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March 11, 2011

CERTIFIED MAIL;
RETURN RECEIPT REQUESTED

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

Subject: Response to Request of Dow AgroSciences LLC for Administrative Hearing Regarding Proposed Order Granting Objections to Tolerances and Denying Request for a Stay

Dear Administrator Jackson:

The purpose of this letter is to respond to the February 18, 2011 request of Dow AgroSciences LLC (Dow) for an administrative hearing regarding your Proposed Order Granting Objections to Tolerances and Denying Request for a Stay (Proposed Order). 76 Fed. Reg. 3422, January 19, 2011. (Dow Letter) The Proposed Order was issued by the U.S. Environmental Protection Agency (EPA or Agency) expressly under the Federal Food, Drug, and Cosmetic Act (FFDCA). It thus reflected the Administrator's analyses and conclusions regarding the safety of tolerances previously established for pesticide chemical residues, in or on food, of sulfuryl fluoride. Relatedly, the registration, re-registration, suspension and cancellation of that pesticide (although not the establishment, suspension or revocation of a tolerance for it) are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The Objectors Fluoride Action Network, Environmental Working Group and Beyond Pesticides, who initiated the proceedings leading to the Proposed Order, urge herein that you deny Dow's request. The Objectors' arguments may be summarized as follows:

- The Administrator's Decision to Proceed Initially under FFDCA Alone Is a Reasonable and Proper Exercise of Her Discretion

- Even if Section 6 of FIFRA Were Applicable, It Does Not Entitle Dow to a Hearing as an Absolute "Matter of Law"

These points are explained more fully below.

I. The Administrator's Decision to Proceed Initially under FFDCA Alone Is a Reasonable and Proper Exercise of Her Discretion

In its Proposed Order, EPA concluded as follows:

> After reviewing the objections and the NRC Report, EPA is proposing to grant the objections because it agrees that aggregate exposure to fluoride for certain major identifiable population subgroups does not meet the safety standard in FFDCA section 408. 76 Fed. Reg. at 3423.

Despite the clear and specific statutory context of this matter, Dow seeks to cast it as "in effect" a proceeding to cancel the pesticide registration of sulfuryl fluoride under Section 6 of FIFRA. Stating that its request is "made in response to the notice of intent to cancel registered uses of the pesticide …as reflected in the Proposed Order," Dow considers that it has no "choice" but to request a hearing under that statute. Dow Letter at 3 and footnote 4. Based on this reasoning, Dow therefore requests that EPA not only proceed under FFDCA tolerance withdrawal provisions but that the Agency "also" engage in a range of actions required by the registration cancellation provisions of FIFRA. Additionally, Dow observes that EPA acknowledged in its Proposed Order the requirement in FFDCA Section 408(l)(1) that "[t]o the extent practicable," suspensions and revocations of tolerances should be coordinated with any "related necessary action" under FIFRA. Dow Letter at 2-3 and footnote 3. Whether Dow is claiming that the present proceedings are "in effect" cancellation proceedings and should thus be conducted as such, or that there should be separate—or perhaps unified—parallel proceedings under each statute, is not entirely clear.

This matter is not at all similar to the dispute in Reckitt Benckiser, Inc. v. Jackson.[1] In that recent case, the United States District Court for the District of Columbia declared invalid EPA's attempt to conduct FIFRA enforcement proceedings for pesticide misbranding *in lieu* of initiating Section 6 cancellation proceedings. To the contrary, these present proceedings were initiated by the Objectors, not EPA, and they have been properly and validly conducted in accordance with applicable law. The resulting Proposed Order contemplates a gradual phase out of the subject tolerances, not an immediate revocation of all of them. And, further unlike the facts in Reckitt Benckiser, the Administrator in this matter has not refused to initiate formal cancellation proceedings. Thus she still has the option to initiate them. Nothing in the Proposed Order expresses or implies an intention by the Agency to deny Dow's due process rights under FIFRA.

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[1] Reckitt Benckiser, Inc. v. Jackson, No. 09-445 (ESH), 2011 U.S. Dist. LEXIS 8400 at *44 (D.D.C. January 28, 2011).

Simply stated, the Administrator has abundant discretion to determine *what* law is applicable and *whether* it is "practicable" to "coordinate" that law (here, FFDCA) with FIFRA cancellation proceedings. Further, to the extent she determines such practicability is present, she also possesses the discretion to decide precisely *how* such coordination should take place. It is the Administrator's "choice" about these questions of coordination, as opposed to that of Dow or the Objectors, that is the only one provided for by applicable law. And this choice would be accorded substantial deference by a court.

Ironically, Dow's elaboration of the extensive and time-consuming steps that FIFRA cancellation proceedings would entail in a case like this may well explain why the Administrator proceeded in the fashion that she has so far. See, Dow Letter at 2-4.

On the one hand, the tolerance provisions of FFDCA, particularly as amended by the Food Quality Protection Act (FQPA), explicitly require the Agency to focus narrowly on the impact of pesticide chemical residues, in or on food, on public health (especially infants and children). Specifically, FFDCA Section 408(a) addresses *solely* the question whether a pesticide chemical residue in or on food is "safe" as a result of the existence of a proper tolerance or exemption. The Objectors proceeded expressly under FFDCA Section 408, seeking withdrawal of certain pesticide chemical residue tolerances that had been established for sulfuryl fluoride. Accordingly, the Administrator also proceeded under FFDCA, and she did so based on the specific statutory framework created by Congress for addressing such requests.

