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

APR 12 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#8E3583. Tolerance Request For Residues of Permethrin in or on Dry Bulb Onions: TAS Dietary Exposure Assessment.

FROM: Susan L. Stanton
Tolerance Assessment Program
HED/RCB (TS-769C)

Susan L. Stanton 04/11/88

THRU: Karl Arne, Ph.D.
Branch Senior Scientist
HED/RCB (TS-769C)

TO: Hoyt Jamerson, PM-43
Emergency Response and Minor Use Section
Registration Division (TS-767C)

Action Requested

Provide a dietary exposure analysis of the proposed tolerance of 0.1 ppm for residues of the insecticide permethrin in or on dry bulb onions.

RCB has reviewed the petition and, TOX considerations permitting, recommends establishment of the proposed tolerance (memo Flood to Jamerson, 04/06/88).

Discussion

1. A routine chronic analysis was conducted using a Reference Dose (ADI) of 0.05 mg/kg body weight/day based on a NOEL of 5 mg/kg/day from a 2-year rat feeding study with a safety factor of 100. This value has been approved by the Tox Branch ADI Committee (09/12/86) and verified by the Agency reference dose committee (10/28/86).

2. The food uses evaluated were those published in 40 CFR 180.378, the proposed use on dry bulb onions, and other pending tolerances (including proposed tolerances on avocados, papayas, and sunflower seeds and a proposed increase in the tolerance for

asparagus from 1 to 2 ppm). Table 1 provides a complete listing of residue information.

3. The TAS routine chronic analysis calculates the Theoretical Maximum Residue Contribution (TMRC) for the U.S. population and each of 22 population subgroups (see Table 2) and compares this exposure estimate to the reference dose (ADI in this case).

The TMRC from all food uses (including the new use on dry bulb onions and other pending tolerances) for the U.S. Population is calculated to be 0.015518 mg/kg body weight/day, which occupies approximately 31% of the ADI. The two most highly exposed population subgroups are infants (TMRC = 0.029017 mg/kg/day or 58% of the ADI) and children, ages 1 to 6 (TMRC = 0.024635 or 49% of the ADI). Table 3 provides a more detailed summary of the analysis for these 3 populations and includes estimates of exposure by tolerance type (published, new action, and other pending).

4. This analysis uses tolerance level residues with an assumption of 100% crop treated, a conservative approach that likely overestimates exposure significantly. However, since estimated exposure and risk using this approach are acceptable, no further data are required at this time.

