UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL and THE XERCES SOCIETY, Plaintiffs,	
-v-	09 Civ. 4317 (DLC)
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Defendant,	OPINION & ORDER
BAYER CROPSCIENCE LP, Defendant-Intervenor.	

APPEARANCES

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DENISE COTE, District Judge:

The United States Environmental Protection Agency ("EPA" or "defendant") registered an insecticide in violation of its statutory duties to publish notice, invite public comment, and publish its registration decisions. This case presents the question of whether the EPA's registration should be vacated in light of these defects. It should be.

BACKGROUND

The Natural Resources Defense Council ("NRDC"), a nonprofit environmental advocacy organization, and the Xerces Society (collectively, "plaintiffs"), a nonprofit wildlife conservation organization, challenge the EPA's registration of the insecticide spirotetramat under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq., claiming procedural and substantive deficiencies in the EPA's approval of it. Plaintiffs are concerned about the effect spirotetramat has on bees.

Intervenor defendant Bayer CropScience ("Bayer") developed spirotetramat and markets it. Spirotetramat is an insecticide that prevents the synthesis of fats necessary for cell

reproduction in insects, which reduces the fertility of female adult insects and the survival of the insect offspring.

FIFRA requires an insecticide containing a new active ingredient to be registered by the EPA in order to be distributed and sold in the United States. 7 U.S.C. § 136a. Insecticide manufacturers must therefore submit an application that contains information about the insecticide's chemical characteristics, mode of action, intended uses, and human health and environmental harms. 7 U.S.C. § 136a(c); 40 C.F.R. Part 158. Between October 2006 and April 2007, Bayer submitted five applications to register spirotetramat under FIFRA for use on various crops in different formulations.

Upon receiving an application, the EPA must publish in the Federal Register a "notice of each application," and solicit comments for at least thirty days. 7 U.S.C. § 136a(c)(4). The EPA concedes that it failed to publish the required notices of applications by Bayer for spirotetramat and invite public comments on those applications.[1]

The EPA may register a pesticide if it determines, inter alia, that the pesticide "will perform its intended function without unreasonable adverse effects on the environment." 7

[1] On July 25, 2007, the EPA solicited comments on the maximum spirotetramat residue permitted on food. Food tolerances are regulated by the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 301, et seq.

U.S.C. § 136a(c)(5). FIFRA defines "unreasonable adverse effects on the environment" in part as, "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb). An application may be approved with or without the condition that further data be submitted to the agency. 7 U.S.C. § 136a(c)(7)(C). In addition, the EPA must determine what conditions of use, if any, to list on the pesticide label. 7 U.S.C. § 136a(c)(5)(B) & 136a(d)(1).

Upon receiving Bayer's applications, the EPA collaborated with Canadian and Austrian counterpart agencies to analyze spirotetramat. The agencies reviewed hundreds of studies in order to assess the insecticide's impact on human and animal health, on non-target organisms, and on the environment. Based on its findings, the EPA conditionally approved Bayer's applications in decisions of June 30, August 8, September 24, and December 16, 2008, which allowed the use of spirotetramat on hundreds of crops.

In the registration process, the EPA identified concerns about the insecticide's effect on bees. The EPA's review of tests exposing honeybees to spirotetramat found, inter alia, "increased mortality in adults and pupae, massive perturbation of brood development, early brood development, and decreased larval abundance." The EPA further found that insecticides that

inhibit lipid biosynthesis have "potential for chronic effects on bee broods and development" and "may adversely affect bee broods and development;" and in 2007 the EPA found there is "uncertainty regarding the potential chronic effects of spirotetramat on pollinators because no long-term data were available." By the time the EPA made its registration decision in June 2008, it had reviewed additional studies on spirotetramat's chronic effect on bees, but it still found the data lacking because the chronic effect studies tested spirotetramat at levels lower than the label-recommended application rate.

