PRECEDENT SETTING DECISION ISSUED
IN PESTICIDE DATA COMPENSATION CASE

In a far-reaching decision, arbitrators have ruled that compensation for pesticide data under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") may include not only the cost of the data, but also "a risk premium or other enhancement of the costs." Significantly, the order goes further than any prior public decision over the last ten years in recognizing that data compensation can be based on more than simply the cost of data.

Under FIFRA Section 3(c)(1)(F), a company may seek to register a new pesticide, or a new use for an existing pesticide, by either generating and submitting its own supporting data to EPA, or else relying on data previously submitted by another company. However, if the so-called "follow on" registrant opts to rely on another company's existing data, it must offer to pay compensation for using that data. If the two companies cannot agree on how much compensation is owed, either may file for binding arbitration.

The recent data compensation decision was issued June 9, 1997 (but only now has been made publicly available), in a case initiated last year by Microgen Inc., a small family-owned company located in West Caldwell, New Jersey, against industry giant Lonza, Inc.

The arbitration concerns Microgen's innovative efforts to register its hospital-grade disinfectants D-125 and Public Places for use against the human hepatitis B virus (HBV). (Under FIFRA, disinfectants must be registered with EPA as pesticides.) To date, Microgen is the only company that has undertaken the high cost and risks associated with generating data required by EPA to establish HBV efficacy. Those data required over seven years of effort on Microgen's part to design and conduct its innovative tests and then wait for an EPA decision on its HBV registration applications. In all, those data cost Microgen approximately $1 million.

Although Lonza was provided with an opportunity in 1991 to generate its own HBV data, it declined to do so due to the risk of proceeding with a then-unproven test methodology. Microgen, however, decided to take the risk and moved forward on its own. After years of effort, Microgen finally succeeded in obtaining EPA approval for its data and obtained its HBV registrations in January 1996. Lonza, after seeing that Microgen's efforts had finally succeeded, then rushed to cite Microgen's data only two months after those data had been approved by EPA. By relying on Microgen's data, Lonza was able to obtain its own HBV registration in October 1996. After the parties were unable to reach agreement on what Lonza owed Microgen for using the HBV data, Microgen was forced to file for arbitration.

The recent order was in response a motion by Lonza seeking to dismiss all aspects of Microgen's claim that sought more than simply a percentage of Microgen's actual data costs. In rejecting Lonza's cost-only arguments, the arbitrators' order states:

[W]e are not prepared to conclude that Congress intended that 'compensation' under [FIFRA] Section 3(c)(1)(F)(iii) be limited to a strict cost sharing based on a percentage or pro rata share of the costs of developing the data at issue. Part of the congressional purpose in providing for compensation to initial registrants was to eliminate the 'free rider' problem that would otherwise reduce incentives to pursue registrations for products as to which the registrant would have no patent or other property rights. Consistent with that goal and the other congressional purposes, companies such as Microgen here may be able to show that they are entitled to a risk premium or other enhancement of the costs they incurred. Moreover, this enhancement may properly be related to the 'early entry' by follow on registrants in the sense that they might otherwise take advantage of the initial registrant's efforts without bearing the costs and risks of doing so. Enhanced compensation may also be needed to ensure that follow on registrants cannot force

initial registrants to accept less compensation than they should receive simply to avoid the delay and costs inherent in FIFRA arbitration proceedings.

However, while recognizing the right of Microgen to seek "enhanced compensation," the arbitrators also rejected a portion of Microgen's claim that sought compensation for what Microgen might have earned if it "had the right to exclude others from the market." According to the arbitrators, a claim based on such a premise would be "antithetical" to FIFRA's goal of encouraging increased competition. (The full text of the order is available on the Internet at www.pesticide.net.)

According to Microgen's vice president, Dr. Daniel Prince, "The arbitrators have confirmed our position that small, innovative companies like Microgen are entitled to seek fair compensation for the costs and risks associated with generating novel data that opens new markets. Despite opposition from a large, well-financed and established company that wanted all the benefits without sharing all the risks, Microgen is now enthusiastic about its ability to obtain full compensation."

Microgen's attorney, James Wright, describes the arbitrators' order as an important victory for his client. "The arbitrators clearly have rejected attempts by market giants like Lonza to get a free ride off the innovative efforts of small companies like Microgen. Microgen simply wants fair compensation based not only the cost of its data, but also the overall value of that data. As the arbitration moves forward, I am confident that we will now succeed in achieving that goal."