



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

## **Sulfoxaflor**

### **Response to Public Comments**

**Proposed Registration for Use on Agricultural Crops, Ornamentals and Turf**

**Docket ID: EPA-HQ-OPP-2010-0889**

## **Background**

On August 19, 2010, the EPA received the application for registration of sulfoxaflor, a new active ingredient, submitted by Dow AgroSciences (DAS). In collaboration with counterpart agencies in Canada and Australia, EPA conducted a “Global Joint Review” (GJR) of sulfoxaflor. Upon completion of the GJR and after public comment, EPA granted an unconditional registration of sulfoxaflor on May 6, 2013.

On July 2, 2013, the Pollinator Stewardship Council and others, petitioned for review of the sulfoxaflor registration in the Ninth Circuit Court of Appeals. On September 10, 2015, the Court issued its opinion, finding that the registration was not supported by substantial evidence to demonstrate no unreasonable adverse effects to honey bees resulting from the registration of sulfoxaflor. Although the initial sulfoxaflor submission contained all the data required by the EPA regulations for registration of a new agricultural insecticide, the Court vacated the registrations and remanded them to the EPA to: “obtain further studies and data regarding the effects of sulfoxaflor on bees as required by EPA regulations.”

Following the remand, the EPA re-evaluated the sulfoxaflor application that was amended by DAS to further reduce/eliminate exposure to pollinators by restricting applications to post-bloom only for all proposed crops that are attractive to bees, to crops that are not attractive to bees, and to crops that are harvested before bloom. Additionally, indeterminate blooming crops that had been registered (citrus, cotton, cucurbits, soybeans and strawberry) were not included in the amended application. With the conclusion that limiting the use of sulfoxaflor as noted above, and restricting the timing of applications resulted in essentially no exposure to bees on the treated field, the EPA announced the proposed decision to unconditionally register sulfoxaflor on May 17, 2016, and held a public comment period for 30 days, closing June 17, 2016. Unique written comments/letters in support of sulfoxaflor totaled about 160 and included numerous University and Extension researchers, individual crop consultants, farmers, various organizations (including some with large memberships, ex. Texas Farm Bureau, >500,000 members), the National Association of State Departments of Agriculture and the USDA. Three letter writing campaigns against sulfoxaflor were from non-governmental organizations (NGOs) and totaled approximately 62,000 signatures. Other commenters both for and against sulfoxaflor included three other NGOs, two beekeepers, some private citizens and a number of individuals who wished to remain anonymous.

The agency’s review and responses are summarized in this document.

### **I. General Comments in Opposition to Sulfoxaflor**

Commenters against the proposed registration were generally just opposed to sulfoxaflor, regardless of restrictions on the use patterns or other limitations. No substantive information or data were provided as evidence against sulfoxaflor. These commenters included 25 anonymous writers, the letter-writing campaigns from NGOs and ten individuals. All expressed concern for the welfare of bees.

## The EPA's Response

The EPA appreciates that many in the public are concerned about bees. The comments received against the proposed registration of sulfoxaflor, however, clearly indicate that there is a false and unsubstantiated impression regarding this compound in the public domain and that impression does not reflect the findings of the EPA scientists and the scientists from the regulatory authorities in Australia, Canada and the European Union.

Many commenters, such as the letter writing campaign in comment 0558<sup>1</sup> expressed concern that sulfoxaflor “is a neonicotinoid.” Sulfoxaflor is a sulfoximine insecticide with a distinct mode of action and it is not a neonicotinoid. Sulfoxaflor has different chemistry since it contains a unique chemical moiety, a sulfoximine.<sup>2</sup> This chemistry confers a unique set of structure/activity relationships compared to other insecticides. Like several chemically diverse classes of insecticides (spinosyns, neonicotinoids, nereistoxin analogs), sulfoxaflor acts on insect nicotinic receptors (nAChRs). However, it operates at a different site on the nicotinic acetylcholine receptor, thus, the characteristics of the sulfoxaflor – nAChR interaction distinguish it from the other nAChR acting insecticides. Sulfoxaflor is effective against a wide range of sap-feeding (piercing, sucking) insect pests that are resistant to other classes of insecticides, including many that are resistant to the neonicotinoids. Growers will use sulfoxaflor instead of neonicotinoids because it actually works on pests that neonicotinoids fail to control.

Additionally, compared to the neonicotinoids, the ecological risk profile of sulfoxaflor is much more favorable which further supports that they are chemically distinct. Sulfoxaflor also poses less risk to fish, aquatic invertebrates, small mammals, wildlife and birds than the broad-spectrum carbamates, organophosphates and pyrethroids.

Sulfoxaflor does not have the adverse effects on beneficial insects that alternative insecticides have. Other insecticides can negatively impact the natural enemies of aphids and other sap-feeding target pests. For example, a field study described in the *Journal of Economic Entomology* compared the effects of sulfoxaflor versus lambda-cyhalothrin (a pyrethroid) on beneficial insect predators (ex. ladybugs). The study found that sulfoxaflor was less harmful to these beneficial insects.<sup>3</sup>

Foliar applications of sulfoxaflor are very short-lived in the field. Through beekeeping journal articles,<sup>4</sup> meetings with associations such as the May 17, 2016 meeting between the American Beekeeping Federation, the American Honey Producer's Association and the EPA's Office of Pesticide Programs and by other communications, beekeepers have frequently informed the EPA that RT<sub>25</sub> data is one of the most important pieces of information for the protection of honey bees.<sup>5</sup> The “Toxicity of Residues” study, also known as RT<sub>25</sub>, refers to the residual time to 25% mortality that is derived from a study of honey bee toxicity of residues on foliage and reflects acute toxicity to bees via direct contact with treated foliage.<sup>6</sup> As discussed in the proposed decision, the

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<sup>1</sup> Earthjustice

<sup>2</sup> <http://www.sciencedirect.com/science/article/pii/S0048357513000989>

<sup>3</sup> <http://jee.oxfordjournals.org/content/early/2016/08/14/jee.tow168>

<sup>4</sup> <http://www.beekeeping.com/catch-the-buzz-epa-gives-some-help-finally/>

<sup>5</sup> Letter re Sulfoxaflor from Steven Coy to Dr. Donald Brady, US EPA, June 19, 2012

<sup>6</sup> <https://www.epa.gov/pollinator-protection/residual-time-25-bee-mortality-rt25-data>

EPA has “RT<sub>25</sub>” data on both of the sulfoxaflor end-use products, Transform and Closer. The EPA determined that an RT<sub>25</sub> value could not be calculated for either the Transform or Closer formulations because the toxicity was too low. This information should reassure beekeepers and other concerned parties that sulfoxaflor is preferential to other toxic insecticides that don’t degrade as rapidly.

