

STURGEON LITIGATION

FROM THE FILES OF D. Bishop

THIS FILE HAS BEEN REVIEWED BY LINDA SHAPIRO

FOR:

- Documents describing the presence or potential presence of dioxin in Monsanto products.
- Documents referring to the toxicity of any Isomer of dioxins.
- Documents referring to the toxicity of any Chlorophenol or Chlorophenol product.
- Documents referring to health effects as they relate to the above.

DATE 4/22/85

Monsanto

FROM : D. R. Bishop - F3EE - 4-2891
ME-LOCATION-PHONE

DATE : August 17, 1983

cc. R. T. Berendt - E2ND
J. F. Hussey - F3EA
J. T. Nolan - D1A
M. C. Throdahl - D1D

SUBJECT :

REFERENCE :

TO : T. M. Bistline - E2ND
W. J. McCarville - G3WG
G. Roush - G2WG

Please review the enclosed draft which is intended to replace our current, March, 1980 Agent Orange backgrounder, also enclosed.

The 1980 version served us well but it has become quite dated and, with the trial anticipated to get underway as early as next summer, now is the time to replace it.

I'd appreciate any comments/suggestions within the next week or so.

Thanks for your prompt attention.

DRB
Dan R. Bishop

DRB:ec

Attachments

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AGENT ORANGE

Background

"Agent Orange" was a U.S. Government code name for one of a number of herbicide mixtures used by the U.S. military during the Vietnam War to strip trees and brush of their foliage, thereby denying the enemy cover and concealment. The use of this defoliant during the war has been credited with saving the lives of thousands of U.S. military personnel.⁽¹⁾ Agent Orange has become a highly emotional public issue as a result of charges made by various Vietnam veterans' organizations alleging that many servicemen and their families are suffering adverse health effects from exposure to Agent Orange while in Vietnam.

Lawsuits filed on behalf of Vietnam veterans against companies that produced Agent Orange for the U.S. Government seek to create a special trust fund, administered by the courts and financed by Agent Orange producers, to compensate the alleged victims.

Monsanto Company of St. Louis, Mo., was one of the companies that produced Agent Orange for the U.S. Government, and is one of the defendants in these suits.

What Are The Facts?

Agent Orange was a 50-50 mixture of two phenoxy herbicides, 2,4-D and 2,4,5-T. The Agent Orange controversy and the alleged health effects claims center on the fact that the herbicide, 2,4,5-T, can contain miniscule amounts of a toxic chemical contaminant which is commonly, albeit imprecisely, referred to as "dioxin."

This unwanted, altogether useless contaminant is actually but one of 75 compounds which together comprise a family of chemical isomers known as

007345

the dibenzo-p-dioxins, all chemically linked by the presence of chlorine atoms. The majority of these dioxin isomers are of no major health concern -- some are even relatively benign.

Of the 75 chlorinated dioxin compounds, there are 22 possible tetrachloro or TCDD isomers of which 2,3,7,8 TCDD is only one. This particular isomer can be unintentionally formed in miniscule amounts as an unwanted contaminant during the manufacture of certain pesticides, including the phenoxy herbicide, 2,4,5-T, and other chlorinated organic chemical compounds. It is extremely toxic to some laboratory animals, less toxic to others, and is of unknown toxicity to humans.

While it is technically incorrect to use the generic term dioxin when referring to the specific isomer 2,3,7,8 TCDD, we will reluctantly do so in this discussion for the sake of both brevity and clarity.

The herbicides 2,4-D and 2,4,5-T, have been used for about 40 years in this country and abroad for crop protection and forest and range management. Their efficacy and economic benefits in controlling weeds and underbrush are well documented.

They are registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and their use is currently regulated by the U.S. Environmental Protection Agency (EPA).

Registration requires producers to include on all labels certain basic information, including the chemical makeup of the formulations, recommended application rates, and all appropriate cautions and warnings.

Monsanto Involvement

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Monsanto Company manufactured 2,4,5-T at its Nitro, W. Va., plant from 1948 until 1969 and made 2,4-D at its William G. Krummrich Plant in Sauget, Ill., (near East St. Louis) from 1946 until 1970.

007346

As one of several U.S. producers of commercial blends of these herbicides, Monsanto was sought out by the federal government and asked to supply a specific mixture. We made Agent Orange at the government's request and formulated to government specifications. The government did not seek our advice on the appropriateness of its plans nor did it tell us how or in what concentrations it intended to use the herbicide mixture. Agent Orange was applied by military personnel, under order of the government, and used in war situations...utterly beyond our control as one of the manufacturers.

