



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

March 4, 2024

Subject: Notice of Use Termination and Existing Stocks Order for Time-Limited Use on Citrus Crop Group 10-10 on Certain Streptomycin Sulfate Products

Product Names: AGRI-SEED™ 50 WP
EAC™ Streptomycin Manufacturing Use Product

Registration Nos.: 80990-3
91275-1

Summary

This document contains two elements: (1) a notice of the use termination for the January 12, 2021 registration amendments adding a time-limited use on citrus crop group 10-10 to two streptomycin sulfate products, and (2) an existing stocks order.

The notice of use termination serves as EPA's notice to all sellers, distributors, and users of AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3) and EAC™ Streptomycin Manufacturing Use Product (EPA Reg. No. 91275-1)¹ of the Ninth Circuit's order in *Migrant Clinicians Network v. EPA*, No. 21-70719, vacating the 2021 registration amendments to these products. As of **February 5, 2024** (the date of the Court's mandate), the use on citrus crop group 10-10 that was added to these registrations by the 2021 registration amendments is terminated and it is unlawful under FIFRA to sell or distribute products allowing such use except to the extent otherwise authorized by EPA.²

The existing stocks order contains EPA's provisions for the disposition of any existing stocks of these streptomycin sulfate products. "Existing stocks" mean those stocks of these streptomycin sulfate products that are labeled for use on citrus crop group 10-10 consistent with the 2021 registration amendments and were packaged, labeled, and released for shipment³ prior to **February 5, 2024**. In light of the Ninth Circuit's order, EPA is issuing this existing stocks order to establish the conditions for lawful sale, distribution, and use of these existing stocks. Under this

¹ In *Migrant Clinicians Network v. EPA* (No. 21-70719), this registration is referred to as "EPA Reg. No. 71185-4" (held by Geo Logic Corporation). However, in 2021, this registration was transferred to Earth Ag Corporation and given the new EPA Reg. No. 91275-1.

² See Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) § 12(a), 7 U.S.C. § 136j(a).

³ "A product becomes released for shipment when the producer has packaged and labeled it in the manner in which it will be distributed or sold, or has stored it in an area where finished products are ordinarily held for shipment." 40 C.F.R. § 152.3.

existing stocks order:

- It is unlawful for the registrants—Agrosource, Inc. and Earth Ag Corporation—to sell or distribute these products except for the purposes of proper disposal, lawful export, or to facilitate return to a registered production establishment for relabeling.
- In all states except Florida: Sale or distribution by persons other than the registrants who are already in possession of these products is permitted until **May 31, 2024**, but thereafter prohibited **except** for the purposes of proper disposal, lawful export, or to facilitate return to the registrant or another registered production establishment designated by the registrant for relabeling. Use of existing stocks of AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3) on citrus crop group 10-10 by any person already in possession of this product or subsequently purchasing existing stocks of this product is prohibited. However, use of existing stocks of AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3) for any other use on the labeling is permitted until all existing 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.
- In Florida: Sale or distribution by persons other than the registrants who are already in possession of these products is prohibited, **except** for the purposes of proper disposal, lawful export, or to facilitate return to the registrant or another registered production establishment designated by the registrant for relabeling. Use of existing stocks of AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3) by any person already in possession of this product or subsequently purchasing existing stocks of this product is permitted until **August 31, 2024** or until all existing stocks are exhausted (whichever is sooner), 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.

Additional details regarding the sale, distribution, and use of these products pursuant to this order are provided below in the section titled “EPA’s Order for the Disposition of Existing Stocks.”

Background

In 2015, Agrosource, Inc. and Geologic Corporation submitted applications to amend the registrations of existing streptomycin sulfate pesticide products to add a new use on citrus crop group 10-10 under FIFRA section 3.⁴ After an opportunity for public comment, EPA granted these registration amendments on January 12, 2021, adding a time-limited use on citrus crop group 10-10 for AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3) and EAC™ Streptomycin Manufacturing Use Product (EPA Reg. No. 71185-4). On March 25, 2021, Migrant Clinicians Network (along with other environmental and farmworker organizations) petitioned the Ninth Circuit Court of Appeals for review of EPA’s registration decisions.⁵ Geologic Corporation transferred EAC™ Streptomycin Manufacturing Use Product (EPA Reg. No. 71185-4) to Earth Ag Corporation on December 31, 2021 (altering the product’s registration number to EPA Reg. No. 91275-1).

