US Environmental Protection Agency
Office of Pesticide Programs

Spirotetramat - Final Cancellation Order

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Summary

This notice announces the Agency's issuance of a final cancellation order for all pesticide products containing the active ingredient spirotetramat 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 spirotetramat products that have been released for shipment prior to today's date. The existing stocks provisions of this final cancellation order modify and supersede the terms contained in the interim cancellation order issued by EPA on March 12, 2010. 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 export. Sale or distribution of spirotetramat products already in the possession of persons other than the registrant is permitted. 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.

On January 25, 2010 EPA published on this website a notice announcing EPA's intention to issue a cancellation order as a result of the December 23, 2009 decision of the U.S. District Court for the Southern District of New York to vacate all spirotetramat registrations that EPA had previously registered in 2008 under FIFRA, and seeking comment on the existing stocks provisions of such cancellation order. The comment period on that notice closed February 8, 2010. The court's vacatur order was stayed by the court itself until February 16, 2010, and later, by the Court of Appeals for the Second Circuit, until the Second Circuit issued a ruling on the registrant's motion for a stay of the District Court's decision pending appeal. On March 10, 2010, the Second Circuit Court of Appeals denied the registrant's motion for a stay pending appeal and lifted its own stay of the District Court's vacatur. Therefore, on March 10, 2010, the vacatur of the spirotetramat registrations that were issued in 2008 became effective, such that the registrations were no longer in effect under FIFRA, and no new spirotetramat material could or can lawfully be released for shipment by manufacturers unless and until new registrations are issued.

On March 12, 2010, EPA issued an interim cancellation order that generally followed the FIFRA statutory defaults with respect to unregistered pesticides (prohibiting sale or distribution of existing stocks by any person, but allowing use of existing stocks), but modified those defaults in two respects: to require users to continue to comply with previously-approved labeling, and to allow distributors and retailers of pesticides to ship product for certain limited purposes (disposal or return to manufacturer). As noted, today's final cancellation order modifies and supersedes the terms contained in the interim cancellation order; specifically, by permitting sale or distribution of existing stocks of spirotetramat products already in the possession of persons other than the registrant.

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, 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. Part of the rationale for the Agency's approval of the spirotetramat applications was the Agency's conclusion that spirotetramat appears to be less risky to the environment and to human health than many of the alternative insecticides currently used on the sites for which spirotetramat was approved.

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 District Court's vacatur order was stayed by the court itself until February 16, 2010, and later, by the Court of Appeals for the Second Circuit, until the Second Circuit issued a ruling on the registrant's motion for a stay of the District Court's decision pending appeal. On March 10, 2010, the Second Circuit Court of Appeals denied the registrant's motion for a stay pending appeal and lifted its own stay of the District Court's vacatur.

As a result of the vacatur of the registrations 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 published a new notice for comment in the Federal Register on February 26, 2010 (75 Fed. Reg. 8939). The comment period ended on March 29, 2010. 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.

Comments Received on Existing Stocks Provision

As noted above, on January 25, 2010, EPA published on its website an opportunity for interested persons to comment on the disposition of existing stocks of spirotetramat in the channels of trade when and if the vacatur of the registrations became effective. Existing stocks are defined as those materials that are manufactured, finally packaged, and released for shipment prior to the effective date of the vacatur.

Slightly more than 100 comments were received during this comment period. Most comments (slightly less than 90%) requested continued use and distribution of existing stocks. Commenters in favor of continued use and distribution cited a number of situations in which spirotetramat has replaced older, more toxic chemistries, including organophosphates and carbamates. It has also replaced use of some pyrethroids and neonicotinoids. Commenters also indicated that for some use patterns, fewer applications of spirotetramat were needed as compared to other insecticides.

Individual growers and grower organizations stated in their comments that spirotetramat has become an important pest management tool. It has been incorporated into a number of integrated pest management (IPM) programs and is reported to control pests that had previously been extremely difficult to control. Growers also noted that spirotetramat has been vital in their struggle against the Asian citrus psyllid, an invasive species of great concern to the citrus industry. Many growers indicated that spirotetramat is more selective to target pests and less injurious to beneficial insects.

