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Benefit/Risk Analysis of Silvex Cancellation[1]

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ABSTRACT

The herbicide 2-(2,4,5-trichlorophenoxy)propionic silvex acid has a low-to-moderate acute and subacute toxicity to a large number of mammals, birds, and aquatic organisms. Toxicity to fish and other aquatic organisms depends a great deal upon the formulation. The potassium salt of silvex in particular has a wide margin of safety for aquatic use. The ester formulations are more toxic than amine formulations. These formulations are used mostly for control of marginal-herbaceous and marginal-woody plants. Review of the literature indicates that commercial formulations of silvex used according to label directions do not result in hazardous acute and subacute toxic exposure levels for domestic and wild animals, fish, handling and application personnel, or the bystander population. Although there are policy considerations that do limit risk assumptions, technical and economic criteria of benefit/risk analysis indicates that net benefits far exceed the cost-at-risk.

Key words: phenoxy herbicides, TCDD, toxicity, dioxin, aquatic plant control.

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INTRODUCTION

Benefit/cost and/or benefit/risk analysis is the term given to the studies made by planners and decision-makers to assist in selecting the best course of action from an economic viewpoint. It differs from routine judgement and decision-making by use of quantitative evaluation, in monetary terms, of the goods and services expected (*ie,* benefits) of an action and the goods and services expended (costs) in undertaking an action. The benefit/risk ratio is the proportion, expressed as a simple numerical fraction, that the benefits bear to the costs-at-risk. A benefit/risk ratio of 1.5:1.0 means that benefits are expected to be 1½ times or 150% of the costs, under the assumptions used for the study. A project having a benefit/risk ratio of 1.0:1.0 means that benefits are expected to equal the costs-at-risk under study.

REVIEW OF THE LITERATURE

Silvex (2-(2.4.5-trichlorophenoxy)propionic) acid is of great benefit in controlling certain unwanted plants (2,6,8) and is relatively non-toxic to a large number of mammals, birds and aquatic organisms, 1,7,11,12). Silvex formulations as dusts, from granules or spray mists from emulsifiable concentrate, can be inhaled into the lungs. This route of entry is important during mixing operations. Inhalation toxicity (TLV) of silvex has been calculated in the range of 10 mg/cm^3/day as measured in rats and dogs and is relatively non-toxic.

Silvex has an acute oral toxicity (LD_{50}) of approximately 650 mg/kg body weight, as determined from feeding studies with rats and dogs, clasified as moderately toxic. The chronic toxicity (LD_{50}) level of silvex is about 40 mg/kg/day, as calculated from feeding studies with rates and dogs and is classified as moderately toxic.

Silvex and related phenoxyalkyl herbicides are moderately toxic to fish (LD_{50} of 500-2000 mg/kg). In general, it is quite similar to other phenoxyalkyl acid herbicides in the range of toxicity and relationship between various esters, salts and amines. The isoctyl ester is among the least toxic of the various esters of silvex. However some esters may be toxic to fish as low as 1 ppm. Under field conditions, the treatment monitored residues of recommended formulations are substantially below the level toxic to fish (14,15,20,22).

A number of studies have shown that direct ingestion of 2,4,5-T (i.e. silvex) at moderate levels is not toxic to humans. Gehring *et al* (9) studied the fate of 2,4,5-T following oral administration. Five male volunteers, ages 31 to 58 years, each ingested a single 5 mg/kg oral dose of analytical grade 2,4,5-T, with a purity greater than 99 percent and less than the detectable level (0.05 ppm) TCDD, directly or as a slurry in milk. Essentially all (88.5 ± 5.11 percent) of the 2,4,5-T ingested by these subjects was excreted unchanged in the urine after 96 hours. No toxic effects were noted among the five subjects studied. This level is 50 times the proposed tolerance level for silvex (2).

Residue tolerances of 0.1 ppm silvex in water, fish and crop plants were proposed at the no-effect level in the pesticide petition 1E1012, submitted to the Environmental Protection Agency by the U.S. Army Corps of Engineers and by the Industry Task Force Interagency Committee on Phenoxy Herbicides, pesticide petitions 1E1012 and 8F0675 (2). Approval was defered pending resolution of the dioxin problem (34,35,36,37).

