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UNITED STATES OF AMERICA

ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In re:	)	
	)	
2,4,5-Trichlorophenoxyacetic Acid	)	FIFRA Docket No. 295

STATEMENT OF POSITION
SECRETARY OF AGRICULTURE OF THE UNITED STATES

UNITED STATES OF AMERICA
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In re:	)	
	)	
2,4,5-Trichlorophenoxyacetic Acid	)	FIFRA Docket No. 295
	)	

STATEMENT OF POSITION

SECRETARY OF AGRICULTURE OF THE UNITED STATES

In accordance with the directive of Chief Administrative Law Judge Herbert L. Perlman at the prehearing conference on November 12, 1973, the Secretary of Agriculture submits the following statement of position.

The statement of position will include:

1. USDA's position relative to the stated issues.

2. USDA's position relative to hearing sites.

1. USDA's Position Relative to the Stated Issues.

The Secretary of Agriculture supports the registered uses of 2,4,5-T [2,4,5-(trichlorophenoxy) acetic acid] and intends to present comprehensive evidence at the hearing relative to the use of 2,4,5-T on range land and forest land. 1/

1/ The herbicide 2,4,5-T is registered to control weeds that adversely affect range and forest lands, rice production, and utility and transportation rights-of-way. While USDA supports all of these registrations, we plan to concentrate our presentation of scientific fact about particular 2,4,5-T uses on evidence relative to major areas of USDA responsibility not comprehensively addressed by other parties--i.e., range and forest land uses. We understand that other parties to the proceeding intend to adduce extensive evidence supporting the other registered 2,4,5-T uses; and reserve the right to introduce additional information that is relevant to such other uses but not unduly repetitious.

I. Whether 2,4,5-Trichlorophenoxyacetic Acid (2,4,5-T) products presently registered, or other material submitted in support of these registrations, complies with the provisions of the Federal Insecticide, Fungicide and Rodenticide Act, as amended.

We believe that 2,4,5-T products presently registered do comply with the provisions of the Federal Insecticide, Fungicide and Rodenticide Act, as amended.

II. Whether 2,4,5-T will perform its intended function without unreasonable adverse effects on the environment.

We believe that 2,4,5-T will perform its intended function without unreasonable adverse effects on the environment.

III. Whether, when used in accordance with widespread and commonly recognized practice, 2,4,5-T generally causes unreasonable adverse effects on the environment, as defined by the Federal Insecticide, Fungicide and Rodenticide Act, as amended.

We believe that the use of 2,4,5-T in accordance with widespread and commonly recognized practice does not generally cause unreasonable adverse effects on the environment, as defined by the Federal Insecticide, Fungicide and Rodenticide Act, as amended.

IV. Whether the registrations of 2,4,5-T should be cancelled or its classification changed.

We do not believe the registrations of 2,4,5-T should be cancelled or its classification changed.

V. A.

1. Is 2,4,5-T or TCDD a teratogen?

There are many compounds commonly used by man such as aspirin, caffeine, nicotine, penicillin, cortisone, and folic acid that are teratogenic in animals if administered at the proper time and dosage during pregnancy. These substances are used by humans for various purposes and are introduced by various routes of administration, e.g., orally, by injection or inhalation.

High doses of 2,4,5-T have been shown to be teratogenic when introduced into experimental animals. However, under the registered uses supported by USDA, 2,4,5-T is applied as a spray or by injection, and it is very unlikely that humans will be exposed to the herbicide by virtue of the registered 2,4,5-T uses.

TCDD has been shown to have a teratogenic potential when in excess of 1 mg/kg. However, this level is unlikely to occur in nature with currently produced 2,4,5-T which has TCDD content of 0.1 ppm or less; and we believe that the exposure of man and the environment to TCDD from registered 2,4,5-T uses does not constitute a teratogenic threat.

2. Does 2,4,5-T or TCDD induce other adverse reproductive effects?

We are aware of no data that shows 2,4,5-T causes other adverse reproductive effects in man. Small dosages of 2,4,5-T affected early oogenesis and caused chromosome disturbances which may result in sterility of Drosophila melanogaster. The adult fruit flies, however,

were unaffected by doses higher than those used in field applications under registered uses.

