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EPN Comments on Memorandum Supporting Proposed Decision to Approve Registration for the New Active Ingredient, Epyrifenacil

EPA-HQ-OPP-2022-0354

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The Environmental Protection Network (EPN) harnesses the expertise of more than 700 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

On November 3, 2025, EPA issued a memorandum supporting its proposed decision to register pesticide products containing the active ingredient epyrifenacil ("Decision Memorandum").[1] The agency placed a number of documents in public docket EPA-HQ-OPP-2022-0354 at www.regulations.gov and invited public comment on the proposed decision. Epyrifenacil[2] is a new systemic herbicide in the pyrimidindione class that is being proposed by Valent U.S.A., LLC (Valent) as a new systemic herbicide for use as a pre-plant burndown herbicide for agricultural use in canola, field corn, soybean, wheat, and fallow land, and for non-agricultural use on non-crop areas. Epyrifenacil is classified as a Group 14 (PPO inhibition) herbicide, one of several in the chemical class of pyrimidindione herbicides. The herbicidal action of epyrifenacil is through inhibition of the protoporphyrinogen-IX-oxidase (PPO) enzyme, which is an important component in the biosynthesis of chlorophyll in plants. PPO inhibition ultimately causes plant cell membranes to leak, rapidly dry out, and disintegrate.

In 2022, Valent originally applied for registration of four products: one (technical) manufacturing-use product and three end-use products. Valent has since voluntarily withdrawn the request for action on one of the end-use, multiple active ingredient-containing products. In this action, EPA is proposing to issue *unconditional* registrations under FIFRA Section 3(c)(5) for three products for use on the sites listed above (canola, field corn, soybean, wheat, fallow land (for corn, soybean, and wheat)), and to maintain bare ground in non-crop areas (including guard rails, above-ground pipelines, railroads and surrounding areas, parking and storage areas, airports, industrial areas, around farm buildings, fence rows, windbreaks, shelterbelts, road surfaces, and shoulders).

Epyrifenacil is one of several PFAS-containing pesticides that has moved unusually rapidly through the Office of Pesticide Programs' (OPP) regulatory process during 2025. As with several of the other pesticides that have been evaluated this year, EPN believes that EPA's assessment of the potential risks to humans and the environment is deficient. In addition, unless corrections are made to the proposed labeling, the application would not meet the statutory standard that the use directions are likely to be read and understood and thus inadequate to protect health and the environment.

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[1] Memorandum Supporting Proposed Decision to Approve Registration for the New Active Ingredient, Epyrifenacil ("Decision Memorandum"), USEPA, 2025. https://www.regulations.gov/document/EPA-HQ-OPP-2022-0354-0013.

[2] ((S-3100), ethyl 2-[[3-[2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2H)-pyrimidinyl]-4-fluorophenoxy]-2-pyridinyl]oxy]acetat; CAS Number: 353292-31-6)

I. Before issuing an unconditional registration under FIFRA section 3(c)(5), EPA must adequately explain why it did not conduct a cumulative risk assessment for epyrifenacil and other substances.

The Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to consider whether a group of chemicals that share a common mechanism of toxicity may cause unsafe exposures through their cumulative effects. To implement the FFDCA requirement, OPP has developed approaches to determine whether or not a cumulative assessment is warranted[3] and, if so, how to conduct such an assessment.[4] FIFRA imports this requirement into decision-making with respect to the registration of food use pesticides. While these guidance documents were originally focused on the assessment of human health, the guidance can be made applicable to ecological risk assessment as well.

EPN has followed the guidance in these documents to determine whether the cumulative effects of epyrifenacil and other chemicals should be assessed. When selecting a group of candidate chemicals to be assessed in a cumulative assessment, several criteria are to be considered:

1. Structural similarity (i.e., membership in the same or similar chemical class)
2. Mechanism of pesticidal action
3. Similar general mechanism/mode of mammalian (including human) and other non-target species toxicity
4. A particular toxic effect in mammals (including humans) and/or other non-target species.

