



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

12/20/88

OFFICE OF
PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Section 18 - Specific Exemption for Feeding Grass Seed Crop Wastes from Use of Propiconazole (Tilt) to Control Diseases on Various Species -- ACTION MEMORANDUM

FROM: Anne E. Lindsay, Acting Director
Registration Division

Anne E. Lindsay

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

APPLICANT'S REQUEST

APPLICANT: Oregon Department of Agriculture

CHEMICAL: Propiconazole [1-((2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl)methyl)-1H-1,2,4-triazole]

PRODUCT: Tilt Fungicide, EPA Reg. No. 100-617, Ciba-Geigy Corp.

SITE: Perennial ryegrass, fescues, bluegrass, orchardgrass and/or wheatgrass (registered sites)

PEST: Rusts (Puccinia spp.), powdery mildew, and Selenophoma stem eyespot (registered pests)

RATE & NO. OF APPL.:

Registered use applications allowed at 4 to 8 fl. ozs. of Tilt product (maximum 4 fl. ozs. on bluegrass) per acre at 14-21 day intervals until control is achieved until seed is mature. Make last application 14 days before seed is mature. This exemption requests a waiver of the label feeding restriction; specifically, "Do not use any part of crop or crop wastes for live-stock feed or bedding."

ACREAGE: Oregon estimates 27% of the 325,000 acres of grass grown for seed may have been treated with one application of Tilt at 4 ounces of product per acre and 8% may have received 2 applications. Less than 5% may have received 3 applications.

USE SEASON: Immediately, and thru July 31, 1989

Emergency: The current Tilt label is restrictive as to feeding of grasses grown for seed (Nebraska, Oregon, Washington, Idaho and Minnesota only). The label indicates as "Notes: To avoid possible illegal residues: (1) Do not graze livestock on treated areas and (2) Do not use any part of crop or crop wastes for livestock feed or bedding."

According to Oregon, grass seed screenings and some straw have historically been fed to livestock. The screenings are usually pelleted, although some loose screenings are mixed with other feed components. The inability to utilize these screenings as a livestock feed would severely impact the livestock and grass seed industries in Oregon. In addition, failure to use such wastes would result in major disposal difficulties and greatly reduce the timely processing of the grass seed crop in Oregon. Untimely processing would adversely impact growers, processors, shippers and associated domestic and foreign markets.

Oregon indicates that with over 300,000 acres (5,500 fields) of grass grown for seed in Oregon yielding over 340,000,000 pounds of seed, there is a considerable amount of straw and screenings produced. There is an average of 2.75 tons of straw per acre remaining after harvest. This amounts to a minimum of 825,000 tons of straw; approximately 140,000 tons, of which, is exported.

In the seed cleaning process, approximately 20% of the crop is screenings. This results in a minimum of 30,000 tons of grass seed screenings. Some of the screenings are plowed under, dumped or burned. Burning creates a smoke problem and dumping is expensive. Realistically, there are not enough dump sites to accept all the straw and screenings. Dump fees are \$30-\$40/ton and fees for 50% of the screenings at \$35/ton would amount to \$525,000. Realistically, there are not enough dump sites to accept all the straw and screenings.

The amount of screenings utilized in feeding livestock is not expected to exceed 25% of the total ration (dry weight basis) for lactating cows and 30% for finishing cattle. The feeding of screenings to market lambs is generally halted at least 30 days before slaughter. Negligible amounts of screenings are fed to goats or hogs.

Economics: Grass seed screenings (pellets and loose) are a valuable and economical source of livestock feed. If approximately 30,000 tons are marketed at \$55/ton, then the value is \$1.65 million. The price of grass seed screening pellets has ranged from \$35-\$75 during the past few years. A typical analysis is 11% protein, 2% fat and 24% fiber. About 90% of the feed pellets are shipped in interstate commerce; the majority of the market is beef feedlots in Washington and Idaho. Commodity brokers usually offer screenings on the basis of one-half to one pound per head per day. Use in dairy rations shows typical feeding levels of two to five pounds per head per day for a lactating cow of 1,200 to 1,400 lbs. body weight.

Exported straw has a farmgate value of \$9.8 million and the final sales value is reported to be as much as \$35 million (140,000 tons x \$250/ton).

EPA EVALUATION

Background. Propiconazole (Tilt Fungicide) is currently registered for use on grasses grown for seed (Nebraska, Oregon, Washington, Idaho and Minnesota only). Tilt controls rusts (Puccinia spp.), powdery mildew, and Selenophoma stem eyespot in perennial ryegrass, fescues, bluegrass, orchardgrass, and wheatgrasses. The label indicates: "Notes: To avoid possible illegal residues: (1) Do not graze livestock on treated areas and (2) Do not use any part of crop or crop wastes for livestock feed or bedding."

Tolerances currently exist for propiconazole and its metabolites in eggs, meat and milk. A petition (9F3706) received in late October seeks a label modification, ostensibly, to allow feeding that does not result in meat and milk residues in excess of existing tolerances.

