



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

Caswell

FEB. 8 1995

FEB - 8 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Fenbuconazole - Request for First Permanent Food Use on
Stone Fruit (Except Plums and Prunes) (PP# 1F3989,
Caswell No. 723Q, PC Code 129011)

FROM: Elizabeth A. Doyle, Ph.D., Section Head *E. A. Doyle*
Dietary Risk Evaluation Section
Science Analysis Branch / HED (7509C)

TO: Cynthia Giles-Parker/James Stone, PM-22
Fungicide-Herbicide Branch
Registration Division (7505C) *W. Burnam*

THRU: William Burnam, Chief
Science Analysis Branch
Health Effects Division (7509C)

Action Requested: Evaluate the effect of production limits on the chronic and oncogenic dietary risks due to the use of fenbuconazole on stone fruit (except plums and prunes).

Background: In a previously conducted DRES analysis (T. Chin to C. Giles-Parker/D. Wilson, Nov. 22, 1994), chronic and oncogenic dietary risk estimates were produced for proposed uses of fenbuconazole on pecans (0.1 ppm), bananas (0.05 ppm) and stone fruits (except plums and prunes) (2.0 ppm). The chronic analysis using the proposed tolerances indicated that the RfD was not exceeded for the general US population or any population subgroup. The oncogenic risk for the three uses combined was 1.04×10^{-5} , which exceeds the 1×10^{-6} oncogenic risk generally considered negligible by the Agency. The stone fruit (except plums and prunes) use alone had an oncogenic risk of 9.97×10^{-6} .

The registrant, Rohm and Haas, proposed pursuing the stone fruit registration only, at this time with the approach of limiting the

[redacted] treat 12.8% of the stone fruit crop, with a three year time-limited tolerance of 2.0 ppm (letter, R. Costlow of Rohm and Haas to D. Stubbs, Dec. 7, 1994).

Chronic Analysis: The chronic dietary risk from stone fruit (except plums and prunes) only was reevaluated using an estimate of 12.8% crop treated as an approximation of the impact of the

COMMERCIAL/FINANCIAL INFORMATION IS NOT INCLUDED



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[REDACTED] analysis, and limiting the analysis to stone fruit (except plums and prunes) only, no population subgroup had a %RfD used in excess of 2.5% (Table 2).

Oncogenic Risk: The same assumption of 12.8% crop treated based upon production limits and a q_1^* of 1.65×10^{-2} were used for the assessment of the oncogenic risk from fenbuconazole on stone fruit (except plums and prunes) only. An oncogenic risk of 1.28×10^{-6} was obtained (Table 3).

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 723Q

DATE: 01/30/95

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Fenbutazone (Fenethanil) Caswell #723Q CAS No. 114369-43-6 A.I. CODE: 129011 CFR No.	2yr feeding - rat NOEL= 3.0300 mg/kg 80.00 ppm LEL= 30.6200 mg/kg 800.00 ppm ONCO: Pending	Decr body wts (F); incr liver wts with centrilobular to midzonal hepatocellular enlargement & vacuolation (M&F).	PADI UF -->100 OPP RfD= 0.030000 EPA RfD= 0.000000	Developmental tox- rabbit (current study maybe up-graded) Chemical was referred to HED Carcinogenicity Peer Review Committee.	RfD/PR reviewed 04/15/93 RfD/PR reviewed 04/29/93

