



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

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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

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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. _____ is one known example, who testified on behalf of Monsanto and probably other industrial defendants. An ongoing case where Dr. _____ 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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