

Sulfoxaflor – Final Cancellation Order

Summary

This notice announces the Agency's issuance of a final cancellation order for all pesticide products containing the active ingredient sulfoxaflor pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. sections 136-136y. This order includes provisions for the disposition of existing stocks of sulfoxaflor products that have been released for shipment prior to today's date. Under the provisions of this final cancellation order, as of today's date, it is unlawful for the registrant to sell or distribute these products except for the purposes of proper disposal or lawful export. Sale or distribution of sulfoxaflor products already in the possession of persons other than the registrant may only be distributed to facilitate return to the manufacturer or for proper disposal or lawful export. Use of existing stocks by end users is permitted provided such use is consistent in all respects with the previously-approved labeling for the product.

Background

In 2010, EPA received applications from Dow AgroSciences (DAS) to register three new pesticide products containing the active ingredient sulfoxaflor – a sulfoxamine insecticide – under section 3 of FIFRA, 7 U.S.C. 136a, for use on a wide variety of agricultural crops. After an opportunity for public comment, EPA issued a decision to register sulfoxaflor on May 6, 2013 with several restrictions intended to reduce sulfoxaflor's risk to bees. Three product registrations containing sulfoxaflor were initially granted in May of 2013, and four registrations were granted later based on the earlier decision to register sulfoxaflor and their similarity to the three initial registrations with respect to sulfoxaflor. The products are: Sulfoxaflor Technical, Closer SC, Transform WG, GF-2860 Ornamental, Seeker, TwinGuard WG, GF-3052 WG (EPA Registration Numbers 62719-631, 62719-623, 62719-625, 62719-676, 62719-677, 62719-678, and 62719-681, respectively).

On July 2, 2013, the Pollinator Stewardship Council along with other pollinator advocates and beekeepers, petitioned for review of EPA's registration of sulfoxaflor decision in the Ninth Circuit Court of Appeals. On September 10, 2015, the Court issued its opinion in *Pollinator Stewardship Council, et al. v. EPA* (No. 13-72346). Finding that EPA's registration of sulfoxaflor was not supported by substantial evidence, the Court vacated the registrations and remanded them to EPA to obtain further studies regarding the effects of sulfoxaflor on bees. The vacatur of the sulfoxaflor registrations became effective November 12, 2015, such that the registrations were no longer in effect under FIFRA, and no new sulfoxaflor material could or can lawfully be released for shipment by manufacturers unless and until new registrations are issued.

Agency Authority to Issue Cancellation Order to Regulate Existing Stocks

Before addressing the appropriateness of allowing sale, distribution, or use of existing stocks of sulfoxaflor, we first address the threshold issue of whether the Agency has the authority to issue a cancellation order in the circumstances presented by the vacatur of sulfoxaflor. EPA

believes that FIFRA is best read as allowing the Agency to issue a cancellation order whenever a pesticide that has been sold with the imprimatur of a registration has that registration terminated, for whatever reason. The fact remains that distributors and end-users may have possession of stocks of a pesticide product purchased in good faith after EPA issued a registration permitting distribution of the product in commerce and establishing conditions pertaining to the use of the product. The issuance of a cancellation order allows the Agency to appropriately regulate distribution and use of those stocks.

In the case of sulfoxaflor, while the Circuit Court determined that the registrations should not be allowed to continue unless and until EPA obtains additional studies and data on sulfoxaflor's effect on bees, the question of what should happen to existing stocks of sulfoxaflor that are already in the channels of trade (*i.e.*, material that has been released for shipment and is in the hands of sellers, distributors, or users) at the time the registrations terminate due to the vacatur was not before the court. In the absence of any action by EPA, all sale and distribution of formerly-registered sulfoxaflor products would be unlawful under FIFRA upon vacatur. The term "distribute or sell" is defined very broadly in FIFRA section 2(gg) (7 U.S.C. §136(gg)), and includes, among other things, any "shipment" of unregistered pesticide. Without action by EPA, the termination of the registrations would thus make illegal not just any sale, but any further movement of material currently in the hands of distributors or retailers. FIFRA section 12(a)(1)(A) (7 U.S.C. §136(j)(a)(1)(A)) makes it a violation of FIFRA for any person to sell or distribute an unregistered pesticide, and subjects any seller/distributor to potential civil or criminal penalties under FIFRA section 14 (7 U.S.C. §136l).

There is no corresponding provision of FIFRA that prohibits *use* (as opposed to distribution or sale) of unregistered pesticides (*see* FIFRA section 12 (7 U.S.C. §136j)). Furthermore, section 12(a)(2)(G) (7 U.S.C. §136j(a)(2)(G)) only makes it a violation of FIFRA for any person to "use any **registered** pesticide in a manner inconsistent with its labeling" (emphases added); there is no provision that requires that unregistered pesticides (including formerly-registered pesticides) be used according to their labels. Thus, in the absence of EPA action, users of unregistered pesticides are not obligated to follow the labeling (which, for registered pesticides, prescribes enforceable conditions for using the particular pesticide, among other things) accompanying the product. Therefore, once the registrations are terminated, unless EPA takes action, persons holding stocks of sulfoxaflor would not be legally precluded from using those stocks without following label directions, including the restrictions intended to reduce the risks to bees.

