its past application of the Treated Article

[8] EPA's lacks regulations for handling public petitions related to pesticides, a problem it has been urged by its Inspector General (IG) to cure. *EPA Needs Policies and Procedures to Manage Public Pesticide Petitions in a Transparent and Efficient Manner*. 2015. IG Report No. 16-P-0019, Washington, D.C., *at* www.epa.gov/sites/production/files/2015-10/documents/20151027-16-p-0019.pdf.

Exemption to seeds coated with systemic insecticides, the agency is urged to grant the requests in this Petition within **180 days** of its filing date.[9]

PETITIONERS

The eleven Petitioners are listed below by three groups: 1) Beekeepers, 2) Farmers and 3) Public Interest Organizations. The Appendix, incorporated herein, describes their particularized interests.

BEEKEEPER PETITIONERS: Bret Adee, American Beekeeping Federation, American Honey Producers Association, Jeff Anderson, David Hackenberg, Pollinator Stewardship Council

FARMER PETITIONERS: Lucas Criswell, Gail Fuller

PUBLIC INTEREST ORGANIZATION PETITIONERS: American Bird Conservancy, Center for Food Safety (CFS), Pesticide Action Network of North America

LEGAL BACKGROUND

FIFRA governs pesticide commercialization and application in the United States. The definition of "pesticide" is (in pertinent part), a "mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." 7 U.S.C. § 136(u)(1). FIFRA makes it unlawful, with a few minor exceptions, for any "person in any State [to] distribute or sell to any person any pesticide that is not registered" under the Act. 7 U.S.C. § 136a(a); *see also* 7 U.S.C. § 136j(a)(1).

FIFRA prohibits EPA from registering a pesticide if its widespread and commonly recognized use would have "unreasonable adverse effects on the environment." 7 U.S.C § 136a(c)(5). EPA has broad discretion to require all data necessary to support the registration (including the conclusion that the pesticide will not have unreasonable adverse environmental effects), including testing of the product for effects on pollinators. *Id.* § 136a(c)(2)(A); *see e.g.,* 40 C.F.R. § 158.630.

[9] EPA has refused to correct these failures regarding its exemption of systemic coated seeds despite prior oral and written requests to do so made by many of the Petitioners since at least 2015.

The Administrator is required to provide public notice and comment opportunities for registrations under 7 U.S.C. § 136a(c)(4):

> Notice of application. The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

EPA's FIFRA-implementing regulations also contain procedural requirements for product registration, including, but not limited to, requiring publication of two classes of notices in the Federal Register. Under 40 C.F.R. § 152.102:

> The Agency will issue in the Federal Register a notice of receipt of each application for registration of a product that contains a new active ingredient or that proposes a new use. After registration of the product, the Agency will issue in the Federal Register a notice of issuance. The notice of issuance will describe the new chemical or new use, summarize the Agency's regulatory conclusions, list missing data and the conditions for their submission, and respond to comments received on the notice of application.

The culmination of the registration process, if followed, is EPA's official approval of a label for the pesticide product, including use directions and appropriate warnings on safety and environmental risks. It is a violation of FIFRA for any person to sell or distribute a "misbranded" pesticide product. 7 U.S.C. § 136j(a)(1)(E). FIFRA is explicit in requiring EPA to find a product misbranded and, under 7 U.S.C. § 136(q)(1), may not be used, if:

> (F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment; [or]
>
> (G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment.

With regard to exemptions from FIFRA, the "Administrator may exempt from the requirements of this subchapter by regulation any pesticide which the Administrator determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this subchapter in order to carry out the purposes of this subchapter." 7 U.S.C. § 136w(b). EPA's implementing regulation for such exemptions, at 40 C.F.R. § 152.25, provides (in pertinent part; this is known as the Treated Article Exemption):

> **Exemptions for pesticides of a character not requiring FIFRA regulation**. The pesticides or classes of pesticides listed in this section have been determined to be of a character not requiring regulation under FIFRA, and are therefore exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified.
>
> (a) Treated articles or substances. An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.

FACTS

I. Characteristics of Neonicotinoid-Coated Seeds.

The systemic nature of neonicotinoid-coated seeds renders them qualitatively and quantitatively different from other seeds. Seeds coated with liquid formulations of these chemicals are pesticide delivery devices. The purpose of this technology is to carry the active ingredient via the growing plants' circulatory systems into the tissues of the plants, which ultimately are typically hundreds or even thousands of times larger in dimension and mass than the seed itself. Common crops with neonicotinoid-coated seeds include, but are not limited to:

canola, field and sweet corn, cotton, cucurbits, legume vegetables, potatoes, soybean, sunflowers, and wheat.[10]

Given the lack of pesticide usage data collected by EPA, comprehensive data on the usage of clothianidin (most common product is Bayer CropScience's Poncho®), thiamethoxam (most common product is Syngenta's Cruiser®), and imidacloprid (most common product is Bayer and Valent USA's Gaucho®) have been scarce. However, EPA's preliminary risk assessments on those three neonicotinoid active ingredients released in January of 2017 revealed that 42 million to 61 million acres of corn are treated with clothianidin via seed coatings annually (45% to 65% of all U.S. corn acres) and 24 million to 42 million acres of corn are treated with thiamethoxam (26% to 45% of all U.S. corn acres).[11] That means close to 100% of U.S. corn acres are likely treated with one of these two neonicotinoid insecticides.

In soybeans, 13 million to 21 million acres are treated with thiamethoxam (16% to 25% of all U.S. soybean acres), and 2.1 million acres are treated with clothianidin each year (3% of all U.S. soybean acres).[12] Although the acreage of imidacloprid-treated soybean was not reported, EPA did report that 36% of all imidacloprid use is on soybeans as seed treatment, representing the largest increase in imidacloprid use from 2004-2013, from 300,000 to 400,000 pounds annually.[13] EPA also included the usage data on imidacloprid from U.S. Geological Survey, indicating that over 800,000 pounds of imidacloprid were applied to soybeans in 2014.[14] For comparison, that is nearly three times the amount of thiamethoxam applied to soybeans each

[10] K. Stoner, Conn. Ag. Expt. Station, *Best Management Practices for Farmers Using Seeds Treated With Neonicotinoid Insecticides*. Unpublished report, *at* www.dem.ri.gov/programs/agriculture/documents/pwg_docs_seeds_neonicotinoids.pdf.
[11] EPA, *Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam,* pp. 33-35, Tables 2.4 and 2.6 (Released Jan. 5, 2017), *at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0865-0173.
[12] *Id.*
[13] EPA, *Preliminary Aquatic Risk Assessment to Support Registration Review of Imidacloprid*, pp. 21-24 (Released Jan. 12, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0844-1086.
[14] *Id.*, p. 23, Fig. 3-3.

year, which accounted for 13 million to 21 million acres. Thus, likely nearly 50% of soybean fields were planted with one of the neonicotinoid coatings.

While even less use data is publicly available for the other crops, EPA has stated in documents and legal filings that the estimated acreage planted with coated seeds amounts to at least 140 million acres nationally.[15] That is close to one-fifteenth of the entire land surface of the lower forty-eight states.[16]

The dried-on insecticidal coatings do not, in the vast majority of their uses, protect the seed itself against any disease or other risk to the seed. The neonicotinoid ingredients are predominately aimed at protecting the growing crop plants, later in time, as demonstrated by the EPA-approved labels placed on the bottles/containers of the liquid coating products. EPA is known to have approved fifteen new coating product registrations and their label language since January 1, 2010.[17] (See Table 1, *infra*.) All but two of those products (i.e., thirteen out of fifteen)

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[15] See n.1, ***supra.***

[16] U.S. land total from *Land and Water Area of States*, www.infoplease.com/ipa/A0108355.html.

[17] The 15 coating products and initial labels are listed below; note that most of these products are labeled for more than one crop use (see Table 1, below): **1**. Prosper Evergol (date of first EPA label approval—May 11, 2012), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000264-01121-20120511.pdf; **2**. Poncho Votivo (date of first label approval—Mar. 16, 2010), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000264-01109-20100316.pdf; **3**. Emesto Quantum (date of first label approval—May 11, 2012), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000264-01125-20120511.pdf; **4**. INOVATE Seed Protectant (date of first label approval—June 21, 2011), *at* https://www3.epa.gov/pesticides/chem_search/ppls/059639-00176-20110621.pdf; **5**. Sepresto 75 WS (date of first label approval—Apr. 28, 2010), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000264-01081-20100428.pdf; **6**. NipsIt SUITE Cereals of Seed Protectant (date of first label approval—Dec. 21, 2011), *at* https://www3.epa.gov/pesticides/chem_search/ppls/059639-00183-20111221.pdf; **7.** PONCHO/GB126 (date of first label approval—Apr. 29, 2011), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000264-01132-20110429.pdf; **8**. Helix Vibrance (date of first label approval—June 3, 2014), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000100-01528-20140603.pdf; **9**. CruiserMaxx Potato Extreme (date of first label approval—June 12, 2013), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000100-01444-20130612.pdf; **10**. CruiserMaxx Vibrance (date of first label approval—Feb. 27, 2014), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000100-01508-20140227.pdf; **11**: Avicta Complete Beans 500 (date of first label approval—Jan. 15, 2013), at https://www3.epa.gov/pesticides/chem_search/ppls/000100-01457-20130115.pdf; **12**: SYT0511 (date of first label approval—Jan. 30, 2013), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000100-01460-20130130.pdf; **13**: SYT0113 (date of first label approval—Jan. 30, 2013), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000100-01459-20130130.pdf; **14**: Cruiser Vibrance Quattro (date of first label approval—May 29, 2014), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000100-01527-20140529.pdf; **15**: Dyna-shield Foothold Virock

lack a clear label claim that the neonicotinoid ingredient protects the planted seed itself; the labels generally state that the neonicotinoids are to kill "chewing and sucking insect pests" of the growing *plants*, not of the seeds.[18] (Several of the labels have unclear claims.) Moreover, the label warnings frequently indicate that the neonicotinoids actually may *harm* the seeds and result in reduced germination and/or reduction of seed and seedling vigor.[19] Depending on the crop, up to ninety percent of the insecticide is either scraped off the seeds and blown away as dust during machine planting, or sloughed off into the surrounding soil and groundwater.[20] In short, the alleged neonicotinoid "treatment" is predominately not "for the protection of the article itself"—the seed.

II. The Treated Article Exemption.

The Treated Article Exemption, 40 C.F.R. § 152.25(a), was first promulgated in 1988. Pesticide-coated seeds were neither mentioned in the regulation text nor in the Federal Register notice accompanying the exemption.[21] In 2003, EPA publicly stated a view on the Treated Article Exemption and pesticide-coated seeds in a paper issued jointly by EPA and the Pest Management Regulatory Agency of Canada, *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States* (hereinafter "Harmonization Paper").[22] The Harmonization Paper mentions pesticide-coated seeds, but it provides no coverage or analysis of systemic insecticide or neonicotinoid-coated seeds. Rather than supporting an interpretation that

(date of first label approval—Apr. 30, 2014), *at* https://www3.epa.gov/pesticides/chem_search/ppls/034704-01090-20140430.pdf.

[18] The exceptions are No. 1, Prosper Evergol, and No. 5 Sepresto 75 WS, above, the labels for which include at least one explicit *seed* protection claim for the neonicotinoid ingredient(s). Several other labels have unclear claims with respect to whether protection of the seed is provided by the neonicotinoid ingredients or other ingredients. Typically it is the *non*-neonicotinoid active ingredients that are claimed to protect the seed *per se*.

[19] *Id.*

[20] Goulson 2014, *supra,* n.4.

[21] EPA, Pesticide Registration Procedures; Pesticide Data Requirements. Final Rule. 53 Fed. Reg. 15,977, May 4, 1988.

[22] *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United* States April 11, 2003, pp. 1-2, (Joint Regulatory Directive of EPA and the Pest Management Regulatory Agency of Canada), perma.cc/3MUH-B9VQ.

systemic, neonicotinoid-coated seeds properly fit within the Treated Article Exemption described in 40 C.F.R. §152.25(a), the Harmonization Paper instead indicates that such coated seeds actually should be *excluded* from the exemption:

> The term "for the protection of the [seed] itself" means that the pesticidal protection imparted to the treated seed *does not extend beyond the seed itself*. . . .[23]

Clear and convincing evidence shows that the pesticidal "protective" effect of the scraped, blown, and sloughed-off neonicotinoid coatings "extends beyond the seed itself," and extends far beyond the full-grown plants. As explained more fully below, these harms stem from both the effects of the coatings that come off the seed and from the gross overuse of this systemic class of insecticides. Uncontained dust and contamination from these coatings is killing honey bees by the many millions and imposing a potentially catastrophic hazard to aquatic systems across the nation.[24] Both freshwater and marine systems and the invertebrate and vertebrate wildlife—such as fish and waterfowl—that they contain are being harmed. In addition to direct mortality to birds from ingesting neonicotinoid-coated seeds, indirect mortality is resulting from the destruction of rural invertebrate life across a vast portion of the United States.[25] Coated seeds are planted year after year and the active ingredients have long half-lives in most soils, exceeding the planting intervals. Thus, the contamination has swiftly built up to, and past, harmful levels in America's lands and waters.

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[23] *Id.* at 2 (emphasis added).

[24] Morrissey, CA, Mineau, P., Devries, JH, Sanchez-Bayo, F., Liess, M, Cavallaro, MC, and Liber, K. 2015. Neonicotinoid contamination of global surface waters and associated risk to aquatic invertebrates: A review. *Environment International*, 74: 291-303; Sánchez-Bayo, F., Goka, K., and Hayasaka, D. 2016 Contamination of the Aquatic Environment with Neonicotinoids and its Implication for Ecosystems. *Front. Environ. Sci. 4:71.* doi: 10.3389/fenvs.2016.00071, *at*: http://journal.frontiersin.org/article/10.3389/fenvs.2016.00071/full; Carnemark, M., Jenkins, P., and Walker, L. 2015. *Water Hazard: Aquatic Contamination by Neonicotinoid Insecticides in The United States*. Unpublished report, CFS, Washington, D.C., *at* www.centerforfoodsafety.org/files/neonic-water-report-final-242016_web_33288.pdf and Carnemark, M. *Water Hazard 2.0,* CFS, 2017.