Notice of Vacatur of EPA’s January 2021 Registration Amendments

On December 13, 2023, the Court issued an opinion vacating the January 2021 registration

⁴ 7 U.S.C. § 136a.

⁵ Petition for Review, *Migrant Clinicians Network v. EPA*, No. 21-70719 (9th Cir. Mar. 25, 2021).

amendments. The vacatur of these registration amendments became effective on February 5, 2024.⁶ Accordingly, as of that date, it is unlawful to sell or distribute these products labeled for use on citrus crop group 10-10 or labeled for use in formulating end-use products for use on citrus crop group 10-10, except as described below in the section titled “EPA’s Order for the Disposition of Existing Stocks.”⁷

Background

Under FIFRA section 3, generally a pesticide product must be registered with EPA before it may be sold or distributed.⁸ EPA may not generally register a pesticide unless, among other things, it first determines that the product and its use will not cause unreasonable adverse effects on the environment.⁹ Once a pesticide product is registered, FIFRA requires the product not be used inconsistent with its labeling.¹⁰ When a court vacates a registration amendment that had granted new uses, EPA believes that the vacatur under FIFRA functions as a termination of those uses. In such cases, EPA may issue an existing stocks order pursuant to FIFRA section 6(a), which provides that “[EPA] may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under [FIFRA sections 3, 4, or 6] to such extent, under such conditions, and for such uses as [EPA] determines that such sale or use is not inconsistent with the purposes of [FIFRA].”¹¹ FIFRA section 6(a) thus allows EPA to issue orders governing the distribution, sale, and use of existing stocks whenever a pesticide that has been sold with the imprimatur of a registration has that registration cancelled or a use terminated for any reason, including vacatur by a federal court. Existing stocks orders can authorize sale or distribution that would otherwise be unlawful and prohibit use that would otherwise be lawful. They can also contain limitations or conditions on the sale, distribution, or use that EPA determines are appropriate to ensure that the sale, distribution, and use is not inconsistent with the purposes of FIFRA. A common example is limiting use of existing stocks to use that is consistent with the previously approved labeling accompanying the product.

In determining whether sale or use in any particular situation is consistent with the purposes of FIFRA, EPA is mindful that the Agency must not allow pesticides to cause unreasonable adverse effects on the environment (defined as an unreasonable risk to man or the environment). But EPA is also mindful of FIFRA’s dictate that EPA consider effects on society, including any unnecessary economic burdens upon pesticide users or distributors when developing any existing stocks order. Here, EPA is also mindful of the Ninth Circuit’s decision to vacate the 2021 registration amendments.

In 1991, EPA issued a policy statement outlining its general considerations for treatment of existing stocks.¹² Where there are no significant risk concerns (*e.g.*, voluntary cancellation), EPA generally will allow unlimited use of existing stocks and unlimited sale and distribution of existing stocks by

⁶ Mandate, *Migrant Clinicians Network v. EPA*, No. 21-70719 (9th Cir. Feb. 5, 2024).

⁷ See FIFRA § 12(a), 7 U.S.C. § 126j(a).

⁸ FIFRA § 3(a), 7 U.S.C. § 136a(a).

⁹ FIFRA § 3(c), 7 U.S.C. § 136a(c).

¹⁰ FIFRA § 12(a)(2)(G), 7 U.S.C. § 136j(a)(2)(G).

¹¹ FIFRA § 6(a)(1), 7 U.S.C. § 136d(a)(1).