Commenters requesting continued use and sale of spirotetramat stated that loss of this insecticide would cause growers to experience significant economic impact and disruption of their IPM programs and their plans for production in the 2010 season. They indicated that they would be forced to rely on older, often more toxic, chemistries.

The comments against allowing continued use, sale and distribution of spirotetramat focused on spirotetramat's asserted risk to bees. Most of these comments were from individual beekeepers, and one comment was from the National Honey Bee Advisory Board. While all of these comments identified serious concerns related to the health of bee populations in the United States, none of these comments pointed to any data to support the opinion that spirotetramat poses a grave risk to bees. Instead, the comments generally relied on statements the Agency has made with respect to spirotetramat, or suggested that pesticides can pose risks to bees and that the Agency should not allow yet another pesticide to threaten bees.

The Natural Resources Defense Council (NRDC) – one of the plaintiffs in the lawsuit that led to the vacatur – filed detailed comments challenging the Agency's legal authority to issue a cancellation order in the circumstances presented by spirotetramat. NRDC's comments were primarily legal in nature, and did not include any new substantive information on risks associated with spirotetramat.

I. Agency Authority to Issue Cancellation Order to Regulate Existing Stocks

Before addressing the appropriateness of allowing sale, distribution, or use of existing stocks of spirotetramat, we first address the threshold issue raised by NRDC of whether the Agency has the authority to issue a cancellation order in the circumstances presented by the vacatur of spirotetramat. While the issue is a novel one, 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 spirotetramat, while the District 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 spriotetramat 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 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 would 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 is therefore issuing a cancellation order under FIFRA section 6(a)(1) that establishes provisions governing the disposition of existing stocks of previously-registered spirotetramat pesticide product.

NRDC, in comments submitted in response to EPA's January 25, 2010 Notice of Intent to Issue a Cancellation Order, argues that EPA lacks authority to issue a cancellation order because the spirotetramat registrations were vacated by a court order.

NRDC's argument proceeds under the premise that the District Court, in vacating EPA's registrations of spirotetramat and "remand[ing] [the matter] to the EPA for further proceedings in accordance with FIFRA and the APA," in fact prescribed the specific steps the agency must take on remand. This is not the case. First, the specific steps required were not part of the Court's order; nor were they briefed by any party. But more significantly, in "remand[ing]" to the agency "for further proceedings in accordance with FIFRA and the APA," the Court followed the well-established rule that "when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the correct legal standards." *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005) (internal quotation marks omitted) ("[T]he district court had jurisdiction only to vacate the Secretary's decision . . . . It did not . . . have jurisdiction to order [specific relief on remand] . . . ."); *see also Riverkeeper, Inc. v. EPA*, 475 F.3d 83, 96 (2d Cir. 2007) ("Where an agency fails to comply with the APA's notice and comment provisions, we remand to the agency for further proceedings."); *Natural Res. Def. Council, Inc. v. Fox*, 93 F. Supp. 2d 531, 536 (S.D.N.Y. 2000) ("The Court's power in this context is limited . . . to vacating unlawful agency action and remanding to the agency for further proceedings . . . ."),

vacated in part on other grounds sub nom. Natural Res. Def. Council, Inc. v. Muszynski, 268 F.3d 91 (2d Cir. 2001).

In addition, NRDC's suggestion that the Court's decision foreclosed EPA's ability to invoke its authority to issue a cancellation order dealing with existing stocks reads into the decision the resolution of matters that were not before the Court. Indeed, EPA had argued that vacatur would not be appropriate in this case due to the existence of the statutory cancellation process, and the Court rejected that argument. *See* 2009 WL 5033959, at *7. In the Court's view, it was not fair to require NRDC to participate in the "costly and time consuming [cancellation process] to revoke [the spirotetramat] registration and remove it from the market." *Id.* Consistent with the Court's order, EPA is not now seeking to invoke the complex, trial-like cancellation procedure before the spirotetramat registration is revoked: the revocation is accomplished by operation of the Court's order at the expiration of the stay. Instead, the Agency believes that the present situation — in which a pesticide that had been previously registered *de facto* (even if as the result of a flawed regulatory process) must now be removed from the market — is sufficiently analogous to the situation at the *conclusion of* a cancellation proceeding that EPA has the authority to issue a "final cancellation order" despite there having been no cancellation proceeding. There is precedent in the Agency's previous regulatory actions for invoking its authority to issue a final cancellation order even where there was no cancellation proceeding. *See* Envtl. Prot. Agency, *Termilind Ltd.; Notice and Order of Revocation of Registrations*, 62 Fed. Reg. 61,890, 61,894 (Nov. 19, 1997)).

