

PETITION FOR RULEMAKING TO ESTABLISH PROCEDURES FOR THE
CREATION AND AMENDMENT OF ENDANGERED SPECIES PROTECTION
BULLETINS

Dow AgroSciences LLC (“DAS”), Makhteshim Agan of North America, Inc. (“MANA”) and Cheminova, Inc. USA (“Cheminova”) petition the U.S. Environmental Protection Agency (“EPA”) to promulgate a rule establishing clear and equitable procedures for creating and amending Endangered Species Protection Bulletins (“County Bulletins”) that the Agency intends to require pesticide registrants to cross-reference on product labels as part of the Agency’s Endangered Species Protection Program (“ESPP”).

Introduction

No pesticide can be distributed or sold for use in the United States unless it has been registered by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”), 7 U.S.C. § 136 *et seq.* Registrations require that products carry labels providing specific directions for the appropriate product, including limitations intended to protect the environment.

The Endangered Species Act (“ESA”), 16 U.S.C. § 1531 *et seq.*, requires that Federal agencies insure that their actions do not cause unacceptable impacts on threatened or endangered species or their habitat. EPA developed the ESPP several years ago as a mechanism for implementing this obligation. *See* 70 Fed. Reg. 66392, 66400 (Nov. 2, 2005) (“ESPP Notice”). As a practical matter, however, the Agency has not yet fully implemented it.

Under the ESPP, if EPA concludes that limitations on pesticide product use are necessary to protect species in a particular geographic area in which use otherwise would be authorized, EPA may require registrants to include on their product labels a direction

that users consult and comply with the County Bulletin that pertains to that area. These County Bulletins, in turn, would be accessible via the internet and set forth geographically-specific use directions.

This mechanism is intended to make the directions included in County Bulletins enforceable under FIFRA. *See* 70 Fed. Reg. at 66392. However, EPA has established no procedures for input by the agricultural or forestry communities, or to assure the pesticide registrant's ability to review, comment upon and/or challenge proposed language in County Bulletins that would be referenced on its label. With dozens of ESA consultations relating to pesticide registrations slated to occur over the next few years, many of which will result in publication of or modification to County Bulletins, appropriate procedures must be established. This need is underlined by the Agency's demand that DAS, MANA and Cheminova amend certain product labels to reference County Bulletins applicable to California, Washington, Oregon and Idaho.

Authority

This petition is filed under Administrative Procedure Act, 5 U.S.C. § 553(e) ("Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule."); the Federal Insecticide Fungicide and Rodenticide Act, FIFRA § 25, 7 U.S.C. § 136w ("The Administrator is authorized . . . to prescribe regulations to carry out the provisions of this subchapter."); and the United States Constitution, U.S. Const., amend. 1 ("Congress shall make no law . . . abridging . . . the right of the people . . . to petition the Government for a redress of grievances.").

Why a Rule is Necessary

The appropriate mechanisms for integrating EPA's FIFRA and ESA responsibilities have long been controversial. What has not been controversial, however, is that that integration should be undertaken in a way sensitive to the needs of the agricultural community. For example, in 1988 Congress enacted (and the President signed) Pub. L. No. 100-478, 102 Stat. 2306. Section 1010 of that statute directed – among other things – that EPA focus on “the means of implementing the endangered species pesticides labeling program or alternatives to such a program, if any, to promote the conservation of endangered or threatened species and to minimize the impacts to persons engaged in agricultural food and fiber commodity production and other affected pesticide users and applicators.” *Id.* § 1010(b).