¹² See 56 Fed. Reg. 29,362 (June 26, 1991).

persons other than the registrant(s), while the registrants are allowed sale and distribution for a year.¹³ Conversely, if there are significant risks, EPA generally will make a case-by-case determination as to whether and how (if at all) to allow continued sale, distribution, or use of existing stocks based on a risk-benefit determination associated with the existing stocks, considering (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 existing 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 existing stocks, and (6) the practicality of implementing restrictions on distribution, sale, or use of the existing stocks.¹⁴

“EPA will generally select the most restrictive existing stocks provision that may apply,” considering whether the distribution, sale, and use of existing stocks is consistent with the purposes of FIFRA.¹⁵ EPA may amend an existing stocks provision “on its own initiative or at the request of any interested person,” for example to allow for additional time to sell or use stocks or to place additional restrictions on the sale or use of existing stocks, if later circumstances warrant.¹⁶ “Finally, unless an existing stocks provision stipulates otherwise, any sale or use of existing stocks must be in accordance with the previously approved label and labeling on, or accompanying, the product.”¹⁷

Application of EPA’s Existing Stocks Authority

The Ninth Circuit has vacated the 2021 registration amendments for these products, holding that EPA failed to fulfill its obligations under the Endangered Species Act prior to granting the 2021 registration amendments.¹⁸ Following the Court’s mandate, EPA believes it appropriate to issue an existing stocks order because distributors and end-users may have possession of stocks of AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3) purchased in good faith after EPA approved the registration amendment permitting sale and distribution of that product in commerce and establishing conditions pertaining to the use of that product.¹⁹ Further, the Ninth Circuit’s vacatur of the 2021 registration amendments leaves behind a more complex scenario than some other vacaturs, such as where the Court vacates the entire registration. While the Court’s order vacating the 2021 registration amendments functionally terminated the use of AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3) on citrus crop group 10-10, the product is still registered for use on other crops. Making the situation more complex, AgroSource, Inc. informed EPA that AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3) is only marketed for use on citrus in Florida. Based on communications with the registrant, EPA is confident that use outside of Florida is only on non-citrus crops.

EPA is issuing this order to appropriately regulate the distribution and use of existing stocks following the Ninth Circuit’s order. The Court’s vacatur of the 2021 registration amendments

¹³ *Id.* at 29,367.

¹⁴ *Id.* at 29,364.

¹⁵ *Id.* at 29,363.

¹⁶ *Id.* at 29,363-64.

¹⁷ *Id.* at 29,364.

¹⁸ *Migrant Clinicians Network v. EPA*, 88 F.4th 830, 849 (Ninth Cir. 2023).

¹⁹ EPA does not expect that downstream distributors or users have possession of stocks of EAC Streptomycin Manufacturing Use Product (EPA Reg. No. 91275-1), which is used to manufacture streptomycin end-use products and not directly on crops.

results in two primary concerns for EPA. First, in the absence of any action by EPA, the Court’s vacatur of EPA’s January 2021 registration amendments would render **all** sale or distribution of the streptomycin sulfate products bearing the citrus use unlawful under FIFRA and subject any person who does sell or distribute such products to potential civil or criminal penalties.²⁰ FIFRA defines the term “distribute or sell” broadly and includes, among other things, any “shipment” of unregistered pesticides.²¹ Therefore, as of February 5, 2024, FIFRA would otherwise prohibit downstream distributors from returning previously purchased product to the manufacturer for relabeling or shipment by any actor to disposal or export facilities. Additionally, FIFRA would prohibit sale and distribution of product labeled for use on citrus, even in states where the product would only be used on non-citrus crops. Second, FIFRA does not prohibit the *use* of unregistered pesticides.²² It is only a violation of FIFRA for a person “to use any **registered** pesticide in a manner inconsistent with its labeling.”²³ EPA wants to ensure that any use of these existing stocks continues to be consistent with its labeling to protect the human health and the environment following the Court’s vacatur of EPA’s January 2021 registration amendments. The below provisions for the disposition of existing stocks address these concerns.

EPA also considered whether issuing a Stop Sale, Use, and Removal Order (SSURO) under FIFRA section 13 would be appropriate. EPA decided not to issue SSUROs for these products because SSUROs must be “issued . . . to any person who owns, controls, or has custody” of the pesticide that is subject to the order and is not effective until that person receives the SSURO.²⁴ In other words, to use a SSURO would require EPA to ensure personal delivery to all such persons. Based on information provided to EPA by the registrants, EPA understands that a significant volume of the end-use product—AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3)—is already in the hands of citrus growers for use in 2024. Given the number of persons potentially in possession of the end-use product, personal delivery would present enormous practical difficulties for EPA and potentially delay addressing the above noted concerns. Accordingly, the Agency does not believe that it is warranted to issue SSUROs at this time.

