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

JAN 14 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Memorandum

Subject: Comments on the Draft Federal Register (FR)
Notice for Chlordimeform Tolerance Revocation.
No Accession Number / No MRID Number
RCB Number 3171, 3173, 3174

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To: Patricia Critchlow
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RCB has been asked to comment on a draft Federal Register (FR) Notice which would revoke all tolerances for the insecticide/acaricide chlordimeform except those for cottonseed (5 ppm), cottonseed hulls (10 ppm), eggs (0.05 ppm), milk (0.05 ppm), the meat, fat and meat by-products of cattle, goats, hogs, horses, and sheep (0.1 ppm), and the meat, fat and meat by-products of poultry (0.25 ppm). (40 CFR 180.285; 21 CFR 193.60, 561.80).

RCB previously commented on this draft FR notice, and our comments were incorporated into this new version (see M. Metzger, 7/29/87). Additionally, some comments received from the USDA, FSIS were included in the revised version of this notice. RCB has no objections to these modifications. In addition, we will comment on questions raised by USDA and not included in the revised notice.

USDA Comment:

"...should 'animals' in line 3 of the second full paragraph [p. 4] be changed to 'livestock', since the document concludes that the tolerance for poultry fat, meat and meat by-products should not be changed?"

RCB Comment:

The tolerance for the meat, fat and meat by-products of poultry should remain the same based on residues found in poultry tissue, and because the increase in tissue residues with increased dietary residue consumption is erratic. We would expect the pesticide residue intake for poultry and other animals to have decreased somewhat in recent years due to the cancelled registrations; however, we conservatively recommend no decrease in the tolerance for residues in poultry tissue due to the erratic data in the available poultry feeding study. However, it is still likely that residues in all animals (including poultry) have decreased since chlordimeform is no longer used on numerous commodities which are animal feeds. Therefore, the use of animals in this context is appropriate.

USDA Comment:

"Also, we believe that before tolerances are set or amended, there should be a validation study of the method of analysis (preferably in three laboratories) which demonstrates its adequacy for enforcement purposes. Has such a study been conducted for chlordimeform? If so, could you provide us with the data?"

RCB Comment:

We consider PAM II, Method II, acceptable for enforcement purposes for animal tissue; and PAM II, Method I, acceptable for enforcement purposes for plant commodities. PAM II, Method I, has undergone a Method Try-Out on cabbage (see J. Mayes, 3/22/71). An MTO was not performed for Method II. Method II would be categorized as 1D (Historical Official Method, considered the best available method at the time of initial acceptance and has continued in use over an extended period) in USDA/FSIS "Compound Evaluation and Analytical Capability Annual Residue Plan" (1986). Method I would be also be classified 1D. Neither of these methods (nor have most PAM methods) have undergone three-laboratory validation.

Codex (International) Considerations

Codex has set the following limits for the sum of chlordimeform and its metabolites containing or hydrolyzable to 4-chloro-o-toluidine determined as 4-chloro-o-toluidine and expressed as chlordimeform:

<u>Commodity</u>	<u>Codex Limit (mg/kg)</u>
Cottonseed	Not to exceed the current limit of detection of 0.05 mg/kg
Cottonseed oil, edible	"
Cottonseed oil, crude	"
Meat of cattle, pigs and sheep	"
Milk products	"
Milk of cattle, goats and sheep	"
Poultry meat	"

These limits are not compatible with the tolerances proposed in this FR notice (except for milk). These are no Canadian or Mexican tolerances for chlordimeform.

Regarding tolerances established by other countries, no residues of chlordimeform were found in FDA domestic or import surveillance monitoring samples from 1978-1985 (FDA methods only partially recover chlordimeform residues). Therefore, residues likely to be found in or on imported commodities are not significant in regard to these tolerance revocations.

Other Considerations

FSIS/USDA (M. Cordle, 10/21/87 letter) made several comments related to what they perceived as inconsistencies in the definition of which cotton commodities are animal feed items (the FR notice lists different cotton-related commodities as animal feeds when referring to the diets of different animals, i.e., poultry vs. other animals). However, there are no inconsistencies here since the FR notice is reflecting particular commodities, selected from all cotton-related commodities by RCB, which would lead to the highest potential residues being found in the tissues of a particular animal. RCB would have no objections to sending USDA/FSIS a copy of RCB's review regarding chlordimeform tolerance revocation (M. Metzger, 7/29/87). RCB also has no objections to including as much information from RCB's 7/29/87 review in the FR notice as deemed appropriate by RD. FSIS should be referred to Subdivision O (Residue Chemistry) of the Pesticide Assessment Guidelines for information regarding RCB's assumptions of the potential dietary intake of various commodities by different animals.

The cattle feeding study used to conclude that the tolerance for the meat, fat and meat by-products of cattle, goats, hogs, horses and sheep should be reduced from 0.25 ppm to 0.1 ppm is adequate for extrapolation from cattle to all other livestock species, including ruminant and non-ruminant animals.

An additional metabolism study showing that the residue of concern is the same for all animals would support this; however, since other metabolism and feeding studies are not available, extrapolating from the cattle feeding study is the most reasonable way of estimating residues in all of the animals covered by the tolerance.

Conclusions and Recommendations

RCB has no objections to this revised FR notice for Chlordimeform Tolerance Revocation. Comments and data analyses from this review and from our previous review (M. Metzger, 7/29/87) can be forwarded to USDA as deemed appropriate by RD.

cc: Chlordimeform S.F., R.F., Reg. Std. S.F., Circu, M.
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