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

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

MEMORANDUM

DATE: November 15, 1990

SUBJECT: Criminal Investigation of Monsanto Corporation
- Cover-up of Dioxin Contamination in Products
- Falsification of Dioxin Health Studies

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As per our meeting yesterday, I am summarizing information available to me supporting allegations of a long pattern of fraud by Monsanto Corporation. The fraud concerns 2,3,7,8-tetrachlorodibenzodioxin (dioxin) contamination of a wide range of Monsanto Corporation products, as well as health studies of Monsanto's dioxin-exposed workers. You indicated that you would contact me regarding the specific documents which would be useful to your investigation.

SIGNIFICANCE OF MONSANTO'S DIOXIN FRAUD

You stated that pursuing a criminal prosecution against Monsanto would require a prior determination of the significance of the fraud. In order for proceedings to be initiated by EPA, the fraud would need to have affected the regulatory process at EPA, and Monsanto would not have knowing submitted the falsified data and health studies to

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EPA in order to affect the regulatory process.

Monsanto has in fact submitted false information to EPA, which directly resulted in weakened regulations under RCRA and FIFRA, since these regulations do not take into account tetrachlorinated dioxin contamination in tri-, tetra-, and pentachlorophenols, as well as 2,4-dichlorophenol and its phenoxy acetate (2,4-D, a currently used herbicide). In addition, Monsanto's failure to report dioxin contamination of the disinfectant in Lysol® has prevented any ban or other alleviation of human exposures to dioxins in this product.

The Monsanto human health studies have been submitted to EPA by Monsanto as part of public comments on proposed dioxin rules and Agency-wide dioxin risk assessments by the Office of Research and Development. These Monsanto health studies are continually relied upon by all offices of EPA to conclude that dioxins have not caused cancer or other health effects (other than chloracne) in humans. Thus, dioxin has been given a lesser carcinogenic potential ranking, which continues to be the basis of less stringent regulations and lesser degrees of environmental controls. The Monsanto studies in question have also been a key basis for denying compensation to Vietnam Veterans exposed to Agent Orange and their children suffering birth defects from such parental exposures.[1]

Monsanto would not be able to support a claim that independent researchers were responsible for the falsifications, because Monsanto personnel compiled all data utilized by these researchers. In addition, the National Institute of Environmental Health Sciences partially funded one of the Monsanto studies in question, providing a basis for charges of the fraudulent use of governmental funds.

DIOXIN CONTAMINATION OF MONSANTO PRODUCTS

Monsanto covered-up the dioxin contamination of a wide range of its products. Monsanto either failed to report contamination, substituted false information purporting to show no contamination, or submitted samples to the government for analysis which had been specially prepared so that dioxin contamination did not exist.

The earliest known efforts by Monsanto to cover-up dioxin contamination of its products involved the herbicide used in Vietnam, Agent Orange (2,4,5-trichlorophenoxy acetate, 2,4,5-T). Available internal Monsanto correspondence in the 1960's shows a knowledge of this contamination, and the fact that the dioxin contaminant was responsible for

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[1] The American Medical Association, concerned about the veracity of one of the Monsanto studies published in its journal, stated that a reassessment would be undertaken if the outcome of appeal of the [redacted] v. Monsanto litigation did not reverse the verdict impugning the credibility of the [redacted]to studies.

kidney and liver damage, as well as the skin condition chloracne.[2]

Early internal Monsanto documents reveal that samples of 2,4,5-T and other chlorinated herbicides and chlorophenols submitted to the U.S. Department of Agriculture in the 1970s were "doctored." In other words, highly contaminated samples were not submitted to the government, and Monsanto samples of penta, tetra-, tri-, dichlorophenol, and associated herbicides never contained tetrachlorinated dioxins. These analyses were subsequently adopted by EPA in a 1980 publication, and were used without any data from other sources as the basis for 1984 regulations under RCRA. As a result, these regulations do not control the chlorophenol/phenoxy acetate products as acutely hazardous due to their contamination of tetrachlorinated dioxins.

Monsanto also submitted assertions to EPA that process chemistry would preclude the formation of tetrachlorinated dioxins in any chlorophenolic product other that 2,4,5-tetrachlorophenol or its phenoxy acetate. Evidence from the Kemner v. Monsanto proceedings revealed that the process chemistry claimed by Monsanto was not always used. In fact, off-specification dichlorophenol, known to be contaminated with tetrachlorinated dioxin, was being used as a feedstock to make pentachlorophenol and other chlorinated products. The result of this alternate synthesis route is the introduction of dioxins as a contaminants. EPA also relied on these "process chemistry" arguments by Monsanto as a basis for not regulating most chlorophenols and 2,4-D for their tetrachlorinated dioxin content.

Another Monsanto document introduced as evidence in the above proceedings shows cross-contamination of a range of Monsanto products with tetrachlorinated dioxins by the following mechanism: The same production equipment is used without cleaning for all chlorinated phenolic products. In 1984, when promulgating the dioxin regulations under RCRA, EPA was only made aware of the cross contamination problem in the event that 2,4-D was made on equipment previously used to make 2,4,5-T. Thus, EPA again was subverted from promulgating adequate regulations for products other than 2,4-D that were cross-contaminated with dioxins.

Members of the Canadian Parliament recently directed investigations by the Royal Canadian Mounted Police and government scientist into the dioxin contamination of disinfectants such as Lysol®, containing Monsanto's Santophen® (ortho-dichloro-para-phenyl phenol), and directed laboratory analyses of existing stocks. This disinfectant uses the ortho-dichlorophenol, discussed above, as a feedstock, which would introduce any dioxins present into the disinfectant. In a 1984 letter to the Canadian government, Monsanto asserted that their disinfectant contained no dioxin. This was later refuted by testimony by Monsanto's chemist.