The EPA agrees that bees and other pollinators must be protected to the extent possible. Protection of bees is considered in evaluating insecticides against FIFRA’s risk/benefit standard. But evaluating insecticides involves considering all of the risks and benefits. Other non-target organisms must also be considered. Sulfoxaflor clearly is a better compound for non-target organisms than nearly all of its alternatives. It poses little risk to fresh or saltwater fish and invertebrates. It poses little risk to mammals and birds. Compared to the alternative insecticides, sulfoxaflor is a compound that is much less hazardous to these non-target organisms. Commenters in support of the registration have repeatedly pointed to research and field experience that show that sulfoxaflor is soft on beneficial insects such as ladybird beetles.<sup>7</sup>

Beekeepers are important stakeholders. The EPA employs some scientists that are beekeepers with hands-on knowledge. Farmers are also our stakeholders and we consider their needs as well. Comment 0560<sup>8</sup> points out that growers and beekeepers working together and acknowledging each other’s needs, is mutually beneficial and there are successful Managed Pollinator Protection Plans (MP3s) in states like Mississippi. EPA agrees with the commenter that the loss of an important crop protection tool like sulfoxaflor because of misinformation significantly hurts growers and leads to a breakdown in the relationship between beekeepers and growers. In fact, this was specifically noted by comment 0495<sup>9</sup> who stated: “The recent cancellation of the Transform registration as a result of the actions of the Pollinator Stewardship Council has severely damaged the relationships between many farmers and beekeepers. Commercial and hobby beekeepers are being asked to remove their bees from some farms throughout the state. If Transform is not re-established soon to growers throughout Missouri, it will set the relationships between farmers and beekeepers back to before the adoption of the Missouri Pollinator Conservancy Program. In fact, those relationships will be more strained than they were before the program.”

The agency has concluded that appropriate risk assessment/risk management based mitigation, combined with protective solutions created at the local level under MP3s will best protect pollinators and meet the needs of growers. For example, comments 0503<sup>10</sup> and 0509<sup>11</sup> both complain that EPA has not defined “petal fall.” The EPA believes that petal fall and designated “bloom periods” are best determined by the experts in each state who are familiar with the crops and local growing conditions, as is done for California citrus (comment 0524<sup>12</sup>).

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<sup>7</sup> <https://entomologytoday.org/2016/08/17/sulfoxaflor-found-to-be-less-harmful-to-beneficial-predators-of-soybean-aphids/>

<sup>8</sup> Jeffrey Gore, Associate Professor, Delta Research and Extension Center, MSU

<sup>9</sup> M. Jones, PhD, University of Missouri Fisher Delta Research Center

<sup>10</sup> Pollinator Stewardship Council

<sup>11</sup> Thomas R. Smith, AZ

<sup>12</sup> J. Cranney, CA Citrus Quality Council

## II. Ninth Circuit Court Decision

Some NGOs<sup>13</sup> and others objected to the proposed registration of sulfoxaflor by referencing the Ninth Circuit Court decision that vacated the sulfoxaflor registration based on their conclusion that the EPA lacked “sufficient data documenting the risk to bees.” These commenters argue that sulfoxaflor should not be registered until EPA receives additional studies.

Comment 0503<sup>14</sup> states that “Tier 2 studies could determine the degradates of sulfoxaflor, the half-life of sulfoxaflor in the soil, and the toxicity in water-run off.”

Comment 0557<sup>15</sup> states that “EPA does not have substantial evidence to meet registration criteria under FIFRA with respect to the harm to pollinators” and points to limitations of the data for brood development and long-term colony strength.”

### The EPA’s Response

The statement from comment 0503 that Tier 2 studies would determine degradates and the half-life of sulfoxaflor is not correct. EPA has all the environmental fate data required for sulfoxaflor, there are no data gaps. Tier 2 testing (semi-field studies where hives are placed in screened “tunnels”) are not designed for obtaining environmental fate information. Determination of degradates and soil half-lives are conducted under established guidelines and protocols. Sulfoxaflor has a half-life of < 1 day when it reaches the soil system where it is subjected to rapid aerobic bio-degradation.<sup>16</sup> In contrast to sulfoxaflor parent, the major degradate X-474 is expected to be highly persistent in aerobic soil/aquatic systems and is expected to dominate the exposure resulting from use of sulfoxaflor. However, X-474 is practically non-toxic to the honey bee.

Rapid soil degradation of sulfoxaflor is expected to limit amounts that may potentially leach and contaminate ground water. Contamination of groundwater by sulfoxaflor will only be expected when excessive rain occurs within a short period (few days) of multiple applications in vulnerable sandy soils. However, the Closer and Transform labels limit the number of applications that may be made and require an interval of 7 – 14 days (depending on the crop) between applications. Sulfoxaflor is not volatile. Any potential contamination of surface water by sulfoxaflor would be limited to drift and very little due to run-off. This is because drifted sulfoxaflor that reaches aquatic systems is expected to persist while that reaching the soil system is expected to degrade quickly with slight chance for it to run-off. However, the sulfoxaflor labels impose drift mitigation that include restrictions on nozzle size, wind speed and release height above the field. These and other criteria are important factors that limit drift as articulated in detail by comment 0516<sup>17</sup>. Sulfoxaflor is applied at very low rates in aqueous solutions. Movement off the field would be in dilute droplets generated by the large nozzle size and would travel only a short distance. The potential contamination of a nearby water body would not present an unreasonable risk.

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<sup>13</sup> Comments: 0503, Pollinator Stewardship Council; 0544, Center for Food Safety; 0548, Beyond Pesticides; 0557, Center for Biological Diversity;

<sup>14</sup> Pollinator Stewardship Council

<sup>15</sup> Center for Biological Diversity

<sup>16</sup> Environmental Fate and Ecological Risk Assessment for Sulfoxaflor Registration; OPP-2010-0889-0022

<sup>17</sup> Andrew Moore, National Agricultural Aviation Association

The EPA has determined that we do have substantial evidence to meet the registration criteria under FIFRA with respect to the harm to pollinators for the use patterns in the DAS amended submission. Risk is a function of toxicity and exposure. Like almost all insecticides, laboratory studies have indicated that sulfoxaflor is acutely toxic to bees by contact. In acknowledgement of the Court's decision, the EPA proposed allowing the use of sulfoxaflor under very limited conditions, where there is essentially no expectation of *exposure* to bees - as there would be when bees are attracted to a field that is treated while the crop is in bloom. Thus, crops like wheat that are not attractive to bees and crops like lettuce that are harvested before bloom are not expected to present a risk to bees from foliar treatments of sulfoxaflor. The proposed crops that are attractive to bees are limited to applications after the bloom period is over and the bees have moved on, presenting a minimal exposure scenario. Further, the required buffer will prevent drift off the field from reaching levels that may be expected to affect bees. Risk is essentially non-existent, therefore additional pollinator studies on sulfoxaflor would not change the risk assessment for these crop situations. Additional data would not meaningfully inform any risk assessment of these use patterns. The data requirement in 40 CFR 158.630 that is required for all outdoor terrestrial use patterns is the honey bee acute contact toxicity study using the technical grade of the active ingredient. DAS submitted this study to the EPA.

