UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Decision Memorandum Supporting the Registration Decision for New Uses of the Active Ingredient Sulfoxaflor on Alfalfa, Cacao, Citrus, Corn, Cotton, Cucurbits, Grains, Pineapple, Sorghum, Soybeans, Strawberries and Tree Plantations and Amendments to the Labels

Date: July 12, 2019
Registration Number: 62719-625, 62719-623, 62719-631
Petition Number: 4F8237
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Approver:

Meredith F. Laws
Branch Chief
Invertebrate-Vertebrate Branch 3
Registration Division

Requested Action

On January 13, 2014 EPA received an application from Dow Agrosciences (DAS) to add new uses to the two end-use products containing sulfoxaflor. DAS proposed to add alfalfa, clover and other non-grass animal feeds (crop group 18), buckwheat, cacao, corn (field, sweet and pop), millet, oats, pineapple, rye, sorghum, teff and teosinte to Transform® WG (EPA Registration Number 62719-625) and to Closer® SC (EPA Registration Number 62719-623).

On December 18, 2014 EPA received an application from DAS to register avocado and rice, and tree plantations to the Transform WG and Closer SC registrations. They also proposed the first residential use (on ornamentals) for sulfoxaflor. DAS also requested to amend the use pattern for greenhouse ornamentals.

On June 11, 2019, DAS[1] withdrew buckwheat and clover.
On May 14, 2019, DAS withdrew their request for the residential use.

[1] DAS is now Corteva Agrisciences

The publication in the Federal Register of a Notice of Filing announcing a request to establish tolerances on rice and avocado was delayed. This is a procedural step required under the Federal Food, Drug and Cosmetic Act. Due to the delay, EPA has not completed the evaluation of these proposed uses.

Background

On August 19, 2010, EPA received the application for registration of sulfoxaflor, a new active ingredient, submitted by DAS. EPA collaborated with counterpart agencies in Canada and Australia to evaluate sulfoxaflor. Scientists from the Australian Pesticides and Veterinary Medicine Authority, the Canadian Pest Management Regulatory Authority and the EPA collaborated to review the full dossier of data submitted, peer reviewed the primary evaluations conducted by their international colleagues and communicated extensively on specific disciplines and issues. Upon completion of the reviews 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. The vacatur of the sulfoxaflor registrations became effective November 12, 2015. On the same day, the EPA issued a cancellation order to address existing stocks. Although the product registrations were vacated, the tolerances for sulfoxaflor residues on treated commodities that were established under the Federal Food, Drug and Cosmetic Act, remain in place.

Following the vacatur, DAS amended the remanded sulfoxaflor application to add restrictions that eliminated exposure to pollinators such as directions that limited applications to post-bloom only for all proposed crops that are attractive to bees and imposed other restrictions (prohibition against crops grown for seed and required a 12-foot down-wind, on-field buffer). The EPA re-evaluated this application and on October 14, 2016 registered the limited uses (barley, triticale, wheat, leafy vegetables, root and tuber vegetables, bulb vegetables, and sod farms, and post-bloom foliar applications to: blueberries, cranberries, canola, fruiting vegetables, okra, ornamentals, pome fruit, potatoes, stone fruit, succulent and dry beans, and tree nut). Indeterminate blooming crops that had been originally registered (citrus, cotton, cucurbits, soybeans and strawberry) were not included in the decision.

Since the vacatur in 2015, DAS has submitted numerous additional pollinator studies. The pollinator data requirements listed in 40 CFR 158.630 have all been submitted or waived. EPA's risk assessment process for pollinators has evolved since those data requirements were promulgated and now EPA generally assesses risks to bees using a three-tier process based on a more robust data set as described in two guidance documents: "*Guidance for Assessing the Risks* *of Pesticides to Bees*" (USEPA 2014)[2] and "*Guidance on Exposure and Effects Testing for Assessing Risks to Bees*" (USEPA 2016)[3]. For sulfoxaflor, all Tier I data have been submitted. Three additional Tier II semi-field (tunnel) studies and two colony feeding studies have been submitted. Pollen and nectar residue data have been submitted for multiple crops. The submitted data covers all of the requested use patterns. For those crops that did not have data specific to pollen and nectar residues, data was extrapolated as appropriate from other crops. All regulatory data requirements for assessing pollinators have now been addressed and the EPA has adequate data to demonstrate that there will be no unreasonable adverse effects to honey bees resulting from the expanded registration of sulfoxaflor.

Regulatory Decision

EPA is granting an unconditional registration under FIFRA section 3(c)(5) for new uses of sulfoxaflor on the Transform WG and Closer SC labels. The new uses for this chemical are alfalfa, corn, cacao, grains (millet, oats), pineapple, sorghum, teff, teosinte and tree plantations. This regulatory action also adds the following crops back on to the Transform WG and Closer SC labels: citrus, cotton, cucurbits, soybeans and strawberry. Finally, certain restrictions that were included when the registrations were granted in October 2016 are being removed.

Notices of Receipt

A Notice of Receipt (NOR) announcing EPA's receipt of an application from DAS to register sulfoxaflor on alfalfa, clover and other non-grass animal feeds (crop group 18); buckwheat; cacao; corn (field, sweet, pop); millet; oats; pineapple; rye; sorghum; teff; and teosinte was published in the Federal Register on April 27, 2014. A 30-day comment period was opened under Docket ID Number EPA-HQ-OPP-2014-0156. In addition to new use requests for sulfoxaflor, the NOR included new use requests for three other chemicals: thiamethoxam, metaldehyde and diflubenzuron and public comments on these chemicals were submitted to the same docket. The comment period closed on May 27, 2014. Forty-seven comments were submitted. Of these, 20 objected specifically to sulfoxaflor, one of these was a letter-writing campaign with approximately 70,000 signatures. Nine comments objected to both sulfoxaflor and thiamethoxam, including one letter-writing campaign with approximately 40,000 signatures. One comment objected specifically to thiamethoxam and one comment requested an extension to the comment period. The remainder were against all pesticides. None of the comments provided new data or other supporting evidence.

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[2] https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf
[3] https://www.epa.gov/sites/production/files/2016-07/documents/guidance-exposure-effects-testing-assessing-risks-bees.pdf

An NOR announcing EPA's receipt of an application from DAS to register sulfoxaflor for rice, avocado, the first residential use (ornamentals), commercial ornamentals (tree farms and plantations) and greenhouses was published in the Federal Register on Oct. 12, 2018. A 30-day comment period was opened under Docket ID Number EPA-HQ-OPP-2018-0599. This NOR also included requests for new uses for two other chemicals: acetamiprid and fenpyroximate. The comment period closed on November 13, 2018. The number of comments received was 124 and most of the comments were specifically opposed to sulfoxaflor. They included a letter-writing campaign from Friends of the Earth (approximately 35,000 signatures and submissions from Beyond Pesticides, Beesponsible and the Center for Biological Diversity. The rest of the comments were almost all from anonymous submitters. None of the comments provided new data for EPA to consider.

Human Health Risk Assessment

A human health risk assessment is the process to estimate the nature and probability of adverse health effects in humans who may be exposed to chemicals in contaminated environmental media, now or in the future. Human health risk assessments address questions such as:

- What types of health problems are caused by pesticides in the environment?
- What is the chance that people will experience problems when exposed to different levels of pesticides?
- Is there a low level below which some chemicals don't pose a human health risk?
- What pesticides are people exposed to and for how long?
- Are legal limits for pesticide residues in food (tolerances or maximum residue limits) protective of human health?
- Are people more likely to be susceptible or exposed to pesticides because of factors such as age, genetics, pre-existing health conditions, ethnic practices, gender, where they work, where they play, what they eat, etc.

EPA uses the National Research Council's four-step process for its human health risk assessments:

- Step 1 - Hazard Identification: examines whether a substance has the potential to cause harm to humans and/or ecological systems, and if so, under what circumstances.
- Step 2 - Dose Response Assessment: examines the numerical relationship between exposure and effects.
- Step 3 - Exposure Assessment: examines what is known about the frequency, timing, and levels of contact with a substance.
- Step 4 - Risk Characterization:
  examines how well the data support conclusions about the nature and extent of the risk from exposure to pesticides.

EPA's Health Effects Division (HED) assessed the risks to human health from the proposed new uses of sulfoxaflor in the following documents:

> "Sulfoxaflor. Human Health Risk Assessment for New Food Uses on Artichoke, Asparagus, Bushberry, Caneberry and Sunflower, and Multiple Crop Group Conversions" DP #44663, 6/19/2019
>
> "Sulfoxaflor. Human Health Risk Assessment for New Food Uses on Numerous Crops, Ornamentals Growing in Greenhouses and Nurseries and Tree Farms and Plantations" DP #438837 & #438838, 6/19/2019

Hazard Determination

The no observed adverse effect level (NOAEL) of 25 milligrams/kilogram/day (mg/kg/day) is the point of departure (POD) for the acute dietary risk assessment and all other short- and intermediate-term durations and population assessments (with the exception of females 13-49 years), based on decreased motor activity at the lowest observed adverse effect level (LOAEL) of 75 mg/kg/day.

