



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

MEMORANDUM

DATE: January 24, 1991

SUBJECT: Impact of Falsified Monsanto Human Studies on Dioxin Regulations by EPA and Other Agencies -- January 24, 1991 NIOSH Study Reverses Monsanto Study Findings and Exposes Certain Fraudulent Methods

FROM: Cate Jenkins, Ph.D., Chemist *Cate Jenkins*
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Kevin Guarino, Special Agent
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National Enforcement Investigations Center, EPA

The following information (in addition to my November 15 memorandum) should be useful in your criminal investigation of fraud by Monsanto. In particular, this should correct certain misinformation being disseminated by an unidentified EPA official (see attached press clippings), claiming that even if the Monsanto human studies on dioxins effects were fraudulent, this had no impact on protecting the public. The assertion was that EPA already imposed the most stringent controls possible, based on an animal study showing dioxins were potent carcinogens.

This is not true. This memorandum outlines the direct changes in environmental regulations, as well as compensation by the government and court system, that would result if dioxins were classified as human, not just animal, carcinogens. The Monsanto studies subject to your investigation have played a major role in preventing the classification of

dioxins as human carcinogens.¹

This memorandum discusses the following:

1. The two classification categories EPA uses to rank dioxin hazards (the "weight-of-evidence" and the "potency"), the impact the Monsanto studies on EPA's dioxin rankings, and the role of today's study (attached) by the National Institute for Occupational Safety and Health on exposing fraudulent methods in the Monsanto studies.
2. The impact of the wrongful classification of dioxins as "animal-evidence-only" carcinogens on environmental regulations, Vietnam veteran compensation, and private litigation against chemical companies.

EPA's CLASSIFICATION OF DIOXINS BY WEIGHT-OF-EVIDENCE AS WELL AS POTENCY, AND IMPACT OF MONSANTO STUDIES ON THESE CLASSIFICATIONS

Ranking by Certainty of Carcinogenicity (Weight-of-Evidence)

Description of EPA's Weight-of-Evidence Classification Scheme. The first classification method for carcinogens is by the "weight-of-evidence." The weight-of-evidence differentiates between carcinogens with positive human epidemiological evidence, only animal evidence, and the quality of the human and/or animal evidence. The weight-of-evidence ranking scheme, therefore, is according to the quality or certainty of data establishing carcinogenicity. The weight-of-evidence classification is independent from any estimate of the potency of the carcinogen, which will be discussed in the following section.

The EPA ranking scheme for weight-of-evidence,² similar to that of the International Agency for Research on Cancer (IARC), is as follows:

Group A: "Human carcinogen" (sufficient evidence from human epidemiological studies).

Group B1: "Probable human carcinogen" (at least limited evidence of carcinogenicity to humans). [*Limited evidence in humans means that at least one adequate human epidemiological study exists demonstrating carcinogenic effects in humans.*]

¹ You both emphasized the importance for a criminal conviction of not only establishing fraud, but also the impact of this fraud on the regulatory process. My November 15 memorandum primarily addressed the regulatory consequences of Monsanto's failure to disclose dioxin contamination in a wide range of its consumer products.

² U.S. EPA (September 24, 1986) 51 FR 33992-34054, reprinted as *The Risk Assessment Guidelines of 1986*, EPA Publication No. EPA/600/8-87/045, August, 1987 page 1-7.

Group B2: "Probable human carcinogen" (usually a combination of sufficient evidence in animals and inadequate data in humans).

Group C: "Possible human carcinogen" (limited evidence of carcinogenicity in animals in the absence of human data).

Group D: "Not classified" (inadequate animal evidence of carcinogenicity).

Group E: "No evidence of carcinogenicity for humans" (no evidence of carcinogenicity could be found in at least two adequate animal tests in different species, or in both human epidemiological studies and animal studies).

A combination of Groups A and B1 are generally considered to constitute "human evidence of carcinogenicity." "Limited evidence in humans" means that at least one adequate human epidemiological study exists. The EPA Risk Assessment Guidelines³ describes the difference between Group A and B1 as depending on "the number of adequate human epidemiological studies that show comparable results on populations exposed to the same agent under different conditions."

Impact of the Monsanto Studies on EPA's Weight-of-Evidence Classification of Dioxins. Dioxins are currently classified as Group B2 carcinogens (animal evidence only of carcinogenicity). This is because the Monsanto studies have been relied upon by EPA to negate a conclusion of human evidence (Group A or B1) for dioxins. Whenever a researcher published a positive human epidemiological study showing statistically significant excess cancers due to dioxin exposures, the Monsanto studies were held up as the definitive refutation of the positive human study. The Monsanto studies were deemed superior since the humans were known to be heavily exposed, but no excess risk of cancer was found in the Monsanto workers.

January 24, 1991 Study Reverses Monsanto's Findings and Exposes Flawed "Scientific Methods" in the Monsanto Studies. Although a complete audit of the Monsanto studies is still required to expose all instances of flawed data and the knowing, inappropriate use of such data (as promised by NEIC), it appears that the National Institute for Occupational Safety and Health (NIOSH) has, in essence, passed judgement on the validity of some of the "scientific methods" used by Monsanto. NIOSH reexamined the health effects of dioxins on workers at the Monsanto plant which produced Agent Orange, along with exposed workers at other chemical manufacturing facilities.⁴ This study was published in today's New England Journal of Medicine (attached).

There was a critical difference between the way in which NIOSH and Monsanto utilized the

³ *Ibid.*, p. 1-6.

⁴ Fingerhut, M. *et al.* (January 24, 1991) *N. Eng. J. Med.*, 324(4):212-218.

same data on the extremely rare cancer, soft tissue sarcoma (STS). The Monsanto study⁵ failed to include two cases of STS in its studies, while the NIOSH study did not find any scientific validity for such an exclusion. These workers correspond to NIOSH Cases 1 and 2, and are highly significant for the following reason: Out of a subgroup of 1520 workers at several U.S. chemical plants, having greater than 20 years of latency from the time of dioxin exposure, NIOSH found just three cases of STS. These three cases alone (which included the two Monsanto cases) were enough to demonstrate a statistically significant increase in STS because of the rarity of this type of cancer. The exclusion of the two STS cases did result in a negative finding of increased STS in the Monsanto studies, and would have had the same effect in the NIOSH study.

Monsanto excluded Cases 1 for the capricious reason that the worker died after 1977, yet the Monsanto study was published in 1983, and the death of the worker was known. Interestingly, Monsanto included this case of STS in an earlier 1980 cancer mortality study,⁶ conveniently omitting the case in the later study. Monsanto excluded Case 2 from its studies on the grounds that pathological examination of tissues from the deceased worker indicated that the STS diagnosis on death certificate was incorrect. NIOSH did not use this excuse to exclude Case 2, since pathological examination of tissue in the exposed cohort would be inconsistent. There was no mechanism for examining tissue in the general population (the controls) to rule out similar incorrect diagnoses. Furthermore, there was a clear chain of custody problem with the tissue from Case 2. There were no established precautions, security, certification procedures, or adequate records to provide verification that Monsanto or other parties had not substituted tissue specimens to support the convenient reclassification of Case 2. In addition, the reclassification of STS for Case 2 to the vague category "carcinoma, poorly differentiated" leaves some doubt as to the genuine classification of the type of cancer.

Monsanto also excluded Case 5, a maintenance worker undoubtedly exposed to high levels of dioxins, who was diagnosed as having died of STS. This case of STS was reported independently in the literature by physicians assisting the worker's union at the Monsanto plant.⁷ NIOSH discussed this additional case of rare STS, but was forced to exclude it since Monsanto had failed to establish exposure levels to dioxins for this worker. Dr. Raymond Suskind, on cross examination in 1985,⁸ failed to give any justification for not determining exposure levels for this particular worker. The inclusion of a broader range of exposed worker would have increased the power of the Monsanto studies to detect rare cancers such as STS. EPA did determine in 1983 that the whole Monsanto plant was highly

⁵ Zack, J. A., W. R. Gaffey (1983) *Environ. Sci. Rev.*, 26:575-91.

⁶ Zack, J. R., R. R. Suskind, 1980, *J. Occup. Med.*, 22:11-14.