NRDC also argues that EPA's invocation of its authority to issue a cancellation order and permit continued sale or use of existing stocks circumvents the Court's decision to vacate the spirotetramat registrations, rather than to remand without vacatur as the Agency had requested. This is not so. There is a vast difference between allowing a registration to remain in place so that more product may be placed into the channels of trade, on the one hand, and simply making some provision for existing stocks of product that are already in the channels of trade, on the other. Were the Court to have remanded the matter to the Agency without vacating the registrations, there would have been no legal restrictions whatsoever on Bayer with respect to further distribution or sale of newly produced spirotetramat products during the Agency's consideration anew of Bayer's registration applications, and distributors and retailers could sell or distribute any new products that were released by Bayer into the channels of trade. In contrast, here, the registrations cease to exist by operation of the Court's order. In issuing a cancellation order, EPA establishes conditions or limits on the further distribution, sale, and use of "existing stocks" of a pesticide, again, defined as those stocks "which have been packaged, labeled, and released for shipment *prior to the effective date* of the [cancellation]." *See also* 7 U.S.C. § 136d(a)(1). However, no matter what provisions a cancellation order makes for existing stocks, it would still be illegal for Bayer to release for shipment any pesticide product after that order's effective date.

Further, NRDC proposes that, on remand from the Court's order, the Agency should not issue a cancellation order for spirotetramat pursuant to 7 U.S.C. § 136d, but rather a "stop sale, use, or removal" order ("SSURO") for the pesticide pursuant to 7 U.S.C. § 136k(a). The Agency considered proceeding via 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 spirotetramat, it 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.

Also, NRDC's insistence that "FIFRA clearly prohibits the *use* of unregistered pesticides" (citing 7 U.S.C. § 136a(a)) (emphasis added), misreads the relevant statutory provision. Its first sentence provides that "no person . . . may *distribute or sell* to any person any pesticide that is not registered under this subchapter." 7 U.S.C. § 136a(a) (emphasis added). "To distribute or sell" a pesticide is defined in the statute, and manifestly does not include a pesticide's "use." *See id.* § 136(gg). The second sentence of § 136a(a), in contrast, gives EPA the authority to issue "regulation[s]" to "limit" the "distribution, sale, *or use*" of unregistered pesticides. *Id.* § 136a(a) (emphasis added). The inclusion of the word "use" only in the second sentence of § 136a(a) makes plain that use of an unregistered pesticide is not unlawful unless such use violates a valid EPA regulation — of which there is none here. *See also id.* § 136j(a)(1)(A) (making it illegal to "distribute or sell," but not to use, an unregistered pesticide). Although it is not a FIFRA violation to use an unregistered pesticide, however, it *is* a FIFRA violation for a person to disobey the terms of a cancellation order, *see id.* § 136j(a)(2)(K), which is one of the reasons why EPA has chosen to issue such an order which would allow the Agency to regulate existing stocks of spirotetramat: EPA routinely includes in its cancellation orders language requiring that end-users continue to follow the previously approved label restrictions of cancelled pesticides.

Finally, NRDC states that "FIFRA section 18 provides a more appropriate mechanism for allowing targeted, specific use of spirotetramat during the remand period, on a sufficient showing of emergency." Certainly, the Agency may issue "emergency exemptions" for the use of spirotetramat pursuant to section 18 of FIFRA even though the registrations issued in 2008 are vacated. However, the Agency disagrees that its authority under section 18 adequately addresses the issues identified concerning existing stocks. The considerations pertinent to issuing an emergency exemption under section 18 of FIFRA are distinct from the considerations pertinent to issuing a cancellation order under section 6 of FIFRA.