The NOAEL of 1.8 mg/kg/day is the POD for the acute dietary and short- and intermediate-term assessments for females 13-49 years of age, based on decreased neonatal survival in post-natal day 0-4 offspring at the LOAEL of 7.1 mg/kg/day.

The NOAEL of 5.13 mg/kg/day is the POD for the chronic dietary assessment, based on liver effects including increased blood cholesterol, liver weight, hypertrophy, fatty change, single-cell necrosis and macrophages in males and females at the LOAEL of 21.3 mg/kg/day.

Food Quality Protection Act (FQPA) Safety Factor

The FQPA safety factor (SF) for sulfoxaflor was reduced from 10X to 1X. This is based on the following considerations: 1) the toxicology database for sulfoxaflor is complete with regard to FQPA consideration, including the required developmental and reproductive toxicity studies; 2) the required neurotoxicity studies, including the developmental neurotoxicity study (DNT), have been submitted and are considered adequate; 3) although there is evidence of quantitative susceptibility in the DNT and developmental rat studies, the endpoints and doses selected for risk assessment are protective for the observed effects; further, HED's degree of concern for human susceptibility is reduced based on the special studies submitted in support of the mode of action; and 4) although some refinements are used in the exposure assessment, the dietary, drinking water, and residential assessments still result in upper-bound estimates of exposure.

DAS submitted mode of action (MOA) data which were sufficient to support reducing the interspecies uncertainty factor (UF) from 10X to 3X for the developmental effects.

The level of concern (LOC) for assessing developmental effects is 30 based on 10X for intra-species variability, 3X for inter-species extrapolation, and 1X FQPA SF. The LOC for all other toxicological effects is 100 based on 10X for intra-species variability, 10X for inter-species extrapolation, and a 1X FQPA SF.

Dietary Risk

The assessment of dietary risk from sulfoxaflor is conservative. For all uses, 100% of the US acreage for every crop was assumed to be treated with sulfoxaflor. The acute dietary risk assessment is based on the maximum observed residue levels from the field trials. The chronic assessment assumes average residues to account for additional metabolites. These metabolites have no acute effect and so are not included in the acute dietary assessment.

The acute dietary (food and drinking water) risk estimate for the general U.S. population is 11% of the acute population adjusted dose (aPAD). The highest acute risk estimate is for females 13-49 years old and is 28% of the aPAD.

The chronic dietary (food and drinking water) risk estimate for the general U.S. population is 11% of the chronic population adjusted dose (cPAD). The highest chronic dietary risk estimate is for children 1-2 years old and is 47% of the cPAD.

HED concluded that the current tolerance expression for sulfoxaflor (Title 40 of the Code of Federal Regulations, 40 CFR §180.668) is adequate and includes both coverage and compliance statements for enforcement purposes.

Occupational Handler and Post-Application Risk

All scenarios resulted in combined (dermal + inhalation) risk estimates >LOCs (dermal and inhalation MOE ≥ 30). MOEs ranged from 50 to 41,000.

There are no risk estimates of concern for post-application activities. All dermal MOEs ranged from 1,600 to 44,000 immediately after application (LOC=30).

No additional data are needed, and there are no risk estimates of concern.

Ecological Risk Assessment

In an ecological risk assessment, EPA evaluates the likelihood that exposure to one or more pesticides may cause harmful ecological effects. The effects can be direct (e.g., fish die from a pesticide entering waterways, or birds do not reproduce normally after ingesting contaminated fish), or indirect (a hawk becomes sick from eating a mouse dying from pesticide poisoning). The studies EPA uses in ecological risk assessments define the chemical properties of the pesticide, how the pesticide behaves in the environment, and its impact on plants and animals not targeted by the pesticide.

EPA's Ecological Fate & Effects Division (EFED) assessed the ecological risks from the proposed new uses of sulfoxaflor in the following document:

> "Sulfoxaflor: Ecological Risk Assessment for Section 3 Registration for Various Proposed New Uses" DP449891, July 10, 2019

A low potential for acute or chronic risk to aquatic animals/plants is indicated from the proposed uses of sulfoxaflor, since risk quotients (RQs) are below EPA's LOC. Sulfoxaflor is practically non-toxic on an acute exposure basis to fresh and saltwater fish, thus resulting in acute RQs <0.01 for both taxonomic groups which is well below the acute risk LOC of 0.5. The chronic RQs were 0.08 for freshwater fish and 0.04 for saltwater fish which are below the chronic risk LOC of 1.0. The acute and chronic RQ values for freshwater and saltwater invertebrates are below the LOC (max acute RQ <0.01; max chronic RQ of 0.5).

There is a potential for marginal acute risk to passerine birds at the LOC but a low potential for chronic risk is indicated. The maximum acute RQ for birds is "<0.6" (based on a non-definitive toxicity value that is considered conservative due to complications in the study). Thus, while the acute risk LOC of 0.5 could be exceeded, such an exceedance would be marginal (<0.6) at most. The maximum chronic RQ for birds (0.2) is below the chronic risk LOC of 1.0.

A low potential for acute risk to mammals is indicated from the proposed uses of sulfoxaflor, but a potential for chronic risk is indicated for some uses with rates ≥ 0.047 lb a.i./A. The maximum acute RQ value for mammals is below the acute risk LOC (0.02), while the maximum chronic RQ exceeds the chronic risk LOC (3.3). Notably, the acute and chronic risk assessments include conservative exposure assumptions such as the use of "high end" estimates of residues and that 100% of the bird or mammal's diet is obtained from the treated field.

Pollinator Risk Assessment

The Tier I bee toxicity data base for sulfoxaflor is complete per the 2016 OPP guidance.[4]

For proposed uses of sulfoxaflor with an application rate of 0.047 pounds active ingredient/acre (lb a.i./A) and greater, a potential for acute risk to bees is evident through direct contact (i.e., interception of spray droplets on and off the field) at the Tier 1 (individual bee) level. For applications to bee-attractive crops, acute contact RQs range from 0.6 to 1.1 for uses with application rates of 0.047 lb a.i./A and higher. Below an application rate of 0.047 lb a.i./A, a low potential for acute contact risk is indicated. A potential for acute contact risk is indicated up to 12 feet beyond the treated field due to spray drift assuming bee-attractive plants are present at the

[4] https://www.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance

field edge. However, the duration that residues of sulfoxaflor are acutely toxic to honey bees via contact with foliage is short as indicated by the "residual toxicity time" (RT_{25}). The RT_{25} is the aging time required for foliar residues to cause 25% mortality to bees.[5] The RT_{25} time for both Transform WG and Closer SC is < 3 hours.

At the Tier I level, acute and chronic risk from oral exposure (consumption of contaminated pollen and nectar) is considered low for the following uses on crops that are either unattractive to honey bees and/or are harvested prior to bloom: brassica, leafy, and bulb vegetables, commercial turfgrass, and conifer/Christmas trees.

Based on default ("high end") estimates of oral exposure, acute and chronic risk to individual honey bees is indicated for all other uses. When the estimates of oral exposure were refined using field data for residues in pollen and nectar, a potential for acute and chronic risks is indicated for at least one caste/life stage of bees at the Tier I level.

Therefore, a Tier II (colony-level) assessment was performed on all uses where risk was indicated at Tier I. This Tier II risk assessment was informed by 3 newly-submitted Tier II tunnel studies and 2 colony feeding studies (CFS), each of which evaluated long-term effects on honey bee colonies, including effects beyond overwintering. In addition, 14 Tier II field residue studies were also submitted and used for assessing oral exposure.

- The Tier II tunnel studies were used to assess risk to honey bees from contact + oral exposure (one application), since applications were made with bees inside mesh tunnels while they were foraging on a crop.
- The CFS studies were used to assess risk from oral exposure (10-42 days), since bees were fed sucrose solutions spiked with varying levels of sulfoxaflor.

The results for the assessment of contact + oral exposure (7-10 days) to application rates of sulfoxaflor varying from 0.02 to 0.09 lb a.i./A showed immediate contact toxicity for up to 3 days after application. There were no observed effects of exposure on long term hive health including hive strength, brood indices and brood strength, food stores prior to overwintering up to the maximum rate of 0.09 lb a.i./A. No effects were seen on the overwintering success of colonies which could be reliably evaluated with one of the three tunnel studies up to an application rate of 0.043 lb a.i./A. While the overwintering components for the remaining two tunnel studies were not reliable due to poor overwintering success in controls, data from insecticides which also act on the nicotinic acetylcholine receptor indicate that effects on overwintering success are not more sensitive than those observed prior to overwintering.

