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Houston Chronicle

Thursday, Nov. 29, 1990

EPA probe of Monsanto is confirmed

Dioxin studies possibly misused

By CHARLES LASERWORK
Knight-Ridder Newspapers

The U.S. Environmental Protection Agency confirmed Wednesday it is investigating whether Monsanto Corp. manipulated and falsified studies of workers exposed to dioxin to make the chemical appear less harmful to humans.

The environmental group Greenpeace, in a report to be released today, claimed that three studies done by the company in the early 1980s, and relied upon by the EPA, falsely concluded there was no apparent link between dioxin and the deaths of employees at the company's Nitro, W.V., herbicide plant.

Don Bishop, director of Monsanto corporate communications in St. Louis, said he was unaware of the investigation, but his company asked the EPA in October to do an audit of the studies.

"I'm delighted to hear it and welcome it," he said of the EPA investigation. "I think that is the only way we can put it to rest. I wish they had started yesterday. We deeply resent these accusations. We stand on the record with these three studies."

But Greenpeace's Joe Thornton, who wrote the report on dioxin, was just as adamant about the Monsanto studies and another one done by the giant German chemical company BASF. Both studied employees who worked routinely with dioxin-contaminated products or were exposed to it through accidents.

"These are politically motivated and untrue," Thornton said of the dioxin studies.

Olivia Brown, an EPA spokeswoman, said the agency had not seen the Greenpeace report and would not be able to comment on it until today. She confirmed there was an investigation under way by the agency's office of criminal investigation into Monsanto's handling of the studies.

The EPA has from time to time said it was going to downgrade the health risk of dioxin, although it has never followed through because of objections from its science advisory board.

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Greenpeace, Chemist Challenge Monsanto On Dioxin Findings

By William H. Freivogel

Post-Dispatch Washington Bureau

WASHINGTON — Greenpeace and a whistle-blower at the Environmental Protection Agency are accusing Monsanto Co. of fraudulently understating the health risks of dioxin.

Both the international environmental organization and the EPA chemist called upon the agency to conduct an independent evaluation of what they say are flawed Monsanto studies indicating that dioxin has little health effect on humans.

The EPA chemist, Cate Jenkins, also urged a criminal investigation of the firm, alleging that it covered up evidence of dioxin's ill effects.

A Monsanto spokesman said Wednesday that there appeared to be a criminal inquiry under way and so declined to comment on Jenkins' charges.

But the company said that Greenpeace's allegations were untrue and that the firm stood by the studies. He noted that Monsanto sent a letter to

Dioxin

From page one

the EPA last month asking it to audit the studies to clear the air.

Jenkins, a chemist in the Regulatory Development Branch at EPA, wrote a memo Nov. 15 to the agency's Office of Criminal Investigations accusing the company of a "long pattern of fraud" concerning "dioxin contamination of a wide range of Monsanto Corp. products, as well as health studies of Monsanto's dioxin-exposed workers."

The memo indicates that Jenkins, known at the EPA as a whistle-blower, met Nov. 14 with agents of the National Enforcement Investigations Center, which conducts EPA's criminal inquiries. EPA refused to comment on whether it was conducting a criminal investigation.

Meanwhile, Greenpeace is releasing a report today that it says exposes "fraudulent and manipulated science" in Monsanto's studies of the effect of dioxin on workers at its plant in Nitro, W. Va. An explosion at the plant in 1967 exposed workers to dioxin.

The Greenpeace report is being released in Washington and at dioxin-contaminated sites around the country, including Times Beach, Mo.

The report, written by former Monsanto Co. chemist Pat Costner,

says that studies done for Monsanto in 1980 and 1983 made several key scientific mistakes.

In two studies, for example, some people exposed to dioxin were included in the "control" group.

Because regulators relied on the Monsanto studies as proof that dioxin is not too dangerous to humans, EPA should revoke all decisions based on those studies, Greenpeace said.

The group also called upon EPA to set up a national dioxin elimination program, which would phase out use of chlorine in the paper industry and chlorinated compounds in pesticides and would eventually ban some wood preservatives.

Dan R. Bishop, director of corporate communications at Monsanto, said that most of the allegations by Jenkins and Greenpeace were not new. He said that Jenkins' memo had been based largely upon claims made in a three-year trial in Bell, Ill., where residents of Sturgeson, Mo., sought damages for exposure to a small amount of dioxin after a tank derailment in 1979.

