



323EE TOX

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

MAY 19 1987

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: TAS Analysis of Tolerance Requests for Banner/Tilt
PP #4G3074, 4G3007, and 4E3026.

TO: Lois Rossi (21)
Registration Division (TS-767)

FROM: D. Stephen Saunders, Ph.D. *DS 5/19/87*
Program Manager, Tolerance Assessment Program
RCB/HED (TS-769C)

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

Action Requested

Provide an analysis of the dietary impact of the requested tolerances for small grains, pecans, meat, milk and eggs, and bananas.

Discussion

1. The Reference Dose (ADI, RFD) used in the analysis was 0.02 mg/kg/day, based on a NOEL of 1.9 mg/kg/day obtained in a 1 year feeding study in dogs, with an Uncertainty Factor of 100. This value has been verified by the Toxicology Branch ADI Committee.

In addition, this compound has been identified as an oncogen in mice, and has been classified as a Category C oncogen by the Toxicology Branch Peer Review Committee. The upper bound potency estimate (Q*) obtained in this study was 7.87×10^{-2} (personal communication, R. Levy).

2. The tolerances evaluated in this analysis have been evaluated in RCB (memo S. Malak to L. Rossi, 5-14-87). It should be noted that RCB has not recommended for the proposed uses due to a number of deficiencies. The residue values used in the analysis were those identified in the RCB memo of 5-14-87 as appropriate for these uses, rather than the values proposed by the Registrant.

3. Evaluation of proposed uses relative to the ADI: If all pending uses are approved, the TMRC for the U.S. population average will be 0.0011 mg/kg/day, equivalent to 5.3% of the ADI. The most highly exposed subgroups were non-nursing infants (0.0041 mg/kg/day, equivalent to 20.6% of the ADI) and children 1-6 years old (0.0027 mg/kg/day, equivalent to 13.5% of the ADI).

4. Calculation of oncogenic risk: Risk was calculated only for the U.S. Population average, in accordance with current HED policy. This value was calculated by the relationship:

$$\text{Risk} = \text{Exposure} \times Q^*$$

For all pending uses, the risk was therefore calculated as:

$$0.0011 \times (7.87 \times 10^{-2}) = \underline{8.7 \times 10^{-5}}.$$

The breakdown by commodity group is as follows:

$$\text{Small grains: } 0.00016 \times (7.87 \times 10^{-2}) = \underline{1.3 \times 10^{-5}}.$$

$$\text{Meat, milk, eggs: } 0.00086 \times (7.87 \times 10^{-2}) = \underline{6.8 \times 10^{-5}}.$$

$$\text{Pecans: } (5 \times 10^{-7}) \times (7.87 \times 10^{-2}) = \underline{3.9 \times 10^{-8}}.$$

$$\text{Bananas: } 0.000046 \times (7.87 \times 10^{-2}) = \underline{3.6 \times 10^{-6}}.$$

Since these risk estimates are based on tolerances rather than actual residues in food as it is eaten, data demonstrating the effect of cooking and other processing steps may result in lower estimates of residues, and therefore lower estimates of risk.

ATTACHMENT

cc: TAS file
Reading file
C. Frick
Banner/Tilt SF
Toxicology Branch
circ.
PMSD

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 05/18/87

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CHEMICAL	STUDY TYPE	EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS
		1yr feeding - dog NOEL = 50.00 mg/kg LEL = 250.00 ppm	Irritation of the stomach in males. Doses based on TMA diet concentrations. Evidence of oncogenicity in mice (male liver), negative in rats.	ADI 100 OPP RfD = 0.020000 EPA RfD = 0.000000	WHO RfD 0.000000 Type:	No data gaps.	TOX complete 5/05/87. ORD not scheduled.	
Barner/tilt Caswell #323EE CAS No. 60207-90-1 A.I. CODE: 122101 CFR No. 180.								
ONCO: Class C (TOX NOTE)								
POPULATION SUBGROUP								
U.S. POPULATION - 48 STATES		0.0000	0.0011	5.3641	5.3641			
U.S. POPULATION - SPRING SEASON		0.0000	0.0010	5.1357	5.1357			
U.S. POPULATION - SUMMER SEASON		0.0000	0.0011	5.3208	5.3208			
U.S. POPULATION - FALL SEASON		0.0000	0.0011	5.5393	5.5393			
U.S. POPULATION - WINTER SEASON		0.0000	0.0011	5.4612	5.4612			
NORTHEAST REGION		0.0000	0.0011	5.5261	5.5261			
NORTH CENTRAL REGION		0.0000	0.0011	5.4410	5.4410			
SOUTHERN REGION		0.0000	0.0010	4.9457	4.9457			
WESTERN REGION		0.0000	0.0012	5.7594	5.7594			
HISPANICS		0.0000	0.0014	6.7746	6.7746			
NON-HISPANIC WHITES		0.0000	0.0011	5.2936	5.2936			
NON-HISPANIC BLACKS		0.0000	0.0010	5.0467	5.0467			
NON-HISPANICS OTHER		0.0000	0.0013	6.3050	6.3050			
NURSING INFANTS (<1 YEAR OLD)		0.0000	0.0012	5.9401	5.9401			
NON-NURSING INFANTS (<1 YEAR OLD)		0.0000	0.0041	20.6337	20.6337			
FEMALES (13+ YEARS, PREGNANT)		0.0000	0.0008	3.7563	3.7563			
FEMALES 13+ YEARS, NURSING		0.0000	0.0009	4.6015	4.6015			
CHILDREN (1-6 YEARS OLD)		0.0000	0.0027	13.4680	13.4680			
CHILDREN (7-12 YEARS OLD)		0.0000	0.0017	8.5449	8.5449			
MALES (13-19 YEARS OLD)		0.0000	0.0012	5.7652	5.7652			
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)		0.0000	0.0009	4.4619	4.4619			
MALES (20 YEARS AND OLDER)		0.0000	0.0008	3.7820	3.7820			
FEMALES (20 YEARS AND OLDER)		0.0000	0.0006	3.1868	3.1868			