⁷ Moses, M. and I. Selikoff (1981) *Lancet*, 1370.

⁸ Raymond Suskind (March 13, 1985), Boggess, *et al.*, v. Monsanto Company, Civil Action 81-2098-265. U. S. District Court, Southern District, West Virginia at Charleston, pp. 28706-28725.

contaminated with dioxins, so that no worker could have escaped exposures.

Ranking of Dioxins by Strength of Carcinogenic Response (Potency)

Description of EPA's Ranking of Carcinogens by Potency. The second method for classifying carcinogens, independent from the weight-of-evidence ranking, is by potency (amount necessary to illicit a carcinogenic response). This is also called a "dose-response assessment," or a "quantitative risk assessment," where an estimate is made of the likely range of excess cancer risk associated with given levels of human exposure.

Carcinogenic potency may be estimated either from human studies, animal studies, or structure-activity relationships to chemically similar carcinogens. Carcinogenic potency estimates are preferably based on human data when available.

Impact of Monsanto Studies on Dioxin Potency Estimates. The Monsanto studies may have fraudulently affected potency estimates made for dioxins by EPA, as well as the weight-of-evidence classification. Today's NIOSH study, which reexamined the Monsanto data, found what appears to be a carcinogenic promotional effect by dioxins in Monsanto's workers as well as a direct carcinogenic response.⁹ Carcinogenic promotion may be seen as the acceleration of any incipient cancer process in the body to an early expression of frank malignancy. This was demonstrated by NIOSH as the elevation of all types of cancer, when data for cancer at different sites was compiled. The current EPA estimates of potency are based on an animal study where direct carcinogenesis only was found (liver cancer). As a result, EPA's potency estimate does not take into account the additional effects of carcinogenic promotion by dioxins. Another recent human epidemiological study also appears to demonstrate (upon closer scrutiny of the data) a carcinogenic promotional effect of dioxins in humans.¹⁰

CONSEQUENCE OF WRONGFUL CLASSIFICATION OF DIOXINS AS ANIMAL-EVIDENCE-ONLY CARCINOGENS

The following describes the impact on EPA regulations, compensation of Vietnam veterans (and probably industrial workers through Workman's Compensation Boards), and private litigation that has resulted from the classification of dioxins as Group B2, animal-evidence-only carcinogens. As stated before, the fraudulent Monsanto studies were responsible for this misclassification.

Differential Environmental Regulations and Prioritizations

Even when two carcinogens are estimated to have the same potency, EPA often allows greater exposures to, or de-prioritizes developing regulations for, those carcinogens without

⁹ Fingerhut, *et al.*, *op. cit.*

¹⁰ Zober, A., P. Meserer, P. Huber (1990) *Int. Arch. Occup. Environ. Health*, 62:139-57.

supporting human evidence of carcinogenicity (Group A or B1). The most important instance directly impacting dioxin controls is probably under the Clean Air Act.

Emission Standards under the Clean Air Act (CAA). Under the CAA, the only hazardous air pollutants for which national emission standards have been set are for Group A or B1 carcinogens, those having supporting human data.¹¹ This is because non-A/B1 carcinogens have been assigned a low priority, no-action policy under the CAA, despite the fact that Section 112(a)(1) of the CAA grants EPA the authority to promulgate emission standards for B2 or other category carcinogens.¹² As a result of this de-prioritization, dioxin emissions standards have not been promulgated. A large volume source of dioxin emissions to the are from municipal incinerators, and are not regulated by the CAA.

The Clean Air Act Amendments of 1990 (CAAA) have attempted to remedy the failure of EPA to regulate a wide range of pollutants, including carcinogens in Groups A and B1, as well as B2. The CAAA established a list of pollutants which EPA must decide to regulate by a fixed schedule. EPA again will be allowed to prioritize new emission standards; only 10 categories on the list must have standards within a year. Dioxins would not be on the initial "top-ten" list unless categorized as either Group A or B1 carcinogens, and therefore would not be required to be regulated for another 4 to 10 years.

Releases of Hazardous Materials, Reportable Quantities (RQs). The quantity of a release into the environment of a hazardous material that must be reported to EPA (the RQ) under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), varies by a factor of ten for Group A, B (B1 or B2), or C carcinogens. The potency estimate is combined with the weight-of-evidence ranking to arrive at a regulatory threshold, the "hazard ranking potency group."¹³

In other words, the RQ threshold for a spill of a carcinogen of medium potency, depending on whether that carcinogen is classified as Group A, B, or C, would be 1, 10, or 100 pounds, respectively. On the other hand, the RQ for a highly potent carcinogen classified as Group A, B, or C, would be 1, 1, or 10 pounds, respectively. Although dioxins are currently considered to be potent carcinogens, and consequently their RQ is the same as for a Group A carcinogens, there is heavy pressure and active programs at EPA to downgrade the potency estimate.

¹¹ 40 CFR 61. There are currently air emission standards only for benzene (Group A), vinyl chloride (Group A), asbestos (Group A), beryllium (Group B1), inorganic arsenic (Group A), radionuclides. (Mercury, not considered a carcinogen, is subject to CAA emission standards due to other toxic effects.)

¹² For example, the authority to promulgate emission standards for methylene chloride, a Group B2 carcinogen, under the CAA was clearly iterated in 1985 (50 FR 42037). Although study and coordination with other statutes was proposed, no action under the CAA or other statutes has been taken.

¹³ 54 FR 33421, August 14, 1989, 40 CFR 302.4.

Drinking Water Maximum Contaminant Level Goals (MCLGs). Under the Safe Drinking Water Act (SDWA), carcinogens are assigned MCLGs¹⁴ of zero if the carcinogen is classified as Group A, B1, or B2.¹⁵ Group C carcinogens are assigned a MCLG designed to reflect that there is "some possible evidence of carcinogenicity in animals." The MCLG for Group C carcinogens, therefore, is only designed to prevent one excess cancer in a population of one hundred thousand (the 10^{-5} risk level). No MCLGs have been developed for dioxins because of the false belief that dioxins will never be found in drinking water.¹⁶

Toxicity Characteristic (TC) for Hazardous Waste. Under the Resource Conservation and Recovery Act (RCRA), a material becomes a hazardous waste if leachable levels of toxicants reach a certain concentration, defined by the TC.¹⁷ The TC only attempts to protect populations from cancer risk at the 10^{-5} risk level (one cancer in 100,000) not only for Group A and B carcinogens, but Group C carcinogens as well. Although the TC is consistent in the level of protection offered for Group A, B, and C carcinogens, it offers the lowest degree of protection (only at the 10^{-5} risk level) for all of these carcinogen categories, compared to regulations under other EPA administered statutes.

Vietnam Veterans Denied Compensation for Exposures to Agent Orange

Veterans exposed to the dioxin-contaminated defoliant Agent Orange in Vietnam have been denied compensation for cancer, other health effects, and birth defects¹⁸ by the Veterans Administration (VA). This is because the VA requires a statistically significant finding of these effects in human, not animal, studies before granting compensation.¹⁹ For carcinogenicity, this would be the equivalent of classifying dioxins as Group A or B1 (known human carcinogen or limited evidence of carcinogenicity in at least one adequate human study).

¹⁴ MCLGs are non-enforceable health goals. The enforceable drinking water limits, the Maximum Concentration Limits (MCLs), must be set as close to the MCLG as is feasible, after considerations of the best available treatment technologies, and the cost for such treatment, according to Section 1412(b) of the SDWA.

¹⁵ 40 CFR 141.11; 50 FR 46948-46950, Nov. 13, 1985; 52 FR 25727-25728.

¹⁶ 50 FR 47008-47010, Nov. 13, 1985.

¹⁷ 40 CFR 261.24; 55 FR 11798, March 29, 1990.

¹⁸ A new study from Harvard has demonstrated statistically significant increases in relative risk for Vietnam veteran fathers having children with one or more major malformations, compared to non-Vietnam veterans. Aschengrau, A. and R. Monson (1990) *Am. J. Public Health*, 80:1218-24.