[25] *Id.*

The risks of the systemic insecticides appear to have not been foreseen by the registrants of the neonicotinoid liquid coating products or by EPA in applying its Treated Article Exemption to the coated seeds. The exemption has allowed these unregistered, unlabeled insecticides to outcompete and displace other *FIFRA-registered* insecticides and other less risky crop protection methods in U.S. agricultural markets. Their aggressive marketing has directly led to vastly more use of insecticides on crops for which no insecticides were needed or used by farmers in the years before these products were sold. This prophylactic use of coated seeds is incompatible with the principles of Integrated Pest Management.[26]

III. EPA's Coating Product Approvals.

While exempting the various neonicotinoid-coated crop seeds themselves, EPA has approved and registered the liquid coating products to be applied to seeds in a facility before sale or in limited cases by farmers themselves. However, EPA has failed to fully assess the adverse effects, described in this Petition, of the systemic insecticide beyond the seed coating process. Table 1 indicates unregistered pesticidal crop seeds with fifteen coating products that EPA approved since January 1, 2010.[27]

[26] Iowa State University, et al. 2015. *The Effectiveness of Neonicotinoid Seed Treatments in Soybean*. Unpublished extension report, *at* www.extension.umn.edu/agriculture/soybean/pest/docs/effectiveness-of-neonicotinoid-seed-treatments-in-soybean.pdf.

[27] See labels listed in n.17, *supra.*

Table 1: Unregistered Pesticidal Crop Seeds Approved Since 2010.

Active Ingredient	Coating Product	Pesticidal Crop Seeds
Clothianidin		
	Prosper Evergol	Canola, rapeseed and mustard
	Poncho Votivo/ Poncho 1250 Votivo	Corn, cotton, sorghum, soybean and sugarbeet
	Ernesto Quantum	Cotton
	Inovate	Soybean
	Sepresto 75 WS	Barley, buckwheat, corn, millet, oats, popcorn, rye, sorghum, teosinte, triticale, wheat, potato seed pieces, carrot, onion bulbs, leek, bunching onion, and broccoli
	NipsIt Suite Cereals Seed Protectant	Barley, oat and wheat
	Poncho/GB126	Sugarbeet, barley, buckwheat, millet, oats, rye, teosinte, triticale and wheat
Thiamethoxam		
	Helix Vibrance	Canola
	CruiserMAXX Potato Extreme	Potato
	CruiserMAXX Vibrance	Soybean
	Avicta Complete Beans	Soybean
	SYT0511 and SYT0113	Soybean
	Cruiser Vibrance Quattro	Small grain cereals
Imidacloprid		
	Dynashield Foothold Virock	Barley and wheat

Source: EPA Pesticide Product and Label System database, *at* https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1.

This Petition addresses all such pesticidal seeds, including both those listed in Table 1 and other older or newer pesticidal seeds products not listed in Table 1. The number of different crops in Table 1 totals at least twenty-five. The seeds are sold by various marketers under a large variety of product line names or numbers that typically, but not always, include the seed coatings.[28]

EPA's Risk Assessments (RAs) for the coating products ignore numerous risks of planting the resulting seeds, such as the toxic abraded dust-off, due to EPA's inclusion of the

[28] A non-exhaustive sample list includes: 1) Wyffels Hybrid corn lines W1526RIB; 1528RIB; and W1690, shipped coated with Poncho, *see* perma.cc/9N92-QAC5; and 2) the Pioneer Brand T Series of soybean seeds coated with Pioneer Premium Seed Treatment, *see* perma.cc/R8X8-FV9A.

coated seeds themselves under the Treated Article Exemption. This is most vividly illustrated in EPA's 2016 *Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid*.[29] It discloses that: "Mitigation of risks from abraded seed coating are addressed *outside* of this process." The identical assertion that EPA's risk assessors are not actually analyzing the external effects and risks of the abraded coatings is repeated in the Preliminary RAs for both thiamethoxam and clothianidin.[30] The Agency's claims that the risks are addressed "outside of" the formal RA process are not supported by any evidence.

Further, the large majority of the coating products listed in Table 1 were "conditionally registered" under FIFRA, indicating that key information needed for their full risk evaluation was not produced by the registrants to allow an unconditional registration.[31] Extensive information gaps remain for the resulting coated seeds.

IV. Major Reviews and Studies on Harms of Coated Seeds.

The full scope of harms have been revealed by extensive scientific monitoring and analysis, including an authoritative 2014 global review of over 800 published studies conducted under the auspices of the International Union for the Conservation of Nature (IUCN).[32] That expert review determined that neonicotinoids were dangerously overused and should be restricted. Based on detailed assessments by the European Food Safety Agency (EFSA), the European Union (EU) voted to prohibit their use on seeds of most crops largely due to dust-off

[29] EPA-HQ-OPP-2008-0844-0140, p. 36, lower left corner of Fig. 2-5 "Tiered approach for assessing risk to honey bees from soil/seed applications," (Released Jan. 6, 2016), *at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0844-0140.

[30] EPA, *Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam*, p. 46, lower left corner of Fig. 2-5 "Tiered approach for assessing risk to honey bees from soil/seed applications," (Released Jan. 5, 2017), *at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0865-0173 .

[31] Conditional registration requires the registrants to meet EPA's conditions regarding missing data, such as to conduct studies to fill specific data gaps, within a set timeframe. 7 U.S.C. § 136a(c)(7)(C).

[32] Van der Sluijs J.P., *et al*., 2014. *Conclusions of the Worldwide Integrated Assessment on the risks of neonicotinoids and fipronil to biodiversity and ecosystem functioning*, Environ. Sci. Pollut. Res. 22 (1), 148-154, *at* perma.cc/7RVA-FMA7.

and other harmful effects on bees.[33] That prohibition has been in effect since the EU vote in 2013.

In a 2017 review and update of the evidence that EFSA considered, Wood and Goulson published the comprehensive *Environmental Risks of neonicotinoid pesticides: a review of the evidence post-2013*.[34] Examining eight risk topics, the authors sought "to summarize how the new evidence has changed our understanding of the likely risks to bees; is it lower, similar or greater than the risk perceived in 2013"? The study vindicated the EU's 2013 prohibition, finding no decreased risk for any topics. For six risk topics they found them to be "Risk Unchanged." Evidence for the two topics connected with seed coatings pointed to a "Greater Risk."[35] Wood and Goulson also found extensive new evidence of what they labeled "broader risks to environmental health" that were not fully understood in 2013. They concluded:

> Field-realistic laboratory experiments and field trials continue to demonstrate that traces of residual neonicotinoids can have a mixture of lethal and sublethal effects on a wide range of taxa. . . . Relative to the risk assessments produced in 2013 for clothianidin, imidacloprid and thiamethoxam which focused on their effects on bees, new research strengthens arguments for the imposition of a moratorium, in particular because it has become evident that they pose significant risks to many non-target organisms, not just bees.

Acting to protect wildlife on Refuges, the U.S. Fish and Wildlife Service (FWS) prohibited all neonicotinoids from use in all National Wildlife Refuges as of January 1, 2016, because the Service: [36]

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[33] Official Journal of the European Union, Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013, amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances, L 139/12; 25.5.2013, *at* http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:139:0012:0026:EN:PDF.

[34] Wood, T.J. and Goulson, D. 2017. *The Environmental Risks of neonicotinoid pesticides: a review of the evidence post-2013***.** Unpublished report for Greenpeace. Paris, France, *available at* http://www.greenpeace.org/international/Global/international/publications/agriculture/2017/neonicotinoid-pesticides.pdf.

[35] Wood and Goulson 2017, *supra*, p. 8. The two "Greater Risk" findings are for these topic areas: "Risk of exposure from and uptake of neonicotinoids in non-crop plants" and "Sublethal effects of neonicotinoids on wild bees."

[36] Memorandum from James W. Kurth, Chief, National Wildlife Refuge System, U.S. Department of the Interior, Fish and Wildlife Service, *Use of Agricultural Practices in Wildlife Management in the National Wildlife Refuge*

> . . . determined . . . prophylactic use, such as a seed treatment, of the neonicotinoid pesticides that can distribute systematically in a plant and can potentially affect a broad spectrum of non-target species.

The FWS also has found that these seeds are among the neonicotinoid uses that are "strongly implicated" as a factor in the "endangered" classification under the ESA that the agency gave to the once-common Rusty Patched Bumble Bee.[37] The agency stated (citations omitted; emphasis added):[38]

> Neonicotinoids are a class of insecticides used to target pests of agricultural crops, forests (for example, emerald ash borer), turf, gardens, and pets and *have been strongly implicated as the cause of the decline of bees in, and specifically for rusty patched bumble bees,* due to the contemporaneous introduction of neonicotinoid use and the precipitous decline of the specie. . . . The use of *neonicotinoids rapidly increased as seed-applied products were introduced* in field crops, marking a shift toward large-scale, preemptive insecticide use.

A major review by the American Bird Conservancy stated that a *single* corn kernel treated with any of the common neonicotinoids could kill a songbird and just one-tenth of a treated corn kernel is enough to adversely affect a songbird's reproduction.[39]

Peer-reviewed, published studies from just the last two years further illustrate harmful effects from these coated seeds, effects that EPA's RAs for the coating chemicals have failed to assess. A list of the studies and excerpts of their abstracts follows:

1) Alburaki et al. 2015.[40] Indicating that neonicotinoid exposures increase pathogen risks

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System 1 (July 17, 2014), *at* www.centerforfoodsafety.com/files/agricultural-practices-in-wildlife-management_20849.pdf.

[37] Department of the Interior, U.S. Fish and Wildlife Service. Final rule, Endangered Species Status for Rusty Patched Bumble Bee, 82 Fed. Reg. 3,186, January 11, 2017, *at* https://www.fws.gov/midwest/endangered/insects/rpbb/pdf/FRFinalListingRuleRPBB11Jan2017.pdf

[38] *Id.,* at p. 3,190; *see also* p. 3,201.

[39] Mineau, P. and Palmer, C. 2013. *The Impact of the Nation's Most Widely Used Insecticides on Birds.* American Bird Conservancy, *at*: www.abcbirds.org/abcprograms/policy/toxins/Neonic_FINAL.pdf.

and weaken honey bee colonies:

> Thirty-two honeybee (Apis mellifera) colonies were studied in order to detect and measure potential in vivo effects of neonicotinoid pesticides used in cornfields (Zea mays spp) on honeybee health . . . Hives were extensively monitored for their performance and health traits over a period of two years. Honeybee viruses (brood queen cell virus BQCV, deformed wing virus DWV, and Israeli acute paralysis virus IAPV) and the brain specific expression of a biomarker of host physiological stress, the Acetylcholinesterase gene AChE, were investigated using RT-qPCR . . . In addition, general hive conditions were assessed by monitoring colony weight and brood development. Neonicotinoids were only identified in corn flowers at low concentrations. However, honeybee colonies located in neonicotinoid treated cornfields expressed significantly higher pathogen infection than those located in untreated cornfields. AChE levels showed elevated levels among honeybees that collected corn pollen from treated fields. *Positive correlations were recorded between pathogens and the treated locations. Our data suggests that neonicotinoids indirectly weaken honeybee health by inducing physiological stress and increasing pathogen loads*.

2) **Botias et al. 2016.**[41] Seed-coating of canola with neonicotinoids in the UK led to frequently high-level contamination of marginal vegetation:

> …we analysed samples of foliage collected from neonicotinoid seed-treated oilseed rape plants and also compared the levels of neonicotinoid residues in foliage (range: 1.4–11 ng/g) with the levels found in pollen collected from the same plants (range: 1.4–22 ng/g). We then analysed residue levels in foliage from non-target plants growing in the crop field margins (range: ≤0.02–106 ng/g). Finally, in order to assess the possible risk posed by the peak levels of neonicotinoids that we detected in foliage for farmland phytophagous and predatory insects, we compared the maximum concentrations found against the LC50 values reported in the literature for a set of relevant insect species. *Our results suggest that neonicotinoid seed dressings lead to widespread contamination of the foliage of field margin plants with mixtures of neonicotinoid residues, where levels are very variable and*

[40] Alburaki, M., Boutin, S., Mercier, PL, Loublier, Y., Chagnon, M., and Derome, N. 2015. Neonicotinoid-coated *Zea mays* seeds indirectly affect honeybee performance and pathogen susceptibility in field trials. *Plos One*, 10(5): p.e0125790, doi:10.1371/journal.pone.012579 (emphasis added).

[41] Botías, C., David, A., Hill, EM, and Goulson, D., 2016. Contamination of wild plants near neonicotinoid seed-treated crops, and implications for non-target insects. *Science of the Total Environment*, 566: 269-278 (emphasis added).

> *discontinuous, but sometimes overlap with lethal concentrations reported for some insect species*.

3) **David et al. 2016.**[42] Marginal vegetation near treated-seed canola fields was contaminated with high levels of neonicotinoids and other chemicals with synergistic effects:

> Here, we quantify concentrations of neonicotinoid insecticides and fungicides in the pollen of oilseed rape, and in pollen of wildflowers growing near arable fields. We then compare this to concentrations of these pesticides found in pollen collected by honey bees and in pollen and adult bees sampled from bumble bee colonies placed on arable farms. We also compared this with levels found in bumble bee colonies placed in urban areas. Pollen of oilseed rape was heavily contaminated with a broad range of pesticides, as was the pollen of wildflowers growing nearby. Consequently, pollen collected by both bee species also contained a wide range of pesticides, notably including the fungicides carbendazim, boscalid, flusilazole, metconazole, tebuconazole and trifloxystrobin and the neonicotinoids thiamethoxam, thiacloprid and imidacloprid. . . *It is notable that pollen collected by bumble bees in rural areas contained high levels of the neonicotinoids thiamethoxam (mean 18 ng/g) and thiacloprid (mean 2.9 ng/g), along with a range of fungicides, some of which are known to act synergistically with neonicotinoids*.

