



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

3/29/1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Section 18 - Specific Exemptions for Use of Oxyfluorfen
(Goal) For Chemical Pruning (Cane Suppression) of
Primocanes in Raspberries Grown in Oregon (95-OR-10)
and Washington (95-WA-03). CC

--ACTION MEMORANDUM --

FROM: James J. Jones, Chief
Registration Support Branch

TO: Stephen L. Johnson, Director
Registration Division
Office of Pesticide Programs

I. APPLICANTS' REQUEST:

APPLICANTS: Oregon and Washington Departments 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 lb. 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. A 50-day PHI will be observed.

NO. OF APPL: Two.

ACREAGE: OR: 4,000 acres in Washington, Multnomah,
Clackamas, Linn, Benton, Polk, Lane, Marion,
Douglas, and Yamhill counties.

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WA: 6,705 acres in counties west of the crest of the Cascade Mountains: Whatcom, Skagit, Snohomish, Clallam, Island, King, Kitsap, Pierce, Thurston, Lewis, Cowlitz, and Clark.

POUNDAGE: OR: approximately 3,000 gallons of product (4,800 lbs. a.i.)
WA: approximately 5,030 gallons of product (8,064 lbs. a.i.)

USE-SEASON: OR: March 1, 1994 through May 15, 1995.
WA: March 1, 1994 through June 1, 1995.

EMERGENCY/REG. ALT.: Chemical pruning of raspberry primocanes with oxyfluorfen is a necessary practice which removes raspberry tree growth at the plant base allowing for the proper operation of harvester catch plates. Also, the pruning of early season vegetative growth diverts nutrients to fruit buds and increases raspberry yields. Since the suspension of dinoseb in 1986, raspberry growers have been searching for alternative, economical methods of primocane suppression. Both Oregon and Washington have been granted 24(c) registrations for use of monourea sulfuric acid (Enquik) to suppress raspberry primocanes. However, Enquik does not provide adequate cane suppression in the cool, moist pacific northwest climates of Oregon and Washington.

The inability to chemically suppress primocanes may cause a total loss of \$3.3 million for Oregon and \$6.4 million for Washington raspberry growers this growing season.

II. BACKGROUND:

This is the sixth year this use of oxyfluorfen has been requested under section 18 of FIFRA. Specific exemptions for the use of oxyfluorfen on raspberries were granted to Oregon and Washington State since 1990.

REREGISTRATION:

- List: B (currently undergoing phase V review by the Agency)
- Registrant: Rohm and Haas
- In Compliance? Yes
- Major Data Gaps: A DCI was issued in August 1993 that required crop-field trial data on 15 crops and residue and environmental fate studies. These studies were requested to replace data previously generated by Craven Laboratories.
- Last Study Due Date: Most of the required studies are due in August 1995.

- Expected RED Completion Date: 4th quarter of 1996.

A substantial portion of the residue data being used to support the existing registrations of oxyfluorfen was generated by Craven Laboratories. Craven Laboratories, its President (Don Craven), and several employees were indicted September 29, 1992, by the Justice Department on 20 felony counts in connection with pesticide testing. The company, Don Craven and 14 former Craven employees were convicted on various counts and sentenced to prison terms and/or fines on February 25, 1994. Data Call-Ins (DCIs) requiring new studies to replace Craven studies were prepared by SRRD, and in July, 1993, OMB approved the Information Collection Request (ICR) for these studies. According to the review manager for oxyfluorfen in the Accelerated Reregistration Branch, the DCI for oxyfluorfen was issued in August 1993.