During the years that Monsanto made Agent Orange for the government, it represented a very small share of Monsanto's sales volume, about .002 percent.

The only markings Monsanto was permitted to place on the containers, according to the contract, were a contract number, a batch number and an orange-colored band -- thus the name "Agent Orange." Under further terms of the contract, the government took title and possession of the material at our plant. It, in turn, shipped the material within and outside the U.S. under government bills of lading. Since Monsanto had no registered label for this specific mixture, the company would have been in violation of FIFRA regulations had it attempted to ship Agent Orange in interstate commerce.

Monsanto was not a basic producer of the raw material, tetra-chloro-benzene, which is used as a starting point in the manufacture of 2,4,5-T. During the Vietnam War, this raw material and others were classified as government priority items. In order to get raw materials in this classification, purchasers were required to obtain "certificates of necessity" from the government. Thus, Monsanto was permitted to purchase only those specific quantities of tetrachlorobenzene needed to fulfill its government contracts for Agent Orange.

During the period, Monsanto was forced to surrender its share of the commercial 2,4,5-T market to competitors who were basic in the raw material. As the war wound down, the company elected, for economic reasons, to shut down the 2,4,5-T unit and get out of the business.

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007347

Human Health Effects from Herbicidal Exposure

The EPA issued an emergency suspension order in March of 1979, preventing some further uses of the herbicide 2,4,5-T. Highly questionable findings from a study which reported an increased number of spontaneous abortions among Oregon women, referred to as the "Alsea II Study," formed the basis for the suspension order. This study was subsequently discredited by at least five independent scientific groups. (2)(3)(4)(5)(6)

In the fall of 1979, EPA's own independent scientific advisory panel advised against banning the remaining uses of the herbicide, citing a lack of evidence linking exposure to adverse human health or environmental effects. (7) The long history of safe use of 2,4,5-T suggests that the dioxin contaminant in the herbicide is well below levels considered potentially hazardous to humans or other living organisms. (8)

Simply stated, the controversy surrounding Agent Orange continues despite the lack of virtually any conclusive scientific evidence to show that this herbicide posed a danger to the veterans. To the contrary, there is a growing and substantial body of scientific and medical evidence on the record, (9)(10)(11)(12)(13)(14)(15)(16)(17)(18) which indicates there is no link between Agent Orange and the long-term health problems claimed by some Vietnam veterans.

Industrial Accidents Involving Exposure To Dioxin

Information on acute and chronic toxicity to humans is being gathered from detailed epidemiology studies of populations exposed to dioxin as a result of industrial accidents. The two most significant and most extensively studied occurred in Seveso, Italy, and Nitro, W.Va.

• Seveso, Italy, July, 1976

The most recent and massive human exposure occurred in Seveso, Italy. An explosion at a chemical plant there spread dioxin -- as a contaminant of the chemical tri-chloro-phenol -- over several hundred acres near the

CONFIDENTIAL

007348

plant. Estimates as to just how much dioxin was dispersed vary from less than one to several kilograms.

Based on projections of acute toxicity from animal studies, the release of even one kilogram should have killed every human being within miles. Indeed, much was written following the Seveso incident forecasting doom and horror of this magnitude. But the only reports of adverse health effects to date are cases of chloracne⁽¹⁹⁾ (a skin condition commonly associated with exposure to dioxin). Thus, it appears that dioxin on an acute (short term) basis is much less toxic to humans than to most species of laboratory animals.

While some researchers classify dioxin as an animal teratogen (a material that causes birth abnormalities), the human experience at Seveso so far has not proved this. Extensive data from Italian health officials and the World Health Organization (WHO) gave absolutely no indication of increases in birth defects, abortion, or other teratogenic effects that could be correlated with the Seveso exposure.⁽²⁰⁾⁽²¹⁾

• Nitro, W.Va. -- March, 1949

The first recorded and widely documented incident of dioxin exposure to a relatively large population occurred during a similar but much smaller industrial accident at Monsanto Company's Nitro, W.Va. manufacturing plant.

On March 8, 1949, about six months after production startup, a violent reaction and decomposition occurred in one of the production steps when temperature and pressure within an autoclave became excessive. The relief valve opened and the fumes and residues from the decomposed contents of the autoclave (1,2,4,5-tetrachlorobenzene, sodium hydroxide and methanol) were discharged into the atmosphere and the interior of the building.