We are aware of research conducted by Forest Service that indicates that abnormally high rates of TCDD cause adverse reproductive effects in snails and worms.

3. Is 2,4,5-T or TCDD a mutagen?

To the best of our knowledge there are no studies which indicate that 2,4,5-T is a mutagen. Although there are some studies indicating that at relatively high concentrations TCDD has caused abnormalties in the cells of the African blood lily and in certain strains of bacteria, there is an absence of evidence indicating any danger of mutagenicity from TCDD at the levels found in currently produced 2,4,5-T.

4. Is 2,4,5-T or TCDD a carcinogen?

We believe that neither 2,4,5-T nor TCDD is carcinogenic. Probative studies of which we are aware do not implicate 2,4,5-T or TCDD as carcinogens, rather one study indicates that 2,4,5-T shows appreciable inhibitory effects on the in vivo development of the Ehrlich ascites tumor in mice.

5. Can exposure to 2,4,5-T or TCDD induce sub-lethal chronic health effects?

Although sub-lethal problems such as chloracne and other disorders have been reported on people exposed during manufacturing

of chlorinated phenols in the mid-60's, we are not aware of such problems existing in the present production of 2,4,5-T.

Most data suggests that exposure to relatively high dosages of 2,4,5-T is required for mammalian toxicity. Therefore, persons involved directly in the manufacture of 2,4,5-T containing minute quantities of TCDD would be most likely to reflect symptoms of toxicity. Long-term human exposure probably presents the most valid data available to test the possibility of hazards associated with the use of 2,4,5-T. The Dow Chemical Company recently gave 64 of their workmen, directly involved with the manufacture of 2,4,5-T, extensive medical tests; and no meaningful differences were noted when the clinical results on these workers were compared to those obtained on a control population of 4600 men not exposed to 2,4-D or 2,4,5-T. The range of exposure was 30 to 40 mg of 2,4,5-T per work day. Fifty-two of the men were karyotyped and "No effect on structural integrity or rearrangement of the genetic material of the lymphocyte chromosomes" was reported. 2/

6. Can chronic, low-level exposure to 2,4,5-T and/or TCDD cause delayed lethality?

We are not aware of any studies which indicate that chronic, low-level exposure to 2,4,5-T can cause delayed lethality. We are,

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2/ "karyotype - the total of characteristics including number, form and size of chromosomes and their grouping in a cell nucleus; characteristic of an individual race, species, genus or larger grouping." Blakiston's New Gould Medical Dictionary, Copyright 1956, p. 630, Normand L. Hoerr, M. D., and Arthur Osol, Ph.D. Ed.

however, aware of a study which indicates there may be delayed death when fish are exposed to low levels of TCDD.

We believe (as indicated in our answer to Question V, A, 5, supra) that studies have shown that exposure to 2,4,5-T with minute amounts of TCDD does not induce sub-lethal, chronic health effects in man; and, we believe it follows that chronic, low-level exposure to 2,4,5-T does not cause delayed

V. B.

1. Can additional TCDD be generated in the environment by the thermal stress of 2,4,5-T or its metabolities?

We are not aware of any studies indicating that additional TCDD has been generated in the environment by the thermal stress of 2,4,5-T or its metabolites.

2. Can 2,4,5-T or TCDD persist and bioaccumulate in the environment?

We do not believe there to be a problem of 2,4,5-T persisting and bioaccumulating in the environment. 2,4,5-T has a short half-life and disappears rather quickly after it is applied. Although TCDD does not disappear as quickly as 2,4,5-T there is no indication of harm to man or the environment from TCDD in currently producted 2,4,5-T. 3/

3/ 2,4,5-T has been used for about 20 years. TCDD is an inseparable impurity produced when manufacturing 2,4,5-T. Early 2,4,5-T contained as much as 27±8 ppm of TCDD. Advanced technology has made it possible to reduce the TCDD impurity to 0.1 ppm or less. We know of no injury to man or the environment attributable to 2,4,5-T on its dioxin during the 20-year period of use.