PROGRESS TOWARD REGISTRATION: A petition in support of a tolerance for residues of oxyfluorfen on raspberries was submitted to the Agency from IR-4 in February 1995. Chemistry Branch I (CB-1) reviewed the tolerance petition and recommended that with minor label revisions the proposed tolerance for oxyfluorfen could be established. Though a DRES run has been requested for this use the results may not be favorable for the pending registration of oxyfluorfen on raspberries due to the estimated lifetime cancer risk from existing uses of oxyfluorfen. Oxyfluorfen is classified in Group C (possible human carcinogen), according to EPA's Cancer Assessment Guidelines, with an upper bound potency estimate (Q_1^*) of 1.28×10^{-1} (mg/kg/day). According to the Agency guidelines dietary cancer risk should not exceed a one-in-a-million (1.0×10^{-6}) probability that an individual would develop cancer from the dietary exposure to a carcinogen over his/her lifetime. According to the Agency's most recent dietary exposure analysis for oxyfluorfen uses, the dietary cancer risk for the general population is 1.6×10^{-6} when available anticipated residue and percent of crop treated data are utilized. This dietary cancer risk level is in the range considered unacceptable by the Agency to allow for the registration of new uses. However, the cancer risk from the use of oxyfluorfen (dietary contribution) on raspberries alone based on proposed tolerance-level residues and assuming that 100% of the crop is treated would be 1.9×10^{-8} which indicates that the registration of this use on raspberries would insignificantly increase the current dietary cancer risk estimate.

It should be noted that a section 18 request for the use of oxyfluorfen on strawberries in Connecticut was denied by the Agency on October 3, 1994. That request was denied because: 1) the dietary cancer risk from the registered uses exceeded a level considered acceptable by the Agency; and 2) BEAD concluded that an emergency situation did not exist for Connecticut strawberry growers. Since the denial of that section 18 request the

Registrant has assured ERMUS that a refined dietary exposure analysis for the registered uses will be submitted in April 1995. The refined dietary exposure data is expected to show that the level of dietary concern from oxyfluorfen exposure is not as high as the present dietary cancer risk calculations indicate and that the registration of oxyfluorfen on raspberries would be feasible.

In assessing section 18 requests, the Agency must take into consideration the progress made toward securing section 3 registration of any proposed use. In consideration of oxyfluorfen on raspberries, a finding that there is adequate progress toward registration can be made. This is because: 1) IR-4 has submitted a complete tolerance petition for this use; 2) HED's chemistry review of the tolerance petition was favorable; and 3) the Registrant intends to submit residue and/or percent of crop treated data to more accurately define the dietary risk exposure estimates and allow for the establishment of a tolerance for oxyfluorfen on raspberries.

SECTION 18 DELANEY POLICY: Oxyfluorfen has been classified as a quantified Group C (possible human) carcinogen. However, the Agency does not require processing studies for raspberries or set food or feed additive tolerances under section 409 of FFDCA for any processed raspberry commodities. Therefore, this exemption request is not affected by the May 7, 1993 EPA/FDA policy on the Delaney Clause and Section 18 Emergency Exemptions under FIFRA.

SPECIAL REVIEW CONSIDERATIONS: 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.

III. EPA EVALUATION:

BEAD REVIEW:

Biological Aspects

BEAD reviewed last year's request from Washington and determined that an urgent, non-routine situation will exist for raspberry growers if oxyfluorfen is not made available to control primocane growth. BEAD's findings coincide with previous Agency reviews of this situation in Oregon and Washington. Since the loss of dinoseb (use was suspended in 1986) for chemically pruning primocanes, an adequate alternative has not been registered. As a result, substantial raspberry yield and harvesting losses are expected. This determination is supported by expert opinion and efficacy data submitted in the study "Possible Alternatives To Dinoseb For Cane Suppression In

Caneberries" (Oregon Horticultural Society), available in Oregon's 1993 section 18 application. BEAD noted that there are no registered alternatives for this use, except Enquik, which is registered under section 24(c) for use in Oregon and Washington State. Due to Enquik's temperature sensitivity, BEAD considers it an ineffective alternative to dinoseb under pacific northwest climatic conditions. 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 further determined that hand-pruning of primocanes is not an economically feasible alternative to chemical control.

Economic Aspects

The 1993 crop loss estimates of 32% by Oregon and up to 45% by Washington would cause a loss in revenue of approximately \$760 per acre for both states. BEAD's previous analysis of the situation found that losses in production of this extent would be outside the "normal" range of profitability for growers.

Conclusion

BEAD's determination that an emergency situation exists is based, in part, on efficacy data and expert opinion previously submitted to the Agency. If Oregon or Washington applies for this request in the future then comparative product performance data (CPPD) should be submitted for oxyfluorfen and the registered alternatives used in controlling primocanes on raspberries. The Agency requested CPPD last year, though due to the resources required for generating such data, BEAD does not expect the applicants to produce this type of data until next growing season.