EPA has acknowledged this policy guidance and taken some (albeit incomplete) steps to respond to it. The ESPP is one of those. For example, in establishing the ESPP, EPA characterized Section 1010 as providing a “clear sense that Congress desires that EPA should fulfill its obligation to conserve listed species, while at the same time considering the needs of agriculture and other pesticide users.” 70 Fed. Reg. 66392, 66393 (Nov. 2, 2005). EPA also consistently has recognized that FIFRA grants pesticide registrants certain substantive and procedural rights regarding the contents of both their labels and any materials cross-referenced in those labels (such as a County Bulletin). As the Agency put it in the ESPP notice:

As with any potential change to a pesticide product label, the registrant of a product for which it has been determined the generic endangered species statement needs to be included, will have an opportunity to review the specific use limitations that may be included in the Bulletins, prior to Bulletin issuance. If once a product is labeled with the

generic statement, changes in the Bulletin which would affect that product's use are necessary, the registrant will have an opportunity to review the changes prior to issuance. Further, the registrants retain any rights they may have under FIFRA, regarding EPA's determination that use of the product needs to be modified.

EPA will publish specific details of this publication participation process on its web site, <http://www.epa.gov/espp>, as they are developed and refined.

Id. at 66401. The Agency reiterated many of these points in a November 16, 2009 letter to Petitioners: “[I]f the registrants object to adding these label statements or if they object to the content of the bulletins in whole or in part, EPA will not publish and compel compliance with unapproved portions of the bulletins unless and until EPA takes appropriate action under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) to require adoption of such use limitations.”¹

However, EPA has never explained what it means by recognizing “any rights” the registrants “may have under FIFRA” or what “appropriate actions” it will take in the event that registrants believe EPA's required language is misdirected or unlawful. Instead, the Agency has embarked – or perhaps more fairly, in light of the litigation to which it has been subject, fallen into – a wholly *ad hoc* County Bulletin development and implementation process. Moreover, that *ad hoc* process is wholly insufficient to protect the rights and interests of registrants and, indeed, the broader agricultural and forestry communities.

¹ Letter from Richard P. Keigwin, Jr. to David B. Weinberg and David E. Menotti (November 16, 2009) (“2009 Keigwin Letter”); *see also* <http://www.epa.gov/espp/basic-info.htm#public> (“EPA will publish specific details of this process on its Web site as they are developed and refined.”)

The flaws in this process have been demonstrated by EPA's response to the November 18, 2008 biological opinion ("BiOp") issued by the National Marine Fisheries Service ("NMFS") regarding the potential impact of chlorpyrifos, malathion and diazinon on salmonids in Washington, Oregon, Idaho and California. That BiOp was the first of seventeen to be issued by February 19, 2012 in accordance with a litigation settlement agreement reached in 2008.² It took EPA almost a year to make an initial determination as to what steps to pursue in light of the BiOp³ and the Agency still has been unable to respond fully to registrants' efforts to obtain further guidance about the content of the proposed County Bulletins, how they will be adopted and revised, or how the Agency intends to pursue label changes in the event that any registrant is not prepared to accept the Agency's demands. The Agency's only guidance to registrants on these issues has been the following, set forth in the November, 2009 letter referenced above:

It is EPA's expectation that the registrants and their formulator customers will, upon approval of the bulletin content, (1) place on all manufacturing use product labels reformulation limitations that require formulators to include on end-use product labeling a statement requiring user adherence to the bulletins; and (2) place on all end use products an instruction that applicators must follow the use limitation of the bulletins ... [I]f the registrants object to adding these label statements or if they object to the content of the bulletins in whole or in part, EPA will not publish and compel compliance with unapproved portions of the bulletins unless and until EPA takes appropriate action under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") to require adoption of such use limitations.⁴

² Stipulated Settlement Agreement and Order of Dismissal, *Northwest Coalition for Alternatives to Pesticides v. NMFS*, No. 07-1791-RSL, Doc. 20 (W.D. Wash. July 30, 2008) (requiring 17 analyses covering a total of 37 pesticide/species combinations).

³ See 2009 Keigwin Letter.

⁴ *Id.* at. 2.

The chlorpyrifos-diazinon-malathion BiOp is only the tip of the iceberg, however. Another BiOp was published by NMFS on April 20, 2009.⁵ NMFS has fifteen more salmonid BiOps in preparation for agricultural and forestry areas in Washington, Oregon, Idaho and California, and many additional consultations (and presumably BiOps) will be forthcoming in the immediate future as a result of other court decisions and consent decrees.⁶

The lack of an established system for addressing restrictions arising from these BiOps will lead to chaos. To ensure that registrants are treated equally and fairly, EPA must act now, and quickly, to put its promised detailed procedures in place.