3. What are the avenues of human and animal exposure to 2,4,5-T and TCDD? For example, can aerial drift or water transport of 2,4,5-T or TCDD cause movement of these compounds away from the site of application?

Water

One study found the maximum concentration of 2,4,5-T in run-off water was 800 ppb immediately following treatment of 2,4,5-T at 1/2 pound per acre on pasture land (following a 1.5-inch rainfall) adjacent to the treated area. However, runoff water contained less than 5 ppb if heavy rainfall occurred 1 month or longer after treatment. Concentration of 2,4,5-T was rapidly diluted by runoff water from surrounding untreated areas.

In most cases, the likelihood of humans drinking water that might have 2,4,5-T in it resulting from drift of the spray when used for weed and brush control on ditchbanks or irrigation canals is extremely small.

Aerial applications of 2,4,5-T to forest lands may result in an initial low-level (0.1 ppm), short-term stream contamination which does not represent a significant hazard to fish or animals. Adsorption and degradation of 2,4,5-T in the forest floor severely restricts movement from treated areas to surface and ground waters. The primary exposure of animals to 2,4,5-T will be by ingestion of treated vegetation. Rainfall, growth dilution, and degradation markedly reduce herbicide residues in vegetation within a few weeks after application.

Occurrences of 2,4,5-T in stream water were at concentrations from 0.01 to 0.07 ppb in 28 of 320 samples taken in the 15 Western States, 1965-1968. In a survey of streams and surface water in Texas in 1970, 2,4,5-T was sometimes found, but in very low quantities. The highest levels of 2,4,5-T were detected in the Houston, Texas area in May 1970, which was 2.1 ug/liter of 2,4,5-T. These concentrations in stream water are far below biologically significant levels.

Air

Assuming a most extreme and improbable exposure of a 130 pound pregnant woman lying naked and prone under the flight-swath of an aerial application of 2 pounds per acre of 2,4,5-T, the "oral equivalent" effective dose on her is estimated at 1/190 that of the "no effect level" suggested in teratogenic studies of 2,4,5-T on mice and rats (50 mg/kg) and if she were 100 feet downwind, her exposure would be about 1/38,000 of the "no effect level." 4/

After discussing the above unlikely exposures, we need to consider the more nearly possible exposures of pregnant women. Pregnant women are not usually engaged in activities related to field spraying. Also, spraying fields while "workers" are in the

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4/ The above calculations were based on the drift studies and on a study which suggested that skin absorptions in animals were perhaps 10-20 times slower than absorption from the gastro-intestinal tract. If the above conditions of skin exposure in the field were met, which is extremely unlikely, the safety factor is still sizeable.

fields is not commonly done. Thus, exposures would not be expected to equal those described in the first paragraph of this section.

Aerial spraying is a common method of applying 2,4,5-T for brush control. Flagmen in such range lands being sprayed usually move upwind before the spray plane reaches the flag stations, thus, they are not sprayed or at most they receive a minimum of spray drift.

Control of poison ivy in wooded areas, and on roadsides is done by using many different kinds of equipment ranging from hand-carried compressed-air sprayers having a single wand and nozzle, to power equipment with either a handgun or spray boom. Most spray operations are conducted using precautions to minimize drift because the poison ivy usually grows near or among other shrubs and ornamental flowers that would be subject to injury. Therefore, the operator, or others in the area, would be expected to be exposed to very little drift.

The likelihood of human exposure to 2,4,5-T suspended in the air is extremely small, based on studies showing the amount of 2,4,5-T in the air. These studies revealed levels of 0.06 micrograms per cubic meter. Assuming a man will inhale about 30 cubic meters of air per day, the exposure would be 1.8 micrograms per day. For a 70 kg man, this would be 0.025 micrograms per kg body weight per day. This is about one-two millionth of the "no effect level" (50 mg/kg) suggested in teratogenic studies.

