



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2026-1420; EPA-HQ-OPP-2026-0991; EPA-HQ-OPP-2026-1256; FRL-13274-01-OCSP]

Pesticide Product Registration; Emergency Exemption Request and Application for a New Active Ingredient

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of receipt and request for comment.

SUMMARY: This document announces the Agency's receipt of and solicits comment on an application from the United States Department of Agriculture (USDA) to register a new pesticide product containing an unregistered pesticide, NovoFly male-only genetically engineered (GE) New World screwworm (NWS) in USDA's Sterile Insect Technique (SIT) programs.

Additionally, the Agency received a Section 18 quarantine emergency exemption application requesting use of the same pesticide to maintain broad suppression of and help prevent the pest from moving further northward from Mexico toward the United States. The Agency is providing this notice in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Due to the urgent nature of the emergency, the limited time available to authorize the Section 18 quarantine emergency exemption request, and the related FIFRA Section 3 product registration application under review for the same use, EPA is waiving the comment period associated with the emergency exemption request, but is soliciting public comment in conjunction with the application for Section 3 product registration of NovoFly.

DATES: Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments on the Section 3 product registration application, identified by the docket identification (ID) number, EPA-HQ-OPP-2026-0991 and the *EPA File Symbol*, 91213-L, as shown in Unit II. of this document, online at <https://www.regulations.gov>.

Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, are available at

<https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Each application summary in Unit II. specifies a contact division. The appropriate division contacts are identified as follows:

- BPPD (Biopesticides and Pollution Prevention Division) (Mail Code 7511M); Shannon Borges; main telephone number: (202) 566-1400; email address: BPPDFRNotices@epa.gov.

- RD (Registration Division) (Mail Code 7505T); Charles Smith; main telephone number: (202) 566-1030; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action provides information that is directed to the public in general.

B. What is the Agency's authority for taking this action?

EPA is taking this action pursuant to section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136a(c)(4), and 40 CFR 152.102.

C. What action is the Agency taking?

EPA is hereby providing notice of receipt of an application to register a new Section 3 pesticide product containing an unregistered active ingredient in addition to receipt of an application requesting authorization of a Section 18 quarantine emergency exemption. EPA is providing an opportunity to comment on the application to register a new Section 3 pesticide product containing an unregistered active ingredient. This document identifies applications that were received and are currently being evaluated by EPA in accordance with FIFRA. Notice of receipt of these applications does not imply a decision by the Agency on either the Section 3

pesticide product registration or Section 18 quarantine emergency exemption applications. For the Section 3 product registration being evaluated under EPA's public participation process, there will be an additional opportunity for public comment on the proposed decisions. Please see EPA's public participation website for additional information on this process (<https://www.epa.gov/pesticide-registration/public-participation-process-registration-actions>).

D. *What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.* Do not submit CBI to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. In addition to one complete version of the comment that includes CBI, a copy of the comment without CBI must be submitted for inclusion in the public docket. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. Applications to Register and Authorize New Pesticide Product and Section 18 Quarantine Emergency Exemption, Respectively

This unit provides the following information about each application received: The EPA File Symbol or Emergency Exemption Number; EPA docket ID number for the application; Name and address of the applicant; Name of the active ingredient, product type and proposed uses; and the division to contact for that application. Additional information about the application may also be available in the docket for the application as identified in this unit.

A. *Application for a New Active Ingredient*

File Symbol: 91213-L. *Docket ID number:* EPA-HQ-OPP-2026-0991. *Applicant:* United States Department of Agriculture – Agricultural Research Service (USDA-ARS), George Washington Carver Center, 5601 Sunnyside Ave., Beltsville, MD 20706. *Product*

Name: NovoFly. *Active Ingredients:* (1) Lshid^{Ala2} protein and the genetic material necessary to produce the protein in vivo in female embryos *Cochliomyia hominivorax*; and (2) tTAo protein and the genetic material necessary to produce the protein in vivo in female embryos *Cochliomyia hominivorax*. *Product Type:* Biopesticide. *Proposed Use:* *Cochliomyia hominivorax* (New World Screwworm) female lethal trait to be used as part of wide area sterilization and eradication program. *Date of Receipt:* January 30, 2026. *Contact:* BPPD.

B. Section 18 Emergency Exemption

Under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), at the discretion of the EPA Administrator, a Federal or State agency may be exempted from any provision of FIFRA if the EPA Administrator determines that emergency conditions exist which require the exemption. This notice does not constitute a decision by EPA on the application itself. The regulations governing FIFRA section 18 require publication of a notice of receipt of an application for a quarantine exemption proposing a new use of a pesticide (*i.e.*, an active ingredient) which has not been registered by EPA. Due to the urgent nature of the emergency, the limited time available to authorize the Section 18 quarantine emergency exemption request, and the related FIFRA Section 3 product registration application under review for the same use, EPA is waiving the comment period associated with the emergency exemption request, but is soliciting public comment in conjunction with the application for product registration of NovoFly.

