



**US Environmental Protection Agency
Office of Pesticide Programs**

**Spirotetramat - Notice of Cancellation Order;
Opportunity for Public Comment**

Spirotetramat – Notice of Cancellation Order; Opportunity for Public Comment

Summary

This notice announces the Agency's intent to issue a cancellation order for the pesticide spirotetramat pursuant to section 6(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136d(a)(1), and the opening of a comment period on the existing stocks provisions of such cancellation order. Comments must be received on or before February 8, 2010.

On December 23, 2009, the U.S. District Court for the Southern District of New York vacated all registrations issued by EPA for pesticide products containing the active ingredient spirotetramat. The basis for the Court's decision was EPA's failure to provide an opportunity for comment on the applications for those registrations before the Agency granted them. The vacatur is currently stayed until February 16, 2010; when the stay is lifted, the spirotetramat registrations will cease to be valid under FIFRA. When that happens, EPA intends to issue a cancellation order that will establish provisions governing the disposition of existing stocks of previously-registered spirotetramat pesticide product already in the channels of trade (*e.g.*, in the hands of wholesalers, retailers, and users). EPA is providing an opportunity for interested parties to comment on how they believe EPA should treat the sale, distribution, and/or use of existing stocks of spirotetramat in the cancellation order.

Due to the short time before vacatur of the registrations will take effect, EPA is publishing this notice on its website rather than through publication in the Federal Register, and comments must be received by February 8, 2010.

How to Submit comments; Agency contact.

Interested parties may submit comments, on or before February 8, 2010, by email to Meredith Laws at: Laws.Meredith@epa.gov. Because of the need to consider the comments quickly in order to issue a cancellation order as early as February 16, 2010, EPA requests that commenters not submit any material that must be treated as confidential business information (CBI). If a commenter finds it essential to submit a comment that contains CBI, the commenter should contact Meredith Laws by email, or by phone at (703) 308-7038. Any other questions should also be directed to Ms. Laws by email or phone.

Background

On October 10, 2006, EPA received applications from Bayer CropScience (Bayer) to register three new pesticide products containing the active ingredient spirotetramat – a tetramic acid derivative insecticide – under section 3 of FIFRA, 7 U.S.C. 136a, for use on a wide variety of agricultural crops and on Christmas trees. On February 5, 2007, EPA received another application from Bayer for a spirotetramat end-use product for insect control in greenhouses, nurseries, and interior plantscapes. On April 27, 2007, EPA received an application from Bayer for another spirotetramat end-use product for agricultural use.

Although later vacated by court order (described below), the Agency approved the applications for the technical and one end-use product on June 30, 2008, as Spirotetramat Technical and Movento (EPA Registration Number 264-1049 and 264-1050, respectively) for control of insects on several agricultural crops and Christmas trees. The Agency approved the application for Spirotetramat 240 SC Greenhouse and Nursery (EPA Registration Number 432-1471) on August 8, 2008 for insect control in greenhouses, nurseries, and interior plantscapes. The Agency approved the application for BYI 8330 150 OD Insecticide (EPA Registration Number 264-1051) on September 24, 2008 for control of insects on several agricultural crops and Christmas tree plantations. The Agency approved the application for Ultor (EPA Registration Number 264-1065) on December 16, 2008 for control of insects on several agricultural crops and Christmas tree plantations.

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 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*, 2009 WL 5033959 (Dec. 23, 2009). The vacatur is currently stayed until February 16, 2010. When the stay is lifted, the registrations will no longer be in effect under FIFRA, and no new spirotetramat material can thereafter lawfully be released for shipment by manufacturers unless and until new registrations are issued.

As a result of the Court's decision to vacate the registrations of the pesticide spirotetramat due to EPA's failure to publish a notice of receipt of the registrations for public comment, EPA intends to treat Bayer's earlier-filed applications for registration as now pending before the Agency. Although EPA commenced a comment period on these applications on August 6, 2009 (74 Fed. Reg. 39321), the Court determined that this was not adequate to correct the original deficiency. Therefore, the Agency intends to publish a new notice for comment in the *Federal Register* in the next few weeks. EPA will consider the comments filed in 2009 in this comment period, as well as any new or additional comments submitted in response to this new notice, and will then determine whether the spirotetramat applications for registration should be granted and, if so, what license conditions and label language would be appropriate under FIFRA.

Existing Stocks Questions to be Addressed

While the Court determined that the registrations should not be allowed to continue unless and until EPA makes a decision on the registration following the process set forth in section 3(c)(4) of FIFRA (7 U.S.C. §136a(c)(4)), the question of what should happen to existing stocks of spirotetramat 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 spirotetramat products will be unlawful under FIFRA once the vacatur goes into effect. 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 could 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 subject 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 spirotetramat will not be legally precluded from using those stocks without following label directions, including the restrictions on timing of applications that EPA required in order to protect 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 spirotetramat, 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 spirotetramat registrations is best viewed under FIFRA as a cancellation of those registrations under section 3 (because the vacatur is based upon the Agency’s failure to comply with the requirements of section 3 of FIFRA). *See* Termilind Limited; Notice and Order of Revocation of Registrations, 62 Fed. Reg. 61890, 61894 (Nov. 19, 1997) (“The Agency has concluded that there is no meaningful distinction between a revocation and a cancellation, and that the revocation of Termilind’s registration was a cancellation under section 3 giving the Agency authority over the sale and use of existing stocks.”). The Agency therefore intends to issue a

cancellation order under FIFRA section 6(a)(1) that will establish provisions governing the disposition of existing stocks of previously-registered spirotetramat pesticide product.

While EPA is not obligated to take public comment on the contents of cancellation orders, the Agency believes that public input in this particular circumstance could be beneficial. EPA is therefore initiating this public comment period to seek input from interested parties on how they believe EPA should treat existing stocks of spirotetramat in a cancellation order. The Agency would like to have the cancellation order ready to take effect when the registrations cease to exist (February 16, 2010 unless the stay is extended), and therefore EPA believes a shortened comment period is necessary in order to allow the Agency to consider the comments before February 16th.

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). Regarding cancelled pesticides, the existing stocks policy identifies particular considerations relevant to five different cancellation scenarios: 1) cancellations where the Agency has identified particular risk concerns; 2) cancellations where a registrant has failed to comply with an obligation of registration; 3) cancellation of products while subject to data call-in notices under section 3(c)(2)(B) of FIFRA; 4) cancellation of registrations subject to reregistration requirements and label improvement programs; and 5) other voluntary cancellations.

In general, if the Agency has no significant risk concerns associated with a cancelled product, 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, 29364.

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 criteria 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.

The Agency believes the criteria outlined in the existing stocks policy are generally appropriate for use in existing stocks situations, and may well be appropriate for use in the case of spirotetramat. However, EPA is also mindful of the fact that spirotetramat is a novel situation different from any the Agency has confronted in the nearly twenty years since the development of the policy statement. While commenters may wish to consider the 1991 policy statement as a starting point for determining what issues to address in their comments, commenters should feel free to raise any issue they believe would be pertinent to the disposition of existing stocks of spirotetramat products after February 16, 2010.