cc: TAS File
Reading File
circ.
PP#8E3583
TOX (Rathman)
Permethrin SF
PMSD

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Table 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 652BB DATE: 04/11/88 PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Permethrin Caswell #652BB CAS No. 52645-53-1 A.I. CODE: 109701 CFR No. 180.378	2yr feeding- rat NOEL= 5.0000 mg/kg 100.00 ppm LEL= 25.0000 mg/kg 500.00 ppm ONCO: Pending WOTE	Decreased liver weights. Slight increase in liver weights noted at 5 mg/kg. Evidence of oncogenicity in mice (liver, lung), negative rat.	ADI SF --> 100 OPP RfD= 0.050000 EPA RfD= 0.050000 WHO RfD 0.050000 Type: ADI	No data gaps. Slight increase in liver weights at 5 mg/kg only noted in 1/3 rat studies, not considered toxicologically significant.	TOX complete 9/12/86. EPA verified 10/28/86. WHO last reviewed 1987; (ADI extended to 25:75 mixture). On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM) PENDING	PUBLISHED
03001AA	ALMONDS	2F2675			0.0500
03005AA	FILBERTS/HAZELNUTS	4F3130			0.0500
03009AA	WALNUTS	4F3130			0.0500
03011AA	PISTACHIO NUTS	4F2995			0.1000
04001AA	APPLES-FRESH	1F2562			0.0500
04001DA	APPLES-DRIED	1F2562			0.0500
04001JA	APPLES-JUICE	1F2562			0.0500
04003AA	PEARS-FRESH	0F2425			3.0000
04003DA	PEARS-DRIED	0F2425			3.0000
05002AA	CHERRIES-FRESH	5F3271			3.0000
05002DA	CHERRIES-DRIED	5F3271			3.0000
05002JA	CHERRIES-JUICE	5F3271			3.0000
05004AA	PEACHES-FRESH	3F2802			5.0000
05004DA	PEACHES-DRIED	3F2802			5.0000
06001AA	AVOCADOS	4E3146		1.0000	
06010AA	PAPAYAS-UNSPECIFIED	4E3146		1.0000	
06010AB	PAPAYAS-PULP	4E3186		1.0000	
06010DA	PAPAYAS-DRIED	4E3186		1.0000	
06010JA	PAPAYAS-JUICE	4E3186		1.0000	
06018AA	KIWI	1E2514			2.0000
08022AA	HORSERADISH	0E2377			1.0000
10002AA	CANTALOUPES-UNSPECIFIED	5E3225			3.0000
10002AB	CANTALOUPES-PULP	5E3225			3.0000
10011AA	PUMPKIN	3E2861			2.0000
11001AA	EGGPLANT	3E2892			1.0000
11003AA	PEPPERS (SWEET/GARDEN)	3E2892			1.0000
11005AA	TOMATOES-WHOLE	4F2985			2.0000
11005JA	TOMATOES-JUICE	4F2985			2.0000
11005RA	TOMATOES-PUREE	4F2985			2.0000
11005TA	TOMATOES-PASTE	4F2985			2.0000
11005UA	TOMATOES-CATSUP	4F2985			2.0000
13002AA	CELERY	8F2099			5.0000
13003AA	CHICORY (FRENCH OR BELGIAN ENDIVE)	4F3018			20.0000
13005AA	BROCCOLI	9F2207			1.0000
13006AA	BRUSSEL SPROUTS	9F2207			1.0000
13007AA	CABBAGE-GREEN AND RED	9F2192			6.0000
13008AA	CAULIFLOWER	9F2207			1.0000
13009AA	COLLARDS	6E3360			20.0000
13010AA	CABBAGE-CHINESE/CELERY (INC. BOK CHOY)	9F2192			6.0000
13013AA	LETTUCE-LEAFY VARIETIES	4F3018			20.0000

Table 1 (con't)

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FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED
13014AA	DANDELION	4F3018			20.0000
13015AA	ENDIVE (CURLEY AND ESCAROLE)	4F3018			20.0000
13016AA	FENNEL	8F2099			5.0000
13017AA	CRESS (GARDEN/FIELD)	4F3018			20.0000
13018AA	ARTICHOKES-GLOBE	4F3114			10.0000
13020AA	LETTUCE-UNSPECIFIED	4F3018			20.0000
13022AA	PARSLEY	4F3018			20.0000
13023AA	RHUBARB	4F3018			20.0000
13024AA	SPINACH	2E2701			20.0000
13025AA	SWISS CHARD	4F3018			20.0000
13026AA	TURNIPS-TOPS	6E3360			20.0000
13027AA	WATERCRESS	4E3113			5.0000
13039AA	CRESS/UPLAND	4F3018			20.0000
13045AA	LETTUCE-HEAD VARIETIES	9F2192			20.0000
14007AA	GARLIC	8E3583	0.1000		
14011AA	ONIONS-DRY-BULB (CIPOLLINI)	8E3583	0.1000		
14011DA	ONIONS-DEHYDRATED OR DRIED	8E3583	0.1000		
14013AA	POTATOES(WHITE)-WHOLE	0F2307			0.0500
14013AB	POTATOES(WHITE)-UNSPECIFIED	0F2307			0.0500
14013AC	POTATOES(WHITE)-PEELED	0F2307			0.0500
14013DA	POTATOES(WHITE)-DRY	0F2307			0.0500
14013HA	POTATOES(WHITE)-PEEL ONLY	0F2307			0.0500
14017AA	SHALLOTS	8E3583	0.1000		
14019AA	TURNIPS-ROOTS	6E3360			1.0000
15004AA	CORN/POP	1F2476			0.0500
15005AA	CORN/SWEET	3F2781			0.1000
15018AA	SUNFLOWER-SEEDS	4F2981		0.0500	
15029AA	SOYBEANS-SPROUTED SEEDS	9F2196			0.0500
16002AA	ASPARAGUS	3E2914			1.0000
16002AA	ASPARAGUS	8F3595		1.0000	
16003AA	MUSHROOMS	2F2752			6.0000
24002EA	CORN/GRAIN-ENDOSPERM	1F2476			0.0500
24002HA	CORN/GRAIN-BRAN	1F2476			0.0500
24002SA	CORN SUGAR	1F2476			0.0500
27002OA	CORN/GRAIN-OIL	1F2476			0.0500
27003OA	COTTONSEED-OIL				0.5000
27003WA	COTTONSEED-MEAL				0.5000
27010OA	SOYBEANS-OIL	9F2196			0.0500
27011OA	SUNFLOWER-OIL	4F2981		0.0500	
28023AA	SOYBEANS-UNSPECIFIED	9F2196			0.0500