¹⁹ 38 CFR 1.17

The decision of EPA to classify dioxins as Group B2, has directly impacted decisions by the VA, and Monsanto's fraudulent dioxin studies have been the basis for these EPA decisions. Thus, the causal effect of the Monsanto studies on the VA are within the scope of the present NEIC investigation.

Not only has the VA adopted for many years EPA's classification of dioxins as Group B2 (animal-evidence-only carcinogens), but the VA has also utilized EPA personnel to sit on its own Scientific Council of the Veterans' Advisory Committee on Environmental Hazards. This committee has been responsible for the continuing decisions for the past years that dioxins have not been demonstrated to cause human cancers, and thus Vietnam should not receive compensation for exposure-related health effects.²⁰

The Monsanto studies have also been utilized by Australia and New Zealand as a basis for denying their Vietnam veterans compensation for health effects related to Agent Orange exposure. Horribly, the Australian Royal Commission set up to review dioxin health evidence lifted language prepared by Monsanto "as is" and used it for a determination that dioxins caused no cancers or other long term effects in humans.

Undoubtedly, various administrative proceedings before Workman's Compensation Boards have also resulted in unsuccessful claims because dioxins are not classified as human carcinogens. This is also properly before the NEIC, since such decisions are the direct result of EPA's leadership role in not classifying dioxins as human carcinogens, based on the Monsanto studies.

Thwarted Private Litigation

In addition to the denial of compensation to veterans through VA administrative procedures and workers through various compensation boards, private litigation has been thwarted by EPA's failure to classify dioxins as either Group A or B1. Suits by Vietnam veterans, Agent Orange production workers, towns exposed to spills of Monsanto's dioxin-laced products, citizens around dioxin-contaminated Superfund sites have all been hampered by the fact that EPA has concluded that there are no adequate human studies showing long-term carcinogenic effects of dioxins. Much of the physical documentation offered to support your investigation is transcripts of such legal proceedings where the Monsanto studies figured predominantly in defending the responsible chemical companies.

Further, EPA personnel have even participated in such legal proceedings as expert witnesses

²⁰ The recent decision by the VA to compensate veterans for Non-Hodgkins Lymphoma was stated to be based on "compassion," not a causal relationship to dioxin exposures. The VA has yet to codify a preliminary decision to compensate veterans for soft tissue sarcoma, purportedly based on a conclusion of dioxin causation.

on behalf of the chemical company.²¹ These EPA officials dutifully parroting EPA's position that dioxins have not been shown to be human carcinogens, based on the Monsanto studies.

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 exposures to dioxins was probable.²²

The bill [to award veteran's compensation for Agent Orange] will make it far more difficult to stop broader victims compensation schemes involving hazardous wastes and substances. Dioxin -- the toxic ingredient in Agent Orange -- is a major issue in this area (Love Canal and Times Beach are largely dioxin exposure cases); we will be in the tenuous position of denying dioxin exposure compensation to private citizens while providing benefits to veterans for in many instances lower levels of exposure.

CONCLUSION

In my opinion, it would be a terrible miscarriage of justice for EPA to simply reclassify dioxins now as "human-evidence" Group A or B1 carcinogens, and let the Monsanto fraud investigation languish. Such a reclassification without concomitant prosecution of Monsanto may prevent injustices in the future, but does little to ameliorate the many years of harm (lenient regulations, denied compensation, unsuccessful litigation) caused by the fraudulent studies.

cc: Admiral E. Zumwalt
 Senator Thomas Daschel
 Congressman Ted Weiss
 American Legion
 National Vietnam Veteran's Coalition
 Oklahoma Agent Orange Foundation
 Independent International Agent Orange Network
 Vietnam Veterans of New Zealand
 Greenpeace, U.S.A.

²¹ Dr. Renate Kimbrough is one known example, who testified on behalf of Monsanto and probably other industrial defendants. An ongoing case where Dr. Kimbrough may be involved on behalf of industry responsible for polychlorinated biphenyl pollution, which are contaminated with chlorinated dioxins and furans.

²² U.S. House of Representatives (1990) *The Agent Orange Coverup: A Case of Flawed Science and Political Manipulation*. Twelfth Report by the Committee on Government Operations, HR 101-672.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 14 1990

OFFICE OF ENFORCEMENT

MEMORANDUM

SUBJECT: Allegations of Fraud Contained in Greenpeace USA Petition

FROM: Michael J. Walker
Acting Associate Enforcement Counsel for
Pesticides and Toxic Substances

Connie Musgrove
Acting Director, Office of Compliance Monitoring

TO: Mark Greenwood
Director, Office of Toxic Substances

Erich W. Bretthauer
Assistant Administrator for Research and Development

Dwain Winters
Coordinator, Greenpeace Section 21 Petition Workgroup

The recent petition filed by Greenpeace USA requests that the Agency commence an investigation to determine whether "fraudulent/invalid studies" have been submitted to the Agency and relied upon by the Agency in its decision-making with respect to 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD). It is our intent to investigate these allegations and, if appropriate, evaluate the full range of enforcement options available.

The purpose of this memo is to request that you and your staff refer allegations of scientific misconduct, data fraud or wrongdoing relating to this matter to Ms. Helene Ambrosino, Office of Enforcement, Toxics Litigation Division, FTS 475-9501. Ms. Ambrosino will coordinate with appropriate Agency staff, such as Michael Calhoun, who coordinates criminal investigation requests for OCM. Any questions concerning such allegations should also be referred to Ms. Ambrosino. Please do not initiate contact with Monsanto, BASF or other potential targets of the investigation without direct approval of enforcement personnel. Should these parties initiate contact with you or a member of your staff, please have the call referred to Ms. Ambrosino immediately. Enclosed is EPA Ethics Advisory 90-2 for your

information.

Should members of the public make inquiries about the status of an Agency investigation, it would be appropriate at this time to report the following:

"EPA fully intends to investigate any allegations of fraud and, if appropriate, evaluate the full range of enforcement options available to address legitimate charges of misconduct. It is EPA policy to neither confirm nor deny the existence of a pending criminal investigation, but to the extent that the progress of any civil investigation can be disclosed without compromising the investigation itself, EPA will disclose such information to the public."

Your full cooperation is appreciated. Please distribute this memorandum and the attachment to your staff.

cc: Pat Alberico, Office of Criminal Enforcement
Richard Emory, Office of Criminal Enforcement
John West, NEIC
Mary Adler, Office of Criminal Enforcement
John Kasper, Press Office

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GREENPEACE NEWS

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EMBARGOED UNTIL:
NOVEMBER 29, 1990

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GREENPEACE EXPOSES FRAUD IN INDUSTRY DIOXIN STUDIES; CALLS FOR EPA ACTIONS TO PREVENT DIOXIN POLLUTION

WASHINGTON, DC -- Exposing fraudulent and manipulated science in several key industry studies of dioxin's health effects on humans, the international environmental group Greenpeace will petition the U.S. Environmental Protection Agency (EPA) on Thursday, November 29, to revoke all past decisions based on these studies. The petition also calls on EPA -- based on new evidence showing dioxin to be far more toxic than previously thought -- to implement a national strategy to eliminate major dioxin sources.

Greenpeace will submit the petition to EPA under the authority of the U.S. Toxic Substances Control Act and release it at a 10.00 a.m. news conference at the National Press Club, Lisagor Room, 14th and F Streets N.W., Washington, D.C.

The Greenpeace petition outlines major flaws in the design, conduct and interpretation of key dioxin studies conducted or funded by Monsanto, one of the world's largest chemical companies. The studies, published between 1980 and 1984, were conducted on workers exposed to dioxin during accidents and the routine production of herbicides at Monsanto's plant in Nitro, West Virginia. Scientists, attorneys and EPA whistleblowers have raised concerns about the studies since 1985; the Greenpeace petition contains the most thorough analysis of the studies to date and the first move for official action to discontinue their use in government policy.

Greenpeace analysis of several of the studies shows 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. In some cases, those classifications were contrary to the studies' stated criteria; in others, the criteria were designed specifically to allow exposed workers to be misclassified. Similar concerns have recently been raised about manipulations in a study conducted by the German chemical company BASF on dioxin-exposed workers at one of its European plants.