In experimental tests, it has been determined that acute TCDD toxicity varies considerably between species. The figure for rats established by Schwetz *et al* (24) agrees well with the earlier data given by Sparschu (26). In longer term feeding studies with TCDD, Harris *et al* (10) found that 30 daily doses of 0.001 mg/kg or six weekly doses of 0.005 mg/kg reduced the growth rate of rats, but other toxic effects were not noted.

While laboratory experiments provide convincing evidence of the teratogenic effects of TCDD in rats and mice these effects have never been observed in other species or outside the laboratory. Moreover, a review of research studies on these teratogenic effects of TCDD indicate that rats and mice are not suitable assay animals for determination of human health effects of TCDD (4,20,21,22,28).

The clinical effects of TCDD are diverse and include necrotic changes in the liver, kidneys, thymus and other lymphoid tissues, together with intestinal hemorrhages. In studies with C^{14} - labelled TCDD, one half of a moderate dose disappeared from the bodies of rats within 17 days. Elimination was mostly via the feces (25).

The FIFRA Scientific Advisory Panel (37) reviewed the major studies of the oncogenicity of TCDD that have been reported. There was an increase in tumors of the liver, lung and hard palates/nasal turbinates in rats fed 0.1 ug/kg/day of TCDD in the diet. At a dose of 0.01 ug/kg/day, there was an increase in hyperplastic nodules in the livers of the female rats. The EPA Carcinogen Assessment Group (CAG) has concluded that this increase in hyperplastic nodules at the dose of 0.01 ug/kg/day indicates that TCDD is weakly carcinogenic at this dosage level (34,35, 36,37).

Based on dermal exposure experiments, human absorption of silvex is estimated to range from less than 0.001 mg/kg/hr to a maximum of 0.095 mg/kg/hr when exposed skin is wet with spray for the entire application period. An operational monitoring study showed human absorption of 0.0001 to 0.05 mg/kg/hr. Addition of a long-sleeved shirt and gloves to work apparel in place of a short-sleeved shirt reduces exposure 91 percent. (3,33).

Observations of pesticide applicators and formulators have shown that occupational hazards to pesticides carry risks similar to that of other occupations. (See table 1). The occupational hazard of the worst case, the backpack spray applicator, is less than one fatality in $5.0x10^{8-}$ per million population per year. Thus, there is a greater safety factor than for the average worker in the United States over most other occupations. (32).

THE DIOXIN PROBLEM

Silvex has a trace contaminant, 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD) (4,13,16,17,18,19). From about 1955 onwards, the toxic properties of TCDD and certain of its chemical relatives were well known to chemical manufacturers. It was found that careful control of reaction conditions, particularly avoidance of high temperatures and pressures, reduced the amount of dioxin to negligible levels (19,21,25). In a survey of samples manufactured in the United States between 1966 and 1970 Woolson *et al* (34) found that 22 out of 42 samples had less than 0.5 ppm of TCDD. The current level in most silvex formulations is about 0.05 ppm TCDD (4,33).

Dow Chemical Company scientist (20) stated that the level at which no oncogenic effects are obtained lies between a dose of 0.1 and 0.01 ug/kg/day in the diet. The EPA Carcinogen Assessment Group concluded that the nononcogenic dose lies between 0.01 and 0.001 ug/kg/day. Thus, there was agreement concerning no oncogenic re-

TABLE 1. OCCUPATIONAL RISKS (ACCIDENTS ONLY) IN NUMBER OF FATALITIES AND THE RISK PER MILLION POPULATION PER YEAR.

