



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

MAR 24 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ID No. 359-686 (RCB No. 3261) - Lindane
Registration Standard Followup - Analytical
Methods for Animal Tissues, Eggs, and Milk - MRID
No. 404312-08

FROM: Nancy Dodd, Chemist *Nancy Dodd*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Amy Rispin, Chief
Science Integration Staff
Hazard Evaluation Division (TS-769C)

and

George T. LaRocca, PM 15
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

and

Toxicology Branch (Attention: Edwin Budd)
Hazard Evaluation Division (TS-769C)

The law firm of McKenna, Conner, and Cuneo on behalf of its client the Centre International d'Etudes du Lindane and the Centre's 3 members holding U.S. Lindane registrations [Rhone-Poulenc, Inc. (representing Rhone-Poulenc Agrochimie), E.M. Industries, Inc. (representing Shell Agrar GmbH and Company, KG), and Inquinoso (Industrias Quimicas del Noroeste, SA)] now submits analytical procedures for Lindane in animal tissues, eggs, and milk in response to the Lindane Registration Standard and the Special Data Call-In Notice of

January 23, 1986. The study is "An Analytical Method for the Determination of Lindane in Animal Tissues, Eggs, and Milk", M. Piznik, Rhone-Poulenc, Inc. (NJ), Laboratory Project ID No. 87/241.

Pertinent data gaps cited in the Registration Standard will be restated below, followed by CIEL's response and RCB's Comments/Conclusions.

Summary of Conclusions re: Animal Analytical Methods

- o Adequate methodology is already available for analysis of lindane (parent compound) in AOAC Group I nonfatty foods, dairy products, fish, and eggs.
- o The registrant's proposed methodology for animal commodities contains some techniques such as use of gel permeation chromatography and rotary evaporation which are not described in Official Methods of Analysis, Association of Official Analytical Chemists. Therefore, if lindane tolerances are to be established for lean animal tissues, an EPA method validation would be needed before RCB could determine whether the submitted method is adequate for enforcement purposes.
- o If lindane per se is not the only residue of toxicological concern, methodology for metabolites would be needed. The registrant is cautioned about using rotary evaporation as the means for concentrating his samples since he has indicated in his poultry metabolism study that some of these metabolites could be lost.

Recommendations

1. If lindane (parent) tolerances are to be established for animal commodities not specified in Section 180 of Title 40 of the Code of Federal Regulations (40 CFR 180), then RCB recommends that an EPA method validation be done on the registrant's proposed procedure.
2. The registrant should delay using his proposed methodology for animal commodities, as is, until those issues relating to ruminant and poultry metabolism have been resolved and a decision has been made as to whether or not any of the lindane metabolites are of toxicological concern.

\$158.125 Residue Chemistry

171-4: Analytical Methods

Animals

The following conclusions concerning analytical methods were made in the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard:

1. "Methodology adequate for enforcement purposes is available for the analysis of lindane per se in the AOAC Group I nonfatty foods* (vegetables and fruits except citrus), dairy products, fish, and eggs. If lindane tolerances are established for lean animal tissues, appropriate methodology may have to be developed. The nature of the residue in plants and animals is not adequately understood. Should the requisite plant and animal metabolism studies establish that other residues of toxicological concern are present in plant and/or animal commodities, appropriate analytical methodology may have to be developed and validated. This is a possible future data gap."
2. "PAM I methods are available for enforcement purposes in terms of lindane per se. However, much of the residue data were generated by methods which are not considered to be acceptable by modern criteria."

CIEL's Response

The petitioner has submitted analytical procedures for lindane per se in animal tissues, eggs, and milk. Animal tissues and eggs are extracted with acetonitrile. Milk is extracted as described in Official Methods of Analysis, Association of Official Analytical Chemists, Section 29.012. All extracts are purified by gel permeation chromatography. The residue can be cleaned up by Florisil column chromatography if necessary. Samples are concentrated using a rotary evaporator.

*Group I nonfatty foods are comprised of apples, apricots, barley, beets, bell peppers, broccoli, cabbage, cantaloupes, cauliflower, celery, collard greens, corn meal and silage, cucumbers, eggplant, endive, grapes, green beans, hay, kale, mustard greens, oats, peaches, pears, peas, plums, popcorn, potatoes, radishes, radish tops, spinach, squash, strawberries, sugar beets, sweet potatoes, tomatoes, turnips, turnip greens, and wheat.

The residues are analyzed by gas liquid chromatography.
Recoveries are summarized below:

<u>Substrate</u>	<u>Fortification Level (ppm)</u>	<u>Range of Recovery (%)</u>	<u>Avg. Recovery (%)</u>
Beef liver	0.01 - 5.00	82.8 - 100.0	91.4
Beef kidney	0.01 - 5.00	84.2 - 103.0	94.4
Beef muscle	0.01 - 10.00	87.7 - 115.4	99.4
Beef fat	0.01 - 2.00	91.1 - 115.4	98.8
Milk	0.001 - 2.0	67.0 - 103.0	79.8
Chicken gizzard	0.01 - 1.0	88.2 - 109.2	98.7
Chicken liver	0.01 - 1.0	92.8 - 105.9	96.5
Chicken muscle	0.01 - 1.0	81.1 - 100.0	94.2
Eggs	0.005 - 1.0	79.1 - 109.1	96.1

The limit of detection of the method is 0.01 ppm for animal tissues, 0.005 ppm for eggs, and 0.001 ppm for milk.

RCB's Discussion/Conclusion re: Analytical Methods in Animal Commodities

Lindane tolerances are established for fat of cattle, goats, hogs, horses, and sheep. No other animal commodity tolerances are established.

RCB determined in the Residue Chemistry Chapter of the September 30, 1985 Registration Standard that adequate methodology is available for analysis of lindane per se in AOAC Group I nonfatty foods (crops), dairy products, fish, and eggs.

If lindane tolerances are to be established for all animal tissues, then an EPA method validation would be needed before RCB could determine whether the submitted method is adequate for enforcement purposes.

Also, if lindane per se is not the only residue of toxicological concern, methodology for metabolites would be needed. If this is the case, the registrant is cautioned about using rotary evaporation as the means for concentrating his samples, since he has indicated in his poultry metabolism study that some of these metabolites could be lost.

cc: RF,SF,Circu,Reviewer-N.Dodd,W.Boodee, Lindane Registration
Standard File, TOX, PM #15, A. Rispin
RDI:JHOnley:3/14/88:RDSchmitt:3/14/88
TS-769:RCB:CM#2:RM810:X1681:NDodd:Kendrick & Co.:3/16/88