United States
Environmental Protection
Agency

Office of
Pesticides and Toxic Substances
Washington DC 20460

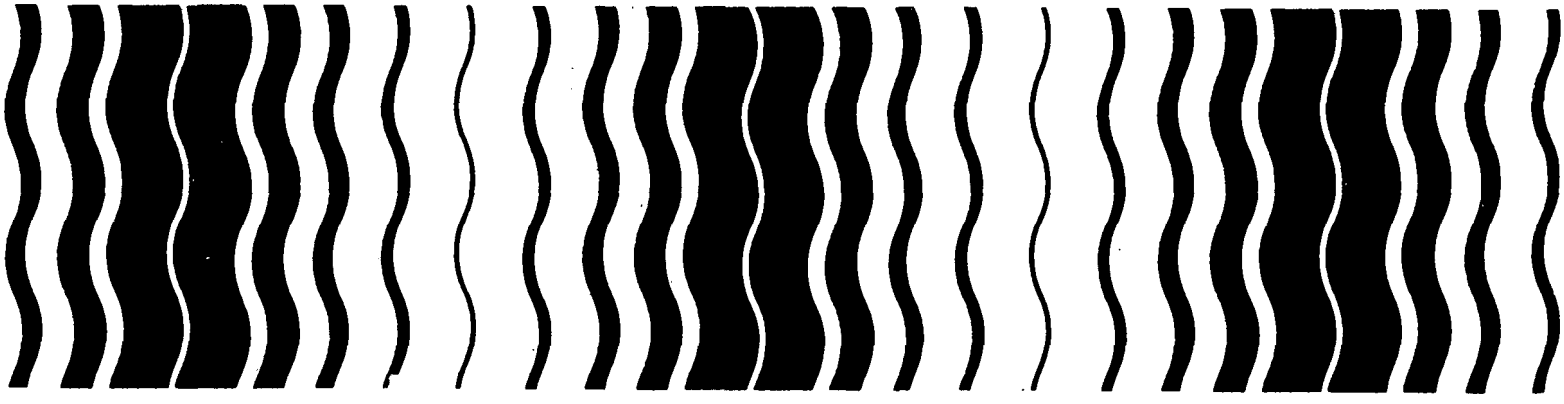
March 1981

Pesticides

EPA

Oxyfluorfen (Goal 2E®)

Position Document No. 1-2-3



OXYFLUORFEN
POSITION DOCUMENT

Office of Pesticide Programs
Environmental Protection Agency

Errata Sheet

Oxyfluorfen PD 1/2/3

The following constitutes a more accurate description of the EXAMS results than was presented in the PD 1/2/3 (page 43, Section II.E.1).

"Evidence that oxyfluorfen is toxic to certain aquatic invertebrates at low levels was also considered (Vilkas, 1978). Although this information raised concerns regarding all uses of oxyfluorfen, there was a special concern with respect to soybeans because a portion of the soybean use pattern area provided habitat for 20 species of endangered freshwater mussels.

The Agency has conducted a computer simulation of the expected aquatic environmental concentration of oxyfluorfen. A small, unstratified lake receiving input from a five acre watershed was simulated with the Exposure Analysis Modeling System (EXAMS) developed by the EPA's Athens, Ga., Environmental Research Laboratory. Using an oxyfluorfen loading value of 0.046 kg/yr, a steady state equilibrium concentration of 30 ppb is attained in the lake hydrosoil. The EXAMS simulation indicates that oxyfluorfen would be relatively persistent, with a half-life for system purification of 127.3 days once the loading ceases."

- ACKNOWLEDGEMENTS -

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I. INTRODUCTION

A. Legislative Background

The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Section 136 et seq.), as amended, gives the Environmental Protection Agency (EPA or the Agency) the authority to regulate pesticide products.

In order to obtain a registration for a pesticide under FIFRA, a manufacturer must demonstrate that the pesticide satisfies the statutory standard for registration. That standard requires (among other things) that the pesticide perform its intended function without causing "unreasonable adverse effects on the environment" [Section 3(c)(5)]. The term "unreasonable adverse effects on the environment" is defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" [FIFRA, Section 2(bb)]. In effect, this standard requires a finding that the benefits of each use of the pesticide exceed the risks of use, when the pesticide is used in accordance with commonly recognized practices. The burden of proving that a pesticide satisfies the standard for registration is on the proponents of registration and continues as long as the registration remains in effect. Under Section 6 of FIFRA, the Administrator is required to deny or cancel the registration of a pesticide or modify the terms and conditions of registration whenever he determines that the pesticide does not satisfy the statutory standard for registration.[1/]

Section 3(c)(7)(B) of FIFRA allows the Administrator to conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that:

-- the applicant has submitted satisfactory data pertaining to the proposed additional use, and

-- amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment.

1/ Another part of the statutory standard for registration is that the pesticide must satisfy the labeling requirements of FIFRA. These requirements are set out in the statutory definition of "misbranded" [FIFRA Section 2(q)]. Among other things, this section provides that a pesticide is misbranded if

> "the labeling * * * does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any * * * (restrictions) imposed under Section 3(d) * * * are adequate to protect health and the environment."

The Agency can require changes to the directions for use of a pesticide in most circumstances either by finding that the pesticide would cause unreasonable adverse effects on the environment, unless labeling changes are made which accomplish risk reductions [Section 6(b) or by finding that the pesticide is misbranded if the labeling is not changed [Section 3(c)(5)].

Section 3(c)(7)(B) states that ...

> "-- no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations issued under this Act, and during the pendancy of any risk-benefit evaluation initiated by such notice, if (i) the additional use of such pesticide involves a major food or feed crop, or (ii) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria."

In order for a pesticide to be sold and used to produce a crop, the pesticide must not only be registered for the particular use under FIFRA, but also must have a tolerance or an exemption from a tolerance for each individual crop on which it will be used. Under section 402 of the Federal Food Drug and Cosmetic Act (FFDCA), a raw agricultural commodity or a processed food or feed which contains a pesticide residue is "adulterated" unless a tolerance (maximum allowable limit of pesticide residue) or an exemption from a tolerance, or a food additive regulation has been established for the pesticide in question. The authority for establishing tolerances and exemptions from tolerances for residues of pesticide chemicals on raw agricultural commodities, and food additive regulations allowing pesticide residues in processed food is found in sections 408 (raw agricultural commodities) and 409 (processed food) of the FFDCA. In 1970, pursuant to the Reorganization Plan No. 3 of 1970, 84 Stat. 3086, the authority for establishing tolerances and exemptions from tolerances under sections 408 and food additive regulations under 409 of the FFDCA was transferred from the Food and Drug Administration to the Administrator of EPA.

B. The RPAR Process

The Agency created the Rebuttable Presumption Against Registration (RPAR) process to facilitate the identification of pesticide uses which may not satisfy the statutory standard for registration and to provide a public, informal procedure for the gathering and evaluation of information about the risks and benefits of these uses.

The regulations governing the RPAR process are set forth in 40 CFR 162.11. This section provides that a rebuttable presumption shall arise if a pesticide meets or exceeds any of the risk criteria set out in the regulations.

The Agency generally announces that an RPAR has arisen by publishing a notice in the Federal Register. After an RPAR is issued, registrants and other interested persons are invited to review the data upon which the presumption is based and to submit data and information to rebut the presumption. Respondents may rebut the presumption of risk by showing that the Agency's initial determination of risk was in error, or by showing that use of the pesticide is not likely to result in any significant exposure to humans or to the animal or plant of concern with regard to the adverse effect in question.[2/] Further, in addition to submitting evidence to rebut the risk presumption, respondents may submit evidence as to whether the economic, social, and environmental benefits of the use of the pesticide subject to the presumption outweigh the risks of use.

The regulations require the Agency to conclude an RPAR by issuing a Proposed Notice of Determination in which the Agency states and explains its position on the question of whether the risk presumptions have been rebutted. If the Agency determines that the presumption is not rebutted, it will then consider information relating to the social, economic, and environmental costs and benefits which registrants and other interested persons submitted to the Agency, and any other benefits information known to the Agency.

A primary purpose of the RPAR process is to screen for those pesticide uses which pose risks which are of sufficient concern to require the Agency to consider whether offsetting benefits justify the risks. Accordingly, the Agency's approach to rebuttal determinations concentrates on whether the risk concerns which are central to each RPAR proceeding have in fact been answered.

After weighing the risks and benefits of a pesticide use, the Administrator may conclude the RPAR process by issuing a proposed notice of intent to cancel or deny registration, or to change the classification of a pesticide pursuant to FIFRA Section 6(b)(1) and Section 3(c)(6) or by issuing a notice of intent to hold a hearing pursuant to Section 6(b)(2) of FIFRA to determine whether the registrations should be cancelled or applications for registration denied.

2/ 40 CFR Section 162.11(a)(4) provides that registrants and applicants may rebut a presumption against registration by sustaining the burden of proving: (i) in the case of a pesticide which meets or exceeds the criteria for risk set forth in paragraphs (a)(3)(i) or (iii) that when considered with the formulation, packaging, method of use, and proposed restrictions on and directions for use, and widespread and commonly recognized practices of use, the anticipated exposure to an applicator or user and to local, regional, or national populations of nontarget organisms is not likely to result in any significant acute adverse effects; or (ii) in the case of a pesticide which meets or exceeds the criteria for risk set forth in paragraph (a)(3)(ii) that when considered with proposed restrictions on use, the pesticide will not concentrate, persist or accrue to levels in man or the environment likely to result in any significant chronic adverse effects; or (iii) that the determination by the Agency that the pesticide meets or exceeds any of these criteria for risk was in error.

In determining whether the use of a pesticide poses risks which are greater than benefits, the Agency considers modifications to the terms and conditions of registration which can reduce risks, and the impacts of such modifications on the benefits of the use. Of the many risk reduction measures short of cancellation which are available to the Agency, two examples are changes in the directions for use on the pesticide's labeling and classification of the pesticide for "restricted use" pursuant to FIFRA Section 3(d).

FIFRA requires the Agency to submit the proposed notices issued pursuant to Section 6 to the Secretary of Agriculture for comment and to provide the Secretary of Agriculture with an analysis of the impact of the proposed action on the agricultural economy [Section 6(b)]. If the Secretary of Agriculture comments in writing within 30 days after receiving the notice, the Agency is required to publish the Secretary's comments and the Administrator's response. FIFRA also requires the Administrator to submit Section 6 notices to a Scientific Advisory Panel for comment on the impact of the proposed action on health and the environment, at the same time and under the same procedures as those described above for review by the Secretary of Agriculture [Section 25(d)].

Although not required to do so under the statute, the Agency has decided that it is consistent with the general theme of the RPAR process and the Agency's overall policy of open decisionmaking to afford registrants and other interested persons an opportunity to comment on the bases for the proposed action during the time that the proposed action is under review by the Secretary of Agriculture and the Scientific Advisory Panel. Accordingly, appropriate steps are taken to make copies of the position document available to registrants and other interested persons at the time the position documents are transmitted for formal external review, through publication of a notice of availability in the Federal Register, or by other means. Registrants and other interested persons are usually allowed the same period of time to comment--30 days--that the statute provides for receipt of comments from the Secretary of Agriculture and the Scientific Advisory Panel. The Agency will formally extend this comment period in cases where the issues are extremely complex or where new data are in the process of being generated.

After completing these external review procedures and making any changes in the proposed action which are deemed appropriate as a result of the comments received, the Agency will proceed to implement the desired regulatory action by preparing appropriate documents and releasing them in the manner prescribed by the statute and by the Agency's rules.

C. Regulatory History

1. Existing Registrations

Rohm and Haas is the sole producer of the herbicide Goal (oxyfluorfen) in the United States. There is one unconditionally registered product containing the active ingredient oxyfluorfen marketed under the trade name Goal 2E. This product has two unconditionally registered uses. Goal 2E was registered on May 17, 1979, for preemergence and postemergence weed control in nonbearing almonds, nectarines, peaches,

grapes, plums and prunes in California only. Subsequently, Goal 2E was registered on March 25, 1980, for preemergence and postemergence weed control in conifer seedbeds throughout the United States, and for preemergence and postemergence weed control in conifer transplants and outplantings. Conditional registration of Goal 2E for use on bearing tree fruits/nuts (as mentioned above) was approved by the Agency on December 18, 1980. The conditions of this registration will be defined in later sections of this document.

2. Experimental Use Permits

Under Section 5 of FIFRA, any person may apply to the Administrator for an experimental use permit (EUP). The Administrator may issue an EUP only if he/she determines that the applicant needs such a permit to accumulate information necessary to register the pesticide under Section 3 of FIFRA.

If the pesticide use under the experimental use permit is likely to result in residues on or in food or feed, the applicant must also petition for the establishment of temporary tolerance levels for the pesticide. Such a temporary tolerance must be established before the experimental permit may be issued. Permits and associated temporary tolerances may be renewed or extended upon request if circumstances, such as providing additional testing, warrant. The Administrator may also revoke an EUP at any time if he determines that its terms or conditions are not being met, or if the terms and conditions are not adequate to avoid unreasonable adverse effects on the environment.

On December 27, 1974, Rohm and Haas submitted an application for the experimental use of Goal 2E on 70,000 acres of soybeans (707-EUP-83) and a petition for a temporary tolerance for residues of oxyfluorfen of 0.05 ppm in soybeans (5G1581). The Agency first issued this permit on June 6, 1975, and has extended it annually since that time. The registrant requested that the current permit, effective for the period June 5, 1979 to June 5, 1980, be extended. This request was granted on March 20, 1980.

On October 13, 1975, Rohm and Haas submitted an application for the experimental use of Goal 2E on certain tree fruits (707-EUP-85) and a petition for a temporary tolerance for residues of oxyfluorfen of 0.05 ppm in almonds, apricots, grapes (intended for the fresh fruit market only), peaches, nectarines, and plums (fresh prunes, intended for the fresh fruit market only) (6G1690). The Agency first issued this permit on May 7, 1976, and has extended it annually since that time. The most recent permit expired on January 9, 1981. Permanent tolerances for these commodities were established December 24, 1980, (45 FR 85021) and conditional registration was approved December 18, 1980.

On December 7, 1977, Rohm and Haas submitted an application for the experimental use of Goal 2E on cotton (707-EUP-91) and a petition for a temporary tolerance for residues of oxyfluorfen of 0.05 ppm in cottonseed, eggs, milk, and meat, fat, and meat by-products of cattle, goats, hogs, horses, poultry, and sheep (8G2028). The Agency issued this permit and the temporary tolerances for the above-mentioned products with effective dates from July 11, 1979 to July 11, 1981. Permanent tolerances for eggs, milk, meat, fat and meat by-products of cattle, goats, hogs, horses, poultry and sheep were established December 24, 1980 (45 FR 85021).

3. Specific Exemptions

Section 18 of FIFRA authorizes the Agency to " . . . exempt any Federal or State Agency from any provision of this Act if [The Administrator] determines that emergency conditions exist which require such exemption."

On May 11, 1979, the Agency granted a specific exemption pursuant to Section 18 of FIFRA and 40 CFR 166.1 to the U.S. Department of Agriculture, Animal Plant Health Inspection Service, to apply Goal 2E on corn in a witchweed eradication program in 30 counties in the states of North and South Carolina. Some of the conditions for the use under this specific exemption were:

--A maximum of two applications per year could be made as a directed ground spray.

--The first application was restricted to the months of May and June and the second to July and August.

--The total quantity applied should not exceed 2.0 pounds active ingredient per acre per year.

--A maximum of 3,000 pounds active ingredient could be applied on a maximum of 2,000 acres in these two states.

--Application was restricted to USDA, Animal, Plant, Health Inspection Service (APHIS), Plant Protection and Quarantine personnel or certified commercial applicators under their supervision.

--Application closer than 60 feet to fish habitat and 120 feet to oyster habitat was prohibited.

--Analysis of water, hydrosoil, and young fish for oxyfluorfen residues in limnetic or estuarine habitat adjacent to a treated field was required.

This specific exemption expired on August 31, 1979. The Agency granted the USDA request for an exemption for 1980. This exemption allowed the use of up to 4,000 pounds of Goal (active ingredient) on a maximum of 2,000 acres of field corn in the Carolinas.

4. Application for Registration

On March 14, 1978, the Rohm and Haas Company submitted an application for the registration of Goal 2E (oxyfluorfen) for use on soybeans, bearing tree fruit/nuts, and corn and at the same time petitioned for establishment of permanent tolerances[3/] for oxyfluorfen residues of 0.05 ppm in soybeans, bearing tree fruits/nuts, and corn.[4/]

3/ This was later amended to include establishment of permanent tolerances on the meat, fat, and meat by-products of cattle, goats, hogs, horses, poultry, and sheep, eggs and milk at the 0.05 ppm level.

4/ The corn use is restricted to application in conjunction with the USDA, Plant Protection and Quarantine Program's Witchweed Eradication Project in North and South Carolina.

5. RPAR Action

Oxyfluorfen was referred to the Special Pesticide Review Division for Rebuttable Presumption Against Registration (RPAR) review in January 1980 because pesticide products containing oxyfluorfen as an active ingredient were shown to be contaminated with perchloroethylene (PCE), a liver carcinogen in B6C3F1 mice (NCI, 1977), which may pose a risk to human health via dietary and work-related exposures. On the basis of the carcinogenic potential of perchloethylene, the Agency determined that oxyfluorfen met or exceeded the RPAR criteria for oncogenicity. This contamination has been reduced by Rohm and Haas from the initial level of 1680 ppm (parts per million) (2-E formulation) to 200 ppm when the Agency performed its exposure and risk analyses for this document.

PCE is a process solvent used in one or more steps in the production of oxyfluorfen. The capabilities of PCE in this regard are unique. During the course of this RPAR review, the registrant was able to reduce the PCE contamination from 1680 ppm to 200 ppm by amending the production process. The registrant asserts that any further reduction in the amount of PCE would also remove an inordinate amount of oxyfluorfen.

In the interest of achieving an expedited review of the uses of oxyfluorfen, the Agency decided to issue a position document which integrated the PD 1 presumption against registration and the PD 2/3 risk/benefit analysis (PD 1/2/3). This approach was possible and desirable in this situation because much of the information which the registrant would have submitted at the PD 2/3 RPAR rebuttal stage was submitted during the current review of oxyfluorfen. It seemed reasonable, therefore, to focus public discussion on the risk/benefit analysis by presenting the Agency's proposed position in a single document followed by a public comment period during which time the registrant and other interested persons may submit comments in response to the Agency's proposed risk/benefit conclusions regarding oxyfluorfen. The Agency believes that neither the registrant nor any other interested person has been prejudiced by this procedural modification since they will not be deprived of their opportunity to participate meaningfully in the administrative decisionmaking process affecting the registration of this pesticide.

This document considers the potential risks and benefits associated with oxyfluorfen use relevant to the proposed issuance of oxyfluorfen tolerances and product registrations either currently registered or proposed.[5/] This review was based upon exposure, risk, and benefits information obtained from readily available published literature on PCE and data supplied by the registrant, Rohm and Haas, the U.S. Department of Agriculture, and various weed scientists throughout the United States.

Information on the potential benefits of registering oxyfluorfen for new uses was obtained by the Agency from the U.S. Department of Agriculture, various state plant scientists, and the applicant for registration.

5/ Currently registered uses includes conifers (seedbeds, transplants and outplantings) and nonbearing and bearing fruit and nut trees in California (almonds, peaches, prunes, plums, and nectarines). Proposed uses include: soybeans in the U.S., and field corn (USDA Witchweed Program only).

D. Chemical Background

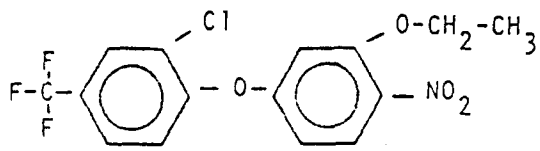
1. Oxyfluorfen

Oxyfluorfen is the common name for [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)-benzene], the selective herbicide sold under the trade name "Goal".

Some of oxyfluorfen's physical-chemical properties are (WSSA, 1979):

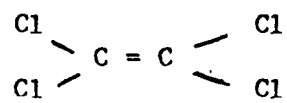
Melting point	65 - 80°C
Boiling point	250 - 300°C
Vapor pressure	2×10^{-6} mm of Hg at 25°C
Water solubility	0.1 ppm
Physical state	Solid at room temperature
Color	Deep red-brown to yellow

The empirical formula for oxyfluorfen is $C_{15}H_{11}ClF_3NO_4$, its molecular weight 361.7, and its structural formula:



2. Perchloroethylene (PCE)

PCE contaminates oxyfluorfen at 0.02% in the formulation marketed as Goal 2E. PCE has a molecular weight of 165.85 and a structural formula of:



Some of PCE's physical-chemical properties are:

Melting point	-23.35°C
Boiling point	121.2°C at 769 mm Hg
Vapor pressure	19 mm Hg at 25°C
Water solubility	0.1 percent at 25°C
Color	Colorless

At high concentrations, PCE has induced toxic effects such as liver and kidney damage, neurophysiological effects, central nervous system depression, and primary eye and skin irritation (NIOSH, 1978). The Agency

has reviewed readily available studies[6/] relevant to these effects of PCE and has determined that a human health hazard for the effects enumerated above is not indicated for those uses of oxyfluorfen discussed in this document due to the relatively low exposure levels which result from the use of Goal 2E (Dykstra, 1980c).

E. Uses and Production

1. Registrations and Use

There is one unconditionally registered product containing the active ingredient oxyfluorfen marketed under the trade name Goal 2E. This product contains 23.5% oxyfluorfen and is labeled for use in the preemergence and postemergence control of certain weeds in nonbearing almonds, nectarines, peaches, plums, and prunes grown in California, the preemergence and post emergence control of various weeds in conifer seedbeds (nationwide), and conifer transplants and out-plantings. Additional registration applications for Goal 2E are pending for use in soybeans, and field corn (for witchweed control only). Goal is conditionally registered for use on bearing tree fruits/nuts (as mentioned above). This registration is subject to the conditions outlined in this position document.

2. Production

a. Oxyfluorfen

Oxyfluorfen is manufactured solely by the Rohm and Haas Company of Philadelphia, Pennsylvania. Information concerning the actual manufacturing process and the amount of oxyfluorfen produced is considered confidential under Section 7 and protected under Section 10 of FIFRA.

b. Perchloroethylene

PCE is a heavily used chemical in commercial dry cleaning and industrial metal degreasing. The chemical has additional uses as an industrial solvent, and as a veterinary antihelmintic. About 700 million pounds of PCE are currently produced in the U.S. each year (NIOSH, 1978).

6/ In addition, the Agency is aware of a number of other reviews of PCE's risk potential. These include reviews by: NIOSH (1976, 1978); US EPA (1979, 1979a, 1980); NCI (1977); CPSC (1976); and Fuller (1976).

F. Tolerances

1. Oxyfluorfen

Section 5(b) of FIFRA states that the Administrator may establish a temporary tolerance level for the residue of a pesticide before issuing an experimental use permit, if he determines that the use of the pesticide may reasonably be expected to result in residues on or in food or feed. Temporary tolerances were established for 0.05 ppm oxyfluorfen in corn and soybeans (Petition No. 5G1581); almonds, apricots, grapes, peaches, nectarines, and plums (all 6G1690); and cottonseed, eggs, milk, meat, fat, and meat by-products of cattle, goats, hogs, horses, poultry, and sheep (Petition No. 8G2028). In addition, there is a temporary tolerance established at 0.2 ppm in cottonseed oil (Petition No. 9H5199). Temporary tolerances are extended or renewed in association with the respective renewals or extensions of experimental use permits.

Rohm and Haas petitioned the Agency on March 8, 1978, for the establishment of permanent tolerances in or on a number of commodities (Petition No. 8F2058) including: soybeans; corn; the meat, fat, and meat by-products of cattle, goats, hogs, horses, poultry, and sheep; eggs; and milk at 0.05 ppm and soybean oil at 0.25 ppm (FAP 9H5230). With the exception of corn, soybeans and soybean oil, permanent tolerances for these commodities were established on December 24, 1980 (45 FR 85021).

2. Perchloroethylene (PCE)

PCE is used as a solvent or cosolvent in a number of pesticide products. As a result of an Agency review (US EPA, 1974), PCE was exempted from the requirement of a tolerance when used in accordance with good agricultural practice as an inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest when present in the pesticide formulation at not more than 0.6% [40 CFR 180.1001(c)].[7/] In addition, PCE was exempted from the requirements of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals at all concentrations [40 CFR 180.1001(e)].

Various agencies and groups have evaluated potential human and environmental effects associated with PCE exposure. Table 1 shows a number of PCE concentrations that have been recommended by these groups as the maximum exposure levels for man or the environment that will not produce harmful effects. It should be noted that these levels were based on the acute effects of PCE and do not consider recent data indicating that PCE is carcinogenic in the B6C3F1 mouse. Current NIOSH interim guidelines indicates that occupational exposure to PCE should be reduced and that a reduction in the number of employees exposed to PCE should also be considered because of PCE's carcinogenic potential.

7/ These exemptions were established prior to the determination in September, 1977, that PCE is a carcinogen in B6C3F1 mice.

A number of other groups in addition to those listed in Table 1 have endorsed the exposure limits shown in that table, have established their own maximum exposure levels, or are currently evaluating effects of PCE on humans. A number of foreign governments have also set maximum exposure levels for PCE ranging from 2 ppm in Czechoslovakia to 100 ppm in the Federal Republic of Germany (US EPA, 1979a).