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 spirotetramat. We turn next to the issue of whether, and to what extent, distribution, sale, or use of existing stocks of spirotetramat should allowed.

II. Risk to Bees

The comments against allowing continued use, sale and distribution of spirotetramat focused on spirotetramat's asserted risk to bees. These comments identified serious concerns related to the health of bee populations in the United States, but did not point to any data to support the opinion that spirotetramat poses a grave risk to bees. Instead, the comments

generally relied on statements the Agency has made with respect to spirotetramat, or suggested that pesticides can pose risks to bees.

As explained in detail below under the heading "No Significant Risk Concerns Associated with Spirotetramat Existing Stocks," the EPA Reduced Risk Committee concluded that spirotetramat poses less overall risk to human health and the environment than its alternatives. Prior to issuing the registrations for spirotetramat in 2008, EPA conducted an extensive analysis in collaboration with counterpart agencies in Canada and Austria and subsequently completed an ecological risk assessment. In light of some uncertainties regarding potential hazard to bees, the Agency required application restrictions designed to protect bees during the pendency of additional studies. EPA concluded that the label restrictions minimized potential risk to bees. In remanding the spirotetramat registration decisions for procedural errors, the federal District Court in New York did not find EPA's substantive conclusions regarding risks to human health or the environment (including bees) to be incorrect. Based on these analyses and the label statement, EPA currently does not have significant risk concerns associated with use of spirotetramat existing stocks.

Statutory Background

As noted earlier, cancellation orders are issued under section 6(a) of FIFRA, which 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]." In determining whether sale or use in any particular situation is consistent with the purposes of FIFRA, EPA is very mindful of the theme running through FIFRA that EPA 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 dictates that EPA consider the benefits pesticides can provide to society, and that (given the cost-benefit balancing test contained in FIFRA) unnecessary economic burdens should not be placed upon pesticide users or distributors.

The Existing Stocks Policy Statement Criteria

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.

In applying the policy to spirotetramat, EPA is aware that the chemical does not fit neatly into any of the categories described in the policy. The spirotetramat registrations were terminated because of judicial action related to a procedural failure on the part of the Agency. The Agency did not articulate any risk concerns associated with the termination. To the contrary, the Agency argued against vacatur because it believed that spirotetramat posed less risk, both to health and to the environment, than most of the registered alternatives that could be used in place of spirotetramat if that chemical were no longer available. In deciding to vacate the registrations rather than remand the matter to EPA without vacatur, the court in its December 23, 2009 Order (at p. 17) determined that EPA failed to "present sufficiently reliable evidence" to support a determination that removal of spirotetramat would be likely to increase harm to the environment. Whatever the state of the administrative record before the court at that time, the Agency has considered this issue again in the context of this cancellation order and has concluded that, in fact, spirotetramat is less toxic to human health, less toxic to the environment generally, and in many cases, less toxic to bees as well (this issue is discussed more fully below).

While there is some uncertainty concerning spirotetramat's risk to bee larvae, that uncertainty must be put in proper context. Spirotetramat is far less toxic to man and the environment than the organophosphates and carbamates that are registered alternatives, and has a preferable risk picture to most of the other alternatives as well. In terms of the risk to bees, EPA required specific directions for spirotetramat use to minimize exposure to bees while more information is being developed. With these directions for use, and taking into account the uncertainties with respect to spirotetramat's risk to bees and the uncertainties associated with the alternatives, EPA concluded that spirotetramat does not appear to pose greater risks to bees than the alternatives. So in terms of the risk profile of spirotetramat, EPA would normally apply the policy in a way that would allow sale, distribution, and use of existing stocks.

In this particular case, EPA nonetheless examined the six criteria laid out in the policy for use in determining whether to allow sale or use of existing stocks when the Agency does have significant risk concerns.