In sum, EPA believes using its authority under FIFRA to issue an order establishing provisions for the existing stocks of these streptomycin sulfate products is “not inconsistent with the purposes” of FIFRA.²⁵

Existing Stocks Determination

As in other circumstances where EPA has been faced with vacatur of a pesticide registration action, EPA gives significant weight to the opinion of the Ninth Circuit, deferring to the Court where its opinion conflicts with the standard six-factor analysis detailed in EPA’s 1991 existing stocks policy. Because the Court vacated the 2021 registration amendments for AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3) and EAC™ Streptomycin Manufacturing Use Product (EPA Reg. No. 91275-1) allowing the use on citrus crop group 10-10, this existing stocks order seeks to limit the avenues for continued use on citrus crop group 10-10. Accordingly, the existing stocks order limits the sale

²⁰ See FIFRA § 12(a), 7 U.S.C. 136j(a); FIFRA § 14, 7 U.S.C. § 136l.

²¹ FIFRA § 2(gg), 7 U.S.C. § 136(gg).

²² See FIFRA § 12, 7 U.S.C. § 136j.

²³ FIFRA § 12(a)(2)(G), 7 U.S.C. § 136j(a)(2)(G) (emphasis added).

²⁴ FIFRA § 13(a), 7 U.S.C. § 136k(a).

²⁵ FIFRA § 6(a)(1), 7 U.S.C. § 136d(a)(1).

and distribution of existing stocks (1) by the registrants to such for purposes of proper disposal, lawful export, or to facilitate return to a registered production establishment for relabeling and (2) by persons other than the registrants in Florida to such for purposes of proper disposal, lawful export, or to facilitate return to the manufacturer or another registered production establishment designated by the registrant for relabeling. EPA is providing only for limited distribution in Florida due to the possibility that sale or distribution would facilitate additional use on citrus crop group 10-10 in Florida beyond the product already possessed by citrus users.

Notwithstanding EPA's limitations of sale and distribution of existing stocks, EPA has reason to believe based on information provided by the registrants that there are likely significant existing stocks already in the hands of citrus growers in Florida. EPA's order requires that users of such existing stock to use it consistent with the product's labeling to protect the human health and the environment and only until **August 31, 2024** or until all existing stocks are exhausted (whichever is sooner). EPA believes—based on its understanding of grower purchasing behaviors and application timetables for the product—that citrus growers who previously purchased product for the upcoming season would use their existing stocks by the end of August. Put another way, this approach maintains the status quo for users who possess existing stocks because the Court's order vacating the registration amendments prevented legal sale and distribution of products labeled for use on citrus crop group 10-10, while incidentally relieving users of any obligation to follow the instructions on the label. EPA's order ensures that any use inconsistent with the product's label is still enforceable under FIFRA. EPA avoids using existing stocks orders to impose stringent restrictions on existing stocks in the hands of end users unless it can ensure that the holders are adequately notified and are likely to comply. EPA would struggle to ensure such notice unless it undertakes to issue SSUROs to all end users who might possess existing stocks, which EPA expects would take significantly longer than six months and would require a significant expenditure of governmental resources.

EPA additionally notes that attempting to retrieve already sold and distributed existing stocks can have significant draw backs. For instance, transportation of opened containers of end use products can present additional risk of spillage and environmental exposure. Further, disposal or return of product already in the hands of end users is typically burdensome on the end user. Disposal is often expensive due to transportation and disposal costs. While registrants may consider buyback programs to defray these costs, EPA has no authority under FIFRA to impose such a program.

EPA does not expect use on citrus outside of Florida but does expect ongoing use on non-citrus crops (*e.g.*, pears) to control fire blight. Therefore, EPA is allowing continued sale and distribution by persons other than the registrants in all states except Florida until **May 31, 2024**. Such allowance is consistent with the Court's order, which did not affect the prior approvals of non-citrus uses. Based on information provided by the registrants, EPA understands that at the time of the Court's decision agricultural distributors other than the registrants already had a significant volume of product on hand for sale to growers for application to non-citrus crops. EPA does not believe that it conflicts with the Court's order to not require relabeling of such product that is not sold to citrus growers for a short period to facilitate such relabeling in a manner that does not disrupt the availability of the product for uses that were not terminated by the Court's vacatur of the 2021 registration amendments. Based on information provided by the registrants, EPA believes that allowing such distribution until May 31, 2024 will provide sufficient time for