TABLE 1

Maximum PCE Exposure Recommendations Based Upon the Acute Toxicity of PCE

ORIGINATOR	STANDARD, RECOMMENDATION, OR MAXIMUM PCE EXPOSURE	MEDIUM	REFERENCE
EPA, Office of Water and Waste Management[a]			
Freshwater			
Chronic Toxic Effect	840 ug/l	Water	US EPA, 1980
Acute Toxic Effect	5280 ug/l	Water	US EPA, 1980
Saltwater			
Chronic Toxic Effect	450 ug/l	Water	US EPA, 1980
Acute Toxic Effect	10,200 ug/l	Water	US EPA, 1980
EPA, Office of Water and Waste Management			
Human Health Effects	8.0 ug/l (for a cancer risk of 10^{-5})	Water	US EPA, 1980
EPA, Office of Drinking Water	0.5 ug/l[b]	Drinking Water	43 FR 5756
NIOSH:			
10-hour time weighted average	50 ppm[c]	Air	NIOSH (1976)
Ceiling	100 ppm	Air	NIOSH (1976)
OSHA:			
8-hour time weighted average	100 ppm	Air	29 CFR 1910.1000
Acceptable Ceiling	200 ppm	Air	29 CFR 1910.1000
Maximum (5 minutes in 3 hours)	300 ppm	Air	29 CFR 1910.1000
ACGIH[d]			
Threshold Limit Value	100 ppm	Air	ACGIH (1976)

a/ Maximum level which will not harm aquatic organisms

b/ A maximum was not set specifically for PCE, however, maximum concentration of volatile halogenated organic compounds must not exceed 0.5 ug/liter.

c/ As a result of an NCI bioassay indicating that PCE is carcinogenic to B6C3F1 mice NIOSH has recommended that exposure to PCE"...should be limited to as few employees as possible, while minimizing workplace exposure levels (NIOSH, 1978)."

d/ American Conference of Governmental Industrial Hygienists.

II. RISK ANALYSIS

A. Environmental Occurrence

A brief survey of published literature resulted in the following information on background levels of PCE in the environment.

Monitoring has been carried out for PCE residues in the environment. PCE was detected in 9 of 105 drinking water samples analyzed between November 1976 and January 1977 at a range from <0.2 to 3.1 ug/liter; median <0.2 ug/liter; mean 0.81 ug/liter (US EPA, 1978). In addition, Dowty et al. (1975) detected PCE among a number of organic compounds in drinking water before, during, and after processing at a municipal water treatment facility in New Orleans, Louisiana.

Pearson and McConnell (1975) determined the concentration of PCE in Liverpool Bay and other areas of the United Kingdom using gas chromatography. This study found PCE levels as follows:

Atmosphere	<0.1 ppb to 40 ppb
Freshwater	0.15 ppb to 0.38 ppb
Seawater	2.6 ppb maximum, 0.12 ppb average
Marine sediments	4.8 ppb maximum
Marine invertebrates	0.05 ppb to 15 ppb
Marine algae	13.0 ppb to 22 ppb
Fish	<0.1 ppb to 41 ppb
Sea and Freshwater Birds	0.7 ppb to 39 ppb
Mammals	0.0 ppb to 19 ppb

McConnell et al. (1975) reported PCE levels in the following materials: in meat ranging from 0.9 to 5.0 ug/kg, in oils and fats from 0.01 to 7.0 ug/kg.

Singh (1977) reported an average northern hemispheric background concentration of 30.7 ppt (parts per trillion). Monitoring was done at a "clean air continental site" (Badger Pass--Yosemite, California) at an elevation of 2,360 meters, which was well above the inversion layer.

Simmonds et al. (1974) found an average PCE concentration of 1.25 ppb (parts per billion) in the air over the Los Angeles Basin in California. The range of PCE contamination in this study was reported to be from <0.01 ppb to 4.2 ppb. These measurements were made at an altitude of 3,200 meters.

Jensen and Ingvordsen (1977) found residues as high as 1,200 ppm in freshly cleaned clothing in self-service dry cleaning machines in Denmark. Air around the machines was found to contain 35 to 250 ppm of PCE.

NIOSH (1976) presented data taken from a study by Kerr (1972) indicating that the average concentration of PCE in various commercial dry cleaning plants ranged from 31 to 270 ppm with the highest level measured being 990 ppm. The same study found concentrations of PCE around the area used by the customers in coin-operated dry cleaners to range from 28 to 121 ppm. The maintenance area of these establishments contained from 93 to 378 ppm PCE.

It should be noted that the Agency is presently examining other non-pesticide uses of PCE and will address their significance under appropriate statutes.

B. Exposure Analysis - PCE

Since Goal was referred to SPRD on the basis of oncogenic risk from PCE contamination, this review will focus on exposure to PCE from use of Goal 2E in soybeans, tree fruits/nuts, field corn and conifers. Exposure from use on cotton will not be considered at this time because no application for use on cotton has been submitted. The exposure analysis prepared by the Agency (Kozak, 1980 as modified by Regelman, 1981) provides much of the basis for the information summarized in this section.

1. Method of Estimating Exposure

The registrant submitted an exposure analysis for PCE which could theoretically result from use of Goal 2E on field corn, tree fruit/nuts and soybeans. No analytical data were provided. This analysis was modified as described below in order to arrive at the Agency's exposure estimates.

Goal is presently registered for use as a pre- and post emergence herbicide in tree fruits/nuts in California and conifer seedbeds, transplants, and outplantings. Registration is pending for use in field corn, and soybeans. Application is by tractor-mounted low boom spray methods for all uses. Both inhalational and dermal exposures will be considered. The inhalation estimate was derived from a model that assumed total vaporization of the PCE in Goal since data on actual PCE levels during application were not available.

While it is recognized that the above approach yields an extremely conservative estimate of inhalational exposure, a number of physical and chemical properties of PCE support this approach. PCE is highly volatile and even though it is photolabile, its reported two-day half-life (Fuller, 1976) suggests that significant photodegradation will not occur during the time required for Goal application. In addition, since PCE has a vapor density 5.5 times greater than that of air, it might tend to spread laterally (instead of upward) under stagnant conditions (Fuller, 1976).

Evaporation of PCE from aqueous solutions is known to be rapid, even in the presence of adsorbing contaminants. In a study by Dilling et al. (1978), a solution of PCE in water at a concentration of 1 ppm was allowed to stand open to the atmosphere at approximately 25°C and stirred gently. The PCE concentration of this solution decreased by 50% after 26 minutes and by 90% after 83 minutes. It is likely that much more rapid evaporation would occur under conditions in which the surface-to-volume ratio of the solution was much greater, such as when the compound was sprayed onto the soil surface in an agricultural spray operation.

2. Applicator/Mixer/Loader Exposure

a. Inhalational Exposure

Daily inhalational exposure levels for applicator/mixer/loaders were calculated[8/] assuming that the average worker weighs 70 kg, applies Goal 2E for 8 hours per day, inhales 14,400 liters of air during a working day, that 100% of inhaled PCE is absorbed (Rohm and Haas, 1978), and that all PCE in the formulated product is volatilized into a rectangular prism of air six feet high above the treated field. The detailed calculation of inhalational exposure along with parameter values for each use is presented in Appendix A.

The estimated daily inhalation exposures to PCE are summarized in Table 2.

The inhalational model did not consider an increment of exposure to PCE during the process of mixing/loading. Instead, it presented PCE exposure assuming a full eight hours of spraying, since a reliable method of quantifying PCE exposure during the mixing/loading operation could not be found. However, based on the physical and chemical characteristics of PCE, as well as on the limited time involved in the mixing/loading operation (less than one hour), it is expected that the quantity of PCE vaporized during mixing/loading operations would be less than that which would occur during application. The Agency estimate, therefore, further tends toward the conservative side, where "conservative" is defined to be protective of human health.

b. Dermal Exposure

Dermal exposure data for applicator/mixer/loaders using tractor-mounted low-boom spray apparatus is limited in the literature. The registrant has, however, developed an estimate of this exposure using the model which takes into account the amount of liquid contacting applicators' skin during spraying (Rohm and Haas, 1978). The registrant assumed that 0.048 pint of diluted spray could contact an applicator's skin during an 8-hour day and that 10% of this amount would be absorbed.

8/ Inhalation Exposure (soybeans) $= \frac{\text{Grams PCE/Acre} \times \text{Volume Air Inhaled/Day}^{a/}}{\text{Volume of Air/acre}^{b/} \times \text{Average Body Weight}}$

$= \frac{0.0645\text{g PCE/Acre} \times 14{,}400 \text{ liters/day} \times 1000 \text{ mg/gm}}{7.4 \times 10^{6} \text{ liters/Acre} \times 70 \text{ kg Body Weight}}$

$= 1.804 \times 10^{-3}$ mg/kg/day

a/ $1.8\ m^3/hr \times 1000\ l/m^3 \times 8\ hr/day = 14{,}400$ liters/day

b/ volume of air/acre $= 6\ ft \times 43{,}560\ ft^2/acre \times 28.3\ l/ft^3$
$= 7.4 \times 10^{6}$ liters of air/acre

TABLE 2.

Daily PCE Inhalation Exposure for Applicator/Mixer/Loaders Using Goal 2E[a/b/]

CROP	(mg/kg bw/day)
Soybeans	1.804×10^{-3}
Field Corn	7.211×10^{-3}
Tree Fruits/Nuts	7.211×10^{-3}
Conifers	7.211×10^{-3}

a/ Assumes 200 ppm PCE in Goal 2E.

b/ Assumes an 8-hour day of spraying.

These values were originally derived from an applicator exposure study for paraquat, conducted by Staiff et al. (1975). The study was performed with workers using tractor-mounted low-boom spray equipment, the method also recommended for Goal 2E. The applicators in that study used a liquid concentrate formulation. Exposure was calculated on the basis of workers wearing short-sleeved, open-necked shirts, no gloves, and no hats. It was further assumed that the clothing worn protected the skin beneath the covered areas.

Use patterns, maximal use conditions and the amount of Goal 2E/PCE in the applied spray were estimated, and were used to compute the dermal exposure estimates[9/] which are summarized in Table 3. The estimates assume that the typical applicator/mixer/loader weighs 70 kg, and spends one hour/day in mixing/loading and 7 hours/day in spraying. The detailed calculation of dermal exposure, along with parameter values for each use is presented in Appendix A.

Since worker exposure does not occur daily throughout the year, nor does it occur throughout the lifetime of an applicator, adjustments to the estimates were made to allow for these variations in exposure. Using an average applicator exposure time of 10 days/year, (62.5 days/year for corn), assuming a working life of 40 years, and a 70-year life-span, the daily average lifetime exposure estimates were calculated,[10/] and are summarized in Table 4. These estimates were

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9/ Daily dermal exposure to PCE through use of Goal 2E in soybeans was calculated as follows:

Dermal Exposure (soybeans) = PCE Concentration in Diluted Spray[a/] x Diluted Spray Contacting Skin[b/] x Weight per Pint of Water x Percent Skin Penetration ÷ Average Body Weight

$$= \frac{0.86 \text{ ug/g} \times 0.048 \text{ pints} \times 454 \text{ g/pint} \times 0.1 \times 1 \text{ mg/1000 ug}}{70 \text{ kg bw}}$$

$$= 2.7 \times 10^{-5} \text{ mg/kg bw/day}$$

a/ PCE Concentration = $\frac{\text{PCE Weight Rate (grams/acre)}}{\text{Spray Weight Rate (grams/acre)}}$

$$= \frac{0.0645 \text{ g/acre} \times 10^6 \text{ ug/g}}{8.34 \text{ lbs/gal } H_2O \times 454 \text{ g/lb} \times 20 \text{ gal } H_2O/\text{acre}}$$

$$= 0.86 \text{ ug PCE/g } H_2O$$

b/ Rohm and Haas, 1978.

10/ $\frac{10 \text{ days/year} \times 40 \text{ years}}{70 \text{ years} \times 365 \text{ days}} = 0.0156$ for soybeans, tree fruit/nuts and conifers

TABLE 3.

Daily PCE Dermal Exposure for Applicator/Mixer/Loaders Using Goal 2E[a/][b/][c/]

CROP	(mg/kg bw/day)
Soybeans	2.7×10^{-5}
Field Corn	2.1×10^{-4}
Tree Fruits/Nuts	2.8×10^{-5}
Conifers	1.1×10^{-4}

a/ Assumes 200 ppm PCE in Goal 2E.

b/ Assumes 1-hour mixing/loading and 7-hour spraying.

c/ Based on Staiff, et al. (1975) work on paraquat.

TABLE 4.

Adjusted Lifetime Average Daily Worker Exposure to PCE from Use of Goal 2E[a/]

Crop	Inhalation mg/kg bw/day	Dermal mg/kg bw/day	Total mg/kg bw/day
Soybeans	2.814×10^{-5}	4.2×10^{-7}	2.8×10^{-5}
Field Corn[b/] [1981]	7.013×10^{-4}	2.0×10^{-5}	7.2×10^{-4}
Tree Fruit/Nuts	1.125×10^{-4}	4.4×10^{-7}	1.1×10^{-4}
Conifer	1.125×10^{-4}	1.7×10^{-6}	1.1×10^{-4}

a/ Assumes 200 ppm PCE in Goal 2E.

b/ Soybean, tree fruit/nuts, and conifer estimates are based on 10 working days per year. Field corn estimates were further adjusted to reflect the number of days that applicators are estimated (Petrie, 1980c) to be treating field corn as part of the USDA Witchweed Eradication Program during 1981 (62.5 days). It is estimated that 100,000 acres of field corn will be treated in 1981.

used by the Agency as the basis for estimating individual lifetime carcinogenic risk (Section II.C. of this document). Further reductions in the level of PCE contamination of Goal 2E would produce proportional decreases in the estimate of worker exposure.

In order to reduce applicator exposure to PCE, a number of protective measures may be taken. Severn (1978), in evaluating citrus use of chlorobenzilate, estimated the reduction in applicator exposure by the use of both protective clothing and respirators. Under the assumptions that the exposed skin surface, in the absence of protective clothing, is 0.29 m^2 (face, neck and "v" of chest, forearms and hands), and that clothing which covers these areas (except the face) completely protect them, the exposed skin surface area of a pesticide applicator is estimated to be reduced from 0.29 m^2 to 0.065 m^2. In addition, the wearing of the respirator during application would be expected to further reduce exposed skin surface to 0.042 m^2. Finally, assuming that a suitable respirator were used, inhalational exposures would be expected to be reduced to extremely low levels.

Table 5 summarizes estimated applicator exposure under these assumptions, reflecting a nearly 85% reduction in dermal exposure (0.042m^2/0.29 m^2 = 0.145), and a 100% reduction in respiratory exposure.

3. Dietary Exposure

While current data show no PCE residues in crops at the limit of detection, the Agency still considers that residues of PCE in Goal-treated commodities may exist below this level. Accordingly, the Agency estimated the theoretical maximum level of PCE in soybeans, field corn grain, and bearing tree fruit/nuts.

Rohm and Haas submitted data indicating the results of analysis for PCE in corn grain, various tree fruit/nuts, and soybeans grown on Goal-treated soil. These analyses indicated that PCE was not detected in these commodities at 0.05 ppm (the analytical sensitivity of the method used) (Perfetti, 1979a). The theoretical maximum dietary exposure was then calculated,[11/] and is summarized in Table 6. Calculations of dietary exposure and parameter values for each use are presented in Appendix A.

11/ Dietary Exposure (Soybeans) = $\dfrac{\text{Daily Consumption}^{a/} \text{ of commodity} \times \text{Sensitivity of analytical method}}{\text{Human Body Weight}}$

$$\frac{0.01819 \text{ kg} \times 0.05 \text{ mg/kg}^{b/}}{70 \text{ kg}} = 1.30 \times 10^{-5} \text{ mg/kg bw/day}$$

a/ Daily consumption of commodity in kg/person/day is based on the average consumption figures for each commodity (Schmitt, 1977).

b/ Assumes that 0.05 ppm level of analytical sensitivity is equivalent to 0.05 mg/kg of commodity.

TABLE 5.

Adjusted Lifetime Average Daily Worker Exposure
to PCE from Use of Goal 2E - Protective Clothing Scenario[a/]

Crop	Inhalation mg/kg bw/day	Dermal mg/kg bw/day	Total mg/kg bw/day
Soybeans	0	6.1×10^{-8}	6.1×10^{-8}
Field Corn [1981]	0	2.9×10^{-6}	2.9×10^{-6}
Tree fruit/Nuts	0	6.4×10^{-8}	6.4×10^{-8}
Conifer	0	2.5×10^{-7}	2.5×10^{-7}

a/ Assumes applicators wear protective clothing and suitable respirator.

TABLE 6.

Theoretical Maximum Dietary Exposure to PCE

Soybeans	1.30×10^{-5} mg/kg bw/day
Field Corn	3.57×10^{-5} mg/kg bw/day
Tree Fruits/Nuts	1.90×10^{-5} mg/kg bw/day

The Agency recognizes that these estimates are conservative, since they assume that all consumed corn, tree fruit/nuts and soybeans contain PCE residues from Goal-treatment. Therefore, further downward adjustments must be made to take into account the percentage of these commodities likely to be treated with Goal.

Estimates of percentage of crop treated are currently 8% for soybeans and 1.6% for corn. In addition, the field corn that will receive Goal treatment under this registration is limited to that grown in witchweed infested areas of North and South Carolina, treated in conjunction with the USDA's Witchweed Eradication Program. These adjustments to the maximum dietary exposure are summarized in Table 7. It is estimated that 50-90% of bearing tree fruits/nuts might possibly be treated with Goal, so that no downward adjustment was made for these commodities.

C. Cancer Risk Assessment

1. Introduction

The Agency's Interim Cancer Assessment Guidelines (Cancer Guidelines) (41 FR 21402) state that when a chemical is judged to be a potential human carcinogen, the Agency will estimate its possible impact on public health at current and anticipated levels of exposure. The Cancer Guidelines also recognize that the available techniques for assessing the magnitude of cancer risk to human populations based on animal data are at best very crude; this is due to uncertainties in the extrapolation of dose-response data to very low dose levels and to differences in levels of susceptibility of animals and humans. Accordingly, these risk estimates are neither scientific certainties nor absolute upper limits on the risk of cancer from use of PCE contaminated Goal. Rather, these estimates should be viewed as a health hazard index that incorporates the degree of carcinogenic activity and human exposure to the compound.

2. Evaluation of Cancer Data

The Agency has prepared an estimate of the carcinogenic risk to agricultural workers and to the U.S. population associated with the use of PCE contaminated Goal 2E. This evaluation was based upon data submitted by the registrant, Rohm and Haas, and studies acquired by the Agency from the open literature. These studies are discussed in the following sections.

a. Perchloroethylene

The following discussion [a.1) through a.6)] was taken from the EPA Carcinogen Assessment Group's risk assessment for PCE (CAG, 1979).

Two long-term animal bioassays have been performed to assess the carcinogenic potential of PCE. In one study (NCI, 1977) in which mice and rats were exposed to PCE by gavage, the National Cancer Institute (NCI) reported the induction of a highly significant number of hepatocellular carcinomas in male and female mice, but concluded that the test with rats was inconclusive due to excessive mortality.

TABLE 7.

Adjusted Maximum Dietary Exposure to PCE

Soybeans	1.04×10^{-6} mg/kg bw/day
Field Corn [1981]a/	4.96×10^{-8} mg/kg bw/day
Tree Fruits/Nuts	1.90×10^{-5} mg/kg bw/day

a/ Up to 100,000 acres of field corn are expected to be treated.

In the other study (Rampy et al., 1978) in which Sprague-Dawley rats were exposed by inhalation of PCE, the authors reported no evidence for the carcinogenicity of the chemical.

1) National Cancer Institute Bioassay (1977)

PCE was one of several halogenated hydrocarbon compounds tested for possible carcinogenicity in male and female (Osborne-Mendel) rats and male and female (B6C3F1) mice by NCI. PCE was administered to the animals in a corn oil vehicle by gastric intubation 5 days a week for 78 weeks. The vehicle control animals were intubated with an amount of pure corn oil equal to the amount given to the high dose animals. At the end of 90 weeks (mice) or 110 weeks (rats), surviving animals were killed, necropsied, and submitted to an extensive gross and microscopic examination.

The summary of tumor incidence in male and female mice at low and high dose levels of PCE is described in Table 8. The results indicate that PCE induced a highly significant increase in the incidence of hepatocellular carcinomas in both sexes of mice as compared to untreated controls or vehicle controls.

In rats, PCE-related chronic nephropathy occurred in exposed groups. The animals were also afflicted with chronic respiratory disease. Survival of PCE-exposed rats was poor, and the decrease in survival was significantly associated with increasing dose levels. No hepatocellular carcinomas were observed in any of the exposed rats. No significant changes in the structure of the liver were observed, and no statistically significant tumor incidence was observed at any anatomical site other than the liver. The National Cancer Institute concluded that the high mortality among rats detracted from the usefulness of the experiment in detecting carcinogenic potential with that species.

In summary, perchloroethylene induced a statistically significant incidence of hepatocellar carcinomas in both sexes of mice at low and high dose levels. However, the bioassay for rats was considered inadequate due to early mortality of many of the study animals (CAG, 1979).

2) Rat Inhalation Study (Rampy et al., 1978)

Male and female Sprague-Dawley rats were exposed to 300 or 600 ppm (2034 or 4068 mg/m^3) PCE in the air five days a week for 12 months. Although many tumors were found both in treated and control animals, there was no statistically significant increase in tumor incidence at any anatomical site.

Increased mortality occurred in the male rats exposed to 600 ppm (4068 mg/m^3). Earlier onset of advanced chronic renal disease appeared to be a contributing factor to the increased mortality rate of this group which also had a statistically significant increase in kidney tumor or tumor-like changes observed in gross pathology. However, light microscopic observation of kidney lesions did not reveal a statistically significant tumor incidence increase as compared to controls. Both

TABLE 8.

Incidence of Hepatocellular Carcinomas in B6C3F1 Mice With PCE Administered by by Gavage (NCI, 1977).

Dose (mg/kg/day)	Hepatocellular Carcinomas
Male	
untreated	2/17 (12%)
vehicle control	2/20 (10%)
536	32/49 (65%)
1072	27/48 (56%)
Female	
untreated	2/20 (10%)
vehicle control	0/20 (0%)
386	19/48 (40%)
772	19/48 (40%)

groups of female rats exposed to PCE showed liver atrophy, and high exposure-level females had an increased incidence of fluid filled cysts in the liver.

The authors of the report concluded that there was no evidence of tumor reponse to PCE because the incidence of tumors was similar for exposed and control rats. However, this study had the following drawbacks: (1) the period of exposure was only 12 months; (2) dose levels employed in this study were not high enough to provide maximum sensitivity. Because of these limitations, this study is inconclusive and not appropriate to use in assessing the carcinogenicity or noncarcinogenicity of PCE (CAG, 1979).

3) Intraperitoneal Administration

Theiss et al. (1977) injected six to eight-week-old, male strain A mice intraperitoneally (i.p.) with doses of 80 mg/kg, or 400 mg/kg PCE. The i.p. injections were given three times a week until 14 injections at 80 mg/kg or 24 injections of 200 or 400 mg/kg were completed. The survivors were sacrificed 24 weeks after the initial injection of PCE. There was no statistically significant increase in lung tumor incidence in treated animals as compared to controls.

4) Skin Painting Study of PCE by Van Duuren et al. (1979)

Van Duuren and his co-workers performed mouse skin bioassays of several halogenated hydrocarbons including PCE in groups of mice (ICR/Ha Swiss) for about one year.

A total of seven papillomas developed on 4 of 30 mice receiving PCE application followed by applications of phorbol myristate in acetone to the skin of the back. Of 90 mice receiving only applications of phorobol myristate acetate, six developed a total of seven skin papillomas. Two of these mice also developed squamous cell carcinomas. However, the results of this study are not statistically significant and this study does not provide evidence of positive carcinogenic effects by this mode of administration (CAG, 1979).

5) Cell Transformation

Price et al. (1978), using a highly sensitive in vitro cell system, demonstrated the transformation of Fischer rat embryo cells (F1706) to tumor-producing cells upon exposure to PCE. When these morphologically-altered cells were injected subcutaneously into newborn (Fischer) rats, tumors developed at the injection sites in all animals in less than two months. Based on this observation, the author concluded that PCE had a carcinogenic potential.

b. Oxyfluorfen

Two long-term rodent feeding studies were performed to assess the carcinogenicity of oxyfluorfen (Bio-Dynamics, 1978; IRDC, 1977).

1) Rat Study (Bio-Dynamics, 1978)

In this study, male and female (Long - Evans) rats were fed oxyfluorfen in the diet at levels of 2 ppm, 40 ppm and 800 ppm (raised to 1600 ppm at week 57 of the test) for 24 months. Interim necropsy was performed on a number of control and high dose animals at 12 months. Terminal sacrifice and necropsy for all surviving animals was performed at 24 months. The oxyfluorfen used in this study contained 5 to 60 ppm PCE (Rohm and Haas, 1978).

The 40 ppm dose level was considered to be the highest dose level giving no observable effect (NOEL). This was the middle dose level of the study. The high-dose level exhibited a mild treatment effect which microscopically was observed as minimal hypertrophy of centrilobular hepatocytes of the liver (1 male and 2 females). The liver cell change seen after 24 months of treatment was histomorphologically similar to that seen in rats examined from 12-month interim necropsy. There was no indication of any tumorigenic activity in any of the tissues examined in rats. The incidence of the neoplastic processes encountered generally was similar among the control and compound-treated groups or occurred in a single animal or at a very low incidence in rats of the various groups. However, further evaluation of this study indicated that the high dose was not reflective of the maximum tolerated dose (MTD) in this species. Therefore the study may be inadequate to determine the oncogenic potential of oxyfluorfen (Albert, 1980; Dykstra, 1981).

2) Mouse 20-Month Feeding Study (IRDC, 1977)

Male and female Charles River CD-1 mice were fed diets containing 2, 20, and 200 ppm Goal (85.7% active ingredient) for 20 months. The following discussion of the results is taken from the EPA Carcinogen Assessment Group (CAG) report on Goal (Albert, 1980).

The results of this study indicate that there was a dose-related toxic response in the livers of both male and female mice and that this was most pronounced in males (Squire, 1980). With respect to carcinogenicity, hepatocellular neoplasms were found in both treated and control animals. The increase in the incidence of liver tumors (carcinomas and adenomas combined) was not statistically significant even in the high dose males ($p = 0.068$) where the largest liver tumor incidence occurred. However, a statistically significant dose trend ($p = 0.008$) was demonstrated for liver tumors (adenomas and carcinomas combined). The Agency therefore determined that the evidence for carcinogenicity in this study is only marginal (Albert, 1980).

