



## MEMORANDUM

### Via E-Mail

DATE: December 21, 2004

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: Petition of Four States Urging EPA to Revoke or Modify Tolerances Based on EPA's Decision Not to Apply the Full 10-Fold FQPA Safety Factor

In a petition dated December 17, 2004, four states -- New York, California, Connecticut, and Massachusetts -- petitioned the U.S. Environmental Protection Agency (EPA) to revoke or modify tolerances five pesticides -- alachlor, chlorothalonil, methomyl, metribuzin, and thiodicarb. The petition is based on the States' assertion that the existing EPA tolerance decisions do not "reflect proper application of the additional tenfold safety factor for the protection of infants and children required by the Food Quality Protection Act ('FQPA')." The petition follows the district court decision dismissing on jurisdictional grounds a request for a declaratory judgment that these tolerance decisions violated FQPA and an injunction vacating those tolerances.<sup>1</sup>

If granted, the petition will have a profound effect on EPA's tolerance decisions, particularly as it approaches the 2006 statutory deadline for tolerance reassessment, and EPA's consideration of the petition now is likely to affect the numerous tolerance decisions currently before EPA that EPA must make before that 2006 deadline. Indeed, the petition expressly asserts that "EPA's misapplication of the FQPA's safety factor requirement extends beyond the reassessment determinations challenged herein," and notes previously submitted comments on "a number of other pesticide chemicals and related determinations of EPA."

The standard for reducing the the FQPA 10-fold safety factor for protection of infants and children stated in the petition is in keeping with past assertions by various non-governmental organizations concerning that standard. The petition states:

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<sup>1</sup> *State of New York v. EPA*, No. 03 Civ. 7155 (S.D.N.Y. July 29, 2004).



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In establishing the subject tolerances, EPA failed to apply the additional tenfold safety factor, which legally can only be reduced or eliminated when, “on the basis of reliable data, such [lesser] margin will be safe for infants and children.” . . . With respect to these tolerances, EPA reduced or eliminated the required safety factor even though it lacked data specifically required by the FQPA to be considered in all EPA tolerance reassessment decisions. The absence of these data made it impossible and legally impermissible for EPA to determine that application of a smaller factor would be “safe for infants and children” with respect to these pesticide chemicals. Therefore the full tenfold safety factor should have been applied.

The petition states more specifically with regard to the “missing” data asserted to be necessary for a legally sound decision not to apply the 10-fold FQPA factor:

Thus, in sum, the FQPA mandates application of the full tenfold safety factor unless “reliable data” supports a determination that use of a lesser factor “will be safe” for infants and children. Since the statute requires that a tolerance safety determination include consideration of the cumulative effects of chemicals with a common mechanism of toxicity, the special neurological susceptibility of infants and children as reflected in developmental neurotoxicity studies, and information concerning endocrine effects, in the absence of these data, the narrow exception to the tenfold safety factor mandate does not and cannot apply.

The petition asserts that because data on common mechanism of toxicity, effects of exposure on neurological development in infants and children, and endocrine disruptor effects “have yet to be produced and were not considered in reassessing the tolerances at issue,” EPA cannot have met its legal obligation to reduce the 10-fold FQPA factor. The petition asserts that EPA lacks the “reliable data” that, it asserts, are required by FQPA. Specific assertions are also made regarding the data available and not available for each of the five pesticides that are subject to the petition.

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