Further, although the focus of these FFDCA proceedings has by law been narrowly directed toward the *threshold question of sulfuryl fluoride pesticide chemical residue safety*, the proceedings have nonetheless been long, tedious, complex and contentious. They would have truly suffered had they been fused with, or transmuted into, registration cancellation proceedings, which are inherently even more complex and broad. Indeed, it was difficult enough to address properly the narrow question presented under FFDCA. For example, the deliberations had to address such concerning safety questions as the fact that EPA had at one *point increased the reference dose (RfD) of sulfuryl fluoride for a 7 kilogram infant twice over four years*, with no formal public input or comment. The Objectors noted in their 2006 Consolidated Objections as follows:

> The disturbing culmination of the increases is that the final RfD for infants (1.14 mg/kg/day) is now ten times higher than the RfD for adults (0.114 mg/kg/day). This makes sulfuryl fluoride the only pesticide ever registered where the allowed safe dosage (RfD) for infants and children is higher than it is for adults.[2]

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[2] Consolidated Objections, p.7, available at http://www.fluoridealert.org/pesticides/sf.nov.2006.submission.pdf.

On the other hand, the registration provisions of FIFRA, which affect *both* food-related and non-food-related pesticides, are part of a *comprehensive regulatory scheme*. Accordingly, it "establishes a detailed, multi-step process that EPA *must* follow when it wants to cancel or suspend a registration."[3] Understandably, the considerations, and thus the procedures, involved in registration cancellation proceedings should entail just the wide-ranging inquiry and governmental coordination called for in that statute. It is entirely conceivable that the Administrator chose to make the determination under FFDCA first, so as to be better informed as to precisely what, if any, "related necessary action" under FIFRA should be "coordinated" with the tolerance revocation proceedings. And the Proposed Order, we note, does not constitute the end of the Agency's FFDCA decisionmaking process.

Conflating the steps involved in the FFDCA proceedings with those of a FIFRA registration cancellation proceeding might well make for efficiency, economy and justice. But, on the other hand, such an action could also be inefficient and confusing. For example, the Administrator has issued a "proposed" order, inviting, and in fact receiving, extensive comments from a wide-ranging spectrum of interested stakeholders. It is not yet clear what will be the nature of the Agency's "final" order. Moreover, as a further example, it is not yet clear whether a modification should be made to the tolerances, be it "in response to a petition" by Dow or "on the Administrator's own initiative," as authorized under FFDCA Section 408(b)(1)(A) and (B).

In light of the context in which this matter arose, given its complexity, and given further the reasonableness of the Administrator's choice to date about how to proceed, the Objectors believe that the present course of action, leading to a final order with respect to the tolerances, is appropriate and proper and that it should be continued.

II. Even if Section 6 of FIFRA Were Applicable, It Does Not Entitle Dow to a Hearing as an Absolute "Matter of Law"

Dow describes its right to a hearing as one to which it is "entitled as a matter of law under FIFRA." Dow Letter at 2. As the discussion below demonstrates, not even a "person adversely affected" by a notice of intent to cancel a registration has an automatic or absolute right to such a hearing.

Section 6 of FIFRA provides as follows:

> **(b) Cancellation and change in classification**
>
> If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes

[3] Reckitt Benckiser, Inc. v. Jackson, No. 09-445 (ESH), 2011 U..S. Dist. LEXIS 8400, at *23-*24 (D.D.C. January 28, 2011)

> unreasonable adverse effects on the environment, the Administrator *may* issue a notice of the Administrator's intent *either*—
>
> **(1)** to cancel its registration or to change its classification together with the reasons (including the factual basis) for the Administrator's action, *or*
>
> **(2)** to hold a hearing to determine whether or not its registration should be canceled or its classification changed. (emphasis supplied)

Thus, under Section 6 of FIFRA, where the Administrator intends to cancel or re-classify a pesticide, she "may" issue a notice of her intent "either" to (1) take such action directly "or" (2) hold a hearing regarding the taking of such action. Obviously, therefore, the Administrator has the discretionary authority to decide whether a hearing is warranted.

Conclusion

In conclusion, the Objectors urge EPA to make a "final decision" regarding the fate of the tolerances under FFDCA Section 408 first, before determining whether cancellation proceedings should be initiated. Given the long and arduous history of the present proceedings since the first Objections were filed in 2004, we believe the introduction at this point of cancellation proceedings would be an invitation to great confusion and even more delay. And all the while, we note, a grave threat to public health and the environment—including the "aggregate exposure to fluoride for certain major identifiable population subgroups" that was the focus of the Proposed Order—would continue.

Sincerely,

Perry E. Wallace
Counsel for the Objectors

cc: Regulatory Public Docket (OPP) (7502))
Docket No. EPA-HQ-OPP-2005-0174

Jon Fleuchaus, OGC