In addition to crops that are not attractive to honey bees or are harvested before bloom, a low potential for colony-level risks to honey bees is indicted from oral exposure to contaminated pollen and nectar for canola, corn, cotton, pome fruit and sorghum. A potential for colony-level

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[5] https://www.epa.gov/pollinator-protection/residual-time-25-bee-mortality-rt25-data

risk is indicated for the remaining crops: stone fruit, small fruits/berries, tree nuts, tree farms, citrus, ornamentals, cucurbits, strawberries, root/tuber vegetables, legumes, fruiting vegetables, animal feeds (i.e., alfalfa), avocado, cacao and pineapple conservatively assuming that bees feed exclusively on the treated crop.

EPA has a very robust set of pollinator exposure and effects data for sulfoxaflor. In addition to the full Tier I suite of studies, the Tier II data set consists of 11 semi-field (tunnel) studies, 2 colony feeding studies and 16 field residue studies analyzing pollen and nectar residues in a dozen crops. This existing suite of semi-field (Tier II) effects and exposure studies enables EPA to conduct a comprehensive and appropriately conservative assessment of the potential risks of sulfoxaflor to bees to support its registration decision. Furthermore, given the limitations and high degree of specificity associated with full field studies, EPA believes that submission of a full field study would have a low potential for altering its risk assessment conclusions and subsequent registration decision. EPA also notes that the conditional requirements for the full field study (850.3040) codified in 40 CFR Part 158.630 do not fully reflect the current state of science supporting the assessment of pesticide risks to bees. After careful consideration of all these factors, the requirement for a full field study is waived. With the relatively large suite of Tier II studies with sulfoxaflor along with conservative assumptions regarding exposure (e.g., colonies get 100% of their diet from the treated crop), EPA believes the submission of one or more full field studies is not likely to add significant value and clarity to its current risk assessment of sulfoxaflor to bees.

Incidents

Sulfoxaflor has been used over the past several years either under Section 18 emergency authorizations on cotton, sorghum, alfalfa grown for seed, and strawberries, or under Section 3 registrations (those in place prior to the 2015 vacatur and uses registered in 2016). Although applications of sulfoxaflor have been wide-spread over many acres, only one incident concerning bees was reported to the Agency. This incident, however, purportedly involved three insecticides; acephate, dicrotophos and sulfoxaflor as well as tank mixes of other unnamed chemicals, applied to watermelons in the summer of 2013. The incident was not reported to EPA until January 2014. There was no confirmation that these specific chemicals were applied or that the bees were exposed to them. Additionally, it should be noted that sulfoxaflor was not registered until May 6, 2013 and was unlikely to have been applied to watermelons in the summer of 2013 since the state specific registrations were in the process of being approved and product had not yet entered channels of trade.

No other sulfoxaflor incidents involving bees or incidents involving other wildlife have been reported to EPA.

Endangered Species

EPA has not made an effects determination for sulfoxaflor. EPA is currently focusing most of its resources for assessing impacts to listed species on its registration review program for currently registered pesticides. EPA believes that, as a general matter, older pesticides present a greater degree of risk to listed species than most new chemistries, including sulfoxaflor, and that it is therefore environmentally preferable in most circumstances for EPA to assess the impacts of existing pesticides sooner in the process than newer pesticides that are designed to compete with more risky alternatives. EPA believes that is especially true for sulfoxaflor, where the alternatives include organophosphates, neonicotinoids and pyrethroids. As a result, EPA does not believe the environment or the public would be best served by delaying the registration of new uses for sulfoxaflor to complete consultation. Focusing the limited resources of EPA, the Fish and Wildlife Service and the National Marine Fisheries Service 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 EPA believes to be more toxic compounds, that, among other things, pose greater risk, to endangered species than does sulfoxaflor.

Benefits and Alternatives

When occupational or ecological risks that are above the Agency's level of concern are identified, EPA's Biological and Economic Analysis Division (BEAD) conducts a benefits assessment to inform a regulatory decision on whether the pesticide poses unreasonable adverse effects on man or the environment. EPA considers the benefits of a pesticide by reviewing information about pesticide use patterns, alternative pesticides or pest control practices in order to achieve an appropriate balance between reducing the identified risks while maintaining the benefits of the pesticide use.

BEAD assessed the benefits from the proposed new uses of sulfoxaflor in the following document:

> "Benefits for New Uses of Sulfoxaflor on Alfalfa, Avocado, Citrus, Corn, Cotton, Cucurbits, Fruiting Vegetables, Pineapple, Pome Fruit (Pre-bloom), Rice, Sorghum, Soybean, Strawberry, Ornamentals and Home Fruit Trees" DP442401 3/7/2019

Additionally, public comments in Docket #EPA-HQ-OPP-2010-0889 that provided specific details on the benefits of sulfoxaflor have also been considered.

The overall general benefits of sulfoxaflor can be summarized by six critical points. Sulfoxaflor:

- is a new mode of action
- performs as well or better than registered insecticides

- targets economically important or hard to control pests
- is highly selective to pests, and less disruptive to beneficial insects and other arthropods
- is compatible with Integrated Pest Management (IPM) and Insect Resistance Management (IRM) programs
- has a better ecological and human health profile than the alternatives.

I. Sulfoxaflor has a unique mode of action.

The Insecticide Resistance Action Committee (IRAC) is an international authority that has classified sulfoxaflor as a "sulfoximine" and has placed it as a subgroup to the IRAC Group 4: "nicotinic acetylcholine receptor agonists." Group 4 is divided into five subgroups; Group 4A: neonicotinoids; Group 4B: nicotine; Group 4C: sulfoximines; Group 4D: Butenolides; and Group 4E: Mesoinoics. The chemicals in these subgroups target the nicotinic acetylcholine receptor in insects but the subgroups have different modes of action. The differences result in wide variations of effectiveness against target pests as well as variations in the ecological impacts.

Sulfoxaflor is the only Group 4C chemical registered in the U.S. Its novel mode of action distinguishes it from all registered alternative insecticides. The structure of sulfoxaflor makes it stable in the presence of a monooxygenase enzyme that was shown to degrade the five registered neonicotinoids in IRAC Group 4A. The stability results in a broad lack of cross-resistance to the neonicotinoids and other insecticide groups.

II. Sulfoxaflor performs as well or better than registered insecticides.

Besides neonicotinoids, the main alternatives to sulfoxaflor are carbamates and organophosphates (IRAC Groups 1A and 1B; acetylcholinesterase inhibitors), pyrethroids (IRAC Group 3A; sodium channel modulators) and spinosyns (IRAC Group 5; nicotinic acetylcholine receptor allosteric modulators). In many crop-pest scenarios, sulfoxaflor has proven to be efficacious against certain target pests that these alternative insecticides fail to control unless they are applied repeatedly to the crop and/or used in tank mix combinations.

Over the years, EPA has heard from many growers, researchers and entomologists advocating strongly in support of sulfoxaflor as a critical pest management tool. They have provided EPA with specific information on how sulfoxaflor will replace alternative insecticides. Several examples are shown in Table 1.

Table 1. Sulfoxaflor performs better than registered alternatives
"The tarnished plant bug, *Lygus lineolaris*, has become the major pest of cotton in Arkansas and the Midsouth. With increasing resistance/tolerance to currently labeled insecticides the control of this pest has become very problematic. Currently Arkansas is averaging around six applications of insecticides per year to control this pest, but in some areas, fields may be sprayed as many as twelve times per year." University of Arkansas[6]
"The insecticides used for managing plant bugs in cotton rely heavily on organophosphates and neonicotinoids. Due to resistance issues we have seen a shift to acephate synergized[7] with pyrethroids, and neonicotinoid/pyrethroid mixtures. These mixtures have been effective but short lived; when immigrating plant bug populations are high, it is not uncommon to have to retreat fields within 5 days. Cotton growing in areas with naturally high plant bug populations in the landscape may require as many as 10 insecticide applications during a year". Louisiana State University[8]
"Sulfoxaflor will likely replace 1-2 applications of neonicotinoids during the early season and 1-2 applications of organophosphate/pyrethroid tank mixtures later in the season. Also, because it has little non-target effect and controls cotton aphids, the numbers of applications targeting other arthropod pests may also be reduced." Mississippi State University[9]
"… the neonicotinoids are weak against one of more troublesome aphid species, woolly apple aphid. Unlike other aphid species, this pest causes chronic debilitation of the tree, and fruit contamination is cited frequently as a cause for rejection or fumigation of exported fruit. The last two conventional materials that were effective (endosulfan and diazinon) are being phased out, leaving a serious gap in our programs; sulfoxaflor is one of the few materials I have tested in the last 10 years that can control woolly apple aphid." Washington State University[10]

The University researchers have a constant presence in the field and interact routinely with the growers in their states as well as others at numerous meetings and conferences. In summary, they state that sulfoxaflor will replace multiple (4, 6, 10 and up to 12) applications of alternative pesticides, which are often combined to target a single pest. In addition to the examples presented above, EPA has heard from growers of other crops who report that sulfoxaflor works better than the registered alternatives in many crop/pest scenarios including pecans/aphids, citrus/psyllids and soybeans/aphids.