I. Quantities of Existing Stocks

In the litigation that led to the District Court's vacatur order, Bayer filed a Memorandum of Law in Opposition to Plaintiffs' Motion for Summary Judgment and in Support of EPA's Cross-Motion for Summary Judgment, along with a Declaration, on December 10, 2009. According to that Declaration, Bayer's total U.S. sales to distributors in 2009 was 34,000 gallons of product, of which approximately 7,600 gallons were still in distributors' hands. $22 million worth of product was held in Bayer's U.S. inventory (which, by extrapolation, appears to have been about 32,500 gallons). EPA does not know how the quantities of existing stocks held by either Bayer or distributors may have changed since December 10, 2009. However, the question of quantities of existing stocks is significantly less important where, as here, there are no significant risk concerns associated with the use of existing stocks.

II. No Significant Risk Concerns Associated with Spirotetramat Existing Stocks

When EPA issued registrations for spirotetramat products in 2008, the Agency found that spirotetramat poses less overall risk to human health and the environment than its alternatives. Further, in light of some uncertainties in the data regarding potential hazard to bees, the Agency required application restrictions designed to protect bees during the pendency of additional studies. EPA concluded that the label restrictions minimized potential risk to bees. The U.S. District Court for the Southern District of New York, in remanding the spirotetramat registration decisions for procedural errors, did not find EPA's substantive conclusions regarding risks to human health or the environment (including bees) to be incorrect. The Agency continues to believe these conclusions to be correct.

EPA conducted an extensive analysis of spirotetramat in collaboration with counterpart agencies in Canada and Austria. In this process, the agencies analyzed voluminous data on such aspects of spirotetramat as its impact on human and animal health, fate and behavior in the environment, and its effects on non-target organisms, *i.e.*, on animals and plants other than the pests it is intended to control. In the course of this analysis, the agencies considered hundreds of published and unpublished studies.

After the conclusion of the joint agency review of data, EPA conducted its own risk assessment of spirotetramat. It conducted a comprehensive analysis of the pesticide's "human health risk," as well as a multi-volume analysis of its "environmental fate and ecological risk." The risk assessment delved deeply into spirotetramat's potential effects on animals, plants, soil, and water, and included detailed calculations of the pesticide's potential effects.

In its June 23, 2008 Decision Document, EPA concluded that "it is in the public interest to register spirotetramat products" because the agency had classified spirotetramat as "a 'reduced risk' pesticide" when used on particular crops in the approved manner, especially as compared to

the pesticides that were already approved for use on those crop types. Specifically, that Reduced Risk Determination (explicitly adopted by the 2008 Decision Document), states:

> On January 16, 2007, the Reduced Risk Committee completed its review . . . and granted reduced risk status to the above uses of spirotetramat. Compared to registered alternatives (especially carbamates and organophosphates), spirotetramat appears to have a more favorable risk profile in terms of both human health and the environment. Spirotetramat exhibits lower acute and chronic toxicity than most registered alternatives, and does not show evidence of carcinogenicity or neurotoxicity. Spirotetramat rapidly degrades in the environment and its low use rates will result in a lower chemical load to the environment. Spirotetramat also represents a new mode of action for several of the pests on these crops, so will fit in well with resistance management strategies, potentially extending the market lifespan of other "reduced risk" chemistries currently being used to control these pests on these crops.

EPA's 2008 Decision Document cited and relied on the findings of the 2007 Reduced Risk Determination and reiterated the finding that "Spirotetramat is expected to be a major alternative to carbamates and organophosphates.... As such, it is in the public interest to register spirotetramat products." Thus, to the extent that the findings of the Reduced Risk Determination were subject to further review, the 2008 Decision Document finalized those findings.

A. EPA continues to believe that spirotetramat has a more favorable risk profile in terms of both human health and the environment than the registered alternatives

EPA's review of comments and its own alternatives analysis indicate that the loss of spirotetramat would likely cause many growers to shift to neonicotinoid insecticides (*e.g.*, imidacloprid, thiacloprid, or thiamethoxam) which control the same spectrum of pests but are often more expensive. Other alternatives that growers may shift to include ones that raise risk concerns to the environment, to human health, or to both, including: organophosphate insecticides (*e.g.*, acephate, azinphos-methyl, chlorpyrifos, diazinon, and phosmet); carbamates (*e.g.*, methomyl, oxamyl, and formetanate hydrochloride); pyrethroid insecticides (esfenvalerate, fenpropathrin, or permethrin); and an organochlorine insecticide (endosulfan).

