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Aminopyralid
PC Code: 005100/005209

Dietary Exposure Assessment

DP Number: D313003
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

Date: June 21, 2005

Subject: **Aminopyralid** Chronic Dietary Exposure Assessment for the Section 3
Registration Action.

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Decision Number: 341121
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Executive Summary

A chronic dietary risk assessment was conducted using the Lifeline™ Model Version 2.0 which uses food consumption data from the United States Department of Agriculture's (USDA's) Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. This highly conservative assessment assumed tolerance-level residues and 100% crop treated. In addition to residues in/on food items, the assessment also addresses potential residues in drinking water. Based on the assumptions noted above, chronic exposure estimates range from 0.0002 to 0.0012 mg/kg/day. Risk estimates for all population subgroups are less than 1% of the chronic population-adjusted dose (cPAD). Generally, HED is concerned about dietary exposure levels

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when risk estimates exceed 100% of the PAD. Dietary risk estimates for aminopyralid are below HED's level of concern for all population subgroups, including those of infants and children.

I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For non-cancer assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to the reference dose (RfD) divided by the special Food Quality Protection Act (FQPA) Safety Factor. HED is concerned when estimated dietary risk exceeds 100% of the PAD. References which discuss risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 6/21/2000, web link: <http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf>; or see SOP 99.6 (8/20/99).

This is the first dietary exposure assessment for aminopyralid.

II. Residue Information

The petitioner has requested use of the herbicide aminopyralid on wheat, pastureland, and rangeland. This assessment includes residue estimates for wheat commodities, livestock commodities, and drinking water. Aminopyralid is a new active ingredient in North America and there are no other uses at this time. The residues of concern for aminopyralid in crops are the combined residues of parent aminopyralid and its glucose conjugates. The analytical method used in the field trials hydrolyzes the glucose conjugates to aminopyralid and, therefore, provides estimates for the residues of concern in plants. In livestock, the residue of concern is aminopyralid, *per se*.

For wheat and livestock commodities, HED has assumed that residues are at the level of the tolerance and that 100% of the crops with requested uses are treated. No processing factors were used in this assessment with the exception of dried beef at 1.92. The complete listing of the food inputs is included in Attachment 1. The Environmental Fate and Effects Division has provided HED with estimated concentrations of aminopyralid in groundwater (0.630 $\mu\text{g/L}$) and surface water (1.937 $\mu\text{g/L}$) for use as drinking water inputs to the chronic dietary risk assessment (R. Kashuba, D301682, 2/3/05). This assessment uses the surface water value for all water sources.

III Program and Consumption Information

Several reasonable peer-reviewed software packages have recently been emerging for modeling dietary exposure to pesticides. For a variety of technical, historical, and availability reasons, DEEM™ was the program generally used by EPA's Office of Pesticide Programs (OPP) for conducting its dietary risk assessments. With the advent and current availability of a number of other exposure software programs, OPP, registrants, and other interested parties have available to them the option of selecting other peer-reviewed exposure software in conducting risk assessments for pesticides. Lifeline™ is one such model and is the software being used in this HED review. Dietary exposure assessments may also be performed with other, similar programs,

and if submitted, such results will be reviewed by EPA for acceptability and comparability to existing peer-reviewed software being used by OPP.

Lifeline™ Program and Consumption Information

Chronic dietary exposure estimates were conducted using the Lifeline™ model (Version 2.0). Lifeline™ uses a recipe file to relate raw agricultural commodities (RACs) to foods “as-eaten.” Lifeline™ converts the RAC residues into food residues by randomly selecting a RAC residue value from the “user defined” residue distribution (created from the residue, percent crop treated, and processing factors data), and calculating a net residue for that food based on the ingredients’ mass contribution to that food item. For example, ‘apple pie’ will have a residue distribution based on the residues provided for apples (adjusted by the appropriate processing factors and percent crop treated), as well as the residues for each of the other ingredients in the apple pie recipe for which there may be tolerances. Lifeline™ calculates dietary exposure from ‘apple pie’ based on the amount eaten and the residue drawn from the ‘apple pie’ residue distribution for that eating occasion. Lifeline™ models the individual’s dietary exposures over a season by selecting a new CSFII diary each day from a set of similar individuals based on age and season attributes. Lifeline™ groups CSFII diaries based on the respondents’ age and the season during which the food diary was recorded. Further information regarding the Lifeline™ model can be found at the following web site: www.theLifelinegroup.org.