RESIDUE CHEMISTRY REVIEW: Tolerance Support - Chemistry Branch (CBTS) reviewed IR-4's requests that tolerances be established for oxyfluorfen and its metabolites containing the diphenyl ether linkage in or on raspberries at a level not to exceed 0.05 ppm. With Tox considerations permitting, CBTS recommends that the proposed tolerances for oxyfluorfen be established once minor adjustments to the label are made. Residues in meat, milk, poultry, and eggs are not expected to result, since no animal feed items are involved. Method I of PAM II is available for enforcement purposes. Reference standards are available from the Pesticides and Industrial Chemicals Repository at RTP, N.C.

The residue data reviewed for this request were not generated by Craven Laboratories.

TOXICOLOGICAL REVIEW: Toxicology Branch I (TOX) reviewed this request 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 with an uncertainty factor of 100. The NOEL is based on a 20-month mouse feeding study where increased absolute liver weight and increased non-neoplastic liver lesions were observed. Existing uses of oxyfluorfen result in a TMRC (Theoretical Maximum Residue Contribution) of 0.000896 mg/kg/day for the overall U.S. population, which utilizes approximately 30% of the RfD. The proposed use on raspberries would increase the TMRC by less than 1% to 0.000001 mg/kg/day and result in a negligible increase in RfD utilization. For the registered uses 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 0.004538 mg/kg/day, which utilizes 151% of the RfD. A DRES analysis incorporating anticipated residue and percent crop treated data estimated an Anticipated Residue Contribution (ARC) for this subgroup of 0.000027 mg/kg/day which utilizes less than 1% 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 considered low.

HED's Peer Review Committee has classified oxyfluorfen as a Group C (possible human) carcinogen with an upper bound potency estimate (Q_1^*), in human equivalents, of 1.28×10^{-1} (mg/kg bwt/day)⁻¹.

I. Dietary Risk Assessment:

The estimated lifetime cancer risk through dietary exposure from existing uses of oxyfluorfen is 1.2×10^{-4} , based on tolerance level residues and assuming 100 percent of the registered crops are treated. The upper-bound estimate of carcinogenic risk for the general population is 1.6×10^{-6} when available anticipated residue and percent of crop treated data are used. Assuming a residue level of 0.05 ppm in or on raspberries, the proposed use would result in an additional lifetime dietary carcinogenic risk of 1.9×10^{-8} based on enforcement level residues and assuming 100 percent of the raspberry crop is treated. Further discussion of the dietary risk from this proposed use is provided in the Progress Toward Registration and the Recommendation sections of this memo.

II. Occupational Exposure Assessment:

Occupational and Residential Exposure Branch (OREB) reviewed this use and provided TOX Branch with estimates of exposure to oxyfluorfen for mixers, loaders, and applicators from this proposed use. Acute margins of exposure (MOEs) for ground spray/mixer/loaders and applicators are greater than 100 and cancer risk is less than 1.0×10^{-6} . If this request is

approved, the authorizing correspondence will require mixer/loaders/applicators to wear protective clothing.

The toxicology studies which the registrant, Rohm and Haas Company, references to support the registration of Goal 1.6E have been performed by the former Cannon Laboratories. These toxicology studies are invalid due to the status of all Cannon toxicology studies and have to be replaced as soon as possible. Additionally, the test material of these invalid studies was not Goal 1.6E, but a 1974 surrogate called RH-2915 EC 24.3%. Goal 1.6E does not appear to have been ever tested toxicologically. However, there are sufficient toxicology data and studies with technical oxyfluorfen to support this section 18 request.

ECOLOGICAL EFFECTS/ENVIRONMENTAL FATE REVIEWS: EEB previously reviewed request 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, one endangered plant, Bradshaw's lomatium, occurs in the Willamette Valley of Oregon.

The Portland office of the United States Fish and Wildlife Service (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. It is recommended that dosage rates be maintained at the lower end of the use rate range (if effective primocane suppression can be achieved) in a further effort to lessen potential impacts to endangered species.