(more)

The results of the Monsanto and BASF studies have been the basis for claims that not one human death can be attributed to dioxin, and for suggestions that humans are not affected by dioxin in the same manner as laboratory animals. They have also been the basis for arguments against compensation for veterans exposed to Agent Orange in Vietnam.

The fraudulent studies have also played a key role in EPA policy. EPA has considered these studies among the most important epidemiological studies of dioxin and has thus approached dioxin's human toxicity with some skepticism. In recent weeks, EPA's Office of Criminal Investigations has begun an inquiry into Monsanto's conduct in the studies and other dioxin-related issues.

"There is a clear pattern of fraudulent misconduct in the dioxin science performed by the chemical industry and its indentured academics," said Dr. Samuel Epstein, Professor of Occupational and Environmental Medicine at the University of Illinois in Chicago, who supported the Greenpeace petition. He called for professional sanctions against industry and academic scientists who knowingly misrepresent critical public health information.

"The failure of EPA, the Centers for Disease Control and the Veterans Administration to take action on dioxin, despite overwhelming evidence of dioxin's great toxicity in humans and laboratory animals, is unprecedented and unacceptable," Dr. Epstein added.

Dioxin is still considered the most toxic synthetic chemical known to science. Its effects on laboratory animals at the lowest doses ever tested have included several types of cancer, birth defects and developmental abnormalities, reproductive dysfunction, immune suppression, neurological toxicity, and damage to the liver, kidneys and skin. Recent studies of humans exposed to dioxin have shown elevated levels of many of these health effects among workers, soldiers and communities exposed to dioxin in the U.S., Europe and Vietnam.

"In the last few years, study after study has shown that dioxin is even more toxic to humans and animals than previously thought," said Pat Costner, Greenpeace's Research Director. "But EPA, bowing to industry's lobbyists and bogus studies, has refused to take action to prevent the continuing tide of dioxin pollution."

Despite demands from environmentalists, community groups, labor, and the recommendation of many scientists, EPA still has not implemented a strategy to phase-out processes that result in dioxin pollution, such as chlorine bleaching of paper pulp and the incineration of garbage and hazardous waste. Instead, EPA has moved to lower its toxicity estimate for dioxin and is allowing states to weaken their own standards, using industry-funded studies for justification.

On the release date, Greenpeace and communities threatened by dioxin contamination will present the petition at events in California, New York, Missouri, and the Great Lakes Basin.

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Lindenhurst. Anglers may need to beware today because temperatures are expected to drop and clouds will arrive by afternoon.

Monday / David L. Polross

Cats
Season

Company's Dioxin Studies Under Fire

by Carolyn Colwell

IAFF WRITER

A chemical company's studies showing that workers are not being seriously harmed by exposure to dioxin are under fire by Greenpeace and new 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, 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 50 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 allegation that the studies are flawed "a bald-faced lie" that the environmental group is using as part of its fund-raising drive.

Dan 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.

NEWSPAP, TUESDAY, JANUARY 29, 1991

27

The Stars and Stripes

The National Tribune

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NUMBER 49

WASHINGTON, D.C., MONDAY, 10 DECEMBER 1990

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EPA Probing Alleged Manipulation Of Dioxin Health Studies

Washington, DC (UPI)—The Environmental Protection Agency is investigating charges that a chemical company improperly manipulated scientific studies to minimize the possible health threat posed by dioxin, officials confirmed 29 Nov.

Disclosure of the EPA probe came as Greenpeace, the international environmental group, released a report detailing alleged irregularities in studies sponsored by Monsanto Co., a maker of pesticides and other chemical products.

Greenpeace also filed a petition with the EPA urging the agency to tighten its controls on dioxin. The petition maintained the EPA heavily relied on the Monsanto studies in setting its regulatory policies, but agency officials said that was not the case.

The petition cited "credible concerns that the agency's existing (dioxin) human effects data base is polluted by incorrect information, that the human health effects of (dioxin) may be far worse than originally believed, and that the polluted data has led the agency to 'go soft' on (dioxin)."

In its report, Greenpeace said the EPA's Office of Criminal Enforcement had begun preliminary inquiries into possible manipulation of three key dioxin studies sponsored by Monsanto.

Asked about the Greenpeace report, an EPA official who asked not to be identified said: "There is an investigation underway." The official declined to elaborate on the specifics of the investigation.

Glynn Young, a spokesman for Monsanto, said the company had not been notified of any EPA investigation and that it stood by the studies as sound and unbiased. At the same time, he said Monsanto had asked the EPA to review the studies again in light of the allegations.

Young said the allegations against the studies arose from litigation against Monsanto in which Greenpeace was an active participant. He characterized the Greenpeace report as a "rehash" of issues raised in court.

The Monsanto studies have been cited by some scientists in challenging federal policies that generally categorize dioxin as a highly toxic agent to humans.

Those critics say while laboratory animal studies suggest high toxicity, harmful effects have not been verified in exposed humans.

Dioxin is a by-product in the manufacture of certain pesticides and herbicides, most notably Agent Orange, the defoliant widely used during the Vietnam War. It also is generated in incineration and the bleaching of wood pulp for white paper products.

The three Monsanto studies at issue examined health effects among workers at the company's herbicide plant in Nitro, WV, who were exposed to dioxin during routine operations from 1955 to 1977 as well as in a 1949 industrial accident that released larger amounts of the contaminant.

The studies, published from 1980 to 1983, are important because they represent one of the most comprehensive assessments of dioxin's health impact on humans.

The Monsanto studies found no conclusive evidence of serious health effects—such as cancer or liver damage—due to dioxin exposure. As with other studies, the Monsanto reports suggest the only

Purple Heart



Joseph R. Homa, left, national officer of the Purple Heart (MOPH), presents the House Veterans' Affairs Committee's book, "Legacy of the Purple Heart," to a group of veterans.

consistent ailment among exposed workers was chloracne, a severe form of skin lesions.

Among other allegations, the Greenpeace report suggested the Monsanto studies were manipulated in that:

GAO: VA Home Loan Program May Lose \$2.5 Million

By Darin Haugen

A rash of housing foreclosures

million outstanding home loans were being serviced by the program. These loans had an esti-

happened in places like Houston, Oklahoma City and Denver," he added. "Now it looks like the problem is going to move into the Northeast and the Midwest, where a general recession is likely to be

he said.

But now, the program is plunging into the red. The present crisis, the VFW spokesman said, can be blamed on two factors: the souring economy and the Reagan administration-mandated VA divestment from its home loan portfolio in the early 1980s.

Manipulation udies

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key dioxin studies
Monsanto.
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A official who asked
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Purple Heart



Joseph R. Hema, left, national senior vice commander of the Military Order of the Purple Heart (MOPH), presents Rep. Christopher Smith (R-NJ), a member of the House Veterans' Affairs Committee, with a commemorative copy of the MOPH's book, "Legacy of the Purple Heart."

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▲ Disease rates among dioxin-
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workers who supposedly were not
exposed, but actually were. As a
result, the report said, differences
EPA Probing, Pg. 15

an Program

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unding home loans
serviced by the pro-
loans had an esti-
value of \$152 billion—
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was holding \$1.2 bil-
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issued for property
the VA through fore-
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occurred in "energy"
economies were de-
mise their natural re-

happened in places like Houston,
Oklahoma City and Denver," he
added. "Now it looks like the prob-
lem is going to move into the
Northeast and the Midwest, where
a general recession is likely to be
felt most."

While some analysts believe
the program was never intended to
be self-sufficient, others claim the
opposite. It depends on how pro-
gram accounting is calculated, the
House Aide said.

"Basically, the VA home loan
program was never self-sufficient
because the government was issu-
ing money through transfers with
the revolving fund," he said.

A spokesman for the Veterans
of Foreign Wars (VFW) in Wash-

he said.

But now, the program is plum-
meting into the red. The present
crisis, the VFW spokesman said,
can be blamed on two factors: the
souring economy and the Reagan
administration-mandated VA di-
vestment from its home loan por-
tfolio in the early 1980s.

"Without a strong portfolio, the
program became unfit for the diffi-
cult financial times which were on
the way," he said.

A spokesman for the American
Legion concurred.