III. Sulfoxaflor targets economically important or hard to control pests.

[6] Gus Lorenz, UA Research & Extension, Docket #EPA-HQ-OPP-2010-0889-0264
[7] EPA believes the writer means "tank-mixed." EPA has not assessed whether there is synergy between these ingredients
[8] David Kerns, LSU, Docket # EPA-HQ-OPP-2010-0889-0059
[9] Jeffrey Gore, MSU, Docket #EPA-OPP-2010-0889-0163
[10] Elizabeth Beers, WSU, Docket # EPA-HQ-OPP-2010-0889-0266

Sulfoxaflor specifically targets piercing/sucking insects such as aphids, mealybugs, psyllids, thrips, plant bugs and whiteflies. These insect pests insert their mouth parts through the surface of the plant and draw the sap into their bodies. With this access to the plant's vascular system, these pests often transfer viral and bacterial diseases. Infections can result in complete loss of a crop, can significantly impact yield or can reduce the quality of the harvested commodity. Worse than the loss of the crop, in the case of Citrus Greening Disease (CGD), the trees die and citrus orchards are lost. Florida conducted a study in 2016 and determined that citrus greening had resulted in the loss of $4.64 billion over 10 seasons, as well as thousands of jobs.[11] Sulfoxaflor is particularly effective against the Citrus psyllid which vectors CGD and can be a very valuable tool for citrus growers.

US growers have requested FIFRA Section 18 Emergency Exemptions (section 18s) to use sulfoxaflor against pests that pose an urgent and nonroutine threat to their crops that would result in significant economic losses. The registered alternatives have lost their efficacy or there are no registered alternatives against a specific target pest, especially invasive pests. The US cotton growers have received section 18 authorizations to use sulfoxaflor against the Tarnished plant bug. Growers of sorghum in the US also demonstrated an urgent need to use sulfoxaflor under the section 18 provision against the invasive Sugarcane aphid. The Pacific NW growers of alfalfa grown-for-seed have requested and received section 18s for use of sulfoxaflor against Lygus bugs. This minor crop is very vulnerable to this pest as there are no effective alternatives. California strawberry growers have also faced an emergency with this pest and have received an exemption.

Individual growers, grower organizations, State Farm Bureaus and State Departments of Agriculture have appealed to EPA on behalf of sulfoxaflor because it is effective against economically important and hard to control pests, including invasive species. Growers of cole crops, leafy vegetables and fruiting vegetables want to use sulfoxaflor against whiteflies, which produce honeydew that causes difficulty in harvest and reduces the quality of the produce. Additionally, whiteflies may transmit plant viruses which can seriously affect yield and the quality of the crop.[12] According to the Center for Invasive Species Research, damage from the Silverleaf whitefly has been estimated to be in excess of $1 billion nationally.[13] Growers represented by organizations such as the Washington State Potato Commission, US Canola Association, American Soybean Association, California Grape & Tree Fruit League and the California Strawberry Commission, have requested registration of sulfoxaflor for a variety of challenging pest situations threatening many crops, including potatoes (psyllid), canola (aphids), and grapes (vine mealybug).[14] Pecan growers have communicated to the EPA that imidacloprid is no longer effective on black margined pecan aphid and black pecan aphid. These aphid

[11] https://www.upi.com/Top_News/US/2019/05/02/Citrus-greening-research-in-Florida-yields-new-tool-in-battle-against-disease/5761556742958/
[12] Hank Giclas, Western Growers, Docket # EPA-HQ-OPP-2010-0889-0362

[13] https://cisr.ucr.edu/silverleaf_whitefly.html
[14] Docket # EPA-HQ-OPP-2010-0889; 0275, 0279, 0305, 0312, 0345

species reduce pecan quality and yield.[15] Sulfoxaflor controls these aphid species. Additional information from the agricultural community expounding sulfoxaflor's benefits against hard to control pests is presented in Table 2.

Table 2. Sulfoxaflor (Closer SC and Transform WG) is efficacious against difficult pests
"Sulfoxaflor is a fast acting insecticide which helps manage sap-feeding pests of potatoes such as aphids, psyllids, leafhoppers, mealybugs, and lygus. The first three of these insects spread plant pathogens to potato, which are the most important economic challenges to growers throughout the U.S. and prohibit trade." Washington State Potato Commission[16]
"Closer is an important tool in controlling citrus psyllid (Diaphorina citri)." "Florida citrus growers need all available tools to control citrus psyllids as they are the vector of HLB. In the last 10 years, our industry has been severely impacted by HLB which is spread by psyllids and our crop has decreased by nearly 60% and now at the lowest yield in almost 60 years. Therefore we must work toward providing all possible tools that offer management options of psyllids to the citrus industry." University of Florida[17]
"On crops such as succulent beans, insecticidal management of silverleaf whitefly SLW is absolutely necessary to effectively slow spread of Bean Golden Mosaic Virus (BGMV). BGMV has a narrow host range compared to aphid-borne viruses. Only a few hours of feeding are required for the whitefly to become infective. Then the insect remains infected/infective for the rest of its life and transmits the BGMV instantaneously upon inserting its stylet into a bean plant. A single infected SLW per 10 bean plants results in a 70 percent incidence of BGMV infected plants throughout the entire field. However, according to the University of Florida's Insects That Affect Vegetable Crops publication (ENY450), currently registered foliar insecticides are of limited value for control of SLW, so a product with sulfoxaflor's capabilities are needed and desired. Florida Fruit & Vegetable Association[18]
"Sulfoxaflor is a key, selective compound with detailed and rigorous research evaluations in Arizona cotton and vegetables showing that its safe and effective use in Arizona agriculture. It provides for effective and selective control of Lygus bugs and Bemisia whiteflies in cotton as well as whiteflies and aphids in produce and cucurbits. The main crops grown in Arizona that would benefit from a sulfoxaflor registration include cotton, melons of all types, lettuces of all types and cole crops." Arizona Pest Management Center[19]
"On average, growers will apply 4 applications (sometimes more under heavy pressure) during a crop season to control a complex of aphid species. To date, spirotetramat is the most commonly used, followed by the neonicotinoids. Among the older products, growers typically use combinations of endosulfan, acephate, dimethoate and pyrethroids. Generally speaking when used in proper rotations,

[15] Brad Lewis, NMSU, Docket # EPA-HQ-OPP-2010-0889-0265

[16] Matt Harris, WSPC, Docket # EPA-HQ-OPP-2010-0889-0535
[17] Stephen Futch, UF, Docket # EPA-HQ-2010-0889-0491
[18] Mike Aerts, FFVA, Docket # EPA-HQ-2010-0889-0006
[19] Peter Ellsworth, U AZ, Docket # EPA-HQ-2010-0889-0380

this arsenal of active ingredients provides economic control of the aphid complex on leafy vegetables. However, there is now a need for new, effective insecticide alternatives in leafy vegetable production." Department of Entomology, Univ. of Arizona[20]
This insecticide is very effective against "piercing sucking" insect pests that are becoming a problem in cranberry. For example, we are seeing scale emerge in MA and OR; and leafhoppers, toad bug and blackbug increasing in NJ. The bluntnosed leafhopper transmits false blossom disease that nearly devastated the NJ cranberry crop in the 1920's. Research and extension personnel continue to report increasing observations of these type of insects every year. The Cranberry Institute[21]
"Vine mealybug occurs in the Coachella and San Joaquin Valleys, Central and North coasts and Sierra foothills; all regions where grapes are produced. Vine mealybug produces honeydew that coats bunches and ruins fruit, reduces sugar levels at harvest, serves as an infection point for neighboring vineyards and can transmit diseases like the leaf roll virus. Current control programs contain several different components, however these materials are not always effective. Effective products, such as Lorsban (chlorpyrifos), are under additional regulatory scrutiny with use restrictions making it more difficult to use." CA Grape & Tree Fruit League[22]
"University of California research has shown that sulfoxaflor is effective in controlling Asian citrus psyllid, citricola scale, and citrus leaf miner. If left uncontrolled, these insects can reduce the vigor of trees or scar the fruit. These effects reduce productivity and the quality of fruit leading to less revenue per acre and lower fruit prices. In the case of Asian citrus psyllid, failure to control this insect will result in the loss of the California citrus industry. Additionally, sulfoxaflor will be valuable to growers because it can be used to help manage citricola scale resistance to chlorpyrifos." CA Citrus Quality Council[23]
"Lygus, also known as tarnished plant bug, is a key pest of U.S. cotton. In fact, it is known to be the second most damaging insect pest to the crop and the primary insect pest of cotton in the Mid-South. The bug if left uncontrolled is known to cause near total crop loss. The pest has also become resistant to multiple existing classes of pesticides. Without multiple modes of action that include sulfoxaflor, we are developing more resistance and weakening farmers' abilities to keep up with pests. The end result is the use of additional pesticides and higher costs to produce crops." Agricultural Council of Arkansas[24]
"There is a significant need for new products for insect pest management in Florida strawberries. Flower thrips, mainly *Frankliniella* spp., can be major pests, particularly during peak production (February and March). Flowers are damaged, fruit-set is reduced, and developing berries are bronzed. Radiant®SC (spinetoram) has been heavily relied on for flower thrips control in recent years, leading to resistance and reported poor efficacy. Thrips management practices in FL strawberries are facing further challenges by chilli thrips, *Scirtothrips dorsalis*. It is an early season (November) foliage and fruit pest, with populations reaching high levels under warmer than normal temperatures – as

