

CONFIDENTIAL

SUBJECT TO PROTECTIVE ORDER.

Monsanto News Backgrounder

MARCH 17, 1980

MONSANTO COMPANY ST. LOUIS, MO.

Agent Orange . . . What are the facts?

Monsanto Company Perspective

004508

Monsanto is involved in numerous lawsuits over its role as one of the companies that supplied the defoliant "Agent Orange" to the U.S. military during the Vietnam War. The company is often asked where it stands on this highly charged, emotional issue. Simply stated, it is Monsanto's position that the available scientific and medical evidence does not support the

claims of adverse health effects alleged in the lawsuits. This White Paper discusses the subject in considerable detail. For more information contact D. R. Bishop, Director, Environmental Communications, Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, Mo. 63166. Telephone: (314) 694-2891.

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. Agent Orange has become a highly emotional public issue in recent months 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?

The principal ingredients of Agent Orange are two phenoxy herbicides, 2,4-D and 2,4,5-T. The concern is with the 2,4,5-T which can contain miniscule amounts of the toxic chemical 2,3,7,8 tetra-chloro-dibenzo-p-dioxin (or TCDD).

This unwanted contaminant is but one of some 72 compounds which together form a family of toxic chemical impurities commonly referred to by the news media as "dioxin." While it is technically incorrect to use the generic term dioxin when referring to a specific compound like TCDD, we will do so in this paper for the sake of brevity. Dioxin can be formed in ultra-trace quantities during the manufacture of tri-chloro-phenol, which is used to make 2,4,5-T. The Agent Orange controversy centers on dioxin, which is extremely toxic to some laboratory animals, less toxic to others, and of unknown toxicity to humans.

The herbicides 2,4-D and 2,4,5-T, have been used for nearly 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

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.

At various times between approximately 1963 and 1969 Monsanto was asked to provide quantities of a specially formulated mixture of 2,4,5-T and 2,4-D to the U.S. Government. 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 specific quantities of tetrachlorobenzene needed to fulfill its government contracts for Agent Orange.

During this 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.

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 no less than five independent scientific groups.^{(1) (2) (3) (4) (5)}

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.⁽⁶⁾ 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.⁽⁷⁾

Simply stated, the available scientific and medical evidence does not support the claims alleged in the veterans lawsuits. This evidence includes the following:

- A 1974 report issued by the National Academy of Sciences⁽⁸⁾ which concluded that there was no evidence of association between exposure to Agent Orange and human health problems.
- The major constituents of Agent Orange—2,4-D and 2,4,5-T—have been the subjects of more than 40,000 scientific papers and technical articles over the past 35 years.⁽⁹⁾ These studies repeatedly concluded that the phenoxy herbicides are

not significantly hazardous to humans or animals under normal and recommended conditions of use.

- Both the Veterans Administration and the EPA have stated publicly and repeatedly that they have found no long-term health hazard related to exposure to Agent Orange.⁽¹⁰⁾
- A series of independent workshops sponsored by the American Farm Bureau to reach an unbiased scientific opinion about the human health effects of exposure to 2,4,5-T announced their findings in June of 1979.⁽¹¹⁾ They reported:
 - 1) "No adverse effects on human reproduction have been observed after exposure to 2,4,5-T or TCDD," and
 - 2) "No evidence (has been found) indicating 2,4,5-T, TCDD or any phenoxyacetic acid herbicide are human carcinogens."

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 plant. Estimates as to just how much dioxin was dispersed center on several kilograms.

Based on projections of acute toxicity from animal studies, the release of several kilograms should have killed every human being within miles. Indeed, much was written following the Seveso incident forecasting doom and horror of this magnitude. But only the reports of adverse health effects to date are cases of chloracne⁽¹²⁾ (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, abortions, or other teratogenic effects that could be correlated with the Seveso exposure.⁽¹³⁾

• Nitro, W. Va.—March, 1949

The first recorded 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 of that year, about six months after production start-up, a violent reaction occurred when temperature and pressure became excessive within an autoclave (pressure vessel). A relief valve opened, discharging fumes and residue

from the autoclave into the atmosphere and into the interior of the building.