"The VA home loan program

was sacked by the Reagan admini-
stration, and the fact that it will be
incurring further losses really
comes as no surprise to us."

This notwithstanding, the GAO
report indicated that foreclosures
actually dropped from 49,000 in
Fiscal Year (FY) 1988 to 43,000 in
FY 1989.

"This was the first year the VA
experienced a lessening of home
loan foreclosures since 1980," the
report said.

Some legislative changes were
made in the last session of the
See GAO, Pg. 15

INSIDE

Desert
Shield Cost

Page 3

percent fee from everyone, under new law veterans will be required to pay from zero to 1.875 percent of the home's down payment to receive a loan. This, according to the House Subcommittee staffer, is expected to reduce the number of loan defaults and subsequently reduce foreclosures in the long run.

The law also created "The

ultimately make the older Loan Guarantee Fund still more reliant on congressional appropriations since new loan origination fees will be deposited in the new fund. "While the future losses don't count against us," the House Appropriations aide said, "it means less money will be available for the VA--and the government generally--in the future." *

EPA Probing

From 1

in disease rates between the two groups were muted.

▲ Dioxin-exposed workers were arbitrarily placed into different groups that were studied separately. The groups were so small in number that it became virtually impossible to detect statistically significant increases in disease among exposed workers compared to the unexposed.

▲ Some cases of cancer and heart disease among dioxin-exposed workers inexplicably were excluded from some studies.

Greenpeace said its report, entitled "Science for Sale," was based on independent analysis of the Monsanto studies, internal Monsanto memos and the sworn testimony of Monsanto employees and consultants.

EPA officials said that, as with other chemicals, the agency largely developed its dioxin policies on the basis of laboratory animal studies in which relatively low doses of dioxin caused cancer, birth defects and liver, kidney and nerve damage.

Those health effects have not been observed in studies of Vietnam veterans exposed to Agent Orange nor in forestry workers with long-term occupational exposure to Agent Orange nor in forestry workers with long-term occupational exposure to dioxin-contaminated herbicides.

The EPA has acknowledged the uncertainty about dioxin's impact on human health, but the agency has decided to err on the side of caution and has pushed the paper industry and others to reduce dioxin contamination. *

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landing near her home south of O'Fallon. The home was destroyed by strong winds Tuesday afternoon. Usery and Jene, were not home at the time of the storm. But their parakeet, "Toto," was home, and it survived.

L.T. Spence/Post-Dispatch

Marquette State Park

killed in a weather-
ment in Chicago.
were injured in the
with four remaining
One is John Frer-
a, who was hunting

with friends in a field north of O'Fallon when he was apparently picked up by a strong wind in Tuesday's storm and slammed against trees. He remained in critical condition with head injuries at St. John's Mercy Medical Center late Wednesday.
Only three people suffered minor

injuries in Columbia.

In Illinois, a man from Chicago who died trying to drive through 12-foot-deep water in a closed viaduct Wednesday was the only person killed in a series of storms that battered the state.

See STORM, Page 18

■ **DATABASE WORKERS** were ready for a disaster, executives say..... Page 15A
■ **COLD SNAP** did little damage to plants in the area, horticulturists say..... Page 15A

Britain's New Premier Names Rivals To Cabinet

Compiled From News Services

LONDON — Prime Minister John Major welcomed his defeated rivals into his Cabinet on Wednesday and called for a nation in which all may prosper according to "their talent, their application and their good fortune."

"I don't promise you that it will be easy, and I don't promise you that it will be quick," Major said outside 10 Downing St. after being confirmed as prime minister by Queen Elizabeth II. "If you forgive me," he added, "I

will go into No. 10 straight away and make a start right now."

Major, at 47 the youngest prime minister of the century, had displayed both talent and tenacity in overcoming childhood poverty and rising rapidly through the government.

It was his fortune to be the popular choice of a party torn by rebellion against his patron, Margaret Thatcher.

Hours after saying farewell to her, Major announced a new Cabinet line-

See MAJOR, Page 12

Greenpeace, Chemist Challenge Monsanto On Dioxin Findings

By William H. Frivolgel
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

See DIOXIN, Page 10



David Sterling

■ Ill (right), president of Bel-Aire Insurance Co.; and son leaving the courthouse in Jefferson City where state is seeking receivership of the firm.

■ President Arthur Blumeyer, representative from and the chairman of the Insurance Committee, 12 in federal court for drug dealing. Blumeyer was arrested last year. Bel-Aire funds owned by Thig-

pen in Arizona and Louisiana.

Also disclosed Wednesday:

■ Blumeyer signed a letter that offered to post \$30,000 of Bel-Aire's funds as a personal recognizance bond for Thigpen in U.S. District Court in Cheyenne, Wyo.

Thigpen pleaded guilty Sept. 13 to charges of violating federal law in the process of bribing the Wyoming insurance commissioner.

■ Seven employees were rejoin-

See BEL-AIRE, Page 10

206-456-5021

206-456-5021

Ecology is for life, not just jobs

Nov. 30, 1990

Edmonton Journal

BOGDAN KIPLING

Washington

Not long ago air pollution was blamed on killer trees. Seriously. Former U.S. president Ronald Reagan's chief of staff, Donald Regan, claimed that trees fouled the air. Smokestacks, car exhausts, industrial fumes, he tried to make us believe, have caused no problems. Trees were the villains.

That kind of crazy talk has been muted in the White House though given half a chance John Sununu, President Bush's Donald Regan, would soon revive it. A month ago he failed, by a mere whisker, to kill the Clean Air Act that Canadians hope will clean up acid rain.

Sununu is not alone. Many dinosaurs roam along the Potomac. The struggle for a cleaner environment can never stop because one person's pollution is another person's profit.

For example. Because herbicides are very profitable, chemical industry giants such as Monsanto and BASF now stand accused — not by any court but by a private organization — of promoting scientifically fraudulent studies minimizing dangers associated with their use.

This particularly nasty case involves

dioxin, a byproduct of herbicides, papermaking, waste incineration and several other industrial processes. Dioxin is one of the most toxic synthetic chemicals known to science.

Greenpeace, the aggressive environmental advocacy organization, petitioned the U.S. Environmental Protection Agency on Thursday to "revoke all past decisions based on these studies." Greenpeace says new scientific evidence shows dioxin to be far more toxic to humans than previously thought.

Reputable scientists have disagreed about dioxin for years and are not likely to reach common ground just to please Greenpeace. But corporate profits are not the only reason for the impasse. Scientific reputations are at stake. The U.S. government could be liable for billions of dollars in damages if the courts found that dioxin gave people cancer while federal regulators winked at scientific fraud.

No, the issue of environmental responsibility is not going to be settled. But not all is bleak. People are beginning to realize the economic cost of pollution is too serious to be left to conventional economists.

Slowly but surely, an emerging academic discipline offers some hope. Call it "ecological economy" — a method of factoring

all expected costs into business or policy decisions.

For example, we no longer build smelly pulp mills in cities because it costs too much to clean up. The same logic applies to most business decisions. That's ecological economics.

It is a reasonable assumption that global warming, poisons in ground water, the ozone hole, oil pollution, and acid rain is corrosive — destroying before our eyes architectural jewels such as Prague and Cracow, would not be as severe had the link between the ecology and economics been acknowledged 30 or 50 years ago.

Instead, the John Sununus of the world keep saying: Money is money. If push comes to shove, the White House has and repeatedly, concerns about the economy will top environmental considerations.

But we can wake up even the brain-dead in policy. Rattle them roughly enough until they see that ecological economics can work — that the cost-benefit analysis of any major economic decision must include probable cost of ecological consequences.

With luck national governments everywhere will wake up in time.

Bogdan Kipling is a Canadian freelance writer living in Washington D.C.

From the editorial page
Anne Notnes

Groups attack dioxin studies, ask MPCA to revoke permits

By Diana B. Haddock
Staff Writer

Four environmental groups urged the Massachusetts Pollution Control Agency Thursday to revoke permits that they contend were based on fraudulent studies of dioxin, a toxic chemical waste, by two major chemical manufacturers.