As part of this request, the applicant asserts that the NWS (*Cochliomyia hominivorax*) is a devastating pest that causes serious and often deadly damage to livestock, wildlife, pets, and in rare cases, humans. Recent detections have been identified, spreading north in Mexico, thereby threatening re-emergence in the United States and necessitating new tools to stop it. If NWS enters and establishes in the United States, widespread economic losses are expected; each outbreak can cause millions of dollars in production losses and economic damage. It has been calculated that an outbreak in Texas would cost \$1.8 billion to the Texas economy today. USDA-

ARS has developed the NovoFly GE NWS using sterile insect technique (SIT), which results in all flies raised being males. Use of male-only NWS populations in SIT effectively doubles the output of traditional SIT (which is dependent on sterile male NWS), providing a significant efficiency. The NovoFly males will be sterilized through irradiation prior to release, which will achieve rapid population control. Current registered insecticides can be applied to animals to control adult flies or kill larvae developing in animal wounds. However, because NWS has been eradicated from the U.S. for so long, many of the products historically applied to animals are no longer available.

File Symbol: 26DA05. *Docket ID number:* EPA-HQ-OPP-2026-1256. *Applicant:* United States Department of Agriculture – Agricultural Research Service (USDA-ARS), George Washington Carver Center, 5601 Sunnyside Ave., Beltsville, MD 20706. *Product Name:* NovoFly. *Active Ingredients:* (1) Lshid^{Ala2} protein and the genetic material necessary to produce the protein in vivo in female embryos *Cochliomyia hominivorax*; and (2) tTAo protein and the genetic material necessary to produce the protein in vivo in female embryos *Cochliomyia hominivorax*. *Product Type:* Biopesticide. *Proposed Use:* *Cochliomyia hominivorax* (New World Screwworm) female lethal trait to be used as part of wide area sterilization and eradication program across areas where NWS is detected, and sterile insect dispersal areas to maintain broad suppression and help prevent the pest from moving further north from Mexico toward the United States. NovoFly NWS *Cochliomyia hominivorax* carry traits that allow inducible sex-selection which is lethal to female NWS at the embryonic stage during production. This genetically engineered trait allows for the controlled mass-rearing of male-only populations of NWS. NovoFly males are sterilized through irradiation using typical SIT procedures prior to release, making them incapable of reproducing. Use of male-only NWS populations in SIT effectively doubles the output of traditional SIT (which is dependent on sterile male NWS), providing a significant efficiency. USDA ARS is requesting that sterile male-only NovoFly be integrated into existing or future mass-rearing and SIT programs to prevent the establishment of, and to

control NWS (*Cochliomyia hominivorax*), a devastating pest that causes serious and often deadly damage to livestock, wildlife, pets, and in rare cases, humans. The applicant proposes the use of a new active ingredient in a pesticide which has not been registered by EPA.

Area-wide releases of sterile, male-only Novofly will follow typical SIT procedures. According to the USDA, sterile insect technique, when paired with surveillance, animal movement restrictions, and education and outreach, is a proven and effective tool for controlling and eradicating NWS. Female NWS flies only mate once in their lives, so if they mate with a sterile male, they lay unfertilized eggs that do not hatch. USDA currently produces sterile flies for dispersal through aerial or ground releases. The historical range (prior to eradication) of NWS is 45° N and 45° S, and NWS could remain established during mild winters as far north as 35° N. USDA closely evaluates the location and circumstances of each new case to adjust sterile insect release efforts and locations as needed. USDA's Animal and Plant Health Inspection Service (APHIS) determines the SIT dispersal area based on NWS detections. Changes to the sterile insect dispersal area, or polygon, occur as needed to maintain broad suppression and help prevent the pest from moving further north toward the United States. For the current dispersal polygon see the current status page on screwworm.gov (<https://www.aphis.usda.gov/livestock-poultry-disease/stop-screwworm/current-status>).

The applicant proposes to release NovoFly males from aircraft and/or via ground releases. Flies are released from the aircraft at a rate of 1500 to 3000 flies per nautical mile. Flight plans typically cover 665 nautical miles flying parallel lines over the specified release polygon. Ground releases utilize hanging chambers which hold up to 10 liters of pupae (roughly 90,000 pupae). For male-only releases, 5 liters (roughly 45,000 pupae) are recommended. As adults emerge, they disperse and provide localized control 2-5 kilometers in radius from the release point. Typically, release chambers are refilled once per week for three subsequent weeks when targeting specific cases. The total release polygon can vary in size from 25 million to 40 million acres. At a maximum production capacity of 5.72 billion flies per year, annual release

density is 143 to 229 flies per acre if the site remains with the polygon. The active ingredients contained in Novofly are (1) Lshid^{Ala2} protein and the genetic material necessary to produce the protein in vivo in female embryos *Cochliomyia hominivorax*, < 0.00007 %; and (2) tTAo protein and the genetic material necessary to produce the protein in vivo in female embryos *Cochliomyia hominivorax*, < 0.00003 %. *Date of Receipt: January 30, 2026. Contact: RD.*

Authority: 7 U.S.C. 136 *et seq.*

Dated: March 25, 2026.

Edward Messina,

Director, Office of Pesticide Programs.

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