Spirotetramat is a key insecticide for control of grape phylloxera on grapes, a pest formerly controlled with carbofuran. The only other viable alternative for this use, imidacloprid, appears to be equally effective although it is more expensive and is much more acutely toxic to honey bees (spirotetramat LD 50 > 100 ug/bee versus imidacloprid LD 50 of 0.04 ug/bee).

The loss of spirotetramat for aphid and scale control on apple, peach, pear, and cherry and for aphid and whitefly control on cabbage, cauliflower, cucurbits, lettuce, pepper, potato, and tomato would likely cause some growers to shift to endosulfan or other registered alternatives. Spirotetramat is also a replacement for some of the uses of formetanate hydrochloride. Both materials control thrips and scales on citrus and pome fruits and thrips on onions.

Spirotetramat exhibits much lower acute toxicity to honeybees than most of the alternatives. For example, the loss of spirotetramat would likely cause grape (wine, fresh, raisins) producers to turn to organophosphates for grape mealybug control. Spirotetramat is greater than three orders or magnitude less toxic than the worst organophosphate alternative. It is also greater than two orders of magnitude less toxic than the worst carbamate alternative, greater than three orders of magnitude less toxic than the worst pyrethroid alternative, and greater than three orders of magnitude less toxic than the worst neonicotinoid alternative. Spirotetramat is also generally more than an order of magnitude less toxic than the least toxic chemicals in the classes discussed above.

Spirotetramat also plays a role in the management of insecticide resistance in resistance-prone pests such as green peach aphid, *Bemesia* whiteflies, citrus thrips and onion thrips. These pests are all listed as resistance-prone pests in the Arthropod Pesticide Resistance Database. Although there are numerous insecticides registered in the United States to control green peach aphid, *Bemesia* whiteflies, onion thrips, and citrus thrips, some have lost their effectiveness due to pest resistance, and others are likely to lose their effectiveness unless resistance management techniques are adopted by users. The lack of effective insecticides could result in higher rates of pesticides needed to provide control, and in growers moving away from insecticides with relatively favorable environmental and human health risks.

From a human health perspective, spirotetramat is orders of magnitude less harmful (based on margins of exposure) regarding risks to workers than the alternatives (organophosphates, carbamates, neonicotinoids, and pyrethroids). From an environmental perspective (considering effects on birds, mammals, fish, and daphnia, but putting aside bees for the moment, which are discussed separately herein) spirotetramat is orders of magnitude less harmful (based on risk quotients) than most of the alternatives in most cases, and in no case is spirotetramat more harmful.

Therefore, EPA continues to believe that spirotetramat has a more favorable risk profile in terms of both human health and the environment than the registered alternatives, and the Agency does not have significant risk concerns associated with spirotetramat existing stocks.

B. EPA continues to believe that the label restrictions minimize any potential risk to bees

As noted, when EPA issued registrations for spirotetramat products in 2008, the agency concluded that although a handful of data gaps still existed regarding potential hazard to bees, it was appropriate to conditionally register spirotetramat, during the pendency of additional studies, with label warnings and strict label restrictions protecting bees. EPA's Environmental Fate and Ecological Risk Assessment concerning spirotetramat included numerous studies regarding spirotetramat's potential effect on pollinators, including honey bees. Specifically, this risk assessment evaluated spirotetramat's potential harm to bees, finding that acutely exposing adult bees to spirotetramat did not produce significant mortality to the exposed adult bees, but that exposing adult bees to spirotetramat could be toxic to the development of bee larvae when the adults returned to the hive (finding, in the latter scenario, evidence of "significant brood effects

including increased mortality in adults and pupae, massive perturbation of brood development, and early brood termination").