The MPCA permits allow the operation of large chemical plants and the burning of waste at two sites in the state. The groups said the permits should be revoked because the studies were contaminated by "gross errors" and that the studies were conducted in "gross violation" of state law.

and advanced health effects.

The studies were conducted at a site owned by Hooker Corp. of St. Louis and BASF Corp. of New Jersey.

MPCA Commissioner Gerald Wilens said the agency shares their concern about the studies. He said the MPCA had been "grossly misled" by the studies and that the agency was "grossly misled" by the studies.

However, Wilens said the MPCA has not yet decided whether to revoke the permits. He said the agency is "grossly misled" by the studies and that the agency was "grossly misled" by the studies.

based on "grossly misleading" information.

"Our primary concern is to get the studies out of the state," Wilens said. "We are not interested in the results of the studies."

He said yesterday in St. Paul with representatives of the four groups, including the Massachusetts Citizens' Union, the New England Anti-Pollution League, the New England Environmental Action Fund, and the New England Environmental Action Fund.

Massachusetts and Open Water Action are national groups that have been

active in Massachusetts. The Dioxin Study Group was formed to fight the agency's proposal to build a large incinerator, and the Open Water Action Group was formed recently to challenge the agency's proposal to build a large incinerator.

The four groups contend that the studies were "grossly misleading" and that the agency was "grossly misled" by the studies.

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UPI Wire & Journal of Commerce Wire Stories on Monsanto fraud

[Via Greenbase]

[2] 30-Nov-90 0:58 EST

(Editors: Repeating earlier story)

EPA probing alleged manipulation of dioxin health studies
By GEORGE LOBSENZ

WASHINGTON (UPI) - The Environmental Protection Agency is investigating charges that a chemical company improperly manipulated scientific studies to minimize the possible health threat posed by dioxin, officials confirmed.

Disclosure of the EPA probe came as Greenpeace, the international environmental group, released a report Thursday detailing alleged irregularities in studies sponsored by Monsanto Co., a maker of pesticides and other chemical products.

Greenpeace also filed a petition with the EPA urging the agency to tighten its controls on dioxin. The petition maintained the EPA heavily relied on the Monsanto studies in setting its regulatory policies, but agency officials said that was not the case.

The petition cited "credible concerns that the agency's existing (dioxin) human effects data base is polluted by incorrect information, that the human health effects of (dioxin) may be far worse than originally believed, and that the polluted data has led the agency to 'go soft' on (dioxin)."

In its report, Greenpeace said the EPA's Office of Criminal Enforcement had begun preliminary inquiries into possible manipulation of three key dioxin studies sponsored by Monsanto.

Asked about the Greenpeace report, an EPA official who asked not to be identified said: "There is an investigation under way." The official declined to elaborate on the specifics of the investigation. Glynn Young, a spokesman for Monsanto, said the company had not been notified of any EPA investigation and that it stood by the studies as sound and unbiased. At the same time, he said Monsanto had asked the EPA to review the studies again in light of the allegations.

Young said the allegations against the studies arose from litigation against Monsanto in which Greenpeace was an active participant. He characterized the Greenpeace report as a "rehash" of issues raised in court.

The Monsanto studies have been cited by some scientists in challenging federal policies that generally categorize dioxin as a highly toxic agent to humans. Those critics say while laboratory animal studies suggest high toxicity, harmful effects have not been verified in exposed humans.

Dioxin is a by-product in the manufacture of certain pesticides and herbicides, most notably Agent Orange, the defoliant widely used during the Vietnam War. It also is generated in incineration and the bleaching of wood pulp for white paper products.

The three Monsanto studies at issue examined health effects among workers at the company's herbicide plant in Nitro, W.Va., who were exposed to dioxin during routine operations from 1955 to 1977 as well as in a 1949 industrial accident that released larger

amounts of the contaminant.

The studies, published from 1980 to 1983, are important because they represent one of the most comprehensive assessments of dioxin's health impact on humans.

The Monsanto studies found no conclusive evidence of serious health effects - such as cancer or liver damage - due to dioxin exposure. As with other studies, the Monsanto reports suggest the only consistent ailment among exposed workers was chloracne, a severe form of skin lesions.

Among other allegations, the Greenpeace report suggested the Monsanto studies were manipulated in that:

- Disease rates among dioxin-exposed workers were compared with illness in a "control" group of workers who supposedly were not exposed, but actually were. As a result, the report said, differences in disease rates between the two groups were muted.

- Dioxin-exposed workers were arbitrarily placed into different groups that were studied separately. The groups were so small in number that it became virtually impossible to detect statistically significant increases in disease among exposed workers compared to the unexposed.

- Some cases of cancer and heart disease among dioxin-exposed workers inexplicably were excluded from some studies.

Greenpeace said its report, entitled "Science for Sale," was based on independent analysis of the Monsanto studies, internal Monsanto memos and the sworn testimony of Monsanto employees and consultants. EPA officials said that, as with other chemicals, the agency largely developed its dioxin policies on the basis of laboratory animal studies in which relatively low doses of dioxin caused cancer, birth defects and liver, kidney and nerve damage.

Those health effects have not been observed in studies of Vietnam veterans exposed to Agent Orange nor in forestry workers with long-term occupational exposure to dioxin-contaminated herbicides.

The EPA has acknowledged the uncertainty about dioxin's impact on human health, but the agency has decided to err on the side of caution and has pushed the paper industry and others to reduce dioxin contamination.

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Charles Laszewski, "EPA to probe alleged problems with Monsanto dioxin studies; Greenpeace says reports falsified," in "The Journal of Commerce," Pacific Edition, November 30, 1990, pp. 7A.

**EPA to probe alleged problems with Monsanto dioxin studies;
Greenpeace says reports falsified**

The U.S. Environmental Protection Agency confirmed Wednesday it was 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, 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.

Dan Bishop, director of Monsanto corporate communications in St. Louis, said he was unaware of that 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 those 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 either worked routinely with dioxin-contaminated products or were exposed to it through accidents.

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

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

The problem is that industries have used the studies to claim that no deaths have occurred because of dioxin exposure, Mr. Thornton said. Also, the studies have been used to convince EPA not to aggressively ban dioxin from the environment, he said.

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. The result has been constant uncertainty on just how dangerous dioxin, which is now present in most humans, might be to health.

Earlier this year, the Minnesota Pollution Control Agency backed off from a stringent dioxin standard for state rivers and lakes that would have required major changes by paper mills in particular. The agency staff was convinced by testimony produced by Boise Cascade that there was lot of uncertainty about dioxin and the EPA might be re-evaluating its toxicity.

But, Mr. Thornton said, Greenpeace's evidence of false studies, combined with numerous other studies that indicate dioxin may cause heart disease, lymphatic cancers and neurological effects, verifies the animal studies that for years have shown dioxin to be one of the most toxic chemicals known. Even minute amounts have caused cancer in lab animals.

Greenpeace was expected to deliver a petition Thursday to the EPA in Washington demanding that the agency stop relying on the Monsanto studies, revise all policy decisions based on it and establish a national dioxin program to eliminate all major sources of dioxins, Mr. Thornton said. That would require phasing out the use of chlorine in pulp and paper mills, prohibit [sic] chlorine in any form in incinerators and eventually eliminating all uses of pure chlorine in industry, he said.

Mr. Thornton said the Monsanto studies included people who were not routinely exposed to dioxin, which diluted the results. Testimony by the researchers in a Missouri court against Monsanto verified many of the study's problems, he said.

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YANNAcone & YANNAcone

ATTORNEYS

Post Office Drawer 109, Patchogue, NY 11772

Victor J. Yannacone (Dec'd)

Victor John Yannacone, jr.

December 4, 1990

Hon. Jack B. Weinstein
United States District Court
Eastern District of New York
225 Cadman Plaza East
Brooklyn, New York 11201

Dear Judge Weinstein:

Enclosed is a memo from an EPA chemist concerning Monsanto's deliberate falsification of information supplied to the government on dioxin. The information on which the memo is based raises serious questions about some of the comments that have been made in the past challenging the validity of the claims that some of the illness, disease, disability, and death among the Viet Nam combat veterans can be associated with their exposure to Dioxin contaminated herbicides in Viet Nam.