The potential carcinogenic role of the perchloroethylene (PCE) contamination of oxyfluorfen in this particular study was o examined in this review. Although the current level of PCE in Goal 2E is 200 ppm, the PCE content of the recrystallized oxfluorfen used in this study ranged from 5 to 60 ppm (Rohm and Haas, 1978). The mg/kg/day of PCE consumed by the high dose mice was calculated and related to animal tumor

incidence based on the NCI bioassay in B6C3F1 mice for oral PCE. Using this information, it was then determined that the incidence of tumors due to PCE contamination would be approximately 8.27×10^{-9}. Since this is too small to have been detectable in this study, it is likely that PCE is not the cause of the small incidence of tumors observed (Albert, 1980).

Certain inconsistencies in the protocol and conduct of the mouse feeding study make it of questionable value for the evaluation of the carcinogenic potential of oxyfluorfen (Albert, 1980). The 200 ppm dose groups were administered 800 ppm during weeks 57 and 58 of the study. Also, the high dose (200 ppm) does not appear to be representative of a maximum tolerated dose (MTD), as evidenced by a lack of change in body weight, food consumption, mortality, or other in-life observations due to compound adminstration. It appears, therefore, that the level of oxyfluorfen used in this study was too low to be of toxicological significance (Albert, 1980).

The Agency considers this study to be inadequate for the accurate evaluation of carcinogenic potential of oxyfluorfen, because of the inconclusiveness of the results and the inconsistencies in the protocol and conduct of this study.

3. Cancer Risk

a. Introduction

The Agency based its estimate of human exposure to the PCE contaminate of Goal 2E on a model which assumed total vaporization of PCE into a stagnant atmosphere during application operations. PCE exposure was calculated for Goal 2E contaminated with 200 ppm PCE (see Tables 2 through 7). In this model, worker exposure can be further reduced in proportion to reductions in PCE contamination in the formulated product and by measures which reduce exposure to workers and to the general population. A complete discussion of the exposure estimate is given in Section II.B. of this document.

Based upon this exposure estimate, the Agency calculated the individual lifetime risk of cancer to agricultural workers and the general population assuming that the risk was a function of the PCE contaminant of oxyfluorfen alone. The Agency calculated the risk associated with exposure levels using the multistage model for risk assessment and based upon the male mouse data from the NCI bioassay for carcinogenicity (discussed earlier in Section II.C.2.b.).

For the multistage model the relationship between dose and risk is as follows:[12/]

$$P = 1-e^{-(q_1d+q_2d^2+q_3d^3+...)}$$

where P = the lifetime probability (risk) of cancer
q = coefficient
d = dose

b. Applicator/Mixer/Loader Risk

Table 4 summarizes the Agency's estimate of applicator/mixer/loader exposure to PCE from the use of Goal 2E in soybeans, field corn (witchweed eradication), various tree fruit/nuts and conifers. These exposure estimates were then used in the multistage model. Table 10 presents the risk estimates using the multistage model. These estimates assume a 40-year working life, a 70-year lifespan, 200 ppm PCE contamination of Goal 2E, application of 10 days per year in soybeans and tree fruit/nuts, and conifers and 62.5 days per applicator in 1981 for corn.

c. Dietary Risk

Table 9 shows the estimate of maximum carcinogenic risk to the general population through the potential ingestion of PCE residues associated with treatment of agricultural sites used for the production of soybeans, field corn (witchweed eradication) and certain tree fruit/nut (Dykstra, 1981b). Although actual PCE residues have not been detected at a 0.05 ppm level of analytical sensitivity in samples of corn grain and soybeans treated with Goal 2E, the Agency assumed that PCE residues could exist in these crops at the level of analytical sensitivity for the purpose of estimating the worst-case dietary risk that might be associated with use of PCE contaminated Goal 2E in these food crops. Therefore, actual residues of PCE in these commodities may be much lower than 0.05 ppm. The Agency calculated the risk associated with exposure levels using the multistage model and based upon the male mouse data from the NCI bioassay for carcinogenicity (discussed earlier in Sections II.C.2.b. and II.C.3.a.).

12/ See Appendix B for sample risk calculation.

TABLE 9.

Carcinogenic Risk to Applicator/Mixer/Loaders and to the General Population Associated with the PCE Contaminant of Goal 2E (Dykstra, 1981b)

Crop	Exposure Estimate (mg/kg/day)	Risk Estimate
Worker:		
Soybeans	2.8×10^{-5}	1.48×10^{-6}
Field Corn	7.2×10^{-4}	3.82×10^{-5}
Tree Fruit/Nuts (bearing; nonbearing)	1.1×10^{-4}	5.84×10^{-6}
Conifers	1.1×10^{-4}	5.84×10^{-6}
Dietary:		
Soybeans	1.0×10^{-6}	5.30×10^{-8}
Field Corn	5.0×10^{-8}	2.65×10^{-9}
Tree Fruit/Nuts (bearing only)	1.9×10^{-5}	1.00×10^{-6}

TABLE 10.

Adjusted Lifetime Average Daily Worker Exposure to and Associated Risk from PCE in Goal[a/]

Crop	Inhalation (mg/kg bw/day)	Dermal (mg/kg bw/day)	Total (mg/kg bw/day)	Risk
Soybeans	0	6.1×10^{-8}	6.1×10^{-8}	3.24×10^{-9}
Field Corn [1981]	0	2.9×10^{-6}	2.9×10^{-6}	1.54×10^{-7}
Tree Fruit/Nuts	0	6.4×10^{-8}	6.4×10^{-8}	3.39×10^{-9}
Conifers	0	2.5×10^{-7}	2.5×10^{-7}	1.33×10^{-8}

a/ Assumes applicators wear protective clothing and suitable respirator.

d. Reduction of Risk by the Use of Protective Clothing and Equipment

The protective equipment and clothing scenario described in Section II.B.2.b. of this document reduces applicator exposure to PCE for all uses of oxyfluorfen. This results in a concomitant reduction in the risk associated with each of the uses. The estimated applicator exposure to PCE and associated risk under the protective equipment scenario are presented in Table 10. Table 11 presents a comparison between risk without protective equipment and the risk to applicators when protective equipment is employed.

D. Other Adverse Effects

1. Mutagenicity

a. Introduction

40 CFR 162.11(a)(3)(ii)(A) provides that a ".... rebuttable presumption shall arise if a pesticide's ingredient(s), metabolite(s), or degradation product(s) ... induces mutagenic effects, as determined by multitest evidence."

The importance of protecting humans against exposure to environmental mutagens is twofold. First, it is essential to protect against germinal mutations which may pose a threat to the health of future generations (i.e., expression of genetic disease) and secondly, to protect against somatic mutations which may be a possible cause of cancer or other genetically mediated disease.

b. Oxyfluorfen Mutagenicity Data

The following mutagenicity review is based on the Reproductive Effects Assessment Group's (REAG) Preliminary Report on the Mutagenicity of Oxyfluorfen (1980).

All oxyfluorfen mutagenicity data reviewed by the Agency have been submitted by the registrant. The submitted studies included tests which examined the ability of oxyfluorfen to cause point mutations and primary DNA damage in bacteria, mitotic recombination in yeast, and chromosome aberrations in rats. Also, attempts were made by the Agency to locate published mutagenicity studies by conducting several literature surveys. No references pertinent to the mutagenicity of oxyfluorfen were found.

TABLE 11.

Comparison of Applicator Risk With and Without the Use of Protective Equipment

Crop	Risk Without Protective Equipment	Risk When Protective Equipment is Employed
Soybeans	1.48×10^{-6}	3.24×10^{-9}
Field Corn [1981]	3.82×10^{-5}	1.54×10^{-7}
Tree Fruit/Nuts	5.84×10^{-6}	3.39×10^{-9}
Conifers	5.84×10^{-6}	1.33×10^{-8}

The Nomura Research Institute (NRI, 1980) evaluated the mutagenicity of Technical Goal (RH-2915, lot number 2-3985) with the Salmonella /microsomal activation system, the Escherichia coli tryptophan reversion assay, and the Rec-assay in Bacillus subtilis. The purity of oxyfluorfen used in these studies was reported as 72.0% (nine kinds of impurities were indicated but were not identified except 0 to 1% perchloroethylene). In the NRI study, Salmonella tests were carried out using the standard plate assay over a 500 fold concentration range (0, 10, 50, 100, 500, 1000, 5000 ug/plate [13/]) of Technical Goal with base-pair substitution sensitive strains TA 1535, TA 100, TA 92, and with frameshift sensitive strains TA 1537, TA 1538, TA 98, and TA 94.

In the absence of in vitro microsomal activation, dose-related positive responses were found with strains TA 100, TA 98, and TA 1538. When revertant counts at the highest concentration tested (5000 ug/plate)are compared to the spontaneous control revertant counts, TA 100 and TA 98 were weakly reverted (2.4 and 1.9 - fold increases in spontaneous revertant counts respectively) and TA 1538 showed a 7-fold increase in the number of spontaneous revertants. The mutagenic activity (expressed as the slope of dose-response curve) of Technical Goal in the presence of rat liver S-9 mix for metabolic activation, appeared to be increased about three-fold over the induced mutagenic activity observed without S-9 mix for TA 100, TA 98, and TA 1538. Strain TA 1537 was weakly reverted by Goal but only after S-9 activation (2.1-fold increase in the negative control value at 5000 ug/plate). Negative results were observed with strains TA 94, TA 92, and TA 1535 when tests were carried out with and without rat-liver enzyme activation. These results indicate the mechanism of genetic activity of Technical Goal for Salmonella is by frameshift mutation.

The Rec-assay (a differential growth inhibition test) conducted by NRI used a strain of Bacillus subtilis which is repair deficient (M45 Rec-) and a strain which is repair competent (H17 Rec+). Tests were carried out in the absence of in vitro mammalian metabolic activation. No growth inhibition in either Rec+ strain or Rec- was observed at concentrations up to 1000 ug/plate well of Technical Goal. Growth inhibition was observed at 5000 ug/well; a 4 to 5 mm difference in growth of Rec- and Rec+ strains was found. At the next concentration tested, 20,000 ug/well, a 3 mm difference was shown. Because this indicates that Technical Goal is causing damage to bacterial DNA that can be repaired, these results are considered to support the positive results reported in Salmonella.

The Escherichia coli WP2 tryptophan reversion assay was also used in the NRI study. The same concentration range (0 to 5000 ug/plate) was examined. Reversion of E. coli WP2 Hcr- by Technical Goal was not observed in the presence or absence of S-9 metabolic activation. It should be pointed out that this test system does not effectively detect frameshift mutagens. In addition, there have been known mutagens which test positive in the Salmonella assay, but which test negative in E. coli WP2 assay (Sugimura et al., 1976; McMahon et al., 1979). Therefore, these negative results do not reduce the weight of the positive results obtained in the Salmonella /microsome test system.

Following the NRI studies in Japan, the registrant initiated another Salmonella /microsome assay (Smith, 1980) using both

13/At 5000 ug/plate crystal formation occurs.

recrystallized oxyfluorfen (99.7% purity, lot TTF-0685) and Technical Goal (72.5% purity, lot 2-3985). It should be noted that the lot of Technical Goal used in this study was the same lot tested by NRI. Oxyfluorfen was examined at a concentration range of 1 to 7500 ug/plate for both technical and recrystallized preparations in strains TA 98 and TA 100 with and without metabolic activation. Briefly, when TA 98 and TA 100 were treated with Technical Goal, dose-related responses, similar to those reported in the NRI study, were observed in both strains. Therefore, these results corroborate the results described in the NRI report for Technical Goal. In contrast, analytical Goal was not detected as mutagenic when tested in TA 98 and TA 100 with and without S-9 activation at 1 to 7500 ug/plate. Because Technical Goal produced point mutations in Salmonella but recrystallized Goal did not, the possibility of an impurity with mutagenic activity in the technical product should be considered. Although perchloroethylene is one of the impurities which is present in Technical Goal, the available evidence suggests that PCE is not detected as mutagenic in bacteria (REAG, 1981).

Highly purified oxyfluorfen was initially examined for mutagenicity in earlier studies submitted by the registrant (Litton Bionetics, 1973). These tests included a bone marrow assay for detecting cytogenetic effects and a host-mediated assay for detecting point mutations. The purity of oxyfluorfen was 99+% (Krzeminski, 1980). In the bone marrow assay, male rats (Sprague-Dawley) were dosed orally by intubation per day at 0.1 mg/kg, 1 mg/kg, and 10 mg/kg of Goal (RH915, BRL 652) for five consecutive days. Five animals were used at each dose. The investigators examined fifty metaphases per animal at the end of treatment for chromosomal effects (chromatid gaps and breaks, chromosome gaps and breaks, reunions, cells with greater than 10 aberrations, polyploidy, pulverization). No detectable aberrations were reported. The criteria used to establish the dosage levels are not clearly defined in the report except that they were based on the registrant's knowledge of the LD_{50} of RH 915 and the anticipated human exposure. Thus, it is possible that the dose levels used were not high enough to induce chromosomal effects to a detectable level (i.e., the maximum tolerated dose may not have been approached). Therefore, the significance of the results is difficult to interpret.

Litton Bionetics, Inc. (1973) also conducted in vivo subacute host-mediated assays with parallel in vitro tests using the mitotic recombination system in Saccharomyces and the histidine reversion assay in Salmonella. In the in vitro Saccharomyces D3 assay, 5% Goal (99 + % purity) tested in liquid suspension for four hours did not demonstrate any genetic activity. At this concentration no appreciable cell killing (9%) occurred. The low toxicity may indicate that this treatment condition was not sufficient to significantly increase mitotic recombination. Negative results were also observed when "pure" Goal (0.1 ml of a saturated solution) was examined in the Ames spot test using the base-pair substitution sensitive strains TA 1530 and G-46 without S-9 activation. Frameshift - sensitive strains were not evaluated in this study. In addition, the spot test is not particularly sensitive for detecting weak mutagenicity due to its qualitative nature. Since the report did not provide information on the number of revertants (experimental and control) and toxicity of dose used, the reported negative result cannot be considered evidence supportive of the nonmutagenicity of oxyfluorfen.

Host-mediated assays using Saccharomyces and Salmonella as indicator organisms and Flow Laboratory ICR random-bred male mice as the host to activate the test substance were conducted. The dosage levels used were 0.1 mg/kg, 1 mg/kg, and 10 mg/kg per day for five days. Mice were dosed by stomach tube and 30 minutes after the last dose the indicator organism was injected into the peritoneum. Goal (99+% purity) did not significantly increase the incidence of recombination or histidine independent revertants in Saccharomyces or Salmonella, respectively. Although a weak response (3.4-fold increase in control value) was observed at 1 mg/kg for yeast, the response was not dose-related. In addition, there are several deficiencies in this report which make the interpretation of the results tenuous. The number of indicator organisms recovered was not given and the standard deviation of the results was not reported. In addition, the criteria used to establish the dose levels to arrive at a maximum tolerated dose are not clearly indicated, thus it is not known if the test material was available at concentrations sufficient to increase the mutation frequency of the indicator organism. It shouldbe noted that in order for Goal to produce mutations in the indicator organism, it (or its active form) must be absorbed and transported to the peritoneum of the host animal.

In summary, results from two independent studies indicated that Technical Goal (72% to 72.5% oxyfluorfen) produced point mutations in Salmonella typhimurium. In addition, a Rec-assay using Bacillus indicated the ability of Technical Goal to damage bacterial DNA. Because recrystallized Goal (99.7% oxyfluorfen) was not detected as mutagenic in Salmonella in the Rohm and Haas study, the possibility of an impurity with mutagenic activity present in the technical grade product cannot be ignored. Nevertheless, the technical product is mutagenic to bacteria and may cause mutations in other organisms as well, including mutations in humans. However, further testing in other organisms should be conducted with Technical Goal to confirm its mutagenic activity.

With respect to mutagenicity testing of highly purified Goal (99+% oxyfluorfen), negative results were reported in the Salmonella/microsome assay (Rohm and Haas, 1980), the bone marrow assay, and the in vivo host-mediated assay with parallel in vitro tests using Salmonella and Saccharomyces (Litton, 1973). The negative results found in these studies do not permit a final judgment on the potential mutagenicity or non-mutagenicity of oxyfluorfen because of the experimental deficiencies found in the studies conducted in 1973 and because the genetic endpoints, point mutations, and chromosomal mutations have not been adequately examined. Therefore, additional studies are needed to refute or confirm the reported negative results for "pure" oxyfluorfen.

c. PCE Mutagenicity Data

Perchloroethylene has been tested for its ability to cause point mutations in bacteria, point mutations and recombination in yeast, and for chromosome aberrations in rodents. These studies are discussed below.

Henschler (1977) found that PCE was not mutagenic when tested using Escherichia coli K_{12} with metabolic activation. The lack of mutagenicity demonstrated for PCE was theorized to be due to the formation of a stable symmetrical configuration of the oxiranes derived from this compound (CAG, 1979).

Greim et al. (1975) reported negative results in a preliminary report of testing employing *in vitro* metabolic activation of analytical grade PCE at 0.9mM (survival 99 ± 1%) for two hours in *Escherichia coli* K_{12} (Mauer, 1980).

Bartsch et al. (1979) investigated the mutagenicity of a number of haloethylenes including PCE. PCE was evaluated in a plate incorporation assay adapted for testing volatile chemicals. Negative results were reported with concentrations up to 4×10^{-3} M PCE using TA 100 in the absence and presence of liver-enzyme activation.

Margard (1978) tested both stabilized and unstabilized PCE in the Ames plate incorporation assay using TA 1535, TA 1537, TA 1538, TA 98, and TA 100. The unstabilized material was identified as purified PCE and the stabilized material was identified as an industrial, degreasing grade of PCE containing 0.07% epichlorohydrin and other stabilizer components (Schlossberg, 1981). Positive responses were reported using the frameshift sensitive strains TA 1538 and TA 98, and the base-pair substitution sensitive strain TA 100 with 0.1 ml (concentration not given) of stabilized PCE per plate both in the presence and absence of liver enzyme activation. It should be stressed, however, that the stabilized test material contained epichlorohydrin which has been shown to be strongly mutagenic in *Salmonella* (McMahon et al.,1979; Andersen et al., 1978). Unstabilized PCE (purified) was not detected as mutagenic in either the presence or absence of metabolic activation up to 0.1 ml per plate. Because stabilized PCE appears to produce point mutations in *Salmonella* and "pure" PCE appears not to be mutagenic, this suggests that an impurity (epichlorohydrin) may be producing the observed mutagenic activity in the stabilized test material. However, with respect to mutagenicity testing of highly purified PCE, it should be emphasized that a negative result in a bacterial point mutation test does not preclude the mutagenic activity of the chemical evaluated. For example, several factors such as the toxicity of the test agent, differences between *in vitro* liver enzyme activation and *in vivo* metabolic activation, and the relative reactivity (e.g., highly reactive intermediates) of the metabolites could result in a chemical not being detected as positive in an *in vitro* test system.

Cerna and Kypenova (Abst. 1977) reported increased mutagenic activity in *Salmonella typhimurium* with PCE (both base-pair substitution as well as frameshift mutation) in the presence and absence of liver microsomal activation. The authors also reported that in the host-mediated assay using tester strains TA 1950, TA 1951, and TA 1952, PCE induced significant increases in the number of revertants (CAG, 1979). However, this report was an abstract which did not include information on the protocol used, did not present data to substantiate the conclusions, and did not report the purity of the test material, or the concentrations used.

Callen et al. (1980) evaluated the ability of PCE (containing 0.01% thymol as a stabilizer) and six other halogenated aliphatic hydrocarbons to cause gene conversion at the *trp-5* locus, mitotic recombination at the *ade-2* locus, and reversion at the *ilv-1* locus in *Saccharomyces cerevisiae* D7. In this organism, a marginal increase in the frequency of gene conversion (19 convertants/10^6 survivors versus 14 convertants/10^6 survivors in the control) and mitotic recombination (530 mitotic recombinants/10^6 survivors versus 330 mitotic recombinants/10^6 survivors in the control) were produced by a one hour treatment at 4.9 mM

(84% survival). When the concentration of PCE was increased to 6.6 mM (58% survival), increases in gene conversion and mitotic recombination (83 convertants/10^6 survivors and 5260 mitotic recombinants/10^6 survivors, respectively) were found. A marginal increase in reversion was observed at 4.9 mM (3.8 revertants/10^6 survivors versus 2.9 revertants/10^6 survivors in control). The reversion frequency was not determined at 6.6 mM. Although concurrent positive controls were not included in this study, the results indicate that PCE (with 0.01% thymol) is genetically active in yeast. However, because there was no concurrent thymol control, the activity of PCE needs to be re-examined in yeast using the "pure" chemical.

Rampy et al. (1978), in a chronic rat study, examined three male and three female rats for chromosome aberrations after the animals had been exposed to 300 or 600 ppm (2.03 or 4.07 mg/l) PCE formulation by inhalation 6 hours/day, 5 days/week, for one year. The authors reported no chromosome or chromatid aberrations in the bone marrow cells of male rats, and indicated that the data for female rats were inadequate for a clear interpretation because of the low number of scorable metaphases. The cytogenetic data and details of the protocol were not provided in this report. Therefore, the negative conclusions forwarded cannot be evaluated. In addition, it does not appear that the highest exposure level is near the maximum tolerated dose for females because no weight loss was reported and no mortality was observed. In males, however, the maximum tolerated dose may have been approached because significant increases in mortality above control values was observed at the highest dose tested. It should be noted that it is not apparent that the investigators determined the toxicity of the test material to arrive at a maximum tolerated dose for this study in that dose levels were based on the threshold limit value of 100 ppm for PCE.

Cerna and Kypenova (1977) reported in an abstract that, male mice (ICR) given an acute intraperitoneal dose or dosed intraperitoneally for five applications did not show cytogenetic effects in the bone marrow cells. Details of the protocol and the cytogenetic data are not available for an evaluation. In addition, purity of the chemical was not reported.

In summary, PCE has not been clearly demonstrated to cause point mutations in bacteria. However, a negative result in a particular bacterial system does not preclude the mutagenic activity of a chemical in other organisms. Only two positive reports were found in the available literature and both utilized the Salmonella system; one was an abstract by Russian authors where the purity of the test material was not reported and the data were not provided to substantiate the reported results (Cerna and Kypenova 1977), and the other indicates that only stabilized test material [the mutagen epichlorohydrin (0.07%) reported to be present] was active and nonstabilized (purified) was not active (Margard, 1978). There is suggestive evidence in yeast, however, that PCE may be genetically active. However, since PCE contained 0.01% thymol as a stabilizer, this positive response needs to be confirmed or refuted by re-examining PCE in yeast using the "pure" chemical. Therefore, to date the bacterial tests

14/ A written request has been made to Dow Chemical Company to secure these data.

appear to be negative and the positive response reported in yeast does not allow for a determination of PCE mutagenicity but emphasizes the need for further studies to evaluate its mutagenicity.

The Agency considers the data base discussed above to be insufficient to characterize PCE or Goal for mutagenicity.

2. Teratogenicity

a. Introduction

40 CFR 162.11(3)(ii)(B) provides that a rebuttable presumption shall arise if a pesticide ingredient(s), metabolite(s), or degradation product(s) ... "produces any chronic or delayed toxic effect in test animals at any dosage up to a level ... which is substantially higher than that to which humans can reasonably be anticipated to be exposed ..."

b. Oxyfluorfen Teratogenicity Data

A rat teratogenicity study which has been submitted by the registrant indicates that the active ingredient of Goal 2E, oxyfluorfen, is not teratogenic at a dosage of 1000 mg/kg (Dykstra, 1979a). The Agency has also reviewed a rabbit teratogenicity study with oxyfluorfen which it determined was unacceptable (Dykstra, 1980d).

The possibility that oxyfluorfen might behave as a teratogen was carefully considered because of the similarity in chemical structure of oxyfluorfen to nitrofen,a known teratogen. However, studies submitted to and reviewed by the Agency failed to detect any teratogenic activity attributable to oxyfluorfen (Dykstra 1980). The data obtained from these studies were not entirely adequate to assess the teratogenic potential of oxyfluorfen because no post-natal evaluations were done in the oxyfluorfen studies. Post-natal observations are of particular importance in the case of oxyfluorfen because observation of the teratogenic effects produced by nitrofen requires a test protocol which includes post-natal evaluation.

Because the rabbit study was not acceptable and because studies submitted to this date did not include post-natal evaluation, the data available are considered to be inadequate to determine the teratogenic potential of oxyfluorfen.

c. PCE Teratogenicity and Fetotoxicity Data

The Agency is not aware of any studies indicating that PCE is a teratogen.

A study done by Schwetz et al. (1975) reports reduced fetal body weight and a slightly elevated fetal resorption incidence for female rats which had inhaled 300 ppm PCE for 7 hours/day on days 6 through 15 of gestation.

At the exposure level of 300 ppm for 7 hours a day, the rat would be exposed to 313 mg/kg/day. This exposure level is higher by a

factor of 6,788 than the highest human exposure calculated here for oxyfluorfen contaminated by 200 ppm PCE (Dykstra, 1981a).

3. Chronic Toxicity

A two year dog feeding study (Hazleton, 1980) submitted by the registrant has been reviewed by the Agency. A no-observed effect level (NOEL) was not established in this study. At the lowest dose tested (100 ppm) the effects observed consisted of the following: bile pigmented hepatocytes, dose-related liver weight increases, dose-related alkaline phosphatase, renal tubular exithelial vacuolization, and lymphocytic thyroiditis (Dykstra, 1980). In order to establish a NOEL for oxyfluorfen in dogs, the Agency believes that this study would need to be repeated at lower dose levels.

E. Environmental Risk

The Agency has evaluated the potential environmental risks associated with use of the active ingredient of Goal 2E (oxyfluorfen). Although data are not currently adequate for determining whether use of this compound would exceed the criteria for risk to wildlife at 40 CFR 162.11(a)(3)(i)(B) or 162.11(a)(3)(ii)(C), Agency scientists have indicated concern over four separate issues with respect to wildlife risks (Hitch, 1980).