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007349

Some 121 employees who either worked in the area or were subsequently involved in the cleanup operation began to develop symptoms immediately following exposure to the discharged materials which are now associated with high peak exposure to dioxin. (Dioxin was first identified, chemically, by German scientists in 1957, but Monsanto's awareness of this dates to the mid-1960s.) The symptoms most frequently observed included a skin condition known as chloracne, eye and respiratory tract irritation, headache, dizziness, nausea, muscle discomfort and liver disorder. All symptoms -- except some cases of residual chloracne -- gradually disappeared. (22)

All affected employees received immediate medical treatment at company expense and those requiring special treatment were referred to outside medical experts, again at company expense. The incident and the health effects observed were reported to the U.S. Public Health Service and the West Virginia State Health Department and both agencies were invited to participate in the followup investigation.

• Nitro Mortality Experience

In 1979, a standardized mortality analysis (study of the cause of death) was conducted on the 32 workers (from this group of 121) who have since died from any and all causes. This medical study, coauthored by Judith A. Zack, a Monsanto epidemiologist, and Raymond R. Suskind, M.D., a recognized expert on the health effects of exposure to dioxin and Director of the Department of Environmental Health at the University of Cincinnati Medical Center, was published in the January, 1980 issue of THE JOURNAL OF OCCUPATIONAL MEDICINE (volume 22, No. 2, pp. 11-14). (22) It is the first long-term study of a group of workers known to have been exposed to relatively high levels of dioxin. The study found no apparent excess in deaths from cancer or cardiovascular disease based on standard cause of death statistics for the U.S. population as a whole. The study also concluded that the 32 deaths were less than would be expected, based on standard U.S. death rate statistics.

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The Nitro Plant mortality analysis has provided important, definitive information on the probability of long-term human health effects from exposure to dioxin. All 121 people who suffered acute effects as a result of the incident were successfully traced through records, thus a complete followup was achieved.

Acute health effects of dioxin exposure are described in the literature,⁽²²⁾ but until recently little was known regarding chronic (or long-term) effects. Thus, the Nitro analysis was particularly significant in that it uncovered no apparent excess of total deaths or deaths from major chronic diseases (cancer or circulatory system) in a controlled and well-identified group of workers known to have experienced a high peak exposure to dioxin and then tracked over a period of nearly 30 years.

In 1980, a follow-up mortality study⁽²³⁾ was done to determine the cause of death of Monsanto employees who had been involved in 2,4,5,-T production at the Nitro plant for one or more years between 1955 and 1977. The results of this investigation, coauthored by Monsanto epidemiologists, Judith A. Zack and William R. Gaffey, also found no apparent relationship between workplace exposure to dioxin and death.

• Nitro Epidemiology Study

Altogether some 400 Monsanto employees worked in the 2,4,5-T production unit (and thus are presumed to have been exposed to some level of dioxin) at one time or another during the 21 years that the Nitro Plant manufactured this herbicide. Other than chloracne, no adverse long-term health effects were ever observed in this group of workers.

This notwithstanding, in mid-1978 Monsanto elected to fund a very thorough epidemiology study of all former 2,4,5-T workers for very specific reasons:

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007351

First, we felt we owed our employees and ourselves the most complete health evaluation possible using modern medical techniques.

Second, this Nitro Plant work group, exposed to 2,4,5-T for sustained periods of time 10 to 30 years ago, represented the best opportunity thus far, anywhere in the world, to study the chronic effects, if any, of exposure to dioxin.

Third, in view of the growing worldwide concern regarding potential human health effects of exposure to dioxin -- fueled by the industrial accident in Seveso, and more recently the Agent Orange controversy -- we felt this study could provide meaningful medical information to help ease the anxieties of those who may have been exposed to dioxin and now fear the worst.

This very comprehensive, independent epidemiology investigation of the Nitro work force is in the process of being finalized by Raymond A. Suskind, M.D., and his medical team at the University of Cincinnati's Department of Environmental Health. This morbidity study involves present and former employees -- still living -- and focuses on current health status. Based on preliminary findings, as reviewed by Dr. Suskind with the plant work force and reported in November of 1982,⁽²⁴⁾ the study found no evidence that would associate exposure to 2,4,5,-T or dioxin with chronic human health effects, other than the skin disease, chloracne.