Occupational activity	Fatalities per year	Risk/yr/million
Mining & Quarrying	500	$6x10^{-4}$
Coal mining:	180	$1.3x10^{-3}$
Agriculture:	2,100	$6.0x10^{-4}$
Trade	1,200	$6.0x10^{-4}$
Manufacturing	1,500	$8.0x10^{-5}$
Service	1,800	$9.0x10^{-5}$
Government	1,100	$1.1x10^{-4}$
Transportation & Utilities	1,600	$3.3x10^{-4}$
Truck driver (1 driver/truck)	400	$1.0x10^{-4}$
Steel worker	66	$2.8x10^{-4}$
Backpack spray applicators of Silvex	1	$5.0x10^{-8}$

Source: Wilson, The risks of pesticides: Their assessment and comparison with benefits. *In Proceedings of the IX International Congress of Plant Protection.* Washington, D.C. 1979. P. 275.

sponse at the dose level of 0.001 ug/kg/day TCDD (34,35, 36,37).

The monitoring data obtained thus far does not suggest that TCDD derived from commercial 2,4,5-T and silvex exhibits any tendency to accumlate in the human food chain in amounts which would pose a substantial risk. For example TCDD has been detected in some fat samples from cows grazed on rangeland immediately after spraying with commercial 2,4,5-T and sacrificed 2 weeks later. If one assumes that all beef fat in the U.S. contains TCDD at the level found in these studies (approximately 10 ppt) and if one assumes further that the average level of beef intake in the U.S. population is 6% of the diet, a risk of 1 to 4 x 10^{-6} can be calculated (37).

Shadoff *et al* (25) have examined fish (bass and catfish) from a reservoir in a rice-growing region of Arkansas where 2,4,5-T had been used annually for more than 20 years. Likewise, fish (walleyes and catfish) were obtained from a reservoir in West Texas where 2,4,5-T had been used for brush control over the past 20 years. No TCDD was detected in any of the samples with a minimum range of detection of 10 ppt and it was concluded that TCDD does not bio accumulate in water under natural conditions. It is probable that aquatic plants metabolize TCDD under natural conditions, or that it is absorbed by bottom sediments (4,25).

The results of the embryo toxicity studies indicate that the no-effect level for TCDD in mice is 0.1 ug/kg/day (days 6-15 of gestation), and in monkeys is 0.2 ug/kg/3 times per week (days 20-40 of gestation). In a two year reproductive study carried out in rats, embryo toxicity was seen at doses of 0.1 and 0.01 ug/kg/day of TCDD. At the dose of 0.001 ug/kg/day there was a decreased gestational survival in the F^2 generation but not in earlier or later generations. The data suggest that the 0.001 ug/kg/day dose is for all practical purposes a no-effect level (19,20,24,25).

Long term feeding studies in monkeys have shown reproductive toxicity from TCDD at levels of 50 ppt in the diet. An intake of TCDD of 50 ppt in the diet is equivalent to approximately 0.002 μg/kg/day. If no reproductive toxicity is seen in the monkeys exposed to TCDD in the diet at 25 ppt, then the no-effect level in the monkey will be similar to that seen in the rat, namely about 0.001 ug/kg/day (19,20,24,26).

RESULTS AND DISCUSSION

Broad general policy for benefit cost analysis is provided legislatively by the River and Harbor Act of 1965 (P.L. 89-298), the Environmental Policy Act of 1969 (P.L. 91-190) and the Federal Insecticide, Fungicide and Rodenticide Act of 1975 (P.L. 92-516) (6). These basic laws governing the Corps of Engineers aquatic control program provide the specific standards, procedures, and/or other required details of conducting economic and environmental evaluation.

The technical and economic criteria for assessing a specific system includes estimates of aggregate risk and benefit to within a plausible range of certainty and the distributions of these risks and benefits to various public sectors. For a risk decision process to be practical, the requirements placed upon the regulators must be considered. If the structure is such that the regulator inevitably is exposed to criticism for being arbitrary or biased, a natural response of the regulator is to avoid making decisions or to slant decisions in favor of the most vocal or powerful of the affected interest groups. In actual practice, isolation from this effect is unlikely, but a clearer understanding of the decision criteria as used in the benefit/risk analysis is thought to be a major contribution to the solution of the problem (3,6,23).