1. Persistence and Bioaccumulation in Aquatic Habitats

The Agency has conducted a computer simulation of the expected aquatic environmental concentration of oxyfluorfen. A small, unstratified lake receiving input from a five acre watershed was simulated with the Exposure Analysis Monitoring System (EXAMS) developed by the EPA, Athens, Ga., Environmental Research Laboratory.

Results of this simulation indicate that oxyfluorfen loading to such an aquatic system would be 0.046 kg per year. The sediment residue after 1 year of loading is predicted to be 30 ppb.

Over the long term, based on model predictions, oxyfluorfen can be expected to persist and accumulate in certain aquatic environments (Hitch, 1980). The EXAMS simulation predicts a half-life for oxyfluorfen in the model aquatic system to be 127.3 days, and that there will be increases in the hydrosoil sediment concentration every year that the pesticide is applied.

The possibility of annual increases in oxyfluorfen concentrations in aquatic habitats limits the accuracy of exposure level predictions for aquatic organisms and consumers of aquatic organisms. The Agency believes that field monitoring of actual oxyfluorfen residues in aquatic habitats is necessary to accurately evaluate the persistence, bioaccumulation and hazard to aquatic organisms.

a. Preliminary Survey of Possible Monitoring Sites

The computer simulation indicating that oxyfluorfen might be transported from treated fields thereby reaching environmentally hazardous levels in aquatic habitats can be evaluated with field monitoring

of actual treatment sites. To begin this evaluation, Agency personnel conducted, from August 13, 1980 to August 15, 1980, a field survey designed to select sites with physical parameters comparable to those used in the computer simulation or with parameters more likely to cause runoff.

The preliminary survey sites were located within the witchweed (Striga asiatica) quarantine area on the coastal plain of North Carolina. Cooperating U.S. Dept. of Agriculture personnel selected three farm sites having soils similar to those of Midwestern corn and soybean fields. Each farm had corn acreage within the watershed of a swamp or pond-like body of water. The R.S. Hilburn farm in Pender County was treated with Goal in 1979 and 1980. The C.E. Quinn farm in Duplin County received Goal treatments in the four years of 1977 thru 1980. Samples from the third site provided controls for other samples. This farm--belonging to F.P. Fensel--was located in Pender County. Corn fields on this farm had not been treated with Goal. Aquatic organisms, soil samples, and hydrosoil samples were collected from all three sites for residue analysis. Because Goal may be expected to be more rapidly assimilated by the aquatic organisms living in or near the hydrosoil, benthic organisms were collected at each site. No, one, suitable, benthic organism taxon was common to any two of the sites. Three different taxa were, therefore, collected: adult crayfish (family: Astacidae), tadpoles (order: Anura), and freshwater clams (class: Pelecypoda).

The EXAMS model simulation was made with the assumption that only the uppermost hydrosoil strata would be reactive with oxyfluorfen. A hydrosoil coring device was, therefore, employed which had been designed by the cooperating USDA personnel to sample the top strata. Table 12 shows the number of samples of each type, the average residue concentration and the range of residue measurements.

b. Conclusions

The 50 ppb mean hydrosoil concentration found at the Quinn farm exceeds the 30 ppb concentration projected with the EXAMS computer model. This correspondence and the fact that the Quinn farm does have treated fields in close proximity to a natural aquatic habitat indicates that a definitive monitoring program at this site might help the Agency determine if unreasonable harm to aquatic organisms is posed by the witchweed use.

In general, however, the fields of the witchweed quarantine areas were found to be of low gradient and to be comprised of sandy soil. Portions of the soybean and bearing fruit use-pattern areas are more highly sloped and contain finer, more organic soils. It is recommended that oxyfluorfen monitoring, in the future, within the witchweed control area include only fields where runoff to valuable aquatic habitats is likely. Monitoring should, in addition, be conducted at aquatic sites within the other major use pattern areas where runoff and transport may be likely.

Some observations made during the survey have given rise to an unexpected concern. Although no field soil residues were found at the 10 ppb detection level at the Hilburn site, Goal apparently was still providing control of the witchweed. This raises the question of whether or not the observed hydrosoil cooncentrations of 50 ppb may not be lethal to

TABLE 12.

Goal Residue Analyses from Samples Taken in the Witchweed Quarantine Area (August 13-15, 1980)

Farm	Sample Type	Number of Samples	Mean (ppb)	Range (ppb)
Quinn (Treated)	Hydrosoil	6	50	10-70
	Field Soil	2	72	42-102
	Benthic Organism	2	20	20
Hilburn (Treated)	Hydrosoil	2	*	*
	Field Soil	2	*	*
	Benthic Organism	2	*	*
Fensel (Control)	Hydrosoil	2	*	*
	Field Soil	2	*	*
	Benthic Organism	2	*	*

* Below 10 ppb detection limit.

aquatic plants residing in the wetlands of the corn and other use pattern areas (Hitch, 1981).

2. Toxicity to Molluscs

Oxyfluorfen has been shown to be toxic to certain aquatic molluscs (Crassostrea virginica) at concentrations which may be expected in the hydrosoil. The oyster larvae water column no effect level has been determined to be 3.2 ppb (Vilkas, 1978). In addition, pelecypods[15] may assimulate significant amounts of pesticides directly from the sediments (Hauer and Morales-Alamo, 1978). Sediment residues were predicted by the EXAMS model to be 30 ppb after one year of loading. Preliminary monitoring data indicate that residue levels predicted by the model can occur in the environment.

The Agency believes that these data are a cause for concern with regard to certain endangered freshwater molluscs. Twenty species of freshwater clams found throughout the Great Mississippi River Basin are on the Department of Interior Endangered Species List (FR Notice 45-99, 1980). A large scale use pattern for oxyfluorfen in this area of the United States may present a hazard to these molluscs. The eight major soybean producing states[16] are drained by the Mississippi River and its tributaries.

Section 7 of the December 28, 1973 Endangered Species Act states that:

> "All...Federal departments and agencies shall...insure that actions authorized... by them do not jeopardize the continued existence of... endangered species and threatened species..."

The U.S. Environmental Protection Agency is, by this portion of section 7, prohibited from authorizing actions--including pesticide usages--which jeopardize endangered and threatened species. In order to remove the jeopardy to endangered molluscs posed by the application of Goal to soybeans, the Agency could request that the registrant provide monitoring data during the conditional registration period. If the monitoring data indicate that lethal concentrations are being approached, then registrations for this use could be cancelled in the counties providing habitat for the endangered clams. The counties providing habitat for endangered clams are listed in Table 13.

15/ Pelecypoda is a class of aquatic mollusc which includes clams, oysters, mussels and scallops.

16/ The eight major soybean producing states in the U.S. are Indiana, Illinois, Missouri, Arkansas, Minnesota, Iowa, Mississippi, and Ohio.

TABLE 13.

States and Counties Providing Habitat for Federally Designated Endangered Mussel Species.

States	Counties
Alabama	Jackson, Limestone, Madison, Marshall, Morgan
Arkansas	Arkansas, Craighead, Cross, Greene, Independence, Izard, Jackson, Lee, Monroe, Poinsett, Prairie, St. Francis, Stone, White, Woodruff
Illinois	Carrol, Gallatin, Hardin, Henderson, Jo Daviess, Massac, Mercer, Pope, Pulaski, Rock Island, White, Whiteside
Indiana	Gibson, Knox, Pike, Posey
Iowa	Allamakee, Clayton, Clinton, Des Moines, Dubuque, Jackson, Louisa, Muscatine, Scott
Kentucky	Ballard, Butler, Crittenden, Edmonson, Hart, Laurel, Livingston, McCracken, Pulasky, Union, Warren
Minnesota	Washington
Missouri	Bolinger, Butler, Carter, Cedar, Cole, Dunklin, Franklin, Gasconade, Jefferson, Maries, Miller, Osage, Pike Ralls, Reynolds, Ripley, St. Clair, St. Louis, Stoddard, Wayne
Ohio	Licking, Morgan, Mushingum, Washington
Tennessee	Bedford, Claiborne, Coffee, Decatur, Franklin, Grainger, Greene, Hardin, Jackson, Lincoln, Madison, Marshall, Maury, Morgan, Perry, Robertson, Smith, Washington, Wayne
Virginia	Washington
West Virginia	Fayette
Wisconsin	Crawford, Grant, Iowa, LaCrosse, Richland, Sauk, St. Croix, Vernon

3. Possible Hazard to Wetlands

Some observations made during the Agency's preliminary survey of monitoring sites have given rise to an unexpected concern. Although no field soil residues were found at the 10 ppb detection level at the Hilburn site, Goal apparently was still providing control of witchweed. This raises the question of whether the observed hydrosoil concentrations of 50 ppb might be lethal to aquatic plants residing in the wetlands of the corn and other use pattern areas.

The ecological importance of the nation's wetlands is widely recognized. Oxyfluorfen appears to be herbicidally active at soil concentrations below 10 ppb. During the preliminary monitoring survey conducted by the Agency in North Carolina, hydrosoil concentrations of up to 70 ppb were found. If oxyfluorfen is as toxic to beneficial aquatic plants as to target weeds, wetlands might be threatened by the use of Goal on nearby fields or orchards. Monitoring studies may indicate that harm would only occur over an area which is geographically insignificant in size or that exposure of wetlands could be reduced by certain management practices. Until such a demonstration is made, the Agency could require labeling to protect wetlands for all proposed Goal uses.

4. Avian Reproductive Study

The Agency has determined that the results of avian reproductive studies submitted by the registrant are inconclusive due to high variability in the controls and significant failure to comply with standard protocols (Hitch, 1980). Therefore, data are currently inadequate to determine whether use of Goal 2E would result in a significant hazard to birds.

III. BENEFITS ANALYSIS

A. Introduction

The applicant for registration, Rohm and Haas, has proposed that oxyfluorfen be registered for control of certain weed species in soybeans and for witchweed control in field corn. In this section, the Agency examines the potential usage of oxyfluorfen on these crops, costs of other pest control programs, and the projected impacts on producers of these commodities if oxyfluorfen were not available. The information in this Section is based upon the analysis provided by the Economic Analysis Branch of the Office of Pesticide Program's, Benefits and Field Studies Division (Devine, 1980a; 1980b). In addition, the Agency is including a qualitative benefits discussion of the currently registered oxyfluorfen uses on bearing and nonbearing tree fruit/nuts, and conifers (seedbeds, transplants and outplantings).

B. Soybeans

1. Soybeans: EPA Registration of Oxyfluorfen and Other Soybean Herbicides[17]

The manufacturer of oxyfluorfen, Rohm and Haas, is seeking registration for Goal 2E use on soybeans to control certain annual broadleaf and grassy weeds, which are listed in Table 14. Numerous herbicides are currently registered for use on soybeans. Major registered soybean herbicides selected for cost comparisons are listed in Table 15.[18]

17/ Limitations of Analysis

a. Application rates for oxyfluorfen and alternatives are estimated from product labels and state recommendations.

b. Alternative herbicide treatments are based on state recommendations, information provided by the Plant Sciences Branch/BFSD, and other sources.

c. For this analysis, it is assumed that no differences exist in application methods or application costs for oxyfluorfen and other soybean herbicides.

d. Calculations of the comparative costs of oxyfluorfen and other herbicides do not reflect any signicant differences in comparative efficacy and performance that may exist.

e. The degree of growers' acceptance of oxyfluorfen over time is unknown.

18/ This analysis mentions four types of soybean herbicide use: preplant incorporated, preemergence, no till and postemergence. Preplant incorporated herbicides are applied to the soil surface and incorporated or mixed into the top two to four inches of soil before or during planting, within a specified period on the herbicide label. Preemergence herbicides are applied to the soil surface during or soon after planting, before the emergence of the crop or weeds. No till herbicides are used in cropping systems in which crops are planted directly into plant residue with a minimum of soil disturbance. Finally, post emergence herbicides are applied after emergence of the crop, weeds, or both (Beck and Petrie, 1981).

TABLE 14.

Weed Species Controlled by Goal 2E (Rohm and Haas, 1979).

Broadleaf Weeds	Grasses
Black nightshade	Barnyard grass
Common Lambsquarters	Fall Panicum
Common ragweed	Giant foxtail
Cutleaf groundcherry	Large crabgrass
Jimsonweed	Broadleaf signalgrass[a/]
Pennsylvania smartweed	Seedling johnsongrass[a/]
Prickly sida	Yellow foxtail[a/]
Red root pigweed	
Velvetleaf	
Common cocklebur[a/]	
Morning glory[a/]	

a/ Under certain conditions, Goal may give sufficient benefit (suppression) to be of value against these weeds.

TABLE 15.

Selected Major Registered Herbicides for Control of Annual Broadleaf and Grassy Weeds in Soybeans[a/]

Application Methods	Herbicides
Preemergence	
Single Herbicide	Alachlor
	Chloramben
	Linuron
	Metribuzin
Tank Mix Combinations	Chloramben/alachlor
	Linuron/alachlor
	Metribuzin/alachlor
Following Preplant - Incorporated Trifluralin Treatment	Trifluralin + Metribuzin
No Till	Linuron/alachlor/paraquat
	Metribuzin/alachlor/paraquat
	Glyphosate/alachlor/linuron
	Glyphosate/alachlor/metribuzin
Postemergence	2,4-DB
	2,4-DB/linuron
	Dinoseb

a/ Devine, 1980a

2. Soybeans: Recommendatons for Using Oxyfluorfen and Other Soybean Herbicides

Since 1974, oxyfluorfen has been used experimentally on soybeans under Section 5 of FIFRA (Malak, 1980). Although oxyfluorfen use on soybeans is currently permitted only on an experimental basis, the Missouri, Ohio, and Wisconsin Extension Services currently recommend its use as an experimental herbicide for the preemergence control of annual broadleaf weeds and grasses. The proposed label for Goal 2E recommends that it be applied on soybeans in one of three ways: preemergence during or soon after planting, no till after emergence of weeds but before emergence of the crop, or postemergence-directed (sprayed between rows to avoid crop injury) after emergence of both crop and weeds. Soybean herbicide recommendations of selected soybean-producing states for those weeds listed on the oxyfluorfen label are presented in Appendix E. USDA recommendations are also shown in Appendix E.

3. Soybeans: Performance Evaluation of Oxyfluorfen and Other Soybean Herbicides

a. Pest Infestation and Damage

Table 14 presents the weed species listed as controlled by oxyfluorfen on the Goal 2E label. The majority of these weeds infest the entire eastern half of the United States and many are widespread throughout the country. The major soybean-producing states, Arkansas, Illinois, Indiana, Iowa, Minnesota, Mississippi, Missouri and Ohio (USDA, 1980a and 1978), are included in the major infested areas of weeds listed on the oxyfluorfen label. Many other soybean-producing states are also affected by several of these weeds (USDA, 1978).

One especially troublesome weed in soybeans, listed as controlled by Goal 2E on the proposed label, is black nightshade (Solanum nigrum) (Table 14). The tough stems of black nightshade can jam the cylinders of combines; and nightshade berries, which are poisonous to humans and animals, are difficult to separate from the harvested soybeans. When crushed by harvesting, the berries produce a sticky juice that stains the soybeans and makes dust and debris adhere to them, reducing marketability of the crop (Seim, 1981).

Other examples of problem weeds in soybeans include weedy vines such as morning glory, which can cause lodging of soybeans. Lodging interferes with harvesting and requires extra drying of the crop because of moisture from the excess green material harvested. Grasses can also hinder harvesting operations because their tough stems are difficult for combines to cut (Caldwell, 1973). The Goal 2E label claims control of morning glory and control or suppression of several grass species (Table 14).

b. Comparative Performance Evaluation

Since 1974, a limited amount of field testing has been done on oxyfluorfen as an experimental soybean herbicide under section 5 of FIFRA. The manufacturer has submitted sufficient efficacy, phytotoxicity and yield data for soybean use to satisfy EPA performance data requirements as they existed prior to the Agency's efficacy data waiver policy, and thus to support initial registration of label-claimed uses of Goal 2E on

soybeans (Petrie, 1980a). Extensive performance evaluations comparing oxyfluorfen with other currently registered soybean herbicides will not be available until after oxyfluorfen is registered and becomes more widely available. Several weed researchers have indicated that there are too many newly registered products in need of performance testing to extensively test all unregistered products at this time (Beck and Petrie, 1980b).

Currently insufficient data are available to make a thorough quantitative comparative performance evaluation of oxyfluorfen and other soybean herbicides. Enough information exists, however, to make a qualitative analysis that identifies a number of situations where oxyfluorfen compares favorably with certain other soybean herbicides.

Because of the small amount of comparative efficacy information available, the comparative performance evaluation analysis was not limited to comparisons of oxyfluorfen with herbicides applied by the same methods. However, in the economic impact analysis oxyfluorfen was only compared to herbicides applied by the same methods: preemergence, no till or postemergence. This greatly reduced the number of comparative cost calculations without sacrificing the usefulness of those calculations in the analysis or altering the Agency's decision (see footnote 19). The same purpose would not be accomplished by making the same limiting assumption in the comparative efficacy discussion. The many possible herbicide treatment programs to control the weeds listed on the Goal 2E label are illustrated in Appendix E.

The manufacturer, Rohm and Haas, characterizes Goal 2E as a specialty herbicide for use where problems of poor weed control or crop phytotoxicity may exist if currently registered herbicides are used (Rohm and Haas, 1980a). Performance data in EPA Registration Division files generally confirm this statement, and agricultural researchers expect oxyfluorfen to occupy such a niche in the soybean herbicide market (Petrie, 1980a; Beck and Petrie, 1980b).

Several advantageous properties and uses of oxyfluorfen are indicated by the manufacturer's registration data and are supported by the experience of agricultural experts. These are described below:

a) Soil texture and organic matter content affect the performance of most soil-applied herbicides. As clay and organic matter content increase, there is greater adsorption of certain of these herbicides by the soil. Soils with more clay and organic matter require higher application rates to offset adsorption, and soils with more sand and less organic matter need lower rates to avoid phytotoxicity or burning of the soybean crop. The labels of several important preplant-incorporated herbicides instruct users to adjust application rates according to soil texture and organic content. Alachlor, chloramben, linuron, metribuzin and trifluralin are examples of such herbicides. Linuron and metribuzin labels do not recommend use of those herbicides in soils of coarse texture and extremely low organic content (sand) in order to avoid phytotoxicity to the crop. Since soil organic matter and texture may vary in different parts of a single field, a uniform application rate for herbicides such as those listed above may cause poor weed control in some areas of the field and crop injury in others (Beck and Petrie, 1980b; Rohm and Haas, 1980a). Unlike most soil-applied soybean herbicides, the application rate and weed control performance of oxyfluorfen does not depend on soil texture or organic matter content, and a single application rate can be used on soils

of any texture with organic matter content ranging from 0-8% (Beck and Petrie, 1980b; Petrie, 1980a; Rohm and Haas, 1980a). Most soybeans are grown in soils containing 8% or less organic matter (Knake, 1980a).

b) Highly alkaline or calcareous soils may prevent use of metribuzin, a major soybean herbicide, which, like oxyfluorfen, lists preemergence, no-till and postemergence directed spray uses on its label. Labels of metribuzin products state that crop injury may result from use in soils with a pH of 7.5 or more. In tests of oxyfluorfen on soils of varying pH, its performance was not significantly affected by soil acidity or alkalinity (Petrie, 1980a; Rohm and Haas, 1980a).

c) According to label instructions, the major preemergence soybean herbicides alachlor, chloramben, linuron and metribuzin require moisture for activation, in the form of rainfall or irrigation within one or two weeks after application. This post-application moisture distributes the herbicide into the weed germination layer of the soil (Caldwell, 1973). In the case of alachlor, soil incorporation may be used to activate the herbicide if the soil is sufficiently moist, and may serve as a substitute for post-application rainfall or irrigation. Oxyfluorfen does not require rainfall, irrigation or soil incorporation after application, since soil moisture adequate for soybean germination is also enough for activation of the herbicide (Beck and Petrie, 1980b; Petrie, 1980a; Rohm and Haas, 1980a).

d) Oxyfluorfen has been reported to be less phytotoxic than other soybean herbicides at normal use levels (Beck and Petrie, 1980b; Knake, 1980). Metribuzin, a major soybean herbicide, causes injury to several soybean varieties, and its label cautions against use on these varieties (Beck and Petrie, 1980b). Oxyfluorfen may be used on these metribuzin-sensitive soybeans (Petrie, 1980a). Some of the other soybean herbicides can also be phytotoxic under extremely wet field conditions, where leaching of the herbicide damages soybean root systems (Beck and Petrie, 1980b) For example, the Lorox (linuron) label warns users about crop injury when fields are very wet. Some herbicides will leach so rapidly in low organic, coarse-textures soils that they have a potential for either harming the crop or providing little weed control (Caldwell, 1973; Rohm and Haas, 1980a). Oxyfluorfen is not prone to leaching due to its low solubility in water and it affinity for soil exchange sites (Petrie, 1980a; Rohm and Haas, 1980a). However, too much rainfall or irrigation immediately after oxyfluorfen preemergence application can cause splashing of the chemical onto newly emerged soybean leaves, and cause contact chemical burning (Ryan, 1978). Yield reduction, crop maturity delay, or both have occasionally resulted from heavy rainfall between application and crop emergence. Significant yield reductions were not found, and the magnitude of this potential problem has not been determined (Petrie and Beck, 1980b; Petrie, 1980a).

e) Oxyfluorfen has a combination of attributes that are well adapted to use in no till systems. Preemergence residual activity of oxyfluorfen is good, and weeds may be controlled up to three months after application (Beck and Petrie, 1980b; Petrie, 1980a; Rohm and Haas, 1980a). In addition, oxyfluorfen is not readily de-activated by the crop trash and stubble present in no till use (Rohm and Haas, 1980a). Agricultural researchers have identified a specific need for oxyfluorfen in a no till

tank mix with alachlor for use in double cropping systems in Kentucky and Illinois (Beck and Petrie, 1980b).

f) The limited field research comparing oxyfluorfen with other soybean herbicides indicates that oxyfluorfen helps control certain problem weeds that infest soybeans. Black nightshade is a particularly troublesome weed in soybeans that is controlled by oxyfluorfen. In field studies, preemergence application of oxyfluorfen has been shown to be more effective than alachlor or trifluralin against black nightshade, and preemergence spraying of an oxyfluorfen/alachlor mixture gave better control over nightshade species than an alachlor/linuron mixture (Petrie, 1980a).

Cutleaf groundcherry is considered to be a problem weed in Arkansas, a major soybean-producing state, and oxyfluorfen has been effective as a post emergence directed spray for control of groundcherry in that state (Petrie, 1980a). In Arkansas tests, oxyfluorfen provided better control than alachlor, and provided residual preemergence control of groundcherry plants germinating after spraying (Petrie, 1980a). Other studies found oxyfluorfen alone to be superior to an alachlor/metribuzin tank mix for groundcherry control (Petrie, 1980a).

Annual morning glory is another weed that is poorly controlled by presently registered herbicides (Petrie, 1980a). The Goal 2E label lists morning glory species among the weeds suppressed by its use, and researchers have identified a need for oxyfluorfen to control annual morning glory in Illinois, Kentucky, and North Carolina (Petrie, 1980a).

4. Soybeans: Economic Impact Analysis

a. Profile of Impacted Area

In 1979, there were approximately 2.3 billion bushels of soybeans harvested from 70.5 million acres in the U.S (USDA, 1980b). The value of soybean production in 1979 was estimated to be about $13.8 billion (Matthews, 1980). The eight largest soybean-producing states (previously listed) accounted for about 70% of the total U.S. soybean production in 1975-79 (USDA, 1980b and 1978).

b. User Impacts

It is assumed for this analysis that if oxyfluorfen is registered, a farmer will continue to use his current method of herbicide application, substituting oxyfluorfen or oxyfluorfen combinations for the herbicides currently used.[19/] Therefore, economic impacts would be limited to differences in herbicide material cost between oxyfluorfen and other soybean herbicides.

19/ The Agency recognizes that farmers may in reality choose among a wide variety of soybean herbicides and application methods, as illustrated in Appendix E. However, the limited economic analysis chosen by the Agency is sufficient to establish that some soybean herbicides are more costly than oxyfluorfen, while others are less costly. Further cost comparisons would not alter the conclusion that oxyfluorfen is competetive in price.

In a typical soybean weed control program, herbicides are initially applied to the soil in a preplant-incorporated, preemergence, or no till (a combination of a nonselective and preemergence herbicides) treatment. This is done either before, during or soon after planting, and before emergence of the crop. If weed problems persist, postemergence herbicides may be applied after emergence of both crop and weeds (Petrie, 1980a). The Goal 2E label allows one application of oxyfluorfen each year, which may be either a preemergence (including no till) or post emergence directed treatment.

1) Preemergence Use

Oxyfluorfen can be applied as either a band or broadcast treatment (Rohm and Haas, 1980a). In this analysis, only broadcast application rates are used to calculate herbicide cost since the majority of preemergence herbicides are applied in this manner (Devine, 1980a). Although the herbicide cost per acre is less for band application, cost differences between herbicides would be relatively the same for both band and broadcast application.

The major preemergence herbicides used for weed control in soybeans include alachlor, chloramben, linuron and metribuzin (Table 15). All of these can be applied by either band or broadcast techniques. The cost associated with the application of oxyfluorfen is compared to these four herbicides in Table 16, and ranges from \$1.56 to \$9.60 per acre less for oxyfluorfen than for the others.[20/]

Oxyfluorfen can also be applied preemergence in a tank mix with alachlor. Other major herbicides that are applied preemergence in a tank mix combination with alachlor include chloramben, linuron and metribuzin (Table 15). Comparisons between oxyfluorfen/alachlor and the other tank mix combinations indicate that the oxyfluorfen/alachlor combination treatment ranges from \$0.30 to \$2.88 less per acre than the other combinations (Table 17).

Oxyfluorfen can also be applied after preplant incorporation of trifluralin (Rohm and Haas, 1980a). Metribuzin is one of the major herbicides applied after trifluralin is preplant incorporated. (Table 15). A treatment of preplant-incorporated trifluralin followed by preemergence oxyfluorfen costs \$2.04 more per acre than the comparable trifluralin/metribuzin treatment (Devine, 1980a) (Table 17).