Thus, Monsanto's Nitro Plant employees have become one of the most medically studied industrial populations in the world. The consistent findings of these investigations clearly document that chloracne is the only significant long-term health effect that this work force has experienced from exposure to dioxin.

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007052

The Agent Orange Trial

The Agent Orange trial, which could begin sometime in 1984, is being presided over by U.S. District Judge George Pratt, Jr. in federal court in Uniondale, N.Y. The trial will address three complex and very specific questions: 1) The so-called government contract defense issue, i.e., did the government know at least as much about the characteristics of Agent Orange as did the manufacturers and did the product supplied to the government meet the product specifications stipulated?; 2) causation, i.e., were the plaintiffs harmed by the product? and 3) liability, i.e., can the companies who produced the product be held liable for alleged ill effects?

Summary

Agent Orange is a complex, highly charged, emotional issue which, from time-to-time is further complicated by the release of information which can be unfairly interpreted out of context. Monsanto continues to believe the court, not the news media, is the proper forum for trying the Agent Orange lawsuit.

Obviously, this conflict is not of our making. However, having been drawn into it, we have no alternative but to defend ourselves. We are confident that good science will ultimately prevail over the emotions of the moment and exonerate the producers of Agent Orange. At the same time, we sincerely hope that good science will also provide many of the answers the Vietnam veterans seek regarding possible service-related health problems.

-oOo-

August, 1983
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CONFIDENTIAL

007353

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8. Council for Agricultural Science and Technology, Aug., 1978. The Phenoxy Herbicides, Second Edition, Report No. 77, p.22.
9. A review of the medical evidence regarding the long-term health effects of Agent Orange and dioxin contaminants, conducted by the American Medical Association's Council on Scientific Affairs and published in the Oct. 15, 1982 issue of the Journal of the American Medical Association (JAMA).
10. A report on "The Toxicity, Environmental Fate and Human Risk of Herbicide Orange and its Associated Dioxin," issued by the USAF Occupational and Environmental Health Laboratory, Brooks AFB, Tex. Report No. USAF OEHL-78-92, October, 1978.
11. An investigation of health effects in U.S. Air Force Personnel ("Ranch Hand Study") following exposure to Herbicide Orange: A Baseline Mortality Assessment, USAF School of Aerospace Medicine, San Antonio, Tex., July, 1983.
12. World Health Organization studies done to date on the human population exposed to high levels of dioxin during an industrial accident in Seveso, Italy in 1976.

CONFIDENTIAL
037354

13. Special review of the latest evidence on the safety of phenoxy herbicides, including 2,4,5-T, by R. Kilpatrick, et al., the Advisory Committee on Pesticides, Ministry of Agriculture, Fisheries and Food, United Kingdom, December, 1982.
14. A study of long-term health effect of occupational exposure to 2,4,5-T and its dioxin contaminants, conducted by Raymond A. Suskind, M.D., University of Cincinnati. The study examined the current health status of 254 present and former Monsanto employees who had worked in the 2,4,5-T production unit at the company's Nitro, W.Va., plant between 1948 and 1969 compared to the status of a control group of 163 employees who worked in other areas of the plant during the same time frame. The results were presented at the "Third International Symposium on Chlorinated Dioxins and Related Compounds," at Salzburg, Austria, Oct. 14, 1982.
15. Two recently completed mortality (cause of death) studies on groups of former Monsanto employees who had worked with 2,4,5-T since 1948. One group experienced high peak exposure over 30 years ago.
16. A survey of 126 workers, 10 years after exposure to dioxin following a 1968 explosion at the Coalite Oil and Chemicals' 2,4,5-T manufacturing plant at Boleover, Derbyshire, U.K. Survey presented at the "Third International Symposium on Chlorinated Dioxins and Related Compounds" at Salzburg, Austria, Oct. 14, 1982.
17. A Dow Chemical study of health effects to the offspring of production workers exposed to 2,4,5-T and its dioxin contaminants, and the pregnancy risk to their wives, reported in Chemical & Engineering News, Jan. 5, 1981.
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23. Monsanto Company news release, Oct. 9, 1980: "Study Fails to Link Agent Orange to Deaths of Industrial Workers."
24. Monsanto Company news release, Nov. 10, 1982: "Report Fails to Find Link Between 2,4,5-T Exposure and Human Health Problems."

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007355