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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ID No. 359-686 (RCB No. 3257). Lindane
Registration Standard Followup. Analytical Methods
for Plants. MRID Nos. 404312-02 and 404312-06.

FROM: Nancy Dodd, Chemist *Nancy Dodd*
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THRU: Charles L. Trichilo, Ph.D., Chief
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TO: Amy Rispin, Chief
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and

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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 & Co., KG), and Inquinsa (Industrias Quimicas del Noroeste, S.A.)] now submits analytical procedures for lindane in cucumbers and spinach in response to the Lindane Registration Standard and the Special Data Call-In Notice of January 23, 1986. The studies are "Insecticides: Lindane: Analytical Procedure for the Determination of Residues in Cucumber," Laboratory Project ID

No. 568, and "Insecticides: Lindane: Analytical Procedure for the Determination of Residues in Spinach," Laboratory Project ID No. 573, both studies by P.J. Godward, May and Baker Ltd. (England), September 18, 1987.

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: Plant Analytical Methods

This method is adequate for determining residues of lindane (parent compound) in nonfatty crops such as cucumber and spinach provided that the parent compound is the only residue of concern. If it is decided that lindane metabolites are of toxicological concern, then probably some changes in the GLC conditions (similar to those used for analyzing the terminal residues in the submitted poultry metabolism study and/or some other appropriate changes) may have to be undertaken.

Recommendations

RCB recommends that the registrant delay using this method, as is, until the plant metabolism issues have been resolved and a decision has been made as to whether or not the metabolites of lindane are of toxicological concern. If they are of toxicological concern, then the registrant will need to make some modifications or develop suitable methodology.

CIEL should refer to the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard and addendums for discussions of the analytical methodology as it relates to metabolism and residue data.

§158.125 Residue Chemistry

171-4: Analytical Methods

Plants

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 in cucumber and spinach. These 2 methods are essentially the same method. The CIEL developed the methods "as part of the policy of ensuring that current information regarding pesticides and their use is kept up to date." (Note: RCB has requested submission of additional residue data on cucumbers and spinach in connection with the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard.)

Cucumber and Spinach

The lindane is extracted from cucumber and spinach samples by blending with acetonitrile. The first clean-up step involves a hexane-acetonitrile partition step. The sample is further cleaned up by using Florisil column chromatography. The sample is analyzed by gas chromatography with electron capture detection. Recoveries at fortifications of 10 ppb to 1 ppm were 87.2 to 105.5 percent (mean 96.7%) for cucumber and 86.8 to 105.9 percent (mean 97.1%) for spinach. The limit of quantification is 0.01 ppm.

*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.

RCB's Discussion/Conclusion Re: Analytical Methods for Plants

RCB concludes that this method is adequate for determining residues of lindane (parent compound) in nonfatty crops such as cucumber and spinach. However, if it is decided that lindane metabolites are of toxicological concern after the plant metabolism issues have been resolved, then the registrant will need to make some modifications in this methodology or develop new methodology that will determine these metabolites.

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:N.Dodd:Kendrick&Co.:3/16/88