

## COURT VOIDS US EPA BAN ON USE OF THIRD-PARTY HUMAN TEST DATA

In a December 14, 2001 press release, the US Environmental Protection Agency (EPA) declared an "interim policy" not to "consider or rely on any such human studies in its regulatory decision making, whether previously or newly submitted." EPA also requested the National Academy of Sciences (NAS) to evaluate the "scientific and ethical issues" posed by EPA's use of third-party human testing and to provide the EPA with guidance in formulating a final policy on the subject. The policy was broad enough to cover all human testing performed by third parties under any EPA program.

Information collected from studies conducted with human volunteers can be among the most accurate, and therefore can play an important role in making judgments about the potential risks of exposure to chemical products. Testing with human volunteers has been supported and performed for many years by federal regulatory agencies such as the US Environmental Protection Agency and the US Food and Drug Administration, as well as international organizations such as the World Health Organization. Data from human testing generally provides more accurate information regarding human exposure or risk assessment than animal data. EPA's current moratorium forces it to ignore relevant data and instead rely on assumptions and default models that may vastly overstate risk. For example, when animal data are used instead of human data, EPA may apply a ten-fold inter-species uncertainty factor.

On February 12, 2002, CropLife America – a US trade association representing manufacturers, formulators, and distributors of agricultural chemical products – and two of its members (AMVAC Chemical Corporation and Aventis Crop Science) filed a petition for review of EPA's policy in the US Court of Appeals for the DC Circuit. *CropLife America v. EPA*, No. 02-1057 (DC Cir.). They asked the court to set aside the moratorium as an unlawful regulation that was issued without proper notice and comment. The Petitioners asserted that the moratorium affects industry members' current or planned scientific or regulatory activities, and therefore is ripe for review. In addition, Petitioners argued that EPA is legally required to base its regulatory decisions on the best scientific data available, including data from human volunteer studies. The American Chemistry Council, represented by Steptoe & Johnson LLP, intervened in the case as a petitioner. The American Chemistry Council's interests extend beyond pesticides to human testing in other EPA programs. The Natural Resource Defenses Council (NRDC) intervened in the case as a respondent.

In May 2003, EPA issued an advance Notice of Proposed Rulemaking announcing the Agency's plan to initiate a rulemaking about the criteria and standards EPA would apply in deciding whether to consider data involving human volunteers. 68 Fed. Reg. 24410 (May 7, 2003).

On June 3, the DC Circuit issued an opinion invalidating the EPA directive as a regulation issued without notice and comment. The court held that when EPA issued a press release in December 2001 announcing that it would no longer consider certain types of test data involving human subjects, it issued a regulation and should have complied with the Administrative Procedures Act. Judge Edwards' opinion also denied EPA's arguments as "meritless", saying that the matter was untimely and unripe, and that the Petitioners lacked standing.

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