A cursory look at the available information on epyrifenacil quickly reveals there is information indicating that several of the criteria are met. More in-depth evaluation would likely uncover more relevant information.

A. The FIFRA registration standard requires that EPA consider the potential for a pesticide to have unsafe cumulative effects.

As the proposed Registration Decision memorandum states, "When EPA grants a registration, FIFRA requires that the pesticide not cause "unreasonable adverse effects on the environment."" This standard consists of two parts: the pesticide may neither cause an "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" nor, in the case of a pesticide resulting in residues in food and feed, cause a "human dietary risk" that is unsafe.

EPA can establish a tolerance for a pesticide chemical residue in food or feed only if the agency determines that "the tolerance is safe."[5] The FFDCA defines "safe" to mean there is a "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."[6] The FFDCA further provides that "In establishing . . . a tolerance for a pesticide chemical residue, the Administrator shall consider . . . available information concerning the *cumulative* effects of such residues and other substances that have a

[3] Guidance for identifying Pesticide Chemicals and Other Substances That Have a Common Mechanism of Toxicity, USEPA, January,1999; Pesticide Cumulative Risk Assessment: Framework for Screening Analysis, USEPA, 2016.
[4] Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity, USEPA, January, 2002.
[5] FFDCA section 408(b)(2)(A)(1).
[6] FFDCA section 408(b)(2)(A)(2).

common mechanism of toxicity."[7] Notably, FIFRA imports the requirements of the FFDCA into the standard for registration of pesticide products under FIFRA section 3(c)(5). Specifically, FIFRA section 3(c)(5)(C) requires the agency to find that a pesticide does not cause "unreasonable adverse effects on the environment" – a term which FIFRA defines to mean, among other things, "(2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard in [FFDCA section 408(b)(2)(A)]."[8] Thus, EPA must, as part of its registration decision, consider the potential for epyrifenacil and other substances to cause unsafe cumulative effects via dietary and other non-occupational exposure pathways.

B. The administrative record for the proposed registration of epyrifenacil does not demonstrate that EPA has determined whether epyrifenacil will cause unsafe cumulative effects.

EPA's Decision Memorandum and other supporting material do not demonstrate that EPA has adequately considered available information, nor does it include any substantive discussion of tolerance-setting for epyrifenacil, as one should expect to see in a Decision document for a food use chemical. Neither did the agency demonstrate that EPA has adequately considered available, reliable information about potential cumulative effects of epyrifenacil and other substances, which also should be a component of a proposed decision. In fact, the only reference to cumulative risk assessment in the document in a very brief statement as to what might happen in the future:

> "vi. Cumulative Risk
>
> Epyrifenacil is a PPO inhibiting herbicide. As part of the ongoing process to review registered pesticides, the Agency intends to apply EPA's Office of Pesticide Programs released a guidance document entitled, Pesticide Cumulative Risk Assessment: Framework for Screening Analysis to determine if the available toxicological data for epyrifenacil suggests a candidate common mechanism group (CMG) may be established with other pesticides. If a CMG is established, a screening-level toxicology and exposure analysis may be conducted to provide an initial screen for multiple pesticide exposure."[9]

Unlike other pesticides for which EPA has considered a cumulative risk assessment approach, EPA has not considered, as it should have, a common mechanism of toxicity finding for epyrifenacil and any other substances or whether it produces the same or similar toxic metabolite(s) as may be produced by other substances.

The FFDCA requires that EPA "shall consider . . . available information" relating to potential cumulative effects, but no document in the administrative record shows that EPA has done so. Instead, EPA describes only what it has not done – "make a common mechanism of toxicity finding." EPA also acknowledges it has not "assumed that epyrifenacil has a common mechanism of toxicity with other substances." In fact, the Decision Memorandum acknowledges that the agency will address the potential for cumulative effects of epyrifenacil and other substances *only* at some later date.