The correspondence 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 and Washington Departments of Agriculture be granted specific exemptions for use of oxyfluorfen for chemical pruning of raspberry primocanes. This recommendation is based on the following:

1. An urgent, non-routine situation will exist for Oregon and Washington raspberry growers if they are unable to use oxyfluorfen to suppress primocane growth. Since the suspension of Dinoseb in 1986 there have been no other effective registered alternatives available to growers.
2. 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 approximately 30% of the RfD for the overall U.S. population. 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 utilizes 151% of the RfD for the registered uses. However, a DRES analysis incorporating available anticipated residue and percent crop treated data estimated that less than 1% of the RfD for this subgroup is utilized. Therefore, the proposed use on raspberries would result in a small increase in dietary exposure for the U.S. population and all of the DRES population subgroups.

Occupational and Residential Exposure Branch (OREB) reviewed this use and provided TOX Branch with estimates of exposure to oxyfluorfen for mixers, loaders, and applicators from this proposed use. Acute margins of exposure (MOEs) for ground spray/mixer/loaders and applicators are greater than 100 and cancer risk is less than 1.0×10^{-6} . The authorizing correspondence will require mixer/loaders/applicators to wear protective clothing.

3. 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.
4. A petition in support of a tolerance for residues of oxyfluorfen on raspberries was submitted to the Agency from

IR-4 in February 1995. Chemistry Branch I (CB-1) reviewed the tolerance petition and recommended that with minor label revisions the proposed tolerance for oxyfluorfen could be established. Though a DRES run has been requested for this use the results may not be favorable for the pending registration of oxyfluorfen on raspberries due to the estimated lifetime cancer risk from existing uses of oxyfluorfen. Oxyfluorfen is classified in Group C (possible human carcinogen), according to EPA's Cancer Assessment Guidelines, with an upper bound potency estimate (Q_1^*) of 1.28×10^{-1} (mg/kg/day). According to Agency guidelines dietary cancer risk should not exceed a one-in-a-million (1.0×10^{-6}) probability that an individual would develop cancer from the dietary exposure to a carcinogen over his/her lifetime. According to the Agency's most recent dietary exposure analysis for oxyfluorfen uses, the dietary cancer risk for the general population is 1.6×10^{-6} when available anticipated residues and percent of crop treated data are utilized. This dietary cancer risk level is in the range considered unacceptable by the Agency to allow for the registration of new uses. However, the cancer risk from the use of oxyfluorfen (dietary contribution) on raspberries alone based on tolerance-level residues and assuming that 100% of the crop is treated would be 1.9×10^{-8} which indicates that the registration of this use on raspberries would insignificantly increase the current dietary cancer risk estimate. The Registrant has assured ERMUS that a refined dietary exposure analysis for the registered uses will be submitted in April 1995. The refined dietary exposure data is expected to show that the level of dietary concern from oxyfluorfen exposure is not as high as the present dietary cancer risk calculations indicate and that the registration of oxyfluorfen on raspberries would be feasible.

In assessing section 18 requests, the Agency must take into consideration the progress made toward securing section 3 registration of any proposed use. In consideration of this request for the use of oxyfluorfen on raspberries, a finding that there is adequate progress toward registration can be made. This is because: 1) IR-4 has submitted a complete tolerance petition for this use; 2) HED's chemistry review of the tolerance petition was favorable; and 3) the Registrant intends to submit residue and/or percent of crop treated data to more accurately define the dietary risk exposure estimates and allow for the establishment of a tolerance for oxyfluorfen on raspberries.

I recommend that Oregon and Washington be advised that future requests for this use must be supported by comparative

product performance data for oxyfluorfen and the registered alternatives used in controlling primocanes on raspberries. I further recommend that the Applicants be advised that the Agency is concerned about the present level of dietary risk posed by the registered uses of oxyfluorfen and that data to more accurately define the dietary risk exposure estimates will be reviewed by the Agency. If the Agency determines that the data submitted by the Registrant does not adequately reduce the present level of risk posed by the registered uses to allow for the establishment of a tolerance for oxyfluorfen on raspberries then future section 18 requests for this use should be denied.

Approve: James Jones for
Stephan Johnson

Disapprove: _____

Date: 3/29/95