Papers From Trial of Former IBT Officers Raise Many Questions on Product Safety

By Bill Richards
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CHICAGO—In 1977, federal investigators made a stunning disclosure: Critical safety tests performed on hundreds of chemicals present in many products allegedly were flawed and sometimes faked by one of the nation's largest commercial testing laboratories, Industrial Bio-Test Laboratories Inc.

Now, during the federal criminal trial of four former senior IBT executives here, the extent of the scandal's repercussions is becoming clear. Documents emerging from regulatory agencies and from the trial raise numerous questions about the methods of ensuring product safety.

In a federal report, one of which has been filed in court, for example, investigators charged that strong evidence exists that three big chemical companies—Monsanto Co., Olin Corp., and FMC Corp.—knowingly submitted flawed data to the Environmental Protection Agency in support of a widely used cutworming pool chlorinator that was suspected of causing kidney and bladder problems.

In addition, the investigators said Monsanto also concealed vital information from EPA regulators that would have cast doubts on the validity of IBT's testing of the rice and sugar cane herbicide butachlor, which the company was seeking to market under the trade name Machete. Monsanto denies this charge.

Assessment of PCBs

Other documents filed in court allege that IBT's president, Joseph Calandra, at the request of Monsanto, the major U.S. maker of polychlorinated biphenyls, or PCBs, until they were banned in late 1978, agreed to soften his lab's assessment of PCBs from "mildly tumorigenic" to "does not appear to be carcinogenic." The testing company, a subsidiary of Naico Chemical Co., also agreed to lobby government regulators to loosen rules on the chemical, according to the documents filed in court.

The three chemical companies deny any wrongdoing and say their products are safe.

Earlier this week, the EPA said that, as a result of the IBT investigations, it is completing a study that raises questions about the safety of nearly 15% of all the pesticide chemicals approved for use on the U.S. market. According to EPA documents, the agency has invalidated 737 of the basic laboratory studies involving more than 200 pesticides tested by IBT.

None of the suspect products has been removed from the U.S. market, although Canadian authorities removed two suspect pesticides tested by IBT from the market and requested warning labels for 24 others. Under U.S. law, however, once a pesticide is on the market in the U.S., it must be retested by the manufacturer and found to cause adverse effects before the EPA can move to withdraw it.

According to an EPA executive summary of the IBT program, federal investigators were restricted further by internal EPA policy decisions. In April 1982, the agency announced a "program change" that ordered investigators to stop reviewing IBT-tested pesticides on the market for "possible adverse effects," even though the agency was aware that many pesticides lacked valid supporting health or safety data, according to the summary. This action by an unidentified official cut short the time allowed for completion of the EPA's damage assessment of IBT work, the summary states.

Senior EPA officials, who asked not to be identified, said this week that the decision to stop reviewing pesticides for possible adverse effects was made because frustrated agency investigators had wasted more than a year trying to evaluate the flawed IBT data submitted by pesticide makers. "It was hopeless," an agency official says.

Investigators charge that big companies knowingly submitted flawed data to the Environmental Protection Agency and concealed vital information.

Considerable time also was wasted, these officials contend, because pesticide makers tried to force regulators to accept the IBT data as valid. They were "trying to make a silk purse out of a sow's ear," a top EPA official says.

The four former IBT officers—Dr. Calandra, Dr. Moreno L. Keplinger, Dr. Paul L. Wright and James B. Plank—are charged with mail fraud, wire fraud and submission of false statements to the government. No charges have been filed against any of IBT's corporate clients.

At the former executives' trial, evidence introduced by federal prosecutors has raised further questions about the actions of some chemical companies involved with IBT.

Pool Chlorinator

Most serious, perhaps, are allegations in a report by investigators who examined records and interviewed officials at IBT's Decatur, Ill., laboratory in 1978. The report describes efforts by Monsanto, Olin and FMC to win approval from EPA for a pool chlorinator they were producing. The companies made the product separately but sponsored health tests jointly.

According to the report, all three companies knew that monosodium cyanurate, an ingredient in the chlorinator, had caused serious kidney problems in test animals in earlier studies. One of IBT's studies had to be restated after an entire test animal group was wiped out in three months by kidney and bladder problems associated with monosodium cyanurate. Monsanto also encountered similar problems with the chemical in its own, earlier in-house testing, the report says.

The investigators said the companies disregarded kidney problems and concentrated on other organs in their final IBT report to the EPA. "There were indications that the kidney problems were deliberately overlooked in the conduct of (the study) in spite of the client's awareness of the problems," the report says.

In a summary of their findings on IBT's tests, the investigators alleged that there were "numerous discrepancies between the records covering test animals . . . missing raw data replaced by after-the-fact generated records . . . [and] issuance of a final report which claimed practices and animal observations that were not done as represented." In addition, they said there was "strong evidence of client's being knowledgeable of inaccuracies in the final report."

The investigators said they found that the study's test protocol was written by Paul L. Wright, a former IBT researcher then employed by Monsanto. Dr. Wright is a defendant in the current trial, which doesn't involve allegations contained in the investigators' report.

Wrongdoing Denied

Monsanto, Olin and FMC all deny any wrongdoing in their handling of the IBT tests on monosodium cyanurate. Monsanto, which markets the chlorinator under its ACL brand name, says: "We deny Monsanto would knowingly submit any fraudulent data. Any document making that claim is false."

An Olin spokesman says the company markets the chlorinator under the trade name Pace. He says the company disagrees with allegations of problems with the IBT tests and cites two pages of examinations on mouse kidneys that he says were submitted to the EPA in the final report. FMC, which sells the chlorinator under its Sun Swimming Pool product line, says it also disagrees with the investigators' findings.

