MEMORANDUM

SUBJECT: Section 18 - Specific Exemptions for Use of Oxyfluorfen (Goal) For Chemical Pruning (Cane Suppression) of Primocanes in Raspberries Grown in Oregon (92-OR-06) and Washington State (92-WA-14)

--ACTION MEMORANDUM--

FROM: Anne E. Lindsay, Director Registration Division

TO: Douglas D. Campt, Director Office of Pesticide Programs

I. APPLICANTS' REQUEST:

APPLICATIONS: Oregon Department of Agriculture Washington State Department of Agriculture

CHEMICAL: Oxyfluorfen

PRODUCT: Goal 1.6E Herbicide, EPA Reg. No. 707-174, manufactured by Rohm and Haas Company

SITE: Raspberries

PEST: Raspberry primocanes

RATE: At a rate of 1 to 4 pints of product (0.2 to 0.8 lbs. a.i.) per broadcast acre per application, with a maximum of 6 pints of product (1.2 lbs. a.i.) per broadcast acre per season.

NO. OF APPL: One or two ground applications made in a minimum of 50 gallons of water/acre, applied to primocanes in a 3-foot band over the row. A 50-day PHI will be observed.
ACREAGE: OR: 4,200 acres in Washington, Multnomah, Clackamas, Linn, Benton, Polk, Lane, Marion, Douglas, and Yamhill counties.
WA: 5,021 acres in counties west of the crest of the Cascade Mountains: Whatcom, Skagit, Snohomish, Clallam, Island, King, Kitsap, Pierce, Thurston, Lewis, Cowlitz, Skamania, and Clark.

POUNDAGE: OR: approximately 945 gallons of product
WA: approximately 1,130 gallons of product

USE-SEASON: OR: March 1, 1992 through May 15, 1992
WA: March 1, 1992 to June 1, 1992

EMERGENCY/REG. ALT.: In the past, dinoseb was used by growers in Oregon and Washington State for chemical pruning of raspberry primocanes. Since the suspension of dinoseb in October of 1986, extension personnel, processor and grower organizations, and private agricultural firms have been searching for economical and efficacious alternatives. Existing supplies of dinoseb have been completely exhausted. According to the applicants, research data show that oxyfluorfen provides the same benefits afforded by dinoseb.

Chemical pruning of raspberry primocanes is important for two reasons. First, mechanical harvesting, which now accounts for approximately 90% of harvested raspberries, requires that growth at the plant base be removed for proper operation of harvester catch plates which "catch" the falling fruit. Secondly, pruning of early season vegetative growth diverts nutrients to fruit buds and increases raspberry yields. The applicants estimate that without an effective herbicide for chemical pruning of primocanes, growers will lose 1.2 to 1.9 tons or more of raspberries per acre.

Both Oregon and Washington State have been granted 24(c) registrations for use of monourea sulfuric acid (Enquik) to suppress raspberry primocanes. However, this chemical is ineffective for the following reasons. Enquik's activity is very temperature-dependent. Ambient temperatures are often not conducive to the degree of activity required to suppress primocanes. In addition, Enquik often cripples the primocanes rather than suppressing them. These crippled canes continue to be a photosynthetic sink, competing with the berries for nutrients and obstructing machine harvesting operations.

According to the applicants, hand pruning is not a realistic alternative. Pruning crews are not generally available in April and May. Also, the cost of labor for a one time removal of new vegetative canes would be prohibitive, approximately $185 per
acre. The additional costs of removing shoots up to 1.5 feet long at the bases of fruiting canes cannot be accurately estimated.

ECONOMICS: Oregon estimates that with the use of oxyfluorfen, growers can expect average yields of 6,000 pounds of raspberries per acre. The total value of Oregon's raspberry crop is expected to be $12.6 million. Without the use of oxyfluorfen, growers expect yield reductions of between 1.2 and 1.9 tons of raspberries per acre. Assuming an average price of $0.50 per pound and reduced yields of 1.2 tons per acre, economic losses in excess of $5.7 million are expected to occur over 4,200 acres.