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
03008AA	PECANS	10 RAW-FRESH OR NFS	1F03995	A 0.100000	0.100000		100.00	0.100000
03008AA	PECANS	21 COOKED-NFS	1F03995	A 0.100000	0.100000		100.00	0.100000
03008AA	PECANS	22 COOKED-FRESH-BAKED	1F03995	A 0.100000	0.100000		100.00	0.100000
03008AA	PECANS	23 COOKED-FRESH-BOILED	1F03995	A 0.100000	0.100000		100.00	0.100000
03008AA	PECANS	62 COOKED-FRESH OR FROZEN-BAKED	1F03995	A 0.100000	0.100000		100.00	0.100000
03008AA	PECANS	10 RAW-FRESH OR NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05001AA	APRICOTS-FRESH	21 COOKED-NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05001AA	APRICOTS-FRESH	31 COOKED-FRESH OR CANNED	1F03989	N 2.000000	2.000000		12.80	0.256000
05001AA	APRICOTS-FRESH	10 RAW-FRESH OR NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05001DA	APRICOTS-DRIED	22 COOKED-FRESH-BAKED	1F03989	N 2.000000	2.000000		12.80	0.256000
05001DA	APRICOTS-DRIED	10 RAW-FRESH OR NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05002AA	CHERRIES-FRESH	21 COOKED-NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05002AA	CHERRIES-FRESH	31 COOKED-FRESH OR CANNED	1F03989	N 2.000000	2.000000		12.80	0.256000
05002AA	CHERRIES-FRESH	62 COOKED-FRESH OR FROZEN-BAKED	1F03989	N 2.000000	2.000000		12.80	0.256000
05002DA	CHERRIES-DRIED	00 NOT SPECIFIED (NO CONSUMPTION)	1F03989	N 2.000000	2.000000		12.80	0.256000
05002JA	CHERRIES-JUICE	15 RAW-FRESH OR CANNED	1F03989	N 2.000000	2.000000		12.80	0.256000
05002JA	CHERRIES-JUICE	21 COOKED-NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05003AA	NECTARINES	10 RAW-FRESH OR NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05004AA	PEACHES-FRESH	10 RAW-FRESH OR NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05004AA	PEACHES-FRESH	21 COOKED-NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05004AA	PEACHES-FRESH	31 COOKED-FRESH OR CANNED	1F03989	N 2.000000	2.000000		12.80	0.256000
05004AA	PEACHES-FRESH	51 COOKED-CANNED	1F03989	N 2.000000	2.000000		12.80	0.256000
05004DA	PEACHES-DRIED	10 RAW-FRESH OR NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05004DA	PEACHES-DRIED	21 COOKED-NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
06002AA	BANANAS-UNSPEC	22 COOKED-FRESH-BAKED	2F04154	A 0.050000	0.050000		100.00	0.050000
06002AB	BANANAS-FRESH	10 RAW-FRESH OR NFS	2F04154	A 0.050000	0.050000		100.00	0.050000
06002AB	BANANAS-FRESH	21 COOKED-NFS	2F04154	A 0.050000	0.050000		100.00	0.050000
06002AB	BANANAS-FRESH	31 COOKED-FRESH OR CANNED	2F04154	A 0.050000	0.050000		100.00	0.050000
06002DA	BANANAS-DRIED	10 RAW-FRESH OR NFS	2F04154	A 0.050000	0.050000		100.00	0.050000
06002DA	BANANAS-DRIED	21 COOKED-NFS	2F04154	A 0.050000	0.050000		100.00	0.050000
06016AA	PLANTAINS	21 COOKED-NFS	2F04154	A 0.050000	0.050000		100.00	0.050000
06016AA	PLANTAINS	23 COOKED-FRESH-BOILED	2F04154	A 0.050000	0.050000		100.00	0.050000
06016AA	PLANTAINS	25 COOKED-FRESH-FRIED	2F04154	A 0.050000	0.050000		100.00	0.050000

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Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 01/30/95

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CHEMICAL INFORMATION		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Fenbutazone (Fenethanil) Caswell #723Q CAS No. 114369-43-6 A.I. CODE: 129011 CFR No.	2yr feeding - rat NOEL= 3.0300 mg/kg 80.00 ppm LEL= 30.6200 mg/kg 800.00 ppm ONCO: Pending	Decr body wts (F); incr liver wts with centrilobular to midzonal hepatocellular enlargement & vacuolation (M&F).		PADI UF -->100 OPP RfD= 0.0300000 EPA RfD= 0.0000000		Developmental tox- rabbit (current study maybe up-graded) Chemical was referred to HED Carcinogenicity Peer Review Committee.		RfD/PR reviewed 04/15/93 RfD/PR reviewed 04/29/93			