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[2] You indicated that NEIC would be reticent to receive documents of this nature suspected to be under a court protective order, but assured me that you would pursue legal routes to obtain them independently.

FRAUDULENT DIOXIN HEALTH STUDIES

As you indicated today, demonstrating criminal fraud in the epidemiological studies performed by Monsanto on its dioxin-exposed workers would necessitate bringing in appropriate groups in EPA capable of performing scientific study audits.[3] You indicated, however, that NEIC did not believe this would be a barrier to the investigation. The following are a few key instances where obvious fraud was utilized in the conduct of these studies:

Dr. Raymond Suskind at the University of Cincinnati was hired by Monsanto to study the workers at Monsanto's Nitro, West Virginia plant. Dr. Suskind stated in published studies in question that chloracne, a skin condition, was the prime indicator of high human dioxin exposures, and no other health effects would be observed in the absence of this condition. Unpublished studies by Suskind, however, indicate the fallacy of this statement. No workers except those having chloracne were ever examined by Suskind or included in his study. In other words, if no workers without chloracne were ever examined for other health effects, there is no basis for asserting that chloracne was "the hallmark of dioxin intoxication."[4] These conclusions have been repeatedly utilized by EPA, the Veterans Administration, etc., to deny any causation by dioxin of health effects of exposed citizens, if these persons did not exhibit chloracne.

The results of Dr. Suskind's studies also were diluted by the fact that the exposed group contained not only individuals having chloracne (a genuine, but not the only effect of dioxin exposure), but also all workers having any type of skin condition, such as a chemical rash. The workers could have had no or negligible dioxin exposures, but they were included in the study as part of the heavily exposed group. This fact was revealed only by the careful reading of the published Suskind study.[5] Further, Dr. Suskind utilized statistics on the skin conditions of workers compiled by a Monsanto clerical

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[3] You should be cautioned regarding any consultation with Dr. Renate Kimbrough at EPA regarding the review of the Monsanto studies. Dr. Kimbrough was contacted by Monsanto during the Kemner v. Monsanto litigation, and provided expert testimony, while an employee of the Centers for Disease Control, on behalf of Monsanto. Dr. Kimbrough has provided expert testimony on behalf of other defendant corporations responsible for dioxin pollution, even co-authoring papers with these defendants.

[4] Suskind examined only one worker without chloracne (Mr. Kiley), and dismissed this individual's health complaints as being those of a complainer.

[5] Later studies by the Centers for Disease Control have demonstrated that any manifestation of chloracne in humans is not correlated with the blood dioxin levels. In other words, individuals with lower blood dioxin have been observed to develop chloracne, while those with higher blood levels did not.

worker, without any independent verification.[6]

Dr. Suskind also covered-up the documented neurological damage from dioxin exposures. At Workers Compensation hearings, Suskind denied that the workers experienced any neurological health effects. In the Kemmner, et al. v. Monsanto proceedings, however, it was revealed that Suskind had in his possession at the time examinations of the workers by Monsanto's physician, Dr. Nestman, documenting neurological health effects. In his later published study, Dr. Suskind denied the continuing documented neurological health effects suffered by the workers, falsely stating that symptoms "had cleared."

All of the Monsanto dioxin studies also suffer another fatal flaw. The purported "dioxin unexposed" control group was selected from other workers at the same Monsanto plant. An earlier court settlement revealed not only that these supposedly unexposed workers were exposed to dioxins, but also to other carcinogens. One of these carcinogens, para-amino biphenyl, was known by Monsanto to be a human carcinogen, and it was also known that workers were heavily exposed.

Another Monsanto study involved independent medical examinations of surviving employees by Monsanto physicians. Several hundred former Monsanto employees were too ill to travel to participate in the study. Monsanto refused to use the attending physicians reports of the illness as part of their study, saying that it would introduce inconsistencies. Thus, any critically ill dioxin-exposed workers with cancers such as Non-Hodgkins lymphoma (associated with dioxin exposures), were conveniently excluded from the Monsanto study.

There are numerous other flaws in the Monsanto health studies. Each of these misrepresentations and falsifications always served to negate any conclusions of adverse health effects from dioxins. A careful audit of these studies by EPA's epidemiological scientists should be obtained as part of your investigation.

The false conclusions contained in the Monsanto studies have recently been refuted by the findings of a recent study by the National Institute of Occupation Safety and Health (NIOSH). This NIOSH study, recently circulated by Dr. Marilyn Fingerhut for review, found a statistically significant increase in cancers at all sites in the Monsanto workers, when dioxin exposed workers at Monsanto and other industrial locations were examined as an aggregate group.[7]

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[6] The deposition of Ms. Jan Young of Monsanto, previously under a protective order, is in the process of release pursuant to a motion by Greenpeace, USA.

[7] This NIOSH study does have an inherent design weakness that would diminish the capability of detecting excess cancers. This is because Monsanto and the other dioxin-producing companies were allowed to independently select the group of dioxin-exposed workers to be studied by NIOSH.

Please do not hesitate to contact me regarding documents to support your investigation, which include testimony and evidentiary documents from the ongoing Kemner v. Monsanto litigation, earlier litigation in West Virginia brought by the Monsanto workers, ongoing investigations by the Canadian government, internal Monsanto documents, as well as documentation of the submission of the fraudulent data and studies by Monsanto to support the rulemaking process under RCRA and other EPA authorities.

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