US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE September 19, 1977

SUBJECT PP#7F1913 - Metalochlor (Dual) in soybeans; amendment of August 1, 1977

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Through: M. Rogoff, Ph. D., PSO/RD WH-567

Recommendation:

We recommend against establishing this proposed tolerance. For further consideration of this proposal, TOX data deficiencies detailed in our review of March 31, 1977 must be corrected.

Basis for the Recommendation:

1. There is a potential for real residues in ~~corn~~ soybeans and in meat, eggs, milk and poultry (see detailed considerations below).

2. In light of previously noted TOX deficiencies we are unable to arrive at a risk assessment for this chemical under this use.

Detailed considerations:

The original tolerance petition, PP#5F1606, proposed and subsequently received, tolerance of 0.1 ppm in corn grain, on the basis that there would be no human exposure to residues of metalochlor (see the FR notice of September 13, 1977, FR 41:178, for the rationale for this finding).

CHM (review of June 14, 1977, D. Reed) has concluded that this use in soybeans would be expected to result in some human exposure to small residues of metalochlor (as opposed to the liklihood that there would be no human or animal exposure to residues from the use in corn.

Toxicological deficiencies were noted in our initial review of March 31, 1977 of this petition and include:

Detailed analytical data of the rat teratology study;

- A multi-generation reproduction study;
- A second chronic feeding/oncogenicity study;
- Full and detailed results of the two year rat and mouse feeding studies;
- Animal metabolism studies in laboratory mammals;
- A mutagenicity assay including at least one mammalian test.

It is important that we have these data in order to make an unbiased hazzard assessment of these metalochlor tolerances, since residues can be expected to occur from the proposed use.