Particularly troubling is the information that there was deliberate falsification or misrepresentation of data concerning the manufacture of 2,4-D, the "other" component of Agent Orange.

In addition, the information on the dioxin contamination of pentachlorophenol, its chemical antecedents and process intermediates vindicates my early concern expressed in the response to the first motions to dismiss the Agent Orange complaints in July 1979.

Unfortunately, the members of the Plaintiff's Management Committee lacked sufficient background in chemical engineering and industrial chemical processes to adequately pursue this line of inquiry during examination of the chemical company witnesses in the later stages of the litigation.

It appears that the several insurance carriers involved in the "Agent Orange" settlement utilized my original apportionment formula developed in 1979 which established the contribution each company made to the overall amount of 2,3,7,8-tetrachloro-dibenzo-p-dioxin to which the troops were exposed in Southeast Asia. By my reckoning, the contributions should have been approximately 30% from Dow and Hercules, and 60% from Monsanto and Diamond Shamrock.

Since it is no longer any secret that settlement negotiations were conducted with Dow representatives in February of 1983, I can tell you that at the time of those settlement negotiations, the nominal demand on behalf of the estimated 25,000 members of the class that we felt were capable of establishing causal relation and substantial special damages was \$2.5 billion. Allowing a substantial discount factor for

YANNAKONE & YANNAKONE

Attorneys and Counselors at Law

settlement and a realistic assessment of the probabilities of success on appeal, we were negotiating with Dow for a settlement in the range of \$100 to \$150 million. Included within that settlement figure was to be some contribution from Hercules.

Although Peter Shuck's book inaccurately reports the substance of these settlement negotiations, it should be reasonably clear that the greed and lack of claims sense manifested by my former colleagues of the Long Island consortium made it impossible to effect a settlement at that time. Nevertheless, it was widely understood that the case against Dow and Hercules would eventually be settled, perhaps on the eve of trial, because Dow and Hercules made relatively uncontaminated 2,4,5-T while Monsanto and Diamond Shamrock not only produced highly contaminated 2,4,5-T, but could be shown to have behaved with bad faith towards the government.

At the time of those negotiations, I was confident that the Viet Nam veterans and their families had a substantial chance of establishing their claim for punitive damages against either or both Monsanto and Diamond Shamrock. I intended to conduct the depositions of both these companies with a view towards establishing their actual knowledge of dioxin contamination of the products they sold and their malevolence in concealing this knowledge first from the Department of Defense and then from other government agencies charged with protecting the public health.

Of critical importance to the ultimate claims of the veterans for benefits under Title 38 was negating the conclusions of the Suskind studies conducted for Monsanto. To that end, I had already established the basis for challenging those studies, but the Plaintiff's Management Committee declined to pursue this line of inquiry.

As you can see from the circulation list, this whistle blower at EPA has apparently become frustrated with the system and widely distributed this document. I have already received a number of calls from veterans and veterans groups demanding to know why we cannot reopen the case against Monsanto and set aside the settlement at least as to that Company.

If the allegations contained in the EPA memorandum are correct, and I have reasonable assurance that they are, then the bad faith manifest by Monsanto should deny them the protection of the settlement negotiated on the eve of trial in 1984. Monsanto should be asked to make a substantial additional contribution to the settlement fund at this time, as should Diamond Shamrock since the fraud perpetrated by Diamond Shamrock is at least as serious and substantial as that of Monsanto.

Recognizing the ease with which Chapter 11 is raised as a means of

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resolving significant liability issues raised by major corporations facing significant liability for toxic torts, I believe that the Agent Orange settlement you fashioned must hold because it represents the only successful way of resolving a mass toxic tort claim as complex as the "Agent Orange" litigation. However, I do not believe that Monsanto and Diamond Shamrock should be allowed to profit from their wrongdoing.

My original estimate was that the combined liability Monsanto and Diamond Shamrock should be approximately \$300 million based on the \$150 million I felt was properly chargeable to Dow and Hercules. I certainly believe that Monsanto has adequate resources to contribute additional funds to the Agent Orange settlement trust provided such contributions are made as originally suggested in my first Agent Orange class action complaint -- from the current earnings of the company together with whatever additional insurance may be available.

As you know, the primary goal of the Viet Nam veterans and their families who brought the "Agent Orange" litigation to this Court as a class action was, as it still is, to obtain the benefits to which they are entitled under Title 38. The assistance available to the veterans in obtaining Title 38 benefits from the VA at the present time is not adequate to meet their needs either in terms of processing the volume of claims or handling the complex medical issues involved. There is only so much that I can do for the veterans on a pro bono basis. The additional funds that could be obtained from Monsanto and eventually Diamond Shamrock could assure the veterans their ultimate right to benefits under Title 38 and do much to complete the healing process that you began when you negotiated the original settlement of the Agent Orange case.

Thank you again for your consideration and concern for the Viet Nam combat veterans and their families.

Very truly yours,

YANNAcone & YANNAcone

Victor John Yannacone, jr.

VJYjr:jp
enc.

NY Times 1/24/91

High Dioxin Levels Linked to Cancer

By WARREN E. LEARY

Special to The New York Times

WASHINGTON, Jan. 23 — A new Federal study suggests that the toxic chemical dioxin causes cancer in people exposed at high levels, but may not pose a substantial risk of cancer at lower levels.

Many Vietnam War veterans are particularly concerned about dioxin because it was a contaminant of Agent Orange, a plant-killing chemical widely used by the United States military during the war.

Soldiers who handled Agent Orange or were accidentally sprayed with it in the field are concerned that the exposures are the cause of cancers and other health problems subsequently found in Vietnam veterans, and they have been lobbying the Government for more compensation for injuries they attribute to the chemical.

The latest study found that industrial workers exposed to much higher levels of dioxin than Vietnam veterans had an increased death rate from cancer, but death from several types of cancers previously linked with the chemical was not significantly increased.

The Largest Workplace Study

The study did find significantly increased mortality from soft-tissue cancers and respiratory cancers in a subgroup of workers that was most exposed to the substance.

A report on the study of 5,172 male workers at 12 plants that produced chemicals contaminated with dioxin is being published in Thursday's issue of The New England Journal of Medicine. It was the largest workplace study ever done involving dioxin.

It included an examination of the death certificates of 1,052 of the workers in the study, and found a small but significant increase in mortality from all cancers combined. Most of the increased cancer mortality was attributed to a group of 1,520 workers who had the highest exposure to dioxin and had worked in the industry for more than 20 years.

Workers in the high-exposure group, who were exposed to 500 times more dioxin than the general public, had a cancer death rate almost 50 percent higher than normal, including greatly increased mortality from a type of cancer called soft-tissue sarcoma and from cancers of the lung and respiratory system.

Risk From High Exposure

Dr. Marilyn A. Fingerhut, an epidemiologist who directed the study, said in a telephone interview that the data strongly suggested that dioxin was a human carcinogen at high-exposure levels.

But she said a study of this type, involving only 5,172 subjects, would not be statistically strong enough to spot certain relatively rare cancers. Death from several cancers previously associated with dioxin exposure, including stomach, liver and nasal cancers and Hodgkin's disease, was not significantly higher than normal in the study, the report said.

Although the study did not confirm findings of previous studies that a number of cancers were associated with dioxin exposure, the researchers said the excess deaths from cancer that it did pick up was probably caused by dioxin. But it is still possible that other factors, like smoking, may have contributed to the excess cancer, they said.

A workplace study finds excess deaths in high exposures.

Dioxin has been a major health concern because studies show it may be the most powerful cancer-causing agent ever tested in laboratory rodents. Dioxin was not a commercial product, but rather, a manufacturing contaminant that found its way into other chemicals, including insecticides.

Results Titled Equivocal

In an editorial accompanying the study, Dr. John C. Bailar 3d of McGill University in Montreal praised the study as well designed and probably the best that could be done. But he said the results, like other studies, are equivocal and likely to be used by people on both sides of the dioxin debate.

"It is conceivable, although by no means certain, that we shall in time converge on a middle position in which dioxin is accepted as a human carcinogen, but one that does not have the extreme potency observed in rodents," he wrote.