As part of this effort, EPA also needs to be transparent as to the “appropriate action” it intends to take if registrants are not prepared to approve County Bulletin language preferred by EPA. As petitioners read FIFRA, the appropriate action would be for EPA to initiate cancellation proceedings under Section 6 of FIFRA. The first steps of that process would be to draft a cancellation notice and provide it to the Department of Agriculture and the FIFRA Scientific Advisory Panel (“SAP”) for review. Among other things, this will assure that the important interests of grower communities are considered by the Agency. *See* FIFRA § 6(b), 7 U.S.C. § 136d(b). Thereafter, if EPA continues to think modifications are necessary, it should pursue a cancellation proceeding that is narrowly focused on the justification for the proposed County Bulletins directions.

⁵ National Marine Fisheries Service, Endangered Species Act Section 7 Consultation, Biological Opinion, Environmental Protection Agency Registration of Pesticides Containing Carbaryl, Carbofuran, and Methomyl (April 20, 2009).

⁶ *See, e.g.*, Stipulated Injunction and Order, *Ctr. for Biological Diversity v. Whitman*, Civ. No. 3:02-1580-JSW, Doc. 242 (N.D. Cal. Oct. 20, 2006); Stipulation of Dismissal with Prejudice, *Ctr. for Biological Diversity v. Leavitt*, Civ. No. 1:04-cv-00126, Doc. 35 (D.D.C. August 22, 2005); Proposed Stipulated Injunction and Order, *Ctr. for Biological Diversity v. EPA*, Civ. No. 07-02794-JCS (N.D. Cal.) (available at <http://www.epa.gov/oppfead1/endanger/litstatus/stipulated-order-6-30-2009.pdf>).

However, there are other approaches EPA theoretically might take, and both registrants and agricultural and forestry interests who depend on the continued availability of pest control products deserve to know the circumstances (if any) in which EPA would seek to invoke them. Of particular concern is the statement in the 2005 ESPP Notice that a product that is labeled consistent with its current registration could nonetheless be considered by EPA to be “misbranded” if a registrant refused to reference use restrictions in County Bulletins. Petitioners believe any such assertion would be inconsistent with the law. *See, e.g.*, FIFRA § 3(f)(2), 7 U.S.C. § 136(a)(f)(2) (“As long as no cancellation proceedings are in effect registration of a pesticide shall be *prima facie* evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter.”) Nonetheless, the 2005 ESPP Notice, and more recent assertions by EPA staff, indicate that EPA invocation of this purported authority is being seriously considered. *See, e.g., Reckitt Benckiser, Inc. v. Jackson*, No. 09-445 ESH, 2009 U.S. Dist. LEXIS 101660, at *7 (D.D.C. Oct. 30, 2009) (EPA advised plaintiffs that their products would be considered misbranded if they did not voluntarily comply with the Agency’s risk mitigation decision).

These procedural issues are central to the operation of the registration program and thus are precisely the sort of issues that should be addressed in rulemaking. *See, e.g.*, 32 Charles A. Wright, *et al.*, *Federal Practice and Procedures* § 8123 (1st ed.) (“An agency should be compelled to advise the public of the processes it will employ in a given context.”); 1 Charles H. Koch, Jr., *Administrative Law and Practice* § 2.12 (2d ed.) (same); 1 Richard J. Pierce, *Administrative Law Treatise* § 6.8 (5th ed.) (rulemaking appropriate for reasons of efficiency and fairness).

Moreover, addressing this issue in rulemaking under FIFRA will provide for meaningful opportunities for input not only from the public and agricultural and forestry interests, but from the Department of Agriculture and the Congress. *See* FIFRA Section 25(a)(2), 7 U.S.C. § 136w(a)(2). Section 1010 of Public Law No. 100-478, described above, underlines the Congressional interest in assuring that the integration of FIFRA and the ESA accommodate those interests.