Foods

On the basis of a comprehensive four-year study, the Food and Drug Administration of the Department of Health, Education and Welfare concluded that there is not a significant problem of food contamination as a result of the use of 2,4,5-T. Specifically, the Food and Drug Administration found:

> Of 5,300 food samples tested for 2,4,5-T residues during the last four-year period, 25 samples indicated trace amounts (less than the 0.1 ppm limit of accuracy of present analytical procedures) and 2 samples showed higher residues. 0.19 ppm 2,4,5-T was detected in one sample of milk taken in 1965 in New England, and one sample of sugar-beets from Ohio in 1966 showed 0.29 ppm 2,4,5-T. The milk had been distributed before analysis was complete and processing of the sugar-beets removes the chemical.

On the basis of this finding, the Food and Drug Administration concluded that "the testing of food over the past several years has revealed no significant problem of food contamination" as a result of the use of 2,4,5-T.

In March 1969 the Pesticides Monitoring Journal calculated the daily intake of pesticide residues by food class expressed in milligrams per day from June 1966 to April 1967 and showed no 2,4,5-T intake from grains and cereals, potatoes, leafy vegetables, legume vegetables, root vegetables, garden fruits, fruits, oils, fats and shortening, sugars and adjuncts, and beverages; trace intake of 2,4,5-T from meat, fish and poultry; and 0.001 ppm intake from dairy products. The report dealing with the period from June 1967 to April 1968 showed no 2,4,5-T

intake from meat, fish and poultry, grains and cereals, potatoes, leafy vegetables, legume vegetables, root vegetables, garden fruits, oils, fats and shortening, sugars and adjuncts, and beverages; and only trace intake from dairy products.

4. Are 2,4,5-T or TCDD residues being stored and accumulated in the human food supply and in human and animal tissue, including humans and wildlife directly exposed to 2,4,5-T?

We do not believe that 2,4,5-T or TCDD residues are being stored and accumulated in the human food supply or in human tissue. We know of no evidence that 2,4,5-T or TCDD residues are being stored and accumulated in wildlife tissue.

Studies involving the administration of 2,4,5-T to various animals at various rates indicate that any concentrations of 2,4,5-T rapidly declined in a matter of a few days, and that repeated subtoxic doses of 2,4,5-T do not lead to excessive accumulation.

5. Are other dioxins and similar contaminants, besides TCDD, present in 2,4,5-T and, if so, what risks to health do they constitute?

6. What are other environmental sources of dioxins particularly TCDD, and do these sources enhance the total dioxin body burden and exacerbate the health risks raised by 2,4,5-T and related TCDD?

7. What are the current levels of dioxins in registered 2,4,5-T products and in technical material used to formulate these products?

8. Do the current methods of manufacture of 2,4,5-T provide for consistently low levels of dioxins in the final technical product and what are the quality control measures used to minimize dioxin levels?

It is our understanding that questions V, B, 5-8 will be thoroughly addressed by the parties who manufacture 2,4,5-T and have the necessary expertise required to answer the questions readily available. For the foregoing reason we will not address those questions in this statement of position.

V. C.

1. What are the pests which each registered use is intended to control and the degree of control achieved by each use?

Forest Uses

The National Forest System includes 187 million acres of land located in 44 States, Puerto Rico, and the Virgin Islands. The National Forests produce five primary resources and benefits - timber, water, forage, wildlife, and recreation.

About one-fourth of all timber harvested in the United States comes from National Forests. Demands for industrial timber products in the United States have been increasing steadily, with a 65 percent rise in use of these products during the past three decades. Further substantial increases in future demands are expected. Also, increased demand for water, forage, wildlife and recreation is projected for the years ahead.

Specific uses of 2,4,5-T are the removal of certain trees and other competing vegetation in the regeneration and improvement of timber stands, and the improvement of forage production by controlling undesirable forage plants, including noxious weeds. This herbicide is also used to maintain desirable plants and control undesirable plants on road and utility rights-of-way, on fire breaks, in clearings made for improved water yields, and in openings designed for improved wildlife habitat.

