

## EPA oversteps bounds claiming public domain of safety data

The rights of U.S. chemical manufacturers are being abused by the Environmental Protection Agency's interpretation of a poorly-constructed section of the Federal Insecticide Fungicide Rodenticide Act on data compensation.

Chemical companies have been, for the most part, good sports playing by a set of frequently-changed rules to get their products registered and on the market.

Their lawyers, like quarterbacks, are forced to anticipate what obstacles EPA will put in their path during the registration process.

The latest word from EPA, regarding Monsanto's Supreme Court case against EPA and Stauffer Chemical Company, oversteps the government's authority over a corporation's property. The property in question is health and safety data, generated at great expense by chemical companies to meet registration requirements.

EPA is telling the Supreme Court this data, once submitted, becomes the property of EPA in exchange for the right of registration. The law provides an arbitration and compensation procedure under the direction of an EPA arbitrator. Only an EPA law judge can overrule the arbitrator's decision. In other words, once submitted, the final word on the value of data rests with EPA, not the chemical company who paid for it.

Monsanto can claim it has a price disadvantage. Other companies using Monsanto's data can charge less since they do not incur the cost of research to produce the data.

Stauffer, and other companies using 'me-too' data, are not guilty. They have been playing the game by EPA's rules.

If a loophole exists, they try it, possibly saving hundreds of thousands of dollars. EPA allowed a big loophole which completely overlooked antitrust implications of the data they were handling.

How EPA ever thought chemical companies would allow expensive 'trade secret' data to be public property is beyond common sense. It shows a complete lack of understanding of business.

Saying the data is public domain because it is a requirement for pesticide registration does not adequately protect chemical companies and their stockholders. Saying safety data is needed in case of emergency is valid, however, and I doubt if any chemical company would argue.

Use of this confidential data should be limited to making a company-by-company determination of benefits versus risk, and to help in cases of emergency.

Negotiating the value of the data between companies should not be an EPA function. It should be up to a company wanting to produce a 'me-too' product to negotiate a price with the original registrant of the data. That is fair and that is business.



*Bruce F. Shank*

by Bruce F. Shank, executive editor

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