

Arent Fox

February 18, 2011

VIA MESSENGER

The Honorable Lisa Perez Jackson
Administrator
U.S. Environmental Protection Agency
Ariel Rios Federal Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Request for Administrative Hearing Under the Federal
Insecticide, Fungicide, and Rodenticide Act by Dow AgroSciences
LLC Regarding Notice of Intent to Cancel Registered Uses of
Sulfuryl Fluoride

Dear Administrator Jackson:

The purpose of this letter is to formally request an administrative hearing on behalf of our client, Dow AgroSciences LLC (“Dow AgroSciences”), pursuant to Section 6(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”). This request is made in response to the notice of intent to cancel registered uses of the pesticide active ingredient sulfuryl fluoride as reflected in the Proposed Order recently issued by the U.S. Environmental Protection Agency (“EPA” or “Agency”) under the pesticide provisions of the Federal Food, Drug, and Cosmetic Act (“FFDCA”). Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay (“Proposed Order”), 76 Fed. Reg. 3422 (January 19, 2011).

Dow AgroSciences holds a conditional registration granted by EPA in 2004 and 2005 for various uses of ProFume® gas fumigant (“ProFume”), a pesticide containing sulfuryl fluoride as the active ingredient. ProFume is approved for use in the control and eradication of a wide range of post-harvest pests such as rats, mice, moths, worms and beetles in flour, grain and other mills, food and feed storage structures and food handling facilities. As the registrant of ProFume and the party requesting the tolerances that are the subject of the Proposed Order, Dow AgroSciences has been an active participant in the subject FFDCA proceeding and intends to submit comments on the Proposed Order to the docket established by EPA for that purpose. That comment opportunity is not, however, either as a matter of law or fact, a substitute for the due process

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rights accorded to an adversely affected party such as Dow AgroSciences under the provisions of FIFRA, nor is it a substitute for the obligations imposed on the Agency under that statute.¹

By way of this letter and as further set forth below, Dow AgroSciences also requests that the Agency comply with its obligations under Sections 6 and 25 of FIFRA, including obtaining the comments of (i) the Secretary of Agriculture, (ii) the Secretary of Health and Human Services, and (iii) an independent Scientific Advisory Panel regarding the proposed cancellation of the ProFume food-related registrations that would result from the actions set forth in the Proposed Order. The hearing requested above, to which Dow AgroSciences is entitled as a matter of law under FIFRA, should occur after all of the aforementioned comments are obtained by the Agency and made publicly available.

If issued in final form, the Agency's Proposed Order would terminate tolerances associated with the food-related uses of ProFume pursuant to a sequential implementation schedule (*i.e.*, immediately upon the effective date of the order for dried eggs and powdered milk tolerances, ninety days after the order for several additional food uses, and three years after the order for structural fumigation and remaining food uses). Pursuant to the Proposed Order, all tolerances for residues that might result in food as a result of the use of ProFume would be terminated by the conclusion of the sequential implementation period. In the absence of approved tolerances, a food containing a sulfuryl fluoride residue would be adulterated under FFDCA Section 402 and could not be legally moved in interstate commerce. Moreover, the termination of tolerances that support the food-related uses of ProFume for the reasons stated in the Proposed Order would require EPA to take action to cancel the underlying FIFRA registered uses and make it a violation of federal law to sell or distribute ProFume for any of those food-related uses. *See, e.g.*, FIFRA Sections 2(bb) and 12(a)(1)(A).²

In enacting the Food Quality Protection Act of 1996 ("FQPA"), Congress went to great lengths to harmonize the relevant amendments to the FFDCA and FIFRA. As stated by EPA, "Congress integrated action under the two statutes by requiring that the safety standard under FFDCA be used as a criterion in FIFRA registration actions as to pesticide uses which result in dietary risk from residues in or on food, (7 U.S.C. 136(bb)), and directing EPA to coordinate, to the extent practicable, revocations of tolerances with pesticide cancellations under FIFRA, (21 U.S.C.

¹ Because EPA is proposing to grant the objections raised against the sulfuryl fluoride and fluoride tolerances, the Agency has concluded that no further action is needed with respect to the Objectors' associated hearing request. 76 Fed. Reg. at 3443. Accordingly no hearing rights are currently available under FFDCA to a party adversely affected by the Proposed Order.

² *See, also*, EPA's implementing regulations requiring an applicant for registration of a food-use pesticide to notify EPA as to whether tolerances are in effect to cover any resulting residues and, if not, to submit a petition for establishment of appropriate tolerances as part of the registration application. 40 C.F.R. 152.50(i).

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346a(l)(1)).”³ 76 Fed. Reg. at 3424. Most importantly, in spite of the numerous amendments made by FQPA to both FIFRA and FFDCAs, Congress never so much as suggested that it intended to diminish in any way the rights and protections afforded to adversely affected parties or the obligations imposed upon EPA under FIFRA since 1972.

Because EPA’s termination of the tolerances as set forth in the Proposed Order would require the Agency to take action to cancel the registration for all food-related uses of ProFume and force Dow AgroSciences to remove all such uses from its ProFume label, the Proposed Order is, in effect, a notice of intent to cancel Dow AgroSciences’ food-use registrations for ProFume.⁴ Accordingly, EPA must follow the administrative procedures for cancellation of registrations required by FIFRA and accord Dow AgroSciences its due process rights thereunder. The fact that these cancellations would result from the second prong (*i.e.*, dietary risk) of the standard for registration under FIFRA rather than the first prong (*i.e.*, unreasonable risk) should have no bearing on the due process rights accorded to Dow AgroSciences and the obligations imposed on the Agency under FIFRA Sections 6 and 25.