[20] John Palumbo, U AZ, Docket # EPA-HQ-2010-0889-0007
[21] Terry Humfeld, The Cranberry Institute, Docket # EPA-HQ-2010-0889-0507
[22] Marcy Martin, CA Grape & Tree Fruit League, Docket # EPA-HQ-2010-0889-0312
[23] James Cranney, CCQC, Docket # EPA-HQ-2010-0889-0319
[24] Andrew Grobmyer, Ag Council of AR, Docket # EPA-HQ-2010-0889-0423

experienced this past growing season. Many of the same products are used for flower and chilli thrips, and if chilli thrips populations are high, few applications of effective products remain for later season flower thrips control. Closer®SC was an effective product for thrips control in strawberries." UF Gulf Coast Research and Education Center[25]

IV. Sulfoxaflor is highly selective to pests, and less disruptive to beneficials arthropods.

While sulfoxaflor will control challenging pests, researchers and crop consultants have informed EPA that sulfoxaflor does not "flare" spider mites as do some organophosphates like acephate, nor does it flare aphids as pyrethroids are known to do. The word "flare" is short for "flare-up" and in agriculture refers to a pest outbreak getting much worse due to the loss of natural predators from a pesticide application. Researchers at LSU, MSU, WSU, UC Davis,[26] and others have observed that sulfoxaflor has low impact on lady beetle larvae and other beneficial insects. Protecting biocontrol efforts by using a compound like sulfoxaflor that has less impact on beneficial predatory beetles and mites, and parasitic wasps, helps to reduce treatment needs for later season damaging pests such as armyworms, spider mites and aphids. Table 3 provides additional information from growers and researchers.

Table 3. Sulfoxaflor has a favorable profile for beneficial arthropods
Another consequence of the increased applications needed to manage insecticide resistant tarnished plant bug is outbreaks of spider mites. Twospotted spider mite has become a season long pest of cotton in Mississippi. The increased incidence of acaricide applications targeting spider mites has coincided with the occurrence of insecticide resistance in tarnished plant bug and there is a strong correlation between the numbers of applications for spider mites and the numbers of applications for tarnished plant bug. Increased applications with high rates of broad spectrum insecticides such as pyrethroids, organophosphates, and neonicotinoids eliminate natural enemy complexes in cotton and create an ideal environment for outbreaks of spider mites. Research by a recent graduate student in Mississippi showed that foliar applications of neonicotinoids, pyrethroids, and organophosphates can flare spider mites in cotton. This has created an additional input cost for growers in the Delta regions of the Mid-South. Mississippi State University[27]
"First generation pecan grower here in central GA. Sulfoxaflor has been very helpful to my operation. It does not harm beneficials I see in the orchard like lady bugs. The pest it does target is Black Pecan Aphid, which can shed almost all the leaves off a pecan tree if left uncontrolled." Georgia Pecan Grower[28]

[25] Justin Renkema, UF, Docket # EPA-HQ-2010-0889-0534
[26] EPA-HQ-OPP-2010-0889-59, -62, -266, -278

[27] Jeffrey Gore, MSU, Docket # EPA-HQ-2010-0889-0163
[28] C. Anderson, GA, Docket # EPA-HQ-2010-0889-0413

"Sulfoxaflor has also been a key product for growers to use in cotton production to fight piercing sucking insects like aphids. Growers who have applied this chemistry have preserved their beneficial insect population throughout their fields and obtained great control of the target pests." Agronomist, Texas[29]
"Farmers are strong advocates of protecting the ecology in their crops. They are diligent in their efforts to protect non-target organisms. The value of Sulfoxaflor in our research trials is that it has a very limited impact on beneficial arthropods. Removing this product will force cotton and citrus producers to rely on broader spectrum insecticides that often lead to secondary pests outbreaks resulting in additional insecticide applications adding to production cost and exposure of non-target organisms to these insecticides." Extension Specialist, TX A&M[30]

V. Sulfoxaflor is compatible with Integrated Pest Management (IPM) and Insect Resistance Management (IRM) programs.

Sulfoxaflor has been highlighted as extremely compatible with growers' IPM practices. Under the initial registration in 2013, sulfoxaflor had been incorporated into many IPM programs. Due to the availability of sulfoxaflor granted to cotton growers by EPA under the provisions of FIFRA section 18 emergency exemption authorizations, a researcher reported to EPA that: "Because of its high level of efficacy, relative safety to beneficial arthropods and pollinators, and protection of cotton yields, Transform has become the foundation of the insecticide component of Missouri's overall IPM program."[31]

Table 4 captures interest in sulfoxaflor from various IPM and IRM programs around the US.

Table 4. Sulfoxaflor fits well in IPM and IRM programs
"Having access to a new class of chemistry without cross resistance to other classes is very important to minimizing downside risks of resistance and is also in the public's interest." Arizona Pest Management Center[32]
"Sulfoxaflor is a much needed tool in our pest management programs. Sulfoxaflor is soft on beneficial insects, importantly, does not flare secondary pests, and has the potential to reduce overall number of pesticide applications in our programs." Aurora Cooperative, Nebraska[33]
"...there is a need for a product with the attributes of sulfoxaflor for cotton IPM in the SJV. My research has shown a high level of activity against both lygus bugs and cotton aphids. The unique mode of action and new class of chemistry are definite advantages for resistance management and key for

[29] Docket # EPA-HQ-2010-0889-0458
[30] Texas A&M, Docket # EPA-HQ-2010-0889-0468
[31] Moneen Jones, U of MO, Fisher Delta Research Center, Docket # EPA-HQ-2010-0889-0495
[32] Peter Ellsworth, AZ Pest Management Center, Docket # EPA-HQ-2010-0889-0380
[33] Dawn Caldwell, Aurora Cooperative, Docket # EPA-HQ-2010-0889-0498

prolonging the effectiveness of other registered products. Sulfoxaflor has less impact on populations of natural enemies than the other insecticides used for lygus bug management (pyrethroids) and protecting these beneficials helps to keep other arthropod pest populations in check (late-season spider mites, beet armyworms, whiteflies, etc.). This helps to reduce treatment needs for these pests." University of California, Davis[34]
"As part of a successful integrated pest management program I always recommend a strong rotation program that uses molecules from different mode of action groups. I believe Isoclast* containing products could be an important part of a strong rotation that is useful to manage greenhouse pests of ornamental plants grown in greenhouses. Especially for ornamentals there are relatively few new products coming into the market which makes establishing a strong rotation program very difficult." Ohio State University[35] *Isoclast is another name for sulfoxaflor
"Last year, pyrethroid resistance was reported to University of Minnesota Extension over a large area of the state. Testing by university personnel confirmed this resistance. Two other insecticide groups (organophosphates and neonicotinoids} are also used for aphid control in Minnesota soybeans. The primary organophosphate used by Minnesota soybean farmers, chlorpyrifos, is effective, but has a short residual control period, which may allow aphids to reach economic levels a second time during aphid outbreaks." "Research presented and published by the University of Minnesota found sulfoxaflor to be effective in controlling soybean aphids and is less toxic to beneficial insects' than. other effective insecticides. This product would enhance soybean aphid control, provide assistance in developing an effective insecticide resistance management program, and enhance biological control by limiting damage to aphid predators. Sulfoxaflor would provide an additional effective chemistry for aphid management that could improve insecticide resistance management programs. The ability for Minnesota soybean growers to use sulfoxaflor as a management tool for soybean aphids would provide significant and widespread economic and environmental benefits to Minnesota as a whole." Minnesota Soybean Growers Association[36]

With the unique chemistry and lack of cross-resistance to the neonicotinoids and other insecticides, sulfoxaflor can be a very valuable tool in managing pesticide resistance. Sulfoxaflor product labels display the Mode of Action identifier and best management practice statements designed to help mitigate pest resistance that is consistent with the EPA's 2017 Pesticide Registration Notice on pesticide resistance management labeling.[37]

VI. Sulfoxaflor has a better ecological and human health profile than the alternatives.

[34] Larry Godfrey, UC Davis, Docket # EPA-HQ-2010-0889-0278
[35] Luis Canas, OSU, Docket # EPA-HQ-2010-0889-0502
[36] Paul Freeman, MSGA, Docket # EPA-HQ-2010-0889-0561
[37] https://www.epa.gov/pesticide-registration/prn-2017-1-guidance-pesticide-registrants-pesticide-resistance-management

In BEAD's most refined query that is crop and pest-spectrum specific to sulfoxaflor, the six identified alternatives listed below are the most commonly used broad-spectrum insecticides currently registered for the proposed uses of sulfoxaflor and they account for 65% of the total acreage treated in those crops targeting sulfoxaflor's target pest spectrum.