In fiscal year 1973, the use of 2,4,5-T on the National Forests was as follows:

Mixture	Pounds Used	Acres Treated
2,4-D and 2,4,5-T	13,650	3,556
2,4,5-T	35,762	19,811
2,4,5-T and Picloram	50	90
		23,457 acres treated

2,4,5-T has been found to be both effective and economical in controlling noxious plants in the forest.

Range Land Uses

The use of 2,4,5-T has been found to be an effective control for a large number of undesirable woody species of weeds that compete with grasses in range land areas. The weeds controlled by 2,4,5-T not only compete for critical water with the grasses consumed by livestock, but some of the weeds, e.g. mesquite, also hinder the rancher and farmer in tending the livestock. Some of the undesirable

plants controlled by the use of 2,4,5-T are pricklypear, chaparral, various oaks, mesquite, and sagebrush.

2. What is the cost, timing, and rate of application of 2,4,5-T for each use?

Forest Uses

Application of 2,4,5-T is usually by broadcast spraying or by individual plant treatment. Broadcast spraying is done by helicopter, fixed wing aircraft, or by a ground spray application. The objective of such spraying is to treat the foliage or bark of all of the plants in certain areas. Because 2,4,5-T is a selective herbicide it can be sprayed on most established conifers without causing damage It only kills undesirable hardwoods and other competing vegetation. Individual plant treatment is done from the ground. The foliage, stem or stump of each tree is sprayed with ground spray rigs or backpack sprayers. Tree injectors are also used to inject the herbicide directly into the stem.

The cost of application of 2,4,5-T varies depending on the amount of foliage or the number of stems per acre needing treatment. However, the cost is generally from $7.00 - $35.00 per acre, and the average cost is approximately $20.00 per acre.

Although the rate of application will vary, depending on the method of application and the number of noxious plants requiring treatment, it is usually less than 4 pounds per acre.

Range Land Uses

The cost of applying 2,4,5-T varies depending on the weed to be controlled as well as the density of the weed. The cost may be no more than $5.00 per acre, or it may be approximately $20.00 per acre in areas with extremely thick brush. Generally, the cost of applying 2,4,5-T for range land uses is $10.00 - $20.00 per acre.

As with the cost of the application, the timing, method, and rate of application depend upon the weed to be controlled and the density of the weed. In addition to considering the weed to be controlled and the density of the weed, it is also necessary to consider the geographical location, soil moisture, temperature and plant foliage when determining the proper time and rate of spray. Therefore, depending on various factors, 2,4,5-T might be used on range land at any time during the year and the rate of application will vary appreciably.

3. What alternative controls exist for each registered use and what is the cost and effectiveness of each alternative?

Forest Uses

Possible alternatives to the use of 2,4,5-T are other chemical controls, burning, biological controls, and removal of the undesirable plants, either by hand or mechanical means. An analysis substituting the alternatives of burning, hand grubbing, and mechanical removal for the proposed F. Y. 1971 2,4,5-T treatments indicated that the use of such alternatives would cost approximately

6 times as much ($19.9 million compared to $3.2 million) as the use of 2,4,5-T. Also, some treatments need to be repeated to attain the same degree of effectiveness as 2,4,5-T.

The use of manual labor to cut and remove individual plants or stems most nearly achieves the effects of the 2,4,5-T treatment. However, this is extremely expensive and sometimes labor is not available. Also, many of the acres that would be hand treated would need an additional treatment within one to three years due to excessive sprouting. Furthermore, some acreage is difficult to reach and not readily accessible to hand treatment.

Along with increased costs, alternative treatments such as fire, chopping, bulldozing, or manual removal could create a different association of plants and a different local environment. Bulldozing might cause soil erosion. Fire might cause the disturbance or death of wildlife and air pollution.

Biological control may be practiced to some extent, but much more needs to be learned about introducing insects and pathogens to control growth or spread of certain species. The Western tent caterpillar feeds on the foliage of red alder; a moth and a weevil on scotch broom; a flea beetle on Canadian thistle; and the California tortoise shell butterfly feeds on varnished leaf ceonothus. There is always the danger of uncontrollable epidemics and possible elimination of host plants when insects or pathogens are introduced either intentionally or accidentally.

