...ENTAL PROTECTION AGENCY
...ASHINGTON, D.C. 20460

21 JUL 1981

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Lindane Dietary Exposure Analysis - PD 4

FROM: Environmental Chemist
Review Section 4
Environmental Fate Branch
Hazard Evaluation Division (TS-769)

TO: Ms. Ann Hollander
Lindane Project Manager
Regulatory Analysis Section
Regulatory Support Branch
Special Pesticide Review Division (TS-791)

THROUGH: Dr. Joe Reinert, Chief
Review Section 4, EFB, HED

Attached are three copies of the lindane dietary exposure analysis for the Position Document 4. This analysis was prepared in the same format as the dietary exposure analysis found in the Dimethoate PD 4. The decision for using this type of format for the Lindane PD 4 was agreed upon by Marcia Williams and Peter McGrath in a meeting in 2/81.

If you have any questions or suggestions concerning the estimates made in this document, please contact me at 557-7347.

Janice K. Jensen

Attachments

cc: Judy Heckman, HED
Chris Chaisson, TB/HED
Mark Dow, PSB, BFSD

Exposure Analysis - Dietary Exposure

a. The Agency's Exposure Calculations in the PD 2/3

The Agency, in calculating an estimate of the dietary exposure of the general population to lindane in Position Document 2/3, used data showing average lindane residues for 12 composite food group categories from the FDA market basket (Total Diet Composites) survey during the period from 1972 to 1975 (EPA, 1978, a). From this average, the daily intake of lindane in mg/1.94 kg diet for each composite category was calculated, then totaled to get the average daily exposure for all 12 food categories. This daily intake was estimated to be 0.00266 mg/1.94 kg diet/day. For a 70 kg adult, this daily intake was 0.038 ug/kg bw/day.

b. Comment on the Agency's Calculation of Dietary Exposure

The Centre International d'Etudes du lindane [CIEL; 94(30000/10C)] represented by C. Edwards agreed that the use of the market baskey survey data was appropriate, but that more recent available market basket data should have been used by the Agency to determine lindane residues in food. Also, Edwards disagreed with the way certain FDA numbers were evaluated by EPA, primarily that trace values were assigned a value of 0.004 ppm, when analytical techniques quantified residues considerably less than 0.004 ppm.

Imported dairy products, according to Edwards, contained the largest proportion of total lindane residues up to 1975. In more recent years, however, sugar and its adjuncts have had larger residues, with residues in meat and poultry remaining fairly constant. Edwards suggested that contamination of food storage bins was a likely source of lindane residues.

c. The Agency's PD 4 Response

The Agency agrees with Edwards that the most current FDA market basket data (Total Diet Composites) should be used to evaluate lindane residues in the diet of the general population. Therefore, the market basket data for FY 1976 - FY 1980, broken down into food group categories, can be found in Table 4. These latest market basket findings were then combined with earlier market basket data covering the time period of FY 1964 - FY 1975 and can be found in Table 5. With the exception of 1974, the residues of lindane in the diet from FY 1973 - FY 1980 have remained relatively constant, using FDA's methods of data evaluation.

In order to be consistent with FDA's evaluation of the lindane market basket data (Total Diet Composites) and with the dietary analysis in the Lindane PD 1, trace findings in the lindane PD 4 are assigned a value of zero, and an average diet (including beverages and water) is considered to be 2916 grams per day.

EPA agrees that imported dairy products contained the largest proportion of lindane residues up to 1975, but that in more recent years, sugars and adjuncts have had the largest proportion of residues, with lindane residues in meat and poultry remaining fairly constant. EPA agrees that lindane used in empty storage bins could be a source of these lindane residues.

As the lindane residues in the FDA market basket surveys (Total Diet Composites) have remained relatively constant from FY 1976 - FY 1980, the average dietary intake in ug/day for the Lindane PD 4 was computed by taking the average from this five year period. Therefore, the average dietary intake for the Lindane PD 4 is estimated to be 0.2141 ug/1.94 kg diet/day. For a 70 kg adult, this daily intake would be 0.0031 ug/kg bw/day.

Table 4

Findings of Lindane in FDA Market Baskets (Total Diet Composites) From FY 1976 - FY 1980

Food Group	FDA Food Factor %	FY 76 (20 Mkt Bskts) Positives	Range(ppm)	Average Intake ug/day	FY 77 (25 Mkt Bskts) Positives	Range(ppm)	Average Intake ug/day	FY 78 (20 Mkt Bskts) Positives	Range(ppm)	Average Intake ug/day	FY 79 (20 Mkt Bskts) Positives	Range(ppm)	Average Intake ug/day	FY 80 (20 Mkt Bskts) Positives	Range(ppm)	Average Intake ug/day
Dairy	26.0	2	T-0.003	0.0117	3	T-0.0005	0.0301	1	0.0006	0.0223	0	-	-	1	0.0003	0.0112
Meat,Fish, & Poultry	9.0	7	T-0.003	0.0731	8	T-0.003	0.0673	3	T-0.0007	0.0092	6	0.0002-0.003	0.0631	8	0.0002-0.001	0.0496
Grains & Cereals	14.4	1	0.0008	0.0164	2	0.0008-0.002	0.0461	1	0.002	0.0435	2	0.002-0.003	0.1049	0	-	-
Potatoes	5.5	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-
Leafy Vegetables	1.9	1	T	not calc.	3	T-0.005	0.0141	0	-	-	1	0.0008	0.0023	0	-	-
Legume Vegetables	2.5	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-
Root Vegetables	1.1	0	-	-	1	0.002	0.0025	0	-	-	1	0.001	0.0016	0	-	-
Garden Fruits	2.9	5	0.001-0.004	0.0366	6	T-0.010	0.0462	5	0.0005-0.005	0.0327	6	0.0002-0.001	0.0099	2	0.0004-0.007	0.0268
Fruits	7.5	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-
Oils and Fats	2.5	0	-	-	1	T	not calc.	0	-	-	0	-	-	0	-	-
Sugars & Adjuncts	2.7	7	T-0.003	0.0386	14	T-0.004	0.0632	12	0.0005-0.005	0.0590	15	0.0002-0.003	0.0814	16	0.0004-0.008	0.1070
Beverages (incl. water)	24.0	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-
Total	100.0			0.1764			0.2695			0.1667			0.2632			0.1946

Table 5

Average Daily Intakes of Lindane in FDA Total Diet Composites from FY 1964 - FY 1980.

Year(s)	Residue Intake ug/kg bw/day	Source of Data
1964-1969	0.0500	EPA Position Document 1
1973	0.0032	DHEW Total Diet
1974	0.0084	Studies (7320.08)
1975	0.0031	"
1976	0.0025	FDA Total Diet Composites
1977	0.0039	"
1978	0.0024	"
1979	0.0038	"
1980	0.0028	"

References Cited

Lindane PD 4 Dietary Exposure Analysis

EPA, 1978a. Residue Chemistry Branch, Hazard Evaluation Division memorandum from Chief, RCB to Dr. Wells, Acting Director, SPRD dated 10/16/78. Lindane RPAR, theoretical maximum human exposure vs. estimated actual exposure. (Unpublished).

Edwards, C.A. 1980. Centre International d'Etudies du Lindane (CIEL). rebuttal comment 94(30000/10C).