20/ Since application rates may vary according to the soil type and organic content, a midpoint of the recommended range of application rates (for medium soils, if listed) from the eight major soybean-producing states was determined. Averages of the midpoints were calculated in order to estimate the per acre costs of other herbicides.

TABLE 16.

Comparison Costs of Goal 2E and Selected Preemergence Herbicides for Control of Annual Broadleaf and Grassy Weeds in Soybeans[a/]

Herbicides	Per Acre Herbicide Cost ($)	Per Acre Difference in Cost Between Oxyfluorfen and Selected Preemergence Herbicides ($)
oxyfluorfen	8.96	———
alachlor	10.88	+1.92
chloramben	18.56	+9.60
linuron	15.07	+6.11
metribuzin	10.52	+1.56

a/ Devine, 1980a

TABLE 17.

Comparison Costs of Goal 2E Combinations and Selected Preemergence Herbicide Combinations Used for Control of Annual Broadleaf and Grassy Weeds in Soybeans[a/]

Herbicides Combinations	Per Acre Herbicide Cost ($)	Per Acre Differences in Cost ($)
Tank Mixes		
oxyfluorfen/alachlor	8.96 + 7.04 = 16.00	———
chloramben/alachlor	11.84 + 7.04 = 18.88	+2.88
linuron/alachlor	9.61 + 8.80 = 18.41	+2.41
metribuzin/alachlor	7.50 + 8.80 = 16.30	+0.30
Preemergence Spray Following Preplant - Incorporated Trifluralin		
trifluralin + oxyfluorfen	6.99 + 8.96 = 15.95	———
trifluralin + metribuzin	5.31 + 8.60 = 13.91	-2.04

a/ Devine, 1980a

2) No Till Use

Oxyfluorfen can also be applied in no till systems as a tank mix with either paraquat or paraquat plus alachlor.[21/] The major alternative herbicide combinations applied to no till systems include: linuron/alachlor/paraquat, metribuzin/alachlor/paraquat, glyphosphate/alachlor/linuron, and glyphosphate/alachlor/metribuzin (Table 15).

The per-acre chemical cost of oxyfluorfen/paraquat/surfactant ranges from $6.57 to $25.29 less per acre than alternative tank mixes. The per-acre chemical cost difference between oxyfluorfen/alachlor/paraquat/surfactant and the other tank mixes ranges from $5.29 to $24.01 less per acre for the oxyfluorfen-containing treatment (Table 18) (Devine, 1980a).

3) Postemergence Use

Oxyfluorfen can also be applied as a postemergence-directed spray. Table 15 lists selected postemergence-directed herbicides and Table 19 lists their comparative costs per acre. The cost of oxyfluorfen treatment per acre falls between the extremes of the per acre herbicide costs calculated. Dinoseb costs $2.32 more per acre, but 2,4-D/linuron and 2,4-DB cost $1.23 and $5.85 less per acre respectively (Devine, 1980a) (Table 19).

4) Summary of User Impacts

Taken as a whole, calculations of comparative cost per acre of oxyfluorfen (used alone, in combination, or in sequence with other herbicides) indicate that it will be competitive in cost with other herbicide treatments used in soybeans. In a number of instances, oxyfluorfen use is less costly than use of other herbicides selected for this analysis: single herbicide preemergence spray, tank mix combination preemergence spray and no till treatment (Tables 16, 17, and 18). For other methods of application, use of oxyfluorfen results in a more expensive treatment program than some of the others selected: sequential program of preplant-incorporated trifluralin and preemergence spray and postemergence directed spray (Tables 17 and 19). The cost figures used to calculate user impacts do not include increased yield, improved crop quality, increased ease of harvesting, or other presently unquantifiable benefits that may result from use of oxyfluorfen in special situations, such as soil composition or problem weeds, that are outlined in the comparative efficacy discussion.

21/ The paraquat label specifies use of x-77 surfactant with all paraquat soybean tank mixes.

TABLE 18.

Comparison Costs of Goal 2E and Selected No Till Herbicides Tank Mixes for Control of Annual Broadleaf and Grassy Weeds in Soybeans[a/]

Herbicides Combinations	Per Acre Herbicide Cost ($)	Per Acre Cost Differences Between Other Tank Mixes and: Oxyfluorfen/ Paraquat ($)	Oxyfluorfen/ Alachlor/Paraquat ($)
oxyfluorfen/paraquat/surfactant	19.74	____	____
oxyfluorfen/alachlor/paraquat/ surfactant	21.02	____	____
linuron/alachlor/paraquat/ surfactant	28.91	+9.17	+7.89
metribuzin/alachlor/paraquat/ surfactant	26.31	+6.57	+5.29
glyphosphate/alachlor/linuron	45.03	+25.29	+24.01
glyphosphate/alachlor/metribuzin	43.55	+23.81	+22.53

a/ Devine, 1980a

TABLE 19.

Comparison Costs of Goal 2E and Selected Postemergence-Directed Herbicides for Control of Annual Broadleaf and Grassy Weeds in Soybeans[a/]

Herbicides/ Herbicide Combinations	Per Acre Herbicide Cost ($)	Per Acre Differences in Cost Between Oxyfluorfen and Selected Postemergence - Directed Herbicides ($)
oxyfluorfen	7.28	____
2,4-DB	1.43	-5.85
dinoseb	9.60	+2.32
2,4-DB/linuron	1.30 + 4.75 = 6.05	-1.23

a/ Devine, 1980a

c. Market and Consumer Impacts

It is not currently possible to determine oxyfluorfen's market acceptance if it is registered. Some state extension personnel estimate that the herbicide could eventually claim up to eight percent of the market if accepted by growers (Coble, 1980; Burnside, 1980). Advantageous characteristics of oxyfluorfen (i.e., less application rate, dependence on soil organic matter content and less soil moisture dependence than many other herbicides) and its competitive price will influence its marketability. The magnitude of such economic impacts cannot be estimated without improved information about comparative cost and performance, as well as the degree of the soybean growers' acceptance of oxyfluorfen over time (Devine, 1980a).

C. Corn

1. Corn: EPA Registrations of Oxyfluorfen and Other Herbicides[22/]

The manufacturer of oxyfluorfen, Rohm and Haas, is currently seeking registration for product use in the USDA/State Cooperative Witchweed Eradication Program. The Eradication Program consists of three main activities: surveys of the infested area and surrounding noninfested areas, quarantines to prevent translocation of the infestation by farm equipment, and weed control by the use of herbicides and germination stimulation techniques (USDA, 1978a). USDA currently holds a section 18[23/] (FIFRA) exemption for use of Goal 2E in the Witchweed Program.

The primary herbicides currently being used in the Eradication Program are oxyfluorfen (under section 18 of FIFRA), 2,4-D, and paraquat (Sand, 1980). Other chemicals, such as ethylene gas, are used to

22/ Limitations of the analysis.

a. A large range in the number of acre treatments per year is possible since the level of Eradication Program support is influenced by the availability of USDA or state financial resources.

b. The future success of the Eradication Program could not be evaluated.

c. The analysis was based on statements by the manufacturer that a Federal registration of the product for corn/witchweed is for USDA use only.

d. Comparative yield data between crops treated with oxyfluorfen and the other major herbicides were not available.

e. The USDA's standard application rates for oxyfluorfen and the other herbicides were used.

23/ This section, "Exemption of Federal Agencies" allows for the exemption of a Federal or State Agency from any provisions of FIFRA if warranted by emergency conditions.

force germination of witchweed seeds. Methyl bromide can be used to fumigate the soil or contaminated farm equipment (USDA, 1979a and 1978a).

2. Corn: Recommendations for Use of Oxyfluorfen and Other Herbicides

In 1978 and 1979, oxyfluorfen was used for witchweed control under section 18 of FIFRA as amended (Sand, 1980). Approximately 1,073 acres of corn were treated in 1978 (USDA, 1979b). The 1979 published exemption for this use limited treatment to a maximum of 2,000 acres (see Section I.C.4. of this document). Of this, about 1,821 acres were actually treated (USDA, 1980a).

Witchweed (Striga asiatica) is a problem weed in a relatively small area of the country (38 counties of the Carolinas) (Langston, 1980). Since certain grasses are host to witchweed, North and South Carolina State recommendations are directed to removal of host species and thereby indirectly reduce witchweed infestation. Herbicides recommended by the Carolinas for this use are presented in Table 20.

The standard application rate for oxyfluorfen is 0.5 pounds active ingredient per acre (Langston, 1980). The major alternative herbicide treatments are: 5-6 applications of 2,4-D (1.0 pound active ingredient per acre), or one treatment of 2,4-D (1.0 pound active ingredient per acre) followed by three paraquat treatments (0.25 pound active ingredient per acre), or four to five applications of a tank mix of 2,4-D (0.50 pound active ingredient per acre) and paraquat (0.10 pound active ingredient per acre) (Langston, 1980).

3. Corn: Performance Evaluation of Oxyfluorfen and Alternatives

a. Pest Infestation and Damage

Witchweed (Striga asiatica) is a parasitic weed that is native to India, first discovered in the United States during 1956 in the eastern parts of North and South Carolina; it now infests about 380,000 acres (Langston, et al., 1979; Sand, 1979).

Witchweed can reproduce wherever a host crop or grassy weed is present. The weed is a parasite of more than 60 different plants in the grass family, including corn, sorghum, rice, sugarcane, crabgrass and Johnsongrass. Infestations in corn, sorghum, sugarcane and rice can contribute to yield reductions of up to 90% (Langston et al., 1979).

Host plant root secretions stimulate witchweed germination. Upon germinating, the seed attaches a rootlike growth to the host and withdraws nutrients. The most serious witchweed damage occurs during the below-ground stage; parasitic action contributes to a drought stricken appearance in an infested field (USDA, 1980a).

Warm temperatures, light soils and high soil moisture content are optimal witchweed growing conditions. However, the conditions prevalent in the major corn/sorghum-producing regions of the United States are also suitable for witchweed growth (USDA 1980a). Therefore, if this pest is not geographically contained, it could cause serious economic damage to U.S. corn, sorghum and other crop production.

TABLE 20.

State Herbicidal Recommendations for Control of Grassy Weed Hosts of Witchweed in Corn[a/]

Preemergence Use	Pre-plant Soil Incorporated	Post Emergence-Directed Use[b/]
Alachlor	Butylate	Ametryn
Alachlor/atrazine	Butylate/atrazine	Atrazine
Alachlor/cyanazine	Butylate/cyanazine	2,4-D
Atrazine	EPTC	Linuron
Atrazine/cyanazine		
Atrazine/simazine		
Cyanazine		
Metolachlor/atrazine		
Pendemethalin		
Pendemethalin/atrazine		
Pendemethalin/cyanazine		
Simazine		

a/ Devine, 1980b

b/ For use in corn up to the last cultivation

b. Comparative Performance Evaluation

Witchweed currently infests about 380,000 acres (Langston et al., 1979). The Eradication Area is the periphery of the infested area and accounts for approximately 50,000 acres (Langston, 1980). The Program consists of moving the periphery inward as the target weed is eliminated from each eradication area (Sand, 1980).

The Program's chemical control consists of: (1) elimination of witchweed seed in the soil and (2) prevention of new witchweed seed production. Stimulants, such as ethylene gas, injected into infested soils induce the seeds to germinate in the absence of host plants. Oxyfluorfen and other herbicides are used to kill existing plants in order to prevent new seed production (Langston et al., 1979).

During 1958-1970, the major herbicide used for witchweed control was 2,4-D. This herbicide was annually applied to some 400,000 to 500,000 acres. However, because of 2,4-D's limitations, witchweed continued to proliferate in soybeans, cotton and other broadleaf crops due to the presence of hosts, such as crabgrass (Langston et al., 1979).

In 1964, the introduction of dinitroaniline herbicides (e.g., trifluralin, nitralin, fluchloralin) increased host grass control greatly (Langston and Eplee, 1974). These chemicals suppressed witchweed emergence from 60-100% (Langston, 1975).

Paraquat, a postemergence herbicide introduced in the late 1960's, kills witchweed as well as grassy hosts. Paraquat's usage reduced the number of 2,4-D applications that were required. Applications of 2,4-D occur every three to four weeks, from June until frost if a grassy weed is present. Paraquat treatments cease when the corn senesces, thereby reducing the number of total applications from six to four (Langston et al., 1979).

Application of 2,4-D alone, 2,4-D followed by paraquat, or 2,4-D/paraquat tank mixes are the major herbicide control methods currently employed by the witchweed Plant Quarantine Program (Langston, 1980; Sand, 1980). Use of 2,4-D alone requires five to six applications. When 2,4-D is followed by paraquat, the number of treatments can be reduced to one application of 2,4-D and three applications of paraquat; the tank mix is applied four or five times (Langston, 1980).

One disadvantage of 2,4-D or paraquat use is that only those weeds that the herbicides contact are killed; therefore, retreatment would be required to control plants emerging after treatment (Beck and Petrie, 1980a). In addition, 2,4-D and paraquat spray operations are not possible if wind lodges the corn or if fields become too wet (Sand, 1980).

Oxyfluorfen has residual preemergence soil activity from preemergence and postemergence treatment (Rohm and Haas, 1980a). Unlike 2,4-D and paraquat, which have no soil preemergence activity, oxyfluorfen can kill witchweed plants that are present at spraying as well as newly germinating witchweed plants (Beck and Petrie, 1980b).

Corn yields differ, depending upon whether oxyfluorfen or the other major herbicides are used (Beck and Petrie, 1980b). By the time witchweed is easily visible and can be treated with a post emergence spray, crop root damage has progressed to the extent that full recovery is not possible. Preemergence treatment with oxyfluorfen reduces damage since the seedling is killed as it emerges through the treated soil. Preemergence and postemergence oxyfluorfen treatments reportedly cause reproductive failure in witchweed plants that survive treatment and thereby effectively reduce those seeds produced by the treated witchweed plant. Oxyfluorfen continues to provide preemergence weed control under conditions that prohibit application of 2,4-D and paraquat (Beck and Petrie, 1980b).

4. Corn: Economic Impact Analysis

a. Profile of Impacted Area

As of November 27, 1979, there were 27 counties in North Carolina and 11 counties in South Carolina that were infested with witchweed (Langston, 1980). The majority of these counties were in North Carolina's Central Coastal and Southern Coastal Crop Reporting Districts and in South Carolina's Eastern Crop Reporting District.

In the infested counties, there were an estimated 907,000 acres of grain corn harvested in North Carolina and 203,600 acres in South Carolina during 1978. In 1978 this area produced an estimated 80,205,000 bushels of grain corn valued at $190.4 million (North Carolina Crop and Livestock Reporting Service, 1980; Rogers, 1980).

b. User Impacts

In order to determine user impacts, the cost of the herbicides as well as the costs of application must be considered. The user, in this case, is the Federal/State Government. In the Eradication Area, the farmer is not involved with herbicide application; all application work is government contracted (Sand, 1980).

To calculate the total treatment cost, the cost of the herbicide as well as the cost of application must be considered. Since the same equipment is used regardless of the herbicide applied, application costs per treatment will not change (Sand, 1980). However, the number of treatments varies with the herbicide used (Table 21).

Oxyfluorfen is normally applied only once. If any witchweed appears after treatment, oxyfluorfen is reapplied. However, reappearance of the weed has occurred on only 9-10% of the oxyfluorfen treated acres (Sand, 1980). Treatments with 2,4-D alone must be applied five to six times during the season. One application of 2,4-D followed by three paraquat applications is another standard treatment. Treatment with a 2,4-D/paraquat tank mix requires four to five applications (Langston, 1980).

Comparison of the total per acre treatment costs indicates that oxyfluorfen ($26.78 per acre) is the least expensive. The per acre cost increases associated with 2,4-D alone, 2,4-D followed by paraquat, or 2,4-D/paraquat tank mix treatments instead of oxyfluorfen are $41.97, $31.98 and $35.19, respectively (Table 21). If oxyfluorfen were

TABLE 21.

Total Per Acre Cost Increases of Using Goal 2E Alternatives for Control of Witchweed in Field Corn in North and South Carolina

Herbicides	Total Herbicide Costs Per Acre Treated Per Season[a/] ($)	Total Application Costs Per Acre Treatment Per Season[b/] ($)	Total Per Acre Treatment Costs ($)	Per Acre Cost Increase ($)
Goal 2E + surfactant	13.03	13.75	26.78	———
2,4-D	8.25	60.50	68.75	41.97
2,4-D + paraquat + surfactant[c/]	14.76	44.00	58.76	31.98
2,4-D/paraquat + surfactant[d/]	12.47	49.50	61.97	35.19

a/ See Devine (1980b).

b/ Based on total number of treatments per season and $11.00 application cost per acre treated which includes a $6.00 per acre contractor charge for the application (Langston, 1980) plus $5.00 per acre USDA monitoring cost (Beck & Petrie, 1980b).

c/ Standard treatment consists of 1 application of 2,4-D followed by 3 applications of paraquat (Langston 1980).

d/ Tank mix.

unavailable, the Federal/State Eradication Program would experience increased treatment costs. Using other herbicides on 1,000 to 2,000 acres (the amount allowed under the current exemption) would increase total costs by about $32,000 to $84,000 (Devine, 1980b). If larger acreage, such as 80,000 to 100,000 acres were treated as desired by USDA, the increase would range from about $2,600,000 to $4,200,000 (Devine, 1980b).

c. Market and Consumer Impacts

A short term reduction in corn yield in witchweed-infested areas (at least 10%) could be expected if oxyfluorfen were no longer available. This reduction would vary depending upon the herbicide employed in control programs by APHIS. Oxyfluorfen is considered the most useful selective herbicide for witchweed control in corn. Without preemergence oxyfluorfen treatment, poor weather conditions in any year could have adverse effects upon witchweed control efforts (Beck and Petrie, 1980a).

Long term economic impacts upon corn and other crop producers as well as consumers could be quite severe if the Eradication Program is not successful in containing witchweed. The magnitude of long term economic impacts are highly conjectural and dependent on the success of the Eradication Program over time.

d. Social/Community/Macroeconomic Impacts

With continuance of a successful Eradication Program in the area presently infested, no social/community/macroeconomic impacts are expected in either the long or short term.

D. Bearing and Nonbearing Tree Fruits/Nuts and Vineyards

1. Fruit/Nut Orchards and Vineyards: EPA Registration of Oxyfluorfen and Other Herbicides

Oxyfluorfen, hereafter referred to as Goal 2E, was registered on May 17, 1979, for preemergence and post emergence[24/] weed control in nonbearing almonds, nectarines, peaches, plums and prunes in California only. (Registration Number: 707-145). Efficacy, crop injury and trunk diameter data of these crops were submitted to the Agency in support of this registration prior to the December 1978 waiver of efficacy data. Four times the maximum label rate of Goal 2E was used to evaluate crop injury and trunk diameter growth rates. No injury or adverse effects were noted on almond, nectarine, peach, plum and prune orchards that were treated with Goal 2E immediately after transplanting (the growth stage at which these young plants would be most susceptible to herbicide injury). Efficacy data were found acceptable by Registration Division (R.D.) in

24/ Preemergence Goal 2E herbicide treatments are applied to the soil surface prior to emergence of weeds from the soil. Post emergence Goal 2E herbicide treatments are applied directly to the surface of emerged weeds growing underneath the tree or vine.

support of those claims on the 707-145 label for Goal 2E alone, Goal 2E plus Paraquat CL and Goal 2E plus Paraquat CL plus Surflan 75W.

Conditional registration for use of Goal on bearing tree fruits/nuts was approved December 18, 1980.

Table 22 presents the other major registered preemergence, postemergence and preemergence and/or post emergence herbicides considered in this analysis.[25/]

2. Tree Fruits/Nuts and Vineyards: Performance of Goal 2E Herbicide

There are an estimated 1.4 million acres of commercially grown tree fruits, tree nuts and vineyards in California. The first harvest from newly planted orchards/vineyards occurs approximately four to five years after transplanting. During this nonbearing to bearing interval, annual weeds can reduce growth of young orchards/vineyards by up to 50 percent where weeds are dense and irrigation is limited. Mechanical methods of weed control such as discing or mowing can compact and mechanically harm the delicate root systems. Biennial and perennial weeds are even more harmful to new transplants than annual weeds due to their persistent hard-to-control nature (Lange, 1976).

Goal 2E is considered an effective herbicide in orchards and vineyards in California for the following reasons:

a) Goal 2E is uniquely effective for control of the following problem weeds in California fruit and nut orchards and vineyards: cheeseweed, henbit, fiddleneck, filaree spp., and nettle. Goal 2E is currently the only herbicide available that effectively controls cheeseweed (Malva parviflora) (Elmore, 1980). Cheeseweed is widely distributed throughout the coastal and inland orchards and vineyards in California. Cheeseweed is a biennial weed that frequently reaches 4 feet in height. By the second year, cheeseweed can reach a stem diameter of 1/2 inch which becomes woody. Cheeseweed has a large taproot and is virtually impossible to pull by hand and must be dug out with a shovel (which is injurious to the tree or vine root system) or flail mowed. After being mowed, cheeseweed will rapidly resprout at the base and continue to rob the tree/vine of moisture, nutrients, and space. If no herbicides are used, growers must flail mow 10 to 12 times per year. Growers are encouraged

25/ Information used in this analysis is taken from the Agency Preliminary Analysis of Oxyfluorfen (Goal 2E) Use for Weed Control in Tree Fruit/Nut and Vineyards in California (Petrie, R. C., 1980c).

TABLE 22

Other Registered Herbicides Used for Weed Control in Tree Fruits/Nuts and Vineyards

Class	Herbicides
Preemergence	Napropamide
	Napropamide/Simazine
	Princep (Simazine)
	Devinol/Simazine
	Oryzalin
	Eptam (EPTC)
	Trifluralin[a/] (incorporated)
	Diphenamid
	Norflurazon
Postemergence	Glyphosate
	Paraquat[b/]
	Dalapon
	2,4-D
	MSMA plus surfactant
Preemergence and/or Postemergence	Diuron
	Diuron/Terbacil
	DNBP or Dinoseb
	Paraquat/Simazine

a/ Trifluralin is currently under RPAR review by the US EPA.

b/ Paraquat is currently under RPAR review by the US EPA.

not to cultivate (disc or harrow) under the trees/vines in order to prevent the spread of diseases. Further, the use of berms[26] by most growers makes cultivation and mowing under the tree and within the row difficult. Similarly, weeds are difficult to remove from under a trellis (vine support for grapes) without damaging vines and roots (USDA, 1977).

b) Goal 2E is versatile because it provides preemergence and postemergence contact weed control from one application of 1 lb AI/acre or more. Based on data in EPA Registration Division files, Goal 2E will control those emerged weeds listed on the label by contact activity. Any Goal that reaches the soil surface will provide three to four months residual control of those germinating weeds listed on the label. Research done by the University of California extension service with Goal demonstrated 99% preemergence control of cheeseweed for 236 days.

c) Goal 2E is more easily used than preplant incorporated herbicides. Preplant incorporated herbicides are applied before weed emergence as are preemergence herbicides, however, most preplant incorporated herbicides must be immediately mechanically mixed into the soil surface top two to four inches after application. The mechanical incorporation operation is difficult to accomplish between the trees/vines due to emerged weeds and berms, thus resulting in loss of herbicide effectiveness.

d) Efficacy data in EPA Registration Division files support the Rohm and Haas claim that "Goal 2E can remain on the ground for up to three to four weeks after application without moisture incorporation with no loss of effectiveness." Therefore, Goal 2E can be used in areas of limited rainfall or where no sprinkler irrigation exists.

e) Goal 2E is not injurious to newly-planted almond, apricots, nectarine, peach, plum or prune trees, nor does it appear to be injurious to vineyards established for three years or more. Due to the efficacy waiver policy, phytotoxicity and efficacy data for apricots and grapes are limited. In the case of apricots, only one test in one growing season in one soil-type climatic area was submitted. For grapes, Goal 2E was evaluated on only 6 of 67 California grape varieties.

f) Goal 2E can be used on all soil textures (sands, silts, clays) and on soils with 0-8% organic matter content with no loss of activity or selectivity. Goal 2E can be used as a preemergence herbicide on low organic matter soils, and where irrigation practices are utilized, without excessive leaching or herbicide injury to crop roots (Lange, 1977).

26/ A berm is a raised mound or ridge on which the tree vine is planted to improve drainage, reduce salt damage and reduce disease problems.

3. Tree Fruits/Nuts and Vineyards: Comparative Performance Evaluation

Goal 2E herbicide is unique in California fruit and nut orchards and vineyards because it provides contact control of label-claimed weeds emerged at the time of treatment (postemergence), as well as long-lasting residual preemergence control of later-germinating seeds. Further, Goal 2E is the only available herbicide that will provide season-long control of the problem weed cheeseweed. Napropamide and norflurazon provide some residual preemergence control of cheeseweed but are ineffective for control of cheeseweed emerged at the time of application and for control of later-germinating cheeseweed.

Of the 14 herbicides other than Goal 2E available for use in the Goal 2E label-claimed orchard/vineyard crops, only paraquat, trifluralin and MSMA plus surfactant are labeled for use on all of the same orchard/vineyard sites as Goal 2E. Trifluralin and MSMA plus surfactant labels do not claim control of cheeseweed. Paraquat will only top kill cheeseweed, resulting in resprouting at the base of the plant.

In contrast with other available herbicides, Goal 2E is ineffective for control of many grassy weeds and, therefore, is recommended for use in tank mix combination with paraquat (for postemergence annual grass control) and/or Devrinol (for preemergence residual grass control). A drawback of Goal 2E on vineyards is that the grower must wait at least three years before applying Goal 2E to new grape plantings. However, only four of the 13 herbicides and herbicide combinations listed for use on grapes can be used soon after planting before grapes are "established" (approximately three years after planting). Of the four, paraquat and MSMA plus surfactant are postemergence directed sprays. A four-week wait after planting is required before applying dichlobenil for preemergence weed control, and trifluralin can be applied for preemergence weed control with no wait after planting. Trifluralin, however, requires mechanical incorporation immediately after application.