IV. Toxicological Information

The aminopyralid assessment team has selected doses and endpoints for use in human health risk assessment. These were confirmed by HED’s Risk Assessment Review Committee (RARC) at a RARC-1 meeting held on 1/12/05. Those doses and endpoints relative to dietary exposure are summarized in Table 1. In evaluating the dietary exposure to aminopyralid, only a chronic assessment has been conducted since acute and cancer assessments are not required for this chemical.

Table 1. Summary of Toxicological Doses and Endpoints for Use in Dietary Human Risk Assessments of Aminopyralid			
Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (general population)	—	—	No appropriate acute endpoint identified for this group. There were no toxic effects attributable to a single dose identified. An acute dietary risk assessment is not required.
Chronic Dietary (all populations)	NOAEL= 50 mg/kg/day UF=100 chronic RfD=0.5 mg/kg/day	FQPA SF = 1 cPAD= cRfd/FQPA SF cPAD=0.5 mg/kg/day	Chronic toxicity/carcinogenicity study LOAEL=500 mg/kg/day based on cecal enlargement, slight mucosal hyperplasia in males and slightly decreased body weights.

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Cancer (oral, dermal, inhalation)	Classification: "Not Likely" A cancer dietary risk assessment is not required.		

V. Results/Discussion

As stated above, for chronic assessments, HED is concerned when dietary risk exceeds 100% of the PAD. The Lifeline™ analyses estimate the dietary exposure of the U.S. population and various population subgroups. The results reported in Table 2 are for the general U.S. Population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, females 13-49, adults 20-49, and adults 50+ years.

The Lifeline™ chronic dietary exposure estimates are based on an average daily exposure from a profile of 1000 individuals over a one year period. The chronic dietary (food + water) exposure estimates range from 0.0002 mg/kg/day for adults 50 years old and older to 0.0012 mg/kg/day for children 1-2 years old. Dietary exposure estimates for all population subgroups are less than 1% of the cPAD (0.5 mg/kg/day). The results are summarized in Table 2.

Population Subgroup	Chronic PAD, mg/kg/day	Chronic Exposure Estimate, mg/kg/day	% cPAD
1. U.S. Population	0.5	0.000296	< 1
2. All infants < 1	0.5	0.000510	< 1
3. Children 1-2	0.5	0.001230	< 1
4. Children 3-5	0.5	0.000946	< 1
5. Children 6-12	0.5	0.000551	< 1
6. Youth 13-19	0.5	0.000260	< 1
7. Adults 20-49	0.5	0.000215	< 1
8. Adults 50+	0.5	0.000208	< 1
9. Females 13-49	0.5	0.000252	< 1

VI. Characterization of Inputs/Outputs

The results of this dietary exposure assessment should be viewed as high-end, based on the assumptions regarding the input values. Tolerances are derived from field trials designed to produce the maximum residue values in a crop. The trials are based on maximum allowable application rate and shortest possible pre-harvest interval. Actual uses often occur at rates below the labeled maximum and the interval between treatment and harvest may be longer than the shortest allowable pre-harvest interval. In addition, it is highly unlikely that 100% of a crop across the entire U.S. would be treated with the compound being assessed. Therefore, actual

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dietary exposures to aminopyralid are likely to be significantly less than those estimated by this assessment.

VII. Conclusions

Based on assumptions that likely overestimate dietary exposure and risk associated with aminopyralid uses on wheat, pastureland, and rangeland, dietary (food + drinking water) risk estimates are well below HED's level of concern for all population subgroups, including those of infants and children.

VIII. List of Attachments

1. Food Residue Inputs for the Chronic Dietary Assessment of Aminopyralid.
2. Water Residue Inputs for the Chronic Dietary Assessment of Aminopyralid.
3. Summary of the Results of the Chronic Dietary Assessment for Aminopyralid.

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Attachment 1. Food Residue Inputs for the Chronic Dietary Assessment of Aminopyralid.