[7] FFDCA section 408(b)(2)(D)(v) (emphasis added)
[8] See FIFRA sections 3(c)(5)(C) and 2(bb)(2).
[9] Decision Memorandum at 14.

In 2016, OPP released a guidance document entitled, Pesticide Cumulative Risk Assessment: Framework for Screening Analysis.[10] This document provides guidance on how EPA plans to screen groups of pesticides for cumulative evaluation using a two-step approach beginning with the evaluation of available toxicological information and followed by a risk-based screening approach, if deemed necessary.. This framework supplements the existing guidance documents for establishing common mechanism groups (CMGs) and conducting cumulative risk assessments (CRAs). The agency will utilize this framework to determine if the available toxicological data for epyrifenacil suggests a candidate CMG may be established with other pesticides. If a CMG is established, a screening level toxicology and exposure analysis may be conducted to provide an initial screen for multiple pesticide exposure.

The screening of chemicals for establishing a candidate assessment group involves consideration of four criteria:

- Structural similarity (i.e., membership in the same or similar chemical class)
- Mechanism of pesticidal action
- Similar general mechanism/mode of mammalian (including human) and other non-target species toxicity
- A particular toxic effect in mammals (including humans) and/or other non-target species.

What the statute requires EPA to do—and what the agency has failed to do but should have before proposing unconditional registration—is to identify relevant, available information and determine whether that information is sufficient to warrant further analysis.

If, as EPN contends, there is sufficient information to indicate epyrifenacil may share a common mechanism of toxicity with other substances, EPA must conduct additional analysis to determine whether cumulative exposure to those chemicals raises a concern about the safety of the residues of epyrifenacil in food.

C. Available information indicates that epyrifenacil and other chemicals may cause unsafe cumulative effects.

In EPN's view, there is enough reliable information to suggest that a CMG does exist for epyrifenacil and other substances. The 1999 Guidance document states that the first step in implementing FFDCA section 408(b)(2)(D)(v) is to identify a Candidate CMG. Under the guidance, the agency uses a weight-of-evidence approach to identifying chemicals that may share a common mechanism of toxicity by looking at similarities in four types of information – chemical structure, mechanism of pesticidal action, general mechanism of mammalian toxicity, and a particular toxic effect. Following this guidance, the Decision Memorandum or another supporting document should identify available information relating to these four categories and discuss whether the information points to the establishment of a Candidate CMG.

EPA's Decision Memorandum refers to information indicating that epyrifenacil shares at least one and possibly more of these similarities with other chemicals. Specifically, epyrifenacil is not the only active ingredient to exert herbicidal effects via inhibition of the PPO enzyme. Missouri's Extension Service lists nine other pesticide active ingredients as having a PPO mode of action.[11]

[10] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework.
[11] See https://extension.missouri.edu/media/wysiwyg/Extensiondata/Pub/pdf/miscpubs/mx1121.pdf.

In addition, epyrifenacil may produce toxic effects through the same adverse outcome pathways as other chemicals. The toxic effects of epyrifenacil, as reported in the Decision Memorandum, are general in nature and include liver and blood effects in mice and rats, an increase in liver weights, hepatocellular hypertrophy, and degeneration/necrosis and a mild decrease in red blood cell parameters resulting in secondary increased erythropoiesis in the bone marrow and increased extramedullary hematopoiesis in the spleen. Hematological changes, typically of a mild and adaptive nature, occurred at doses where more observable and notable liver-related effects were seen. Following a nine-day inhalation exposure in rats, adverse portal of entry effects included degenerative and inflammatory changes occurring in the upper respiratory tract (turbinates and pharynx). There was evidence of increased qualitative susceptibility in the two-generation reproductive toxicity study in rats. In a rat developmental study, adverse developmental toxicity (increased presence of supernumerary ribs in the cervical region) was observed at a higher dose than maternal toxicity.