In addition to the data requirements currently codified in 40 CFR Part 158, in 2012 the EPA began to employ a new risk assessment framework for assessing risk to bees. The framework suggests certain studies for informing the risk assessment, but those studies are not yet required by regulation. The EPA has required submission of additional studies on a case-by-case basis as appropriate to the use pattern being assessed. The EPA's risk assessment framework for bees relies on a tiered process<sup>18</sup>. Tier I data (laboratory studies) are useful for interpreting higher tier effects studies, field residue data and the overall weight of the evidence for characterizing risk. Tier II studies provide data for assessing colony level effects as a function of application rate and also establish a dose-response relationship between residues in diet and effects on the colony. Given the use patterns on the sulfoxaflor labels, bees will not be foraging on the treated crop. There would not be oral exposure from contaminated pollen and nectar and there would not be contact exposure to adult foragers on the field. Tier II studies are based on subjecting the bees to a contaminated diet either through confinement on a treated crop or through a supplemental sucrose solution that contains sulfoxaflor. Confinement on a treated crop in a tunnel study also ensures contact exposure. These scenarios do not represent what will occur with the labeled use patterns. Therefore, Tier II studies are not necessary to assess the risks of these uses and the EPA has not required they be submitted.

### **III. Failure to Follow the FIFRA Risk/Benefit Standard**

Many commenters stated that EPA failed to follow the statutory risk/benefit determination process in the proposed decision. They made the following assertions:

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<sup>18</sup> <https://www.epa.gov/pollinator-protection/how-we-assess-risks-pollinators#overview>

Comment 0423<sup>19</sup>: “We believe that the removal of cotton from the Section 3 label is based on unfounded assumptions related to certain pollinators, and we believe that the EPA should better comply with FIFRA’s risk-benefit analysis and base rules that are absolutely supported by exposure data and science.”

Comment 0455<sup>20</sup>: “Further, it appears that EPA has failed to comply with FIFRA’s risk-benefit analysis mandate and has taken an overly precautionary position that is not supported by available exposure data.”

Comment 0457<sup>21</sup>: “Most disturbingly, it appears as though EPA has taken a “precautionary” approach to reducing exposure to pollinators rather than conducting a cost-benefit analysis that weighs bee losses against economic crop losses and increased use due to using less effective pesticides. This is most troubling and goes against EPA’s mandate.”

Comment 0511<sup>22</sup>: “Additionally, we believe the agency has failed to meet its obligation under FIFRA which requires a risk-benefit assessment.”

Comment 0514<sup>23</sup>: “We believe that the removal of citrus from the Section 3 label is based on unfounded assumptions related to certain pollinators, and we believe that the EPA should better comply with FIFRA’s risk-benefit analysis and base rules that are absolutely supported by exposure data and science.”

Comment 0515<sup>24</sup>: “USDA requests a fuller explanation of the FIFRA-mandated risk-benefit analyses that would restrict use of this material to post-bloom, only, or from use on the crops that have been removed from the previous sulfoxaflor label (citrus, cotton, cucurbits, soybeans, and strawberry).”

Comment 0519<sup>25</sup>: “...Our Associations believe there has be a failure to comply with FIFRA’s risk-benefit analysis and has taken an overly precautionary stance that is not supported by data.”

Comment 0526<sup>26</sup>: “The NCC further requests the EPA to recognize that the EPA provided no “benefits” analysis for the removal of cotton, soybeans, strawberry, cucurbits and citrus. The NCC requests compliance with FIFRA’s risk-benefits mandates.”

Comment 0528<sup>27</sup>: “NASDA has several concerns with a number of elements under EPA’s proposed registration, which does not comply with its obligations under FIFRA’s risk-benefit analysis.”

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<sup>19</sup> Agriculture Council of AR

<sup>20</sup> Plains Cotton Growers, Inc.

<sup>21</sup> MS Farm Bureau

<sup>22</sup> AZ Farm Bureau

<sup>23</sup> TX Citrus Mutual

<sup>24</sup> USDA OPMP

<sup>25</sup> CA Cotton Ginners & Growers Association

<sup>26</sup> National Cotton Council

<sup>27</sup> NASDA

Comment 0537<sup>28</sup>: “we believe EPA should aggressively meet its mandate to provide growers with the tools they need to manage their operations in a scientifically sound, environmentally friendly manner that promotes efficiency and productivity.”

Comment 0542<sup>29</sup>: “According to the proposal, the agency has made the decision to adopt a “no risk,” and “no exposure” approach for bees to crop protection tools. While the focus of this proposal is sulfoxaflor, there is no reason to believe the approach would be limited to sulfoxaflor and creates a decision matrix that places bees above all else, including feeding and clothing our population. The agency has chosen this path without calculating the risks to bees and no evaluation of the lost benefits to crops like cotton, citrus, cucurbits, soybeans and strawberries. To call this anything other than an adoption of the “precautionary principle” is to either misunderstand the phrase or ignore the realities.”

Comment 0551<sup>30</sup>: “MDAC urges the EPA to use risk/benefit principal when evaluating tools and production practices that are incorporated on Mississippi’s more than 37,000 farms.”

Comment 0559<sup>31</sup>: “According to the proposal, the agency has made the decision to adopt a “no risk,” and “no exposure” approach for bees to crop protection tools. While the focus of this proposal is sulfoxaflor there is no reason to believe that the approach would be limited to sulfoxaflor and creates a decision matrix that places bees above all else, including feeding and clothing our population. The agency has chosen this path without calculating the risk to bees and no evaluation of the lost benefits to crops like cotton, citrus, cucurbits, soybeans and strawberries.”

### **The EPA’s Response:**

The EPA recognizes that FIFRA is a risk/benefit statute and we apply this principle daily in our regulatory decisions. The Ninth Circuit Court in their decision to vacate the sulfoxaflor registration disagreed with the EPA’s conclusion that the benefits of sulfoxaflor outweighed the environmental risks. The Court cited the “precariousness of bee populations” in their determination that sulfoxaflor poses “unreasonable adverse effects. Further, the Court ordered the EPA “to obtain further studies and data regarding the effects of sulfoxaflor on bees, as required by EPA regulations.”

In acknowledgement of the Court’s decision and the Court’s order, the EPA is unable to grant a registration that would need to be based on those additional studies before those studies have been submitted. Accordingly, DAS has amended their application to include only uses which the EPA has determined will not require additional studies to inform a risk determination. The registration is structured to allow sulfoxaflor to be used by some growers, giving them access to a new mode of

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<sup>28</sup> American Farm Bureau Federation

<sup>29</sup> National Sorghum Producers

<sup>30</sup> Commissioner, Agriculture and Commerce, State of MS

<sup>31</sup> Delta Council

action that poses less risk to other non-target organisms while additional studies are conducted. Bees are not expected to be in these fields or orchards under the limits of this label and any exposure is negligible. The EPA agrees that the use patterns and crops on this sulfoxaflor label are not the ones that are most valuable and of most critical need, including against Asian citrus psyllid in citrus orchards and Tarnished Plant Bug in cotton, sorghum and strawberry fields. DAS is welcome to apply for additional uses when they have the additional studies ready to submit.

#### **IV. Unreasonable Adverse Effects Standard**

Comment 0557<sup>32</sup> asserts that “The EPA cannot meet [the unreasonable adverse effects standard] without requiring, evaluating, and considering all information that causes adverse effects from use of this pesticide.”

##### **The EPA’s Response**

All required information about adverse effects for these uses has been submitted and the EPA has considered it all in making its determination that the benefits of these uses outweigh their risks.