The EPA therefore conditioned its approval of spirotetramat on the completion of studies plugging the data gaps on the chronic effects of spirotetramat on bees.[2] Additionally, it

[2] The EPA's risk assessment of spirotetramat found:

> Despite that the intrinsic hazard potential to bees based on the acute oral and contact studies with honey bees appears to be low, brood feeding tests with bees and acute toxicity contact studies with other nontarget insects (e.g. parasitoid wasps and predatory mites) conducted at less than the maximum application rate suggest there is potential for mortality in adults and pupae, massive perturbation of brood development, and early brood termination as a result of spirotetramat use. This information, coupled with the fact that two other chemicals representing the ketoenole class of compounds (spiromesifen and spirodiclofen) have also demonstrated the potential for chronic effects on bee broods and development while displaying low acute toxicity, suggests that the mode of action of

required all end-use products containing spirotetramat to include the following language on their warning labels:

> 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.

The "directions for use" for specific crops prohibited using spirotetramat on plants during those periods when the plants are flowering and are most likely to attract bees.

Within thirty days of approving an insecticide, the EPA must publicly disclose all information supporting the application, id. § 136a(c)(2)(A), and it must publish in the Federal Register a "notice of issuance" of the registration that includes a description of the new insecticide, a summary of the agency's regulatory conclusions, and responses to comments received on the notice of application. 40 C.F.R. § 152.102. In

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> these compounds (i.e., inhibition of lipid biosynthesis) may adversely affect bee broods and development. Although a study has been submitted for spirotetramat under guideline 850.3040, it was conducted at application rates approximately half of the label-recommended rates and it was not designed in such a manner that adverse effects resulting from treatment could be statistically determined. Therefore, it is recommended that a study design be developed in collaboration with the Environmental Fate and Effects Division [of the EPA].

The EPA's registration of spirotetramat required completion of this recommended study within two years of registration.

June 2008, the EPA published on its website a spirotetramat "Pesticide Fact Sheet," which explained that spirotetramat had been conditionally registered, and summarized the EPA's rationale behind that decision. The EPA concedes, however, that it did not publish a notice of registration in the Federal Register for any of these decisions until August 6, 2009, three months after the plaintiffs filed this lawsuit.

FIFRA provides procedures for canceling the registration of a pesticide. If the EPA determines that a registered pesticide causes "unreasonable adverse effects on the environment," the EPA must order a public hearing; or it must consult with the Secretary of Agriculture and then give interested parties notice of its intent to cancel the registration, and those parties may request a public hearing. 7 U.S.C. § 136d(b). If the EPA holds a hearing, an Administrative Law Judge ("ALJ") may subpoena testimony or documents; and the ALJ must refer relevant questions of scientific fact to a Committee of the National Academy of Sciences if a party requests a referral or if the ALJ determines it is necessary. 7 U.S.C. § 136d(d). Before canceling a pesticide registration altogether, the EPA must consider restricting the pesticide's use as an alternative. 7 U.S.C. § 136d(b).

The plaintiffs filed their complaint on May 4, 2009, alleging, inter alia, that the EPA failed to publish notice of

Bayer's applications, solicit comments on those applications, and publish notice of its registration decisions. As already noted, on August 6, 2009, the EPA published a notice in the Federal Register announcing its prior registration of spirotetramat and inviting public comments. In response, the EPA received five comments, including one from the NRDC and one from Bayer.

On August 21, the plaintiffs filed an amended complaint claiming the EPA violated FIFRA, and the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 et seq., by failing to: (1) provide notice and opportunity for comment on Bayer's applications; (2) provide notices of issuance for each registration decision; (3) take into account the economic, social, and environmental costs and benefits of the use of spirotetramat; and (4) make the required safety finding and conduct the complete scientific review necessary to support that safety finding.

On October 21, the plaintiffs moved for summary judgment on all four of their claims. On November 13, the EPA cross-moved for partial summary judgment on the plaintiffs' third and fourth claims. Bayer moved to intervene as a defendant on November 17. Following approval of that application, on December 10 it filed a memorandum in opposition to the plaintiffs' motion for summary judgment and in support of the EPA's cross-motion for partial

summary judgment. These cross-motions for summary judgment became fully submitted on December 18.