FIFRA contains a provision that allows EPA to issue enforceable orders governing the sale, distribution, and use of existing stocks of cancelled pesticides. Specifically, section 6(a)(1) of FIFRA (7 U.S.C. §136d(a)(1)) provides that: "The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under [sections 3, 4 or 6 of FIFRA] to such extent, under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of [FIFRA]." Section 12(a)(2)(K) of FIFRA (7 U.S.C. §136j(a)(2)(K)) makes the failure to comply with a cancellation order enforceable under FIFRA. Whenever EPA cancels a registration, it issues such a cancellation order establishing enforceable provisions concerning the disposition of existing stocks. Such orders can authorize sale or distribution that would otherwise be unlawful,

and they can prohibit use that would otherwise be lawful. They can also contain limitations or conditions on the sale, distribution, or use that the Administrator determines to be appropriate; one such limitation that EPA frequently applies to existing stocks is a condition that any authorization of use of such stocks is limited to use that is consistent with the previously-approved labeling accompanying the product.

In the case of sulfoxaflor, the registrations are being vacated by court order, rather than cancelled by EPA itself. Nonetheless, the Agency believes that the Court's action in vacating the sulfoxaflor registrations is best viewed under FIFRA as a cancellation of those registrations under section 3 (because the vacatur is based upon the lack of substantial evidence to support the registrations under section 3 of FIFRA). EPA followed this same approach when registrations of spirotetramat were vacated by the U.S. District Court for the Southern District of New York. *See* Spirotetramat Final Cancellation Order, available at <http://www2.epa.gov/ingredients-used-pesticide-products/final-cancellation-order-issued-spirotetramat>. *See also* Termilind Limited; Notice and Order of Revocation of Registrations, 62 Fed. Reg. 61890 (Nov. 19, 1997). The Agency is therefore issuing a cancellation order under FIFRA section 6(a)(1) that establishes provisions governing the disposition of existing stocks of previously-registered sulfoxaflor pesticide product.

In similar situations, the Agency has considered proceeding via Stop Sale, Use, and Removal Order (SSURO) rather than a cancellation order, but rejected this course of action. Section 136k(a) requires SSUROs to be "issued . . . to any person who owns, controls, or has custody" of the pesticide that is subject to the order, which order is effective as to that person only "after [he] recei[ves] . . . that order." EPA interprets this language to require personal delivery to each such person. For such a widely used pesticide as sulfoxaflor, personal delivery would present enormous practical difficulties for EPA to ascertain the names and addresses of all such persons (including all end-users) and issue SSUROs to them, which the Agency does not believe is warranted in the instant circumstance.

In sum, EPA believes that it has the authority under FIFRA to issue a cancellation order establishing provisions for the disposition of existing stocks of sulfoxaflor. We turn next to the issue of whether, and to what extent, distribution, sale, or use of existing stocks of sulfoxaflor should be allowed.

Existing Stocks Determination

EPA issued in 1991 a policy statement outlining the considerations it generally applies in determining how to treat existing stocks in cancellation orders. *See* 56 Fed. Reg. 29362 (June 26, 1991). In general, if no significant risk concerns have been identified for a cancelled product, such as when a product is voluntarily cancelled, the policy statement suggests that the Agency will generally allow unlimited use of existing stocks, and unlimited sale by persons other than the registrant. A registrant will generally be allowed to continue to sell existing stocks for 1 year after the date cancellation is requested, or 1 year after the date the registrant has ceased to comply with the responsibilities that are placed upon registrants, whichever date is sooner. 56 Fed. Reg. at 29362, 29367.

If there are significant risk concerns associated with a cancelled pesticide, the policy statement states that the Agency will generally make a case-by-case determination as to whether to allow the continued sale or use of existing stocks of the pesticide. That determination, like the initial decision to register a pesticide, will focus on the social, economic, and environmental risks and benefits associated with such sale and use. But while the registration decision focuses almost exclusively on the risks and benefits associated with the use of the pesticide, the existing stocks determination is somewhat different because it focuses on product already manufactured and (in many cases) sold to others. Thus, EPA identified in the policy statement six factors it might consider in making such risk benefit decisions, including: 1) the quantity of existing stocks at each level of the channels of trade; 2) the risks resulting from the use of the existing stocks; 3) the benefits resulting from the use of such stocks; 4) the financial expenditures users and others have already spent on existing stocks; 5) the risks and costs of disposal or alternative disposition of the stocks; and 6) the practicality of implementing restrictions on distribution, sale, or use of the existing stocks. 56 Fed. Reg. at 29364.

In considering how to apply the policy to sulfoxaflor, EPA decided that the opinion of the Ninth Circuit Court of Appeals was a more important consideration than the standard six factors it generally considers. The sulfoxaflor registrations were terminated because of judicial action where the Court found the registrations were not supported by substantial evidence. In deciding to vacate the registrations rather than remand the matter to EPA without vacatur, the court, in its September 10, 2015 opinion, pointed to the precariousness of bee populations for its determination that leaving the registrations in place risks more potential environmental harm than vacating them. In remanding the registration to the Agency, the Court ordered EPA to obtain further studies and data regarding the effects of sulfoxaflor on bees before issuing similar registrations.