4) **Millot et al.**[43] Review of bird mortalities in France documented a high proportion resulted from common farmland birds consuming neonicotinoid-coated seeds:

> The large-scale use of neonicotinoid insecticides has raised growing concerns about their potential adverse effects on farmland birds, and more generally on biodiversity. Imidacloprid, the first neonicotinoid commercialized, has been identified as posing a risk for seed-eating birds when it is used as seed treatment of some crops since the consumption of a few dressed seeds could cause mortality. But evidence of direct effects in the field is lacking. Here, we reviewed the 103 wildlife mortality incidents reported by

[42] David, A., Botías, C., Abdul-Sada, A., Nicholls, E., Rotheray, EL, Hill, EM, and Goulson, D., 2016. Widespread contamination of wildflower and bee-collected pollen with complex mixtures of neonicotinoids and fungicides commonly applied to crops. *Environment International*, 88: 169-178 (emphasis added).

[43] Millot, F., Decours, A. *et al.*, 2016. Field evidence of bird poisonings by imidacloprid-treated seeds: a review of incidents reported by the French SAGIR network from 1995 to 2014 Environ *Sci Pollut Res* DOI 10.1007/s11356-016-8272-y (emphasis added).

> the French SAGIR Network from 1995 to 2014, for which toxicological analyses detected imidacloprid residues. One hundred and one incidents totalling at least 734 dead animals were consistent with an agricultural use as seed treatment. Grey partridges (Perdix perdix) and "pigeons" (Columba palumbus, Columba livia and Columba oenas) were the main species found. More than 70% of incidents occurred during autumn cereal sowings. Furthermore, since there is no biomarker for diagnosing neonicotinoid poisonings, we developed a diagnostic approach to estimate the degree of certainty that these mortalities were due to imidacloprid poisoning. By this way, *the probability that mortality was due to poisoning by imidacloprid treated seeds was ranked as at least "likely" in 70% of incidents. As a result, this work provides clear evidence to risk managers that lethal effects due to the consumption by birds of imidacloprid-treated seeds regularly occur in the field*. This in turn raises the question of the effectiveness of the two main factors (seed burying and imidacloprid-treated seeds avoidance) that are supposed to make the risk to birds negligible.

5) Mogren and Lundgren. 2016.[44] Set-aside vegetation strips near farms did not protect bees from nutritional harms caused by adjacent corn fields planted with clothianidin-coated seeds:

> Pollinator strips were tested for clothianidin contamination in plant tissues, and the risks to honey bees assessed. An enzyme-linked immunosorbent assay (ELISA) quantified clothianidin in leaf, nectar, honey, and bee bread at organic and seed-treated farms. Total glycogen, lipids, and protein from honey bee workers were quantified. The proportion of plants testing positive for clothianidin were the same between treatments. Leaf tissue and honey had similar concentrations of clothianidin between organic and seed-treated farms. Honey (mean ±SE: 6.61 ± 0.88 ppb clothianidin per hive) had seven times greater concentrations than nectar collected by bees (0.94 ± 0.09 ppb). Bee bread collected from organic sites (25.8 ± 3.0 ppb) had significantly less clothianidin than those at seed treated locations (41.6 ± 2.9 ppb). Increasing concentrations of clothianidin in bee bread were correlated with decreased glycogen, lipid, and protein in workers. *This study shows that small, isolated areas set aside for conservation do not provide spatial or temporal relief from*

[44] Mogren, CL and Lundgren, JG, 2016. Neonicotinoid-contaminated pollinator strips adjacent to cropland reduce honey bee nutritional status. *Scientific Reports*, 6:29608; DOI: 10.1038/srep29608 (emphasis added).

> *neonicotinoid exposures in agricultural regions where their use is largely prophylactic*.

6) **Rundlof et al**. **2015.**[45] Harm to wild bumblebees and other wild bees (which mostly are solitary) from clothianidin-coated canola seeds in a major field study in Sweden, published in *Nature*:

> Here we show that a commonly used insecticide seed coating in a flowering crop can have serious consequences for wild bees. In a study with replicated and matched landscapes, we found that *seed coating with Elado, an insecticide containing a combination of the neonicotinoid clothianidin and the non-systemic pyrethroid b-cyfluthrin, applied to oilseed rape seeds, reduced wild bee density, solitary bee nesting, and bumblebee colony growth and reproduction under field conditions. Hence, such insecticidal use can pose a substantial risk to wild bees in agricultural landscapes, and the contribution of pesticides to the global decline of wild bees may have been underestimated*. The lack of a significant response in honeybee colonies suggests that reported pesticide effects on honeybees cannot always be extrapolated to wild bees.

7) **Woodcock et al**. **2016.**[46] Planting neonicotinoid-treated canola seed is an important factor in the *extinction* of wild bee species in Britain:

> *We relate 18 years of UK national wild bee distribution data for 62 species to amounts of neonicotinoid use in oilseed rape. Using a multi-species dynamic Bayesian occupancy analysis, we find evidence of increased population extinction rates in response to neonicotinoid seed treatment use on oilseed rape*. Species foraging on oilseed rape benefit from the cover of this crop, but were on average three times more negatively affected by exposure to neonicotinoids than non-crop foragers. Our results suggest that sub-lethal effects of neonicotinoids could scale up to cause losses of bee biodiversity. *Restrictions on neonicotinoid use may reduce population declines*.

[45] Rundlöf, M., Andersson, GK, Bommarco, R., Fries, I., Hederström, V., Herbertsson, L., Jonsson, O., Klatt, BK, Pedersen, TR, Yourstone, J., and Smith, HG, 2015. Seed coating with a neonicotinoid insecticide negatively affects wild bees. *Nature*, 521(7550): 77-80. (emphasis added).

[46] Woodcock, BA, NJ Isaac, JM Bullock, DB Roy, DG Garthwaite, A Crowe, and RF Pywell. 2016. Impacts of neonicotinoid use on long-term population changes in wild bees in England. *Nature Communications*, 7: 12459 (emphasis added).

V. Honey Bee Kills and Other Costs.

Pervasive use of these chemicals, particularly on corn and soybeans, is resulting in pesticide contamination of vast areas extending far beyond the planted fields. Many beekeepers have observed toxic dust clouds billowing from seed planting machines, spreading the insecticides far and wide: to neighboring farms, onto marginal vegetation visited by their bees, into waterways, and even directly onto their beehives. Honey bee kill incidents caused by neonicotinoid-coated seeds have numbered in the hundreds and likely many more.[47] These incidents have likely killed hundreds of millions of individual bees due to acute dust-off kills and chronic damage to bee hives. As a result, for Beekeeper Petitioners Anderson, Adee, and Hackenberg and other beekeepers represented by Petitioners American Beekeeping Federation, American Honey Producers Association and Pollinator Stewardship Council, their honey production and the overall profitability of their business have drastically declined, while their workloads and personal stress have multiplied.

A recent scientific study from England showed high and unexpected contamination in honey bee hives resulting from seed coatings, originating with contaminated marginal vegetation near the canola fields rather than from the canola pollen.[48] Honey bees examined in the study were collecting enough neonicotinoids to damage their productivity and reproduction rate. Similarly, a Canadian study found unexpectedly high levels of neonicotinoids in the surface dust of arable fields and evidence that this dust blows into adjoining fields, contaminating them and

[47] For a source on beekills that is not comprehensive but is illustrative of the problem, see Pollinator Stewardship Council, Reported Bee Kills, at http://pollinatorstewardship.org/?page_id=1428. Beekeepers typically do not report their dust-off kills systematically as there are no Federal or State enforcement responses due to the exemption that is the focus of this Petition.

[48] Botias, *et al*., 2015. Neonicotinoid rresidues in wwildflowers, a ppotential rroute of cchronic cexposure for bees, *Environ. Sci. Technol.* 49(21): 12731-12740, *available at* perma.cc/G2PY-UF25.

putting surface-living beneficial species at risk.[49] Sublethal doses can result in honey bee colony damage through chronic effects, including compromising the behavior, health, and immunity of colonies, thus causing them to collapse under the additional stress of pathogens and parasites.[50]

The costs of neonicotinoid-coated seeds and their resulting contamination include, at a minimum, these foreseeable categories: 1) harmful honey bee colony effects and resulting reduced yields of pollinated crops; 2) reduced production of honey and other bee products; 3) financial harm to beekeepers and consumers; 4) loss of ecosystem services; and 5) market damage from contamination events.[51] Estimated cumulative, direct, and indirect costs of this contamination to date across these five categories are in the tens of *billions* of dollars.[52] The Beekeeper Petitioners have personally experienced many of the economic harms associated with bee kills and the decline of pollinators, as stated in the Interests of the Petitioners in the Appendix.

The harm to native bees, which are essential pollinators but that lack commercial valuation, is nationwide and incalculable. Unmanaged and often living in contaminated soil, species such as bumblebees, ground-nesting mining bees, alkali bees, squash bees, and long-horned sunflower bees are harmed by repeated, persistent use of the coated seeds. Adverse impacts to other species of native bees that are not ground nesters also has been identified, particularly due to the high toxicity of neonicotinoids to blue orchard bees and alfalfa leafcutter

[49] Victor Limay-Rios, *et al*., 2015. Neonicotinoid insecticide residues in soil dust and associated parent soil in fields with a history of seed treatment use on crops in Southwestern Ontario, *Environ. Toxicol. Chem.* 35(2):303-10. doi: 10.1002/etc.3257, *available at* perma.cc/4PTA-HQRN.

[50] Dussaubat, C., Maisonnasse, A., Crauser, D., Tchamitchian, S., Bonnet, M., Cousin, M., Kretzschmar, A., Brunet, JL, and Le Conte, Y., 2016. Combined neonicotinoid pesticide and parasite stress alter honeybee queens' physiology and survival. *Scientific Reports*, 6:31430; DOI: 10.1038/srep31430; Sánchez-Bayo, F., Goulson, D., Pennacchio, F., Nazzi, F., Goka, K., and Desneux, N., 2016. Are bee diseases linked to pesticides?—a brief review. *Environment International*, 89:7-11.

[51] Stevens S., and Jenkins, P., 2014. *Heavy Costs: Weighing the Value of Neonicotinoid Insecticides in Agriculture.* Unpublished report, CFS, Washington, D.C., pp. 12-15, *at* http://www.centerforfoodsafety.org/files/neonic-efficacy_digital_29226.pdf.

[52] *Id.*

bees.[53] While blue orchard and leafcutter bees do not nest in the soil, they rely on plant materials and mud for building their brood cells and can be contaminated through those nesting materials and other exposure routes. None of the risks to native bees are captured in EPA's Pollinator RAs issued in 2016 and 2017 for the three main active ingredients in the seed coating products: imidacloprid, clothianidin and thiamethoxam.

VI. Harm to Threatened and Endangered Species.

The sum lesson of the voluminous science cited throughout this Petition is that the pesticidal coated-seeds may affect broad groups of non-target animals. These range from direct harm to both managed and wild bees and other beneficial terrestrial insects, to contaminated run-off decimating aquatic invertebrates, to both acute and chronic effects on birds that ingest the seeds. Within each of those animal groups are many threatened and endangered species protected under the ESA. The 2017 listing of the rusty patched bumble bee, mentioned above, is one example of species listed partially because it is directly affected by the use of neonicotinoid coated seeds. Two butterflies listed in 2014 also had neonicotinoid-coated seeds explicitly singled out by the FWS as a significant factor that led to their listings: Dakota skipper (*Hesperia dacotae*) and Poweshiek skipperling (*Oarisma poweshiek*).[54]

Nationally and internationally recognized experts, Drs. John Stark of Washington State University, John Losey of Cornell University, and Pierre Mineau, a consultant formerly with Environment Canada, have submitted formal expert opinions identifying at least these five

[53] Hopwood, J., Code, A., Vaughan, M., Biddinger, D., Shepherd, M., Black, S.H., Mader, E., and Mazzacano, C., 2016 *How Neonicotinoids Can Kill Bees* 2d Ed., Unpublished report, Xerces Society for Invertebrate Conservation, Portland, OR, *at* www.xerces.org/wp-content/uploads/2016/10/HowNeonicsCanKillBees_XercesSociety_Nov2016.pdf.

[54] 79 Fed. Reg. 63,672 (Oct. 24, 2014)(codified at 50 C.F.R. pt. 17), *available at* https://www.fws.gov/midwest/endangered/insects/dask/pdf/FRButterflyFinalListing24Oct2014.pdf.

additional ESA-protected species, beyond the two butterflies above (which they also identified), as potentially affected by coated seed use:[55]

> **Invertebrates:** Hine's emerald dragonfly (*Somatochlora hineana*); Salt Creek tiger beetle (*Cicindela nevadica lincolniana*).
>
> **Birds:** Mississippi sandhill crane (*Grus canadensis pulla*), whooping crane (*Grus Americana*), Attwater's prairie chicken (*Tympanuchus cupido attwateri*).

The analyses by Drs. Stark, Losey, and Mineau focused just on a small number of case study species (three species per expert). They stated in their opinions that likely many other similarly-exposed ESA-listed species could be affected.[56] The following is an illustrative, non-exhaustive, list of ten threatened and endangered terrestrial insects that EPA should consider as an additional starting point:[57]

> 1) American burying beetle (*Nicrophorus americanus*); 2) Behren's fritillary (or Behren's silverspot) (*Speyeria zerene behrensii*); 3) Callippe silverspot (*Speyeria callippe callippe*); Fender's blue (*Icaricia icarioides fender*); 4) Karner blue (*Plebejus melissa samuelis*); 5) Lange's metalmark (*Apodemia mormo langei*); 6) Mitchell's satyr butterfly *Neonympha mitchellii mitchelli*; 7) Myrtle's silverspot (*Speyeria zerene myrtleae*); 8) Quino checkerspot butterfly (*Euphydryas editha quino*); 9) San Bruno elfin (*Callophrys mossii bayensis*); and 10) Schaus swallowtail (*Papilio aristodemus ponceanus*).

