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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUN 15 1987

MEMORANDUM

Subject: Tolerance Assessment Analysis on the Chemical Bifenthrin. (New Chemical). Temporary Tolerances Proposals for Strawberries (5G3289), Pecans (6G3313), Pears (6G3314), Peaches (6G3315), Corn, Meat, and Milk (5G3235) and Walnuts (5G3238).

To: George LaRocca PM# 15
Registration Division

From: Charles Frick c.frick 6/9/87 DSD 6/11/87
Tolerance Assessment Program
Hazard Evaluation Division

Thru: Charles L. Trichilo, Ph.D.
Chief, Residue Chemistry Branch
Hazard Evaluation Division

Please find attached the Tolerance Assessment System (TAS) tolerance assessment for Bifenthrin, which was conducted on request from Dr. Reto Engler, Toxicology Branch, HED, to evaluate the dietary risk for proposed tolerances on strawberries, pecans, walnuts, corn, meat and milk This is in compliance with the recent policy established in HED that TAS will be used for all Registration Standards, Special Reviews, and tolerances on new chemicals.

The product manager should inform the registrant that processing and/or cooking studies will be required for consideration of permanent tolerances at the same levels on these crops.

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TOLERANCE ASSESSMENT

CHEMICAL: BIFENTHRIN

1. The Reference Dose (RFD) for this chemical is 0.0075 mg/kg/day (PADI). This value has not been approved by the Toxicology Branch or Agency Reference Dose Committees.

This chemical has been classified as a C(q) oncogen by the Toxicology Branch Peer Review Committee. The potency estimate Q^* has been calculated as 5.4×10^{-2} $(mg/kg/day)^{-1}$. The calculation is based on male mouse urinary bladder tumors (Leiomyosarcomas)

2. The food uses evaluated by the Tolerance Assessment System (TAS) are proposed temporary tolerances; no permanent tolerances have been established for this chemical. (A list of these tolerances is appended).

3. A comparison of these proposed tolerances to the PADI was conducted using the TAS Routine Chronic Analysis. The TAS analysis estimates the potential dietary exposures for the U.S. population average and for 22 subgroups. (A summary table is appended). The Theoretical Maximum Residue Contribution (TMRC) for the U.S. population is 0.0013 mg/kg/day, which is equal to 17.7% of the PADI.

4. The subgroup with the highest calculated exposure — correction Byron Backus 6/18/87. as non-nursing infants (0.0078 mg/kg/day, 98% of the PADI). The majority of exposure to this subgroup came from peaches (0.0042 mg/kg/day, 55.6% of the PADI) and milk (0.0019 mg/kg/day, 26.2% of the PADI).

5. An assessment of the oncogenic risk follows on the next page.

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Biphenthrin Caswell #463F CAS No. 82657-04-3 A.I. CODE: 128825 CFR No. 180.	1yr feeding- dog NOEL= 0.7500 mg/kg 0.00 ppm LEL= 0.0000 mg/kg 0.00 ppm ONCO: Class C (TOX WOTE)	Evidence of oncogenicity in mice (bladder, males); negative in the rat.	PADI 100 OPP RfD= 0.007500 EPA RfD= 0.000000 WHO RfD 0.000000 Type:	Data gaps, critical study not evaluated by TOX ADI Committee.	RFD NOT VERIFIED BY AGENCY COMMITTEES.

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
U.S. POPULATION - 48 STATES	0.0000	0.0013	17.6979	17.6979		
U.S. POPULATION - SPRING SEASON	0.0000	0.0013	17.5946	17.5946		
U.S. POPULATION - SUMMER SEASON	0.0000	0.0016	21.0970	21.0970		
U.S. POPULATION - FALL SEASON	0.0000	0.0012	16.0324	16.0324		
U.S. POPULATION - WINTER SEASON	0.0000	0.0012	16.0791	16.0791		
NORTHEAST REGION	0.0000	0.0014	18.2265	18.2265		
NORTH CENTRAL REGION	0.0000	0.0014	18.6509	18.6509		
SOUTHERN REGION	0.0000	0.0012	15.5917	15.5917		
WESTERN REGION	0.0000	0.0014	19.2457	19.2457		
HISPANICS	0.0000	0.0016	20.6719	20.6719		
NON-HISPANIC WHITES	0.0000	0.0013	17.7677	17.7677		
NON-HISPANIC BLACKS	0.0000	0.0012	15.7482	15.7482		
NON-HISPANICS OTHER	0.0000	0.0014	18.5332	18.5332		
NURSING INFANTS (<1 YEAR OLD)	0.0000	0.0039	52.4191	52.4191		
NON-NURSING INFANTS (<1 YEAR OLD)	0.0000	0.0074	98.1212	98.1212		
FEMALES (13+ YEARS, PREGNANT)	0.0000	0.0009	12.3822	12.3822		
FEMALES 13+ YEARS, NURSING	0.0000	0.0011	14.8770	14.8770		
CHILDREN (1-6 YEARS OLD)	0.0000	0.0030	39.7510	39.7510		
CHILDREN (7-12 YEARS OLD)	0.0000	0.0020	27.0899	27.0899		
MALES (13-19 YEARS OLD)	0.0000	0.0012	16.5459	16.5459		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.0000	0.0010	13.7931	13.7931		
MALES (20 YEARS AND OLDER)	0.0000	0.0009	12.3392	12.3392		
FEMALES (20 YEARS AND OLDER)	0.0000	0.0009	11.5698	11.5698		

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

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LISTING OF EXPOSURE BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOOD NAME	TOLERANCE (PPM) NEW	PENDING	PUBLISHED	EXISTING TOLERANCES TMRC (UG/KG/DAY)	%RfD	NEW, PENDING & PUBLISHED TOLERANCES NEW TMRC (UG/KG/DAY)	NEW %RFD
53005BB	SHEEP(ORGAN MEATS)-OTHER	0.1000					0.0000	0.0000
53005FA	SHEEP(BONELESS)-FAT	0.5000					0.0021	0.0286
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	0.1000					0.0000	0.0000
53005LA	SHEEP(ORGAN MEATS)-LIVER	0.1000					0.0000	0.0000
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT	0.1000					0.0012	0.0166
53006BA	PORK-MEAT BYPRODUCTS	0.3000					0.0075	0.1003
53006BB	PORK(ORGAN MEATS)-OTHER	0.1000					0.0004	0.0051
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	0.5000					0.1041	1.3880
53006KA	PORK(ORGAN MEATS)-KIDNEY	0.1000					0.0000	0.0000
53006LA	PORK(ORGAN MEATS)-LIVER	0.1000					0.0005	0.0064
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0.1000					0.0391	0.5217
	CROP GROUP TOTALS FOR RED MEAT:				0.0000	0.0000	0.4656	6.2077
50000DB	MILK-NON-FAT SOLIDS	0.0300					0.2141	2.8545
50000FA	MILK-FAT SOLIDS	0.0300					0.1018	1.3579
50000SA	MILK SUGAR (LACTOSE)	0.0300					0.0011	0.0150
	CROP GROUP TOTALS FOR DAIRY PRODUCTS:				0.0000	0.0000	0.3171	4.2274