Washington State estimates that yields will be reduced as much as 45% without an effective chemical means of primocane suppression. In 1991, raspberry yields in Washington State averaged 6,331 pounds per acre with an average price of $0.50 per pound. Based on these figures, yield reductions of 45% could result in economic losses of approximately $1,424 per acre or $7.1 million over the entire 5,000 acres.

II. BACKGROUND:

This is the third year this use of oxyfluorfen has been requested under section 18 of FIFRA. Specific exemptions for use of oxyfluorfen on raspberries were granted to both Oregon and Washington State in March 1990 and February 1991.

Reregistration/Special Review considerations

Oxyfluorfen is a List B chemical, which is currently undergoing Phase V review at the Agency. The registrant has requested a waiver for the currently requested mesocosm study and several other studies. These requests are currently being reviewed by the Agency. The registrant has committed to fulfill all data requirements for reregistration.

A Special Review of oxyfluorfen was completed in January of 1982. The review was initiated due to concerns over contamination of oxyfluorfen with perchloroethylene (PCE), a carcinogen. A decision was made to continue use of the herbicide subject to restriction of the contaminant PCE (not to exceed 200 ppm) in the formulated product.

Progress towards registration

IR-4 project #3486 has been initiated to generate data in support of a tolerance for residues of oxyfluorfen in or on raspberries. The 1989 field data from Oregon have been sent to IR-4 headquarters for analysis.

III. EPA EVALUATION:
BEAD Review

BEAD reviewed the 1990 requests from Oregon and Washington State and concluded that an urgent, non-routine situation exists, since dinoseb is no longer available for use. BEAD also concluded that substantial yield and harvesting losses are expected to occur without an adequate alternative. There are no registered alternatives for this use, except Enquik, which is registered under section 24(c) for use in Oregon and Washington State. BEAD agreed with the applicants' assertion that Enquik is not an effective alternative to dinoseb, due to its temperature sensitivity. Enquik is only effective when the weather is unusually warm at the time of first treatment. Applications of Enquik when the weather is too cold may actually be counterproductive. BEAD also agreed with the applicants' assertion that hand-pruning of primocanes was not an economically feasible alternative to chemical control.

According to BEAD's estimates, growers can expect yield reductions as high as 2 tons per acre if an effective alternative to dinoseb is not found. Even the more conservative loss estimate of 1.2 tons per acre in Oregon's submission would cause a revenue loss of $1,200 per acre, roughly equivalent to 40% of the 5 year average per acre revenue of $2,975. Such a loss would be well outside the "normal" range in profitability.

Residue Chemistry

Tolerance Support - Chemistry Branch reviewed Oregon's 1991 section 18 request and concluded that residues of oxyfluorfen and its metabolites containing the diphenyl ether linkage are not expected to exceed 0.05 ppm in or on raspberries as a result of the proposed use. Residues in meat, milk, poultry, and eggs are not expected to result, since no animal feed items are involved. Adequate methodology for enforcement purposes may be found in PAM II, and reference standards are available from the Pesticides and Industrial Chemicals Repository at RTP, N.C.

Toxicological Review

Toxicology Branch I (TOX) reviewed this request in 1991 for use of oxyfluorfen on raspberries and concluded that data are adequate to support the proposed use under an emergency exemption.