As discussed in the Argument section, below, EPA has never once consulted with the expert agencies—the FWS or National Marine Fisheries Service (NMFS)—on any neonicotinoid insecticide product registration or on the exempted coated seeds as required under the ESA when

[55] Expert Declarations of Drs. John Stark, John Losey, and Pierre Mineau, filed with this Petition; these were originally prepared in support of Plaintiffs' Memorandum of Points and Authorities in Support of Motion for Summary Judgment, *Ellis v. Housenger,* No. 3:13-cv-01266-MMC, ECF No. 215-1 (N.D. Cal. Apr. 14, 2016).
[56] Decl. Mineau ¶¶ 9, 23, 43, 45; Decl. Stark ¶¶ 17, 49; Decl. Losey ¶ 8, 10, 12, 14.
[57] *See* listings in FWS ECOS Environmental Conservation Online System, http://ecos.fws.gov/ecp0/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&mapstatus=3&fcrithab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. This list will need updating as more species are regularly added and numerous "Candidate" species await further action.

"effects" on any listed species or their critical habitats are foreseeable. Since ninety-five percent of the land area in the country that is affected by any neonicotinoid product is affected by the coated seeds, obviously consultation on the seeds' effects is required. The more than 140 million acres planted across the country overlaps the habitats of, or otherwise affects, literally *hundreds* of listed species. EPA's own internal risk assessments for various seed treatment uses of clothianidin and thiamethoxam going back at least seventeen years explicitly reveal that the agency is fully aware that likely many hundreds of species may be affected.[58]

The *obvious* failures to date are the three ESA-listed species for which the planting of neonicotinoid-coated seeds already are labeled by the FWS as significant factors in their listings, again, the rusty patched bumble bee, Dakota skipper and Poweshiek skipperling. EPA's ongoing

[58] The following 13 risk assessments and similar documents are illustrative of numerous documents in EPA's own files just for clothianidin and thiamethoxam that show foreseeable effects of the coated seeds on hundreds of ESA-listed species nationwide. This is not exhaustive. As EPA has copies of its own very lengthy assessments, copies are not being attached with this Petition:

1) Clothianidin Pesticide Fact Sheet, dated May 30, 2003.
2) EFED Risk Assessment for the Seed Treatment of Clothianidin 600FS on Corn and Canola, dated Feb. 20, 2003.
3) "Addendum" to the above-referenced EFED Risk Assessment, dated Apr. 10, 2003.
4) EFED Registration Chapter for Clothianidin for Use on Potatoes and Grapes as a spray treatment and as a Seed Treatment for Sorghum and Cotton, dated Sept. 28, 2005.
5) Revised Assessment for Clothianidin Registration of Prosper T400 Seed Treatment on Mustard Seed and Poncho/Votivo Seed Treatment on Cotton, dated Dec. 2, 2010.
6) Environmental Fate and Ecological Risk Assessment for the Use of Thiamethoxam as a Seed Treatment to Control Grape Colapsis on Arkansas Rice, dated Feb. 26, 2009.
7) Ecological Risk Assessment for the Proposed New Uses of Thiamethoxam Seed Treatment for Dry Bulb Onions and Peanuts and Registered Seed Treatment for Corn, Carrots, Leafy Vegetables, and Brassica (Cole) Leafy Vegetables, dated May 18, 2010.
8) Ecological Risk Assessment for the Proposed New Uses of Thiamethoxam Seed Treatment on Alfalfa, dated Dec. 28, 2010.
9) Environmental Fate and Ecological Risk Assessment for the Registration of Thiamethoxam On Ornamentals, Brassica (Cole) and Non-Brassica Leafy Vegetables, Pecans, Succulent Beans, Sunflower, and Stone fruit, dated June 1, 2009.
10) Section 3 Registration Request for Use of Thiamethoxam on Multiple Crops, dated June 11, 2001.
11) Section 3 Registration Request for Thiamethoxam (Chemical #060109, DP Barcode D251956) Use as a Seed Treatment, dated Dec. 14, 2000.
12) Ecological Risk Assessment for the Proposed New Use of Thiamethoxam as a Seed Treatment for Cereal Grains, dated Aug. 30, 2011.
13) Ecological Risk Assessment for the Section 3 New Use Registration of Thiamethoxam on Tropical Fruits, Sugar Beet Seed, Rice Seed, Cranberry, Bushberry Subgroup 13-07B, Low Growing Berry Subgroup 13-07G, Caneberry Subgroup 13-07A, and Small Fruit Vine Climbing Subgroup 13, dated May 18, 2009.

refusal to consult under the ESA must change or else these—and other—valued, irreplaceable, native species may face severe jeopardy of extinction now directly under the agency's watch.

VII. Lack of Yield Benefits.

Two thorough reviews of the published science on crop yields by Petitioner Center for Food Safety (CFS), first in 2014 and then updated in 2016, show that use of neonicotinoid-coated seeds actually provides no net yield benefit to farmers across the majority of crop-planting contexts.[59] The 2016 report *Net Loss* report summarizes the current knowledge**:**

> [T]he broad lack of independent data showing economic justification for [neonicotinoids] use on seeds indicates that they are grossly over-used. In the European Union (EU), there is no evidence that crop production declined due to the 2013 prohibition on most crop-seed uses of neonicotinoids, which was adopted across the continent despite extremely dire industry predictions made at the time. In fact, on average, production to date has risen for major crops. Thus, prohibiting use of the neonicotinoid seed coatings did not deny European farmers any significant economic benefits.
>
> Further, agricultural scientists and other experts in the United States and the United Kingdom have issued extensive new studies and reviews on the lack of overall efficacy of this technology. The lack of economic justification for the prophylactic use of neonicotinoid-coated seeds for soybeans (the second most extensively planted U.S. crop after corn), is virtually uncontested based on the overwhelming weight of independent reviews. Published evidence on weak or non-existent benefits exists for other crops as well, although it is more sporadic.

The most detailed report on the "efficacy" question for soybeans came from EPA itself, issued in 2015.[60] The Agency's Biological and Economic Analysis Division (BEAD) stated:

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[59] Stevens and Jenkins, 2014, *supra*; Jenkins, P., *Net Loss—Economic Efficacy and Costs of Neonicotinoid Insecticides Used as Seed Coatings: Updates from the United States and Europe* (2016), unpublished report, CFS, Washington, D.C., *at* www.centerforfoodsafety.org/files/efficacy-netloss12616_38208.pdf.

[60] Myers, C., Hill, E., *Memorandum: Benefits of Neonicotinoid Seed Treatments to Soybean Production* at 9, United States Environmental Protection Agency (Oct. 15, 2014), *at* www.epa.gov/sites/production/files/2014-10/documents/benefits_of_neonicotinoid_seed_treatments_to_soybean_production_2.pdf.

> This analysis provides evidence that U.S. soybean growers derive limited to no benefit from neonicotinoid seed treatments in most instances. Published data indicate that most usage of neonicotinoid seed treatments does not protect soybean yield any better than doing no pest control. Given that much of the reported seed treatment usage in the U.S. on soybeans is not associated with a target pest, BEAD concludes that much of the observed use is preventative and may not be currently providing any actual pest management benefits.

BEAD went on to observe, based on EPA's survey of agriculture extension experts nationwide, that when asked how the use of neonicotinoid-treated seeds affected soybean yields, *seventy-four percent* of respondents stated that *yield either stayed the same or decreased.*[61] EPA must heed its own analysis. The lack of yield benefits in most cases, and actual yield *reductions* in many cases, reinforces the experience of the Farmer Petitioners Criswell and Fuller. Despite paying for the seed coating protections when they bought seeds in the past, the farmers' yields did not benefit. And the beneficial insects in or near their farms and other aspects of their soil health were harmed.[62]

VIII. Aquatic Contamination.

Recent studies address the severe aquatic contamination associated with neonicotinoids, which are water soluble.[63] Their increasing contamination of ditches, streams, groundwater, lakes, rivers, and marine areas is now being documented. Researchers across the United States are finding high levels, exceeding vital standards set by experts to protect aquatic life. The coatings applied to crop seeds are a primary source of the contamination. The 2015 CFS report, *Water Hazard—Aquatic Contamination by Neonicotinoid Insecticides in the United States,* describes numerous exceedances of safe levels, including many findings exceeding EPA

[61] *Id*., pp. 9-10 (emphasis added).
[62] *See* Petitioners' Interests in Appendix, Section II.
[63] Morrissey, C.A., *et al*. 2015, *supra,* n.24, Neonicotinoid contamination of global surface waters and associated risk to aquatic invertebrates: A review.

benchmarks.[64] It documents contamination caused by coated seeds in a wide variety of rural habitats nationwide, typically via pathways that EPA failed to consider adequately when it approved the coating products.

Water concerns were clearly illuminated in late 2016 in another review paper by Sanchez-Bayo, *et al*.[65] The implications, partly attributable to coated seeds, are extremely alarming, summed in the Conclusion as:

> Negative impacts of neonicotinoids in aquatic environments are a reality. Initial assessments that considered these insecticides harmless to aquatic organisms may have led to a relaxation of monitoring efforts, resulting in the worldwide contamination of many aquatic ecosystems with neonicotinoids.
>
> The decline of many populations of invertebrates, due mostly to the widespread presence of waterborne residues and the extreme chronic toxicity of neonicotinoids, is affecting the structure and function of aquatic ecosystems. Consequently, vertebrates that depend on insects and other aquatic invertebrates as their sole or main food resource are being affected. Declines of insectivore bird species are quite evident so far, but many other terrestrial and amphibian species may be at risk.
>
> *Solutions must be found soon if we are to save the biodiversity not only of aquatic ecosystems, but all other ecosystems linked by the food web*.

On January 12, 2017, EPA released its *Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid.*[66] While containing many conservative assumptions and admitted uncertainties, for seed treatment uses EPA found ongoing *chronic* effects for many aquatic invertebrates and some group likely to suffer *acute* effects. As discussed above, *supra* Section VI, while EPA failed to do the required ESA Section 7 analysis, it is transparent that

[64] Carnemark, M., Jenkins, P., and Walker, L., *Water Hazard—Aquatic Contamination by Neonicotinoid Insecticides in the United States*, CFS, Washington, D.C., 2015, *at* www.centerforfoodsafety.org/files/neonic-water-report-final-242016_web_33288.pdf and Carnemark, M. *Water Hazard 2.0,* CFS, 2017.
[65] Sánchez-Bayo F., Goka K., Hayasaka, D., *Contamination of the aquatic environment with neonicotinoids and its implication for ecosystems,* Front. Environ. Sci. 4:71 (2016) doi: 10.3389/fenvs.2016.00071, *at* http://journal.frontiersin.org/article/10.3389/fenvs.2016.00071/full (emphasis added).
[66] EPA-HQ-OPP-2008-0844-1086, *at* www.regulations.gov/document?D=EPA-HQ-OPP-2008-0844-1086.

listed threatened and endangered aquatic invertebrates may be adversely affected by the same chronic and/or acute effects. Despite its own findings the agency has failed to take—or even propose—any solutions needed to alleviate these effects on those species or those essential aquatic ecosystems as urged by Sanchez-Bayo, *et al*., *supra*.

IX. Labels on Neonicotinoid-Coated Seed Bags and Tags.

EPA requires labels to be placed onto the bags or other containers, or onto the affixed tags, of the unregistered pesticidal seeds, which include some sparse warnings superficially aimed at protecting pollinators and other environmental values.[67] While these amount to admissions of the seeds' pesticidal effects, the label language itself is unenforceable by EPA's own statements and its inactions.[68]

Even were it enforceable, the seed bag or tag language is utterly inadequate to reduce or mitigate the harm caused by contaminated neonicotinoid dust and talc, or the grown plants themselves, to honey bees—including those owned by the Beekeeper Petitioners. Further, the bag labels are inadequate to protect against the vast spectrum of other environmental and economic impacts, including, but not limited to, damage to soil health, harm to ESA-protected species and the extensive water contamination described above.

On the inadequacy of the labels, Petitioner Bret Adee (representing the nation's largest commercial beekeeping company) has stated:

> …[a]s shown in our massive 2015 bee kill, the exemption of toxic dust coming off of the neonicotinoid-coated corn seeds means there are no legal consequences for the seed coaters or pesticide manufacturers whose chemicals killed our bees. Neither the state enforcement agents nor EPA's enforcement agents will take any action to stop or mitigate the harms. There are no enforceable labels on the seed bags that the farmer must follow to not cause

[67] *See* n.17, *supra.*
[68] *See* EPA, Sulfoxaflor—Final Cancellation Order, dated Nov. 12, 2015, p.2, *at* https://www.epa.gov/sites/production/files/2015-11/documents/final_cancellation_order-sulfoxaflor.pdf.

> dust-off that will kill honeybees. My direct experience is that whatever language EPA asks to be put on those seed bags is inadequate to protect bees. From my perspective, my right as a beekeeper to obtain pesticide law enforcement for such dust-off kills has become non-existent. That reduces not only my ability to protect my valuable livestock, but also my ability to make any civil or other claim that I might seek to bring against those in the chain of production and use of these pesticides.[69]

The seed coating companies that apply the liquid chemicals to the various crop seeds are not the applicators of the ultimate pesticidal products—the seeds. Rather, the crop farmers who plant the seeds are, including the Petitioner farmers herein. The farmers are the "users" who need—and in many cases, desire—clear label warnings and strong directions in order to protect their own surrounding environment. EPA misuses its labeling authority and arbitrarily assumes that the seed coating companies—applying the liquid coatings mostly in industrial buildings—can be given warnings and use directions adequate to ensure that FIFRA's safety standards will be met during the actual use of the pesticidal seeds in the environment.

X. Past Statements by EPA, USDA Officials and Others.

Extensive statements by EPA and USDA officials, and in documents before the agencies, underscore their awareness of the harms of the coated seeds and the associated dust-off. Below is a non-exhaustive example of such statements:

A) EPA's Pesticide Fact Sheet—Clothianidin:[70]

> …assessments show that exposure to treated seeds through ingestion may result in chronic toxic risk to non-endangered and endangered small birds (e.g., songbirds) and acute/chronic toxicity risk to non-endangered and endangered mammals. Clothianidin has the potential for toxic chronic exposure to honey bees, as well as other nontarget pollinators, through the translocation of clothianidin residues in nectar and pollen … [It] is

[69] Decl. Adee p.2, *Anderson v. McCarthy,* No. 3:16-cv-00068-WHA, ECF No. 58 (N.D. Cal. Apr. 14, 2016).
[70] EPA, Office of Prevention, Pesticides and Toxic Substances. Pesticide Fact Sheet—Clothianidin (May 30, 2003), *at* https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/fs_PC-044309_30-May-03.pdf.

a systemic insecticide that is persistent and mobile, stable to hydrolysis, and has potential to leach to ground water, as well as runoff to surface waters.