Range Land Uses

Generally mechanical controls could be utilized as alternatives for 2,4,5-T. However, in some instances only another chemical control would be an alternative to 2,4,5-T; and, in controlling the mescalbean and the running type of mesquite, there are no known mechanical or chemical alternatives available.

In order to obtain the control provided by 2,4,5-T, it would generally cost appreciably more to use the available alternatives. Quite often the cost of using the alternative would be more than twice the cost of using 2,4,5-T.

4. Do alternative pesticide products cause adverse environmental effects?

Forest Uses

There are alternative pesticide products available, such as picloram, silvex, ammate, dicamba, amitrole, TBA and MSMA. However, these alternative products do not effectively control as many weeds as does 2,4,5-T. Other herbicides are not only less effective than 2,4,5-T on woody plants, research to date also indicates that other herbicides are less readily biodegradable, are more persistent in the environment and more damaging to conifers. Use of more specific herbicides could result in greater contamination of the environment because two or three applications of the specific herbicides would be needed to achieve the same degree of control obtained with one effective broad spectrum herbicide like 2,4,5-T and this would result in two or three times as much chemical being introduced into the

environment per acre. Overall, there is generally less information available about the environmental effect of the alternative chemicals.

Range Land Uses

Usually the alternative pesticide products silvex, dicamba, ammate, and picloram do not cause adverse environmental effects, however, the same precautions in using 2,4,5-T around sensitive crops apply to other herbicides. Care should be taken not to allow drift of herbicides from target areas onto susceptible crops such as cotton, soybeans, tobacco, alfalfa, clover, and broad-leaf vegetables.

5. What are the economic implications of these alternatives, including that of no control?

Forest Use

Possible alternatives would cost up to 6 times as much as the use of 2,4,5-T:

COMPARISON OF 2,4,5-T WITH OTHER HERBICIDES
1971

Herbicide	Chemical cost per acre 5/	Persistence in soil	Effectiveness on shrubs	Conifer damage
2,4,5-T	$2.18	Short	Excellent	Little
Silvex	2.62	S	-	+
TBA	9.15	+	-	S
Ammate x	15.00	S	-	+
2,4-D	1.15	S	-	+
2,4-DB	18.00	S	-	+
Picloram	8.14	++	S	++
Dicamba	9.50	+	S	++
MSMA	---	+	-	+
Amitrole	7.85	S	-	+
Amitrole-T	8.35	S	-	+
2,4-DP	4.80	S	-	+

5/ Based on GSA contract prices
Ratings: S=similar to 2,4,5-T; (-) = less effective on shrubs; (+) = more persistent in soil or more damaging to conifers.

No control would reduce timber products by 30% as well as devastate priceless resources.

Range Land Use

Substituting mechanical brush control methods or other chemical control methods will usually increase costs of control from 2 to 20 times. On range land, with limited profit margin, many thousands of acres that need treatment would go untreated. Increased cost of beef production will be reflected in higher beef prices for the consumer. Mechanical brush control methods are costly and temporary. In addition, the grass turf in many instances is destroyed leaving the soil open to wind and water erosion.

About 3.4 million acres of farmland and 4.5 million acres of nonfarmland were treated with an estimated 8.9 million pounds of the 2,4,5-T in 1969. If 2,4,5-T were restricted, the economic costs to domestic users would have been $52 million in 1969, providing all other herbicides could still be used. However, costs would have increased to $172 million if other phenoxy herbicides were also prohibited. Additional costs to replace 2,4,5-T, if other phenoxys could have been used as alternatives, were estimated at $32 million for farmers and $20 million for other domestic users (public utility companies, Government agencies, homeowners, recreation, and timber industries). Without other phenoxys, additional costs would have increased to $44 million for farmers and to $128 million for nonfarm users.

Ten Additional Issues To Be Addressed

(1) A contaminant of 2,4,5-T -- tetrachlorodibenzoparadioxin (TCDD, or dioxin) -- is one of the most teratogenic chemicals known. The registrants have not established that 1 part per million of this contaminant -- or even 0.1 ppm -- in 2,4,5-T does not pose a danger to the public health and safety.