HED has established an RfD for oxyfluorfen of 0.003 mg/kg/day, based on the NOEL of 0.3 mg/kg/day from a 20-month mouse feeding study with an uncertainty factor of 100. Existing uses of oxyfluorfen result in a TMRC (Theoretical Maximum Residue Contribution) of 0.000895 mg/kg/day for the overall U.S. population, which utilizes 29.8% of the RfD. The proposed use on raspberries would increase the TMRC by 0.00000014 mg/kg/day and
result in a negligible increase in RfD utilization. The only DRES population subgroup with a TMRC in excess of the RfD is non-nursing infants, less than 1 year old. The TMRC for this group is 0.004537 mg/kg/day, which utilizes 151% of the RfD. A DRES analysis incorporating available anticipated residue and percent crop treated data estimated an ARC (Anticipated Residue Contribution) for this subgroup of 0.000027 mg/kg/day, which utilizes only 0.9% of the RfD. The proposed use on raspberries is not expected to measurably increase dietary exposure to oxyfluorfen for infants, since infant consumption of raspberries is negligible.

HED's Peer Review Committee has classified oxyfluorfen as a Group C (possible human) carcinogen with an upper bound potency estimate ($Q_{m}$), in human equivalents, of $1.28 \times 10^{-7}$ (mg/kg/day). TOX deferred to the Science Analysis and Coordination Branch (SACB) and the Occupational and Residential Exposure Branch (OREB) for dietary and non-dietary exposure analyses, respectively. The results of these analyses are discussed below.

I. Dietary Risk Assessment:

SACB has previously estimated a lifetime dietary risk of $1.1 \times 10^{-4}$ from existing uses of oxyfluorfen, based on tolerance level residues and assuming 100 percent of the registered crops are treated. SACB has also completed a revised risk assessment, which incorporates available anticipated residue and percent crop treated information. SACB's revised lifetime dietary carcinogenic risk estimate is $1.4 \times 10^{-6}$. Assuming a residue level of 0.05 ppm in raspberries, the proposed use would result in a lifetime dietary carcinogenic risk of $1.8 \times 10^{-6}$.

II. Occupational Exposure Assessment:

OREB confirmed that the occupational exposure situation for these workers (mixers, loaders, and applicators) should be similar to the exposure situation derived from surrogate data for the use of oxyfluorfen on grass grown for seed in Oregon previously authorized under section 18. Based on OREB's exposure estimates, TOX Branch I calculated the total (dermal and inhalation) occupational carcinogenic risk to workers who mix/load and apply oxyfluorfen under that exemption to be on the order of $10^{-7}$ provided protective clothing (long-sleeve shirts, hats, long pants, work footwear, and chemical resistant gloves) are worn by workers involved in the mixing and loading of oxyfluorfen. Occupational carcinogenic risk estimates for this use would be on the same order of magnitude. The milligrams authorizing this use will require mixers and loaders to use protective clothing.
A rat teratology study for oxyfluorfen recently submitted under 6 (a)(2) has reduced the NOEL for developmental effects from the previous 30 mg/kg/day to a NOEL of 15 mg/kg/day. TOX Branch I calculated the margins of exposure (MOE) for developmental effects for a 70 kg woman involved in the use of oxyfluorfen on grasses to be 2080. The MOE for this use would be similar.

OREB emphasized that a data gap would remain due to the lack of precise exposure data for this use and recommended that Rohm and Haas provide exposure data in support of the pending section 3 registration for this use. The PM will be notified of their recommendation via a copy of this decision memorandum.

Ecological Effects Review/Environmental Fate Review

EEB reviewed the 1990 requests from Oregon and Washington State and concluded that the proposed use is not expected to pose an unreasonable risk of adverse effects on birds, mammals, or aquatic organisms, but does pose a risk to non-target plant species. Although there are no endangered plant species in Washington State, one endangered plant, Bradshaw's lomatium, occurs in the Willamette Valley of Oregon. EEB recommended that applications of oxyfluorfen be prohibited within 100 yards of "all lowland prairie communities, all wetlands, and all other aquatic habitats including drainage courses, and other water ways" in Benton, Lane, Linn, Marion, and Polk counties to minimize risk of exposure of this endangered plant. This restriction was imposed as a condition of Oregon's 1990 specific exemption for the use of oxyfluorfen on raspberries.