It is also clear that epyrifenacil does belong to the same chemical class as other active ingredients in PPO herbicides or with other chemicals to which the public is exposed. According to the Weed Science Society of America (WSSA) classification, the PPO inhibitors fall into several different chemical classes: diphenylether, N-phenylphthalimide, oxadiazole, pyridinecarboxamides, thiadiazole, triazolinone, benzoxazine (1,3,5-triazinane) and pyrimidinedione. Both saflufenacil and butafenacil are also members of the same class, the pyrimidindiones. Since epyrifenacil belongs to the same class as at least two other PPO inhibitors, EPA should further determine whether to consider them a Candidate CMG.

Further, with respect to chemical structure, it is also asserted that, because of the fluorine bonds in the epyrifenacil molecule, the new active ingredient belongs to the PFAS chemical class. Consequently, EPA should explain how it views the chemical structure of epyrifenacil since it has avoided providing any definition of the term PFAS.[12]

Even if EPA does not consider epyrifenacil to be a PFAS, the agency should specifically address whether there is a potential for cumulative effects from exposure to epyrifenacil and other compounds with similar chemical structures.

In sum, before sanctioning registration of products containing epyrifenacil, EPA needs to review the available information and provide better support for its conclusion that the agency does not need to perform a human health (or ecological) cumulative risk assessment for products containing epyrifenacil. If it cannot make that argument, then it must assess the cumulative effects of the chemicals belonging to the CMG.

Many of the considerations relevant to the human health risk assessment also apply to the ecological risk assessment. EPN has reviewed EPA's draft assessment of environmental fate, toxicity, and risk posed by the herbicide epyrifenacil and related products. The toxicity of the epyrifenacil active ingredient and its end-use product co-formulated active ingredients, flumioxazin and pyroxasulfone, were evaluated in a wide variety of taxonomic groups. The following comments address that assessment.

The agency used previous assessments of flumioxazin and pyroxasulfone to assess their toxicities relevant to the proposed co-formulated products. EPA modeled exposure concentrations of these co-formulated active

[12] See OPP website: Pesticides Containing a Fluorinated Carbon https://www.epa.gov/ingredients-used-pesticide-products/pesticides-containing-fluorinated-carbon

ingredients (co-formulants) based on the proposed application rates of the product; the residue of concern (ROC) is the parent only for both compounds.

The agency conclusions apply to exposure only to technical epyrifenacil or the three-chemical active ingredients in the end-use products. No true cumulative ecological risk assessments with additional substances were conducted. The risk conclusions might differ if such assessments were carried out.

The agency's findings:

Aquatic Vertebrates: "Overall, there are low risk concerns for epyrifenacil and its co-formulated a.i. for non-listed fish and for aquatic-phase amphibians and low potential for direct effects to listed fish and aquatic-phase amphibians. Therefore, no direct risks of concern are expected for these taxa."[13]

Aquatic Invertebrates: "There are low risk concerns for non-listed aquatic invertebrates and low potential for direct effects to listed aquatic invertebrates. Therefore, no direct risks of concern are expected for this taxon."[14]

Aquatic Plants: "Direct risks of concern are expected for this taxon, and effects to [prey, pollination, habitat, and dispersal (PPHD)] may occur for species that depend on aquatic plants for food or habitat."[15]

Terrestrial Vertebrates (Mammals, Birds, Reptiles, and Terrestrial-phase Amphibians): "Direct risks of concern are not expected for this taxon."[16]

Terrestrial Invertebrates (Honeybees and Other Terrestrial Invertebrates): "Direct risks of concern are not expected for this taxon."[17]

Terrestrial Plants: "Direct risks of concern are expected for this taxon, and effects to PPHD may occur for species that depend on terrestrial or wetland plants for food or habitat."[18]

To summarize, the agency determined that there were no direct risks of concern for non-listed and listed aquatic vertebrates and invertebrates or terrestrial vertebrates and invertebrates. On the other hand, direct risks of concern are expected to occur in aquatic and terrestrial plants. The potential direct effects on plants indicate potential for PPHD effects to listed animals that rely on plants for food or habitat.

