



MEMORANDUM

Via E-Mail

DATE: August 24, 2006

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: Court Affirms Important Pesticide Industry Victory in Tolerance Reassessment Case

On August 22, 2006, the U.S. Court of Appeals for the Second Circuit affirmed the U.S. District Court for the Southern District of New York's decision to dismiss a complaint filed by a coalition of public interest groups against the U.S. Environmental Protection Agency (EPA).¹ The coalition, led by the Natural Resources Defense Council (NRDC), challenged EPA's tolerance reassessments for several pesticides, claiming 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 10x safety factor required under the Food Quality Protection Act (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. The lower court, in its July 29, 2004, decision, granted motions by EPA and Intervenor-Defendant CropLife America, Inc. to dismiss NRDC's complaint for lack of subject matter jurisdiction. On appeal, NRDC argued that Section 408(h) of the Federal Food, Drug, and Cosmetic Act (FFDCA) governs judicial review only of EPA decisions to establish, modify, or revoke tolerances and that decisions to leave tolerances in effect are reviewable in the district courts pursuant to the Administrative Procedure Act (APA). The court rejected NRDC's argument and affirmed the lower court's decision.

Before examining whether NRDC's argument that the APA applies, allowing for judicial review of EPA's tolerance reassessment decisions in district court, the court first addressed whether EPA's tolerance reassessment decisions represent final agency action. The court agreed with the district court that "the tolerance reassessments challenged were final agency actions and adopt its reasoning." The lower court ruled that, with respect to the tolerance

¹ *NRDC v. EPA*, Docket No. 04-5337-cv (Aug. 22, 2006) (appended).



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reassessment portion of reregistration eligibility decisions (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.”

After affirming that EPA’s tolerance reassessments represent final agency action, the court then analyzed whether FFDCA precludes judicial review under the APA. The court concluded: “Despite the absence of an overarching judicial review provision, both the language and the statutory scheme of Section 346a indicate that the district court lacked jurisdiction to adjudicate actions such as those brought by the NRDC Appellants.” According to the court, NRDC could have filed a petition to modify or revoke the tolerances. Because NRDC failed to do so, the court concludes that NRDC is precluded from obtaining judicial review under the APA. The court noted that, under NRDC’s arguments, the same tolerance could be subject to review by both the district courts and the courts of appeals at the same time: “One party could directly challenge the EPA’s decision to leave a tolerance in effect in a district court using APA review while, simultaneously, another party could trigger Section 346a(h) review in a court of appeals by following the administrative review process established in Section 346a(g) -- commencing with a Section 346a(d) petition to modify or revoke the same tolerance.” The court concluded: “No evident policy goal would be served by such a scheme, and the statutory language clearly suggests it was not intended.”

NRDC argued that, even if the FFDCA precluded their claims, FIFRA Section 16a provides an alternative ground for jurisdiction because, according to NRDC, EPA “used a confidential computer model to conduct pesticide exposure assessments even though under FIFRA such a model must ‘be available for disclosure to the public.’” The court concluded, however, that NRDC’s claims are reviewable “only in the courts of appeals, and only after they have exhausted the statutory provisions for administrative review.”

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

[Attachment](#)