The Portland office of the USFWS reviewed a similar use of oxyfluorfen on grasses grown for seed in Oregon and concluded that the existing environmental hazards statements on the Goal 1.6E label should be adequate to protect Bradshaw's lomatium without the need to impose buffer zones in the counties where it is present. However, USFWS noted that, while wet prairie plant communities have become rare in the Willamette Valley due to agriculture and development, small remnant patches persist along fence rows, roadsides, and drainage courses. These communities contain not only the endangered plant, Bradshaw's lomatium, but also other plants (Aster curtis, Erigeron decumbens, etc.) which, although they are not federally listed endangered plants at this time, share the same problems and threats as the lomatium and would also be susceptible to Goal. USFWS, therefore, recommended that a label statement such as the one below be included on Oregon's section 18 labels as a discretionary conservation measure:

Due to the close proximity of native prairie remnants to agricultural areas and the potential for these areas to be adversely affected by herbicides through drift or possible
runoff/soil movement, it is recommended that Goal 1.6E herbicide not be applied directly to native prairie habitats in Benton, Clackamas, Lane, Linn, Marion, Polk, and Yamhill counties of Oregon.

The mailgram authorizing this use in Oregon will require this statement to appear on the section 18 label.

Oxyfluorfen does not appear on EFGWB's list of chemicals with ground water concerns.

IV. RECOMMENDATION:

I recommend that the Oregon Department of Agriculture and Washington State Department of Agriculture be granted specific exemptions for use of oxyfluorfen for chemical pruning of raspberry primocanes. This recommendation is based on the following:

1. Dinoseb has been used in the past for chemical pruning of raspberry primocanes. Dinoseb was suspended in 1986, and existing supplies are now exhausted. There are no other effective registered alternatives available for use.

2. Without the use of oxyfluorfen this season, growers are expected to suffer significant economic losses of approximately $1,200 per acre or $5.0 million over the entire 4,200 acres in Oregon and $6.0 million over the entire 5,000 acres in Washington State.

3. Residues of oxyfluorfen are not expected to exceed 0.05 ppm in or on raspberries as a result of the proposed use. This level can be toxicologically supported. Existing uses of oxyfluorfen utilize 29.8% of the RfD for the overall U.S. population and 151% (or 0.9% based on available anticipated residue and percent crop treated information) of the RfD for non-nursing infants. The proposed use on raspberries would result in a negligible increase in dietary exposure for the U.S. population and all of the DRES population subgroups.

Existing uses of oxyfluorfen result in a lifetime dietary carcinogenic risk of 1.1 X 10^{-4}, based on tolerance level residues, and 1.4 X 10^{-6}, based on available anticipated residue and percent crop treated data. The proposed use on raspberries would result in a negligible increase in risk (10^{-7}).

The total occupational carcinogenic risk to workers who mix/load and apply oxyfluorfen under this specific exemption is estimated to be on the order of 10^{-7}, provided protective clothing (long-sleeve shirts, hats, long pants, work
footwear, and chemical resistant gloves) are worn by workers involved in the mixing and loading of oxyfluorfen.

TOX Branch I calculated the margins of exposure (MOE) for developmental effects of oxyfluorfen on grasses for a 70 kg woman involved in the use of oxyfluorfen to be 2080. MOE for this use would be similar.

4. The proposed use should not pose an unreasonable risk of adverse effects on non-target birds, mammals, or aquatic organisms. The use does pose a risk of adverse effects on the endangered plant, Bradshaw's lomatium, found in certain counties in Oregon. Existing Goal label statements and the inclusion of a precautionary statement recommended by the Oregon office of the USFWS should be adequate to protect this species.

5. Progress toward registration of the proposed use appears to have been made. An IR-4 project is underway to collect data in support of a permanent raspberry tolerance. Data from 1989 field trials in Oregon have been submitted to an IR-4 laboratory for analysis.

Approve: 

Disapprove: 

Date: 9/20/92