EPA thus required that all labels for end-use pesticide products containing spirotetramat include the following warning language:

> This product is potentially toxic to honey bee larvae through residues in pollen and nectar, but not to adult honey bees. Exposure of adult bees to direct treatment or residues on blooming crops can lead to effects on honey bee larvae. See the "Directions for Use" section of this label for specific crop application instructions that minimize risk to honey bee larvae.

Emphasis added.

Most significantly, EPA required the registrant to include federally enforceable use limitations in the "Directions for Use" sections of all labels for end-use pesticides containing spirotetramat that prohibit use of the pesticide on certain plants within specified time limits before and after the plants produce flowers — *i.e.*, when they may attract bees. For example, the following label restriction was required for citrus fruits: "Do not apply this product within 10 days prior to bloom, during bloom, or until petal fall is complete."

Uncertainties in the data regarding potential hazard to bees still exist. However, these very specific, unambiguous, mandatory use restrictions prohibiting application of spirotetramat to particular crop types when flowers are blooming (and thus when bees may be foraging) minimize risk to bee larvae.

III. Benefits resulting from the use of such stocks

As described in detail, above, spirotetramat has a more favorable risk profile in terms of both human health and the environment than the registered alternatives. The loss of spirotetramat may result in some growers shifting to those alternatives, including some insecticides for which the Agency has risk concerns. The reduced-risk profile of spirotetramat is one source of beneficial results associated with allowing the sale and use of existing stocks. While spirotetramat's risk profile makes other benefits information less important, EPA also notes that a number of commenters suggested that use of spirotetramat is more efficacious against certain pests and disease vectors (*e.g.*, Iris Yellow Spot Fever and thrips on onions; potato psyllid; aphids; mealybug; whitefly; Asian citrus psyllid; California red scale; cotton aphid; citrus leafminer; citrus red mite; citrus thrips; grape phylloxera; macadamia felted coccid; *et cetera*), and that one application of spirotetramat could in some circumstances replace multiple applications of alternatives.

IV. Financial expenditures users and others have already spent on existing stocks

Whenever EPA considers the disposition of existing stocks, it takes into account the fact that users and distributors have already purchased and stocked product. For users, a cancellation order that prohibits use means that users could suffer the financial loss resulting from having to

purchase a replacement product. At the very least, a user would have to spend the time (and associated travel costs) to purchase a second product; if users had to absorb the costs associated with the existing stock that they are not permitted to use, they would end up paying for twice the product for a single application. A number of commenters suggested that EPA order a recall of spirotetramat stocks, presumably to spare users this double expense. FIFRA section 19 provides the only authority for EPA to order a recall of pesticide products; that authority does not appear to extend to the termination of the registrations in this case. *See* section 19(b) (recall authority only exists where a pesticide is suspended and then canceled under section 6 of FIFRA). Even if Bayer or distributors were inclined to voluntarily initiate a recall, it is far from clear that they would extend such a recall to include opened containers in the hands of users.

The issue is somewhat similar for distributors. They may have to locate and acquire replacement products to sell to their customers, and they must do something with the canceled material that they are not allowed to sell further. Even if the registrant agrees to take material back, distributors will suffer some disruptive impact. If the registrant does not agree to take material back, distributors could suffer economically as well (from some or all of increased storage costs, disposal, transportation, or not being able to recoup the purchase price).

If distributors or the registrant do agree to take back product, a recall itself requires time, human resources, transportation costs, and financial resources (which include, but are not limited to, the sunk costs associated with having manufactured and transported the material in the first place).

Given that EPA has determined that spirotetramat appears to be favorable from a risk perspective than its alternatives, the imposition of financial costs that would stem from a prohibition on the sale or use of existing stocks seems inappropriate.