In her memo, Jenkins wrote "Monsanto covered up the dioxin contamination of a wide range of its products including Lysol, the disinfectant. Members of the Canadian Parliament recently began an investigation of product contamination," she wrote.

The memo also maintained that according to internal Monsanto documents, samples of herbicides submitted by the company to the Department of Agriculture in the 1970s had been "doctored" and that highly contaminated samples had not been submitted. The herbicides were used in the Agent Orange defoliants during the Vietnam War.

The main criticism in Jenkins' memo and the Greenpeace report is targeted at the 1980 and 1983 studies of Monsanto workers, which were supervised by Dr. Raymond Siskind of the Kettering Institute in Cincinnati.

ST. LOUIS POST DISPATCH
THURSDAY, NOVEMBER 29, 1990

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Greenpeace attacks dioxin studies

By Grant Perkins

STAFF WRITER

When a 1949 explosion at Monsanto's Nitro complex sent clouds of dioxin through the plant and into the atmosphere, workers were overcome with the chemical's effects — skin lesions, nerve and kidney damage.

Monsanto later commissioned health studies on the workers' problems. The studies' findings — that dioxin cannot be linked directly to cancer in humans — have become cornerstones of chemical companies' defenses in lawsuits across the nation.

Now the international environmental group Greenpeace is attacking those studies as frauds.

In a report released today to the Environmental Protection Agency, Greenpeace researchers blast the study's methods, analysis and findings.

The organization is asking the EPA, which uses the study as a basis for its own dioxin policies, to review its stand on the man-made chemical that causes cancer in rats.

"In recent months, new information

has come to light which indicates a clear pattern of manipulation and misconduct in the studies."

Joe Thornton,
Greenpeace researcher

has come to light which indicates a clear pattern of manipulation and misconduct in the studies," Greenpeace research analyst Joe Thornton writes in his study, titled "Science for Sale."

Thornton charges in his 43-page critique that an examination of the original report showed "a pattern of deliberate manipulation of data and study methods in order to obtain the predetermined result that dioxin had no negative effects on worker health."

Monsanto officials denounced the report.

"That critique reflects their total ig-

norance of epidemiology," said corporate spokesman Dan Bishop. "That study has stood for years. It was peer-reviewed by other scientists before it was published."

Greenpeace has several problems with the Monsanto-funded studies that were published in the early 1980s:

• The studies compared workers who were exposed to dioxin during the explosion with other workers in the plant who were presumed to have avoided the chemical. Both groups, Thornton says, had already been exposed to high levels of dioxin simply by working at the plant.

• Using other groups of the same people, original researchers separated workers by type of exposure. That made each group smaller and the results less reliable.

• Researchers relied on only the appearance of chloracne — a severe skin disease — as the criteria for dioxin exposure in some cases. That move put dioxin-exposed workers without the disease into the control group, contaminating results.

• In parts of the studies, workers were eliminated from certain groups; researchers failed to follow stated procedures and ill workers without chloracne were ignored.

"As a result of these manipulations, the data and conclusions of the three Monsanto studies are essentially meaningless," the critique said.

"However, it is noteworthy that, after at least partial correction of the most glaring manipulations of this flawed information, the data indicate substantially elevated rates of many health effects among dioxin-exposed workers."

(Please turn to Page 4D, col. 1)

Greenpeace vs. studies

(Continued from Page 1D)

Greenpeace is calling on the EPA to investigate the studies, bar federal officials from relying on the studies and establish a national dioxin elimination program.

Bishop, with Monsanto, says Greenpeace's claims are bunk.

"This review by Greenpeace is nothing more than a rehash of issues brought up in other trials," he said. "These were highly qualified scientists, and their work has never been challenged by competent scientists."

Greenpeace is using the issue in its fund-raising effort, he said. The group has not brought up any points that have not already been challenged in court and defeated.

Bishop declined to go over Greenpeace's charges point by point, but said other studies, including one by the workers' union, came up with the same findings.

"We stand by the studies," he said. "And we're outraged."

The studies played a central role in a mid-1990s Charleston court case brought by workers who had been exposed to dioxin during the explosion and in a line that produced herbicide.

While the lawyers on each side of the case differ on Greenpeace's

claims, they do agree that any tampering with the original studies would have profound effects on future litigation.