Goal 2E has proven especially effective for control of label-claimed weeds in the Compositae family such as sowthistle, prickly lettuce and common groundsel (Elmore, 1980). As a postemergence herbicide, Goal 2E is superior to paraquat and dinitro products for control of cheeseweed, filare and nettle (Elmore, 1980).

Nonherbicidal alternatives include mechanical methods of weed control such as discing or mowing. Such methods can result in damage to vines and delicate root systems. Use of berms by most growers makes mowing under trees and within rows difficult. Hand hoeing involves high labor costs and may still result in root damage.

4. Tree Fruit/Nuts and Vineyards: Economic Impact Analysis

a. Profile of Impacted Area

California accounted for 50-100% of the total U.S. production in 1979 of each of the following: peaches, nectarines, plums, grapes, apricots and almonds (USDA, 1980). Commercial orchards and vineyards make up 1.4 million acres in this state. It is estimated that

80% of the coastal orchards and vineyards and 70% of the Northern California acreage is infested with cheeseweed.

b. User Impacts

It is assumed that oxyfluorfen's registration for use on bearing tree fruit/nuts will result in a farmer applying it using his current application method. Therefore, economic impacts would be limited to cost differences between oxyfluorfen and other herbicides. Total cost will also vary because the number of treatments vary with the herbicide used. Goal 2E is normally applied only once per season. Since Goal has both preemergence and postemergence activity, use of Goal 2E may reduce the need for application of a second, postemergence herbicide.

E. Conifers [27]

1. Conifers: EPA Registration of Oxyfluorfen and Other Herbicides

Oxyfluorfen (Goal 2E), was federally registered by the Agency on March 25, 1980, for preemergence and postemergence weed control in conifer seedbeds throughout the U.S.[28] and for preemergence and post-emergence weed control in certain conifer transplants.[29]

Conifer transplants, as referred to on the Goal 2E label, are conifer seedlings that are taken from the seedbed after one year's growth and are re-planted (transplanted) into a well-tilled, weed free bed. When transplanted, they are "lined-out" or evenly spaced in rows.

27/ Information used in this analysis is taken from the Agency Preliminary Analysis of Oxyfluorfen Use for Weed Control in Conifer Seedbeds throughout the U.S.; and for Weed Control in Conifer Transplants (Petrie, R.C., 1980d).

Limitations of this analysis include:

a. No benefits or efficacy data were available in Agency files because of the efficacy data waiver policy. (Dec., 1978).

b. Where label claims have been compared, it is assumed that these claims are accurate and in conformance with agency-industry performance standards.

28/ Preemergence treatment is made after seeding into the seed bed but before conifer and weed seed germination. Postemergence treatments are made after conifer seedlings are at least five weeks old and after weeds have emerged from the soil.

29/ Preemergence treatment refers to application of Goal 2E immediately after transplanting before weeds emerge from the soil. Postemergence refers to application of Goal 2E after weeds have emerged from the soil.

a. Conifers - Seedbeds:

Goal 2E can be used at up to 1 lb.AI per acre as a preemergence treatment and up to three times at a maximum rate of 0.5 lb. AI/per acre per each treatment as a postemergence spray (for a maximum possible total of 2.5 lb. AI per acre per season) without injury to loblolly pine, slash pine, longleaf pine, shortleaf pine, eastern white pine, Virginia pine, ponderosa pine, lodgepole pine, Douglas fir and Colorado blue spruce.

Conifer seeds are planted into well tilled, weed free seedbeds. Most seedbeds are either fumigated before or receive herbicide treatments before and after planting. The decision of whether or not to fumigate is, in most cases, determined by the relative value of the conifers and on the need for disease and/or fungus control. The fumigant formulation selected varies with the seriousness of the disease and/or fungus problem. Therefore, herbicide seedbed treatments may be necessary after seedling emergence even if a fumigant is used before planting.

b. Conifers - Transplants and Outplantings:

On spring transplanted conifers, up to 2 lb. AI per acre Goal 2E can be applied as a preemergence or postemergence treatment (one treatment per season). On fall transplanted conifers, Goal 2E can be applied at up to 2 lb. AI per acre as a preemergence or postemergence treatment up to two times per season (for a maximum possible total of 4 lb. AI per acre per season). At the recommended rates, Goal 2E will not injure: pyramid arborvitae, golden pfitzer juniper, tam juniper, mugho pine, dwarf Alberta spruce, bird's nest spruce, Himalayan pine, scotch pine, noble fir, Norway spruce and Colorado spruce.

The conifer seedbed and transplant uses were approved by Registration Division after the agricultural herbicide efficacy data waiver policy took effect. Therefore, there are no benefits data in Agency files to support the registered Goal 2E label claims (Reg. No. 707-145).

The conifer transplants are dormant at the time they are transplanted. If fall transplanted, they remain dormant all winter and break dormancy (resume growth) in late May or early June the following spring. If transplanted in the spring (usually March to April), the conifer transplants break dormancy approximately 30 days later (late May to early June). Fall herbicide applications are desirable because (1) labor is usually more available in the fall and (2) fall herbicide treatments prevent weed infestations during the early spring digging and transplanting season. Fall herbicide treatments are usually followed by treatments in late spring to control summer weeds. Goal 2E is recommended for use only while the conifer transplants are still in dormancy. The dormancy period soon following transplanting is the most critical period concerning the need for effective weed control. Weeds start germinating soon after the bed has been prepared and can quickly outgrow the conifer transplants (which are only six to eight inches tall and still dormant) and eventually kill them by shading. Hand pulling of weeds is not possible for up to two years after transplanting (most transplants are in the transplant bed for only one year). Because the transplants are planted in light-sandy soil for drainage and aeration purposes and because the conifer transplants have such delicate root systems (especially while still dormant), the pulling up

of weeds results in the pulling up of conifer transplants as well. Hand weeding can be done on a limited scale between rows. However, labor costs are usually prohibitive.

Most conifer transplants stay in the transplant bed one year before being "outplanted" (transplanted to the field). Conifer transplant species listed on the Goal 2E label are used primarily along interstate highways and for other landscaping purposes.

Conifer transplants are considered "established" only after the new growth is fully expanded and has hardened off (soft growth becomes hardened with age) and after the root system has expanded. If transplanted around the first of April, it would take approximately 2.5 months for the transplants to break dormancy and become "established." Having to wait this late after transplanting, before application of preemergence herbicides usually defeats their purpose because the weeds have already emerged and are vigorously growing. Most of the preemergence herbicides have no postemergence weed control activity, as does Goal 2E. The Goal 2E label does not recommend use on "established" transplants.

c. Other Registered Herbicides

Major registered preemergence and postemergence herbicides other than Goal 2E, for weed control in conifers are presented in Table 23.

2. Conifers: Performance of Goal 2E Herbicide

A qualitative analysis of the benefits of Goal 2E use on conifers follows.

a) With the exception of soil fumigants, there are currently only two herbicides registered for use on conifer seedbeds beside Goal 2E.[30/] They are bifenox and diphenamid. Neither bifenox nor diphenamid can be used on all of the same conifer species that are listed on the Goal 2E label.

b) Of the herbicides listed in Table 31 under transplants, only chlorpropham, naptalam, and DCPA can be used on all of the same conifer species that are listed on the Goal 2E label. None of the three herbicide labels claim control of all the Goal 2E label claimed species.

c) Goal 2E can be applied as a preemergence treatment for residual control of label claimed weeds or as a postemergence treatment for contact control of label claimed species. Most growers prefer to use Goal 2E preemergence before weeds can become established and do damage.

30/ State Recommendations (Ark., Wash., Kans., La., Miss., Va., New England) (Petrie, 1980d) and 1980 Weed Control Manual - Agricultural Consultant and Fieldman.

TABLE 23

Other Registered Herbicides Used for Weed Control in Conifers

Use	Class	Herbicide
Seedbeds	Preemergence	Methyl Bromide[a/] Metham[a/] Bifenox Diphenamid
Transplants	Preemergence Weed Control - Applied before transplanting conifers	Methyl Bromide Metham Naptalam Trifluralin[b/d/]
Transplants	Preemergence Weed Control - Applied immediately after transplanting during conifer dormancy (similar to oxyfluorfen)	Alachlor[f/] Chloramben[f/] Chlorpropham[e/] DCPA[f/] Diphenamid[f/] EPTC[b/f/] Napropamide[b/f/] Naptalam[e/] Oxadiazon[f/] Pronamide[f/]
Transplants	Preemergence Weed Control - Applied after transplants are "established"	Alachlor[e/] Bensulide[f/] Chloramben[f/] DCPA[e/] Dichlobenil[f/] Dipenamid EPTC[b/e/] Napropamide[f/] Naptalam[e/] Oryzalin[f/] Oxadiazon[e/] Trifluralin[b/d/e/]
Transplants	Post Emergence Weed Control	Chlorpropham[e/g/i/] DCPA[c/e/d/] Glyphosate[e/] Paraquat[d/h/] Pronamide[f/]

a/ Fumigants
b/ Requires mechanical or moisture incorporation
c/ Postemergence control of creeping speedwell
d/ Presently under RPAR review by US EPA
e/ Applied as a directed treatment
f/ Applied as a broadcast
g/ Limited post emergence control of seedling pigweed and smartweed, chickweed, purslane and field dodder. (These claims taken from 1979 "Herbicide Handbook", WSSA; not from registered labels)
h/ Applied as a directed treatment anytime after transplanting and after conifers are established
i/ Applied after conifers are "established"

Also, Goal 2E provides season-long weed control (until fall dormancy in November) from the preemergence application. The preemergence - postemergence utility virtually ensures season-long control of the Goal 2E label claimed weed species (Comegys, 1980).

d) Goal 2E is not injurious to the label claimed conifer species and therefore can be applied just before and soon after seeding and immediately after transplanting into a bed when weeds can be the most damaging to conifer seedlings and transplants. Goal 2E can be applied as a postemergence spray directly over-the-top of label claimed conifer species with no injury (when applied as directed by the label). Many other herbicides cannot contact the conifer foliage without causing injury, or must be directed to the middle of the rows. This type of restriction prevents the treatment of weeds growing close to the transplant and in the row.

e) Goal 2E is more easily used than preplant incorporated herbicides. Use of Goal 2E preemergence eliminates the need for mechanical incorporation (rototilling or hand-hoeing) required immediately after application of most preplant incorporated herbicides.

f) Goal 2E can be used on all soil textures (sands, silts, clays) and on soils with 0-8% organic matter content with no loss of activity or selectivity.

g) Sandy soils used in seedbeds and transplant beds, and continuous irrigation increase the chances for herbicide injury to young conifers by leaching into the root zone. Rohm and Haas has previously reported that Goal 2E does not leach through soil due to its low water solubility (0.1 ppm) and Goal's affinity for soil exchange sites.

3. Conifers: Comparative Performance Evaluation

Goal 2E is considered a unique herbicide for the following reasons: (1) Goal 2E provides preemergence residual and/or postemergence contact control of label claimed weed species. This preemergence/post-emergence utility virtually ensures season-long control of the label claimed weed species at a time in conifer growth when weed control is essential; (2) Goal 2E can be applied over-the-top of five week old seedlings of label claimed conifers without causing injury. Up to three over-the-top applications are allowed per season; (3) Goal 2E can be applied over-the-top of newly transplanted label-claimed conifers while they are still dormant without causing injury. Effective weed control is critically needed after transplanting while conifers are dormant because weeds can very quickly outgrow the six to eight inch tall dormant conifers.

Fumigants such as methyl bromide or metham are used primarily for disease and fungus control in seedbeds and transplant beds. Their use, however, is quite often limited by their high human toxicity and the high labor costs associated with their use. Weed control by these products is considered incidental to disease and fungus control. Most weed seeds present at the time of fumigation are killed, but there is no residual protection from weed seeds deposited later.

Bifenox and diphenamid are herbicides that can be used for preemergence weed control in conifer seedbeds. However, these herbicides cannot be used on all Goal 2E label claimed conifer species nor do they claim control of all weed species claimed on the Goal 2E label.

Of the 12 herbicides other than Goal 2E that can be used for weed control in newly transplanted conifers, only three (DCPA, chloropropham and naptalam) are registered for use on all of the same conifer species as Goal 2E. None of the labels for these three herbicides claim control of the following 18 weed species claimed on the Goal 2E label: annual morning glory, scarlet pimpernel, mayweed, wild mustard, lesser bittercress, sticky chickweed, bull thistle, fireweed, prickly lettuce, ladysthumb, common groundsel, hairy nightshade, annual sowthistle, corn and sand spurrys, red and white clovers and birds eye speedwell.

Nonherbicidal methods of weed control, used to a limited extent in small nurseries, include (1) mulching with organic materials such as peat, bark, wood chips, sawdust, straw, cattle manure, waste newsprint and pine needles and; (2) plastic sheeting. A one to two inch deep mulch reduces water loss from the soil, tends to insulate the soil to prevent wide temperature fluctuations and shades out small weedy seedling plants. A fresh sawdust mulch, however, can rapidly deplete the soil of nitrogen needed for plant growth. Also, the temperature under black plastic mulch can sometimes raise the soil temperature to a lethal level. Mulch is not effective for control of emerged weeds at the time it is applied.

Hand pulling of weeds in seedbeds or in transplant beds has proven injurious to the conifer seedlings/transplants because of the tendency to pull up the weak-rooted conifers as well.

No comparative efficacy or phytotoxicity data are currently available due to the efficacy data waiver policy which took effect in December 1978.

4. Conifers: Economic Impact Analysis

a. Profile of Impacted Area

Goal 2E is registered for weed control in certain conifer seedbeds throughout the entire United States. State recommendations include Arkansas - 1980, Washington - 1980, Kansas - 1978, Louisiana - 1980, Mississippi - 1980, Virginia - 1980, New England - 1979, and Idaho - 1979. Goal 2E is registered for weed control in certain conifer transplants throughout the United States.

b. User Impacts

Nurserymen have very limited experience with Goal 2E for weed control in conifer seedbeds and conifer transplants because 1980 was the first year that most were able to use it. Goal 2E was first registered for use on these sites on March 25, 1980. Those that have used the chemical under experimental permit (Dr. Illo Gauditz and Dr. William Morris of Weyerhauser; Mr. John Grim of Industrial Forest Association, Dr. Clyde Elmore, Weed Scientist of the University of California, Davis) report excellent control of label claimed weeds with no conifer phytotoxicity when used as directed by the label in small nursery plots.

Weyerhauser almost always fumigates their Pacific N.W. seedbeds. Weyerhauser's southern (Hot Springs, Arkansas) loblolly pine seedbeds are fumigated every other year for disease control. Weyerhauser grows only loblolly pines on their 600 acres of seedbeds in Arkansas. Unlike the Pacific N.W. conifer species, loblolly pine seedlings remain in the seedbed for only ten months and are then transplanted directly to the field (outplanted). Goal 2E was used preemergence and postemergence on 200 of the 600 total acres of southern seedbeds this year with no injury to the loblolly pine seedlings. Dr. Morris reported excellent control of crabgrass, goosegrass and dallisgrass from the low rate of 0.25 lb. AI per acre applied preemergence.

No comparative performance data are currently available to compare most differences between Goal 2E and other herbicides. For nonherbicidal alternatives, Dr. Gauditz of Weyerhauser estimated that hand weeding would cost Weyerhauser $50,000.00 to $100,000.00 per year if no herbicides were used, due to the need to hand weed carefully and often (this figure does not include the cost of replacing trees pulled out with the weeds).

IV. RISK/BENEFIT ANALYSIS: DEVELOPMENT OF REGULATORY OPTIONS

A. Introduction

In the previous Sections II and III, the potential human risks associated with the proposed use of oxyfluorfen were examined, and the potential benefits associated with each use were identified in light of available data. FIFRA requires the Agency to achieve a balance between the competing considerations of risks and benefits. To carry out that mandate, the Agency has developed various regulatory options and has evaluated each option for its impacts on risks and benefits.

This section of the Position Document describes the rationale for the development of regulatory options and discusses the options which were selected for consideration.

1. Rationale For Development Of Regulatory Options

In its simplest terms, FIFRA provides for two basic options concerning the regulation of pesticides: to grant or to deny registration. For new pesticide products, these options are represented in terms of the approval or the denial of applications for registration. For previously registered products, they are framed in terms of a decision either to allow continued registration or to cancel registration.

Denial/cancellation of registration represents an absolute regulatory response which means that the sale or the distribution of the pesticide for the use(s) at issue is prohibited. Registration, on the other hand, represents a range of regulatory options, since the Administrator may specify the terms and conditions of registration for some or all uses. He may, among other things, require the label and the labeling of a pesticide product to contain certain language which he considers necessary for the adequate protection of health and the environment, or he may classify the use of a pesticide product for restricted use, and limit its application to certified applicators or persons under their direct supervision.

While cancellation/denial and unrestricted registration fall at opposite ends of the regulatory spectrum, the development of intermediate regulatory options involves the formulation (and/or modification) of the terms and conditions of registration which are intended to reduce the risks attendant to the use(s) of the pesticide. The concept of incremental unreasonable risk also comes into play in assessing whether the use of a pesticide causes unreasonable adverse effects on the environment. Under this concept, a risk which is small or marginal is still not acceptable if risk reduction measures can be implemented without an adverse impact on the benefit of use. Thus, for any given use situation, the Agency seeks to reduce the risk to the lowest possible level without reducing the benefits of use. Each option is then evaluated on a use-by-use basis to determine whether it achieves an adequate reduction in risk without causing unacceptable economic consequences, so that the remaining benefits of each use exceed the remaining risks.

2. Salient Risk/Benefit Considerations

The Agency has determined that both technical and formulated oxyfluorfen meet or exceed the criterion for carcinogenic risk under 40 CFR 162.11(a)(3)(ii) since they both contain the carcinogenic contaminant PCE. The carcinogenic risk to humans associated with this PCE contaminant of oxyfluorfen was the primary risk consideration in the regulatory decision recommended in this Position Document. No other human or environmental risk criteria as described in 40 CFR 162.11(a)(3) have been met or exceeded by the proposed uses of oxyfluorfen or its PCE contaminant at this time. However, with respect to oxyfluorfen itself, there are certain areas for which information is currently inadequate for the Agency to determine hazard potential. These areas were discussed in Section II and include oncogenicity, teratogenicity, mutagenicity, persistence and bioaccumulation in aquatic habitats and hazard to aquatic molluscs and wetlands.

The Agency identified a number of situations which have the potential to cause human exposure to the PCE contaminant of oxyfluorfen. These situations include the mixing, loading, and application of oxyfluorfen to crops. During these activities both dermal and inhalational exposure to PCE are to be expected. In addition, PCE exposure to the general population through ingestion of residues on oxyfluorfen-treated crops was considered possible (see Section II.B.).

The benefits of oxyfluorfen were assessed in terms of the economic impact which would result if the Agency did not register the proposed uses and cancelled the currently registered uses of this herbicide. For this assessment the Agency assumed that oxyfluorfen would be as efficacious as the herbicides now registered for these proposed uses. The Agency considers that there may be an efficacy differential between oxyfluorfen and certain of these other herbicides especially for the control of witchweed in field corn. However, data have not been developed to quantify these differences. Benefits estimates are therefore expressed in terms of treatment costs differences between oxyfluorfen and those alternatives, or qualitative descriptions of the utility of oxyfluorfen in these use patterns. A quantitative analysis of the benefits was not available for tree fruits/nuts and conifer uses, making qualitative descriptions particularly necessary for the appraisal of these uses.

In Section III of the this document, herbicides which may be considered alternatives to Goal 2E were presented for each use pattern. The Agency has, in the past, often considered the risks of alternative pesticides in its risk/benefit determinations. In the case of Goal 2E data currently available to the Agency are inadequate to predict what, if any impact the availability of Goal 2E will have on the use of other herbicides. Market acceptence of Goal 2E is still relatively unknown for most uses. Also, for most uses, Goal is likely to be used in conjunction with other herbicides rather than in place of them.

The Agency does believe that it is important to note that some of the alternatives listed in Section III currently are under review by the Agency. There alternatives have a number of possible adverse effects and data gaps which are being evaluated. However, no final determination has been made by the Agency on these herbicides.

Therefore, in this instance the Agency did not perform a formal comparative risk analysis between Goal and other weed control treatments.

The Agency has determined that the lifetime individual cancer risk to agricultural-workers using oxyfluorfen in soybeans, field corn (Witchweed Eradication Program only), and tree fruit/nuts and conifers would range from about 1.48×10^{-6} to 3.82×10^{-5} and that the maximum dietary cancer risk estimate would range from 2.65×10^{-9} to 1.0×10^{-6}. The benefit to agricultural producers from registering oxyfluorfen on soybeans would range from about -$6.00 per acre to + $24.00 per acre and for corn (Witchweed Eradication Program only) from about +$32.00 to +$42.00 per acre.[31/] Goal's preemergence and post-emergence effectiveness, its selective control of cheeseweed, and its lack of phytotoxic effects on conifer species are among the qualitative benefits to agricultural producers from registering Goal for use on tree fruits/nuts and conifers.

B. Regulatory Options Considered

The regulatory options considered for the present action on oxyfluorfen focused on methods to reduce levels of human exposure to the PCE contaminant. The Agency also considered requiring the submission, by Rohm and Haas, of additional risk data for oxyfluorfen itself. The Agency considered basic regulatory options for each use. The specific regulatory options for each use are explained in the following sections.

Option 1: Specify a maximum PCE contamination level of 200 ppm in formulated oxyfluorfen products (Goal 2E).

The choice of this option would indicate that:

- The Agency accepts the registrants assertion that 200 ppm is the lowest PCE level which is technologically and economically feasible. Further risk reduction, if warranted could be accomplished via other means, such as requiring the use of protective equipment.

- Allowing greater than 200 ppm PCE in formulated oxyfluorfen products wold increase the risk from use of these products to unacceptable levels.

Option 2: Require the protective equipment scenario described in Section II.C.3.d.

The choice of this option would indicate that:

- The Agency has concluded that the risk from the uses of oxyfluorfen products outweighs the benefits, but that the use of protective equipment by applicators will significantly reduce the risk from PCE associated with these uses.

31/ A negative value indicates that oxyfluorfen per acre-treatment costs are greater than that of the currently registered alternatives; a positive value indicates the opposite.

Option 3: Prohibit use of oxyfluorfen products in counties providing habitat for species of endangered clams.

The choice of this option would indicate that:

o The Agency has concluded that based on current information the use of oxyfluorfen products in certain counties poses a threat to federally designated endangered species (clams).

Option 4: Require labeling for the soybean use in order to protect aquatic molluscs.

The choice of this option would indicate that:

o The Agency has concluded that the risks from PCE associated with the use if oxyfluorfen are outweighed by the benefits of such uses, but that the incremental risk to aquatic molluscs from oxyfluorfen can be reduced by labeling without an adverse impact on benefits.

Option 5: Require labeling for all uses for the protection of aquatic plants, aquatic invertebrates, wildlife and fish.

The choice of this option would indicate that:

o The Agency has concluded that the risks from PCE from the use of oxyflurofen products are outweighed by the benefits of such uses, but that the incremental risk to aquatic plants and animals from oxyfluorfen itself can be reduced by labeling without an adverse impact on benefits.

Option 6: Require certain data on the possible adverse effects of oxyfluorfen on man and the environment to be submitted to the Agency by the registrant. The areas of concern for which the data would be required include: oncogenicity, mutagenicity, teratogenicity, persistence and bioaccumulation in the environment, and toxicity to fish and wildlife.

The choice of this option would indicate that:

o The Agency believes that currently available data are inadequate to accurately evaluate the possible adverse effects of oxyfluorfen in the areas listed above.

Option 7: Cancel and/or deny registrations for oxyfluorfen uses.

The choice of this option would indicate that:

o The Agency has concluded that the risks from PCE associated with the uses of oxyfluorfen outweigh the benefits of such uses and that there are no viable means short of cancellation or denial of registration which would reduce these risks to an acceptable level.

C. Risk/Benefit Analysis and Proposed Decision

The purpose of this section is to compare the risk and benefits for each use under each of the options considered. Since the risks and benefits have been discussed in detail in Section II and III the following evaluation will be presented in general terms. Following the risk benefit evaluations under each option, is the proposed regulatory decision for that particular use.

1. Nonbearing Tree Fruit/Nuts

a. Risk/Benefit Analysis

If continued use of Goal in nonbearing tree fruit/nuts were allowed, lifetime cancer risk to agricultural workers, assuming a 200 ppm contamination level of PCE, would be 5.8×10^{-6}. It is assumed that continued registration presents no cancer risk (dietary) to the general population.

Benefits for use of Goal on nonbearing tree fruit/nuts cannot be quantified from available data. However, the general performance of Goal compared to other currently available registered herbicides has been judged to be quite good (Section III.D.). Goal is apparently the most effective herbicide treatment for preemergent control of cheeseweed in orchards and vineyards and its persistence indicates that it would be effective against annual weeds that threaten new transplants, and other crops that would otherwise require extensive cultivation. Goal, in combination with other chemicals (e.g., paraquat, devrinol), would provide maximal control of cheeseweed and grassy weeds. Mechanical weeding as an alternative would damage vines and root systems and it is estimated that hand hoeing would prove more expensive than use of Goal. Cost differences between Goal and other herbicidal alternatives would vary according to the number of treatments, and treatment and application methods.

If continued use in nonbearing tree fruit/nuts were allowed with additional requirements for protective clothing the following would result. Agricultural workers would be required to wear hats, gloves, forearm protection, shirt with the collar buttoned and long pants during mixing/loading and application of Goal. Since inhalational exposure is higher then dermal exposure, respirators would also be required.

Reduction of total cancer risk from the use of both protective clothing and a respirator would be from 5.8×10^{-6} to 3.4×10^{-9}. The benefits postulated for use of Goal (Section III.D.) would not be affected by this option.

If registration of Goal (oxyfluorfen) use on nonbearing tree fruit/nuts were cancelled, lifetime cancer risks to agricultural workers would be reduced from 5.8×10^{-6} to 0. The nonavailability of Goal would prevent the farmer from obtaining effective herbicidal control of cheeseweed and would force him to incur the costs of hand hoeing or experience damage to his crops from mechanical weeding. No quantitative amounts can be calculated to predict costs of other herbicides for control of other weeds (Section III.D.).