1. Lambda-cyhalothrin (pyrethroid)
2. Bifenthrin (pyrethroid)
3. Chlorpyrifos (organophosphate)
4. Acephate (organophosphate)
5. Dicrotophos (organophosphate)
6. Imidacloprid (neonicotinoid)

EFED provided a hazard comparison of these six insecticides to sulfoxaflor, see EFED memorandum dated July 10, 2019, DP452640. This memorandum is included as an addendum to this decision document.

Sulfoxaflor's toxicity to non-target organisms is generally much lower than the toxicity of these alternatives and in some cases by many orders of magnitude lower. It is particularly noteworthy that sulfoxaflor presents no acute or chronic risk to aquatic animals or plants. It is very unusual for an insecticide to pose no acute or chronic risk of concern to aquatic invertebrates. Sulfoxaflor is truly unique in this regard. It also poses no acute or chronic risk of concern to fish. The comparison of sulfoxaflor's toxicity endpoints for these taxa to the endpoints of the six alternatives underscores the wide spectrum of difference between these different insecticides. An excellent example is the following comparison of the acute LC_{50} (µg a.i/L) endpoint for freshwater invertebrates:

Chemical	**Freshwater Invertebrate Acute LC_{50} (µg a.i/L)**
Sulfoxaflor	>4000000
Lambda-cyhalothrin	0.0003
Bifenthrin	0.00049
Chlorpyrifos	0.06
Imidacloprid	0.77
Dicrotophos	12.6
Acephate	26

This table indicates that lambda-cyhalothrin is the most toxic chemical to freshwater invertebrates because the acute lethal concentration is only 0.0003 µg/a.i./L. This means it takes only 0.0003 micrograms of lambda-cyhalothrin in a liter of water to kill 50% of a test population of a freshwater invertebrate. The contrast to sulfoxaflor is dramatic since it would take >4,000,000 micrograms of sulfoxaflor to kill 50% of the same population. A similar example is the acute LC_{50} endpoint for freshwater fish:

Chemical	Freshwater Fish Acute LC_{50} (μg a.i/L)
Sulfoxaflor	>363000
Lambda-cyhalothrin	0.029
Bifenthrin	0.15
Chlorpyrifos	1.8
Imidacloprid	229000
Dicrotophos	5700
Acephate	25000

In this case, lambda-cyhalothrin is again the most toxic compared to the other six insecticides and sulfoxaflor is the least toxic.

The sulfoxaflor chronic endpoints for freshwater organisms, and the acute and chronic endpoints for estuarine and marine organisms compare similarly to those shown above in that sulfoxaflor exhibits lower toxicity compared to the alternatives.

For terrestrial organisms, sulfoxaflor has a better toxicity profile for birds across nearly all endpoints, including the acute oral LD_{50}, the acute dietary LC_{50}, and the reproductive NOAEC. An example of this comparison of sulfoxaflor's low toxicity to birds compared to the six alternatives is shown in the following table of the acute dietary LC_{50} (mg a.i/kg-diet) for each of the chemicals:

Chemical	Avian Acute Dietary LC_{50} (mg a.i/kg-diet)
Sulfoxaflor	>5620
Lambda-cyhalothrin	3948
Bifenthrin	1280
Chlorpyrifos	136
Imidacloprid	1536
Dicrotophos	13
Acephate	42

For terrestrial mammals, sulfoxaflor is far less toxic than the six alternative insecticides when comparing the acute oral LD_{50} (the lethal dose in milligrams active ingredient per kilogram of body weight, ie. mg a.i/kg-bw) values:

Chemical	Mammalian Acute Oral LD_{50} (mg a.i/kg-bw)
Sulfoxaflor	750
Lambda-cyhalothrin	56

Bifenthrin	53.8
Chlorpyrifos	118
Imidacloprid	424
Dicrotophos	8.0
Acephate	15.6

Impact on Pollinators:

EPA recognizes that honey bees are the most important managed pollinators in the U.S. Honey bees enable the production of at least 90 commercially grown crops when utilized by commercial beekeepers to provide pollination services.[38] In the U.S., commercial beekeeping adds between $15 and $20 billion in economic value to agriculture each year.[39] Other managed pollinators utilized by growers include alkali bees, leaf-cutting bees and bumblebees. EPA believes that sulfoxaflor has less of an impact on bees than its main alternatives.

A full comparison of honeybee toxicity for sulfoxaflor and its main alternatives cannot be made because EPA does not yet have all the data for the other insecticides. For example, only sulfoxaflor has the Tier I larval toxicity study. Sulfoxaflor as well as the alternatives, are characterized as acutely toxic by contact exposure, as shown in the table below.

Chemical	**Acute Contact LD_{50} (µg/bee)**
Sulfoxaflor	0.130
Lambda-cyhalothrin	0.038
Bifenthrin	0.015
Chlorpyrifos	0.059
Imidacloprid	0.043
Dicrotophos	0.76
Acephate	1.2

The formulation-specific RT_{25} values, are available for products containing four of the alternatives. Sulfoxaflor formulated as Transform WG and Closer SC has a much shorter RT_{25} value than the other products suggesting that it dissipates from treated foliage in the field faster than the registered alternatives.

Chemical	**RT_{25} (hours)**
Sulfoxaflor	<3
Lambda-cyhalothrin	54
Bifenthrin	24 - 48

[38] https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Blog/PPAP_2016.pdf
[39] http://cues.cfans.umn.edu/old/pollinators/pdf-value/EconomicValueCommercialBeekeeping.pdf

Chlorpyrifos	>24
Imidacloprid	8
Dicrotophos	No data available
Acephate	No data available

In addition, DAS has submitted 16 field trials that analyzed sulfoxaflor residues in pollen and nectar for multiple crops. Given the short persistence of sulfoxaflor in pollen and nectar (dissipation half-life values are typically 2 days or less), sulfoxaflor is not expected to sequentially accumulate in pollen and nectar with repeated applications based on the proposed application intervals. Pollen and nectar residue data are available for imidacloprid but are not available for the other alternatives.

Additionally, the studies show that when sprayed directly on foraging honey bees, the impacts of sulfoxaflor was short-lived (3 days or less) and long-term effects on the colonies was not indicated. Residues of sulfoxaflor in pollen and nectar also tended to be short-lived, disappearing by 50% or more usually within 2 days or less. The importance of honey bees and other pollinators to the U.S. food supply, and the significant value of pollination services warrants the registration of crop protection pesticides that improve the existing risk situation for bees. EPA believes that sulfoxaflor is better for bees than the registered alternatives.

Synergy – Patent Information

DAS conducted a United States patent search and information retrieval for any patents making assertions of "greater than additive" (GTA) interactions of sulfoxaflor when mixed with other pesticidal active ingredients. The search was a generalized search for assertions of mixtures with any pesticide active ingredients and so was not limited to a specific set of combinations with other active ingredients. The patent search returned 85 related results and all 85 were determined to not be relevant to the ecological risk assessment based on the relevancy criteria.

For 83 of 85 (98%) of these patents, at least one relevancy criterion was not met, and therefore these patents were not further considered. Two additional patents (US7960354B2 and US8685423B2) were determined to meet all relevancy criteria. For each of these patents, EFED evaluated the reported supporting effects data to determine if the information available from the patent could support a statistical comparison of empirical mixture results with those expected for the mixture under an assumption of additivity.

Following this evaluation, EFED concluded these patent data sets do not warrant a consideration of the quantitative impact on the ecological risk assessment due to their insufficiency to support such an analysis.

Data Gaps

There are no data gaps for sulfoxaflor.