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

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CHEMICAL		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Banner/Tilt Caswell #323EE CAS No. 60207-90-1 A.I. CODE: 122101 CFR No. 180.		1yr feeding- dog NOEL= 1.9000 mg/kg 50.00 ppm LEL= 8.4000 mg/kg 250.00 ppm		Irritation of the stomach in males. Doses based on TWA diet concentrations. Evidence of oncogenicity in mice (male liver), negative in rats.		ADI 100 OPP Rfd= 0.020000 EPA Rfd= 0.000000 WHO Rfd 0.000000 Type:		No data gaps.		TOX complete 5/05/87. ORD not scheduled.	

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

LISTING OF EXPOSURE BY RAC FOR: U.S. POPULATION 40 STATES							EXISTING TOLERANCES		EFFECT OF NEW TOLERANCES	
FOOD CODE	FOOD NAME	NEW	TOLERANCE (PPM)	APPROVED	PUBLISHED	THRC (UG/KG/DAY)	%RFD	NEW THRC (UG/KG/DAY)	NEW %RFD	
06002AA	BANANAS-UNSPECIFIED	0.2000						0.0007	0.0033	
06002AB	BANANAS-FRESH	0.2000				0.0448		0.2240		
06002DA	BANANAS-DRIED	0.2000				0.0003		0.0017		
CROP GROUP TOTALS FOR UNSPECIFIED:							0.0000	0.0000	0.0458	0.2291
24001AA	BARLEY	0.1000						0.0057	0.0286	
24004AA	RICE-ROUGH	0.1000						0.0003	0.0015	
24004AB	RICE-MILLED	0.1000						0.0155	0.0776	
24005AA	RYE-ROUGH	0.1000						0.0000	0.0000	
24005GA	RYE-GERM	0.1000						0.0001	0.0001	
24005NA	RYE-FLOUR	0.1000						0.0004	0.0020	
24007AA	WHEAT-ROUGH	0.1000						0.0141	0.0703	
24007GA	WHEAT-GERM	0.1000						0.0001	0.0004	
24007HA	WHEAT-BRAN	0.1000						0.0012	0.0061	
24007NA	WHEAT-FLOUR	0.1000						0.1257	0.6286	
CROP GROUP TOTALS FOR CEREAL GRAINS:							0.0000	0.0000	0.1631	0.8154
03008AA	PECANS	0.1000						0.0005	0.0024	
CROP GROUP TOTALS FOR TREE NUTS:							0.0000	0.0000	0.0005	0.0024
53001BA	BEEF-MEAT BYPRODUCTS	0.1000						0.0018	0.0088	
53001BB	BEEF(ORGAN MEATS)-OTHER	0.1000						0.0006	0.0030	
53001DA	BEEF-DRIED	0.1000						0.0003	0.0013	
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	0.1000						0.0372	0.1860	
53001KA	BEEF(ORGAN MEATS)-KIDNEY	0.2000						0.0001	0.0005	
53001LA	BEEF(ORGAN MEATS)-LIVER	0.2000						0.0041	0.0207	
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0.1000						0.1162	0.5810	
53002BA	GOAT-MEAT BYPRODUCTS	0.1000						0.0000	0.0000	
53002BB	GOAT(ORGAN MEATS)-OTHER	0.1000						0.0000	0.0000	
53002FA	GOAT(BONELESS)-FAT	0.1000						0.0000	0.0000	
53002KA	GOAT(ORGAN MEATS)-KIDNEY	0.2000						0.0000	0.0000	
53002LA	GOAT(ORGAN MEATS)-LIVER	0.2000						0.0000	0.0000	
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0.1000						0.0001	0.0001	
53003AA	HORSE	0.1000						0.0000	0.0000	
53003BA	SHEEP-MEAT BYPRODUCTS	0.1000						0.0000	0.0000	
53003BB	SHEEP(ORGAN MEATS)-OTHER	0.1000						0.0000	0.0000	
53003FA	SHEEP(BONELESS)-FAT	0.1000						0.0004	0.0022	
53003KA	SHEEP(ORGAN MEATS)-KIDNEY	0.2000						0.0000	0.0000	