DISCUSSION

The parties refer to the plaintiffs' first two claims as "procedural" and their last two claims as "substantive." As discussed above, the EPA concedes that it committed the errors the plaintiffs allege in the two procedural claims. The parties agree that these errors require a remand to the agency, but dispute whether the remand should be accompanied by an order vacating the registration of spirotetramat. For the following reasons, the registrations will be vacated.[3]

A. Rule of Prejudicial Error

If a court finds that an agency committed an error, the court must take "due account" of "the rule of prejudicial error." 5 U.S.C. § 706(2)(F). "The rule of prejudicial error typically eliminates the necessity of remand following judicial review when the error that the agency has made was not prejudicial and did not impinge on fundamental rights." Green

[3] It is undisputed that the plaintiffs have standing to bring this case. See Connecticut v. Am. Elec. Power Co., 582 F.3d 309, 339 (2d Cir. 2009) ("An association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." (citation omitted)).

Island Power Auth. v. F.E.R.C., 577 F.3d 148, 165 (2d Cir. 2009) (citation omitted). Prejudicial error analysis is unnecessary here because the EPA concedes that the procedural deficiencies accompanying the registration of spirotetramat require remand.

B. Remanding With or Without Vacatur

In deciding whether the remand should be coupled with a vacatur of registration, decisions rendered by courts applying both FIFRA and the APA will be considered. Since FIFRA does not provide a standard for judicial review, the EPA's failure to comply with FIFRA is governed by the standards established by the APA, 5 U.S.C. § 706. Cf. LaFleur v. Whitman, 300 F.3d 256, 267 (2d Cir. 2002) (evaluating agency action under the APA because the Clean Air Act does not provide a separate standard of review). The APA mandates that agency actions that violate the law be set aside. It provides that "[t]he reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . without observance of procedure required by law." 5 U.S.C. § 706(2)(D).[4]

[4] The D.C. Circuit has discussed whether the statutory command to "set aside" unlawful agency action requires vacatur of all agency actions that are flawed in the ways described in § 706(2). Compare Checkosky v. SEC, 23 F.3d 452, 462-66 (D.C. Cir. 1994) (Silberman, J., separate opinion) (declaring remand without vacatur under § 706(2) lawful), and Sugar Cane Growers Co-op. v. Veneman, 289 F.3d 89, 98 (D.C. Cir. 2002) (same), with Checkosky, 23 F.3d at 490-93 (Randolph, J., separate opinion) (declaring the practice unlawful), Milk Train, Inc. v. Veneman,

Where an agency action is remanded for further proceedings, the determination of whether or not also to vacate the agency action is left to the court's discretion.[5] Sugar Cane Growers Co-op. of Fla. v. Veneman, 289 F.3d 89, 98 (D.C. Cir. 2002). To determine if vacatur is appropriate, a court must weigh the "seriousness of the [agency action's] deficiency (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed." Comcast Corp. v. F.C.C., 579 F.3d 1, 8 (D.C. Cir. 2009) (citation omitted).

"[W]hen equity demands, an unlawfully promulgated regulation can be left in place while the agency provides the proper procedural remedy." Fertilizer Inst. v. E.P.A., 935 F.2d 1303, 1312 (D.C. Cir. 1991). Accordingly, the D.C. Circuit has left rules in place when doing so serves the public interest

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310 F.3d 747, 757-58 (D.C. Cir. 2002) (Sentelle, J., dissenting) (same), and Comcast Corp. v. F.C.C., 579 F.3d 1, 10-12 (D.C. Cir. 2009) (Randolph, concurring) (same). Since vacatur is appropriate here, the Court assumes without deciding that a court has discretion to refuse to vacate an unlawful agency action despite the statutory direction that "[t]he reviewing court shall . . . set aside" such actions. 5 U.S.C. § 706(2)(D).

