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INTRODUCTION

Prior to 1978, experimentation with Dibenzo-P-Dioxins and related chemicals including herbicides in general was regarded as rather routine. Since that time, however, numerous veteran groups ~~reports have surfaced~~ which suggest that veterans who served in Vietnam may be at health risk as a result of possible exposure to herbicides, ~~particularly~~ the toxic dioxin, 2,3,7,8-tetrachloro Dibenzo-P-Dioxins, sprayed over the Vietnam jungle. This notion, real or perceived, has resulted in the regarding of the herbicide issue as important politically as it is scientifically. The purpose of this paper is to illustrate and recount, in a step-wise manner, the procedures followed by the Veterans Administration to guarantee the safety of all laboratory personnel handling and experimenting with Dibenzo-P-Dioxins and related chemicals. Equally as important, it is the intent of the VA to convince the public that in its zeal to find answers to the vexing herbicide issue, safety has not been overlooked.

The possibility that veterans exposed to herbicides sprayed over Vietnam between 1962 and 1971 may have been adversely affected was first brought to the attention of the VA in 1978. After several months of deliberations involving key government agencies, in 1979 the VA was mandated by Congress to conduct an epidemiology study: (1) into the potential, adverse health effects of veterans who served in Vietnam during the spraying episodes. Just prior to the VA's mandate, the Air Force voluntarily agreed to conduct an epidemiology study of its own involving the most heavily exposed

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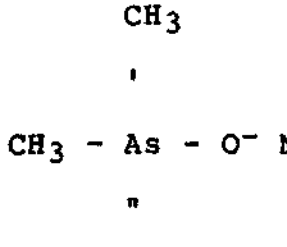
group of individuals to herbicide orange, the Ranch Handers, who served in Vietnam; (2) In the absence of a sufficient data base of information that would allow the determination of a reliable exposure index of individuals, VA Research and Development (R&D) was consulted. Research and Development responded by issuing a special solicitation for basic laboratory animal studies for the purpose of producing information which would assist in the interpretation of the findings of the various epidemiological studies. Specifically, the solicitation was issued to all VA medical centers in August 1981 and focused on the ~~two most prevalent~~ dioxin containing herbicides ~~(Orange and Blue)~~ that ~~was~~ were sprayed over Vietnam.

Herbicide Orange, the most frequently used herbicide, or Agent Orange as it was commonly referred to by military personnel, was so named because of an identifying orange stripe painted around the barrels which contained the herbicide. The primary use of Agent Orange was for the defoliation of the Canopy provided by forests and mangroves although it was generally effective on a wide variety of woody and broadleaf herbaceous species; (3) Orange was formulated to contain a 50:50 mixture of the N-butyl esters of 2,4-dichlorophenoxyacetic acid (2,4-D) and 2,4,5-trichlerophenoxyacetic acid (2,4,5-T).

An unavoidable contaminant which results when 2,4-D and 2,4,5-T are combined to form Agent Orange is the highly toxic chemical, 2,3,7,8-tetrachlorodi-benzo-para-dioxin (TCDD).

Because different chemical companies manufactured herbicide orange and because the process for manufacturing it improved with time, the level of TCDD varied rather widely in the lots of Agnet Orange that was sprayed over the Vietnam jungles.

Herbicide Blue, the second most frequently used herbicide, or Agnet Blue received its nomenclature the same way that Agent Orange was named. The primary purpose of Agent Blue was for the destruction of cereal or grain crops (monocotyledons). The remaining Blue was used in defoliation or in control of grass around base perimeters. The principal component of Agent Blue is the sodium salt of hydroxydimenthylarsine oxide (cacodylic acid).



sodium salt of hydroxydimethylarsine oxide (cacodylic acid)

When the call for research proposals was issued, guidelines for the use and disposal of Herbicides Orange and Blue existed as agricultural and forestry chemicals, [redacted]. No such guidelines, however, existed for their use as research chemicals in a laboratory environment. This time period represented the height of public concern over the dioxin issue especially its potential adverse health effect on humans. In view of this concern, Research and Development undertook every conceivable precaution to insure the safety of all individuals having responsibility for handling these agents in the laboratories.

I. Preparation of Formal Protocols:

The VA researchers were requested to submit their proposal on standard VA forms. A comprehensive International Literature Survey of the status of herbicide research supported by VA funds was provided to all VA medical centers during the preparation of proposals. In the absence of adequate safety guidelines from the Environmental Protection Agency (EPA) or other Federal regulatory agencies, applicants were asked to incorporate safety provisions that would ordinarily accompany applications which propose to use toxic or hazardous chemicals, not herbicide specific. A carefully selected panel of expert scientists representing academia, the Federal sector and the private sector was assembled for the scientific review of the proposals. The panel was also asked to comment on safety aspects of individual proposals and recommend a strategy to

maximize both individual safety and safety of the work place. Inasmuch as there were only ten research proposals that merited funding, it was decided to invite the principal investigator of each proposal to Central Office to participate in a safety symposium. A panel of safety experts representing the National Institute of Environmental Health Sciences (NIEHS), the Food and Drug Administration (FDA) and the Air Force (DOD) was assembled to recommend individual and general safety measures to each investigator. In general, the recommendations were based on: (1) type of chemical used; (2) animal system employed; (3) ~~employees~~ mode of administration of chemical; (4) purity of chemical materials; (5) concentration of chemicals; and, (6) the extent to which safety had already been addressed in the original application. Initially, a general, but brief, presentation was made to the principal investigators by each panel member. Following each presentation, time was allotted for questions and comments. Finally, each proposal was individually reviewed and specific recommendations were given to each investigator based on the uniqueness of his/her proposal. Based on these recommendations and coupled with the safety manual assembled by Dr. Alvin Young, the investigators were instructed to return to their respective medical centers and prepare a detailed safety plan including a floor plan of their proposed research laboratory. The safety plans, which uniformly required additional funding, had to be locally approved before forwarding to Central Office for approval. Upon receipt of the plans, they were administratively reviewed

by Research and Development staff and technically reviewed a member of the safety panel. The plans were uniformly accepted, and the investigators were promptly notified of this acceptance. When the investigators were notified of the approval of their plans, they were provided the additional funds needed to implement their respective safety plans for the initial year as well as each succeeding year of fiscal support.