Specific labeling to protect endangered molluscs was not considered because the nonbearing tree fruit/nuts use pattern area (California) does not provide habitat for these species.

If labeling to protect aquatic plants, aquatic invertebrates, wildlife and fish were required, risk to the environment would be reduced with no concurrent reduction in the benefits of oxyfluorfen use on tree fruit/nuts.

b. Proposed Regulatory Decision

Having evaluated both the carcinogenic risk posed to agricultural workers in conjunction with PCE-contaminated oxyfluorfen use on nonbearing tree fruit/nuts and the benefits of such use, the Agency has determined that, with a maximum PCE level of 200 ppm, the benefit of use outweigh the risk from PCE.

Benefits of Goal 2E are discussed fully in Section III.D. Briefly, Goal is particularly effective in the control of cheeseweed in California orchards and vineyards and is preferable to mechanical weeding and less expensive than hand hoeing.

The Agency recognizes that the risk estimated for this use pattern is based upon estimates of the worst case exposure (See section II.C.). However, in the absence of field monitoring data indicating actual PCE exposure levels during the mixing, loading, and applying of formulated oxyfluorfen products under typical conditions, the Agency must base its regulatory decision on the worst case estimate of exposure. Therefore, the use of a respirator to reduce the risk (5.8×10^{-6} to 3.4×10^{-9}) to agricultural workers is justified. Because dermal exposure contributes very little to the total risk to applicators/mixers/loaders, protective clothing will not be required.

Cancellation of this use is not justifiable since the Agency has determined that the benefits outweigh the risk.

The Agency proposes that the following be implemented:

- Continue the registration of Goal 2E for use on nonbearing tree fruits/nuts in California with the requirement that the PCE level in the formulated product not exceed 200 ppm.

- A pesticide respirator jointly approved by the Mining Enforcement and Safety Administration (formerly the U.S. Bureau of Mines) and by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part II for perchloroethylene must be used during the mixing, loading and application of all oxyfluorfen products. This requirement will take effect six months after the date of publication of the Notice announcing the final determination concluding the oxyfluorfen RPAR, unless by that time the registrant submits field monitoring data to the Agency establishing that the inhalation exposure for the maximum application rate for each registered use is significantly lower than the inhalation exposure estimated by the Agency.

- o Require labeling to protect aquatic plants, aquatic invertebrates, wildlife and fish. This labeling will take the form of the following statement:

  "This pesticide is highly toxic to aquatic plants, aquatic invertebrates, wildlife and fish. Use with care when applying in areas frequented by wildlife or adjacent to any body of water or wetland area. Do not apply when weather conditions favor drift or erosion from target area. Do not contaminate water by cleaning of equipment or disposal of wastes."

- o Require the registrant to submit to the Agency data in a number of areas where current information is inadequate to accurately evaluate the hazard potential of oxyfluorfen. These areas include oncogenicity, mutagenicity, teratogenicity, chronic toxicity, and toxicity to wildlife. The studies required in each of these areas are listed in the summary of the Agency's proposed decision at the end of this Section.

2. Conifers

a. Risk/Benefit Analysis

If the Agency were to allow continued use of Goal (oxyfluorfen) on conifers assuming a 200 ppm or less level of PCE contamination, total cancer risk for mixer/loader/applicators would be 5.8×10^{-6}.

The continuation of Goal use in conifer seedbeds would be considered advantageous to growers because only bifenox and diphenamid are registered for preemergence weed control in conifer seedbeds. However, these herbicides cannot be used on all Goal 2E label claimed weed species. The continuation of Goal 2E use in conifer transplant beds is also advantageous in that of the 12 herbicides registered for weed control in newly transplanted conifers, only three (DCPA, chloropropham, and naptalam) are registered for use on all the same conifer species as are listed on the Goal 2E label. Hand weeding without the use of currently registered herbicides to control weeds in conifer transplant beds would cost substantially more than the use of chemicals, according to estimates of Weyerhauser personnel.

If the Agency were to allow continued use of Goal (oxyfluorfen) on conifers with additional requirements for protective equipment the following would result. Mixer/loader/applicators would be required to wear hat, gloves, forearm protection, shirt with the collar buttoned and long trousers. If the Agency were to impose the additional requirement of a respirator along with protective clothing for mixer/loader/applicators, cancer risk would be reduced from 5.8×10^{-6} to 1.3×10^{-6}. The provisions of this option would not be expected to affect the benefits for Goal use on conifers.

If the Agency were to cancel the use of Goal 2E on conifers the risk to applicators from PCE would be reduced to 0.

The nonavailability of Goal would deprive growers of an effective pre- and post emergence herbicide for use on seedbeds, transplants and outplantings. There are only two alternative herbicides registered for use on seedbeds and neither of these can be used on all conifer species listed on the Goal label.

Fumigants such as methyl bromide, are used on seedbeds primarily for disease and fungus control with weed control being incidental. Also, fumigants are associated with high acute toxicity to humans and incur high labor costs.

For transplants and outplantings, loss of Goal would deprive growers of herbicidal control of certain weed species not controlled by other herbicides registered for use or the same conifer species. Hand weeding is injurious to transplants and costs substantially more than chemical control.

Labeling for the protection of fish and wildlife would serve to reduce the risk to the environment from oxyfluorfen without an adverse impact on the benefit of Goal use on conifers:

b. Proposed Regulatory Decision

Regarding the use of Goal 2E on conifers, the Agency has examined both the risk from PCE contamination and the benefits associated with this use of oxyfluorfen. Based on a maximum PCE level of 200 ppm the risk has been determined to be 5.8×10^{-6}. The Agency has determined that the benefits of this use of Goal on conifers (discussed in Section III. E.)outweigh the risk. Therefore, cancellation of the registration of Goal for use on conifers, is not justifiable.

The Agency recognizes that the worker risk estimates for this use pattern (5.8×10^{-6}) is based on a worst case estimate of exposure to PCE. However, in the absence of field monitoring data indicating actual PCE exposure levels during the mixing, loading, and applying of formulated oxyfluorfen products under typical conditions, the Agency must base its regulatory decision on the worst case estimate exposure. Therefore, the use of respirators to reduce the risk to agricultural workers is justified. Because dermal exposure contributes very little to the total risk to applicators/mixers/loaders, protective clothing will not be required.

The Agency therefore proposes that the following be implemented for the use of oxyfluorfen on conifers.

- o Continue the registration of Goal 2E for use on conifers with the requirement that the PCE level in the formulated product not exceed 200 ppm.

- o A pesticide respirator jointly approved by the Mining Enforcement and Safety Administration (formerly the U.S. Bureau of Mines) and by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part II for perchloroethylene must be used during the mixing, loading and application of all oxyfluorfen products. This requirement will take effect six months after the date of publication of the Notice announcing the final determination concluding the oxyfluorfen RPAR, unless by that time the registrant submits field monitoring data to the Agency establishing that the inhalation exposure for the maximum application rate for each registered use is significantly lower than the inhalation exposure estimated by the Agency.

- o Require labeling to protect aquatic plants, aquatic invertebrates, wildlife and fish. This labeling will take the form of the following statement:

  "This pesticide is highly toxic to aquatic plants, aquatic invertebrates, wildlife and fish. Use with care when applying in areas frequented by wildlife or adjacent to any body of water or wetland area. Do not apply when weather conditions favor drift or erosion from target area. Do not contaminate water by cleaning of equipment or disposal of wastes."

- o Require the registrant to submit to the Agency data in a number of areas where current information is inadequate to accurately evaluate the hazard potential of oxyfluorfen. These areas include oncogenicity, mutagenicity, teratogenicity, chronic toxicity, and toxicity to wildlife. The studies required in each of these areas are listed in the summary of the Agency's proposed decision at the end of this Section.

3. Soybeans

a. Risk/Benefit Analysis

If the Agency were to register Goal 2E for use on soybeans, lifetime cancer risk for agricultural workers (based on 200 ppm PCE in the formulated product) from use on soybeans would be 1.5×10^{-6}. Lifetime cancer risk to the general public (via dietary exposure) is estimated to be 5.3×10^{-8}. The choice of this option would make available to the grower a herbicide which can be used in situations where soil conditions or special weed problems make the use of other herbicides undesirable or ineffective. In some cases, use of oxyfluorfen in weed control would be less expensive than alternative treatments.

If registration for use of Goal on soybeans were granted with the additional requirement for protective equipment cancer risk to applicators from exposure to PCE would be reduced from 1.5×10^{-6} to 3.2×10^{-9} (see Table 11). This option would have no impact on the risk to the general public from dietary exposure. This option would also not be expected to affect the benefits of Goal use on soybeans.

If registration of Goal for use on soybeans were denied, all risks from PCE contamination of oxyfluorfen would be eliminated. This option would deny the soybean grower another soybean herbicide which could be particularly effective in certain situations. The economic impact of the nonavailability of Goal for use on soybeans would range from a cost of $24.00 more per acre to $6.00 less per acre depending upon the weed control treatment being considered. The actual impact of the nonavailability of Goal cannot be quantified because it has never been registered for use on soybeans.

Labeling to protect freshwater clams, oysters, aquatic invertebrates and aquatic plants would reduce the risk to the environment from oxyfluorfen without an adverse impact on the predicted benefits associated with the use of Goal 2E on soybeans.

If the option to prohibit the use of Goal 2E in counties providing habitat for endangered freshwater clams were chosen, possible hazard to these animals would be significantly reduced. The benefits of using Goal on soybeans in these counties cannot be determined at this time, because the market acceptability of Goal 2E is not yet known. (See Section III).

b. Proposed Regulatory Decision

Having evaluated the risk to both applicators and the general public from the potential benefits associated with the use of Goal on soybeans, the Agency has determined that the benefits outweigh the risk. Therefore, denial of registration for soybeans is not justifiable.

Requiring protective equipment for applicators would reduce risk from PCE from 1.5×10^{-6} to 3.2×10^{-9}. The Agency recognizes that the worker risk estimates for this use pattern (1.5×10^{-5}) is based on a worst case estimate of exposure to PCE. However, in the absence of field monitoring data indicating actual PCE exposure levels during the mixing, loading, and applying of formulated oxyfluorfen products under typical conditions, the Agency must base its regulatory decision on the worst case estimate exposure. Therefore, the use of respirators to reduce the risk to agricultural workers is justified. Because dermal exposure contributes very little to the total risk to applicators/mixers/loaders, protective clothing will not be required.

Since actual field monitoring data from the soybean use pattern area are not currently available to accurately determine the hazard to endangered clams, prohibiting the use of Goal 2E in counties providing habitat for these species is not warranted at this time. However, protective labeling can reduce the potential risk to these molluscs while appropriate field studies are being conducted.

The Agency, therefore, has determined that amending the terms and conditions of the Goal 2E registration to include use on soybeans does not significantly increase the risk of unreasonable adverse effects on man or the environment. The Agency has, however, identified certain measures which can be taken to further reduce risk and has also identified areas where data are currently inadequate to accurately assess possible risk. Therefore, the Agency recommends that the following restrictions and/or conditions apply to subsequent registration actions regarding the use of Goal 2E on soybeans.

- o Require that the level of PCE in the formulated product not exceed 200 ppm. Permanent tolerances will be established in conjunction with this registration.

- o A pesticide respirator jointly approved by the Mining Enforcement and Safety Administration (formerly the U.S. Bureau of Mines) and by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part II for perchloroethylene must be used during the mixing, loading and application of all oxyfluorfen products. This requirement will take effect six months after the date of publication of the Notice announcing the final determination concluding the oxyfluorfen RPAR, unless by that time the registrant submits field monitoring data to the Agency establishing that the inhalation exposure for the maximum application rate for each registered use is significantly lower than the inhalation exposure estimated by the Agency.

- o Require labeling to protect aquatic invertebrates and plants. The labeling will take the form of the following statement:

  "This product is highly toxic to freshwater clams, oysters, aquatic invertebrates and aquatic plants. Do not apply Goal where visible erosion to aquatic habitats and wetlands occurs."

- o Require the registrant to submit to the Agency data from field monitoring studies conducted in the soybean use pattern area. The studies should be submitted within two years of the date of conditional registration. A fuller discussion of the required data appears in Appendix D. Protocols for these studies should be submitted to the Agency prior to the initiation of these studies.

- o Require the registrant to submit to the Agency data in a number of areas where current information is inadequate to accurately evaluate the hazard potential of oxyfluorfen. These areas include oncogenicity, mutagenicity, teratogenicity, chronic toxicity, and toxicity to wildlife. The studies required in each of these areas are listed in the summary of the Agency's proposed decision at the end of this Section.

4. Corn

a. Risk/Benefit Analysis

Based upon a PCE level of 200 ppm in formulated Goal 2E, the lifetime cancer risk from PCE for applicators has been estimated to be 3.8×10^{-5} for the 1981 season. Risk to the general public (dietary) would be 2.7×10^{-9}.

The availability of Goal 2E would provide the USDA program with the most versatile selective herbicide currently available for witchweed control in corn. Also, use of Goal in the Witchweed Eradication Program would cost $32.00 to 42.00 less per acre than other herbicidal weed control treatments.

If registration for use of Goal 2E on corn (in conjunction with the USDA Witchweed Eradication Program) were granted with the additional requirement for protective clothing equipment, total cancer risk from PCE for agricultural workers would be reduced from 3.8×10^{-5} to 1.5×10^{-7} (See Table 11).

Requiring protective clothing and a respirator would not be expected to affect the benefits of Goal 2E use on corn.

If registration of Goal for use on corn for the Witchweed Eradication Program were not granted, all risks from PCE contamination of oxyfluorfen would be eliminated. The nonavailability of Goal for this use could have adverse effects on witchweed control efforts (See Section III C). Also, it has been estimated that it would cost $32.00 to $42.00 more per acre to use Goal. The major alternative witchweed control treatment is the repeated (four to five times) application of 2,4-D and/or paraquat. These herbicides are currently being reviewed by the Agency for a number of possible adverse effects.

Labeling to protect aquatic plants, aquatic invertebrates, wildlife and fish would reduce the risk to the environment without an adverse impact on benefits.

Because there are no counties providing habitat for endangered mussel species within the witchweed Eradication Program area, the option to prohibit the use of Goal in certain counties was not considered for this use.

b. Proposed Regulatory Decision

Having evaluated both the risks and the benefits of the use of Goal 2E on field corn in conjunction with the USDA Witchweed Eradication Program, the Agency has determined that the benefits of such use outweigh the risk from PCE. Therefore, the Agency has rejected the Option to deny the application for registration of Goal on corn.

The risk to applicators of Goal 2E in the field corn use has been estimated to be 3.8×10^{-5}, based on a total of 100,000 acres expected to be treated in 1981. The Agency recognizes that this risk estimate is based on a model of the "worst case" exposure. However, in the absence of field monitoring data indicating actual PCE exposure levels during the mixing, loading, and applying of formulated oxyfluorfen products under typical conditions, the Agency must base its regulatory decision on the worst case estimate exposure. Therefore, the use of respirators to reduce the risk to agricultural workers from 3.8×10^{-5} to 1.5×10^{-7} is justified. Because dermal exposure contributes very little to the total risk to applicators/mixers/loaders, protective clothing will not be required.

As discussed above, the option to prohibit the use of Goal 2E in certain counties is not relevant to this use.

The Agency therefore has determined that amending the terms and conditions of the Goal 2E registration to include use on field corn in conjunction with the USDA Witchweed Eradication Program does not significantly increase the risk of unreasonable adverse effects on man or the environment. The Agency has, however, identified certain measures which can be taken to further reduce risk and has also identified areas where data are currently inadequate to accurately assess possible risk. Therefore, the Agency recommends that the following restrictions and/or conditions apply to subsequent registration actions regarding the use of Goal 2E on field corn in the USDA Witchweed Program.

- Conditionally register Goal 2E for use on field corn in conjunction with the USDA Witchweed Eradication Program with the requirement that the level of PCE in the formulated product not exceed 200 ppm. Permanent tolerances will be established in conjunction with this registration.

- A pesticide respirator jointly approved by the Mining Enforcement and Safety Administration (formerly the U.S. Bureau of Mines) and by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part II for perchloroethylene must be used during the mixing, loading and application of all oxyfluorfen products. This requirement will take effect six months after the date of publication of the Notice announcing the final determination concluding the oxyfluorfen RPAR, unless by that time the registrant submits field monitoring data to the Agency establishing that the inhalation exposure for the maximum application rate for each registered use is significantly lower than the inhalation exposure estimated by the Agency.

- Require labeling to protect aquatic invertebrates, aquatic plants, wildlife and fish. The labeling will take the form of the following statement:

"This pesticide is highly toxic to aquatic plants, aquatic invertebrates, wildlife and fish. Use with care when applying in areas frequented by wildlife or adjacent to any body of water or wetland area. Do not apply when weather conditions favor drift or erosion from target area. Do not contaminate water by cleaning of equipment or disposal of wastes."

- o Require the registrant to submit to the Agency, data from field monitoring studies conducted in the corn use area. These studies should be submitted within two years of the date of conditional registration. A further discussion of the required data is presented in Appendix D. Protocols for these studies should be submitted to the Agency prior to the initiation of these studies.

- o Require the registrant to submit to the Agency data in a number of areas where current information is inadequate to accurately evaluate the hazard potential of oxyfluorfen. These areas include oncogenicity, mutagenicity, teratogenicity, chronic toxicity, and toxicity to wildlife. The studies required in each of these areas are listed in summary of the Agency's proposed decision at the end of this Section.

5. Bearing Tree Fruits/Nuts

a. Risk/Benefit Analysis

If continued registration of Goal 2E in bearing tree fruits/nuts were allowed, assuming a 200 ppm contamination level of PCE, the lifetime cancer risk to agricultural workers, would be 5.8×10^{-6}. Lifetime cancer risk (dietary) to the general population is estimated to be 1.0×10^{-6}.

Benefits for use of Goal on bearing tree fruits/nuts cannot be quantified from available data. However, the general performance of Goal compared to other currently available herbicides has been judged to be good (See Section III. D.). Goal is apparently the most effective herbicide treatment for preemergent control of cheeseweed in orchards and vineyards. Cost differences between Goal and other registered herbicide treatments would vary according to the number of treatments and application methods. Since Goal has both preemergence and post emergence activity, use of Goal many reduce the need for application of a second, post emergence herbicide.

If registration of Goal 2E for use on bearing tree fruits/nuts were allowed with additional requirements for protective equipment (as described in Section II. C.) cancer risk to agricultural workers would be reduced from 5.8×10^{-6} to 3.4×10^{-6}. The general population would experience no change in the level of cancer risk (dietary) from the choice of this option. The benefits from this use of Goal 2E (Section III. D.) would not be affected by this option.

If the Agency were to cancel the use of Goal 2E on bearing tree fruits/nuts, cancer risks to both applicators and the general public from PCE would be eliminated. The nonavailability of Goal would deprive growers of an effective herbicide treatment for control of cheeseweed in orchards and vineyards. Choice of this option would also deprive growers of a herbicide which provides control of label claimed weeds at the time of treatment (post emergence) as well as long-lasting residual preemergence control of later germinating seeds. Mechanical methods of weed control can damage vines and root systems and hand-hoeing involves high labor costs.

Labeling to protect aquatic plants, aquatic invertebrates, wildlife and fish would reduce the risk to the environment without an adverse impact on benefit of this use.

Because there are no counties providing habitat for endangered mussel species in this use pattern area, the option to prohibit the use of Goal 2E in such counties was not considered for this use.

b. Proposed Regulatory Decision

Having evaluated the carcinogenic risk posed to both agricultural workers and the general public in conjunction with the use of PCE-contaminated oxyfluorfen (Goal) on bearing tree fruits/nuts, the Agency has determined that the benefits associated with this use outweigh the risk. Therefore, cancelling the registration of Goal for use on bearing tree fruit/nuts is not justifiable. The Agency recognizes that the worker risk (5.8×10^{-6}) estimated for this use pattern is based on a worst case estimate of exposure to PCE. However, in the absence of field monitoring data indicating actual PCE exposure levels during the mixing, loading, and applying of formulated oxyfluorfen products under typical conditions, the Agency must base its regulatory decision on the worst case estimate exposure. Therefore, the use of respirators to reduce the risk to agricultural workers is justified. Because dermal exposure contributes very little to the total risk to applicators/mixers/loaders, protective clothing will not be required.

Since the Agency has determined that the benefits of this use discussed in Section III.D. outweigh the risk associated with the use, the Agency proposes that the following be implemented:

- Continue the conditional registration for the use of Goal 2E on bearing tree fruit/nuts with the requirement that the level of PCE in the formulated product not exceed 200 ppm.

- A pesticide respirator jointly approved by the Mining Enforcement and Safety Administration (formerly the U.S. Bureau of Mines) and by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part II for perchloroethylene must be used during the mixing, loading and application of all oxyfluorfen products. This requirement will take effect six months after the date of publication of the Notice announcing the final determination concluding the oxyfluorfen RPAR, unless by that time the

registrant submits field monitoring data to the Agency establishing that the inhalation exposure for the maximum application rate for each registered use is significantly lower than the inhalation exposure estimated by the Agency.

- o Require labeling to protect aquatic invertebrates, aquatic plants, wildlife and fish. The labeling will take the form of the following statement:

  "This pesticide is highly toxic to aquatic plants, aquatic invertebrates, wildlife and fish. Use with care when applying in areas frequented by wildlife or adjacent to any body of water or wetland area. Do not apply when weather conditions favor drift or erosion from target area. Do not contaminate water by cleaning of equipment of disposal of wastes."

- o Require the registrant to submit to the Agency, data from field monitoring studies conducted in the bearing tree fruit/nuts use pattern area. These studies should be submitted within two years of the date of the Agency's final decision. A fuller discussion of the required data is presented in Appendix D. Protocols for these studies should be submitted to the Agency prior to the initiation of testing.

- o Require the registrant to submit to the Agency data in a number of areas where current information is inadequate to accurately evaluate the hazard potential of oxyfluorfen. These areas include oncogenicity, mutagenicity, teratogenicity, chronic toxicity, and toxicity to wildlife. The studies required in each of these areas are listed in the summary of the Agency's proposed decision at the end of this Section.

D. Summary of Proposed Regulatory Decision

For all uses of Goal 2E (currently registered and proposed) the Agency has determined that:

- o The PCE contamination of formulated oxyfluorfen products (Goal 2E) may not exceed 200 ppm and that a statement to that effect be added to the confidential statement of formula for each registered oxyfluorfen product.

- o A pesticide respirator jointly approved by the Mining Enforcement and Safety Administration (formerly the U.S. Bureau of Mines) and by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part II for perchloroethylene must be used during the mixing, loading and application of all oxyfluorfen products. This requirement will take effect six months after the date of publication of the Notice announcing the final determination concluding the oxyfluorfen RPAR, unless by that time the registrant submits field

monitoring data to the Agency establishing that the inhalation exposure for the maximum application rate for each registered use is significantly lower than the inhalation exposure estimated by the Agency.

- o Labeling for the protection of wetlands and other aquatic resources is required. Specific label statements have been presented in the Proposed Regulatory Decision Section for each use.

The Agency has also determined that with the above mentioned provisions, amending the existing Goal 2E registration to include use on soybeans, field corn, and bearing tree fruits/nuts would not significantly increase the risk of unreasonable adverse effects on man or the environment. The Agency, therefore, recommends that subsequent registrations for the proposed uses include the following conditon:

- o Extensive field monitoring for oxyfluorfen residues in each proposed use pattern area is required. The registrant will submit these data to the Agency within two years of the date of conditional registration.

In an action independent of the RPAR, the Agency will require the registrant to submit the following oxyfluorfen studies to the Agency in support of all registrations.

- o The registrant is required to submit to the Agency an oxyfluorfen oncogenicity study in mice and an oxyflurofen oncogenicity study in rats. Protocols for these studies are to be submitted before initiation of testing.

- o The registrant is required to submit to the Agency an oxyfluorfen teratogenicity study in rabbits. The protocol of this study should include post-natal evaluation and should be submitted to the Agency prior to initiation of testing.

- o A tiered series of mutagenicity tests must be submitted to the Agency. An outline of the testing scheme is presented in Appendix C. Protocols should be submitted to the Agency prior to the initiation of testing.

- o The registrant is required to submit a 6-month (or longer) dog feeding study which demonstrates a NOEL. Protocols for this study have been published in 43 FR 37536, August 22, 1978.

- o The registrant is required to submit avian reproduction studies with mallard ducks and bobwhite quail.

Appendix A

Parameter Values and Exposure Calculations for Uses of Oxyfluorfen

1. Parameter Value for each Use of Goal 2E.

Maximal Goal 2E Use Parameters[a/]

	Pounds AI/acre[b/]	Quarts Goal 2E/ acre	dilution volume (gal./acre)	pounds applied
Soybeans	0.5	1	20	1
Field Corn	2	4	10	1 (or 2)
Tree Fruit/Nuts	2	4	75	1
Conifers	2	4	20	1 (or 2)

a/ Rohm and Haas, 1978.

b/ The combined amount of Goal 2E applied annually may not exceed 2 lb AI/acre.

Maximal PCE Applied Under Goal 2E Use Conditions[a/]

Crop	Application Rate: Goal (lb/A) A.I.	Goal 2E[d/]	Perchloroethylene lb/acre[c/]	gm/acre[b/]
Soybeans	0.5	0.71	0.000143	0.0645
Field Corn	2.0	2.86	0.000571	0.2594
Tree Fruit/Nuts	2.0	2.86	0.000571	0.2594
Conifers	2.0	2.86	0.000571	0.2594

a/ Rohm and Haas, 1978. (modified). Assumes 200 ppm PCE in Goal 2E.

b/ 70% A.I. minimum.

c/ 0.71 lb. Goal 2E/acre x 0.0002 [200 ppm] = 0.000142 lb. PCE/acre.

d/ 454 gm = 1 lb.