As discussed in answer to Question V, A, 1, (p. 3) TCDD has been shown to have a teratogenic potential when in excess of 1 mg/kg. However, this level is unlikely to occur in nature with current production of 2,4,5-T with TCDD content of 0.1 ppm or less.

(2) There is a substantial possibility that even "pure" 2,4,5-T is itself a hazard to man and the environment.

We do not believe there is a substantial possibility that "pure" 2,4,5-T is itself a hazard to man and the environment. As we indicated in Question V, A, 1, (p. 3) there are many compounds commonly used by man that are teratogenic in animals if administered at the proper time and dosage during pregnancy. Present uses of 2,4,5-T do not present a realistic danger of exposure to 2,4,5-T to either man or animals.

Also, as discussed supra, (p. 4) 2,4,5-T is not a mutagen or a carcinogen, and we do not believe there to be a danger from chronic low level exposure to 2,4,5-T. Moreover, as we have shown (ibid.) there is no known danger of 2,4,5-T persisting and bioaccumulating in the environment

(3) The dose-response curves for 2,4,5-T and dioxin have not been determined, and the possibility of "no effect" levels for these chemicals is only a matter of conjecture at this time.

Contrary to the above statement, dose-response curves for 2,4,5-T and dioxin have been determined in a large number of experiments and with several species of animals, Also, it is incorrect to state that the possibility of "no effect" levels for these chemicals is only a matter of conjecture at this time. As we have shown above (pp. 2-11) the present registered uses of 2,4,5-T do not endanger man or his environment.

(4) As with another well-known teratogen, thalidomide, the possibility exists that dioxin may be many times more potent in humans than in test animals (thalidomide was 60 times more dangerous to humans than to mice, and 700 times more dangerous than to hamsters; the usual margin of safety for humans is set at one-tenth the teratogenic level in test animals).

2,4,5-T has been used extensively as an effective herbicide for about 20 years. During this lengthy period of use there has been no indication that any dioxin in 2,4,5-T is more potent in humans than in test animals. Obviously in 20 years of use there has been considerable exposure of humans to 2,4,5-T, however, in all this time there has been nothing to indicate that 2,4,5-T should be compared to thalidomide. See note 3, supra.

(5) The registrants have not established that dioxin and 2,4,5-T do not accumulate in body tissues. If one or both does accumulate, even small doses could build up to dangerous levels within man and animals, and possibly in the food chain as well.

We believe that the discussion in our answer to Question V, B, 4, (p. 11) indicates that there is not a danger of dioxin or 2,4,5-T accumulating in human or wildlife tissues.

(6) The question of whether there are other sources of dioxin in the environment has not been fully explored. Such other sources, when added to the amount of dioxin from 2,4,5-T, could result in a substantial total body burden for certain segments of the population.

Although the question of other sources of dioxin in the environment has not been completely explored, the process of research is ever-continuing. To talk about the effect of unknown sources would be purely speculative. However, it can be said that if other sources of dioxin were found, 2,4,5-T would not add significant amounts of dioxin to the environment.

(7) The registrants have not established that there is no danger from dioxins other than TCDD, such as the hexa- and heptadioxin isomers, which also can be present in 2,4,5-T, and which are known to be teratogenic.

We are not aware of any significant evidence that dioxins other than TCDD are in commercially produced 2,4,5-T.

(8) There is evidence that the polychlorophenols in 2,4,5-T may decompose into dioxin when exposed to high temperatures, such as might occur with incineration or even in the cooking of food.

Experiments in this area are limited and have been confined to laboratory conditions. In those experiments where TCDD was found it occurred in very small amounts.

In common practice on the range land, brush and trees treated with 2,4,5-T are rarely, if ever, burned.

Also, as indicated in our response to Question V, B, 3, (p. 10) the likelihood of finding 2,4,5-T residues in food is extremely remote.

(9) Studies of medical records in Vietnam hospitals and clinics below the district capital level suggest a correlation between the spraying of 2,4,5-T defoliant and the incidence of birth defects.