B) Report on the National Stakeholders Conference on Honey Bee Health:[71]

It is clear, however, that in some instances honey bee colonies can be severely harmed by exposure to high doses of insecticides when these compounds are used on crops, or via drift onto flowers in areas adjacent to crops that are attractive to bees. For example, dust produced in the process of planting pesticide-coated seeds has been shown to contain high levels of insecticide with the potential to harm bees.

C) EPA's Team Preparing the 2013 *Guidance for Inspecting Alleged Cases of Pesticide-Related Bee Incidents*:[72]

Keen interest has been expressed by outside groups in contributing to the bee guidance, which has been under development since mid-2012, following a spring with an unusual number of bee mortality incidents either unexplained or which appeared to be associated with treated seed.

D) Evidence EPA Collected from Non-Federal Experts in the Preparation of its 2013 Guidance:

For background on its Bee Incident Guidance, above, EPA convened a panel of experts, several of whom highlighted the role of neonicotinoid-coated seeds. Commercial beekeeper Randy Oliver identified: "dust from fields . . . dust from corn seeding . . . transport of systemic pesticides into crops or exposed weeds" as routes of pesticide exposure to his hives. Oliver also stated to EPA: "Exposure to planting dust kills the 'pollen hogs'—newly-emerged workers and drones that are feeding heavily on beebread. Next would be effects upon the nurse bees, who also consume the bulk of pollen in the hive."[73] The most devastating effect of exposure by bees to neonicotinoid pesticides is a large number of dead bees appearing in front of and surrounding a hive. Other sub-lethal effects can be just as devastating, including "queen failure,

[71] USDA, October 2012 Report on the National Stakeholders Conference on Honey Bee Health, p. 16, *at* http://www.usda.gov/documents/ReportHoneyBee Health.pdf.

[72] EPA, undated memorandum (likely 2013). Draft Guidance for Investigation of Alleged Cases of Pesticide-Related Bee Mortality: Pros and Cons of Issues Surrounding Review and Release of the Guidance, *available at* perma.cc/P5VX-JS6T.

[73] EPA, Undated survey responses. *Responses From Bee Experts* (collected in preparation for EPA's 2013 *Guidance for Inspecting Alleged Cases of Pesticide Related Bee Incidents*); Randy Oliver responses, pp. 1, 6.

> [inability] to navigate correctly, inability to supersede during queen failure, sterile drones and/or inability to successfully copulate with virgin queens," and "loss of vigor by foragers, lack of veteran foragers that harvest proposes, [and] shortened lifespan of foragers."[74] Dr. Eric Mussen of University of California, Davis, stated, "bees exposed to neonicotinoids looked 'anemic'; the bee colony is not necessarily killed; there seems to be 'downstream sickness' and the bees tend to be sluggish."[75]

E) EPA's Scientific Advisory Panel (SAP), Pollinator Risk Assessment Framework:

> During that SAP in 2012, Purdue University Professor of Entomology Dr. Greg Hunt stated:
>
> Well, I'll just speak to the seed treatment. Neonicotinoid seed treatments in particular, in the conceptual model, this is modeled—the EPA White Paper is only looking primarily at systemic movement plant parts**.** But clearly, we're seeing a problem with dust, particularly with corn planting and in regards to the soil. We see at least twice the concentrations of Clothianidin that we find in corn pollen. We're seeing a lot of reports, many of which apparently aren't getting transmitted to the EPA, and I think there is a lag in that also because, for example, in Indiana, the office of the state chemist has looked at 14 incident reports and they all came up positive for Clothianidin. In Ohio, there was something like 50 reports, incident reports, which again have not gotten their way to the EPA. In Ontario and Quebec, there are a lot of positive reports—over 130 of them, I understand—just from this year.[76]

XI. Other Systemic Seed Coating Chemicals.

The same factual concerns discussed above apply to other non-neonicotinoid, systemic seed coating products that EPA has already approved or has indicated its intent to approve, including, but not limited to, Fipronil, Sulfoxaflor, Cyantraniloprole and Flupyradifurone. Some of these may not yet be registered for seed coating use; however, based on EPA's practices with the neonicotinoids, it is foreseeable EPA will approve them for that use. If so approved they are likely to present the same class of harms to Petitioners as do neonicotinoid-coated seeds.

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[74] *Id.,* Randy Verhoek response, p. 5.
[75] EPA, 2013. Meeting Minutes Teleconference: EPA and 'Bee Experts.' Tues. Feb. 26, Eric Mussen ("EMu") response, p. 2.
[76] FIFRA Scientific Advisory Panel, 2012, Open meeting, Pollinator Risk Assessment Framework, Docket number: EPA-HQ-OPP-2012-0543 p.411, *at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0543-0039.

ARGUMENT

I. EPA Has the Authority and Duty To Regulate Coated Seeds Under FIFRA.

Systemic neonicotinoid-coated seeds clearly fit within FIFRA's definition of "pesticide" because they are a "mixture of substances that are intended to prevent, destroy, repel or mitigate a pest," and would otherwise require registration prior to sale. 7 U.S.C. § 136(u)(1). Under FIFRA, EPA is charged with regulating pesticides, absent an exemption, including directing what data will support registration and evaluating whether a given pesticide meets FIFRA's safety standard. *Id.* § 136a. Specifically, EPA may not register a pesticide unless it determines that "it will perform its intended function without unreasonable adverse effects on the environment; and when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 36a(c)(5)(C), (D).

EPA is authorized under FIFRA to exempt certain pesticides from FIFRA's requirements. Namely, under 7 U.S.C. § 136w(b), the "Administrator may exempt from the requirements of this subchapter by regulation any pesticide which the Administrator determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this subchapter in order to carry out the purposes of this subchapter." Given that EPA is not allowed to *register* a pesticide which will cause unreasonable adverse effects on the environment, it follows that EPA may not *exempt* pesticides that would cause unreasonable adverse effects on the environment. Put another way, EPA could not lawfully determine that a pesticide that causes "unreasonable adverse effects on the environment" is "of a character which is unnecessary to be subject to" FIFRA.

Pursuant to its authority under 7 U.S.C. § 136w(b)(2), EPA promulgated the Treated

Article Exemption, for "[a]n article or substance treated with, or containing, a pesticide to protect the article or substance itself." 40 C.F.R. §152.25(a). As currently written, the plain language of that exemption does not include systemic insecticide-coated seeds. Coated seeds do not fit within 40 C.F.R. §152.25(a) (which lacks any mention of "seeds"), because they are not intended "to protect the article or substance itself" as the regulation requires. First, the actual intent behind coating crop seeds with neonicotinoids and other systemic insecticides predominately is to protect the growing plant from pests that prey on living plant tissues, not to protect the seed "itself." As indicated, reviewing the fifteen coating product labels that EPA has registered since 2010 reveals that on thirteen of those labels the neonicotinoid ingredients are intended to protect the growing crop plants.[77] Only two of those labels explicitly claim protection of the planted seed itself by the neonicotinoid ingredient. Second, the coatings of these seeds do not remain on the seed, but instead "dust-off" into the air during planting, or slough off into the soil. The fact that 80% to 90% of the coating chemicals move off the seed and plant into the surrounding air, soil, marginal vegetation and waters, illustrates that the bulk of the treatment does not remain in or on the "treated article." Because the Treated Article Exemption requires that the treatment be for the protection of the article itself, it should be a necessary condition that the treatment largely remains *on the treated article.*

However, EPA's current interpretation of the Treated Article Exemption includes systemic coated seeds under this exemption, despite the intended and actual pesticidal effects beyond the articles (seeds) themselves.[78] While the Agency has not made this interpretation clear in any regulation or formal interpretation, EPA's practice of neither requiring registration of the seeds nor imposing enforceable labeling on their bags or tags speaks clearly. EPA can and must

[77] *See* n.17, *supra.*
[78] EPA, 2013 *Guidance for Inspecting Alleged Cases of Pesticide Related Bee Incidents*, p. 7, *at* https://www.epa.gov/sites/production/files/2013-09/documents/bee-inspection-guide.pdf.

correct this interpretation and practice of exempting coated seeds from registration and labeling by clarifying that the Treated Article Exemption does not include systemic coated seeds.

Not only does the extension of the Treated Article Exemption to these pesticidal seeds violate its plain language, it violates the basic FIFRA safety standard. EPA cannot exempt a pesticide that violates this safety standard, i.e., that the pesticides as commonly used will not cause unreasonable adverse effects to the environment. 7 U.S.C. § 136a(c)(5). As shown above, these seeds *do* cause unreasonable adverse effects to the environment, including to the pollinators that support U.S. agriculture and make up the livelihoods of the Beekeeper Petitioners. EPA has failed to fully evaluate the harms from coated seeds in its approvals of the liquid coating products alone. EPA's own pollinator RAs for imidacloprid, clothianidin, and thiamethoxam do not fully examine their risks when used as seed treatments, due to EPA's exemption for the seeds. Most explicitly, the RAs *exclude* any risk assessment or mitigation for the abraded seed coatings and the associated "dust-off," despite EPA's awareness that these insecticides are spread far from where the exempted seeds were planted.[79] Even though agency officials are aware of harm occurring as a result of these seeds, their exemption blinds them to the full magnitude of the damage. Many incidents of damage from coated seeds simply go uninvestigated. Even reports of massive honey bee colony kills due to coated seeds may never lead to enforcement because they are not caused by registered "pesticides" covered under FIFRA. Petitioner beekeepers have no incentive to report such kills to the agency due to its well-known lack of enforcement.

By approving only the liquid coating products applied to the seeds indoors, EPA allows manufacturers of systemic seeds of the various crops (>24) to avoid a comprehensive EPA

[79] EPA's Preliminary Pollinator/Bee Risk Assessments for Imidacloprid, Clothianidin and Thiamethoxam cited in n.29 and n.30, *supra*.

determination of whether those particular crop seeds and their associated dust-off, soil and water contamination and other externalized effects constitute "unreasonable adverse effects on the environment" as required under 7 U.S.C § 136a(c) (5). Further, EPA's exemption allows manufacturers of the various pesticidal seeds to evade the two classes of EPA notices that must go in the Federal Register under FIFRA and EPA's regulations. 7 U.S.C. § 136a(c)(4); 40 C.F.R. § 152.102. This evasion denies Petitioners and the public essential notice by which they could be allowed to comment to EPA on proposed registrations. The lack of the required published notices also denies Petitioner beekeepers the information needed to protect their bees from fields planted with the numerous exempted crop seeds.

If EPA had followed the FIFRA-mandated registration process for the pesticidal seeds at issue, many of them likely would not have been registered, not been heavily advertised and sold, and they would not have inflicted the damages the Petitioners that they now inflict. Other regulators (in Europe and on our own U.S. wildlife refuges) are taking action to restrict or stop the use of these dangerous pesticides.[80] EPA cannot continue to exempt them from FIFRA. Without the requested action, EPA will allow the continued destruction of the nation's commercial and wild pollinators, damage to agricultural soils, and harm to non-target wildlife including ESA-protected species, to the severe detriment of U.S. agriculture and contrary to EPA's duty to regulate pesticides to protect the public and the environment.

II. EPA's Exemption of Coated Seeds Is Unlawful.

EPA does not have the authority to continue its wholesale exemption of coated seeds from FIFRA's requirements, because FIFRA does not authorize exemptions of pesticides that require regulation, especially not those pesticides that cause unreasonable adverse effects to the environment. Accordingly, EPA's current interpretation of the Treated Article Exemption and

[80] *See* EU and U.S. National Wildlife Refuge System measures cited in n.33 and n.36, *supra*.

practice of exempting coated seeds from registration and labeling is *ultra vires.* 5 U.S.C. § 706(2)(C).

EPA's exemption of coated seeds is also arbitrary and capricious under the APA. *Id.* § 706(2)(A). First, EPA's actions are arbitrary and capricious because they are counter to the available evidence that coated seeds cause significant adverse effects on the environment. *Motor Vehicle Manufacturers Assoc. v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29 (1983). Second, EPA's interpretation of the Treated Article Exemption as to coated seeds is inconsistent with its other interpretations in comparable situations where the agency found a treated article not to be exempted due to adverse pesticidal effects beyond the article itself, including its non-exemption of anti-fouling boat paint and other articles.[81]

Finally, EPA's exemption of these coated seeds violates its duty under ESA to ensure that its actions do not jeopardize the continued existence of any protected species. 16 U.S.C. § 1536(a). As shown above, among the impacts from these pesticidal seeds are harms to threatened and endangered species, including invertebrates and birds. Despite the fact that the pesticidal seeds unregulated by EPA "may affect" many protected species either directly or indirectly, EPA has never consulted with the expert Services to determine whether its exemption of coated seeds is likely to jeopardize these species. Moreover, this assessment is missing from EPA's registration of the liquid coating products and active ingredients. As noted above, even if EPA were to consult under the ESA on these products, to date the agency has ignored the full effects of the use of the coated seeds in the field due to its exemption.

Because EPA's ongoing exemption of coated seeds violates FIFRA and the APA and poses adverse effects to a large number of threatened and endangered species protected under the

[81] *See* sample boat hull paint label for *Pro-Line 1080 H Hard Vinyl Anti-Fouling Paint*, EPA registration number 577-549, *at* https://www3.epa.gov/pesticides/chem_search/ppls/000577-00549-20031002.pdf.

ESA, EPA must take the requested actions.

CONCLUSION

For the reasons stated herein Petitioners request that EPA either amend or formally re-interpret the Treated Article Exemption, 40 C.F.R. §152.25(a), to clearly communicate to the regulated community that systemic pesticidal seeds intended to kill pests of the plants are not included under the Treated Article Exemption and are therefore subject to FIFRA's requirements for registration and labeling. Petitioners also request EPA to aggressively enforce FIFRA's registration and labeling requirements for each separate seed product coated in systemic insecticides, in order to properly discharge its duty to protect the public and environment.

