US EPA ARCHIVE DOCUMENT

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

JAN 25 1991

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for the Proposed Use of Triasulfuron on Wheat and Barley (PP#8F3658)

FROM: Stephen A. Schaible, Biologist
HED/SACB (H7509C)

THROUGH: James P. Kariya
Chief, Dietary Exposure Section
Health Effects Division

TO: Robert Taylor, PM 25
Herbicide-Fungicide Branch
Registration Division (H7505C)

Action Requested

New tolerances for wheat, barley, meat, and milk. This analysis was run to evaluate exposures.

Discussion

1. Toxicology Endpoint: The routine chronic DRES analysis used a reference dose (RfD) of 0.01 mg/kg body weight/day, based on a NOEL of 1.2 mg/kg body weight/day and an uncertainty factor of 100. These values were derived from a two year mouse feeding study, with the effect of this study being centrilobular hepatocytomegaly in males. The reference dose of 0.010 mg/kg body weight/day was rounded off from 0.012 mg/kg body weight/day (R. Whiting). This value has been approved by HED (4/11/90) and Agency (8/22/90) reference dose committees.

2. Residue Information: Food uses evaluated were for new tolerances. A summary of the residue information used in the analysis is attached as Table 1. A default conversion factor of 7.784 was used for milk in the analysis, which overestimated the residue. In addition, the tolerance of 0.1 ppm, proposed for meat, fat, and meat by-products (excluding kidney, which had a proposed tolerance of 0.2 ppm), was assumed for all other Raw Agricultural Commodities (RAC's) listed under cattle, goats, hogs, horses, and sheep (excluding kidneys).

3. Exposure Analysis: The DRES chronic exposure analysis uses tolerance level residues and 100 percent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups, which are

TABLE 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 861C

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Triasulfuron (Amber) Caswell #861C CAS No. 82097-50-5 A.I. CODE: 128985 CFR No. 180.	2yr feeding- mouse NOEL= 1.2000 mg/kg 10.00 ppm LEL= 12.9000 mg/kg 1000.00 ppm ONCO: Negative- 2 species.	Centrilobular hepatocyto-megaly in males. No evidence of carcino-genicity in rats or mice.	PADI UF -->100 OPP RfD= 0.010000 EPA RfD= 0.000000	Chronic feed/onco- rat (Current study maybe up-graded).	HED complete 04/11/90. EPA verified 08/22/90.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED
24001AA	BARLEY	8F3658	0.020000		
24007AA	WHEAT-ROUGH	8F3658	0.020000		
24007GA	WHEAT-GERM	8F3658	0.020000		
24007HA	WHEAT-BRAN	8F3658	0.020000		
24007WA	WHEAT-FLOUR	8F3658	0.020000		
50000DB	MILK-NON-FAT SOLIDS	8F3658	0.020000		
50000FA	MILK-FAT SOLIDS	8F3658	0.020000		
50000SA	MILK SUGAR (LACTOSE)	8F3658	0.020000		
53001BA	BEEF-MEAT BYPRODUCTS	8F3658	0.100000		
53001BB	BEEF(ORGAN MEATS)-OTHER	8F3658	0.100000		
53001DA	BEEF-DRIED	8F3658	0.100000		
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	8F3658	0.100000		
53001KA	BEEF(ORGAN MEATS)-KIDNEY	8F3658	0.200000		
53001LA	BEEF(ORGAN MEATS)-LIVER	8F3658	0.100000		
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	8F3658	0.100000		
53002BA	GOAT-MEAT BYPRODUCTS	8F3658	0.100000		
53002BB	GOAT(ORGAN MEATS)-OTHER	8F3658	0.100000		
53002FA	GOAT(BONELESS)-FAT	8F3658	0.100000		
53002KA	GOAT(ORGAN MEATS)-KIDNEY	8F3658	0.200000		
53002LA	GOAT(ORGAN MEATS)-LIVER	8F3658	0.100000		
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	8F3658	0.100000		
53003AA	HORSE	8F3658	0.100000		
53005BA	SHEEP-MEAT BYPRODUCTS	8F3658	0.100000		
53005BB	SHEEP(ORGAN MEATS)-OTHER	8F3658	0.100000		
53005FA	SHEEP(BONELESS)-FAT	8F3658	0.100000		
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	8F3658	0.200000		
53005LA	SHEEP(ORGAN MEATS)-LIVER	8F3658	0.100000		
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT	8F3658	0.100000		
53006BA	PORK-MEAT BYPRODUCTS	8F3658	0.100000		
53006BB	PORK(ORGAN MEATS)-OTHER	8F3658	0.100000		
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	8F3658	0.100000		
53006KA	PORK(ORGAN MEATS)-KIDNEY	8F3658	0.200000		
53006LA	PORK(ORGAN MEATS)-LIVER	8F3658	0.100000		
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	8F3658	0.100000		