EPA also conducted a Biological Evaluation (BE) for federally-listed threatened and endangered ("listed") species and designated critical habitat (CH) for all proposed uses of epyrifenacil. EPA determined "No Effect" (NE) for 82 species and 78 designated Critical Habitats (CHs) and "Not Likely to Adversely Affect" (NLAA) for an additional 1,063 species and 628 CHs. However, EPA made "likely to Adversely Affect" (LAA) determinations for 601 species, including for 29 species under the authority of the National Marine Fisheries Service (NMFS), and made draft predictions of a potential likelihood of future jeopardy for nine species (all Vulnerable Species Action Plan (VSAP) plants under the authority of the Fish and Wildlife

[13]Decision Memorandum at 19
[14] Id. at 20.
[15] Id. at 21.
[16] Id. at 22.
[17] Id. at 23.
[18] Id.

Service (FWS)). EPA made LAA determinations for 212 CH and did not make draft or final predictions of a potential likelihood of future Adverse Modification (AM) for any CH.

While EPA has not yet consulted with NMFS or FWS, it apparently did work with Valent to identify mitigation measures that could address the LAA concerns. EPA predicted that, with the proposed mitigation measures in place, "the registration of epyrifenacil for the proposed uses is not likely to jeopardize any listed species nor lead to adverse modification of any listed species' designated CH." However, success in protection of at-risk species and habitats is highly dependent upon product labeling and subsequent adherence to the directions for use on the label. Only then can we judge whether or not these mitigation measures are reasonable and workable in providing adequate protection for the environment.

II. EPA should require Valent to improve the labeling of its end-use products.

EPA's determination that epyrifenacil products meet the statutory standards for an unconditional registration under FIFRA section 3(c)(5) fails to adequately consider the criterion in FIFRA section 3(c)(5)(B). In addition to finding that the use of the pesticide product will not cause "unreasonable adverse effects on the environment" as specified in FIFRA section 3(c)(5)(C) and (D), FIFRA section 3(c)(5)(B) requires the agency to determine that a pesticide's "labeling and other material required to be submitted comply with the requirements of [FIFRA]." Among other FIFRA requirements pertaining to pesticide labeling, it is unlawful to sell or distribute a pesticide that is "misbranded."[19] FIFRA sections 2(q)(1)(E), (F) defines "misbranded" as follows:

> A pesticide is misbranded if– . . .
>
> > (E) any word, statement, or other information required by or under the authority of [FIFRA] to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
> >
> > (F) the labeling accompanying it does not contain directions for use which are necessary . . . and if complied with, . . . are adequate to protect public health and the environment.

Note: FIFRA section 2(p)(2) defines the term "labeling" to include any source of information to which reference is made. Thus, if the labeling refers to the Bulletins Live! Two website (BLT), the Bulletins found on EPA's website become labeling. Likewise, reference to the Worker Protection Standard in 40 CFR part 156 makes the content of the rule "labeling."

Together, these provisions require EPA to examine closely whether the labeling of an applicant's pesticide is "likely to be read and understood" such that following the use directions is "adequate to protect public health and the environment." If not, the agency cannot make the finding required by FIFRA section 3(c)(5)(B) that is a prerequisite for an unconditional registration. EPA's Decision Memorandum does not address whether the pesticide's labeling is "likely to be read and understood." EPN believes the proposed labeling does not satisfy that standard.

[19] FIFRA section 12(a)(1)(E).

As discussed in more detail below, we think that, if approved with the proposed labeling, end-use epyrifenacil products should be deemed "misbranded." In the case of labeling designed to protect threatened and endangered species and their critical habitats, the labeling is not "likely to be read and understood." In the case of labeling text designed to tell users how to control spray drift, the labeling is not "adequate to protect public health and the environment."