DATED this 26th day of April, 2017.

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APPENDIX

PETITIONERS' INTERESTS

The eleven Petitioners are nationally-representative beekeepers, farmers, and public interest organizations harmed by EPA's actions and inactions described, *supra*.

Beekeeper Petitioners

Petitioner **Bret Adee** is a resident of Bruce, South Dakota. He is a third-generation commercial beekeeper and a co-owner of Adee Honey Farms. Founded in 1957, Adee Honey Farms is the nation's largest beekeeping operation. It manages some 90,000 honey bee colonies and has about fifty full-time employees. Its operations have been harmed over several years by the neonicotinoid seed coatings. The colonies, in many cases, cannot be placed so that the free-ranging bees will be able to avoid contaminated crops, dust, soil, marginal vegetation, and water that results from the seed coatings, which are overused. Adee Honey Farms has experienced abnormally high incidences of hive failure in recent years. Prior to 2005, they would expect to lose between three to eight percent of their colonies over the winter. Now, they consider it a good year if they lose only twenty percent. In 2012, for example, they lost forty-two percent of their hives over winter, but by the time they came around to pollinate almonds in the early spring, their losses were at fifty-five percent. For the summer of 2015, the Adees had a massive exposure to clothianidin dust-off that resulted in an estimated 10,000 severely weakened honey bee colonies. The results to the company include lost income, increased expenses and work overload, and emotional distress from seeing their animals killed or weakened. Mr. Adee and his family fear for the future of their business—and commercial beekeeping in general—if the current overuse of neonicotinoids and other pesticides continues. Mr. Adee is the President of the Pollinator Stewardship Council and co-Chair of the National Honey Bee Advisory Board. He also is a member of the American Honey Producers Association, the South Dakota Beekeepers Association, and the California State Beekeepers Association.

Petitioner **American Beekeeping Federation** (ABF) is a 501(c)(5) organization founded in 1943, headquartered in Atlanta, Georgia. ABF is dedicated to advancing the interests of all beekeepers, large or small, and other interests associated with the industry to ensure the future of the honey bee. ABF currently has approximately 1,500 members, making it the largest beekeeping organization in the United States. Approximately twenty-five percent of the commercial beekeepers in the United States are members of ABF. ABF members harvest roughly thirty percent of the honey produced in the United States each year, a lot of that from smaller producers.

Petitioner **American Honey Producers Association** (AHPA) is a non-profit agricultural association incorporated in Oklahoma in 1969. The organization is dedicated to promoting the common interest and general welfare of the American honey producer. AHPA currently has about 400 members who make their living from the production of honey. Collectively, AHPA members produce as much as fifty percent of the United States' honey.

Petitioner **Jeff Anderson** has been the owner of California Minnesota Honey Farms for nineteen years. It is a migratory beekeeping operation based in Eagle Bend, Minnesota; and Oakdale, California. In addition to Mr. Anderson, the business employs one full-time employee, as well as three seasonal employees. He has been a commercial beekeeper since 1976. Mr. Anderson is a member of the Minnesota Honey Producers Association, the California State Beekeepers Association, the American Honey Producers Association, the National Honey Bee Advisory Board, and the Pollinator Stewardship Council. Since about 2004-05, his percentage of hives lost each year has increased dramatically. In 2012, for example, he had 3,150 hives in April, but by February 2013, he was down to just 998 hives, meaning he lost almost 70% of hives that year. Not only is Mr. Anderson losing hives at rates that are unprecedented, but remaining hives are far less robust. It is plain from recent years that he is getting significant *summer* mortality—a time when bee populations should be healthy due to warm weather, long days, and food abundance—from the dominant Minnesota crops: corn and soybeans. It is virtually impossible for honey bees to avoid these crops in central Minnesota; nearly all of them are seed-treated with a combination of two neonicotinoid pesticides, clothianidin and thiamethoxam. There are other consequences of this hive health pattern which adversely affect his business and livelihood. First, sick or poorly-populated hives cannot produce much honey. This is apparent when observing his annual honey production records. Prior to 2005, he would expect to harvest an average eighty pounds of honey per live hive annually. In recent seasons, Mr. Anderson's hives have averaged only about forty pounds of honey. His income has drastically suffered as a result and his expenses to keep his remaining hives alive have dramatically increased. The workload and personal stress are intense. His experience and observations are that the exempted neonicotinoid seed coatings, toxic dust, and other contamination from them have played a major role. Test results for some incidents confirm this.

Petitioner **David Hackenberg** is a commercial beekeeper residing in Lewisburg, Pennsylvania. He has been keeping bees for fifty-four years, through his family business Hackenberg Apiaries. His experience includes serving twelve years on the National Honey Board, has served as President of the American Beekeeping Federation, and as Chair and co-Chair of the National Honey Bee Advisory Board. The ongoing effects of excessive overwintering mortality and other excess losses of honey bees have damaged his operation. In 2006, he saw huge losses and was the first beekeeper known to suffer what was described by scientists as Colony Collapse Disorder. These disappearances coincided with the exempted neonicotinoid pesticidal seeds coming on the market in large numbers. This damage at least partly resulted from the use of neonicotinoid seed coatings in row crops nationwide. This is compounded by the lack of labels on the seed bags adequate to inform the crop farmers how to avoid harm to bees, and the lack of any enforcement when bees are harmed by these seed coating. Mr. Hackenberg has about 2,000 hives now. His annual losses have run seventy-five to eighty percent or with continual protein feeding, they can be held closer to sixty percent losses, but both these levels are excessive. The economic damage to his business, increased expenses and work demand, and personal stress from seeing huge numbers of his bees die have all directly harmed him. His experience and direct observations are that the seed coatings, dust, and other contamination from them have played a major role.

Petitioner **Pollinator Stewardship Council (PSC)** is a nonprofit organization incorporated in Kansas in 2012. The mission of PSC is to defend managed and native pollinators

vital to a sustainable and affordable food supply from the adverse impacts of pesticides. As pollination is required for one-third of the nation's food supply, PSC accomplishes it mission by: (1) ensuring that state agencies and EPA enforce laws to protect pollinators from pesticides; (2) providing advocacy, guidance, and tools for beekeepers to defend their bees from the detrimental effects of pesticides; and (3) raising awareness about the adverse impacts of pesticides on pollinators. PSC has previously stated its position in opposition to the "treated article" exemption being applied to neonicotinoid-coated seeds because it leads to excessive and unnecessary use of these insecticides. Beekeepers that PSC represents typically cannot escape many harmful effects of this overuse, nor will EPA or the state agencies enforce against misapplication of the exempted seed coatings, even when major bee kills result. Additionally, the losses inflicted on native pollinators, which lack any management, in many cases may be more severe than the damage to managed pollinators. On the whole, the damages resulting from the exemption EPA has given to the pesticidal coated seeds are unacceptable to PSC.

Farmer Petitioners

Petitioner **Lucas Criswell** resides near Lewisburg, in central Pennsylvania. He farms about 1,800 acres total of mostly corn, soybeans, and small grains. He has been doing this for twenty years, and is familiar with the seed choices for these crops and the effects of using different seeds as well as the effects of neonicotinoid coatings. He is very concerned about the non-availability of uncoated corn seeds of the high-quality hybrid varieties. He also is concerned because he has seen that the exempted neonicotinoid-coated seeds are used as a form of "insurance," when in most situations farmers do not need coated seeds. As a result of their overuse, he has observed harm to beneficial insects and the overall health of the soil. In the case of soybeans, Mr. Criswell planted coated seeds for several years and then quit. Unlike corn, there are many good uncoated soybean varieties available from seed dealers. When he switched, he saw no decrease in overall average yields or profitability from his soybean acreage. He switched because it was clear that the coated seeds he used in the past were causing an increase in slugs in the fields, a harmful and hard-to-control crop pest. There were slug outbreaks because the neonicotinoid killed beetles that kept the slugs under control. Mr. Criswell also quit because he was concerned the unnecessary overuse of the chemicals violated Integrated Pest Management, an important principle for his farming. He switched away from neonicotinoid-coated corn seeds more recently, but it is challenging due to their near complete domination of the available corn seed market. Mr. Criswell is concerned that too many farmers, including him at times, have been using them unnecessarily and paying unnecessary costs for the pesticidal coating. He is concerned that the overall effect harms the soil and farmers themselves in the long run.

Petitioner **Gail Fuller** is a farmer residing near Emporia, Kansas. He farms about 1,000 acres of mixed grains, including sorghum, corn, barley, soybeans, and wheat. He regularly used neonicotinoid-coated seeds in the past on some of his crops. He has switched to non-coated seeds for all the crops where it was feasible based on seed availability. Mr. Fuller is an active proponent for soil health and he has noticed that the neonicotinoids can damage soil health and beneficial insects. He is concerned that he used these chemicals unnecessarily as that is not consistent with good soil health or good farming. He is concerned about how the exempted neonicotinoids appear to put monarch butterflies, honey bees, and other beneficial insects at risk.

Since cutting back on coated seeds, he has observed more biologically diverse and sustainable ecosystems on and around his farmland, without reducing his typical yields.

Public Interest Organization Petitioners

Petitioner **American Bird Conservancy (ABC)** is a national, nonprofit membership organization, headquartered in The Plains, Virginia, dedicated to conserving native birds and their habitat throughout the Americas. With more than 10,000 members nationwide, ABC works to innovate and build on sound science to halt extinctions, protect habitats, eliminate threats, and build capacity for bird conservation. ABC has had a long-standing program to address the significant threat that pesticides pose to birds. It works to cancel or restrict the registrations of the most dangerous products, to improve the evaluation and monitoring of pesticides and their effects on birds, to spearhead scientific research, and to engage the public in protecting birds and other wildlife. The 2013 ABC report, *The Impact of the Nation's Most Widely Used Insecticides on Birds*, concluded that neonicotinoid-coated seeds are lethal to birds and to the aquatic biological diversity upon which they depend. The nation's birds, and ABC's members, are directly and indirectly harmed by the neonicotinoid seed coating chemicals that are blanketing croplands, contaminating watersheds, and poisoning birds, bees, butterflies, and other organisms. ABC has advocated for more than three years to EPA and other federal agencies to curb the overuse of coated seeds. ABC also has urged the Agency to eliminate the coated seeds' exemption from registration as pesticides under FIFRA.

Petitioner **Center for Food Safety (CFS)** is a Washington, D.C.-based, public interest, nonprofit membership organization with offices in San Francisco, CA; Portland, OR; Honolulu, HI; and Washington, D.C. CFS's mission is to empower people, support farmers and protect the earth from the harmful impacts of industrial agriculture. Through legal, scientific, and grassroots action, CFS protects and promotes the public's right to safe food and the environment. CFS has more than 830,000 consumer and farmer supporters across the country. It seeks to protect human health and the environment by advocating for thorough, science-based safety testing of new agricultural products prior to any marketing and cultivation of crops in a manner that minimizes negative impacts such as increased use of pesticides and evolution of resistant pests and weeds. A foundational part of CFS's mission is to further the public's and its members' fundamental right to know what is in their food and food production methods and technologies.

Petitioner **Pesticide Action Network of North America (PANNA)** is an Oakland, California-based, nonprofit corporation that serves as an independent regional center of Pesticide Action Network International, a coalition of public interest organizations in more than ninety countries. For nearly thirty years, PANNA has worked to replace the use of hazardous pesticides with healthier, ecologically sound pest management across the United States and around the world. PANNA provides scientific expertise, public education and access to pesticide data and analysis, and policy development and coalition support to more than 100 affiliated organizations in North America. PANNA has more than 125,000 members across the United States. PANNA's members live, work, farm, and recreate in areas of the country where pesticides such as the neonicotinoid insecticides are applied, and in which the pesticides and contaminated dust drift and transport occurs, and thus have a strong interest in ensuring that EPA protect public health and the environment from this contamination. PANNA's members are highly concerned by the

effects of the unregulated neonicotinoid-coated seeds on honey bees, bumble bees, butterflies, beneficial invertebrates, wild pollinators, water, aquatic invertebrates, food chains, ecosystem sustainability generally, and ultimately on humans via food and water consumption. The lack of enforceable labeling on these pesticidal seeds, and their prophylactic overuse, violate bedrock principles PANNA seeks to protect as far as only using pesticides as a last resort, and then only when they have strong and clear warnings and enforceable use directions. PANNA has urged EPA to eliminate the coated seeds' exemption from registration as pesticides. PANNA has also urged EPA (as well as the United States Department of Agriculture and Department of Justice) to address issues around the lack of fairness, transparency, and farmer choice in the seed marketplace.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Mitchell Yergert, Director
Division of Plant Industry
Colorado Department of Agriculture
305 Interlocken Parkway
Broomfield, Colorado 80021

MAY 19 2015

Subject: Special Local Needs Registration for pesticide uses for legal marijuana production in Colorado

Dear Mr. Yergert:

Thank you for your inquiry regarding the utilization of Special Local Need (SLN) registrations of pesticides under FIFRA section 24(c) for use on cannabis. As you are aware, EPA's regulations, 40 CFR 162.152(a)(4), state that any SLN registration must be in accord with the purposes of FIFRA, which authorizes the registration of a pesticide only on a finding that it will not lead to "unreasonable adverse effects on the environment." In order to facilitate this finding, EPA strongly encourages a State to pursue SLN authorizations only where a federally registered pesticide is approved for use(s) similar to the manner in which the SLN pesticide would be used. EPA expects that a showing of such similarity would provide the best support for making the necessary determinations. Given our understanding of how cannabis is cultivated and the intended way cannabis plant materials may be consumed by humans, we anticipate that a federally registered pesticide would be regarded as having similar use patterns if the federally registered pesticide is approved for use:

1. on food (in order to have a complete toxicity database to evaluate the potential toxicity of acute, short-term, intermediate, and chronic exposure);
2. on tobacco (in order to have a pyrolysis study to determine the breakdown products formed when the treated plant material is burned);
3. by the same type(s) of application methods (in order to assess the exposure of workers who mix, load, and apply the pesticides);
4. on crops with agronomic characteristics similar to cannabis (in order to adequately protect workers reentering areas following application of the pesticide); and
5. in the same kind of structure (e.g., greenhouses/shadehouses) or on the same kind of site (e.g., outdoor dryland site) as the proposed SLN use (in order to ensure that workers handling the pesticide are adequately protected when applying the pesticide – for example, ensuring that the adequate personal protective equipment is required – and that the environmental fate and effects of the SLN use are adequately understood and that any appropriate measures are in place to protect non-target organisms and water resources).

