

Backgrounder Testing fraud: IBT and Craven LaboratoriesJune 2005

IBT Laboratories

In 1976, during a routine inspection of a testing company named Industrial Bio-Test Laboratories (IBT), the U.S. Food and Drug Administration (FDA) uncovered discrepancies between raw data and reports of pesticide toxicology studies IBT had conducted. As a result, the U.S. Environmental Protection Agency (EPA) ordered an audit of all IBT studies conducted in support of pesticide product registration. Monsanto was one of several pesticide manufacturers who had used IBT test results. The audit found some toxicology studies conducted with the original Roundup® herbicide to be invalid.

As a result, Monsanto repeated all the studies in accordance with applicable EPA testing guidelines. Today, no IBT-generated data are used to support glyphosate registration anywhere in the world.

Craven Laboratories

In 1990, the pesticide industry was once again the victim of testing fraud. This time, the studies were not toxicology studies but analyses to determine the amount of pesticide residues in treated crops. A pesticide industry task force discovered irregularities in testing conducted at Craven Laboratories of Dallas, Texas, and alerted the EPA. An investigation was initiated.

The U.S. Department of Justice announced February 25, 1994, that Don Craven, company president, and 14 former employees of Craven Laboratories received punishments ranging from fines to prison terms following their convictions on charges of falsifying pesticide residue tests conducted over a 10-year period.

Hundreds of residue studies for Monsanto agricultural products, required for product registration by the EPA, have been completed by Monsanto or by one of 16 independent laboratories that are used under contract. Of these, a small fraction were conducted at Craven Laboratories.

Monsanto, along with other pesticide manufacturers, repeated the pesticide residue studies conducted at Craven Laboratories. The repeat studies cost Monsanto approximately \$6.5 million. The damage caused to Monsanto's reputation by discussion of this issue by the media, and then further use by activists to question the integrity of Monsanto's data, cannot be calculated. All affected residue studies have been repeated and the data are sound, up-to-date and have been accepted by the EPA.

After the testing problems, the EPA instituted procedures known as Good Laboratory Practices, which are designed to ensure reliable generation and verification of all data. The penalties for falsifying data are severe, including large fines and prison terms.

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¹ "Roundup" refers to the original Roundup agricultural herbicide (MON 2139), which contained the active ingredient glyphosate (as the isopropylamine salt), water and a surfactant (polyoxyethylene-alkylamine or POEA).