A. EPA should require Valent to offer more user-friendly labeling to protect listed species.

Considering EPA's ecological risk assessment showing the proposed registrations of epyrifenacil products would entail significant risks to threatened and endangered species (listed species) and to their designated critical habitats, the agency needs to do more to protect listed species and their habitats. The agency concluded that the use of Valent's products would be "likely to adversely affect" 601 listed species and likely to adversely modify 212 designated critical habitats.[20] EPA also determined that epyrifenacil use "may affect" an additional 1,063 listed species and 628 more designated critical habitats.[21]

Under the Endangered Species Act, federal agencies like EPA are required to take reasonable and prudent actions to avoid causing jeopardy and/or adverse modification (J/AM) of listed species' critical habitats and to take reasonable and prudent measures to minimize "take," i.e., adverse effects on listed species. To address the potential of epyrifenacil products to cause J/AM and to minimize take, EPA's proposed registration decisions rely on labeling that would require users to follow certain practices to avoid harming listed species and their critical habitats. To access such requirements, users would need to repeatedly check multiple websites for applicable restrictions. Reliance on such labeling to secure compliance is unrealistic and likely to fail. Given the magnitude of the risks identified, EPA must do better; we propose that EPA use a different approach to labeling.

The Decision Memorandum supporting EPA's proposal to register epyrifenacil products states that the products intended for agriculture use must bear a label statement reading:

> "ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS: Before using this product, you must obtain any applicable Endangered Species Protection Bulletins ('Bulletins') within six months prior to or on the day of application. To obtain Bulletins, go to Bulletins Live! Two (BLT) at https://www.epa.gov/pesticides/bulletins. When using this product, you must follow all directions and restrictions contained in any applicable Bulletin(s) for the area where you are applying the product, including any restrictions on application timing if applicable. It is a violation of Federal law to use this product in a manner inconsistent with its labeling, including this labeling instruction to follow all directions and restrictions contained in any applicable Bulletin(s). For general questions or technical help, call 1-844-447-3813, or email ESPP@epa.gov."[22]

The result of including this labeling text is to make the provisions of the BLT website a part of the product's enforceable labeling.

[20] Decision Memorandum at 31.
[21] Id.
[22] Id. at 38.

The Endangered and Threatened Species statement requires a user to consult BLT – a website that we consider not user-friendly. (EPA's tutorial on using BLT contains eight modules covering five distinct steps a user needs to follow to identify relevant restrictions.) To locate any additional restrictions on the use of the product, the user must first go through multiple steps – entering information on the location of intended use, the month of intended use, and the product registration number. We feel there is potential for user error when entering the product registration number, because of the presence on labels of multiple, potentially confusing identifiers, such as establishment numbers and batch codes. Assuming the user goes to the website and enters correct information, the website brings up one or more Bulletins for the intended use site(s). The user must then search the Bulletin(s) to locate the restrictions that may pertain to the specific product they intend to use and the location where the product will be used.

EPA is being totally unrealistic if the agency thinks that the vast majority of users will follow these steps and will correctly understand what they are (and are not) allowed to do. A large body of anecdotal information indicates that many pesticide users do not even read pesticide products' labeling before each use. Many may read the labeling when they first use a product but thereafter, many rely on their memory or other sources (e.g., crop advisors, agriculture products dealers, friends) to supply whatever information is deemed essential. Such an approach, however, would not comply with the labeling requirement to check BLT during the six months before every use. Making the user go through so many additional steps,[23] at least annually if not more often, would only make it less likely that the user will not even attempt to get the required information.