POPULATION SUBGROUP	TOTAL THRC (MG/KG BODY WEIGHT/DAY)		NEW THRC**		NEW THRC AS PERCENT OF RFD		DIFFERENCE AS PERCENT OF RFD		EFFECT OF ANTICIPATED RESIDUES	
	CURRENT THRC*								ARC	%RFD
U.S. POPULATION - 48 STATES	0.000000		0.000616		2.054127		2.054127		0.000089	0.29786
U.S. POPULATION - SPRING SEASON	0.000000		0.000630		2.098630		2.098630		0.000090	0.30154
U.S. POPULATION - SUMMER SEASON	0.000000		0.000961		3.202823		3.202823		0.000134	0.44554
U.S. POPULATION - FALL SEASON	0.000000		0.000427		1.423033		1.423033		0.000065	0.21776
U.S. POPULATION - WINTER SEASON	0.000000		0.000449		1.495480		1.495480		0.000068	0.22706
NORTHEAST REGION	0.000000		0.000646		2.151707		2.151707		0.000093	0.30954
NORTH CENTRAL REGION	0.000000		0.000656		2.187720		2.187720		0.000094	0.31246
SOUTHERN REGION	0.000000		0.000461		1.536520		1.536520		0.000068	0.22729
WESTERN REGION	0.000000		0.000788		2.625653		2.625653		0.000115	0.38329
HISPANICS	0.000000		0.000671		2.238143		2.238143		0.000103	0.34491
NON-HISPANIC WHITES	0.000000		0.000635		2.117107		2.117107		0.000092	0.30605
NON-HISPANIC BLACKS	0.000000		0.000472		1.572533		1.572533		0.000067	0.22274
NON-HISPANIC OTHERS	0.000000		0.000584		1.947640		1.947640		0.000090	0.29873
NURSING INFANTS (< 1 YEAR OLD)	0.000000		0.003083		10.277767		10.277767		0.000435	1.44953
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000000		0.005216		17.386597		17.386597		0.000715	2.38309
FEMALES (13+ YEARS, PREGNANT)	0.000000		0.000458		1.526680		1.526680		0.000064	0.21458
FEMALES 13+ YEARS, NURSING	0.000000		0.000585		1.950250		1.950250		0.000083	0.27799
CHILDREN (1-6 YEARS OLD)	0.000000		0.001444		4.812677		4.812677		0.000217	0.72472
CHILDREN (7-12 YEARS OLD)	0.000000		0.000905		3.017387		3.017387		0.000130	0.43168
MALES (13-19 YEARS OLD)	0.000000		0.000397		1.323817		1.323817		0.000058	0.19395
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000000		0.000398		1.325973		1.325973		0.000057	0.19052
MALES (20 YEARS AND OLDER)	0.000000		0.000357		1.189397		1.189397		0.000052	0.17464
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000000		0.000433		1.444720		1.444720		0.000062	0.20763

*Current THRC does not include new or pending tolerances.

**New THRC includes new, pending, and published tolerances.

Table 3.

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 01/30/95

PAGE: 1

CHEMICAL INFORMATION		STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Fenbutazone (Fenethanil)	2yr feeding - rat	NOEL= 3.0300 mg/kg 80.00 ppm LEL= 30.6200 mg/kg 800.00 ppm ONCO: Pending	Decr body wts (F); incr liver wts with centrilobular to midzonal hepatocellular enlargement & vacuolation (M&F).	PADI UF -->100 OPP Rfd= 0.030000 EPA Rfd= 0.000000	Developmental tox- rabbit (current study maybe up-graded) Chemical was referred to HED Carcinogenicity Peer Review Committee.	Rfd/PR reviewed 04/15/93 Rfd/PR reviewed 04/29/93
Caswell #7230						
CAS No. 114369-43-6						
A.I. CODE: 129011						
CFR No.						