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TABLE 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

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CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Triasulfuron (Amber) Caswell #861C CAS No. 82097-50-5 A.I. CODE: 128985 CFR No. 180.	2yr feeding- mouse NOEL= 1.2000 mg/kg 10.00 ppm LEL= 12.9000 mg/kg 1000.00 ppm ONCO: Negative- 2 species.	Centrilobular hepatocyto-megaly in males. No evidence of carcino-genicity in rats or mice.	PADI UF -->100 OPP RfD= 0.010000 EPA RfD= 0.000000	Chronic feed/onco- rat (Current study maybe up-graded).	HED complete 04/11/90. EPA verified 08/22/90.

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	0.000000	0.000463	4.632670	4.632670		
U.S. POPULATION - SPRING SEASON	0.000000	0.000446	4.462670	4.462670		
U.S. POPULATION - SUMMER SEASON	0.000000	0.000463	4.633430	4.633430		
U.S. POPULATION - FALL SEASON	0.000000	0.000477	4.770670	4.770670		
U.S. POPULATION - WINTER SEASON	0.000000	0.000466	4.664540	4.664540		
NORTHEAST REGION	0.000000	0.000475	4.746590	4.746590		
NORTH CENTRAL REGION	0.000000	0.000484	4.841970	4.841970		
SOUTHERN REGION	0.000000	0.000425	4.247660	4.247660		
WESTERN REGION	0.000000	0.000484	4.840720	4.840720		
HISPANICS	0.000000	0.000563	5.634850	5.634850		
NON-HISPANIC WHITES	0.000000	0.000461	4.606400	4.606400		
NON-HISPANIC BLACKS	0.000000	0.000428	4.283660	4.283660		
NON-HISPANIC OTHERS	0.000000	0.000503	5.034200	5.034200		
NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.000398	3.978770	3.978770		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.001543	15.434480	15.434480		
FEMALES (13+ YEARS, PREGNANT)	0.000000	0.000332	3.317490	3.317490		
FEMALES 13+ YEARS, NURSING	0.000000	0.000383	3.828220	3.828220		
CHILDREN (1-6 YEARS OLD)	0.000000	0.001090	10.904990	10.904990		
CHILDREN (7-12 YEARS OLD)	0.000000	0.000734	7.338070	7.338070		
MALES (13-19 YEARS OLD)	0.000000	0.000516	5.157710	5.157710		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000000	0.000397	3.974550	3.974550		
MALES (20 YEARS AND OLDER)	0.000000	0.000346	3.462170	3.462170		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000000	0.000283	2.833280	2.833280		

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

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summarized in Table 2. The TMRC of the overall U.S. population is 0.000463 mg/kg body weight/day which represents 4.63 percent of the RfD. The estimated TMRC's for non-nursing infants and children ages 1 to 6 are 0.001543 mg/kg/day (15.4% of the RfD) and 0.001090 mg/kg/day (10.9% of the RfD), respectively. The TMRC estimate was less than the RfD for all DRES population groups.

Attachments

cc: DES, CB-TS, Caswell # 861C, Tox 1