Dr. Fingerhut said the Government researchers measured the blood levels of 253 workers for dioxin, which has a long residual life in the body, and found that those who were exposed to the chemical the longest had peak blood levels of 3,600 parts of dioxin per tril-

lion. The average American has a blood level of 7 parts per trillion.

Another group of workers, those who handled dioxin for less than a year, had blood levels of 640 parts per trillion, or 90 times the level of the general public, but the study found their cancer death rate 20 years later to be almost identical to that of the general public. This indicates that the greatest cancer risk from dioxin resides mostly with the highest exposures, Dr. Fingerhut said.

Veterans' Figures Compared

Relating these figures to Vietnam veterans, Government surveys have found that members of the armed forces who handled Agent Orange regularly had mean peak blood levels of about 400 parts per trillion at the time, and that ground troops who were sprayed with the chemical had blood levels of up to 45 parts per trillion.

Dr. Fingerhut declined to relate the results of her study to veterans, but said people could use the data to make their own evaluations.

Dr. Jeanne Stellman, an associate professor of clinical public health at Columbia University, who also is a consultant to the American Legion, was skeptical about attributing any meaning to blood test results because no one knows how present readings relate to actual exposure.

"There is much more we need to know before we can extrapolate these results back to veterans," she said. "But there is enough here, from a policy point of view, to give veterans the benefit of the doubt and attribute some of these cancers to dioxin exposure."

Extensive Study Finds Reduced Dioxin Danger

By Malcolm Gladwell
Washington Post Staff Writer

Dioxin—the chemical that has come to symbolize the dangers of industrial pollution—appears to be less dangerous than previously thought, according to one of the most comprehensive epidemiological studies of the contaminant ever conducted.

Using the health records of 5,000 chemical industry workers exposed to the chemical over the past 40 years, government scientists were able to find a "slight" excess cancer risk only among workers with dioxin levels absorbed by their tissues some 500 times higher than normal.

The results suggest that public concern over the levels of dioxin typically found in the environment may be largely unfounded. It also appears to bolster the growing view of many scientists that U.S. policy toward the chemical, a common byproduct of industrial processes notorious for its presence in the defoliant Agent Orange, are far too strict and that millions of dollars are being wasted in its unnecessary regulation.

"This is very reassuring," said George Carlo, chairman of the Health and Environmental Sciences Group and one of the nation's leading dioxin experts. "Here we have the group of people who have been exposed to higher levels of dioxin than perhaps anyone in the world, followed for a longer period of time than any other study, and it is not bearing out the cancer risk hypothesis. If we were going to see something we would see it here in spades. And we haven't."

The question of dioxin's safety has been a subject of debate among scientists and environmentalists since tests of the chemical on rats and mice in the 1970s showed it to be, for them, a potent carcinogen.

Since that time, however, two developments have led many scientists to revise their earlier opinion of dioxin. The first is an analysis and reinterpretation of the original animal tests, which showed that the conclusions drawn from the data may have been overstated. The second is that repeated studies of people exposed to unusually high levels of dioxin have not confirmed the picture of the chemical painted by the animal tests.

For example, even after years of

monitoring, no appreciable dioxin-linked health effects have been found in Vietnam veterans who came in contact with dioxin contained in the defoliant Agent Orange used in that war.

The study of chemical industry workers, conducted by scientists at the National Institute for Occupational Safety and Health and published in today's issue of the *New England Journal of Medicine*, appears to confirm this view.

After examining medical records of the 5,000 chemical factory workers, the scientists concluded that only those exposed to massive amounts of dioxin suffered any ill effects, and those effects formed only a modest indictment against the chemical.

For example, the average exposure of workers to dioxin was 2.7 years, but the average time they spent working in chemical plants was 12.6 years. This raises the possibility, the researchers said, that dioxin may have been only one of many potentially harmful substances that the workers had come into contact with during their careers. The "study could not completely exclude the possible contribution of other occupational carcinogens or smoking . . .," they said.

This possibility, some experts said, was also suggested by the puzzling pattern in cancers observed among the workers. No increases in liver cancer were found in the group, despite the fact that the liver is the organ known from animal tests to be the primary target of dioxin. What the study did find was an excess in lung cancer, which had not previously been suspected to be a tumor caused by dioxin. The researchers said that it is conceivable that the lung tumors were caused by the exposure of some workers to asbestos or smoking.

Despite the study's qualifications, however, many dioxin experts welcomed it as providing the first definitive evidence that risk from the chemical is linked to the amount of exposure.

The study found increased cancer risk only among the about 1,500 workers who had what are estimated to be the highest exposure levels in history—500 times the norm. No increased risk, by contrast, was found among the other 3,500 workers even though they had, on average, dioxin levels 90 times higher than normal.

DIOXINS OF OMISSION

LAST THURSDAY, THE international environmental group Greenpeace released the most extensive report to date on fraudulent dioxin health-effects studies conducted by two of the world's largest chemical companies, Monsanto and BASF. Greenpeace also called on the U.S. Environmental Protection Agency to revoke any past dioxin decisions based on the information provided by the two companies.

"It's a pattern of manipulation," said Greenpeace Research Analyst Joe Thornton. "The harm done by Monsanto's dioxin pollution is incalculable."

From 1980 to 1984, Monsanto and BASF conducted health studies on workers exposed to dioxin during accidents and the routine production of herbicides at plants in West Virginia and Ludwigshafen, West Germany. The Greenpeace report outlines how the two companies shifted dozens of workers with cancer and heart disease to unexposed control groups or excluded them from the studies altogether. When the workers are returned to their normal control groups, the Greenpeace report said, the data clearly indicates greater levels of disease among dioxin-exposed workers. (Monsanto also has neglected to report dioxin contamination of Lysol, the widely used disinfectant that it produces.)

Various scientists and EPA whistleblowers have raised concerns about the Monsanto studies since 1985. Monsanto's misconduct officially became public last year, when a West Virginia community won \$16 million in punitive damages from the chemical producer. But the EPA has apparently been left in the dust. (A SHOULD READ SURGEON, MO)

"EPA has been asleep at the wheel," said Thornton. "This perception [created by the studies] that humans are somehow immune to dioxin has stopped the agency from phasing it out. It's almost like they have a pro-dioxin policy."

The EPA presently regards information connecting dioxin exposure with cancer and heart disease as "inconclusive." EPA spokeswoman Gwen Brown said last week that the agency's dioxin policies were not influenced by the Monsanto studies, but Dr. Cate Jenkins, a chemist in the EPA's Regulatory Development Branch and an EPA whistleblower, disagreed.

"Monsanto has in fact submitted false information to EPA, which directly resulted in weakened regulations..." Jenkins wrote in a Nov. 15 memo to the EPA's Office of Criminal Investigations, which is probing the Monsanto studies. "In addition, Monsanto's failure to report dioxin contamination of the disinfectant in Lysol has prevented any ban or other limitation of human exposures to dioxins in its product."

Although EPA's criminal investigation of Monsanto has been going on for several weeks, Thornton said Greenpeace is not as concerned about punishing the company as it is about eliminating dioxin pollution.

"The EPA is discoing around," he said. "What we want is not a new risk assessment on dioxin, we want a prevention program."

—Mike Goudreau

NEWSBITES

PESTICIDE CONTROL: If the New York Coalition for Alternatives to Pesticides and more than a dozen public-interest groups get their wish, pesticide users and dealers in the state will be regulated more heavily by the Department of Environmental Conservation without additional cost to the government. In a letter expected to be sent to DEC Commissioner Thomas Jorling and Gov. Mario M. Cuomo today (Thursday), the groups are calling for a 1 percent "green tax" on gross pesticide sales in New York state.

The state has not increased fees for the registering of pesticide products for sale since 1978, and attempts at new legislation have failed for the last five years. The resulting small revenues have allowed DEC to perform only about 1,000 inspections a year when the state has more than 30,000 licensed applicators and tens of thousands more commercial applicators who need not be licensed. Some 13,000 pesticide products are registered for sale in New York. Tracy Frisch, coordinator of NYCAP, called the green tax "a fresh approach," adding that DEC had "high-level discussions" on the tax during the summer.

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Write: Letters

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