



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

PM/ISO/ISB

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JUL 7 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: I.D. No. 6704-Q. Rotenone data requirements and
7/1/87 conference. [RCB#'s 2420, 2421]

FROM: Richard Loranger, Chemist *R. Loranger*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: Andrew Rathman, Section Head *ARR*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: William Miller/Dan Peacock, PM Team 16
Insecticide Rodenticide Branch
Registration Division (TS-767)

On 5/14/87 the Fish and Wildlife Service (FWS) of the U.S. Department of Interior (USDI) submitted tables summarizing the status of data required for continued registration of the piscicidal use of rotenone. FWS has been generating data for about 8 years to support reregistration of rotenone even though a registration standard has yet to be issued. Although the only data RCB has reviewed to this point is a fish metabolism study (J. Garbus, 11/21/85), we have attended several conferences in the past with USDI concerning data needed for the piscicide (see 7/8/82 and 3/11/86 R. Loranger memos of conference). This memorandum will serve as a written record of what discussion occurred at the 7/1/87 conference.

Attendees at 7/1/87 conference:

Bill Mason, Rowan Gould-U.S. Dept. of Interior
Bill Gingerich, Rosalie Schnick- " " "
Paul Schroeder, Dan Peacock-Registration Division, EPA
Ray Matheny, John Noles-Ecological Effects Branch, EPA
Jim Adams, Brinson Conerly-Exposure Assessment Branch, EPA
Roger Gardner-Toxicology Branch, EPA
Richard Loranger-Residue Chemistry Branch, EPA

The initial discussion at the conference dealt with attempts to identify polar metabolites in fish bile as requested by Exposure Assessment Branch (EAB). After collecting ug quantities of the major metabolite over several months, mass spectral data has been inadequate to identify this metabolite. EAB will decide whether sufficient effort has been made at identifying metabolites present at >0.05 ppm in the fish accumulation study.

RCB stated that our concern with fish lies in identification of residues in edible tissues. Earlier work showed that the polar unidentified residues are less prevalent in edible tissue than in the viscera. Parent compound and several identifiable, organosoluble metabolites were observed in edible tissues. We stated that continued use of the piscicide would require a method to measure rotenone and these metabolites in fish and water. At this point FWS indicated that a major problem exists. Standards are no longer available for the metabolites. They are complex molecules formed by biological oxidations that are very difficult to duplicate in the lab. Quotes have been in the range of \$30-50K for preparation of these compounds. In light of this, the FWS representatives inquired as to what could be done to avoid the data requirements for the metabolites in fish and water.

Two options were presented to the visitors:

- (1) Submit a petition for a tolerance for residues of rotenone per se in fish.
- (2) Submit a request for an exemption from the requirement of a tolerance for the piscicidal use of rotenone.

In either case, Toxicology Branch would have major input as to whether such a proposal is supportable. In the first case, a judgment would have to be made concerning the toxicity of the metabolites since they would not be measured and regulated. In the second case, the overall safety of the rotenone itself is a critical consideration.

Basically, the same type of information would be needed for either option. These include the following:

- °Goat and fish ¹⁴C metabolism studies.
- °Data on behavior of rotenone in water. (Such data should be available in EAB reviews/files.)
- °Analytical method for rotenone in water and fish (detailed description, chromatograms, recovery data).
- °Residue data for rotenone in water, fish, and shellfish. The water data should be obtained outdoors. The fish data may be collected using tanks with both predators and bottom feeders included. The dead fish should be sampled as soon as they float to the surface since this is how they are commonly gathered for consumption. Residues should be analyzed and reported in terms of the edible portion of fish.
- °Irrigated crop residue data. This work is under contract, but will not be available for a submission in the next few months. Therefore, considering the screening process now in place in OPP, the visitors were advised to submit theoretical calculations of residues on crops and request the exemption from a tolerance. To set numerical tolerances, actual residue data are necessary.
- °Meat, milk, poultry, egg information. The goat ¹⁴C study should be used to address possible residues in animal commodities from ingestion of treated water.

We noted that the Rotenone Registration Standard is scheduled for completion next spring. It is likely that the RCB chapter will call for a complete data set, especially considering the use of rotenone on crops (particularly home gardens). However, the Standard is not a final document. The piscicide use is unique among pesticides in that any given body of water is treated only every 3-10 years to kill trash fish. The infrequent exposure to consumers from this use should be emphasized by USDI in the tolerance petition or exemption request.

The visitors were told that, although residue data are required to assess the safety of drinking treated water, a tolerance is no longer set on potable water by OPP. The Office of Drinking Water establishes an allowable residue level for water.

Some concern was expressed by FWS regarding product chemistry data requirements. Numerous inert plant extractives are present at low levels with great variability from batch to batch. We stated that these will be handled like pyrethrin products where identification of the basic classes of compounds (eg., fatty acids) has been requested. However, certain rotenone products apparently are highly purified (few inert plant constituents). The standard product chemistry data will be necessary for these.

NOTE TO PRODUCT MANAGER: A copy of this memo of conference should be sent to USDI since it spells out what must be submitted for a petition/exemption request. Also, the tables provided by USDI on 5/14/87 have an error under 171-13: Submittal of analytical reference standards. The request should be for just pure active ingredient (PAI), not radiolabeled material (PAIRA).

cc: Circu, RF, Rotenone SF, J. Garbus, Loranger, PMSD/ISB
RDI: Section Head: ARRathman: 7/6/87: RDSchmitt: 7/6/87
TS-769: RCB: 557-7324: RAL: ral(12): CM#2: RM. 810: Date: 7/7/87