[5] The Second Circuit has not discussed the standard for determining whether vacatur is appropriate when an agency has failed to provide notice and an opportunity to comment, but it has shown a willingness to look to the law of other circuits -- particularly the D.C. Circuit -- for guidance on the issue. See, e.g., Riverkeeper, Inc. v. E.P.A., 475 F.3d 83, 96 (2d Cir. 2007) (citing Sprint Corp. v. FCC, 315 F.3d 369, 371 (D.C. Cir. 2003)).

more so than vacating them would. See, e.g., Natural Res. Defense Council v. EPA, 489 F.3d 1250, 1265 (D.C. Cir. 2007) (Rogers, J., concurring in part and dissenting in part) ("[T]he court has traditionally not vacated the rule if doing so would have serious adverse implications for public health and the environment."); Fertilizer Inst., 935 F.2d at 1312 ("Because the removal of the EPA's exemptions may affect the EPA's ability to respond adequately to serious safety hazards, we are reluctant to remove the exemptions here.").

In addition, the D.C. Circuit has remanded without vacatur when vacatur would not actually undo the agency action. By the time the D.C. Circuit reviewed the regulatory program at issue in Sugar Cane Growers, for example, farmers across the country had already plowed under their crops. 289 F.3d at 97. The court held that vacatur was inappropriate because "[t]he egg has been scrambled and there is no apparent way to restore the status quo ante." Id.; see also Milk Train, Inc. v. Veneman, 310 F.3d 747, 756 (D.C. Cir. 2002) (monies distributed three years earlier to dairy producers were not recoverable).

a. Seriousness of the Lack of Notice and Comment

The D.C. Circuit has emphasized the importance of notice and comment to regulatory proceedings. It has said that

> notice requirements are designed (1) to ensure that agency regulations are tested via exposure to

> diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review.

Am. Coke and Coal Chems. Inst. v. E.P.A., 452 F.3d 930, 938 (D.C. Cir. 2006).[6] See also Riverkeeper, Inc. v. E.P.A., 475 F.3d 83, 112-113 (2d Cir. 2007). Accordingly, the lack of notice and comment is "a fundamental flaw that 'normally' requires vacatur of the rule." Heartland Reg'l Med. Ctr. v. Sebelius, 566 F.3d 193, 199 (D.C. Cir. 2009). Indeed, the D.C. Circuit has vacated agency actions in a number of cases where notice and comment was lacking. See, e.g., Envtl. Integrity Project v. E.P.A., 425 F.3d 992, 998 (D.C. Cir. 2005); Int'l Union, United Mine Workers of Am., 407 F.3d 1250, 1261 (D.C. Cir. 2005); Util. Solid Waste Activities Group v. EPA, 236 F.3d 749, 755 (D.C. Cir. 2001).

The EPA's failure to provide notice, invite comment, and publish its registration in this case constitutes a serious deficiency. Despite FIFRA's requirement that the EPA take each of these measures, the EPA utterly failed to comply with these procedural requirements and has offered no explanation whatsoever for these shortcomings.

[6] American Coke, 452 F.3d 930, refers to the importance of notice requirements under the APA. As discussed below, the distinctions between the FIFRA and the APA notice regimes do not diminish the importance of notice and comment in the FIFRA regulatory process.

The EPA claims that it has cured its failure to provide notice and comment. It argues that the plaintiffs have not actually been deprived of their ability to participate in the agency's decisionmaking process because the EPA solicited comments in response to the August 2009 publication of its registration decisions, and the NRDC has submitted a comment. This argument is unpersuasive. Giving notice and inviting comments before an agency takes action "ensure[s] that affected parties have an opportunity to participate in and influence agency decision making at an early stage, when the agency is more likely to give real consideration to alternative ideas." New Jersey v. EPA, 626 F.2d 1038, 1049 (D.C. Cir. 1980); accord Advocates for Highway and Auto Safety v. Fed. Highway Admin., 28 F.3d 1288, 1291 (D.C. Cir. 1994) (stressing the importance of the "requirement that the parties be able to comment on the rule while it is still in the formative or 'proposed' stage to ensure that the agency maintains a flexible and open-minded attitude" (citation omitted)). When considering whether a post-decision notice and opportunity to comment cures earlier notice and comment defects, "[t]he touchstone of our inquiry is thus the agency's open-mindedness, because the concern is that an agency is not likely to be receptive to suggested changes once the agency puts its credibility on the line in the form of final

rules." Highway and Auto Safety, 28 F.3d at 1292 (citation omitted).