Regulatory Rationale

EPA is unconditionally granting new uses for sulfoxaflor under section 3(c)(5) of FIFRA. The entirely new uses are alfalfa, corn, cacao, grains (millet, oats), pineapple, sorghum, teff, teosinte and tree plantations. The new uses that had previously been granted and vacated are citrus, cotton, cucurbits, soybeans and strawberry. This regulatory action adds these crops to the labels for Transform WG (EPA Registration No. 62719- 625), Closer SC (EPA Registration No, 62719-623) and Sulfoxaflor Technical (EPA Registration No. 62719-631). EPA is also granting amendments to the Transform WG and Closer SC labels that remove certain restrictions.

The regulatory decision for these crops is supported by the conclusion that the benefits of sulfoxaflor outweigh the risks as discussed below.

- In addition to bees foraging on the treated field, bees may also be foraging on blooming plants adjacent to the treated fields. In these situations, bees may become exposed through interception of pesticide spray droplets that drift off site during application. Since the drift of ground and aerial sprays declines exponentially with distance from the treated field, the highest off-field exposures occur at the near edge of treated fields. EPA determined that for Closer SC applied at the maximum rate of 0.09 lb a.i./A, the acute risk LOC is exceeded for bees potentially foraging in sites ranging up to 2 feet from the treated field during a ground application to 12 feet during an aerial application. Furthermore, Transform WG is roughly 50% less toxic on an acute contact exposure basis than Closer SC; therefore, the distances at which the acute contact risk LOC is exceeded will be shorter for Transform WG at the maximum application rate of 0.09 lb a.i./A. As noted, the risk is *potential* as bees will only be exposed if there is blooming vegetation that attracts them within the 2 -12 foot off-field distances. Additionally, the labels include spray drift mitigation requirements to limit drift. At this time, the alternative chemicals do not have on-field buffers although off-field risk assessments for bees have been conducted for the four neonicotinoid insecticides. In comparison to sulfoxaflor, the calculated buffers for which there is an LOC exceedance off the field for imidacloprid have a ground range of 62-66 feet and an aerial (depending on droplet size) range of 141-381 feet. These buffers are substantially larger than the 2-12 feet for sulfoxaflor. The alternative insecticides, including imidacloprid, do not currently have on-field buffers. Considering this and the information noted above, EPA is removing the requirement for a 12 foot down-wind, on-field aerial buffer from the Closer SC and Transform WG labels.

- Grains, such as millet, oats and teff, are not considered honey bee attractive. Off-field risk is considered minimal because the maximum application rate is 0.043 lb a.i./A which is half the rate discussed above. The target pests are aphids, including Russian wheat aphid and greenbug which have been problematic for growers in the past. Sulfoxaflor will add a new mode of action against the aphids and will fit well into IPM and IRM programs. EPA concludes that the risk to bees is minimal when sulfoxaflor is used on these grain crops and the benefits outweigh the risk. The FIFRA standard is met for the registration of sulfoxaflor on millet, oats and teff.

- The risk estimate for honey bees is below the LOC for the use of sulfoxaflor on: corn (including teosinte), cotton and sorghum. Off-field risk is considered minimal because the maximum application rate for corn and sorghum is 0.043 lb a.i./A and is 0.07 lb a.i./A for cotton, which is less than the rate of 0.09 lb a.i./A discussed above and would result in lower risk to bees.

  Furthermore, registering sulfoxaflor on these crops will provide a new mode of action against the emergency exemption pests (e.g. Tarnished plant bug, Sugarcane aphid) and other problematic pests. Sulfoxaflor has a better ecological profile compared to the registered alternatives used on these crops, such as organophosphates (e.g. chlorpyrifos), pyrethroids (e.g. lambda-cyhalothrin) and neonicotinoids (e.g. imidacloprid). These alternatives are highly toxic to bees and are generally applied more frequently and at higher rates than sulfoxaflor. For example, the total amount of acephate that may be applied to cotton to control aphids is 4 lbs a.i/A/year versus 0.266 lbs a.i./A/year for sulfoxaflor. The higher rates and/or more frequent applications of the alternatives put bees at a higher risk of exposure. Additionally, as discussed above, studies suggest that sulfoxaflor dissipates fairly quickly in the field.

  Given that sulfoxaflor provides high benefits to growers, especially of cotton and sorghum who are facing very challenging pests, and that use of sulfoxaflor on these crops is below the LOC for nontarget organisms, including bees, EPA finds that the benefits outweigh the risks. The FIFRA standard is met for registration of sulfoxaflor on corn, cotton and sorghum.

- The risk estimate for honey bees is above the LOC for alfalfa, cacao, citrus, cucurbits, pineapple, soybeans and strawberry. The regulatory rationale for registering these crops is based on the following:

  - Alfalfa: alfalfa is cut multiple times/season, generally before bloom. Sulfoxaflor is limited to two applications/cutting and has a maximum application rate of 0.09 lb/a.i./A with a maximum of 0.266 lb a.i./A/year, limiting sulfoxaflor to only 3 applications/acre/year at the maximum rate. The maximum application rate of 0.09 lb a.i./A is used against Lygus bugs ("Tarnished plant bug") but when used to control aphids, the maximum application rate for sulfoxaflor is 0.031 lb a.i./A. As discussed above, the off-field risk of sulfoxaflor when used at the maximum rate just for Lygus, poses a risk if bees are foraging downwind on blooming plants 2 -12 feet off the treated field. This risk is acknowledged but judged to be minimal since any blooming plants are likely to be random and scattered within this relatively small area (≤ 12 feet).

Alfalfa grown for seed is a very specialized crop whose growers utilize alkali bees and imported leaf-cutter bees. While not required, growers often apply insecticides at night to protect these specialized bees. This practice is protective of other bees as well. For several years, alfalfa seed growers have struggled to control Lygus bugs and Washington state growers sought and were granted an emergency exemption to use sulfoxaflor against this pest since they were faced with significant economic damage to their crop. Sulfoxaflor will be a new mode of action for alfalfa growers and can be used as an alternative to organophosphates, carbamates, pyrethroids and neonicotinoids. Since the growing practices for alfalfa and alfalfa grown for seed generally limit exposure to bees from pesticide applications and since sulfoxaflor has a much better ecological profile than the alternatives and is the most efficacious insecticide against Lygus bugs, EPA finds that the benefits of sulfoxaflor outweigh the risks. The FIFRA standard is met for registering sulfoxaflor on alfalfa.

- <u>Cacao</u>: cacao is a very minor crop in the US, grown commercially on about 100 acres on Hawaii. Sulfoxaflor is being registered on cacao for only one pest, the Black citrus aphid, which is the most common aphid pest of cacao world-wide.[40] The maximum application rate is low, limited to 0.038 lb a.i./A, and a 28-day interval must be observed between applications. Sulfoxaflor provides another mode of action for control of this aphid. The low rate indicates that there is low potential for off-field risk to bees. Sulfoxaflor will be a useful tool for growers of this specialty crop; therefore, EPA concludes that the benefits outweigh the risk. The FIFRA standard is met for registering sulfoxaflor on cacao.

- <u>Citrus</u>: citrus growers have a critical need for sulfoxaflor to combat the Asian citrus psyllid (ACP). The sulfoxaflor labels limit applications when the crop is attractive to honey bees to only one application between three days before bloom and until after petal fall, which reduces the exposure to bees. Sulfoxaflor will provide citrus growers with a new mode of action against this and other serious pests of citrus. It will be an alternative to more toxic compounds, including organophosphates, neonicotinoids, abamectin and pyrethroids. The citrus industry in the US is in a desperate situation in Florida from the ACP and other pests, and citrus in Texas and California are threatened. Growers have relied on alternative insecticides, such as neonicotinoids and organophosphates, that are more toxic to non-target organisms

[40] https://www.cabdirect.org/cabdirect/abstract/19770544274

than sulfoxaflor. The benefits to this industry outweigh the risk and EPA concludes that the FIFRA standard is met for registration of sulfoxaflor on citrus.

- Cucurbits: Cucurbit vegetables are indeterminate bloomers, meaning they bloom continuously, making at-bloom restrictions impractical and therefore treatments are expected to cause some exposure to bees. The maximum application rate for sulfoxaflor on cucurbits is 0.071 lbs. a.i./A. It may be applied up to four times and has a seven-day interval between applications. Pollen and nectar residue trials conducted in France, Germany and the US showed 29 out of 32 samples below the "no observed effect level." The residues declined within three days; therefore, with the seven-day application interval, accumulation is unlikely across multiple applications. Sulfoxaflor targets aphids and whiteflies on cucurbits, both of which are able to develop resistance fairly rapidly, thus, the new mode of action will fit well with IRM programs. Sulfoxaflor will also be an alternative to neonicotinoids and pyrethroids which have a more toxic ecological profile to other species. As noted above, sulfoxaflor is not as harsh on beneficial insects such as predatory beetles (e.g. ladybugs) which prey on aphids, and will fit well into IPM strategies. EPA concludes that the benefits of using sulfoxaflor outweigh the risks, especially compared to the alternative pesticides. The FIFRA standard is met for registration of sulfoxaflor on cucurbits.

