MEMORANDUM

SUBJECT: Section 18 - Specific Exemption for Use of Oxyfluorfen (Goal) to Control Various Weeds in Grasses Grown for Seed in Oregon -- ACTION MEMORANDUM

FROM: Anne E. Lindsay, Director
Registration Division

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

I. APPLICANT'S REQUEST:

APPLICANT: Oregon Department of Agriculture

CHEMICAL: Oxyfluorfen

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

SITE: Grasses grown for seed

PEST: Various weeds, grasses, and volunteer crops

RATE & NO. OF APPL.: One or two ground applications at a rate of up to 30 oz. product (.375 lb. a.i.) per acre and a PHI of 150 days.

ACREAGE: 165,800 acres

USE-SEASON: September 1, 1989 through January 15, 1990

REG. ALT.: Herbicides currently registered for grass seed fields were developed for use in conjunction with thermal sanitation (field burning) and do not adequately control weeds in unburned situations. Restricted availability of open field burning and withdrawal of registrations for atrazine, simazine, propham, and
chlorpropham jeopardize the entire industry. Diuron and terbacil are the only broad-spectrum, soil residual herbicides registered and available and each is registered only on certain species of grasses.

ECONOMICS: Without the use of oxyfluorfen, the Applicant expects a loss of $63 million in sales.

II. BACKGROUND:

This is the first request for a specific exemption for this use received to date. Tolerances have been established (40 CFR 180.381) on a number of commodities including corn, soybeans, cottonseed and meat. No petitions for tolerances for residues associated with this use are pending. The registrant was contacted in order to determine if registration of this use will be pursued. Rohm and Haas (Tom Rodgers) was contacted concerning registration of the proposed use. Rohm and Haas is currently collecting data and conducting the necessary studies to register Goal on alfalfa grown for animal feed. Rohm and Haas plans to use the studies submitted for the alfalfa study to support the registration of Goal on grasses grown for seed. Mr. Rodgers could not give the Agency an estimate of when the registration on grasses would be submitted, but he thought it would be within the next couple of years.

A Special Review of oxyfluorfen was completed in January of 1982; the issue was contamination of oxyfluorfen with perchloroethylene (PCE). PCE was previously demonstrated to be a liver carcinogen in mice. A decision was made to continue use of the herbicide subject to restriction of the metabolite PCE (not to exceed 200 ppm) in the formulation of the product.

A Registration Standard for oxyfluorfen is not currently available.

A Notice of Receipt of this specific exemption request was published in the FEDERAL REGISTER in accordance with 40 CFR 166.24 (a)(5). The comment period closed July 27, with no comments received.
III. EPA EVALUATION

Biological and Economic Analysis Division (BEAD) reviewed this request and concluded that the restrictions on open field burning as a sanitation practice, in addition to the loss of simazine, atrazine, propanil, and chlorpropham for use on grass for seed, may not only bring severe yield losses but may jeopardize the grass seed industry in Oregon. The use of oxyfluorfen will provide an appropriate remedy to avoid the $63 million loss predicted by the Applicant.

Health Effects Division (HED) reviewed this use and concluded that residues of oxyfluorfen and its metabolites containing the diphenyl ether linkage are not likely to exceed 0.05 ppm in or on grass screenings as a result of the proposed use. Secondary residues are not likely to exceed the established tolerance of 0.05 ppm in milk, eggs, and the meat, fat, and meat by-products of cattle, goats, hogs, horses, poultry, and sheep. Analytical methodology and reference standards are available.

There are no toxicological data gaps for oxyfluorfen. The ADI based on the chronic mouse feeding study NOEL of 0.3 mg/kg of bw/day and using a hundred fold safety factor is calculated to be 0.003 mg./kg of bw/day. The existing published tolerances result in a TMRC that utilizes 30.08% of the total U.S. population ADI. As grass screenings are not a human food, this use will not affect that percentage.