#### **V. Failure to Consult Under the Endangered Species Act**

Comment 0557 states: “The EPA must comply with its duties under Section 7 of the Endangered Species Act (ESA) including completion of consultation before final registration. Similarly, comment 0544<sup>33</sup> states: “...EPA cannot approve the proposals prior to the completion of consultations with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service, which it has failed to do for either the original or the revised actions.”

##### **The EPA’s Response**

The agency acknowledges the comments from the Center for Biological Diversity (CBD)<sup>34</sup> and others regarding the duty to consult with the U.S. Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS) in regard to risk to endangered species. These considerations are encompassed in the extensive efforts and resource investments the Agency is focusing to assess impacts to listed species in the Agency’s registration review program for currently registered pesticides. The EPA believes that, as a general matter, older chemistries present a greater degree of risk to listed species than most new chemistries coming to market. The EPA strongly believes that this includes sulfoxaflor, since registration standards have increased over time. Therefore, it is environmentally preferable in most circumstances for the EPA to focus resources to assess the impacts of existing pesticides sooner in the process than newer pesticides that have been held to

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<sup>32</sup> Center for Biological Diversity

<sup>33</sup> Center for Food Safety

<sup>34</sup> Comment 0557

higher standards to meet current registration requirements such as new guideline studies to assess risk to additional species and through new exposure pathways.

As a result, the EPA does not believe the environment or the public would be best served by delaying the registration of sulfoxaflor to complete consultation. Focusing the EPA's, FWS', and NMFS' limited resources on completing a consultation on the effects of sulfoxaflor would by necessity come at the expense of putting more resources into evaluating – and consequently regulating, where appropriate - what the EPA believes to be more toxic compounds, that, among other things, pose greater risk, to endangered species than does sulfoxaflor. It is important to understand that the development of the Interim Approaches does not by its terms suggest that existing or recently developed risk assessments using the criteria articulated in OPP's 2004 Overview document<sup>35</sup> are necessarily "under-protective." The Interim Approaches are intended to identify interim thresholds for interagency review as the Agencies jointly work to implement the recommendations of the National Academy of Science on certain specific registration review actions. The Agencies have made no determination that these thresholds are necessary to prevent take and preclude likely jeopardy and, in any case, the Interim Approaches do not establish legally binding thresholds for consultation under the Services' implementing regulations. As the EPA and the Services work through the initial actions that are being reviewed under the Interim Approaches, the Agencies will determine whether these thresholds should be modified before they are extended more broadly to additional regulatory actions. The details of the joint Interim Approaches are contained in the white paper *Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April/2013 Report*, dated November 1, 2013.<sup>36</sup>

For the reasons explained above, the EPA is not consulting with the Services on the registration of sulfoxaflor.

## **VI. Requirement for an On-Field Buffer**

Several comments were received supporting the concept of the on-field buffer zones (also referred to as an “in-field buffer”) with the caveat that the agency had not gone far enough with the 12-foot restriction. Comment 0548<sup>37</sup> cited a study on the drift of ten herbicides after a tractor spray application that reported detection of spray drift up to 150 meters from the treated site. They also cited recommendations from the National Marine Fisheries Service for buffer zones to protect aquatic organisms from runoff and from the Xerces Society to protect foragers from drift along field margins. The comment recommends a buffer zone for sulfoxaflor of at least 20 – 50 feet. Comment 0509<sup>38</sup> states “The border areas which carry or catch water off the field will retain moisture longer than the field. This will result in bloom occurring in those border areas longer than the crop on the field.” The commenter believes that it is preferable to remove this “potentially contaminated forage” than to allow a “contamination risk to managed and native pollinators.”

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<sup>35</sup> <https://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf>

<sup>36</sup> <https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf>

<sup>37</sup> Beyond Pesticides

<sup>38</sup> Thomas R. Smith, AZ

Thirty three commenters submitted substantive objections to the on-field buffer zone restriction. The predominate concerns were that the on-field buffer zones would create a refuge for the pests within the fields leading to reinfestations; the farmers would have to apply more pesticides which would lead to more negative impact on non-targets and beneficials; growers that have been planting bee attractive flowers in-between fields/rows to promote the health of bees will probably just mow them down so as to not have to follow the restriction; and the cost will be prohibitive especially in agricultural production. Text from some of these comments include the following:

Comment 0419<sup>39</sup>: “Aphid populations first develop around the edge of the field and they work their way towards the middle. Imposing a 12 foot buffer strip around the edge of the field would cause problems.... It would not take long for the aphids in the buffer zone to come back and bring the field above threshold. There would be more resprays, more insecticides used, and lower yield. I want to use as little as insecticides as possible and I feel this buffer proposal would cause more insecticides to be used.”

Comment 0465<sup>40</sup>: “An in-field buffer would increase risks of crop damage, reduce crop acreage, increase management complexity for growers, increase pest pressure, and reduce economic returns for growers. It is important that the agricultural industry has the needed tools to manage pests in crop production.”

Comment 0513<sup>41</sup>: “The 12 foot downwind on-field buffer would be extremely difficult for growers to accomplish. To comply with this, growers would basically have to restrict applications to ground machinery and make applications when there is no wind at all or leave an in-field buffer. Not only would these practices be an economic burden to growers, but could also have inadvertent negative impacts on pollinators. In many instances initial insect infestations begin along the margins of fields and spread across the field as populations increase. In these situations, border treatments can be highly effective at preventing infestations across the entire field. This practice has several economic and ecological benefits, which include lower costs for growers and less total area treated. On-field buffers would prohibit this management strategy in many cases. Prohibition of border treatments, especially in irregular shaped fields, would result in large areas that would serve as reservoirs of insect pests that would infest the remainder of the field. This would result in increased total insecticide applications to the entire field. In-field buffers would have similar impacts, but with a much larger magnitude. The result of both would be increased insecticide applications to fields.”

Comment 0515<sup>42</sup>: “For growers that forgo producing in areas that are subject to buffers, impacts vary by field size. Average field sizes associated with specific crops also varies. For example, the average canola field in the United States is approximately 60 acres, while a typical eggplant field is two acres (USDA FSA, 201 0-2014). A 12 foot buffer on a 2:1 rectangular canola field is expected to result in about 1% of the field being subject to the buffer; however, for an eggplant field this *loss* is around 6%. Note these estimates reflect

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<sup>39</sup> River Region Coop, Brown County, MN

<sup>40</sup> R. Long, Farm Advisor, UCA Cooperative Extension, Yolo County, CA

<sup>41</sup> D. Cook, Research Entomologist, MSU

<sup>42</sup> USDA OPMP

average size fields, although in many cases the percent of land impacted could be significantly higher for smaller fields. Impacts will also vary depending on the shape of the field.”