We disagree with the above conclusion. Rather than showing a correlation between the spraying of 2,4,5-T and the incidence of birth defects in Vietnam, we believe that studies of the medical records in Vietnam have failed to show a correlation between the spraying of 2,4,5-T and the incidence of birth defects.

(10) The registrants have not established the need for 2,4,5-T in light of the above-mentioned risks. Benefits from 2,4,5-T should be determined at a public hearing, but tentative studies by the agency have shown little necessity for those uses of 2,4,5-T which are now at issue.

Contrary to the above statement we believe that 2,4,5-T as presently registered is an indispensable tool in providing the Nation with its necessary supply of food, fiber, and timber safely and economically. It is also essential to the clearing and maintenance of important rights-of-way vital to transportation and energy in this country. We intend clearly to establish at this hearing that the use of 2,4,5-T provides not only an effective and economical control of herbacious weeds and brush, but also 2,4,5-T provides such control without endangering human health and without unreasonable adverse effects on the environment.

2. USDA's Position Relative to Hearing Sites

In presenting evidence relative to the range land uses of 2,4,5-T, USDA will present a sizeable number of witnesses from the southwestern region of the United States, particularly Texas. The witnesses to be presented in regard to this use will largely be user witnesses who are ranchers and farmers. It will be a tremendous inconvenience, and very disruptive to the ranching and farming operations of these witnesses if they must make a lengthy trip to testify at these hearings. Therefore, because of the sizeable number of witnesses in the southwestern area, and considering the necessity for these witnesses to remain close to their livelihood, we are requesting a session of the hearing be held in Texas. We would suggest Dallas, Texas as an appropriate location.

We are not requesting field hearings for our forestry witnesses. Although we believe field hearings generally to be desirable, after considering the convenience of all parties involved, the critical need to conserve fuel, and the probable number of forestry witnesses to be presented, we believe it would be more economical and efficient to present our forestry witnesses in Washington, D.C.

Conclusions

On the basis of the foregoing, it is obvious that any risk to man or the environment associated with the registered uses

of 2,4,5-T is exceedingly minimal. Further, it is apparent that virtually every alarm about the registered uses of 2,4,5-T is based largely on speculation. In view of these facts, in addition to developing a full record comprised entirely of factual scientific data, we also intend to establish our position that the ultimate decision about the registered uses of 2,4,5-T must be based on a "rule of reason". In simplest terms, "rule of reason" means that in all aspects of life, including the introduction and use of any technology, decisions affecting the quality of life must be based on scientific fact and a weighing of both the risks and benefits known to exist. The mere presence of risk cannot be the sole criterion upon which a decision to use technology is made. Intelligent decisions require recognition and evaluation of realistic risks and benefits; and, most importantly, dismissal of inadequately founded concern. Total society can best be served only by the application of this formula. Such an objective risk-benefit evaluation can be applied not only to technology, but to any force that impacts society, whether it be a societal structure, a political philosophy, or an economic decision to devalue the dollar. The key point is that possible risks are inevitably associated with every decision. Those who advocate the avoidance of all risks in the use of technology or decisions founded on unwarranted concern support an extreme position that is indefensible if an advanced society is to survive.

Stated otherwise, responsible decisions must emanate from a careful evaluation of realistic risks and benefits; not from fears based wholly or largely on speculation.

In summary, we intend to show that when a "rule of reason" is applied to the stated issues in this proceeding there is no basis for cancelling or changing any registration of 2,4,5-T.

Finally, we submit that our request for hearing sites is reasonable and should be granted.

Respectfully submitted,

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UNITED STATES OF AMERICA

ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In re:	)	
	)	
2,4,5-Trichlorophenoxyacetic Acid	)	FIFRA Docket No. 295

INDEX OF DOCUMENTS

The attached documents and index of documents are submitted pursuant to the Administrative Law Judge's directive at the prehearing conference on November 12, 1973. The Secretary of Agriculture respectfully requests the right to supplement this material on February 22, 1974.

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