Specifically, under FIFRA Section 6(b), before making public its notice to cancel a pesticide registration, EPA is required to “include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.” FIFRA also requires EPA to provide the Secretary of Agriculture with notice of the proposed action that would result in registration cancellation and a copy of the EPA’s analysis of the impact on the agricultural economy. EPA is required to publish in the Federal Register any input on the proposed action from the Secretary of Agriculture. *Id.* Similarly, EPA is required to consult with the Secretary of Health and Human

³ The statute actually requires coordination of tolerance actions “to the extent practicable ... with any *related necessary* action” under FIFRA. FFDCAs Section 408(l)(1) (emphasis supplied). EPA concedes that this coordination provision is relevant to the tolerance withdrawal actions set out in the Proposed Order. 76 Fed. Reg. at 3424. In that regard, the withdrawal of the sulfur dioxide and fluoride tolerances under FFDCAs as set out in the Proposed Order is clearly “related” to cancellation of the underlying food-related uses of ProFume under FIFRA that would result from those tolerance actions. Indeed, EPA expressly linked the existence of those tolerances to ProFume’s registration in the terms of the ProFume registration itself. In addition, FIFRA Section 6(b) makes clear that compliance with its cancellation procedures is mandatory and therefore “necessary”. Finally, no basis has been identified in the Agency’s Proposed Order or elsewhere to make compliance with required FIFRA cancellation procedures impracticable. This is especially true in light of the facts that (i) the Proposed Order sets forth a sequential implementation period and (ii) there is no imminent health hazard that would be cured by termination of the tolerances at issue and cancellation of the underlying registered uses.

⁴ In the absence of a conventional Notice of Intent to Cancel from the Agency, Dow AgroSciences has no choice but to treat the Proposed Order as constructive notice and file this request in order to protect its rights under FIFRA.

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Services with respect to the proposed action, and publish the Secretary's comments. *Id.* Moreover, EPA is required to present its case for the proposed action to an independent Scientific Advisory Panel ("SAP") and the SAP's comments and recommendations are to be published in the Federal Register. FIFRA Section 25(d).⁵

Finally, FIFRA Section 6(b) allows a "person adversely affected by" the proposed action that would result in the cancellation of a registration to request a hearing. As the registrant of ProFume, Dow AgroSciences is clearly a person adversely affected by the threatened cancellation of ProFume's food uses, is thus entitled to request a hearing pursuant to FIFRA, and formally does so by way of this letter. In order to ensure that the hearing is efficient, informed and just, Dow AgroSciences requests that EPA follow the required procedures outlined above with respect to consultation regarding the proposed cancellation of ProFume's food uses with the Secretaries of Agriculture and Health and Human Services and an independent SAP and make public all comments resulting from their review as well as all comments on the Proposed Order submitted to the public docket *before* a hearing takes place.⁶

Dow AgroSciences has numerous objections to the proposed cancellation of its ProFume food uses that should be addressed at the time of the hearing, all of which arise for the first time as a result of the issuance of the Proposed Order and the risk assessments underlying same. In addition to the procedural deficiencies identified above, these objections include, but are not limited to, EPA's failure to:

- (1) follow the terms of the conditional registration issued to Dow AgroSciences for ProFume before issuing the Proposed Order;
- (2) first determine whether the maximum contaminant level for fluoride in drinking water should be revised prior to determining a new Reference Dose for fluoride;
- (3) use the best available data and apply sound scientific principles in reaching its determination of a new Reference Dose for fluoride;
- (4) consider reasonable and appropriate alternatives to the termination of the subject tolerances and cancellation of the underlying ProFume uses;

⁵ Pursuant to FIFRA Sections 6 and 25, all of these procedures should have been followed *prior to* issuance of the Proposed Order.

⁶ Dow AgroSciences specifically reserves and does not waive any of its rights to challenge EPA's failure to comply with the FIFRA cancellation procedures prior to issuance of the Proposed Order.

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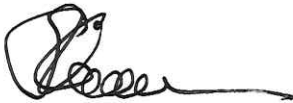
(5) reach a proposed cancellation decision only after a full and fair review of the impact of the proposed action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy; and

(6) properly consider the benefits of continued ProFume use to health, safety and the environment including with respect to the sequential implementation dates that would apply to termination of the subject tolerances and cancellation of the underlying ProFume uses.

A more detailed listing and discussion of Dow AgroSciences' objections will be filed once the comments of the SAP and the Secretaries of Agriculture and Health and Human Services are made public and the docket closes on the Proposed Order.

Dow AgroSciences appreciates your attention to the foregoing. Should the Agency have any questions concerning this request or require additional information, please contact the undersigned.

Sincerely,



Stanley H. Abramson
Donald C. McLean
Counsel for Dow AgroSciences LLC

cc: OPP Regulatory Public Docket (7502P)
Environmental Protection Agency
Docket ID Number EPA-HQ-OPP-2005-0174

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The Honorable Thomas J. Vilsack, USDA
The Honorable Kathleen Sebelius, HHS
The Honorable Stephen A. Owens, USEPA
The Honorable Regina A. McCarthy, USEPA
The Honorable Colin Scott Cole Fulton, USEPA

The Honorable Debbie Stabenow, US Senate
The Honorable Frank D. Lucas, US House of Representatives

Ms. Nancy Stoner, USEPA
Mr. Robert M. Sussman, USEPA
Mr. Lawrence Elworth, USEPA
Mr. Dan Reifschneider, DOS
Mr. John Thompson, DOS