"That study is a very powerful defense for industry in case after case," said attorney Stuart Calwell, who brought the suit against Monsanto for the dioxin-exposed workers. "I've always felt that study was flawed."

Calwell cited many of the same problems Greenpeace listed. He helped the organization get Monsanto records by filing briefs with the courts.

"What they did in the original study was like going into a cancer ward, dividing it in half and then saying that there was no difference between the two halves," Calwell said.

Charles Love, who argued for Monsanto in the case, said the Monsanto studies are important, but others have corroborated its findings as well.

"It's preposterous to suggest that someone would manipulate the study," Love said. "In the trial, epidemiologists from all over the country were there and I never heard one say anything about the types of problems Greenpeace is raising."

MEMORANDUM, TUESDAY, JANUARY 29, 1991

27

Company's Dioxin Studies Under Fire

By Carolyn Colwell

STAFF WRITER

A chemical company's studies showing that workers have not been seriously harmed by exposure to dioxin have come under fire by Greenpeace and now scrutiny by the U.S. Environmental Protection Agency.

The EPA has launched a criminal investigation of whether the dioxin studies by Monsanto Corp., a St. Louis-based chemical company, are fraudulent, according to an internal EPA memo. And the environmental organization Greenpeace has petitioned the EPA to reassess the validity of the studies and the agency's regulation of dioxin, which Greenpeace alleges has been adversely influenced by the Monsanto research.

The studies by Monsanto of workers at its Nitro, W.Va., plant have been relied on by the federal government to show that dioxin exposure has not been harmful to humans and does not require more stringent regulation or classification as a significant human carcinogen. The government and chemical companies have used the studies to discredit claims by Vietnam veterans that their exposure to the dioxin-contaminated herbicide Agent Orange has damaged their health.

A study published in a medical journal last week showed that chemical workers exposed to 500 times the normal amount of dioxin for at least a year are nearly 80 percent more likely to develop some kinds of cancer. The study, carried out by the National Insti-

tute for Occupational Safety and Health, suggested that lesser exposure is not dangerous.

A Monsanto spokesman in St. Louis said earlier this month the company welcomes the EPA investigation and called Greenpeace's allegations that the studies are flawed "a bald-faced lie" that the environmental group is using as part of its fund-raising drive.

Don R. Bishop, Monsanto's director of corporate communications, said the company thinks the EPA investigation is "the only way to put the matter to rest." He added in a press release that, "The company stands by its findings, welcomes any legitimate scientific audit and is absolutely certain that its studies will continue to withstand legitimate scientific scrutiny."

In addition, Bishop said that before news of the EPA investigation first surfaced late last year, Monsanto had independently requested an EPA audit of its studies "to settle this matter for once and for all."

A spokesman for the EPA in Washington, D.C., Dwayne Winters, said earlier this month that he cannot confirm or deny that a criminal investigation is under way, but said the agency is studying the issues raised by Greenpeace's Nov. 29 petition. Winters said the agency will respond to the petition by Feb. 28.

According to a memo from EPA chemist Dr. Cate Jenkins to the EPA's Office of Criminal Investigations in Denver, one of the key flaws in the Monsanto studies was the inclusion of exposed workers in the unexposed group and vice versa. Consequently, the incidence of cancers and other illnesses in the exposed

group would have been diluted by the inclusion of unexposed workers, Jenkins explained.

This issue was raised in a successful federal suit against Monsanto by workers at one of its plants in East St. Louis, Ill. Monsanto has appealed that verdict.

Greenpeace raised the same question in the critique of the Monsanto studies, which it appended to its petition. The critique was based on court documents and published research. "The Greenpeace analysis of several of the studies show that dozens of workers with cancer and heart disease, who were known to be exposed to dioxin, were inappropriately shifted into unexposed 'control' groups or excluded from the studies altogether," Greenpeace said in November.

Joe Thornton, author of the Greenpeace critique, said in a telephone interview this month: "We're relying on scientists who are paid and hired by the corporations who are producing these chemicals to formulate policies and these regulations . . . We really need to rethink our reliance on corporate-paid experts."