A petition (9F3706) requesting removal of the grazing and feeding restrictions from use on grasses grown from seed from the registered use of propiconazole has been submitted to the Agency and is currently under review. Reviews were requested November 30, 1988, and are due February 18, 1989. The DRAFT label for Tilt indicates: "Note: To avoid possible illegal residues, do not: 1) feed hay cut within 20 days of the last application or 2) graze treated areas within 140 days of the last application."

A Registration Standard for propiconazole is not currently available.

Reviews: Biological and Economic Analysis Division reviews of alternative pesticides and economic losses anticipated are not yet available. However, the Applicant has not shown that an urgent, non-routine situation exists as a result of a pest outbreak. There is no indication that the pest situation is any worse than it has ever been. Both triadimefon (Bayleton) and propiconazole (Tilt) are registered and will control the fungal pest. Obviously, more money can be made if screenings can be sold and fed rather than destroyed. This does not represent an emergency situation and, therefore, should not be allowed under section 18. The section 3 process is more appropriate.

TB(HFAS)/HED indicates in previous reviews of other uses that propiconazole at a high dietary exposure level has been associated with development of liver tumors in male mice. A 2-year mouse chronic feeding/oncogenicity study with a NOEL of 15 mg/kg/day indicated a statistically significant increase in combined adenomas and carcinomas of the liver in male mice at approximately 375 mg/kg, the highest dose tested.

The Agency carried out a weight-of-evidence review of all relevant data and concluded that the fungicide is a Category C oncogen (possible human carcinogen with limited evidence of carcinogenicity in animals in the absence of human data). The current Agency position (although this is currently in review) is that propiconazole is a category C oncogen with a Q^* of 7.87×10^{-2} (mg/kg/day)⁻¹.

Based on a NOEL of 1.25 mg/kg/day in a 1 year dog feeding study and a safety factor of 100, the ADI was set at 0.013 mg/kg/day. This value has been approved by the Agency reference dose committee (5/25/88). The registered uses for propiconazole utilizing anticipated residues and percentage of crop treated instead of the established tolerances pose a lifetime risk of 1.4×10^{-6} for the general U.S. population.

DEB/HED has not concluded their review of the proposed use and has not yet projected residues levels of propiconazole and its metabolites on grass screenings and straw. However, DEB/HED verbally indicates that even if: 1) residues of propiconazole can be determined for grasses grown for seed screenings and straw, 2) use will not result in residues of propiconazole (Tilt) in meat and milk in excess of existing tolerances, and 3) therefore, does not increase dietary risk with respect to this single pesticide; this use cannot be supported. The Food and Drug Administration reported finding residues of propiconazole of up to 1.6 ppm in seed screenings. An analytical method and reference standards are available. Published tolerances utilize 8.36% of the Reference Dose for the U.S. population in general. Using anticipated residues and the percent of the crop treated, instead of the published tolerances, reduces the percent of the Reference Dose for the general U.S. population to 0.17%.

Oregon indicates that approximately 325,000 acres of grass were grown for seed in 1988 and that fungicides registered for disease control on these grasses include: Tilt (propiconazole), Bravo (chlorothalonil) and Bayleton (triadimefon). Both Tilt and Bravo have feeding restrictions. Bayleton does have tolerances on both grass seed cleanings (including hulls) and on grass seed straw (including chaff) with residue levels at 145 ppm and 105 ppm, respectively. Concentration on processing of grass for seed seems evident.

Additionally, Oregon indicated that most grass grown for seed is threshed by single processing mills, usually on a county wide basis. Screenings and straw from Tilt treated fields could, therefore, easily be mixed with screenings and straw treated with a variety of other pesticides.

DEB/HED cannot determine the residues in screenings and straw of "grasses grown for seed" to which a variety of pesticides could have been legally applied and which have grazing and feeding restrictions that under this request could be fed to livestock if subsequently treated with Tilt.

The proposed use on grasses in Oregon is not expected to result in potential adverse effects to groundwater, environmental fate and/or ecological effects beyond any that might result from already registered uses.

RECOMMENDATION

I recommend that the Oregon Department of Agriculture be denied a specific exemption to allow livestock feeding of propiconazole (Tilt) treated grass seed screenings and straw.

Section 18 of Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA), allows the Administrator to exempt a state agency from any provision of FIFRA when an emergency condition exists. FIFRA regulates the shipment and use of pesticides. Tilt is currently registered for use on grass grown for seed and, therefore, an exemption is not required for this use.

It appears that the emergency exemption program is being used to try to obtain an allowable level for propiconazole residues in adulterated grass screenings and hay, resulting from the apparent disregard of the pesticide label restrictions, in order to allow for interstate shipment of these feed commodities. Residues of pesticides in food or feed are governed under the Federal Food, Drug, and Cosmetic Act (FFDCA); FIFRA section 18 is not the proper mechanism to deal with adulterated feed.

Approve: _____

Disapprove: _____

Date: _____

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