

ADDENDUM TO MEMORANDUM OF AUGUST 11, 1989 (OXYFLUORFEN)

Subsequent to the circulation of the attached memorandum dated August 11, 1989, dealing with a specific exemption for use of oxyfluorfen on grasses grown for seed for control of grasses, two issues arose.

The first involved a question by a freelance reporter (see attached note) regarding the PD4 requirement (published in January 1982) that a pesticide respirator must be used during the mixing, loading, and application of oxyfluorfen. The requirement for the use of a respirator was subsequently removed because the risk from inhalation of the low levels of perchloroethene presence in Goal products did not justify the required use of a respirator. Written documentation is not readily available; but Jim Akerman recalls a meeting shortly after PD4 in which it was agreed that respirators would not be required. This is further corroborated by the fact that the statement has never appeared on the registered labels.

The second issue which we subsequently became aware of is that on May 24, 1989, the Agency Peer Review Committee met to evaluate the oncogenic potential of oxyfluorfen. The following facts are among those important in a weight of evidence determination of oncogenic potential:

1. Oxyfluorfen was associated with significant positive dose-related trends for adenoma and/or carcinoma in male mice.
2. Technical grade oxyfluorfen was found positive for inducing gene mutations in the Salmonella and the mouse lymphoma assays suggesting it has mutagenic capability.
3. The Peer Review Committee unanimously concluded that the data available for oxyfluorfen provided evidence to classify oxyfluorfen as a Category C oncogen. The Committee concluded that quantification of oncogenic risk by oxyfluorfen was not appropriate at this time.

This finding of oncogenicity does not affect my original recommendation with respect to this action. While the residues of concern in connection with this section 18 use are on grass screenings, an animal feed item, for regulatory purposes this use will not result in a need for a feed additive tolerance as the residues on grass screenings will not exceed those on the raw agricultural commodity, grass. At the time registration of this use is requested the corresponding tolerance petition will propose levels on grass and possibly increased meat and milk levels. The possibility of an increase in the currently established meat and milk residue levels from the use on grass is one of the reasons why, for purposes of this section 18, the Applicant is proposing a grazing restriction, leaving only the residues on grass screenings in connection with this section 18 for consideration.

NOTE TO DOUG CAMPT

Subject: Press Interest in the Specific Exemption for
Use of Oxyflurofen on Grasses Grown for Seed
for Control of Weeds

From: Anne Lindsay, Director
Registration Division

On August 9, 1989, the Emergency Response and Minor Use Section received a call from a Mr. Nick Facaros (503) 378 6032 who identified himself as a freelance reporter. Mr. Facaros was interested in the above specific exemption. Mr. Facaros was interested in how the specific exemption would be processed and when a decision could be expected. Mr. Facaros was told a decision was expected sometime in the next two weeks.

Mr. Facaros then asked why oxyflurofen was not being regulated as an oncogen from the contamination of oxyflurofen with PCE and why applicators are not required to wear respirators. Mr. Facaros was directed to the Product Manager to have these questions answered.

Karl Arne of Region 10 was contacted and does not know why Mr. Facaros is interested in the specific exemption.

The Registrant, Rohm & Haas, was contacted about the respirator question. According to Rohm & Haas, the use of respirators was proposed by the Agency as part of the Special Review of oxyflurofen (discussed in Action Memo). The Company submitted studies to demonstrate that applicators are not exposed to PCE through inhalation and therefore the use of a respirator was never a label requirement.