relabeling in an undisruptive manner. While EPA does not expect use of AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3) on citrus outside of Florida, EPA acknowledges that there is citrus crop in other states (*e.g.*, California). Accordingly, EPA is prohibiting the use of existing stocks of AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3) on citrus crop group 10-10 outside of Florida. EPA believes that this immediate prohibition on use on citrus is appropriate (in contrast to the delay in Florida) because use on citrus is not expected outside of Florida.²⁶ Further, EPA believes that allowing use of existing stocks on non-citrus crops while the registrants update labeling for products in the channels of commerce is consistent with the Courts order and is “not inconsistent with the purposes of [FIFRA].”²⁷

EPA’s Existing Stocks Order²⁸

1. Pursuant to FIFRA Section 6(a)(1), EPA hereby issues an existing stocks order for AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3) and EAC™ Streptomycin Manufacturing Use Product (EPA Reg. No. 91275-1). This order will remain in effect unless or until subsequent action is taken. The issuance of this order did not follow a public hearing. This is a final agency action, judicially reviewable under FIFRA section 16(a). Any sale, distribution, or use of existing stocks of these products inconsistent with this order is prohibited.
2. **Existing Stocks.** For purposes of this order, “existing stocks” means those stocks of previously registered pesticide products that are currently in the United States and were packaged, labeled, and released for shipment prior to **February 5, 2024** (the effective date of the Ninth Circuit’s vacatur of the 2021 registration amendments). Pursuant to FIFRA section 6(a)(1), this use termination order includes the following existing stock provisions:
 - a. **Sale or Distribution by the Registrants.** As of the date of this order, sale or distribution by the registrant of these products is prohibited, **except** for the purposes of proper disposal, lawful export, or to facilitate return to a registered production establishment for relabeling.
 - b. **Sale or Distribution by Persons other than the Registrants in All States EXCEPT Florida.** As of the date of this order and until **May 31, 2024**, sale or distribution by persons other than the registrants who are already in possession of these products is permitted. After **May 31, 2024**, sale or distribution by persons other than the registrants who are already in possession of these products is prohibited **except** for the purposes of proper disposal, lawful export, or to facilitate

²⁶ Similar to *supra* note 27, EPA would consider whether SSUROs were appropriate if facts come to light challenging EPA’s expectation that AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3) is not being used on citrus outside of Florida.

²⁷ FIFRA § 6(a)(1), 7 U.S.C. § 136d(a)(1).

²⁸ EPA intends that each provision of this order be severable. In the event of litigation staying, remanding, or invalidating all or a portion of a provision of this order, EPA intends to preserve all other provisions of this order to the fullest extent possible. EPA evaluated the consistency of each of the provisions of this order with the purposes of FIFRA, consistent with FIFRA § 6(a)(1), 7 U.S.C. § 136d(a)(1). Further, the Agency has crafted this order so that different provisions are capable of operating independently. Accordingly, EPA has organized this order so that if any provision is determined by judicial review or operation of law to be invalid, that partial invalidation will not render the remainder of this order invalid.

return to the registrant or another registered production establishment designated by the registrant for relabeling.

- c. **Sale or Distribution by Persons other than the Registrants in Florida.** As of the date of this order, sale or distribution by persons other than the registrants who are already in possession of these products is prohibited, except for the purposes of proper disposal, lawful export, or to facilitate return to the registrant or another registered production establishment designated by the registrant for relabeling.
- d. **Use of Existing Stocks of AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3) in All States EXCEPT Florida.** As of the date of this order, use by any person already in possession of this product or subsequently purchasing existing stocks of this product (consistent with ¶ 2.b) is prohibited from using this product on citrus crop group 10-10. However, use for any other use on the labeling is permitted until all existing 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.
- e. **Use of Existing Stocks of AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3) in Florida.** As of the date of this order, use of AGRI-SEED™ 50 WP (EPA Reg. No. 80990-3) that any person already in possession of this product is permitted until August 31, 2024 or until all existing stocks are exhausted (whichever is sooner), 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.

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