Comment 0525<sup>43</sup>: “Common concerns regarding the proposed 12-ft buffer relate to potential impacts to on-farm biodiversity. The inclusion of blooming plants on the perimeter of agricultural fields is a practice that provides habitat for beneficial insects, resulting in effective natural pest control and a reduction in the use of pesticides. Researchers, extension agents, and crop consultants have made significant investments in encouraging growers to increase this type of biodiversity on their farms. While in general, buffers can be compatible with on-farm biodiversity, imposing a buffer for sulfoxaflor could result in growers being forced into either choosing a potentially more toxic product that does not have the same buffer requirement, increasing potential negative impacts to pollinators, or removal of flowering plants adjacent to fields, in order to accommodate the restriction. This type of decision-making could negatively impact the continued and desirable use of on farm flowering plants and insectary planting, and could indirectly encourage the removal of on-farm biodiversity and diverse floral resources, which would degrade not only the success of pollinators, but also the ability of natural enemy populations to offer effective pest control services.”

The Delta Research and Extension Center (comment 0560<sup>44</sup>) reported that they “recommend eliminating flowering hosts adjacent to cotton fields that serve as a source of infestations. This practice, in and of itself, should be sufficient to minimize the exposure of pollinators without having explicit restrictions stated on the label. Currently, growers make border sprays during times of heavy plant bug migration into cotton fields. This involves spraying the first 40-50 feet of cotton on the edge of a cotton field to minimize migration across the entire field.”

### **The EPA’s Response:**

The EPA’s proposal to require an on-field buffer for sulfoxaflor treated fields was intended to eliminate any potential risk to bees when they are foraging on blooming vegetation that is present on the down-wind edge of the field. Because the buffer eliminates risk to bees, the EPA has determined that no additional data is needed to assess the effects on bees before granting registration with these uses.

It is important to note that the EPA assumed in the assessment of sulfoxaflor drift that 100% of the bees’ diet will come from this blooming border. This is a very conservative assumption and does not reflect regular foraging behavior. It is notable that even with the 100% dietary assumption, the area of concern is only 12 feet. Despite this fairly shallow border, commenters opposed to requiring a protective on-field buffer cited a number of problems that leaving even a small area of the field untreated would cause.

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<sup>43</sup> K. Smith, Integrated Plant Protection Center. OR State U, on behalf of Western IPM Center

<sup>44</sup> Jeffrey Gore, Associate Professor, Delta Research and Extension Center. MSU

By imposing the on-field buffer, the EPA acknowledges that the performance of sulfoxaflor could be altered, resulting in sublethal dosing from drift into the buffer zone which will encourage a much faster development of insecticide resistance by the target pests. The buffer zones may become holding/breeding grounds for these pests and will likely require farmers to make additional applications of insecticides or increase application rates to compensate, which runs counter to risk management goals. This practice could exacerbate an “edge effect” which would be particularly problematic for certain pests. Farmers may resort to use of other/harsher and more broad-spectrum chemistries in conjunction with sulfoxaflor to kill the same pests (i.e., organophosphates, pyrethroids, neonicotinoids). We understand that these are bad outcomes but the agency’s approval of this registration is limited by the Court Order requiring the EPA to obtain additional data. When more data is submitted, the EPA will reconsider the buffer requirement.

The agency acknowledges that requiring the 12 foot on-field buffer may cause undue hardship on growers and is not warranted by the potential risk posed by drift in the conservative assessment. However, as a potential risk was identified in the conservative assessment, the EPA acknowledges the comments from two parties (0509 and 0560) that blooming vegetation on the field edge should be removed.

## **VII. Uncertainty in Potential Synergistic Effects Related to Tank Mixing**

Over 50 commenters submitted substantive objections to a tank mix restriction on sulfoxaflor. Objections to the tank mix restriction cited concerns such as increased labor, fuel and management costs which would raise the cost of commodities, adverse impacts on IPM programs, cause greater environmental contamination from multiple field treatments and provoke the switch from target pest specific compounds to broad spectrum products such as organophosphates. Highlights from some of the comments include the following:

Comment 0420<sup>45</sup>: “The potential restriction on tank mixing sulfoxaflor with other pesticides without specific issues identified is a potentially disastrous precedent. If specific tank mix partners have been identified as a problem, these should be specified on the label. To propose restrictions based on “potential” synergism without any data indicating such would open all pesticide labels to similar considerations. Attempts to evaluate all potential combinations of pesticides would be unmanageable and waste valuable resources”

Comment 0428<sup>46</sup>: “The ability to combine and mix pesticides is a vital tool for the American farmer. Such activities have been taking place for decades as a method of practical and effective pest control. Tank mixing offers both economic and environmental benefits on the farm. Such activities serve an important part of integrated pest management, reduce energy usage, employee time and reduces agriculture's carbon footprint with few trips over the field”

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<sup>45</sup> Anonymous

<sup>46</sup> GA Agribusiness Council

Comment 0457<sup>47</sup>: “If EPA has specific knowledge of tank-mixes that have synergistic effects, or has scientifically defensible information that suggests there are synergistic effects, that information should be included in the docket. Otherwise, we would not support a restriction based on speculation, uncertainty, or as a precautionary measure”

Comment 0465<sup>48</sup>: “Prohibiting or limiting tank mixing and requiring extensive research on every conceivable tank mix would severely inhibit US growers from managing pests efficiently and effectively. It would substantially increase application costs, the carbon footprint created by multiple applications and ultimately the cost of US agricultural commodities”

Comment 0499<sup>49</sup>: “To be of value to growers, the label should permit tank mixing with other products (i.e. foliar fertilizers, etc..) which are almost always applied at the same time as pesticide inputs. It is not practical or feasible for a grower to spray a single product at a time across 100s if not 1000s of acres and be able to maintain the health and economic viability of their operations”

Comment 0501<sup>50</sup>: “...I don't see any scientific justification for how tank mix restrictions will provide any useful contribution to risk mitigation. They will only hinder integrated pest management strategies, detract from resistance management programs, and prevent growers from targeting two different life stages of the same pest with narrow-spectrum insecticides. This has the potential to significantly increase the use of broad-spectrum organophosphates, carbamates, and pyrethroids that growers are trying to avoid and that have greater environmental risks than the newer products being restricted”

Comment 0508<sup>51</sup>: “...achieving enhanced activity against one pest is not the objective of tank-mixing in our IPM systems, rather the intent is to achieve cross- or broad-spectrum insect control rather than enhanced or synergized activity against a single pest. Finally, and perhaps most importantly, because there is a lack of scientific data on the risks of tank-mixtures causing unreasonable adverse effects on pollinators and non-target enemies, I don't believe it is advisable for EPA to restrict tank-mixing on sulfoxaflor or other insecticide registrations until such time data becomes available to support such an assumption”

Comment 0513<sup>52</sup>: “Generally, a single insecticide will not provide satisfactory control of all insect pests (especially if the insect pests are in different insect orders, ex. Lepidoptera and Hemiptera) that are present due to numerous factors including insecticide resistance and the more narrow spectrum of activity of newer insecticides”

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<sup>47</sup> MS Farm Bureau Federation

<sup>48</sup> R. Long, Farm Advisor, UCCE Yolo County

<sup>49</sup> M. Rogers, UF/FAS/Citrus Research & Education Center

<sup>50</sup> D. Haviland, Extension Entomologist, U CA

<sup>51</sup> J. Palumbo, Professor, U AZ

<sup>52</sup> D. Cook, Research Entomologist, MSU

Comment 0515<sup>53</sup>: “A prohibition on tank mixing of sulfoxaflor with other insecticides to control co-occurring insect pests, or mixing with fungicides and bactericides to manage co-occurring diseases will render its use impracticable, and in effect will act as a de-facto ban”

Comment 0542<sup>54</sup>: Tank mixing also allows for growers to carefully plan when applications are made while also providing the flexibility for timely applications in responding to pest pressure. With significant breaks in applications, growers can work with applicators and pest scouts to make informed decisions on the timing of treatments. Shifting to a single chemistry per application approach would stretch the availability of applicators beyond their current capacity and require applications to be scheduled well in advance. This would cause the end of integrated pest management programs and require farmers to “calendar” pesticide treatments rather than making informed decisions based on observed circumstances in the field.