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CHEMICAL		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Barner/Tilt		1yr feeding- dog		Irritation of the stomach		ADI 100		No data gaps.		TOX complete 5/05/87.	
Caswell #323EE		NOEL=	1,9000 mg/kg	in males. Doses based on		OPP RfD= 0.020000				ORD not scheduled.	
CAS No. 60207-90-1		LEL=	50.00 ppm	TMA diet concentrations.		EPA RfD= 0.000000					
A.I. CODE: 122101			8,4000 mg/kg	Evidence of oncogenicity		WHO RfD 0.000000					
CFR No. 180.			250.00 ppm	in mice (male liver),		Type:					
		ONCO: Class C (TOX NOTE)		negative in rats.							

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

LISTING OF EXPOSURE BY KAC FOR: U.S. POPULATION - NO STATES									
FOOD CODE	FOOD NAME	NEW	TOLERANCE (PPM)		EXISTING TOLERANCES		EFFECT OF NEW TOLERANCES		
			APPROVED	PUBLISHED	TMRC (UG/KG/DAY)	%RfD	NEW TMRC (UG/KG/DAY)	NEW %RfD	
53005LA	SHEEP(ORGAN MEATS)-LIVER	0.2000					0.0000	0.0000	
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT	0.1000					0.0012	0.0062	
53006BA	PORK-MEAT BYPRODUCTS	0.1000					0.0025	0.0125	
53006BB	PORK(ORGAN MEATS)-OTHER	0.1000					0.0004	0.0019	
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	0.1000					0.0208	0.1041	
53006KA	PORK(ORGAN MEATS)-KIDNEY	0.2000					0.0000	0.0000	
53006LA	PORK(ORGAN MEATS)-LIVER	0.2000					0.0010	0.0048	
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0.1000					0.0391	0.1956	
CROP GROUP TOTALS FOR RED MEAT:					0.0000	0.0000	0.2258	1.1289	
55008BA	TURKEY-BYPRODUCTS	0.1000					0.0000	0.0001	
55008LA	TURKEY-GIBLETS (LIVER)	0.2000					0.0000	0.0001	
55008MA	TURKEY-FLESH(W/O SKIN, W/O BONES)	0.1000					0.0008	0.0040	
55008MB	TURKEY-FLESH(+SKIN,W/O BONES)	0.1000					0.0048	0.0241	
55008MC	TURKEY-UNSPECIFIED	0.1000					0.0000	0.0001	
55013BA	POULTRY,OTHER-BYPRODUCTS	0.1000					0.0000	0.0000	
55013LA	POULTRY,OTHER-GIBLETS(LIVER)	0.2000					0.0000	0.0002	
55013MA	POULTRY,OTHER-FLESH (+SKIN,W/O BONES)	0.1000					0.0005	0.0027	
55015BA	CHICKEN-BYPRODUCTS	0.1000					0.0000	0.0000	
55015LA	CHICKEN-GIBLETS(LIVER)	0.2000					0.0010	0.0051	
55015MA	CHICKEN-FLESH(W/O SKIN, W/O BONES)	0.1000					0.0060	0.0301	
55015MB	CHICKEN-FLESH(+SKIN, W/O BONES)	0.1000					0.0379	0.1897	
CROP GROUP TOTALS FOR POULTRY:					0.0000	0.0000	0.0512	0.2560	
50000DB	MILK-NON-FAT SOLIDS	0.0500					0.3568	1.7841	
50000FA	MILK-FAT SOLIDS	0.0500					0.1697	0.8487	
50000SA	MILK SUGAR (LACTOSE)	0.0500					0.0019	0.0094	
55014AA	EGGS-WHOLE	0.1000					0.0565	0.2823	
55014AB	EGGS-WHITE ONLY	0.1000					0.0009	0.0046	
55014AC	EGGS-YOLK ONLY	0.1000					0.0007	0.0033	
CROP GROUP TOTALS FOR DAIRY PRODUCTS:					0.0000	0.0000	0.5865	2.9323	