Table 1 (con't)

CHEMICAL INFORMATION FOR CASWELL NUMBER 652BB DATE: 04/11/88 PAGE: 3

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FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED	
28023AB	SOYBEANS-MATURE/SEEDS DRY	9F2196			0.0500	
28023WA	SOYBEANS-FLOUR/FULL FAT	9F2196			0.0500	
28023WB	SOYBEANS-FLOUR/LOW FAT	9F2196			0.0500	
28023WC	SOYBEANS-FLOUR/DEFATTED	9F2196			0.0500	
50000FA	MILK-FAT SOLIDS	3F2781			3.7500	H
53001BA	BEEF-MEAT BYPRODUCTS	1F2564			1.0000	
53001BB	BEEF(ORGAN MEATS)-OTHER	1F2564			1.0000	
53001DA	BEEF-DRIED	1F2564			0.1500	
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	1F2564			2.0000	
53001KA	BEEF(ORGAN MEATS)-KIDNEY	1F2564			1.0000	
53001LA	BEEF(ORGAN MEATS)-LIVER	1F2564			1.0000	
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F2564			0.1500	
53002BA	GOAT-MEAT BYPRODUCTS	1F2564			1.0000	
53002BB	GOAT(ORGAN MEATS)-OTHER	1F2564			1.0000	
53002FA	GOAT(BONELESS)-FAT	1F2564			2.0000	
53002KA	GOAT(ORGAN MEATS)-KIDNEY	1F2564			1.0000	
53002LA	GOAT(ORGAN MEATS)-LIVER	1F2564			1.0000	
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F2564			0.1500	
53003AA	HORSE	1F2564			2.0000	
53005BA	SHEEP-MEAT BYPRODUCTS	1F2564			1.0000	
53005BB	SHEEP(ORGAN MEATS)-OTHER	1F2564			1.0000	
53005FA	SHEEP(BONELESS)-FAT	1F2564			2.0000	
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	1F2564			1.0000	
53005LA	SHEEP(ORGAN MEATS)-LIVER	1F2564			1.0000	
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT	1F2564			0.1500	
53006BA	PORK-MEAT BYPRODUCTS	1F2546			3.0000	
53006BB	PORK(ORGAN MEATS)-OTHER	1F2546			3.0000	
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	1F2546			2.0000	
53006KA	PORK(ORGAN MEATS)-KIDNEY	1F2546			3.0000	
53006LA	PORK(ORGAN MEATS)-LIVER	1F2546			3.0000	
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F2546			0.1500	
55008BA	TURKEY-BYPRODUCTS	1F2564			0.0500	
55008LA	TURKEY-GIBLETS (LIVER)	1F2564			0.0500	
55008MA	TURKEY-FLESH(W/O SKIN & W/O BONES)	1F2564			0.0500	
55008MB	TURKEY-FLESH(+SKIN & W/O BONES)	1F2564			0.0500	
55008MC	TURKEY-UNSPECIFIED	1F2564			0.0500	
55013BA	POULTRY/OTHER-BYPRODUCTS	1F2564			0.0500	
55013LA	POULTRY/OTHER-GIBLETS (LIVER)	1F2564			0.0500	
55013MA	POULTRY/OTHER-FLESH (+SKIN & W/O BONES)	1F2564			0.0500	
55014AA	EGGS-WHOLE	1F2564			0.0500	