Some 121 employees who either worked in the area or were subsequently involved in the cleanup immediately began to develop symptoms now associated with exposure to dioxin. These symptoms included chloracne, eye and respiratory tract irritation, headache, dizziness, nausea, muscle discomfort and liver disorder. All symptoms—except some cases of residual chloracne—gradually disappeared.

• Nitro Mortality Experience

A standardized mortality analysis (study of the cause of death) was recently conducted on the 32 workers (from this group of 121) who have since died from any and all causes. This medical study, co-authored 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 Institute 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. 1, pp. 11-14). 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.

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 follow-up was achieved.

Acute health effects of dioxin exposure are described in the literature, but until now little has been known regarding chronic (or long-term) effects. Thus, the Nitro analysis is 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.

• Nitro Epidemiology Study

Altogether some 400 Monsanto employees worked in the 2,4,5-T production unit (and thus they are assumed to have been exposed to some degree 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 have been observed in this group of workers on the basis of regular health surveillance and medical monitoring programs in effect at this and all other Monsanto locations.

This is a longstanding, in mid-1978 Monsanto decided to fund a second health study—a much thorough epidemiology study of the former 2,4,5-T workers for very specific reasons:

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 conclusions to ease the anxieties of those who may have been exposed to dioxin and now fear the worst.

This health study is being administered, controlled and conducted by Dr. Suskind and his medical team from the University of Cincinnati. We expect it to be completed in the spring of 1980. After review by and publication in an appropriate medical journal, the results will be made available to the public at the earliest possible date.

References Cited

1. Lamm, S.H. 1979. An epidemiologic assessment of the Alsea II Report. Paper submitted to the FIFRA Scientific Advisory Panel, U.S. Environmental Protection Agency. Tabershaw Occupational Medicine Associates, Rockville, Maryland.
2. Mantel, N. 1979. An evaluation of the statistical methods used in EPA's "Report of assessment of a field investigation of six-year spontaneous abortion rates in three Oregon areas in relation to forest 2,4,5-T spray practices" (the Alsea II Report). Paper submitted to the FIFRA Scientific Advisory Panel, U.S. Environmental Protection Agency. George Washington University, Washington, D.C.
3. Newton, M. 1979. Letter to Congressman Les Au Coin. March 15, 1979. School of Forestry, Oregon State University, Corvallis.
4. Smith, A.H. 1979. Seasonal analysis of Oregon data on spontaneous abortions and 2,4,5-T spraying. Paper presented at Annual Conference, New Zealand Branch, ANZSERCH, Dunedin, New Zealand, August 1979. Wellington Clinical School of Medicine, Wellington, New Zealand.
5. Wagner, S.L., J.M. Witt, L.A. Norris, J.E. Higgins, A. Agresti, and M. Ortiz, Jr. 1979. A scientific critique of the EPA Alsea II study and report. Environmental Health Sciences Center, Oregon State University, Corvallis.
6. Toxic Materials News, Sept. 26, 1979, p. 306.
7. Council for Agricultural Science and Technology, Aug., 1978. The Phenoxy Herbicides, Second Edition, Report No. 77, p. 22.
8. Committee on the effects of herbicides in South Vietnam, 1974. Part A. Summary and Conclusions, National Academy of Sciences, Wash., D.C., 398 pp.
9. Council for Agricultural Science and Technology, Aug., 1978. The Phenoxy Herbicides, Second Edition, Report No. 77, p. 22.
10. Art Kaufman, Globe-Democrat, St. Louis writer, St. Louis Globe-Democrat, March 1979, p. 1.
11. Toxic Materials News, June 21, 1979, p. 188.
- 12 & 13. Chemical & Engineering News Magazine, Feb. 12, 1979. American Chemical Society, Wash., D.C., p. 25.