One comment in favor of a tank mix restriction for sulfoxaflor stated: “EPA continues to ‘presume,’ be ‘somewhat uncertain,’ acknowledge “chemical companies have made claims,” and is “under the assumption that synergism is not occurring” in tank mixed chemicals.” (Comment 0503<sup>55</sup>). Another party stated that the EPA must prohibit tank mixtures unless it is certain they will not cause synergistic effects (comment 0557<sup>56</sup>).

### **The EPA’s Response:**

The EPA acknowledges the benefits of tank mixing. The reasons they have provided are logical and quantifiable. Tank mixing uses less fuel and there are less equipment emissions from fossil fuels when applications can be made by one trip into or over the field rather than multiple trips. Comment 0515<sup>57</sup> states that the economic impacts on growers from tank mix restrictions are expected to be severe. This comment provides detailed economic information using the example of apple growers and the resulting impact on them from blanket tank mix prohibitions. West coast apple producers would experience an increase of 200-750% in the number of field passes, and East Coast producers would experience an increase in field passes of 150-369%. In addition to this substantial increased fuel use, it is clear that tank mix prohibitions could result in much greater risk to applicators and workers. Farming has been ranked as one of the most dangerous jobs in the country.<sup>58 59</sup> The EPA notes that we must take into account the physical burden the tank mix restriction places on the human resources involved in agricultural production, as well as the increased exposure they would experience from multiple pesticide applications.

Comment 0515 also notes that prohibiting tank mixing will also cause greater soil compaction from repeated passes of tractors and sprayers that will result in less productive agricultural systems. In maintaining productivity, growers also follow integrated pest management programs

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<sup>53</sup> USDA OPMP

<sup>54</sup> National Sorghum Producers

<sup>55</sup> Pollinator Stewardship Council

<sup>56</sup> Center for Biological Diversity

<sup>57</sup> U.S. Department of Agriculture, Office of Pest Management Policy

<sup>58</sup> <http://www.agweb.com/article/farming-construction-rank-among-most-dangerous-jobs--naa-associated-press/>

<sup>59</sup> <http://time.com/4326676/dangerous-jobs-america/>

that inform the use of pesticides in order to maintain their efficacy by avoiding the development of resistance. Historically, the EPA has encouraged tank mixing in IPM programs and provides guidance on resistance management. In Pesticide Registration (PR) Notice 2001-5, “Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling”<sup>60</sup> the EPA states that one pest control strategy is rotating pesticides and/or using tank mixtures or premixes with different mode/target sites of action. The labels for the sulfoxaflor products Closure and Transform both follow the guidance of PRN 2005-1. Rather than applications of broad spectrum insecticides that act against multiple insect species and life stages, the EPA supports a more targeted approach. Additionally, the sulfoxaflor labels state that applications should be made when field scouting indicates target pest densities have reached the economic threshold.

The one comment (0503) that supported the tank mix restriction on sulfoxaflor did not provide any solid reasons that would suggest that tank mixes are harmful to bees but alluded to “uncertainty” in the EPA’s risk conclusions. The agency acknowledges that there will always be uncertainties in ecological risk assessments but accounts for these by making conservative assumptions. Examples include assuming that foraging bees will obtain 100% of their diet from blooming plants in a treated field.

The EPA recognizes the importance of exposure to mixtures but assesses the environmental exposure of a single active ingredient (USEPA, 2004<sup>61</sup>). There are many types of environmental mixtures. First, some pesticides might contain more than one active ingredient, or in the case of formulated end-use products, they contain additional chemicals that are typically designated as inerts which are specific to each product. Second, pesticides are often mixed with other chemicals before their application. (*e.g.*, tank mixes with other pesticides, fertilizers, and adjuvants). Third, chemicals from other sources are already in the environment (*e.g.*, environmental mixtures). Ideally, assessments should be based on exposure to all pesticide components and to other chemicals that are present in the environment. However, quantitative estimates of exposure to environmental mixtures are difficult given the dynamic state of environmental mixtures over space and time. In any given location, the amounts of pesticide active ingredients, inerts, adjuvants, and other environmental chemicals are highly variable and depend on pesticide uses and other sources of environmental contamination. A quantitative assessment of the risk posed by chemical mixtures requires extensive data, including data on the identity, concentration, and toxicity of mixture components. Challenges in assessing risk to species posed by mixtures of chemicals including pesticides arise largely because of the lack of such data and the lack of understanding of the potential for interactions among mixture components. In the absence of such quantitative data, the possible contribution of specific mixture components to the toxicity of a pesticide active ingredient cannot be incorporated into a quantitative risk assessment. Ecological risk assessments are generally conservative, using unrefined assumptions such as assuming 100% contamination of food sources. The conservative nature of the assessment overestimates risk from each pesticide used on its own. Thus, a mixture would incorporate the individually applied conservative assumptions and represent a margin of protection.

If, however, evidence from incidents or field observations suggest that tank mixed products may be impacting non-target organisms, the EPA may require additional studies to be conducted.

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<sup>60</sup> <https://www.epa.gov/sites/production/files/2014-04/documents/pr2001-5.pdf>

<sup>61</sup> <https://www.epa.gov/endangered-species/ecological-risk-assessment-process-under-endangered-species-act>

Studies of tank mixes conducted by independent researchers can be and have been used to inform risk assessments.

The EPA is not aware of any information from the field use of sulfoxaflor applied as tank mix that resulted in adverse incidents. However, the EPA also acknowledges that at least some information exists in patent applications that suggests sulfoxaflor has a synergistic effect with the following eight active ingredients:

- Five Insecticides: Spinosad, Spinetoram, Gamma-cyhalothrin, Methoxyfenozide, Chlorpyrifos
- One Herbicide: Halauxifen-methyl
- Two Fungicides: Penflufen, Mandestrobin

The EPA has not reviewed the information or data (if any) that were submitted to the U.S. Patent Office to support the claims of synergy. Until the EPA has reviewed the information, it is requiring a restriction on the sulfoxaflor end-use product labels that prohibit tank mixing with the eight active ingredients listed above. If the agency determines that true synergistic effects with a particular active ingredient do not exist, DAS may request an amendment to remove that active ingredient from the list of restricted tank mix combinations.

## **VIII. Clarification of Prohibition to Crops Grown for Seed Production**

Sulfoxaflor was proposed for use on commercial turf. It will not be registered at this time for crops grown for seed. Commenter 0496<sup>62</sup> requested clarity on whether turf grown for seed is included in this restriction.