COMMODITY CONTRIBUTION BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPM)	TYPE	TMRC (UG/KG/DAY)	%RFD	TMRC ONCO RISK	ANTICIPATED RESIDUE (PPM)	ARC (UG/KG/DAY)	%RFD	ONCO RISK
06002AA	BANANAS-UNSPECIFIED	0.050	A	0.000165	0.001	0.00000000272	0.05000	0.000165	0.001	0.00000000272
	22 COOKED-FRESH-BAKED									
06002AB	BANANAS-FRESH	0.050	A	0.011202	0.037	0.00000018483	0.05000	0.009888	0.033	0.00000016315
	10 RAW-FRESH OR NFS						0.05000	0.000270	0.001	0.00000000446
	21 COOKED-NFS						0.05000	0.001044	0.003	0.00000001723
	31 COOKED-FRESH OR CANNED									
06002DA	BANANAS-DRIED	0.050	A	0.000088	0.000	0.00000000145	0.05000	0.000027	0.000	0.00000000045
	10 RAW-FRESH OR NFS						0.05000	0.000060	0.000	0.00000000099
	21 COOKED-NFS									
06016AA	PLANTAINS	0.050	A	0.000082	0.000	0.00000000135	0.05000	0.000000	0.000	0.00000000000
	21 COOKED-NFS						0.05000	0.000040	0.000	0.00000000066
	23 COOKED-FRESH-BOILED						0.05000	0.000042	0.000	0.00000000069
	25 COOKED-FRESH-FRIED									
CROP GROUP TOTALS FOR UNSPECIFIED:										
				0.011537	0.038	0.00000019036		0.011536	0.038	0.00000019034
05001AA	APRICOTS-FRESH	2.000	N	0.067379	0.225	0.00000011175	0.25600	0.001463	0.005	0.00000002414
	10 RAW-FRESH OR NFS						0.25600	0.001992	0.007	0.00000003287
	21 COOKED-NFS						0.25600	0.005170	0.017	0.00000008531
05001DA	APRICOTS-DRIED	2.000	N	0.004848	0.016	0.00000007999	0.25600	0.000526	0.002	0.00000000868
	10 RAW-FRESH OR NFS						0.25600	0.000094	0.000	0.00000000155
	22 COOKED-FRESH-BAKED									
05002AA	CHERRIES-FRESH	2.000	N	0.064351	0.215	0.00000106179	0.25600	0.001888	0.006	0.00000003115
	10 RAW-FRESH OR NFS						0.25600	0.001129	0.004	0.00000001863
	21 COOKED-NFS						0.25600	0.003211	0.011	0.00000005298
	31 COOKED-FRESH OR CANNED						0.25600	0.002008	0.007	0.00000003313
	62 COOKED-FRESH OR FROZEN-BAKED									
05002DA	CHERRIES-DRIED	2.000	N	0.000008	0.000	0.00000000013	0.25600	0.000001	0.000	0.00000000002
	00 NOT SPECIFIED (NO CONSUMPTION)									
05002JA	CHERRIES-JUICE	2.000	N	0.010224	0.034	0.00000016870	0.25600	0.001200	0.004	0.00000001980
	15 RAW-FRESH OR CANNED						0.25600	0.000108	0.000	0.00000000178
	21 COOKED-NFS									
05003AA	NECTARINES	2.000	N	0.025932	0.086	0.000000042788	0.25600	0.003319	0.011	0.00000005476
	10 RAW-FRESH OR NFS									
05004AA	PEACHES-FRESH	2.000	N	0.430783	1.436	0.000000710792	0.25600	0.025721	0.086	0.00000004240
	10 RAW-FRESH OR NFS						0.25600	0.002518	0.008	0.000000004155
	21 COOKED-NFS						0.25600	0.020450	0.068	0.000000033743
	31 COOKED-FRESH OR CANNED						0.25600	0.006451	0.022	0.00000010644
	51 COOKED-CANNED									
05004DA	PEACHES-DRIED	2.000	N	0.000694	0.002	0.00000001145	0.25600	0.000047	0.000	0.00000000078
	10 RAW-FRESH OR NFS									

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TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

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CHEMICAL INFORMATION		STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Fenbutazone (Fenethanil)		2yr feeding - rat	Decr body wts (F); incr liver wts with centrilobular to midzonal hepatocellular enlargement & vacuolation (M&F).	PADI UF --> 100 OPP RfD= 0.030000 EPA RfD= 0.000000	Developmental tox- rabbit (current study maybe up-graded) Chemical was referred to HED Carcinogenicity Peer Review Committee.	RfD/PR reviewed 04/15/93 RfD/PR reviewed 04/29/93
Caswell #723Q	NOEL=	3.0300 mg/kg				
CAS No. 114369-43-6		80.00 ppm				
A.I. CODE: 129011		LEL= 30.6200 mg/kg				
CFR No.		800.00 ppm				
		ONCO: Pending				

COMMODITY CONTRIBUTION BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPM)	TMRC TYPE (UG/KG/DAY)	TMRC %RFD	TMRC ONCO RISK	ANTICIPATED RESIDUE (PPM)	ARC (UG/KG/DAY)	%RFD	ARC ONCO RISK
	21 COOKED-NFS					0.25600	0.000042	0.000	0.00000000069
CROP GROUP TOTALS FOR STONE FRUITS:									
		0.000000	0.000000	0.000	0.00000996961	0.000000	0.000000	0.000	0.00000127608
03008AA	PECANS	0.100	A	0.000482	0.002	0.000000000795	0.000068	0.000	0.00000000112
	10 RAW-FRESH OR NFS					0.10000	0.000068	0.000	0.00000000010
	21 COOKED-NFS					0.10000	0.000068	0.000	0.00000000013
	22 COOKED-FRESH-BAKED					0.10000	0.000111	0.000	0.000000000388
	23 COOKED-FRESH-BOILED					0.10000	0.000235	0.001	0.000000000104
	62 COOKED-FRESH OR FROZEN-BAKED					0.10000	0.000063	0.000	0.000000000797
CROP GROUP TOTALS FOR TREE NUTS:									
		0.000482	0.002	0.000000000795		0.000483		0.002	

GRAND TOTALS FOR U.S. POPULATION - 48 STATES

0.616238	2.054	0.00001016793	0.089357	0.298	0.00000147439
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TOLERANCE TYPE: N=NEW; A=PENDING; P=PUBLISHED
 TMRC=THEORETICAL MAXIMUM RESIDUE CONTRIBUTION
 ARC = ANTICIPATED RESIDUE CONTRIBUTION
 RFD = REFERENCE DOSE

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