While the Agency had determined that the benefits of sulfoxaflor outweighed that uncertain risk when mitigation measures were applied, EPA will not second-guess the Court's conclusion that the registrations at issue in the case were not supported by substantial evidence. The Court vacated those registrations ordering EPA to obtain further studies and data regarding the effects on sulfoxaflor on bees, as required by EPA regulations. EPA has not yet obtained additional data nor has EPA assessed whether the currently available data could support a subset of uses without triggering the additional data that the Court determined were required for the registrations as EPA had approved them. Therefore, because the Court rejected EPA's conclusions that sulfoxaflor could be registered, the cancellation order issued today restricts sale and distribution of existing stocks of sulfoxaflor except for safe disposal, lawful export or to facilitate return to the manufacturer.

Nonetheless, some existing stocks of sulfoxaflor are also held by end-users. For users, EPA will allow continued use of sulfoxaflor, other than use by manufacturers for formulation into other pesticide products, provided that use is consistent with the previously approved-labeling accompanying the product. While EPA agrees that there is uncertainty about sulfoxaflor's risks to bees, EPA does not believe use of existing stocks of sulfoxaflor would significantly impact bees. The previously-approved sulfoxaflor labeling contains extensive mitigation measures intended to reduce the risk of adverse effects on bees. This includes low maximum application rates, long intervals required between applications and for some crops

restrictions against applying before or during bloom when bees are most likely to be present. Other crops for which sulfoxaflor was registered are not bee-attractive or are harvested before they bloom which reduces the exposure to bees.

In addition, disposal or return of product already in users hands is burdensome, especially in a case where EPA does not believe there is a substantial or imminent risk to continued use. Disposal can be expensive with costs both for transportation and disposal itself. When containers of sulfoxaflor have already been opened, transporting them can create a greater risk of spillage. Opened containers also create additional burden when sent for disposal because proper disposal may require that the content be verified, adding additional expense. While some states provide programs for free disposal of pesticides, such programs only shift the expense to states rather than users.

Finally, as a general matter, EPA believes it a mistake to issue restrictions on existing stocks unless the holders of stocks are notified of the restrictions and are likely to comply with them. While EPA believes it likely that most distributors of sulfoxaflor will learn of the restrictions on sale being imposed, it is less likely that users who already hold sulfoxaflor stocks will be aware. As mentioned above in connection with the possibility of personally serving SSUROs, it would be highly impractical to ensure that all sulfoxaflor users are notified and such notification would entail the devotion of significant governmental resources. EPA expects that users that are unaware of this cancellation order will continue to use the products consistent with their labeling because that is their regular practice when using pesticides. Therefore, EPA has concluded that such expenditures are unwarranted under the facts presented by sulfoxaflor.

For these reasons, EPA considers it appropriate to allow existing stocks of sulfoxaflor in the hands of users to be used until exhausted.

Final Cancellation Order, Including Provisions for Existing Stocks

1. Pursuant to section 6 of FIFRA, EPA hereby issues a final cancellation order for the registrations of all sulfoxaflor registrations listed below. Any distribution, sale, or use of these products in a manner inconsistent with this order, including the provisions below regarding the disposition of existing stocks, will be considered a violation of section 12(a)(2)(K) and/or 12(a)(1)(A) of FIFRA. This order will remain in effect unless and until it is amended.
2. Existing Stocks. For purposes of this order, the term “existing stocks” is defined, pursuant to EPA’s existing stocks policy (56 FR 29362, June 26, 1991) as those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the vacatur (termination) of the affected registrations. Pursuant to section 6(a)(1) of FIFRA, this cancellation order includes the following existing stocks provisions.

- a. Distribution or sale by the registrant. Distribution or sale by the registrant of all cancelled products listed below is prohibited effective as of today's date, except for the purposes of proper disposal or to facilitate lawful export.
- b. Distribution or sale by persons other than the registrant. Distribution or sale of the cancelled products listed below already in the possession of persons other than the registrant is permitted only for the purposes of proper disposal, lawful export, or to facilitate return to the manufacturer.
- c. Use. Use of the cancelled products listed below, other than Sulfoxaflor Technical, is permitted until such stocks are exhausted, provided that such use of existing stocks is consistent in all respects with the previously-approved labeling accompanying the product and the use is covered by any necessary tolerances.

3. List of Cancelled Products

Sulfoxaflor Technical, EPA Reg. No. 62719-631
Closer SC, EPA Reg. No. 62719-623
Transform WG, EPA Reg. No. 62719-625
GF-2860 Ornamental, EPA Reg. No. 62719-676
Seeker, EPA Reg. No. 62719-677
TwinGuard WG, EPA Reg. No. 62719-678
GF-3052 WG, EPA Reg. No. 62719-681



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11/12/2015
Date