Oxyfluorfen does not appear on Environmental Fate and Effects Division's (EFED) list of chemicals with groundwater concerns.

EFED indicates that minimal hazard is expected for aquatic and terrestrial species from this proposed use. However, one endangered plant, Bradshaw's lomatium, may be at risk from runoff. To prevent hazard, the Applicant should develop conservation measures necessary to avoid effects to Bradshaw's lomatium. These measures should be submitted to Diana Huang of the USFWS Portland Field Office for approval. A copy of the approved measures must be submitted to this Agency.

RECOMMENDATION

I recommend that this specific exemption be granted subject to the conditions and restrictions listed in the authorizing mailgram (attached). This recommendation is based on the following:
1. There are no registered alternative pesticides which will provide adequate control of these weeds in unburned fields of grasses grown for seed.

2. A significant economic loss may result if an effective pesticide is not made available. This loss may be as great as $63 million.

3. Residues of oxyfluorfen and its metabolites containing the diphenyl ether linkage will not exceed 0.05 ppm in or on grass screenings. This residue level can be toxicologically supported and will not pose a threat to the public health. This use will not raise the current percent ADI occupied (30.08%).

4. With measures to protect the Bradshaw's lomatium as a condition for this approval, this use should not pose an unreasonable hazard to non-target species or the environment.

5. Rohm and Haas indicated they will pursue registration of the proposed use and the registration should be submitted within the three year period specified in the section 18 regulations.

Approved: [Signature]
Disapproved: [Signature]  AUG 30 1989
Dated: [Signature]

Attachments
The Environmental Protection Agency hereby grants a specific exemption under the provisions of section 18 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, to the Oregon Department of Agriculture for the use of oxyfluorfen (Goal) for control of various weeds, grasses, and volunteer crops in grasses grown for seed. This specific exemption is subject to the following conditions and restrictions:

1. The Oregon Department of Agriculture is responsible for ensuring that all provisions of this specific exemption are met. It is also responsible for providing information in accordance with 40 CFR 166.32. This information must be submitted to EPA Headquarters through the EPA Regional Office.

2. The product Goal 1.6E (EPA Reg. No. 707-174), manufactured by Rohm & Haas, may be applied. All applicable directions, restrictions and precautions on the EPA-registered product label must be followed.
3. A maximum of two ground applications at a maximum rate of 30 ounces product (.375 pound active ingredient) may be made per acre.

4. A maximum of 165,800 acres of grass grown for seed may be treated.

5. Applications will not be made within 150 days of harvest.

6. Do not graze treated stands.

7. An endangered plant, Bradshaw's lomatium, may be at risk from runoff. To prevent hazard, the Oregon Department of Agriculture must develop conservation measures necessary to avoid adverse effects to Bradshaw's lomatium. These measures should be submitted to Diana Huang of the USFWS Portland Field Office for approval. A copy of the approved measures must be submitted to this Agency.

8. Applications made in accordance with the above provisions are not expected to result in residues of oxyfluorfen and its metabolites containing the diphenyl ether linkage in excess of 0.05 ppm in or on grass screenings. This Agency has determined that this level is adequate to protect the public health. The Food and Drug Administration, DHHS, has been advised of this action. Analytical methodology is available in PAM II.

9. The EPA shall be immediately informed of any adverse effects resulting from the use of this pesticide in connection with this exemption.

10. A report summarizing the results of this program must be submitted by July 15, 1990.

11. This specific exemption expires January 15, 1990.

12. Any future correspondence in connection with this exemption should refer to file symbol: 89-OR-21.

Please note that the regulations governing section 18 require the Agency to consider the progress toward registration of repeated emergency uses. In the event that an emergency exemption is requested in the future, the Agency will consider, in its decision of whether to grant the request, the progress along these lines. It would be to your advantage to keep current on such progress.

Douglas D. Campt, Director
Office of Pesticide Programs

Dated: Aug 30, 1983