In addition, EPA encourages the State to consider pesticides for which the agency's aggregate and cumulative risk assessment indicate that some modest additional exposure would not approach a risk of concern, i.e., that there is "room in the human health risk cup."

If the State decides to pursue a SLN registration for use of a pesticide on cannabis, it could meet its responsibility for showing that a proposed SLN registration would be appropriate by identifying a federally registered pesticide with similar use(s) and relying on the agency's most recent risk assessments showing that the pesticide meets the no "unreasonable adverse effects on the environment" standard. In addition, please be certain that any submission contains the information described in 40 CFR part 162 and characterized at the following website: http://www.epa.gov/opprd001/24c/. Like other SLN registrations, the State would need to submit a full label that describes the use pattern and associated mitigation for protecting human health and the environment.

EPA agrees with the State's assessment that pesticides considered for an SLN use on cannabis should have an appropriate dataset for use in assessing the potential for use of the pesticide and for residues on treated plant material to cause human health and environmental risks. In the event that the State cannot identify a federally registered pesticide with use(s) similar to the proposed SLN use, EPA would expect the requesting State to take responsibility for providing information and analysis to support the SLN registration for cannabis. To aid the State in preparing these assessments, an overview of the human and ecological risk assessment methodologies used by the Office of Pesticide Programs (OPP) is presented in the attachment. OPP is available to provide further guidance or answer any questions as to how to ensure the safety of a use under an SLN on cannabis.

Sincerely,

Jack E. Housenger, Director
Office of Pesticide Programs

Attachment

cc: Mr. John Scott, Pesticides Section Chief, Colorado Department of Agriculture
Ms. Laura Quakenbush, Pesticide Registration Coordinator, Colorado Department of Agriculture
Mr. Eric Johansen, Washington State Department of Agriculture
Ms. Melanie Wood, Division Director, Pesticides Program, EPA Region 8
Ms. Jennifer Schuller, Pesticides Team Leader, EPA Region 8
Ms. Rebecca Perrin, Agriculture Advisor, EPA Region 8
Mr. Ed Kowalski, Division Director, Pesticides Program, EPA Region 10
Ms. Kelly McFadden, Section Chief, Pesticides Program, EPA Region 10

ATTACHMENT

The following sections describe how EPA assesses the risks to human health and the environment resulting from use of pesticides.

I. HUMAN HEALTH ASSESSMENT

OPP evaluates pesticide chemicals prior to registration, and reevaluates older pesticides already on the market, to ensure that they can be used without causing unreasonable adverse effects on the environment. OPP employs the National Research Council's four-step process for human health risk assessment: hazard assessment; exposure assessment; risk characterization; and risk assessment. Details are available at http://www.epa.gov/pesticides/factsheets/riskassess.htm

1. Hazard Assessment

In evaluating toxicity or hazard, OPP reviews toxicity data, typically from studies with laboratory animals, to identify any adverse effects on the test animals. Where available and appropriate, OPP will also take into account studies involving humans, including human epidemiological studies. An extensive battery of toxicological studies are required for full pesticide registration. Toxicology data requirements are described in 40 CFR §158 subpart F http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm. Toxicology data requirements for a food-use chemical are presented in Table 1.

Once a pesticide's potential hazards are identified, OPP determines a toxicological endpoint of concern for evaluating the risk posed by human exposure to the pesticide. Two critical parts of this evaluation involve identification of a quantitative dose level(s) from these studies to be used in assessing the pesticide's safety to humans, referred to as the Point of Departure (POD), and selection of appropriate uncertainty/safety factors for translating the results of toxicity studies in relatively small groups of animals or humans to the overall human population, including major identifiable subgroups of consumers.

A POD is the dose serving as the 'starting point' in extrapolating a risk to the human population. The POD can be a no observed adverse effect level (NOAEL), the lowest-observed adverse effect level (LOAEL) or an extrapolated benchmark dose (BMD). For details refer to http://www.epa.gov/raf/publications/pdfs/rfd-final.pdf.

For threshold effects, risk assessments are normally conducted using the Reference Dose (RfD) approach. The RfD is calculated by dividing the POD by the appropriate uncertainty/safety factors. OPP's safety/uncertainty factor practice with regard to pesticides was altered to a degree by the Food Quality Protection Act (FQPA). FQPA requires EPA to use an additional safety factor of 10X to protect infants and children, unless EPA determines, based on reliable data, that use of another safety factor would protect infants and children. For pesticides, a Population Adjusted Dose (PAD) is derived by dividing the RfD by the FQPA Safety Factor. For complete details, refer to http://www.epa.gov/pesticides/trac/science/determ.pdf. An example of the toxicity endpoint selection is presented in Table 2.

For compounds causing non-threshold effects, such as carcinogens, an RfD approach is not used. Instead, a cancer risk assessment is conducted which provides an estimate (expressed as a probability) of the excess cancer risk resulting from exposure to a pesticide chemical. http://www.epa.gov/raf/publications/pdfs/

As an unreasonable adverse effects finding is developed for any prospective SLN, EPA encourages you to use the assessment endpoints that have been identified by EPA for that chemical.

2. Dietary Exposure Assessment

Acute, chronic, and cancer dietary exposure and risk assessments are conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID). This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). The Agency is in the process of transitioning from the 2003-2008 NHANES/WWEIA consumption data to the 2005-2010 NHANES/WWEIA consumption data. The DEEM model that incorporates the 2005-2010 consumption data can be downloaded from http://www.epa.gov/pesticides/science/deem/

Generally, it would not be expected that the requesting State would have the residue and consumption data needed to perform a quantitative assessment of oral exposure for a SLN on cannabis. In the absence of such data, however, the State could estimate potential dietary exposure by making reasonable assumptions about high end consumption and residue levels. In addition, the State's risk assessment should address, at least qualitatively, why the additional exposure from the use of SLN on cannabis would not result in exposure exceeding the remaining room in the "human health risk cup." We expect that such an assessment will be more straight-forward if the active ingredient being proposed for the SLN registration has ample room in the risk cup for the new use.

3. Occupational and Residential Exposure Assessment

Occupational and residential exposure data requirements are described in 40 CFR part 158 subpart H available at http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series875.htm

In general, the data needed for a human health risk assessment for an agricultural crop, outdoor residential use, and a greenhouse use are similar; however, the exposure scenarios assessed may differ. A typical exposure assessment is divided into two parts. The handler assessment addresses potential exposure from the individuals who mix, load, and apply a pesticide, and the post-application assessment addresses the potential exposure of individuals who enter into previously treated areas and engage in activities that bring them into contact with pesticide residues. An overview of the residential human health risk assessment methodology and corresponding data for the various residential handler and post-application scenarios can be found at http://www.epa.gov/pesticides/science/residential-exposure-sop.html.

Occupational handler scenarios are assessed for the dermal and inhalation exposure pathways. (http://www.epa.gov/pesticides/science/handler-exposure-data.html) OPP uses non-chemical specific unit exposures and information from the labels about application type, site, formulation, rates, and personal protective equipment (PPE) to define each scenario. The resulting risk estimates from the handler assessment inform the risk management decisions on whether additional PPE requirements or other mitigation measures are necessary. PPE requirements on the label also fall under the Worker Protection Standard (WPS) related to the acute toxicity of the end-use product.

The occupational post-application scenarios are assessed for the dermal exposure pathway. OPP uses non-chemical specific transfer coefficients to capture the potential dermal exposure from different crop and activity combinations (http://www.epa.gov/opp00001/science/post-app-exposure-data.html).

OPP also uses chemical-specific data to inform the potential pesticide residue that is available on a foliar surface after an application; these data are referred to as dislodgeable foliar residue (DFR) and turf transferable residue (TTR) studies. When these data are not available, OPP currently uses default assumptions of 25% for DFR and 1% and 0.2% for TTR for the liquid and granular formulations, respectively. The post-application risk estimates determine how many days after treatment an individual may safely reenter the treated area for routine post-application activities. The more protective Restricted Entry Interval value is typically required on the labels. In addition, specifically for greenhouse uses, the WPS provides information on proper ventilation requirements to protect workers from post-application inhalation exposure.

If the pesticide proposed for a SLN use has no federally registered indoor uses, the State should specifically address whether handlers applying the pesticide indoors or others who would contact the pesticide treated plants would be adequately protected without additional PPE, and if not, what additional PPE would be needed to prevent unacceptable exposures from the anticipated application and post-application scenarios.

4. Risk Characterization and Risk Assessment

(i) Dietary Exposure Risk Assessment

The State's risk assessment should provide a general characterization of risk for the general population and should take into account both potential acute and chronic exposures.

(ii) Occupational Exposure Risk Assessment

- Occupational Handlers

In this section, the State's risk assessment should identify the occupational handler exposure scenarios based on the proposed use (list representative scenarios only). Briefly describe the data sources used such as an existing EPA risk assessment or, if a new assessment is being conducted, PHED, biomonitoring studies, or chemical specific data. Summarize the risks assessed. If there are no risks at baseline PPE, simply state the lowest Margin of Exposures (MOEs). If there are scenarios with risks of concern at baseline and additional personal protective equipment (PPE) will be needed to

achieve MOEs greater than the level of concern (LOC), summarize the MOEs at different PPE levels. The summary can be in tabular or paragraph form. As noted earlier, we encourage the State to use existing risk assessments to prepare this information.

- Occupational Post-Application

In this section, identify the occupational post application exposure scenarios based on the proposed use in a general manner. Briefly describe the data sources used such as an existing EPA risk assessment or, if a new assessment is being conducted, biomonitoring studies or chemical-specific data. Indicate whether or not dislodgeable foliar residue (DFR) studies are available. Indicate whether or not the most recent transfer coefficients were used to determine post-application exposure and risk. Summarize the scenarios with risks of concern, and provide a summary of the MOEs. Data can be in tabular or text form.

- Inhalation Exposure Assessment

It is OPP's policy to assess risk following short-term exposure to pesticide residues in tobacco products as the chronic health effects from tobacco use are well documented. OPP uses data from a pyrolysis study (Test Guideline 860.1000) and a magnitude of residue study (Test Guideline 860.1500) for this assessment. This assessment assumes: (1) 100% of the inhaled residue is absorbed; (2) the average U.S. smoker smokes 15 cigarettes per day (Pierce, J. P., *et al.* (1989), Tobacco use in 1986 – Methods and Basic Tabulations from Adult Use of Tobacco Survey, U.S. Dept. of Health and Human Services Publication Number OM90-2004, Office on Smoking and Health, Rockville, Maryland); (3) 1 gram of tobacco per cigarette; and (4) male/female body weight of 70/60 Kg. The POD established for short-term exposure is used to derive a MOE for expressing risk via this exposure scenario. If there is no federally registered tobacco use of the proposed SLN pesticide, the State's risk assessment should assess the potential acute risk from inhaling residues from smoking treated plant material; the assessment should use the above assumptions or justify the use of different assumptions.

II. ECOLOGICAL EFFECTS AND ENVIRONMENTAL FATE

In general, the types of data used to support an ecological risk assessment for a SLN pesticide registration should be comparable to the ecological effects and environmental fate data required for a Section 3 pesticide registration (see 40 CFR part158, subpart G and subpart N). Note the data requirements for outdoor terrestrial uses and greenhouse/indoor uses are substantially different in regards to the number and types of studies required for registration. Outdoor terrestrial uses are also subject to the data requirements for pollinators (see Guidance for Assessing Pesticide Risks to Bees). Tables 3 and 4 provide an overview of the data requirements for ecological effects and environmental fate respectively. An overview of the ecological risk assessment framework and supporting documentation can be found at: http://www.epa.gov/oppefed1/ecorisk_ders/.

The ecological risk assessment should consist of a problem formulation, an analysis characterizing the exposure and effects of the chemical stressor and a risk characterization.

1. Problem Formulation

Problem formulation provides the foundation for the ecological risk assessment. It is an iterative process for generating hypotheses concerning whether ecological effects could occur from human activities. The problem formulation articulates the purpose and objectives of the risk assessment and defines the problem and regulatory action. The quality of the assessment depends on rigorous development of the following products of problem formulation: 1) assessment endpoints that reflect management goals and the ecosystem they represent; 2) conceptual model(s) that represents predicted key relationships between stressor(s) and assessment endpoint(s); and 3) a plan for analyzing the risk.

2. Analysis of Exposure and Effects

For a pesticide risk assessment, the exposure characterization describes the potential or actual contact of a pesticide with a plant, animal, or media. The objective is to describe exposure in terms of intensity, space, and time and to describe the exposure pathway(s). A complete picture of how, when, and where exposure occurs or has occurred is developed by evaluating sources and releases of the pesticide, distribution of the pesticide in the environment, and extent and pattern of contact with the pesticide.

For greenhouse/indoor uses there are several factors the State will need to consider. First there is a difference between a greenhouse and a shadehouse. A greenhouse is defined as "operations that produce agricultural plants indoors in an area that is enclosed with nonporous covering and that is large enough to allow a person to enter." Shadehouses are defined as "a roof made of fencing or fabric to provide shade on plants (no walls)." Growing operations in a shadehouses are typically considered an outdoor terrestrial use.

The other factor to consider in the risk assessment for greenhouse/indoor use is the potential for "Down the Drain" release to publically owned treatment works or in some cases direct discharge to the environment. The "Down the Drain" assessment accounts for the normal use of a pesticide in a greenhouse, not the illegal disposal of a pesticide.

An ecological effects characterization describes how toxic a pesticide is to different organisms and/or to other ecological entities (e.g., community), what effects it produces, how the effects relate to the assessment endpoints, and how these effects change with varying levels of pesticide exposure. This characterization is based on a stressor-response profile that describes how toxic a pesticide is to various plants and animals, the cause-and-effect relationships, how fast the organism(s) recovers, relationships between the assessment endpoints and measures of effect, and the uncertainties and assumptions associated with the analysis. The stressor-response profile is the final product of the ecological effects characterization.