V. Risks and costs of disposal or alternative disposition of the stocks

Similar to the issue of the financial expenditures made by persons holding existing stocks for use or sale, this issue becomes significantly less important where there are no significant risk concerns associated with the use of existing stocks. Disposal of pesticide material in unopened containers requires transportation as well as the payment for disposal itself. Whatever the costs, the Agency does not believe that holders of such stocks (or any other persons or governmental entities) should be forced to assume the expense of such disposal unless there are important reasons not to allow the product to be used. Given that the reasons for the vacatur of the spirotetramat registrations are at heart procedural; that EPA itself does not believe that the use of existing stocks in the hands of distributors or users would pose significant environmental risks; that to the contrary, EPA believes that such use would pose less risk than alternative pesticides that users would be likely to apply if spirotetramat were unavailable; and that no commenter provided additional scientific information on the risks posed by spirotetramat or the alternative compounds, EPA sees no reason to require that holders of existing stocks (or other entities) bear the costs associated with disposal.

The situation with respect to opened containers in users' hands tilts even further in favor of allowing use of existing stocks. Transportation of opened containers presents a greater risk of

spillage, while disposal activities may also require additional effort and expense to verify the contents of the material being presented for disposal. For material in users' hands, many states provide free disposal services for users – but such programs impose expense on the state itself, and EPA has in the past been asked by states not to unnecessarily burden state disposal programs by requiring disposal in circumstances where disposal might not be necessary from an environmental perspective. At least one state – Pennsylvania – submitted comments in response to EPA's January 25, 2010 notice of intent to issue a cancellation order that pointed to this "disposal and enforcement dilemma … at a time when states are facing extremely challenging economic circumstances."

VI. Practicality of implementing restrictions on distribution, sale, or use of the existing stocks

As a general matter, EPA believes it a mistake to issue restrictions on distribution, sale or use of existing stocks unless holders of stocks are notified of the restrictions and are likely to comply with them. While EPA believes it likely that most distributors would comply with restrictions on sale if they were aware of such restrictions, and that many users would likely comply as well, EPA is concerned that notification of sellers and users would entail the devotion of significant governmental resources, and that such expenditures are unwarranted under the facts presented by spirotetramat. Again, the reasons for the vacatur and the Agency's conclusions about the nature of spirotetramat suggest that the resources that would be needed to inform people quickly that they may not sell or use existing stocks of spirotetramat could be better used elsewhere.

VII. Material in the hands of Bayer

The Agency has determined not to allow Bayer to sell or distribute existing stocks of spirotetramat product in its control. This decision was a close call – the comparative risk profile of spirotetramat militates in favor of allowing Bayer, like all other distributors, to sell existing stocks until exhausted. EPA was ultimately swayed, however, by the fact that the effective date of the vacatur called for in the District Court's December 23, 2009 decision was not until March 10, 2010 – more than 70 days after the decision was issued. That 70 day period should have allowed Bayer to distribute stocks that had been released for shipment prior to December 23, 2009. As a party to the court case, Bayer knew that its registration was under challenge and that plaintiffs were seeking termination of the registration. After December 23, 2009, while Bayer exercised its right to challenge the court's decision, Bayer knew that the registrations could be vacated in the near future. The Agency does not know whether Bayer continued to release product for shipment after December 23, 2009, and such activity would have been lawful. The Agency believes, however, that where risk considerations do not point otherwise, equities generally favor allowing distributors and users to sell or use existing stocks because these people generally have little or no advance knowledge of or control over the regulatory circumstances in which they find themselves. The same logic does not apply to Bayer, and especially does not apply to material that Bayer could have released for shipment after December 23, 2009 (if, in fact, Bayer did release any such material).

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 product registrations 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 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 amendment or cancellation action. 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 export.

   b. Distribution or sale by persons other than the registrant. Distribution or sale of spirotetramat products already in the possession of persons other than the registrant is permitted until such stocks are depleted.

   c. Use. Use of the cancelled products listed below is permitted until such stocks are depleted, provided that such use of existing stocks is consistent in all respects with the previously-approved labeling accompanying the product.

3. List of Cancelled Products

Spirotetramat Technical; EPA Registration No. 264-1049
Movento; EPA Registration No. 264-1050
BYI8330 150 OD Insecticide; EPA Registration No. 264-1051
Ultor; EPA Registration No. 264-1065
Spirotetramat 240 SC Greenhouse and Nursery Insecticide/Miticide; EPA Registration No. 432-1471

for Lois Rossi
Lois Rossi
Director, Registration Division

5 April 2010
Date