Regarding the Machete test, federal investigators say, unreported animals were substituted for test animals that died and that there were other significant problems with the tests as well. The report says there was "evidence of client's knowledge of situation prior to submitting their report to the U.S. government."

Machete never has been formally approved for marketing by the EPA, although the agency granted emergency permits to several Southern states for the pesticide's use on rice and sugar cane in 1980, 1981 and

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1982. According to the EPA, Texas, Arkansas, Louisiana and Mississippi were authorized to spray Machete over 555,000 acres in 1982. Last month, EPA denied further spray permits to the states, citing problems with the IBT tests on Machete and the availability of replacement herbicides. "The agency cannot at this time establish an allowable daily intake for this chemical," the EPA said.

Monsanto says it "is aware of no health-related problems here or abroad in the connection with the manufacture or use of Machete." A company spokesman says the herbicide is made in the U.S. in Muscatine, Iowa, and widely used in Japan, Korea, the Philippines, Taiwan and Brazil. He says Monsanto is retesting Machete and expects to submit its findings to revalidation by EPA in about two years.

So close was Monsanto's relationship with IBT—the lab performed 219 major animal studies on Monsanto pesticides—that on July 18, 1975, George J. Levinskas, manager of Monsanto's environmental assessment and toxicology program, sought in a letter to IBT's president, Dr. Calandra, to have the lab soften the language of its test results on Monsanto's Aroclor. About two weeks later, according to the documents, Dr. Calandra notified Monsanto that the change had been made.

Aroclor is an electrical equipment insulator and coolant that contains PCBs, which have produced cancerous tumors in laboratory rats and are a suspected human carcinogen.

In a separate letter from Dr. Calandra to Monsanto's Dr. George Rouse Jr. in April of 1975, which is filed in court here, IBT's president noted that a federal researcher, Dr. Renate Kimbrough, recently had reported that Aroclor caused cancers in female rats. Dr. Calandra noted that Dr. Kimbrough's findings had been "successfully counteracted" by IBT and Monsanto officials, according to the court documents, and promised "to assist Monsanto in any adversary situation in or out of government."

Dr. Kimbrough, a toxicologist at the Center for Disease Control in Atlanta, said yesterday that Dr. Calandra and other IBT officials had lobbied several regulatory agencies in 1975 against her findings and in favor of an IBT study that showed Aroclor didn't cause cancer in test animals. A year later, EPA banned the production of PCBs and began a program to phase them out of the environment.

In an interview recently, Dr. Levinskas said that at the time of his request to Dr. Calandra, the FDA was attempting to set human tolerance levels for PCBs. His request to change the lab's wording of its conclusion was made, he said, "Because we wanted the most reliable and direct statement that addressed the issue." He said the IBT test on Aroclor was part of an "information package" Monsanto submitted to the FDA on PCBs.

Other Monsanto spokesmen say the IBT tests on Aroclor weren't redone because the company stopped making the PCB product in 1977. They say, however, that conclusive evidence showing that PCBs can cause human cancers still doesn't exist.

Agent Orange Lawsuit Vacated for 4 Concerns; 5 Firms Now Face Trial

A WALL STREET JOURNAL *News Roundup*

A federal court in New York dismissed a consolidated suit filed against Hercules Inc. and three other chemical companies by Vietnam veterans and their families. The plaintiffs claimed they were injured by exposure to a herbicide known as Agent Orange.

However, the court denied motions by Dow Chemical Co., Thompson-Hayward Chemical Co. and Uniroyal Inc. that also sought dismissal. Two other defendants, Monsanto Co. and Diamond Shamrock Corp., didn't seek dismissal. These five companies now face a trial in connection with the suit, the court said. A trial date hasn't been set.

Agent Orange, a mixture of toxic compounds known as 24D and 245T, was made under a Defense Department contract and used as a defoliant during the Vietnam war. Some plaintiffs alleged that servicemen and their children had died as a result of exposure to the product. Others claimed they suffered from cancer and other ailments as a consequence of the exposure.

Federal Judge George Pratt granted the requests of Hercules, Riverdale Chemical Co., Hoffman-Taff Co. and Thompson Chemical Co. for a summary judgment, effectively excusing these companies from the case. An appeal by plaintiffs is probable, the judge's law clerk said.

Hercules, in a statement, said that the judge's decision affirms "what we believe is the correct rule of law, that there should be no company liability for the supply of military products meeting government requirements when the government has equal or superior knowledge as to the risks, if any, involved in their use."

The company said it is confident that the decision would be upheld on appeal.

In Midland, Mich., Dow said it is "disappointed" with the court's decision against dismissal of Dow's role in the Agent Orange dispute, and that it is "confident Dow will be vindicated when the issue is resolved" at a trial. Dow also said it is "considering the possibility of an appeal."

In St. Louis, Louis Fernandez, Monsanto vice chairman, said: "Monsanto considers the ruling to be very favorable. The indefinite postponement of the trial gives the defendants the opportunity to continue to develop facts relating to the government-contract defense issue." Mr. Fernandez added: "In the past few weeks, we have managed to discover significant new information and have obtained revealing depositions from former government officials who were actively involved in the Agent Orange program." He didn't elaborate.

More than 350 lawsuits involving more than 5,000 plaintiffs and asking hundreds of millions of dollars in damages were brought against makers of Agent Orange. The cases were consolidated for pretrial purposes.