Goal 2E and PCE Spray Rates, by Crop[a/]

Crop	Goal Spray Rate		PCE Spray Rate		
	Volume (gal./acre)	Weight[b/] (gm/acre)	Weight (gm/acre)	Concentration (gm/gm H_2O)	(ppm)
Soybeans	20	7.57×10^4	0.0649	8.57×10^{-7}	0.86
Field Corn	10	3.79×10^4	0.2594	6.84×10^{-6}	6.84
Tree Fruit/Nuts	75	2.84×10^5	0.2594	9.13×10^{-7}	0.91
Conifers	20	7.57×10^4	0.2594	3.43×10^{-6}	3.43

a/ Rohm and Haas, 1978. (modified). Assumes 200 ppm PCE in Goal 2E.

b/ 1 gallon of H_2O weighs 8.34 pounds

2. Sample calculations for inhalational, dermal, dietary exposure estimates.

$$\text{Inhalational Exposure (soybeans)} = \frac{\text{Grams PCE/Acre} \times \text{Volume Air Inhaled/Day}^{a/}}{\text{Volume of Air/acre}^{b/} \times \text{Average Body Weight}}$$

$$= \frac{0.065 \text{ gm PCE/Acre} \times 14{,}400 \text{ liters/day} \times 1000 \text{ mg/gm}}{7.4 \times 10^{6} \text{ liters/Acre} \times 70 \text{ kg Body Weight}}$$

$$= 1.804 \times 10^{-3} \text{ mg/kg bw/day}$$

---

a/ $1.8\ m^3 hr \times 1000\ l/m^3 \times 8\ hr/day = 14{,}400$ liters/ day

b/ volume of air/acre = $6\ ft \times 43{,}560\ ft^2$ acre $\times 28.3\ l/ft^3$

$= 7.4 \times 10^{6}$ liters of air/acre

$$\text{Dermal Exposure (soybeans)} = \frac{\text{PCE Concentrations in Diluted Spray} \times \text{Diluted Spray Contacting Skin} \times \text{Weight per Pint of Water} \times \text{Percent Skin Penetration}}{\text{Average Body Weight}}$$

$$= \frac{0.86 \text{ ug/g} \times 0.048 \text{ pints}^{a/} \times 454 \text{ g/pint} \times 0.1^{a/} \times 1 \text{ mg/1000 ug}}{70 \text{ kg bw}}$$

$$= 2.7 \times 10^{-5} \text{ mg/kg bw/day}$$

a/ Values for the amount of liquid contacting on applicator's skin (0.048 pints) and percentage skin penetration (10%) were estimated by the registrant (Rohm and Haas, 1978).

$$\text{Dietary Exposure (soybeans)} = \frac{\text{Daily consumption of commodity}^{a/} \times \text{sensitivity of analytical method}}{\text{Human Body Weight}}$$

$$\frac{0.01819 \text{ kg} \times 0.05 \text{ mg/kg}^{b/}}{70 \text{ kg}} = 1.30 \times 10^{-5} \text{ mg/kg bw/day}$$

a/ Daily consumption of commodity in kg/person/day is based on the average consumption figures for each commodity (Schmitt, 1977).

b/ Assumes that 0.05 ppm level of analytical sensitivity is equivalent to 0.05 mg/kg of commodity.

Appendix B

Calculation of Cancer Risk from PCE Using the Multistage Model. (CAG, 1980)

The NCI bioassay of tetrachloroethylene showed that 32/49 (65%) and 27/48 (56%) of male mice had hepatocellular carcinomas of the liver after oral intubation of tetrachloroethylene at an average dose level of 536 and 1072 mg/kg/day, 5 day/week, for 78 weeks during the 90-week study period. The vehicle control male mice had 10% (2/20) incidence rate of the same tumor type.

The lifetime average dose for the animals in the low dose group is

$$536 \times \frac{78}{90} \times \frac{5}{7} = 322 \text{ mg/kg/day}$$

The equivalent human lifetime dose is

$$332 \times \frac{(0.03)}{(70)}^{1/3} = 25.031 \text{ mg/kg/day}$$

assuming the average human body weight of 70 kg and the average male mice body weight of 0.03 kg. The value $(0.03 - 70)^{1/3}$ is a factor converting the effective dose from mice to humans assuming that the amount of the direct-acting agent is proportional to the body surface.

The unit risk calculation is based on the hepatocellular carcinoma from the male mice. The data from the highest dose group is excluded in fitting the multistage model due to the lack of fit.

The 95% confidence upper limit for the carcinogenic potency (slope) for the human is

$$q_1^* = 5.31 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$$

For exposures (mg/kg/day) lower than those used in the animal study

$$\text{Risk} = q_1^* \times \text{exposure}$$

Using the soybean situation as an example, the lifetime cancer risk from PCE associated with the application of Goal 2E on soybeans is

$$5.31 \times 10^{-2} \text{ (mg/kg/day)}^{-1} \times 2.5 \times 10^{-5} \text{ mg/kg/day} = \underline{1.48 \times 10^{-6}}$$

Appendix C

Proposed Testing for Assessing the Mutagenic Potential of Goal

To adequately evaluate the mutagenic risk posed by human exposure to a chemical substance, a mutagenicity testing program should incorporate tests which evaluate both the intrinsic potential of a chemical or its metabolites to cause mutations and its ability to reach the germinal tissue of whole mammals in an active form. The most direct tests for determining germinal mutagenicity are the whole mammal test systems (e.g. mouse specific locus test) which are capable of demonstrating the ability of a chemical substance to reach the germinal tissue and cause heritable mutations. However, these tests are not only time consuming and expensive to perform, but also only a few laboratories have the experienced personnel and facilities to conduct these tests. Thus, for practical purposes, short-term mutagenicity test systems may be chosen as an alternative. Short-term tests, which detect mutagenic activity, can adequately address the issue of germinal mutagencity if they are utilized in combination with tests which determine the ability of a chemical to reach mammalian gonads. This approach is in accordance with the Agency's recently published Proposed Mutagenicity Guidelines for Risk Assessment (45 FR 74984-74988).

The testing Strategy described below is considered necessary to better characterize the mutagenic potential of the pesticide Goal.

Because human exposure is to the commercial product containing Technical Goal, the proposed testing scheme is described for technical Goal. If an impurity in the technical material is found to be mutagenic and the registrant attempts to alter the manufacturing process to eliminate the mutagenic contaminant(s), the proposed testing strategy would also be applicable to the "altered" Technical Goal product. In addition, because the proposed approach is a general one, it may be useful to confirm or refute the negative results reported for "pure" oxyfluorfen. Of course, it is not possible to rigidly establish a testing scheme and modifications may be necessary for the testing of altered technical material or "pure" Goal.

The testing strategy is illustrated in Figure 1 and involves an approach where the sequence of testing to be followed depends on the results of the previous test. The short-term genetic tests which can be used in this scheme are listed in the FIFRA's Proposed Rules for Mutagenicity Testing (43 FR 163.84 pp. 37388-37394).

Because the results generated by the required testing will be used to support potential regulatory action for Goal, it is essential that careful attention be given to the design and conduct of the proposed studies (See FIFRA's Proposed Rules for Mutagenicity Testing; 43 FR 163: pp. 37388-37394). In addition, because this testing approach provides general guidance only, the Registrant (Rohm and Haas) should submit the details of testing protocols to the Agency for review prior to the initiation of testing.

A. Tests to Determine Mutagenic Activity

B. Tests to Determine Whether the Chemical Reaches the Germinal Tissue of Whole Mammals in an Active Form

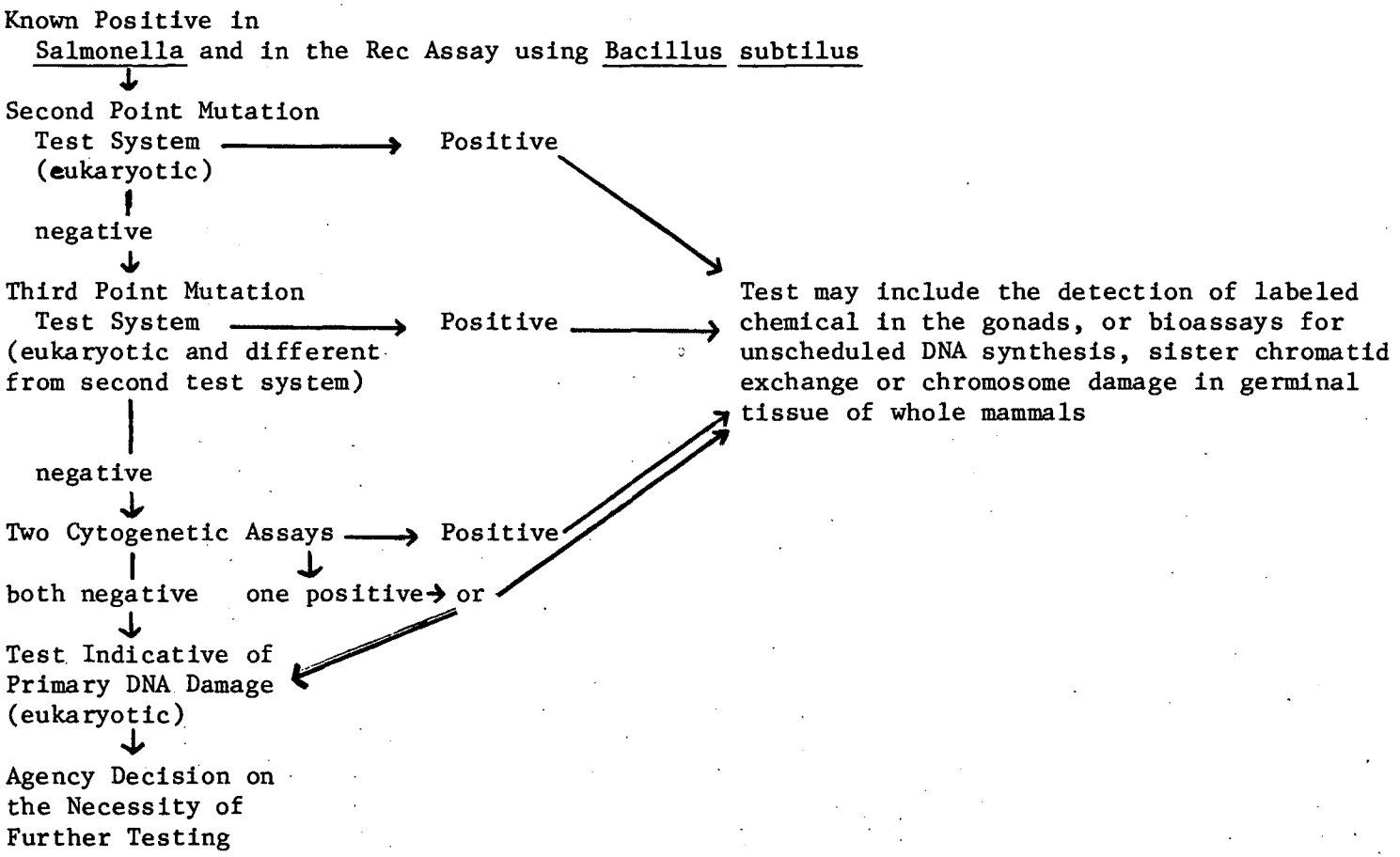

Figure 1. Test strategy to assess the ability of Goal to be a potential human mutagen.

TESTING FOR MUTAGENIC ACTIVITY

To insure that the positive response reported in Salmonella was not a species-specific positive or a false-positive result, it is necessary to conduct a point mutation test other than bacteria (e.g. mammalian cells in culture, Drosophila, yeast). If positive results are obtained in this second test, then this plus the positive response obtained in Salmonella are considered to be sufficient evidence to classify the chemical as having mutagenic activity. However, if Goal is not demonstrated to be a mutagen by the second confirmatory point mutation test, the limitations and strengths of this second assay and the previously employed test system (Salmonella/ microsome assay) should be re-evaluated to choose a third point mutation test system to further examine the ability of the chemical to cause point mutations. The third point mutation test should be a eukaryotic test system different from the second confirmatory system. As described above, if the test agent proves positive in this third assay, it is considered to have mutagenic activity.

If the chemical is adequately tested in the proposed point mutation systems and results are negative, unlike the first test in Salmonella, two additional tests which assay for numerical and morphological chromosome aberrations should be performed. This step will screen for another kind of genetic damage. The testing can either include two different in vivo somatic cell cytogenetic tests or an in vivo somatic cell cytogenetic test system plus an in vitro cytogenetic test system (e.g. mammalian cells in vitro). If the test material is positive in both assays, it is designated as a potential mutagen. When a positive result is obtained in only one of the cytogenetic tests, depending on the nature of the test and the response, the Agency will decide whether to classify the chemical as a mutagen or to recommend additional primary DNA damage assay (nonbacterial). The inclusion of a nonbacterial primary DNA damage assay (e.g. unscheduled DNA synthesis in mammaliam cells in vitro) may determine the ability of the chemical to interact with eukaryotic DNA. When both cytogenetic tests are negative, additional eukaryotic primary DNA damage assay will be required. At this stage, the Agency will examine the weight of evidence and decide whether further testing will be warranted, or whether to provisionaly classify the chemical as a nonmutagen.

TESTING FOR THE ABILITY OF THE CHEMICAL TO REACH THE GERMINAL TISSUE OF WHOLE MAMMALS

In the event the short-term tests establish that the chemical has mutagenic activity further studies should be conducted to determine whether or not the active form of the chemical reaches the germinal tissue of whole mammals. If the observed mutagenic activity can be attributed to a chemical which can be radioactively labeled, radiotracer studies should be conducted. However, if the chemical responsible for the mutagenic activity cannot be identified or labeled, then other studies which are considered to provide evidence that a chemical reaches mammalian germinal tissue and causes DNA damage will be required. These may involve examination of the germinal tissue of mammals for evidence of unscheduled DNA synthesis, chromosome damage, or sister chromatid exchange formation.

The test substance will be classified as a mutagen with the potential to cause heritable genetic effects in humans if it is shown to possess mutagenic activity and is demonstrated to reach the mammalian gonad. If the chemical has intrinsic mutagenicity but cannot be shown to reach mammalian germinal tissue, and thus is not likely to cause germinal mutations, it will be operationally designated as a mutagen which may have the potential to cause somatic cell mutations which may be involved in the etiology of a cancer or genetically mediated disease.

If Goal is shown to have the potential for being a germ-cell mutagen to humans, the Agency may require supplementary tests to quantitatively estimate the mutagenic risk posed to humans. The approaches for quantitatively assessing mutagenic risk are described in the Agency's Proposed Guidelines for Risk Assessment (45 FR 221:74984-74988).

Appendix D

Field Monitoring[a/] during the Conditional Registration Period

Preliminary field monitoring and exposure modeling indicate that harmful residues of oxyfluorfen may accrue in aquatic habitats. The registrant is, therefore, requested by the Agency to submit the results of field monitoring studies within the first two years of the conditional registration period.

The purpose of the field studies will be to determine the tendency of lethal pesticide residues to be transported away from the site of application. Chemical analyses of water courses and aquatic habitats adjacent to the treated fields will provide some indication of pesticide movement. Because oxyflourfen may be detrimental to nontarget plants at residue levels below the analytical detection limit, the Agency requests that the productivity and density of aquatic plants adjoining the treated fields also be monitored. These productivity and density parameters will be compared to those for similar plant populations adjacent to untreated fields. The comparison will form a field bioassay to determine the presence or absence of herbicidal pesticide residues.

The field study sites should be selected within the soybean, corn, and bearing fruit and nut use pattern areas. Each study site should adjoin a small limnetic habitat containing submerged aquatic plants including members of the grass family (Gramineae). Submerged aquatic plant populations in untreated watersheds should also be located within close commuting distances. One of the soybean field study sites should be located within the Chesapeake Bay Drainage area, as persistent herbicides have been implicated in the apparent depletion of submerged aquatic vegetation in the bay.

The registrant may wish to augment the natural rainfall with irrigation at any or all of the study sites. An abnormally low natural rainfall might otherwise necessitate that the studies be repeated.

It is well known that good soil management practices can reduce the runoff of sediment-bound pesticides. If such practices are used during this field runoff study, they should be practices already in general use or practices which could be readily understood by agricultural workers after having read label instructions. That is, if this field study indicates that certain management practices are required to reduce runoff to safe levels, then those practices should be described and required by future Goal labels.

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a/ Due to the expected stability of oxyfluorfen the registrant will be expected to monitor for the parent chemical only. If metabolites are present they will be expected to be below the detection limit of the analytical method. The detection limit should be 0.01 ppm.

Specific items to be included in the registrants's field study protocol for each use pattern include:

Meteorological

1. Pan evaporation - daily
2. Temperature monitoring - continuous
3. Rainfall monitoring - continuous
   (rainwater itself should be analyzed for oxyfluorfen)
4. Volume of runoff water - per runoff event.

Soil

5. Soil profile description to one meter - once per season
6. Soil density - once per season
7. Soil organic matter content - once per season
8. Soil moisture holding capacity - once per season
9. Soil infiltratin rate - once per season

Biological

10. Comparison of the productivity and density of indigenous submerged aquatic plant populations growing adjacent to treated fields to the productivity and density of such populations growing adjacent to untreated fields. The protocol for this comparison should include an estimation of the real differences that can be detected by the test at the 95% confidence level. Pesticide residue analyses of hydrosoil surrounding the roots of these plants should be provided monthly.

Pesticide Residues. (10% of these analyses should be duplicated by mass spectrometry where appropriate).

11. Hydrosoil concentrations - Measurements in top 5 cm may be combined with hydrosoil measurements described under "Biological" above, where appropriate - monthly.

12. Benthic invertebrate's tissue residue (oligochaetes, burrowing mayflies, chironomids) - monthly.

13. Concentration of dissolved residues in runoff - per rainfall event.

14. Concentration of sediment-bound residues - per rainfall event (Analyses of spiked samples should be submitted to demonstrate percentage recovery.)

15. Treated soil pesticide concentrations - should be measured from 0 to 8cm in 2cm increments monthly. (Analyses of spiked samples should be submitted for each sampling interval to demonstrate percentage recovery.)

16. Total discharge of bound and unbound pesticide from treated fields. - estimated monthly.

Some references may be of aid to the registrant when writing the protocol. Field plot statistical design is discussed, generally, by LeClerq et al. (1962). Specific runoff monitoring protocols were detailed by the Agency (U.S. Environmental Protection Agency, 1978) as were collecting techniques for benthic organisms (U.S. Environmental Protection Agency, 1973).

The above study should extend for one year after the last appplication of Goal.

Appendix E

The following tables indicate the variety of herbicides and herbicide combinations recommended for use on soybeans for control of the weeds listed on the proposed Goal 2E soybean label (Table 14). Herbicides are recommended by at least one of the states listed, and control at least one of the weed species listed on Goal 2E label. None of the herbicides listed controls the same weed spectrum as oxyfluorfen (Beck and Petrie, 1981).

Table E1.

State Herbicide Recommendations for Weed Control in Soybeans: Preemergence[a/]

Herbicide	Also Used in Combination With:
Alachlor[b/]	Acifluorfen, Bentazon, Bifenox, Chloramben, Chlorpropham, Dinoseb Dinoseb/Naptalam, Linuron, Linuron/ Paraquat or Metribuzin
Bifenox	Alachlor or Trifluralin
Chloramben	Alachlor, Dinoseb, Linuron, Metolachlor, Metribuzin or Trifluralin
Chlorbromuron[c/]	Linuron
Chlorpropham[c/]	Alachlor
DCPA	———
Dinitramine[c/]	Metribuzin
Dinoseb	Alachlor, Diphenamid or Naptalam
Dinoseb/Naptalam	Alachlor, Metolachlor, Oryzalin, Profluralin or Vernolate
Diphenamid	———
Linuron[b/]	Alachlor, Chloramben, Chlorbromuron, Metolachlor, Metolachlor/Paraquat, Oryzalin, Oryzalin/Paraquat, Pendimethalin, Profluralin, Propachlor, Trifluralin or Vernolate

Metolachlor	Chloramben, Dinoseb/Naptalam, Linuron, Linuron/Paraquat, Metribuzin or Metribuzin/ Paraquat
Metribuzin	Alachlor, Alachlor/Paraquat Chloramben, Dinitramine, Metolachlor, Metolachlor/ Paraquat, Oryzalin, Pendimethalin or Trifluralin
Naptalam/Dinoseb	Alachlor, Metolachlor, Oryzalin, Profluralin or Vernolate
Oryzalin	Chloramben, Dinoseb/Naptalam, Linuron, Linuron/Paraquat Metribuzin or Metribuzin/Paraquat
Oxyfluorfen[d/]	———
Pendimethalin	Chloramben, Linuron or Metribuzin
Propachlor	———
Trifluralin[c/]	Bentazon, Bifenox, Chloramben, Chlorpropham, Dinitramine, Linuron or Metribuzin
Vernolate[c/]	Dinoseb/Naptalam, Linuron

a/ Taken from 1979 or 1980 state recommendations for Alabama, Arkansas, Delaware, Illinois, Iowa, Indiana, Kansas, Kentucky, Louisiana, Michigan, Mississippi, Missouri, Ohio, and Wisconsin (Beck and Petrie, 1981). These states have been chosen to represent a variety of soybean growing practices and herbicide recommendations.

b/ Most frequently recommended.

c/ Recommended in combination with other herbicides only.

d/ Experimental use only.

Table E2.

State Herbicide Recommendations for Weed Control in Soybeans:

Preplant Incorporated[a/]

Herbicide	Also Used in Combination With:
Alachlor	Bifenox, Metribuzin
Dinitramine	Metribuzin
Fluchloralin	Metribuzin
Metolachlor	Chloramben, Metribuzin
Pendimethalin	Metribuzin
Profluralin	Chloramben, Metribuzin or Chlorpropham
Trifluralin	Bifenox, Chloramben, Chlorprophan, Metribuzin
Vernolate	Chlorpropham, Trifluralin

a/ From 1979 or 1980 state recommendations for Alabama, Arkansas, Delaware, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisana, Michigan, Mississippi, Missouri, Ohio, and Wisconsin (Beck and Petrie, 1981). These states have been chosen to represent a variety of soybean growing practices and herbicide recommendations.

Table E3.

State Herbicide Recommendations for Weed Control in Soybeans:

Preplant Incorporated Followed by Preemergence Overlay Treatment[a/]

Preplant Incorporated Herbicide	Preemergence Overlay Herbicide
Fluchloralin	Metribuzin
Dinitramine	Metribuzin
Metolachlor	Chloramben, Metribuzin
Pendimethalin	Chloramben, Linuron or Metribuzin
Profluralin	Chlorpropham, Linuron or Metribuzin
Trifluralin	Bifenox, Chloramben, Chlorpropham, Linuron or Metribuzin
Vernolate	Chloramben, Chlorpropham or Linuron

a/ Taken from 1979 or 1980 state recommendations for Arkansas, Iowa, Kansas, Kentucky, Michigan, Mississippi, and Wisconsin (Beck and Petrie, 1981). These states have been chosen to represent a variety of soybean growing practices and herbicide recommendations.

Table E4.

State Herbicide Recommendations for Weed Control in Soybeans:

Post Emergence[a/]

Broadcast	Directed Spray
Acifluorfen	Chloroxuron
Acifluorfen/Alachlor	2,4-DB[b/]
Alachlor/Dinoseb/Naptalam	Dinoseb[b/]
Bentazon[b/]	Glyphosate[b/]
Chloramben	Linuron
Chloroxuron	Linuron/2,4-DB
2,4-DB	Linuron/Paraquat
Dichlofop	Metribuzin
Dinoseb	Metribuzin/2,4-DB
Dinoseb/Alachlor	Paraquat[b/]
Dinoseb/Naptalam[b/]	Paraquat/2,4-DB[c/]
Fluchloralin/Bentazon	
Metolachlor	
Metolachlor/Acifluorfen	
Metolachlor/Dinoseb/Naptalam	
Oryzalin/Acifluorfen	

a/ Taken from 1979 or 1980 state recommendations for Alabama, Arkansas, Delaware, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Mississippi, Missouri, Ohio, and Wisconsin (Beck and Petrie, 1981). These states have been chosen to represent a variety of soybean growing practices and herbicide recommendations.

b/ Most frequently recommended.

c/ Arkansas recommendations only.

Table E5.

State Herbicide Recommendations for Weed Control in Soybeans: No Till[a/]

Herbicide or Herbicide Combination
Alachlor/Glyphosate/Linuron[b/]
Alachlor/Linuron
Alachlor/Linuron/Metribuzin
Alachlor/Linuron/Paraquat[b/]
Alachlor/Metribuzin
Alachlor/Metribuzin/Paraquat
Glyphosate
Glyphosate/Linuron/Oryzalin
Glyphosate/Linuron/Metolachlor
Glyphosate/Metolachlor/Metribuzin
Glyphosate/Metribuzin/Oryzalin
Linuron/Paraquat
Linuron/Metolachlor/Paraquat
Linuron/Oryzalin/Paraquat[b/]
Metolachlor/Linuron
Metolachlor/Metribuzin
Metolachlor/Metribuzin/Paraquat
Metribuzin/Oryzalin/Paraquat
Paraquat

a/ Taken from state recommendations for Alabama, Kentucky, Illinois, Indiana and Iowa (Beck and Petrie, 1981). These states have been chosen to represent a variety of soybean growing practices and herbicide recommendations.

b/ Most frequently recommended.

Table E6.

USDA Herbicide Recommendations for Weed Control in Soybeans[a/]

Preplant Incorporated	Preemergence	Post Emergence
Dinitramine	Alachlor	Bentazon
Fluchloralin	Bifenox	Chloroxuron
Pendimethalin	Chloramben	2,4-DB
Trifluralin	Chlorbromuron	Dinoseb
Vernolate	Chlorpropham	Linuron
	Dalapon[b/]	Naptalam/Dinoseb
	Glyphosate[c/]	Paraquat
	Linuron	
	Metribuzin	
	Naptalam[d/]	
	Naptalam/Dinoseb	
	Oryzalin	
	Paraquat	

a/ USDA, 1980c

b/ Recommended for use in Arkansas, Kentucky, Louisiana and Mississippi only.

c/ Applied preplant, post emergent to weeds.

d/ Recommended for use in Nebraska only.

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