The EPA's simple assurance that the "NRDC's comments, along with all others received, will be considered by EPA as required by law" is insufficient to demonstrate adequate open-mindedness. Cf. Id. (placing burden on agency to overcome presumption of closed mind by "mak[ing] a compelling showing" that it has considered subsequent comments with an open mind). Allowing such an assurance to cure the EPA's complete disregard for notice, comment, and publication procedures would render FIFRA's requirements "virtually unenforceable." New Jersey v. EPA, 626 F.2d at 1049 (citation omitted).

Intervenor defendant Bayer argues that since FIFRA's notice and comment requirement is more limited than the APA's notice and comment requirement for rulemaking, the lack of notice and comment under FIFRA does not constitute a serious deficiency. Whereas the APA requires an agency to publish "the terms or substance of the proposed rule or a description of the subjects and issues involved" and the underlying data and methodology in advance of a comment period, 5 U.S.C. § 553(b)(3); Am. Radio Relay League, Inc. v. F.C.C., 524 F.3d 227, 246 (D.C. Cir. 2008) (Kavanaugh, J., concurring in part and dissenting in part), FIFRA requires only notice of the application for registration and solicitation of comments. FIFRA does not require disclosure

of the EPA's analysis and supporting data until after the EPA issues its registration decision. 7 U.S.C. § 136a(c)(2)(A) & 136c(a). The distinction between the disclosure regimes of the two statutes does not eviscerate FIFRA's notice, comment, and publication requirements or materially affect this analysis. Notices of applications under FIFRA, which alert the public to certain key pieces of information such as the pesticide's active ingredient and intended use, 7 U.S.C. § 136a(3)(c)(4), serve the same central purposes as do notices of proposed rules under the APA. The EPA's failure to abide by FIFRA's unambiguous requirements, particularly when unaccompanied by any explanation or justification, constitutes a fundamental flaw and serious deficiency. Permitting post hoc notice and comment to cure this breach would render the statutory requirements meaningless.

b. Disruption Caused by Vacatur

The second factor that must be weighed in evaluating whether vacatur is appropriate is the disruption that would be caused by a vacatur. Comcast, 579 F.3d at 8. None of the potential disruptions identified by either the EPA or Bayer are sufficiently serious to counsel against that remedy.

The EPA suggests that the removal of spirotetramat from the market "may cause growers to use pesticides other than spirotetramat to treat their crops, which EPA has concluded are

more harmful to the environment and to human health than spirotetramat." (Emphasis supplied). If there were reliable evidence in the administrative record that the removal of spirotetramat from the marketplace would be likely to increase harm to the environment, that would weigh heavily against vacatur. The EPA has failed to present sufficiently reliable evidence, however, of such an impact.

To support its assertion of increased harm to the environment from the removal of spirotetramat from the marketplace, the EPA relies solely on its 2007 letter to Bayer concerning Bayer's "Reduced Risk Request for Spirotetramat." Bayer's "Reduced Risk Request" was submitted to the EPA pursuant to the Pesticide Registration Improvement Act ("PRIA"), 7 U.S.C. § 136a(3)(c)(10), which provides for expedited review of pesticides that pose less risk to human health and the environment than existing alternatives. To gain expedited processing of its spirotetramat applications under the PRIA, Bayer submitted, inter alia, its own comparison of spirotetramat's toxicity relative to other pesticides. The EPA reviewed Bayer's submissions and explained that it

> has not had an opportunity to review any of the environmental fate and ecological effects/toxicity data beyond this reduced risk screening assessment. This reduced risk screen must therefore rely on the accuracy of the registrant's (Bayer CropScience) interpretation of these data. . . . EFED has not

> conducted an assessment of whether the alternative pesticides pose less ecological risk.