Since absolute safety is an impossible goal, attention should be focused on "socially acceptable risks." This concept is supported by logic and by numerous Federal statutes, including the Occupational Safety and Health Act. Emphasis should be on relative risk levels. Occupational risks associated with exposure to herbicides must be related to other occupational and nonoccupational risks, such as those for traveling by airplane or automobile, or for building a bridge or a highway (3,5,23,32).

Whyte and Burton (30) have discussed the possible levels of carcinogenic compounds in the environment and point out that we live in a world whose environment contains natural carcinogens from which there is no escape. One must therefore look upon The Delaney Amendment as a "false proposition" from which there can be no logical deduction. No law or federal rule will stop the occurance of cancer *per se* by such defacto denial of the facts of life.

BENEFIT/RISK ANALYSIS

Benefit/risk analysis is properly thought of as a subset or particular type of the benefit/cost approach. The focus is on how the risks (as one type of social cost) compare with the monetary terms, the analysis frequently takes the form of a comparison of the potential exposure hazard expressed as a margin of safety, *ie* residue tolerance level. However, benefit/risk analysis can also be made on the basis of the insured risk, *ie* the insured cost-at-risk compared to the net benefits of the program, as is commonly used in the management of risk in most business situations (26), *ie* (1) workmans compensation, (2) general liability, (3) automobile liability, (4) aircraft and passenger liability and (5) comprehensive chemical liability damage. The insured cost-at-risk of the program to use silvex for weed control is summarized in table 2.

The cost-at-risk is calculated on the basis of the insurance cost according to provisions of a contract award, DACW 29-82-C-0349, U.S. Army Engineer District, New Orleans, 8 July 82. The operation and insurance cost-at-risk are approximately $10,000, a total cost-at-risk is for 64 hr (approximately 3,000 acres) is $34,112, and other operation and maintenance costs-at-risk are approximately $10,000, a total cost-at-risk of $44,112. The ground rig cost--at-risk is approximately 7.5 times aircraft application. The cost per acre is multiplied by the number of acres controlled to obtain the cost-at-risk for each type of control program.

Treatment of 20,000 acres of submersed weeds with a ground rig using a two man crew treating 10 acres per day involve approximately 4,000 man-days per year, and 320 man-days per year for the potential bystander population.

TABLE 2. BENEFIT/RISK ANALYSIS OF AQUATIC WEED CONTROL WITH SILEX

Item	Benefit	Cost-at-Risk
	Submersed aquatic plants	
Total benefit	5,619,600	
Costs[a]	1,700,000	
Net benefits	3,919,600	$2,205,500
Benefit/risk ratio		1.7
	Marginal-herbaceous aquatic plants	
Total benefit	28,969,556	
Costs[b]	1,440,592	
Net benefits	27,508,964	$2,297,500
Benefit/risk ratio		12.0
	Marginal-woody aquatic plants	
Total benefit	5,441,920	
Costs[c]	440,000	
Net benefits	5,001,920	$ 294,080
Benefit/risk ratio		17.0
Sum total-benefits	$40,031,076	
Sum total-costs	3,580,592	
Net benefits	36,450,484	$4,797,180
Sum total benefit/risk ratio		7.6

[a]20,000 acres per year @ $85 per acre.
[b]20,656 acres per year @ $70 per acre.
[c]20,000 acres per year @ $22 per acre.

The insured cost-at-risk is estimated at $2,205,600, with benefit/cost at risk ratio of 1.7.

Treatment of 20,656 acres of marginal-herbaceous plants using a ground rig and a two man crew, treating 10 acres per day, involve approximately 4,130 man-days per year, and 330-man days for the bystander population. The insured cost-at risk is estimated at $2,297,500, with a benefit/cost-at-risk ratio of 12.0.

Treatment of 20,000 acres of marginal-woody plants with a two man crew by aircraft treating 75 acres per day involve approximately 534 man-days per year, and 320 man-days per year for the bystander population. The insured cost-at-risk is estimated at $294,080, with a benefit/cost-at-risk ration of 17.0

A total of $36,450,484 net benefits are obtained for a total cost-at-risk of $4,797,180 with a total benefit/risk ratio of costs of 7.6 to 1.

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