



## MEMORANDUM

### Via E-Mail

DATE: August 6, 2004

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: Pesticide Industry Wins Important Victory in Tolerance Reassessment Case

On July 29, 2004, the U.S. District Court for the Southern District of New York dismissed, on grounds that it lacked subject matter jurisdiction, the challenge of the States of New York, New Jersey, Connecticut, and Massachusetts and eleven non-governmental public interest organizations to tolerances for nine pesticides reassessed under Section 408(q) of the Food Quality Protection Act (FQPA). *State of New York v. U.S. Environmental Protection Agency*, 03 Civ. 7155 (S.D.N.Y. July 29, 2004). The appended ruling is important for several reasons: (1) it affirms that Section 408(h) of the Federal Food, Drug, and Cosmetic Act (FFDCA) sets forth the exclusive process for obtaining judicial review of tolerance determinations; (2) it confirms that the application of the 10x safety factor required under FQPA to account for potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children is expressly subject to the Section 408(h) judicial review process, at least in the context of specific tolerance reassessments; (3) it concludes, interestingly, that the “issuance of a [Reregistration Eligibility Decision (RED)], whether it be one revoking, modifying, or leaving in place a tolerance, constitutes the agency’s final determination, at the conclusion of a statutorily mandated review process, on the safety of the tolerance in question”; and (4) it confirms that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) offers no additional avenue for judicial appeal of a tolerance assessment. Based on its analyses of the available, and unavailable, avenues for review of the challenged tolerance assessments, the court granted the U.S. Environmental Protection Agency’s (EPA) and Intervenor-Defendant CropLife America, Inc.’s motions to dismiss. As of this writing, it is unclear if any or all plaintiffs will appeal to the U.S. Court of Appeals for the Second Circuit.



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## Background

Plaintiffs sued EPA earlier this year, challenging EPA's determinations on its reassessments of tolerances for nine pesticides. Plaintiffs claimed that EPA failed to take into account scientific data demonstrating serious safety risks, or that it otherwise acted in the absence of "reliable data" when it left certain existing tolerances in place without applying the FQPA 10x safety factor noted above.

Defendants moved to dismiss the action on three grounds, the court's discussion of which provides an insightful tour of the threshold jurisdictional issues, as well as the specific jurisdictional provisions of the FFDCA. Defendants claimed that FFDCA Section 408(h) provides an exclusive procedure for obtaining judicial review of a tolerance determination; that the challenged tolerance determinations did not qualify as "final agency action" subject to judicial review under the Administrative Procedure Act (APA); and that plaintiffs had not exhausted their administrative remedies under FFDCA Section 408(h) and thus the court should dismiss the action because this necessary prerequisite to Section 408(h) jurisdiction was not met.

Although the court ultimately would grant the motion to dismiss, it rejected, in the process, defendants' arguments that EPA's tolerance reassessments were not "final agency" action for purposes of APA review. Among the several reasons cited by the judge was his conclusion that the tolerance determinations were "final" even though they were announced through the issuance of a RED, rather than a regulation. EPA's long-held contrary position has been that its statements made in a RED or registration standard are neither rules nor binding norms, but rather general guidance intended to assist pesticide registrants and others. The court, however, ruled that, at least with respect to the tolerance reassessment portion of the RED, the "determinations thus marked the culmination of the review process mandated under section 408(q), and discharged the EPA's legal duty under the FQPA to reassess tolerances according to a new, more stringent set of criteria."

Although agreeing with the plaintiffs on the finality question, the court agreed with the defendants on the determinative issue of exclusivity, concluding that, under the express terms of Section 408(h), the challenged tolerance reassessment process was reviewable only in the courts of appeals and that such review was precluded unless and until the available administrative remedies were exhausted. The court emphasized the broad sweep of Section 408(h)(5), which applies to "any issue as to which review *is or was obtainable*."<sup>1</sup>

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<sup>1</sup> Opinion at 14 (emphasis in original).



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### Implications

At the least, the decision will discourage the judicial challenge of tolerance assessments on the grounds presented in this case and force review of tolerance assessments pursuant to the provisions of FFDCFA Section 408(h), unless the dismissal is appealed and the Second Circuit reverses on this ground. Absent additional review, it is unclear if additional challenges in other jurisdictions will be pursued with the hope that EPA will apply the 10x safety factor as plaintiffs urged.

The court also made it clear that any generalized challenge to EPA's safety factor policy -- rather than a challenge "as applied" in a specific case -- would likely run afoul on standing issues. The opinion discusses the "double bind" that the plaintiffs faced. As the Supreme Court has made evident, an across-the-board, generic policy challenge to EPA's application of the safety factor would fail to meet the APA's final agency action requirement. On the other hand, a challenge to a specific set of tolerances -- while avoiding the standing problem -- will run head-on into the exclusivity and exhaustion provisions in Section 408(h). The court minced no words: "[Plaintiffs'] attempt to have it both ways by identifying a specific set of tolerances in their pleadings, while insisting in their briefing that their challenge was really to the process rather than the outcome of the determination is ultimately unconvincing."<sup>2</sup>

The court also gave no credence to the plaintiffs' claim that EPA's decisions under Section 408(q) to leave in place existing tolerances are different, for reviewability purposes, from EPA's decisions to modify or revoke them. The court explained that a decision to leave an existing tolerance in effect is reviewable in exactly the same manner as would be any existing tolerance -- by "any person" petitioning EPA under Section 408(d) to modify or revoke the tolerance at issue and, if necessary, filing a subsequent objection under Section 408(g) to EPA's determination.<sup>3</sup>

It is unclear what effect, if any, the decision will have on EPA's characterization of REDs. Read more narrowly, the decision means one district court views a tolerance determination as set forth in a RED as final agency action for purposes of the APA's provisions for judicial review. Whether more can be made of the decision is unclear.

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<sup>2</sup> Opinion at 28.

<sup>3</sup> Opinion at 19.



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On the finality issue, the court's decision may be relevant to the claim made in some judicial challenges to EPA's reregistration decisions under FIFRA that the issuance of an interim reregistration eligibility decision (IREED) is judicially reviewable as a "final agency action." The decision raises a number of issues that likely will be explored in these and other challenges relating to EPA's REDs and IREEDs.

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We hope this information is helpful. As always, please call if you have any questions.

[Attachment](#)