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

MAR 16 1994

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 (94-OR-09) and Washington (94-WA-05).
--ACTION MEMORANDUM --

FROM: Stephen L. Johnson, Acting Director
Registration Division

TO: Susan H. Wayland, Deputy Director
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 ground applications made in a minimum of 50 gallons of water/acre.

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

WA: 5,133 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 3,000 gallons of product (4,800 lbs. a.i.)
WA: approximately 3,850 gallons of product (6,160 lbs. a.i.)

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

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 net revenue loss per acre of approximately $760 for Oregon and Washington raspberry growers.

II. BACKGROUND:

This is the fifth 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 (not including raspberries). The list included residue chemistry and occupational exposure 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; however, time frames have not been finalized.
- Expected RED Completion Date: 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: IR-4 project #3486 and #3486A (trials done after a GLP on raspberries) were initiated to generate data in support of a tolerance for residues of oxyfluorfen in or on raspberries. Analyses of the 1989 field trial data from Oregon were completed and a draft petition has been reviewed by the registrant. IR-4 anticipates a petition will be sent to EPA by June 1994. They will be requesting a tolerance of 0.05 ppm on raspberries. According to IR-4 there were no detectable residues even at exaggerated rates.

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 EPA/FDA policy on the Delaney Clause and Section 18 Emergency Exemptions under FIFRA, which became effective May 7, 1993.

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 this year's request from Washington and determined that an urgent, non-routine situation will exist for raspberry growers if oxyfluorfen is not made available for growers to control primocanes. 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 Enquick'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 existed 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 should be submitted for oxyfluorfen and the registered alternatives used in controlling primocanes on raspberries. Due to the resources required for generating such data, BEAD does not expect the applicants to produce this type of data in just one growing season; however, data would be expected as soon as feasibly possible. If the applicants submit an emergency exemption request next growing season then a status report on the progress toward development of this data must be submitted to the Agency.

RESIDUE CHEMISTRY REVIEW: 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 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 0.000896 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 0.000001 mg/kg/day and result in a small 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 0.004538 mg/kg/day, which utilizes 151% of the RfD. A DRES analysis incorporating available 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 dietary risk 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 anticipated residues and percents of crop treated are used. Assuming a residue level of 0.05 ppm in raspberries, the proposed use would result in an additional lifetime dietary carcinogenic risk of 1.9×10^{-8}.

II. Occupational Exposure Assessment:

Acute margins of exposure (MOEs) for ground spray mixer/loaders and applicators are greater than 1000 and the five year cancer risk is less than 1.0×10^{-7}. Estimates were adjusted for dermal absorption of 3.0% which was derived from a dermal penetration study.

Margins of exposure (MOE's) for acute exposure to oxyfluorfen were calculated using the rabbit developmental NOEL

of 10 mg/kg/day. Acute MOEs for mixer/loaders of oxyfluorfen are 1,136 and 20,000 for ground applicators, respectively. Estimated cancer risk calculations are based on 2 days/year exposure, with a 5/70 year lifespan exposure (since this is the fifth year this section 18 has been requested). TOX Branch I calculated the total (dermal and inhalation) occupational carcinogenic risk to workers who mix/load oxyfluorfen under the exemption to be 4.4×10^{-7} and 2.5×10^{-8} for ground applicators. These estimates were based on the use of protective clothing (long-sleeve shirts, hats, long pants, work footwear, and chemical resistant gloves) worn by workers involved in the mixing and loading of oxyfluorfen. The correspondence to the states will require mixers and loaders to use protective clothing.

TOX Branch I noted that the toxicology studies which the Registrant, Rohm and Haas Co., referenced to support the registration of Goal 1.6E were performed by Craven Laboratories and that these toxicology studies should 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 ever been tested toxicologically. However, there are sufficient toxicology data and studies with technical oxyfluorfen to support this use under Section 18. The product manager has been advised of this by a copy of the toxicology review.

ECOLOGICAL EFFECTS/ENVIRONMENTAL FATE REVIEWS: EEB reviewed this year's 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 in Benton, Clackamas, Lane, Linn, Marion, Polk, and Yamhill counties of Oregon.

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 would 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 and 151% (or less than 1% 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 small increase in dietary exposure for the U.S. population and all of the DRES population subgroups. The estimated lifetime dietary risk 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 anticipated residues and percents of crop treated are used. The proposed use on raspberries would result in an additional lifetime dietary carcinogenic risk of 1.9×10^{-8}.

   Acute margins of exposure (MOEs) for ground spray mixer/loaders and applications are greater than 1000 and fifth year cancer risk is less than 1.0×10^{-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.

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. Progress toward registration of oxyfluorfen on raspberries appears to have been made. IR-4 anticipates a petition will be sent to EPA by June 1994.

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. A status report on the progress toward development of these data must be included in any future section 18 request for this use.

Susan H. Haytaian

Approve:_____

Disapprove:_____

Date:_____

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