The Greenpeace petition also asks that the EPA not rely on the studies as part of its regulatory efforts or assessments of carcinogenic risk and that the agency establish a national dioxin-elimination program to control the release of dioxin into the environment. Under Section 21 of the Toxic Substances Control Act, the EPA has until Feb. 28 to answer the petition. "I can tell you that we take any Section 21 request rather seriously," Winters said. If the petition is denied, the petitioner can go to federal court for a hearing.

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FYI from a L.I. Newspaper

Alan Perce

cc: Alan Bishop
John H. Moore

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The FDA official added that his agency intends to follow this enforcement approach until EPA promulgates a new tolerance regulation for alachlor residues or makes some other regulatory decision regarding the pesticide.

● DOWNGRADING OF CODEX COMMODITY COMMITTEES RECOMMENDED

The Secretariat of the Joint FAO/WHO Food Standards Program has recommended delegating greater responsibility to the Codex Alimentarius Commission's general committees and lessening the role of Codex commodity committees in areas such as contaminants, methods of analysis, sampling and product certification.

In a paper prepared for the FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade, to be held in Rome in March, the Secretariat said the conference may also want to review Codex acceptance procedures "so as to bring these procedures into conformity with true government practices and reflect the situation in the international food trade."

Noting that there have been recent far-reaching proposals to review existing Codex standards so as to emphasize only those aspects responsible for rejection of shipments at borders, the Secretariat stated that such a move would "present the risk of rendering obsolete to a large extent many existing standards (and) would require careful review to determine which aspects of the standards would need to be maintained or transferred to general standards" and which "would need to be maintained in the interest of harmonizing specific quality requirements for individual products."

Codex standards "should reflect the regulatory practices in the majority of member countries, bearing in mind that regulatory practices change over the years in response to a variety of external factors," the Secretariat declared, adding, "The conference may wish to recommend that the CAC review carefully its criteria for the establishment of work priorities."

● EPA-er JENKINS RENEWS DIOXIN STUDY FRAUD CHARGES

Renewing charges that Monsanto didn't count some dioxin victims in its epidemiology studies of dioxin, EPA's Cate Jenkins wrote Jan. 24 to the agency's Office of Criminal Investigations (OCI) to list the impacts the studies may have had on EPA's regulatory program (See March 7, Pages 2 and 26; Nov. 28, Page 12, and Dec. 5, Page 23).

She also said the National Institute for Occupational Safety and Health found no reason to exclude cases of soft tissue sarcoma although Monsanto had (See Jan. 23, Page 46). Noting that EPA classifies dioxin as a B2 carcinogen (animal evidence only), Jenkins said the agency relied primarily on the Monsanto studies for the classification.

Because of that classification, she said, dioxins would not be listed as priority pollutants under the new Clean Air Act and have not been regulated under current air emissions standards.

Superfund's Reportable Quantities (RQs) vary by a factor of 10 according to whether the substance is deemed a Group A, B1, B2 or C carcinogen, she said, but continued:

"Although dioxins are currently considered to be potent carcinogens, and consequently their RQ is the same as for a Group A carcinogen, there (are) heavy pressure and active programs at EPA to downgrade the potency estimate."

She said no 'Maximum Contaminant Level Goals' have been developed in EPA's drinking water program "because of the false belief that dioxins will never be found in drinking water." Jenkins also objected that RCRA's Toxicity Characteristic (TC) program, although it offers equal protection for Group A, B and C carcinogens, is only protective at the one in 100,000 level.

EPA's cancer classification for dioxin also has denied veterans benefits from the Veterans Administration (VA), Jenkins said, "because VA requires a statistically significant finding of these effects in human, not animal, studies." Australia and New Zealand also have refused veterans benefits based on the Monsanto studies, she said, and:

"The White House itself recognized what the impact would be on private litigation of classifying dioxins as human carcinogens. A White House memorandum coerced the Centers for Disease Control not to find cancer and other health effects in our Vietnam veterans, since this would have a profound effect on litigation by private citizens around Superfund sites, where even higher exposure to dioxins was probable."

Jenkins said her latest memo was prompted by the statement from the agency's OCI that for a criminal conviction it would be necessary to establish not only fraud, but the "impact of this fraud on the regulatory process."

● ATRAZINE PERSISTENT IN SOIL SUBSURFACE, HYDROLOGISTS FIND

Atrazine is more persistent in the subsurface than in surface soils, research hydrologists told an American Geophysical Union meeting in San Francisco Dec. 5-6.