(Emphasis supplied). Upon reviewing Bayer's data, the EPA noted, inter alia, "although the acute toxicity of spirotetramat to bees is categorized as practically non-toxic, there is uncertainty regarding the potential chronic effects of spirotetramat on pollinators because no long-term data were available."[7] On the basis of Bayer's submissions, the EPA nonetheless granted spirotetramat reduced risk status in a February 22, 2007 letter to Bayer that stated:

> 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.

(Emphasis supplied). The February 2007 letter notes that this is "an initial assessment" of spirotetramat's reduced risk status, and it reserves the opportunity to "re-evaluate and possibly revoke" that status upon further review of data. It is on this February 2007 letter that the EPA relies for its assertion that the removal of spirotetramat might cause growers to use pesticides that are more harmful than spirotetramat.

[7] As noted above, the EPA's concerns about the quality of data available in chronic effect studies persisted through the time of its June 2008 registration decision.

While this correspondence raises important issues, it is insufficient in the context of this record to counsel against vacatur. Since the February 2007 letter contains only an "initial" assessment of spirotetramat's relative risk profile, is admittedly based solely on Bayer's own incomplete data, and is subject to revocation based on further data, that 2007 assessment does not sufficiently support a finding that removing spirotetramat from the market will be likely to result in growers using appreciable amounts of pesticides in 2010 that are more harmful to the environment than spirotetramat.

The EPA next argues that vacatur would be disruptive insofar as it would require the EPA to "retread largely the same path" it trod in the registration process "at great expense." This argument fails.[8] The EPA has not identified what work it would have to duplicate if the registration decisions were

[8] The EPA notes that in Idaho Farm Bureau Fed'n v. Babbit, 58 F.3d 1392 (9th Cir. 1995), the Ninth Circuit found the Fish and Wildlife Service's designation of a snail species as endangered should be set aside for lack of proper notice and comment, yet it left the designation in place, in part, because "the significant expenditure of public resources, including the $400,000 spent on [two federally-funded] studies, would be unnecessarily wasted." Id. at 1405-06. That case does not help the EPA. First, the FWS failed to disclose a study during the comment period, but it did not entirely ignore its statutory notice and comment duties, as the EPA did here. More to the point, the Ninth Circuit's decision to leave the designation in place depended in the first instance on the court's concern for the "potential extinction" of the snails if the designation were vacated. Id. at 1405. As discussed above, no similar environmental concern supports leaving the registration of spirotetramat in place.

vacated. For instance, it has identified no federally-funded research that would have to be redone. Nor has it identified any administrative effort that would be more burdensome than the work it must typically undertake when it complies with FIFRA's notice and comment regime.

The EPA argues as well that vacatur would "upend the carefully balanced statutory scheme devised by Congress for cancellation of a pesticide." It will not. For starters, the cancellation process applies to lawfully registered pesticides, and spirotetramat was not lawfully registered. In any event, the complexity and demands of what the EPA calls the "detailed FIFRA cancellation process," if anything, weigh in favor of vacatur. Once a pesticide is registered and on the market, it is costly and time consuming to revoke that registration and remove it from the market. Since spirotetramat was not lawfully registered in the first place, it is more appropriate to vacate the registration and place the burden on the EPA to register the pesticide lawfully, rather than to place the burden on opponents to navigate the cancellation process.

Finally, the EPA argues that the NRDC's recent comments in response to the August 2009 Federal Register notice suggest that there is no great harm to the environment from the continued use of spirotetramat during this period of agency review. In those comments, the NRDC advocates stricter crop-specific restrictions

and further study of spirotetramat. The NRDC's advocacy regarding the limitations that it contends should be imposed on any use of spirotetramat does not address the question at stake here: whether withdrawal of spirotetramat from the market pending the EPA's compliance with the notice, comment, and registration procedures is likely to cause serious disruptions. As a result, even if it is appropriate to consider the NRDC comments,[9] they do not weigh against vacatur.