Comment 0509<sup>63</sup> states that sulfoxaflor could be safely applied to a turf grass and a number of crops grown for seed if applied after petal fall and notes that these seed crops are very vulnerable to pests from petal fall to harvest.

### **The EPA's Response**

The prohibition against crops grown for seed production does apply to turf grass grown for seed. In the amended submission, DAS did not request use on all crops grown for seed.

## **IX. Sulfoxaflor Labeling**

Commenter 0503<sup>64</sup> states that sulfoxaflor should be labeled with the bee icon and Pollinator Protector Box that were imposed on the four nitroguanidine neonicotinoids and two other acutely toxic compounds.

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<sup>62</sup> The Scotts Company

<sup>63</sup> Thomas R. Smith

<sup>64</sup> Pollinator Stewardship Council

Commenter 0503 objects to the proposed labeling that states that risk to managed bees and native pollinators can be minimized when applications are made when the temperature is below 55°F.

### **The EPA's Response**

Beekeepers and other stakeholders - including comment 0503's organization - were highly critical of the bee icon/Pollinator box, and so the agency has decided not to require that labeling on other compounds. Instead, acknowledging the early success of state programs in fostering communication between beekeepers and growers as noted by comment 0560<sup>65</sup>, the EPA has encouraged state and tribal agencies to develop and implement local pollinator protection plans, known as Managed Pollinator Protection Plans (MP3s) and has incorporated the concept into the agency's "Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products."<sup>66</sup> Further, comment 0511<sup>67</sup> does not agree with imposing label restrictions on sulfoxaflor and believes that "The EPA has failed to evaluate current practices to protect bees and state MP3 as methods to mitigate bee exposure."

Under this registration decision, sulfoxaflor will be used on crops that are not attractive, or are not in bloom. The crops will not be usable as a forage site for bees and other pollinators. Thus, the pollinator protective labeling that was on the original labels is not relevant to these use patterns.

## **X. Incident Reporting**

Comment 0503<sup>68</sup> states that the EPA's "Ecological Incident Information" was "a good idea that failed years ago." They also believe that the Agency's incident system is "broken" and conveys little data.

### **The EPA's Response**

The EPA has dedicated significant resources so that pesticide incidents involving bee kills may be directly reported to [beekill@epa.gov](mailto:beekill@epa.gov). This link is clearly represented on the EPA's Pollinator Protection website with an icon that is very prominent<sup>69</sup>. This link has been advertised in bee journals and presented at numerous public meetings. Staff of the EPA's Environmental Fate and Effects Division directly contact and interview people submitting incidents. Incidents are also reported to the National Pesticide Information Center (NPIC)<sup>70</sup> and these are referred to the EPA. Again, the EPA staff follow-up on these reports.

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<sup>65</sup> J. Gore, Delta Research and Extension Center, MSU

<sup>66</sup> <https://www.epa.gov/pollinator-protection/proposal-protect-bees-acutely-toxic-pesticides>

<sup>67</sup> AZ Farm Bureau Federation

<sup>68</sup> Pollinator Stewardship Council

<sup>69</sup> <https://www.epa.gov/pollinator-protection>

<sup>70</sup> <http://pi.ace.orst.edu/erep/>

Historically, commercial beekeepers in particular have shown great reluctance to report incidents. State Lead Agencies and the EPA have been told that beekeepers do not wish to offend growers who either hire their pollination services, or allow them on their land. The EPA is also aware that some beekeepers are concerned that residues of pesticides used in their hives illegally to control Varroa mite or other pests may be discovered during the investigation. However, the EPA has reached out continuously, both on an individual basis, and publicly to convince beekeepers of the importance of incident information and to urge beekeepers to report incidents.

Finally, under FIFRA section 6(a)(2), pesticide registrants are legally required to submit factual information regarding unreasonable adverse effects on the environment. Such incident reports on bee kills have provided useful information on residues (or lack thereof) that were later corroborated by the state lead agencies. Further, incident reports have been submitted to the Agency reporting adverse effects in on-going studies in the European Union. These reports have alerted the EPA to effects well before the study was completed and are used to inform risk assessments.

## **XI. Sulfoxaflor is Systemic**

Some commenters opposed to sulfoxaflor, including 0548<sup>71</sup> and 0558<sup>72</sup>, have expressed concern that it is a systemic insecticide and therefore should not be registered.

### **The EPA's Response**

Insecticides that are systemic are soluble in water which means they can be absorbed by the plant and moved around in its tissues.<sup>73</sup> Sulfoxaflor is xylem-mobile and follows the direction of water transport in the plant, meaning it travels upward through the stem or trunk of the plant and outward in the leaves and shoots. It is also absorbed by the leaves. Applications of sulfoxaflor in the U.S. are made only as sprays directed at the plant's foliage. A study examining movement from leaf surfaces indicated little movement of <sup>14</sup>C-labeled sulfoxaflor when applied to the cotton leaf (mainly outward to leaf edge).<sup>74</sup> Sulfoxaflor has not been proposed for use as a "systemic treatment" where it would be carried upward in the stem from the roots, and it was never used that way. It is not applied in the U.S. as a seed treatment, through drip irrigation, or as a soil drench.

Compounds like sulfoxaflor that are water soluble and thus systemic, are not a new development. Aldicarb, a carbamate insecticide, is systemic and was registered in 1970.<sup>75</sup> Dimethoate, an organophosphate, is systemic and was registered in 1962.<sup>76</sup> Both compounds are currently registered for use in the U.S. Systemic insecticides are particularly effective on sap feeding insects such as psyllids, aphids, whiteflies and stinkbugs. These insects pierce the

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<sup>71</sup> Beyond Pesticides

<sup>72</sup> Earthjustice

<sup>73</sup> <http://citybugs.tamu.edu/factsheets/landscape/sapfeed/ent-6006/>

<sup>74</sup> Environmental Fate and Ecological Risk Assessment for Sulfoxaflor Registration; OPP-2010-0889-0022

<sup>75</sup> [https://www3.epa.gov/pesticides/chem\\_search/reg\\_actions/reregistration/red\\_PC-098301\\_1-Sep-07.pdf](https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-098301_1-Sep-07.pdf)

<sup>76</sup> [https://archive.epa.gov/pesticides/reregistration/web/pdf/dimethoate\\_ired\\_revised.pdf](https://archive.epa.gov/pesticides/reregistration/web/pdf/dimethoate_ired_revised.pdf)

plant and suck the juices, often at the same time transmitting diseases as mosquitoes do to humans. Sulfoxaflor stays in the leaf tissue, moving to the leaf margin where these pests can access it. Multiple sprays across the field as done with broad-spectrum insecticides like pyrethroids is not necessary when the leaf tissue retains the insecticide. The targeted activity of systemic insecticides is beneficial to growers. Because a compound is water soluble and can move systemically through a plant, it is not a reason to not register it. The properties of these pesticides are adequately assessed, for example, by reviewing nectar and pollen residue data.