To simplify the steps and improve the chances that users will obtain accurate information, EPA should require Valent to develop and place in the labeling of the affected end-use epyrifenacil products a simplified way to obtain requirements relating to the protection of listed species and their habitat. We recommend the use of a QR code on each product's label that would take the user to a website where the user would enter (ideally by selecting values from a drop-down menu) the relevant information for the product – location of intended use, type of site treated, and date(s) of intended application. It would capture not only the information in any relevant Bulletin but also display the information about the number of required points and the options for achieving the required points and then tally the points for measures the user selects. The website would also reconcile the website's restrictions with any more stringent restrictions in the labeling. Such a feature should make it possible for users to access in many fewer steps the information that otherwise would spread across multiple websites. We understand that at least two different entities, a student team at San Jose State University and a contractor working with the Tennessee Department of Agriculture have made substantial progress toward developing software with the requisite capabilities.

B. EPA should reconsider the labeling directed at controlling spray drift.

Spray drift of herbicide products has been an ongoing concern for EPA, applicators and their neighbors, and the environment for many years. While we recognize that most spray applications of herbicides do not result in damaging drift, the incidence of problems remains frustratingly high. As explained below, we

[23] We note that there is no access to the internet using broadband services in many rural areas where epyrifenacil pesticides are going to be used. If a user cannot reach the BLT website, the user would need to call or send an email to EPA asking for "technical help." In our view, users are even less likely to take this step than they are to connect to multiple websites. EPA's Decision Memorandum should address whether FIFRA 3(c)(5)(B) is satisfied by a label instruction that can be met only by calling an EPA hotline or sending an email to EPA.

recommend that labeling to address spray drift should add a performance-based restriction related to spray drift (a "no harm" standard).

EPA should require Valent to add the following text to the spray drift labeling section: "Do not apply this product in a manner resulting in spray drift that causes harm." We think this restriction is reasonable, objective, and measurable. Drift which causes any type of harm beyond the treated site is a problem, and it is reasonable and desirable to prevent such drift during an application, if harmful drift can be avoided. If harmful drift cannot be prevented for a particular application because of unfavorable conditions, then the application should not occur. "Harm" is also an objective, measurable concept. Drift which damages property or non-target animals, plants, or people is harmful. Property damage could include causing a neighbor's crop to violate a tolerance requirement or organic status or reducing the crop's quality or yield. It could also include damaging ornamental plants or causing illness in pets or livestock. Drift that contaminates water at levels unsafe for consumption, irrigation, or recreational use is also harmful. We note that the state of Indiana has long had a regulation applicable to drift of pesticide sprays that is effectively comparable to our recommended labeling requirement. Including our suggested language would provide an additional backstop to use restrictions that are critical to the protection of listed species.

Moreover, our proposed labeling text would be easier to enforce than the spray drift restrictions on the proposed labeling. The Decision Memorandum proposes to require extensive instructions describing how to apply the pesticide, e.g., restrictions on release height, wind speed, and droplet size. To determine whether a user complied with the labeling, an official would have to observe the actual application to determine whether the spray boom was too high, the droplets too fine, or the wind too strong. When no enforcement personnel are present at the time of application, users may be less likely to comply with spray drift restrictions in a product's labeling, and that in turn could lead to harm through excessive off-target drift. However, if our proposed labeling is added a user would understand that a violation could be found by collecting information on the impacts of an application after the application was over, and thus he would be more likely to comply.

Conclusions

EPN respectfully requests that EPA *not* finalize the registration of epyrifenacil products as proposed. As explained in more detail in these comments, there are significant deficiencies in the human and ecological health risk assessments, and the draft labeling should be reevaluated. While EPA may eventually conclude the epyrifenacil products do meet the statutory standards for registration, the information in the record accompanying the proposal does not currently support such a conclusion. EPA will not have an adequate record until EPA has more comprehensively analyzed and fully explained its analysis of the potential risks to human and ecological health and has examined whether the labeling meets the standards in FIFRA section 2(q)(1)(E) and (F).

EPN has concluded that there has been a rush to judgment in this instance (i.e., proposed approval of an unconditional registration of a new technical and two end-use products) in the absence of the usual and expected fulsome consideration of all of the relevant information required and reviewed to reach a credible and supportable outcome.