- Pineapple: The target pest for sulfoxaflor is mealybugs which vector "Pineapple Mealybug Wilt Associated Virus." Sulfoxaflor is limited to two applications per year on pineapple. It will be an alternative to the organophosphates; malathion and diazinon, as well as to pyrethroid insecticides. As discussed above, these compounds are more toxic to nontarget organisms than sulfoxaflor. Pineapple is a very minor crop in the US and growers would benefit from another tool to combat mealybugs. EPA concludes that the FIFRA standard is met for the registration of sulfoxaflor on pineapple.

- Soybeans: The main target pest for sulfoxaflor is the soybean aphid and the maximum application rate is just 0.031 lb ai/A. Sulfoxaflor will be an alternative to more toxic compounds such as lambda-cyhalothrin (a pyrethroid), chlorpyrifos (an organophosphate) and neonicotinoids for soybean aphid. The US soybean growers need another tool to help control this aphid pest. The unique mode of action that sulfoxaflor will provide benefit the growers. While soybeans are attractive to bees, the low rate and 14-day interval between applications help minimize the risk. EPA concludes that the benefits of registering sulfoxaflor on soybeans outweigh the risks and the FIFRA standard is met.

- Strawberry: like cucurbits, strawberries are an indeterminate-blooming crop and at-bloom restrictions are impractical. Alternatives to sulfoxaflor include malathion (an organophosphate) and pyrethroids but these insecticides are no longer effectively controlling Lygus bugs. Since sulfoxaflor is very effective against this pest, California growers were granted an emergency exemption to use sulfoxaflor against Lygus. These growers documented that the registered alternatives were not effective and that they were facing a significant economic loss of at least 20% without the use of sulfoxaflor. Sulfoxaflor has a better ecological profile than these alternatives and will provide high benefit to strawberry growers in the US. In light of these conclusions, EPA believes that the FIFRA standard is met for registering sulfoxaflor on strawberries.

With this regulatory decision, EPA is also removing the 2016 restriction against use on crops grown for seed. The pollinator protective restrictions that are present on some crops (e.g. canola) apply whether the crop is grown for seed or for commodity harvest. The alternative chemicals are not restricted from use on crops grown for seed and they pose a higher ecological risk to non-target organisms than does sulfoxaflor.

EPA is also removing the limitation to post-bloom applications only that was imposed in 2016 on canola, fruiting vegetables, ornamentals, pome fruit, potato, and succulent and dry beans, for the following reasons:

- The use of sulfoxaflor on canola and pome fruit is below the LOC.

- The use on ornamentals during bloom is limited to one application only.

The use on fruiting vegetables and potato is above the LOC but fruiting vegetables (except okra) and potato (except sweet potato) are not particularly attractive to honey bees. The Tier I risk slightly exceeds the chronic oral LOC (sweet potato RQ = 3.7, okra RQ = 8.4). The use on succulent and dry beans also exceeds the LOC, however the estimated risk broadly covers a large number of varieties (crops) in this category. There are over 30 minor varieties listed on the Transform label and the attractiveness and bloom duration is highly variable across this category. The maximum application rate for sulfoxaflor on all these crops is low for aphid control, at only 0.031 lb a.i./A and for plant bugs, it is 0.071 lb a.i./A. The registered alternative insecticides used on succulent and dry beans include organophosphates, neonicotinoids and pyrethroids which have more toxic ecological profiles than sulfoxaflor.

- Registering sulfoxaflor with restrictions may limit the ability of some growers to use a new tool against challenging pests and cause them to rely on the more toxic alternatives. Additionally, sulfoxaflor presents less risk to beneficial arthropods (predatory mites, beetles etc) than the registered alternatives and so will fit well into IPM programs that strive to maintain healthy populations of these biocontrol species.

Finally, EPA is also removing the 2016 restriction against tank mixing. EPA has received information that indicates there is no additive risk when sulfoxaflor is tank mixed with other compounds. EPA's review of this information is documented in "Response to the Patent Search for Possible Claims of GTA Effects in Support of the Section 3 Environmental Fate and Ecological Risk Assessment for Sulfoxaflor" DP453000, July 2, 2019.

The database for sulfoxaflor submitted to support the assessment of human health risk is sufficient for a full hazard evaluation and is considered adequate to evaluate risks to infants and children. The Agency has not identified any risks of concern to human health, including all population subgroups, or for occupational handlers. The assessment is conservative.

The ecological risk assessment is conservative and overall presents a low risk to aquatic and terrestrial organisms. The database on pollinators is robust, the Tier I data set is complete. The Tier II data set includes semi-field (tunnel) studies, colony-feeding studies and field trials of residues in nectar and pollen. As discussed above, the relatively large suite of sulfoxaflor Tier II studies and with consideration of the conservative assumptions regarding exposure (e.g., colonies get 100% of their diet from the treated crop) used in the risk assessment, the requirement for a full field study has been waived. EPA believes that a full-field study will not add meaningful input to our conclusions.

The formulated products each have a residual toxicity time (RT_{25}) of < 3 hours. Furthermore, the relatively short persistence of sulfoxaflor in pollen and nectar is expected to reduce the duration of exposure of bees. With the remaining label restrictions, EPA has determined that the risk to bees and other nontarget organisms is not unreasonable when balances against the benefits that sulfoxaflor will provide.

EPA has determined that the composition of the sulfoxaflor registration warrants the proposed claims and that the labeling for Transform WG and Closer SC comply with the requirements of FIFRA. EPA has also determined that sulfoxaflor will perform its intended function without unreasonable adverse effects on the environment. EPA finds that when used in accordance with widespread and commonly recognized practices, sulfoxaflor will not generally cause unreasonable adverse effects on the environment. Therefore, EPA is unconditionally granting the new uses for sulfoxaflor as described above and approving the amended labeling as described above, under section 3(c)(5) of FIFRA.

Mitigation and Labeling Requirements:

1. There are no label changes required for protection of applicators or workers.

2. The Transform WG label contains the following language for protection of applicators:

- Applicators and other handlers must wear: Long-sleeved shirt and long pants, shoes plus socks, protective eyewear.
- Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours.

3. The Closer SC label contains the following language for protection of applicators:
   - Applicators and other handlers must wear: Long-sleeved shirt and long pants, shoes plus socks.
   - Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

4. The following text must appear in the Environmental Hazards Statement on both Transform WG and Closer SC:

   > "This product is highly toxic to bees and other pollinating insects exposed to direct treatment or to residues in/on blooming crops or weeds. Protect pollinating insects by following label directions intended to minimize drift and reduce pesticide risk to these organisms."

5. To limit spray drift, the Directions for Use requires medium or coarser spray nozzles; a boom height of <4 feet is specified for ground applications; and aerial applications are limited to a height no greater than 10 feet above the crop. Applications are prohibited when the wind speed exceeds 10 miles per hour.

6. The following crop-specific restrictions requested by DAS to protect pollinators are included in the Directions for Use:

   - Citrus: Only one application is allowed between 3 days before bloom and until after petal fall per year

   - Ornamentals: Do not make more than one application during bloom. The single application during bloom must not exceed a rate of 0.071 lb ai/acre.

   - Pome Fruit, Stone Fruit, Tree Nuts and Pistachio: Do not apply this product any time between 3 days prior to bloom and until after petal fall.

   - Small Fruit Vine Climbing & Low Growing Berry, Tree Plantations: Do not apply this product any time between 3 days prior to bloom and until after petal fall.

7. Labeling recommendations that are intended to increase awareness and promote pollinator protection through communication have been added to the labels for both products. Additionally, EPA has heard from beekeepers, growers and state lead agencies that products with low residual toxicity (referred to as RT_{25} data) could be used during

bloom and lead to little harm to managed pollinators. Both sulfoxaflor products have low residual toxicity and the RT_{25} has been added to the labels.

> "Notifying known beekeepers within 1 mile of the treatment area 48 hours before the product is applied will allow them to take additional steps to protect their bees. Also, limiting application to times when managed bees and native pollinators are least active, *e.g.* 2 hours prior to sunset or when the temperature is below 50°F at the site of application will minimize risk to bees."
>
> "The RT25 for this product is less than or equal to 3 hours."

8. The following restrictions required in October 2016 are removed: prohibition of use on crops grown for seed, a 12' on-field aerial buffer, and the prohibition of tank-mixing. These restrictions were imposed until EPA received synergy (patent) information to address the potential increased risk to non-target organisms from tank-mixing and to limit exposure to bees from blooming crops grown for seed and from off-site drift until EPA received additional bee studies. As explained above, EPA has received the synergy information and the bee studies.