3. Risk Characterization

The risk characterization integrates the analyses from the exposure characterization and ecological effects characterization; describes the uncertainties, assumptions, and strengths and limitations of the analyses; and synthesizes the overall conclusion about risk that is used by risk managers in making risk management decisions.

Risk characterization has two major components: risk estimation and risk description. Risk estimation compares exposure and effects data, considers integrated exposure and effects data in context of Levels of Concern (LOCs), and states the potential for risk. The risk description interprets risks based on assessment endpoints. In interpreting the risk, the risk assessor evaluates the lines of evidence supporting or refuting risk estimates in terms of the following factors: adequacy and quality of data; degree and type of uncertainty; and the relationship of evidence to risk assessment questions.

As noted above for the human health risk assessment, EPA encourages the State to consider and use EPA's existing ecological risk assessments. where appropriate, to assess the environmental fate and ecological effects of any proposed SLN on cannabis.

Table 1. Toxicology Data Requirements

The requirements (40 CFR 158.340) for a typical food-use chemical are listed below:

Study Type		Requirement
870.1100	Acute Oral Toxicity	yes
870.1200	Acute Dermal Toxicity	yes
870.1300	Acute Inhalation Toxicity	yes
870.2400	Primary Eye Irritation	yes
870.2500	Primary Dermal Irritation	yes
870.2600	Dermal Sensitization	yes
870.3100	Oral Subchronic (rodent)	yes
870.3150	Oral Subchronic (nonrodent)	yes
870.3200	21-Day Dermal	yes
870.3250	90-Day Dermal	No
870.3465	90-Day Inhalation	**CR**
870.3700a	Developmental Toxicity (rodent)	yes
870.3700b	Developmental Toxicity (nonrodent)	yes
870.3800	Reproduction toxicity	yes
870.4100a	Chronic Toxicity (rodent)	yes
870.4100b	Chronic Toxicity (nonrodent)	yes
870.4200a	Carcinogenicity (rat)	yes
870.4200b	Carcinogenicity (mouse)	yes
870.4300	Combined chronic toxicity/carcinogenicity	yes
870.5100	Mutagenicity—Gene Mutation - bacterial	yes
870.5300	Mutagenicity—Gene Mutation - mammalian	yes
870.5xxx	Mutagenicity—Structural Chromosomal Aberrations	yes
870.5xxx	Mutagenicity—Other Genotoxic Effects	yes
870.6100a	Acute Delayed Neurotoxicity (hen)	no
870.6100b	90-Day Neurotoxicity (hen)	no
870.6200a	Acute Neurotoxicity Screening Battery (rat)	yes
870.6200b	90-Day Neurotoxicity Screening Battery (rat)	yes
870.6300	Develop. Neurotoxicity	**CR**
870.7485	General Metabolism	yes
870.7600	Dermal Penetration	yes
870.7800	Immunotoxicity	yes

CR= Conditionally Required. See footnotes in Part 158 Table.

Table 2. Summary of Points of Departure and Toxicity Endpoints Used in Human Risk Assessment

Summary of Toxicological Doses and Endpoints for [Chemical] for Use in Dietary and Non-Occupational Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty/FQPA Safety Factors**	**RfD, PAD, Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Acute Dietary (General Population, including Infants and Children)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Acute RfD = [ ] mg/kg/day aPAD =[ ] mg/kg/day	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Acute Dietary (Females 13-49 years of age)	NOAEL = [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Acute RfD = [ ] mg/kg/day	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Chronic Dietary (All Populations)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Chronic RfD = [ ] mg/kg/day cPAD = [ ] mg/kg/day	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Incidental Oral Short-Term (1-30 days)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Incidental Oral Intermediate-Term (1-6 months)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Dermal Short-Term (1-30 days)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Dermal Intermediate-Term (1-6 months)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Inhalation Short-Term (1-30 days)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Inhalation Intermediate-Term (1-6 months)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]

Summary of Toxicological Doses and Endpoints for [Chemical] for Use in Dietary and Non-Occupational Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty/FQPA Safety Factors**	**RfD, PAD, Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Cancer (oral, dermal, inhalation)	Classification: This should be consistent with section 4.5.3 and the CARC document.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key data (i.e., lack of a critical study). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

Summary of Toxicological Doses and Endpoints for [*Chemical*] for Use in Occupational Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty Factors**	**Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Dermal Short-Term (1-30 days)	NOAEL= [ ] mg/kg/day	UF_A=10x UF_H=10x	Occupational LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Dermal Intermediate-Term (1-6 months)	NOAEL= [ ] mg/kg/day	UF_A=10x UF_H=10x	Occupational LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Inhalation Short-Term (1-30 days)	NOAEL= [ ] mg/kg/day	UF_A=10x UF_H=10x	Occupational LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Inhalation Intermediate-term (1-6 months)	NOAEL= [ ] mg/kg/day	UF_A=10x UF_H=10x	Occupational LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Cancer (oral, dermal, inhalation)	Classification: This should be consistent with section 4.5.3 and the CARC document.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key data (i.e., lack of a critical study). MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

Table 3. Ecotoxicology Studies[1]

Guideline	Study Type	Comments
850.2100	Avian acute oral	Data required for a passerine species and either a waterfowl or upland game species
850.2200	Avian sub-acute dietary	Data required for a waterfowl and upland game species
850.2300	Avian reproduction study	Data required for a waterfowl and upland game species
850.1075	Acute freshwater fish	Data required for a cold water species and a warm water species
850.1075	Acute estuarine/marine fish	
850.1010	Acute freshwater invertebrates	
850.1025 850.1035 850.1045 850.1055	Acute toxicity to estuarine/marine invertebrates	Data required for one mollusk and one invertebrate
850.1300	Chronic freshwater invertebrate	
850.1350	Chronic estuarine/marine invertebrate	Conditionally required depending on exposure and toxicity (see CFR 158 for more details)
850.1400 or 850.1500	Chronic freshwater fish	
850.1400 or 850.1500	Chronic estuarine/marine fish	Conditionally required depending on exposure and toxicity (see CFR 158 for more details)
850.1735	Acute sediment toxicity to freshwater benthic organisms	Conditionally required depending on the physical properties of the chemical and toxicity to non-benthic organisms (see CFR 158 for more details)
850.1740	Acute sediment toxicity to estuarine/marine benthic organisms	Conditionally required if chemical is applied directly to estuarine/marine water bodies or expected to enter them in significant amounts. Also depends depending on the physical properties of the chemical and toxicity to non-benthic organisms (see CFR 158 for more details)
Non-guideline	Chronic sediment toxicity	Conditionally required depending on the physical properties of the chemical and toxicity to non-benthic organisms (see CFR 158 for more details)
850.3020	Acute contact toxicity to honeybee	
OECD 213	Acute oral toxicity to adult honeybee	Pollinator Guidance Document requirement (not in CFR 158)
Non-guideline	Subchronic 10-day toxicity to adult honeybees	Pollinator Guidance Document requirement (not in CFR 158)

[1] With the exception of non-guideline data requirements, the studies listed in this table were compiled from tables in the CFR "Terrestrial and aquatic nontarget organisms data requirements table" in 40 CFR §158.630 and "Nontarget plant protection data requirements table" in 40 CFR §158.660. Please see the CFR for the full tables, all applicable footnotes, and several additional studies which are not typically required but may be required in specific instances.

Guideline	Study Type	Comments
Non-guideline	Acute and chronic larval honeybee toxicity	Pollinator Guidance Document requirement (not in CFR 158)
Non-guideline	Pesticide residues in pollen and nectar	Conditionally required if honeybee concerns are identified from the laboratory tests. Pollinator Guidance Document requirement (not in CFR 158)
850.3040	Field testing for pollinators	Conditionally required if honeybee concerns are identified from the laboratory tests.
850.4100	Seedling emergence	
850.4150	Vegetative vigor	
850.4400	Vascular aquatic plant testing	
850.4500	Non-vascular aquatic plant testing	Testing is required for one freshwater algal species, freshwater diatom, and estuarine/marine diatom
850.4550	Cyanobacteria toxicity	
870.1100	Acute mammalian oral toxicity	
870.3800	Two-generation rat reproduction study	

Table 4. Environmental Fate Studies[2]

Guideline	Study Type	Comments
835.2120	Hydrolysis	
835.2240	Photodegradation in water	
835.2410	Photodegradation in soil	
835.2370	Photodegradation in air	Conditionally required for terrestrial and greenhouse use patterns depending on Henry's law constant and other chemical factors. (See CFR 158 for more details.)
835.4100	Aerobic soil metabolism	
835.4200	Anaerobic soil metabolism	
835.4300	Aerobic aquatic metabolism	
835.4400	Anaerobic aquatic metabolism	
835.1230 835.1240	Leaching and adsorption / desorption	
835.1410	Volatility – laboratory	Conditionally required. (See CFR 158 for more details.)
835.8100	Volatility - field	Conditionally required. (See CFR 158 for more details.)
835.6100	Terrestrial field dissipation	
835.6200	Aquatic field dissipation	Conditionally required. (See CFR 158 for more details.)
835.7100	Ground water monitoring	Conditionally required. (See CFR 158 for more details.)

[2] The studies listed in this table were compiled from the "Environmental fate data requirements table" in 40 CFR §158.1300. Please see the CFR for the full table, all applicable footnotes, and several additional studies which are not typically required but may be required in specific instances.

E. SCOTT PRUITT
ADMINISTRATOR

July 3, 2017

Mr. James R. Barbee
Director
Nevada Department of Agriculture
405 South 21st Street
Sparks, Nevada 89431

SUBJECT: **NOTICE OF DISAPPROVAL**
SLN No. NV170003 – General Hydroponics Prevasyn (EPA Reg. No. 91865-1)
SLN No. NV170004 – General Hydroponics Exile (EPA Reg. No. 91865-2)
SLN No. NV170005 – General Hydroponics Defguard (EPA Reg. No. 91865-3)
SLN No. NV170006 – General Hydroponics Azamax (EPA Reg. No. 91865-4)

Dear Mr. Barbee:

On April 5, 2017, the Nevada Department of Agriculture issued Special Local Need registrations under Section 24(c) of the Federal Insecticide, Fungicide and Rodenticide Act as amended, to Hawthorne Hydroponics LLC d/b/a General Hydroponics. These state registrations, submitted to the U.S. Environmental Protection Agency by Jian (Jim) Zhang of NDA, were issued for the application of the following chemicals: capsicum oleoresin extract, garlic oil and soybean oil (NV170003), potassium salts of fatty acids (NV170004), *Bacillus amyloliquefaciens* strain D747 (NV170005) and azadirachtin (NV170006) to control various insect pests, mites and/or diseases on cannabis. The aforementioned chemicals are not registered by the EPA for use on cannabis. On June 22, 2017, the agency sent the NDA a Notice of Intent to Disapprove the four SLN registrations. On June 29, 2017, the NDA consulted with the agency about the SLN registrations.

Decision: The EPA concludes that SLN Nos. NV170003, NV170004, NV170005 and NV170006 are disapproved, effective immediately, for the reasons provided below.

Reasons for Disapproval: During the consultation on June 29, 2017, the NDA expressed their interest in pesticide use for the marijuana industry in Nevada. However, pursuant to FIFRA section 24(c), the EPA's regulations pertaining to state registrations of pesticides to meet special local needs state that "the Administrator may disapprove, on any reasonable grounds, any state registration which, when compared to a federally registered product, does not have . . . a similar

use pattern . . .." 40 C.F.R. § 162.154(a)(1). The regulations define "similar use pattern" to mean "a use of a pesticide product . . . which is [among other things] substantially the same as the federally registered use." 40 C.F.R. § 162.151. Under federal law, cultivation (along with sale and use) of cannabis is generally unlawful as a schedule I controlled substance under the Controlled Substances Act.[1] The EPA finds that the general illegality of cannabis cultivation makes pesticide use on cannabis a fundamentally different use pattern.

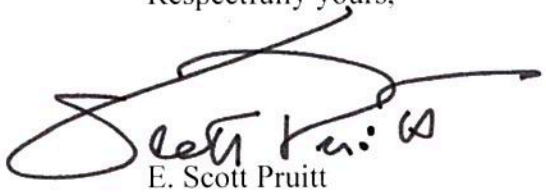
The Administrator may disapprove a different use pattern "on any reasonable grounds." Here, in accordance with 40 C.F.R. section 162.154, the Administrator has determined disapproval is reasonable because the EPA does not believe that Congress intended the process under section 24(c) of FIFRA to be used for the purpose of facilitating activities that are generally in violation of federal law. While the EPA believes that it is not required to consider the general cost-benefit standard applicable to FIFRA registrations when disapproving a registration that is inextricably linked with violations of federal law, application of the cost-benefit standard would not yield a different result – any economic, social or environmental costs associated with pesticide use on cannabis would not be reasonable or justified in light of the fact that such use is in furtherance of an illegal act. The EPA has reviewed the SLN registrations submitted by the state and has not identified any significant risks associated with the SLN registrations; the EPA would not have been inclined to disapprove these registrations were cultivation and sale of marijuana generally lawful in the United States.

Disposition of Existing Stocks: The disapprovals of SLN Nos. NV170003, NV170004, NV170005 and NV170006 are effective immediately. You must take steps to halt any further sale or distribution of products under these SLN registrations. For uses subject to the disapproval, distribution or sale of existing stocks of all disapproved products listed above is prohibited. Sale or distribution of the EPA-registered products is still permitted, as long as the products are still properly labeled and the SLN labeling does not accompany the product.

Per 40 CFR § 162.154(c), a notice of the disapproval of these SLN registrations will be published in the Federal Register. However, this disapproval is effective immediately, as of the date of this letter.

If you have any questions, please contact Nancy Beck at (202) 564-2910 or beck.nancy@epa.gov.

Respectfully yours,



E. Scott Pruitt

Cc: Jian (Jim) Zhang, Nevada Department of Agriculture
Alexis Strauss, Acting Regional Administrator, EPA Region 9

[1] Marihuana, an older spelling of marijuana, and tetrahydrocannabinols are listed under schedule 1 in 21 U.S.C section 812(c).