Bayer adds one additional argument to those presented by the EPA. It argues that it has already invested $90 million on the testing and registration of spirotetramat and stands to lose tens of millions of dollars in sales if the EPA's registration decisions are vacated. Bayer relies on MCI Telecomms. Corp v. FCC, 143 F.3d 606 (D.C. Cir. 1998), for the proposition that potential "disruptions to business plans and economic harms" warrant a remand-only remedy. MCI does not help Bayer. In MCI, the court reviewed the rate that the FCC allowed payphone operators to charge service providers for coinless calls. The court found that the FCC had failed to explain "adequately" its

[9] The parties debate the extent to which a court may rely on evidence outside the administrative record in assessing a remedy. The EPA contends such extra-record evidence is only permitted to show that an agency has rectified a violation after the onset of legal proceedings. If this test were applied here, the EPA's references to the NRDC's comments in response to the August 2009 notice would be ignored.

derivation of the rate, in violation of its statutory duty to do so, but the court chose

> not to vacate the . . . rate on the clear understanding that if and when on remand the Commission establishes some different rate of fair compensation for coinless payphone calls, the Commission may order payphone service providers to refund to their customers any excess charges for coinless calls collected pursuant to the current rate.

Id. at 609. MCI is not an example, therefore, of an agency's complete disregard of the notice, comment, and publication procedures. As significantly, Congress had required the FCC to prescribe regulations setting a fair fee, and thus there was no dispute that customers should be required to pay some fee for their telephone service. Finally, this case does not afford any comparable opportunity to "refund" any damage that might be done to the environment by leaving the agency action in place.

Even assuming that a company's commercial fortunes can properly be weighed in a vacatur decision,[10] Bayer has not shown that either its prior investment in product development or current commercial success should prevent a vacatur that is otherwise warranted. First, Bayer made its investment before making its FIFRA application, and without any guarantee of FIFRA

[10] The EPA contends that Congress did not intend "economic considerations to play much of a role" in the EPA's registration decisions. If that is so, then it may also be true that they should be given limited weight in deciding whether to vacate illegal registrations.

approval. As for the product's commercial success, if the product merits registration it should survive FIFRA's notice and comment period and reexamination by the EPA, and it will return to the market. If it does not, then it should never have been registered and sold. The fact that Bayer has already begun reaping the rewards of the outcome of a flawed regulatory process does not prevent the EPA's registration from being vacated and that regulatory error from being corrected.[11]

Plaintiffs are challenging the illegal registration of spirotetramat. The EPA -- through its finding that spirotetramat causes "increased mortality in [bee] adults and pupae, massive perturbation of brood development, early brood termination, and decrased larval abundance," its requirement of additional studies on the chronic effects of spirotetramat on bees, and its warning label requirements -- has evinced some concern for the harmful effects spirotetramat may have on bees. Vacating the EPA's registrations of this potentially harmful insecticide furthers the environmental and agricultural interests FIFRA aims to protect and vindicates FIFRA's procedural requirements.

[11] Since this Opinion concludes that remand with vacatur is the proper remedy for the EPA's procedural arrors, it is unnecessary to reach the cross-motions for summary judgment on the plaintiffs' allegations of the EPA's substantive errors.

CONCLUSION

The plaintiffs' October 21, 2009 motion for summary judgment is granted only as to the first two claims in the August 21, 2009 amended complaint. The EPA's June 30, August 8, September 24, and December 16, 2008 approvals of registrations of spirotetramat are vacated, and the matter is remanded to the EPA for further proceedings in accordance with FIFRA and the APA. The defendant's November 13, 2009 cross-motion for partial summary judgment is denied as moot. This decision is stayed until January 15, 2010. The Clerk of Court shall close the case.

SO ORDERED:

Dated: New York, New York
December 23, 2009

DENISE COTE
United States District Judge