As reported by EPA's Elizabeth Behl in a memo circulated by the Office of Pesticides and Toxic Substances, researchers at Kerr Lab in Ada, Okla., found little or no adsorption or degradation of atrazine at a depth of 11 meters. The study also found that atrazine concentrations decreased less rapidly in sterile soils, biodegradation was affected by sediment type (perhaps due to lower organic matter content), and atrazine did not mineralize.

Other research findings reported by Behl involved cyanazine, alachlor and triazine herbicides. A study of herbicides in surface waters of the Midwest by D.A. Goolsby, of the U.S. Geological Survey's Denver office, found concentrations of herbicides surging in the post-application period from a median concentration. Herbicides were found year-round in surface water samples from the Midwest, the study reported; samples showed a 10-fold increase in concentrations following runoff events. Researchers noted that concentrations of alachlor and atrazine may exceed MCLs for several weeks to months following applications.

In a study led by G.N. Delin, USGS St. Paul, researchers found that changes in nitrate concentration correlated well with cropping systems employed. However, concentrations of atrazine did not. In addition, atrazine was found to be "quite persistent" in the unsaturated zone, they said.

Monsanto

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March 25, 1991

Editor - Letters
Science
1333 H Street, NW
Washington, DC 20005

Editor, Science

In the February 8, 1991 edition of *Science*, the article on dioxins included a box on page 626 with the title "Monsanto Studies Under Fire." Since reading this commentary on studies performed a decade ago by epidemiologists and physicians from Monsanto and the University of Cincinnati -- and about alleged fraudulent manipulation of data and criminal investigation -- I have been doing the proverbial "slow burn"; hence this delay in response.

Even though *Science* provided a Monsanto spokesman with the opportunity to firmly deny all of these allegations and so reported in the article, I am very disappointed that a publication dedicated to science would stoop to dignifying hearsay and allegations stemming from lawsuits. Despite our denials as you reported, hype such as this may raise unwarranted suspicion in the minds of some readers, despite the fact Monsanto invited an EPA/NIOSH audit of the studies in order to resolve the matters.

Especially repugnant to me was a sentence in the last paragraph which read "Everyone *Science* spoke with who is familiar with the Monsanto studies agrees that they are flawed, but probably not as the result of criminal intent." Who are these unidentified "experts" who, without a detailed review of the actual study, its analysis and interpretations, can render judgment on flaws (let alone gratuitously comment on criminal intent)? Are you aware that no expert -- either epidemiologist or trained public health physician -- has ever come forward to actually criticize the adequacy of these studies? Are you aware that one of the "scientific experts" quoted extensively in your dioxin article participated as an expert witness in dioxin-related suits against Monsanto and can hardly be considered disinterested? Are you aware that the allegations pertaining to the studies stem only from an attorney's argument in the courtroom, unsupported by any expert testimony or expert reexamination of the data? Finally, are you aware that a morbidity study at the same Monsanto plant --

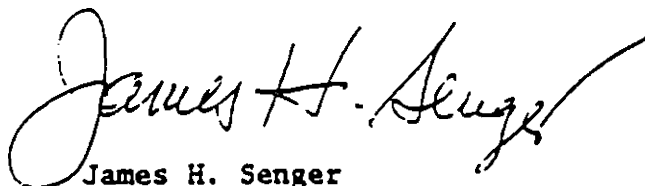
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commissioned and paid for by the union representing workers at that plant -- was conducted by Drs. Irving Selikoff, Marion Moses et al (ref: American Journal of Industrial Medicine 5:161-182 (1984)) and arrived at essentially the same conclusion reached by the University of Cincinnati: that chloracne was the only evident finding and "that it is unlikely that permanent, severe, and debilitating toxicological sequelae are inevitable after exposure to TCDD sufficient to product chloracne."

In my opinion, a publication with the stature of *Science* has better things to do than involve itself in the sort of half-truths, politics and litigation embodied in the mess described on page 626. The tone of the article is more befitting of a tabloid in the checkout line of a super market.

Sincerely,

A handwritten signature in cursive script, reading "James H. Senger". The signature is written in dark ink and is positioned above the printed name and title.

James H. Senger
Vice President
Environmental Policy Staff

bcc: D. R. Bishop
D. F. Snively
W. J. McCarville
M. A. Pierle
B. R. Friedlander/J. J. Collins

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