On August 9, 2018, the majority of a three-judge panel of the U.S. Court of Appeals for the Ninth Circuit (Ninth Circuit) issued an opinion in the latest chlorpyrifos case (League of United Latin American Citizens (LULAC) v. Wheeler, No. 17-71636) granting the petition for review of a 2017 order by the U.S. Environmental Protection Agency (EPA) that denied an administrative petition to revoke the tolerances for chlorpyrifos; vacating the 2017 order; and remanding the matter back to EPA with explicit directions to EPA to “revoke all tolerances and cancel all registrations for chlorpyrifos within 60 days.” A separate dissent stated that the court should have dismissed the case for lack of jurisdiction.

Please see our blog item “EPA Denies Petition to Ban Chlorpyrifos” for more information on EPA’s denial of the petition in 2017.

EPA argued in its brief that the court lacks jurisdiction to review the 2017 order denying the petition to revoke the tolerances for chlorpyrifos because Section 408(g)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to rule on administrative objections to its denial of the petition to revoke the tolerances for chlorpyrifos before judicial review is available under FFDCA Section 408(h)(1). The majority opinion rejected this argument, stating that FFDCA Section 408(h)(1) “does not ‘clearly state’ that obtaining a section (g)(2)(C) order in response to administrative objections is a jurisdictional requirement.” Rather than a jurisdictional limitation, the majority construed the objections process in FFDCA as a non-jurisdictional “claims-processing rule.” In contrast, the dissenting judge agreed with EPA’s argument that the court lacks jurisdiction to review this matter until after EPA responds to their objections before obtaining judicial review.

After concluding that the objections process is not jurisdictional in character, the majority next considered whether the petitioners should nonetheless be required to exhaust their administrative remedies by waiting until EPA responds to their objections before obtaining judicial review. Although FFDCA Section 408(g)(2)(C) requires EPA to rule on the objections “as soon as practicable,” EPA had taken no action for 13 months after the objections were filed. The majority concluded that the exhaustion requirement should be waived “in light of the strong individual interests against requiring exhaustion and weak institutional interests in favor of it.”

EPA did not specifically address the substantive merits of the 2017 order in its brief, and the majority found that EPA has consequently “forfeited any merits-based argument.” The 2017 order was issued in the context of an administrative record in which EPA has repeatedly determined that the FFDCA standard for maintenance of chlorpyrifos tolerances (“a reasonable certainty that no harm will result from aggregate exposure to the pesticide”) could not be met because of the risk of neurodevelopmental effects. The standard for registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) incorporates this same FFDCA standard. Although the 2017 order stated that “the science addressing neurodevelopmental effects is unresolved,” it did
nothing to alter these prior EPA determinations. The majority noted that EPA’s assertion that “significant uncertainty” remains regarding the health effects of chlorpyrifos being directly at odds with the “reasonably certainty” standard and “therefore mandates revoking the tolerance under [FFDCA Section 408(b)(2)(A)(i)].” The majority concluded that the possibility that future evidence may contradict EPA’s current determinations cannot justify continued inaction, and that the failure of EPA to proceed with the revocation of the tolerances and the cancellation of the registrations for chlorpyrifos “has now placed the agency in direct contravention of the FFDCA and FIFRA.”

Commentary

The court’s direct instruction requiring EPA to proceed promptly with revocation of all tolerances and cancellations of all registrations for chlorpyrifos represents an unusually aggressive judicial intervention in the administrative process. Nevertheless, this outcome must be viewed in the context of an eleven year history beginning with an administrative petition that requested the same relief, followed by a writ of mandamus in 2015 from the same court requiring EPA to make a prompt decision on the petition. Although substantial controversy remains concerning the correct interpretation of epidemiology studies with chlorpyrifos, it appears that the court believes that EPA has not taken any action that would support a change in EPA’s prior conclusion that these studies constitute evidence of potential neurodevelopmental effects in children at chlorpyrifos exposure levels below the threshold for acetylcholinesterase (AChE) inhibition. Had EPA’s 2017 denial of the administrative petition been accompanied by an amended risk assessment for chlorpyrifos which articulated a changed conclusion, the court may have been less likely to substitute its judgment for that of EPA. The court seemed to find that because the scientific assessments in the current administrative record could not support the “reasonable certainty” standard in the FFDCA, the conclusion it reached on the merits was unavoidable.

Please see our blog item “Oral Argument Held in Case Challenging EPA’s Denial of Petition to Revoke Chlorpyrifos Tolerances” for information on the oral argument that took place on July 9, 2018, and the briefing in this case.

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