Finally, it would be fundamentally unfair to require registrants who are unsatisfied with EPA's ESPP program to challenge the Agency's procedures in the context of a pesticide-specific cancellation hearing. If it turns out that judicial review of EPA's proposed implementation approach is necessary, it will be most fairly obtained before a court focused on interpretation of the inter-relationship between FIFRA and the ESA. This would best occur in an independent review proceeding, brought pursuant to FIFRA Section 16 and the Administrative Procedure Act.

Action Requested

The Code of Federal Regulations, Part 152, Subpart G Title 40, generally sets forth the "Obligations and Rights of Registrants." Petitioners request that EPA promulgate a new Section 152.136 that include procedures for requiring labels to cross-reference County Bulletins and/or for creating and amending all County Bulletins that are cross-referenced in approved labels, and sets forth the Agency's procedures in the event a registrant is not willing to accept proposed amendments.

The new Section 152.136 should include the following:

- Provisions granting to all registrants whose labels include cross-references to County Bulletins (or are to be amended to do so) the following rights:

- Timely notification to any registrant of a product containing a specific active ingredient whenever the creation or amendment to a County Bulletin that might apply to the registrant's product is contemplated. The regulation should also set forth the minimum content of such a notice, including both the proposed revision and the rationale for it.
- Not less than thirty days for a registrant and potentially affected pesticide users and state governments to submit comments.
- A commitment by EPA to evaluate all comments and inform all affected registrants of a decision in advance of the ultimate decision on any County Bulletin language.
- The opportunity for a registrant or registrants to negotiate with EPA regarding the Agency's response to comments, if it/they so desire(s).
- A commitment on the part of EPA that, if any potentially affected registrant cannot reach agreement with EPA regarding acceptable County Bulletin language, the Agency will make no changes in the language, so as to avoid commercial prejudice to those who choose not to contest EPA's demands.
- Confirmation that FIFRA Section 6 Procedures will apply when consultation with a Service, or any other EPA analysis (including registration review), results in a desire on EPA's part to amend labeling of an existing product to address ESA concerns by inserting directions to

consult any County Bulletin(s), or to make revisions to a previously cross-referenced County Bulletin that are unacceptable to a potentially-affected registrant. Confirmation that the cancellation procedures are exclusive, and that no other administrative procedure will be followed or other enforcement action undertaken unless specified criteria are met that indicate there is an extraordinary, substantial and newly-identified immediate threat to a listed endangered species.

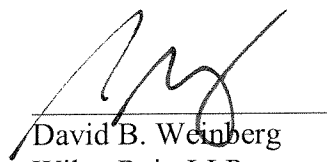
- Notification to all registrants of the active ingredient of the results of any cancellation hearing, and a commitment that if the cancellation hearing results in a finding that the proposed language is not appropriate, no County Bulletin(s) will be revised to include it.

Promulgation of this rule should not result in any undue delay in implementing BiOps and other ESA determinations, since EPA already has indicated as part of its ESPP that its intention is to update County Bulletins on a regular basis and to preserve review and approval rights regarding that process. Instead, it will simply regularize the process for such updating. If EPA intends to update Bulletins, EPA simply will have to formulate its proposal(s) earlier and provide notice of its proposal and allow time for consideration of and action upon any comments received.

Conclusion

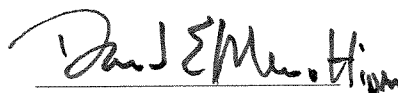
In light of current uncertainties with regard to the products of Petitioners subject to the November, 2008 BiOp, we request a response to this Petition within thirty days.

Respectfully submitted,



David B. Weinberg
Wiley Rein LLP
1776 K Street
Washington, DC 20006

*Attorney for Dow AgroSciences LLC and
Makhteshim Agan of North America, Inc*



David E. Menotti
Pillsbury Winthrop Shaw Pittman LLP
2300 N Street, NW
Washington, DC 20037

Attorney for Cheminova, Inc. USA

January 19, 2010

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