## **XII. Post Bloom Applications Are Not Sufficient**

Comment 0557<sup>77</sup> alleges that restricting the use of sulfoxaflor to non-attractive crops, crops harvested before bloom and to post bloom only for certain attractive crops will not sufficiently protect pollinators. They note that “an unknown number of fields may have blooming flowers and weeds within the field at times when the crop itself is not blooming...” They state that EPA did not analyze for this possible exposure. They also state that the EPA did not account for solitary bees that may nest in the ground of the treated field and therefore the EPA cannot claim there is essentially no exposure to bees on the treated field.

### **The EPA’s Response**

The EPA stands by its conclusion that by limiting the use pattern for sulfoxaflor as described in the proposed decision, there is essentially no exposure to bees on the treated field. The agency does not think it is necessary to require growers to scout their fields to locate any blooming weeds and remove them mechanically or chemically. Growers, however, are provided with information about best management practices for protecting bees through other parties. This information from groups such as the Pollinator Partnership in their document “Securing Pollinator Health and Crop Protection”<sup>78</sup> includes recommendations to remove weeds from orchards and fields.

Based on the approved sulfoxaflor use patterns, solitary bees that may nest in the ground of the treated field would forage off the field. The sulfoxaflor products Transform and Closer are short-lived in the field as indicated by the RT25 data. Sulfoxaflor also has a half-life of less than one day when it hits the soil system. While the EPA acknowledges the potential for risk to these solitary species, exposure has been mitigated by the label restrictions and the characteristics of the compound.

## **XIII. Section 18 Authorizations**

Two parties took issue with the authorization of FIFRA section 18 emergency exemptions for the use of sulfoxaflor by growers experiencing serious pest situations. In 2016, the EPA authorized a number of section 18s for use by cotton growers against Tarnished plant bug (*Lygus* bugs), and for sorghum growers against Sugarcane aphid. Both of these pests were expected to cause significant

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<sup>77</sup> Center for Biological Diversity

<sup>78</sup> <http://pollinator.org/PDFs/SecuringPollinatorHealthCropProtection.pdf>

economic losses to growers. Comment 0557<sup>79</sup> states that the EPA must take into account the additive and cumulative effect on all pollinators from the proposed registration and the section 18 uses. Comment 0503<sup>80</sup> states that EPA should not authorize any more section 18s until USDA has completed a study on the efficacy of certain pesticides on pests of alfalfa, including Lygus bug.

### **The EPA's Response**

Section 18 of FIFRA authorizes the EPA to exempt State and Federal agencies from any provision of FIFRA, if EPA determines that emergency conditions exist which require an exemption. The EPA can exercise this authority through the procedures in 40 CFR Part 166 to allow the emergency use of pesticides. In the case of the exemptions authorized for cotton and sorghum, the growers were faced with serious pest situations for which there were no registered alternatives. Substantial losses would have been incurred without the ability to use sulfoxaflor. In regard to the threat posed by the Sugarcane aphid to sorghum, comment 0423<sup>81</sup> wrote: "The bug if left uncontrolled is known to cause near total crop loss." Section 18s are time-limited and are re-evaluated before they are reauthorized. For the cotton and sorghum requests, the EPA's evaluation did not determine an unreasonable risk to bees that would warrant denial of the requests.

As discussed in the proposed decision, sulfoxaflor is very short-lived in the field, the toxicity of residues studies demonstrated that an RT25 value was too low to calculate. We would not expect an "additive" or "cumulative" effect on pollinators because the compound goes away. Additionally the timing of pest treatments varies from crop to crop and applications of sulfoxaflor have labeled intervals with recommendations to rotate to another chemistry for pest resistance. It seems that the commenter is theorizing that different crops that may be treated with sulfoxaflor would all be in bloom at the same time and have a co-occurrence of a labeled target pest so that applications of sulfoxaflor are made on the same day at the same time to multiple sites and that pollinators are moving from treated field to treated field and get a continuous, ie. "additive" exposure. The EPA does not agree that this is a realistic scenario.

Regarding an ongoing alfalfa efficacy study apparently underway by USDA's Agricultural Research Service, it is unclear why commenter 0503 feels it is necessary or beneficial for the EPA to wait for the completion of the study. It is also not clear what information it would provide that would be useful to the Agency. As has been noted in the past, the FIFRA Emergency Exemption program has long supported the beekeeping industry. More section 18 authorizations have been issued to help beekeepers than have been issued to any other group. Certainly beekeepers would not agree with the EPA delaying an authorization decision on their emergency exemption requests to wait for a completion of a study that is unrelated to their need.

## **XIV. Use of Alternative Chemistries**

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<sup>79</sup> Center for Biological Diversity

<sup>80</sup> Pollinator Stewardship Council

<sup>81</sup> Andrew Grobmyer, Agricultural Council of AR

Comment 0557<sup>82</sup> states that the EPA's assertion that sulfoxaflor will replace older chemistries that present greater risk is not supported. They state that the EPA must "include a term in the new registration that requires the registrant to reduce sale or distribution through amended registration of other procedures."

### **The EPA's Response**

Other commenters do support the EPA assertion that sulfoxaflor will replace older chemistries that present a greater risk. Comment 0419<sup>83</sup> stated that sulfoxaflor works on pyrethroid-resistant aphids and that "the only other options to use are the organophosphates, which are more dangerous to use." Comment 0525<sup>84</sup> states "With its previous registration in strawberry, sulfoxaflor was a replacement for neonicotinoid, synthetic pyrethroid, and organophosphate chemistries that had been previously used to control aphids." Comment 0560<sup>85</sup> concurs, writing "Without sulfoxaflor, growers will be forced to use more toxic and broad spectrum insecticides at much higher rates."

The EPA cannot affect the sale and distribution of other pesticides through the registration of products containing sulfoxaflor.

## **XV. "Chemical Trespass"**

In their comment<sup>86</sup> The Pollinator Stewardship Council objected to the registration of sulfoxaflor due to possible off-site exposure to honey bees and native bees as a result of spray drift. To support their objection, they included an excerpt from the book "Poison Spring: The Secret History of Pollution and the EPA" that refers to "chemical trespass." The author of the text wrote that "only minute amounts of sprayed pesticides actually reach their target pest insects and plant pathogens."

### **The EPA's Response**

The EPA is requiring an on-field buffer to protect pollinators who may be foraging on blooming plants bordering the field. The labels also have requirements to minimize drift that include medium to coarse nozzles and a restriction on wind speed. The EPA has imposed strong language to minimize drift to the extent possible while still ensuring efficacious use of sulfoxaflor. The author claims that miniscule amounts of sprays reach their target pests with the example that only "0.0000001% of spray reaches heliothis caterpillars in cotton fields." The author does not acknowledge that pesticides such as Transform WG and Closer SC are mixed with water and the spray applied to the field consists largely of water. The EPA does not agree with the concept of "chemical trespass" as declared by this author.

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<sup>82</sup> Center for Biological Diversity

<sup>83</sup> River Region Coop, Brown County, MN

<sup>84</sup> Integrated Plant Protection Center, OR State

<sup>85</sup> Jeffrey Gore, Delta Research & Extension Center, MSU

<sup>86</sup> Comment 0503