

US EPA ARCHIVE DOCUMENT



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Movento (EPA Registration Number 264-1050) – Amended Cancellation Order

Summary

This notice announces EPA's issuance, pursuant to section 6(a)(1) of FIFRA, of an amended cancellation order for the pesticide product Movento (EPA Reg. No. 264-1050), a pesticide product containing the active ingredient spirotetramat. This order includes provisions for the disposition of existing stocks of Movento that were released for shipment prior to March 10, 2010 – the effective date of the court-ordered vacatur of spirotetramat products previously registered by the Agency. Existing stocks are defined as those materials that were manufactured, finally packaged, and released for shipment (as defined at 40 CFR 152.3) prior to the effective date of the vacatur. The existing stocks provisions of this amended cancellation order for Movento modify and supersede certain provisions contained in the final cancellation order for all spirotetramat pesticide products issued by EPA on April 5, 2010 (which modified and superseded the provisions contained in the interim cancellation order issued by EPA on March 12, 2010). All provisions of the April 5, 2010 cancellation order that are not in conflict with today's order remain in effect. This amended cancellation order is effective immediately.

Under the provisions of this amended cancellation order as specified below, sale or distribution of existing stocks of Movento by the registrant is permitted provided that the label of those stocks does not include any directions for use on Cucurbit Vegetables (Crop Group 9). This amended order does not permit sale or distribution by the registrant of any existing stocks bearing labels with directions for use on cucurbits.

Background

Although later vacated by court order, EPA approved applications from Bayer CropScience (Bayer) for pesticide products containing spirotetramat, including Movento, in 2008. On December 23, 2009, due to lack of publication of a notice of receipt of the

spirotetramat registration applications in the *Federal Register* under section 3(c)(4) of FIFRA, the U.S. District Court for the Southern District of New York issued an order vacating the spirotetramat registrations that the Agency had issued in 2008, and remanding the matter to EPA for further proceedings in accordance with FIFRA and the Administrative Procedure Act (APA). See *Natural Resources Defense Council, Inc. v. EPA*, 676 F. Supp. 2d 307 (S.D.N.Y. 2009). The District Court's vacatur order took effect on March 10, 2010.

As a result of the vacatur, EPA treated Bayer's earlier-filed applications for registration as then-pending before the Agency. In order to address existing stocks of spirotetramat products, including Movento, while the Agency considered the applications anew, EPA issued an interim cancellation order on March 12, 2010 and a final cancellation order on April 5, 2010, both of which, *inter alia*, prohibited sale or distribution of existing stocks of spirotetramat products, including Movento, by Bayer.

The Agency published a new notice of receipt of the applications for comment in the *Federal Register* on February 26, 2010 (75 Fed. Reg. 8939). The comment period ended on March 29, 2010. EPA issued new conditional registrations for spirotetramat pesticide products, including Movento, on October 15, 2010 (docket available at <http://www.regulations.gov/search/Regs/home.html#docketDetail?R=EPA-HQ-OPP-2010-0130>).

The October 15, 2010 Notice of Registration (NOR) for Movento requires that Bayer make certain changes to the previously approved Movento label in existence when the vacatur took effect on March 10, 2010. Specifically, the October 15, 2010 NOR states, in relevant part to today's order, that Bayer must do the following:

2. Make the following label changes before you release the product for shipment:
 - a. Add the phrase "EPA Registration Number 264-1050."
 - b. Delete the crop group Cucurbit Vegetables (Crop Group 9).
 - c. On page 2, delete the statement, "OBSERVE THE FOLLOWING PRECAUTIONS WHEN SPRAYING IN THE VICINITY OF AQUATIC AREAS SUCH AS LAKES; RESERVOIRS; RIVERS; PERMANENT STREAMS; MARSHES OR NATURAL PONDS; ESTUARIES AND COMMERCIAL FISH FARM PONDS."
 - d. On page 4, delete the statement "Timing and application must be based on careful scouting for insect pests and local thresholds."
 - e. On page 4, delete "unless specified otherwise by state-specific supplemental labeling" from the fifth paragraph under APPLICATION INFORMATION.

- f. Explain the acronym “PVA” the first time it appears in the label.
- g. Provide information about Net Contents on the last page.
- h. Change “certain insects” to “listed insects” on the front panel.

Notice of Registration for Movento (EPA Reg. No. 264-1050), October 15, 2010, *available at* <http://www.regulations.gov/search/Regs/home.html#docketDetail?R=EPA-HQ-OPP-2010-0130>.

Amendment of Final Cancellation Order as to Existing Stocks of Movento

EPA issued the interim and final cancellation orders on March 12 and April 5, 2010, respectively, to address existing stocks of spirotetramat pesticide products while the Agency considered anew the spirotetramat registration applications following the vacatur of the spirotetramat registrations effective on March 10, 2010 (*i.e.*, while no registration for spirotetramat pesticide product was in existence). However, circumstances have changed since the final cancellation order was issued on April 5, 2010. Specifically, on October 15, 2010, EPA issued new registrations for spirotetramat products, including Movento, having determined that such pesticides meet the requirements for registration under section 3(c)(7)(C) of FIFRA.

With the exception of the label change required in paragraph 2(b) of the October 15, 2010 Movento NOR (“Delete the crop group Cucurbit Vegetables (Crop Group 9)”), EPA believes that the remaining label changes required in paragraph 2 of the October 15, 2010 NOR are sufficiently minor that existing stocks of Movento may be distributed or sold by Bayer without making these changes to the previously approved label. Again, however, the requirement in paragraph 2(b) of the October 15, 2010 Movento NOR that Movento may not be labeled for use on the crop group Cucurbit Vegetables (Crop Group 9), is a significant change from the previously approved label. Therefore, this amended order does not authorize Bayer to distribute or sell any existing stocks of Movento that are labeled for use on the crop group Cucurbit Vegetables (Crop Group 9). Bayer has stated that this use has never been printed on the commercial label

Amended Cancellation Order, Including Provisions for Existing Stocks

1. Pursuant to section 6 of FIFRA, EPA hereby issues an amended cancellation order for the registration of Movento (EPA Reg. No. 264-1050) that was vacated by the December 23, 2009 order of the U.S. District Court for the Southern District of New York, which vacatur went into effect on March 10, 2010. Any distribution, sale, or use of this product 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.

Pursuant to section 6(a)(1) of FIFRA, this cancellation order includes the following existing stocks provisions.

- a. Distribution or sale by the registrant of existing stocks of Movento (EPA Registration No. 264-1050) with labels that do not contain directions for use on cucurbits is permitted until such stocks are depleted.
- b. Distribution or sale by the registrant of existing stocks of Movento (EPA Registration No. 264-1050) with labels that contain directions for use on cucurbits is prohibited.
- c. All provisions of the April 5, 2010 final cancellation order that are not in conflict with today's amended cancellation order, including all provisions relating to sale, distribution, and use of existing stocks by persons other than the registrant, are unaffected by this amended order and remain in effect.



Lois Rossi
Director, Registration Division

October 28, 2010

Date