Table 1 (con't)

CHEMICAL INFORMATION FOR CASWELL NUMBER 652BB DATE: 04/11/88 PAGE: 4

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
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FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED
55014AB	EGGS-WHITE ONLY	1F2564			0.0500
55014AC	EGGS-YOLK ONLY	1F2564			0.0500
55015BA	CHICKEN-BYPRODUCTS	1F2564			0.0500
55015LA	CHICKEN-GIBLETS(LIVER)	1F2564			0.0500
55015MA	CHICKEN-FLESH(W/O SKIN & W/O BONES)	1F2564			0.0500
55015MB	CHICKEN-FLESH(+SKIN & W/O BONES)	1F2564			0.0500
90997AA	INEST. RACS--TOLERANCE TOO SPECIFIC	1F2546			
90999AA	FEED RACS--INEST. FROM USDA SURVEY	2F2675			

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Table 3

TOLERANCE ASSESSMENT SUMMARY FOR Permethrin DATE: 04/11/88
CASWELL #652BB

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.015461	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	30.921034	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000011	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.021640	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.015471	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	30.942674	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.000047	MG/KG/DAY
THIS TMRC WILL OCCUPY	0.093232	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.015518	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	31.035906	% OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.029004	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	58.007220	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000004	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.008126	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.029008	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	58.015346	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.000009	MG/KG/DAY
THIS TMRC WILL OCCUPY	0.017870	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.029017	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	58.033216	% OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: CHILDREN (1-6 YEARS OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.024570	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	49.140124	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000018	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.036422	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.024588	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	49.176546	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.000047	MG/KG/DAY
THIS TMRC WILL OCCUPY	0.093248	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.024635	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	49.269794	% OF THE ADI.

Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS DATE: 04/11/88 PAGE: 1

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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	0.015461	0.015518	31.035906	0.114872		
U.S. POPULATION - SPRING SEASON	0.015735	0.015817	31.633384	0.163478		
U.S. POPULATION - SUMMER SEASON	0.016169	0.016211	32.421766	0.084274		
U.S. POPULATION - FALL SEASON	0.014907	0.014956	29.911758	0.098718		
U.S. POPULATION - WINTER SEASON	0.015028	0.015085	30.169246	0.112472		
NORTHEAST REGION	0.015873	0.015927	31.853304	0.107594		
NORTH CENTRAL REGION	0.015109	0.015154	30.307972	0.089814		
SOUTHREN REGION	0.014257	0.014302	28.603532	0.089026		
WESTERN REGION	0.017503	0.017606	35.212982	0.206042		
HISPANICS	0.015958	0.016041	32.081274	0.165814		
NON-HISPANIC WHITES	0.015344	0.015402	30.804630	0.117614		
NON-HISPANIC BLACKS	0.015686	0.015723	31.446558	0.074382		
NON-HISPANIC OTHERS	0.017983	0.018033	36.065520	0.098988		
NURSING INFANTS (< 1 YEAR OLD)	0.013301	0.013302	26.604746	0.003662		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.029004	0.029017	58.033216	0.025996		
FEMALES (13+ YEARS, PREGNANT)	0.012279	0.012308	24.615902	0.058328		
FEMALES 13+ YEARS, NURSING	0.016248	0.016290	32.580772	0.084986		
CHILDREN (1-6 YEARS OLD)	0.024570	0.024635	49.269794	0.129670		
CHILDREN (7-12 YEARS OLD)	0.020830	0.020867	41.733462	0.073700		
MALES (13-19 YEARS OLD)	0.014273	0.014309	28.617734	0.071498		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.013113	0.013166	26.332452	0.107274		
MALES (20 YEARS AND OLDER)	0.012813	0.012874	25.748808	0.122180		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.013810	0.013876	27.752200	0.132374		

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