Code	Crop Group	Code	Commodity	Residue (ppm)	Dehydration
15	CEREAL GRAINS	3810	Triticale, flour	0.04	
15	CEREAL GRAINS	3811	Triticale, flour- babyfood	0.04	
15	CEREAL GRAINS	4010	Wheat, grain	0.04	
15	CEREAL GRAINS	4011	Wheat, grain - babyfood	0.04	
15	CEREAL GRAINS	4020	Wheat, flour	0.04	
15	CEREAL GRAINS	4021	Wheat, flour- babyfood	0.04	
15	CEREAL GRAINS	4030	Wheat, germ	0.04	
15	CEREAL GRAINS	4040	Wheat, bran	0.1	
21	BEEF	441	Beef, meat- babyfood	0.02	
21	BEEF	450	Beef, meat, dried	0.02	1.92
21	BEEF	460	Beef, meat byproducts	0.02	
21	BEEF	461	Beef, meat byproducts- babyfood	0.02	
21	BEEF	470	Beef, fat	0.02	
21	BEEF	471	Beef, fat- babyfood	0.02	
21	BEEF	480	Beef, kidney	0.3	
21	BEEF	490	Beef, liver	0.02	
21	BEEF	491	Beef, liver- babyfood	0.02	
21	BEEF	440	Beef, meat	0.02	
23	GOAT	1700	Goat, meat byproducts	0.02	
23	GOAT	1710	Goat, fat	0.02	
23	GOAT	1720	Goat, kidney	0.3	
23	GOAT	1730	Goat, liver	0.02	
23	GOAT	1690	Goat, meat	0.02	
24	HORSE	1890	Horse, meat	0.02	
26	SHEEP	3391	Sheep, meat- babyfood	0.02	
26	SHEEP	3400	Sheep, meat byproducts	0.02	
26	SHEEP	3410	Sheep, fat	0.02	
26	SHEEP	3411	Sheep, fat- babyfood	0.02	
26	SHEEP	3420	Sheep, kidney	0.3	
26	SHEEP	3430	Sheep, liver	0.02	
26	SHEEP	3390	Sheep, meat	0.02	
27	MILK	2221	Milk, fat - baby food/infant formula	0.03	
27	MILK	2230	Milk, nonfat solids	0.03	
27	MILK	2231	Milk, nonfat solids- baby food/infant formula	0.03	
27	MILK	2240	Milk, water	0.03	
27	MILK	2241	Milk, water- babyfood/infant formula	0.03	
27	MILK	2251	Milk, sugar (lactose)- baby food/infant formula	0.03	
27	MILK	2220	Milk, fat	0.03	
28	GAME	2210	Meat, game	0.02	
29	RABBIT	3120	Rabbit, meat	0.02	

Attachment 2. Water Residue Inputs for the Chronic Dietary Assessment of Aminopyralid.

Note: The minimum and maximum concentrations are the same (0.001937 mg/L) for all regions, seasons, and water systems.

North East	Public or private water system	Minimum conc. (mg/L)	Maximum conc. (mg/L)
Spring	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Summer	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Fall	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Winter	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
North East	Individual well		
Spring	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Summer	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Fall	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Winter	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
North East	Other source		
Spring	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Summer	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Fall	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Winter	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Mid West	Public or private water system		
Spring	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Summer	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Fall	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Winter	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Mid West	Individual well		
Spring	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Summer	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Fall	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Winter	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Mid West	Other source		
Spring	Rural	0.001937	0.001937
	Urban	0.001937	0.001937

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Summer	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Fall	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Winter	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
South	Public or private water system		
Spring	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Summer	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Fall	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Winter	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
South	Individual well		
Spring	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Summer	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Fall	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Winter	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
South	Other source		
Spring	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Summer	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Fall	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Winter	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
West	Public or private water system		
Spring	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Summer	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Fall	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Winter	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
West	Individual well		
Spring	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Summer	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Fall	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Winter	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
West	Other source		
Spring	Rural	0.001937	0.001937

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	Urban	0.001937	0.001937
Summer	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Fall	Rural	0.001937	0.001937
	Urban	0.001937	0.001937
Winter	Rural	0.001937	0.001937
	Urban	0.001937	0.001937

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Attachment 3. Summary of the Results of the Chronic Dietary Assessment for Aminopyralid.

Population Subgroup	Chronic PAD, mg/kg/day	Chronic Exposure Estimate, mg/kg/day	% cPAD
1. U.S. Population	0.5	0.000296	0.06
2. All infants < 1	0.5	0.000510	0.10
3. Children 1-2	0.5	0.001230	0.25
4. Children 3-5	0.5	0.000946	0.19
5. Children 6-12	0.5	0.000551	0.11
6. Youth 13-19	0.5	0.000260	0.05
7. Adults 20-49	0.5	0.000215	0.04
8. Adults 50+	0.5	0.000208	0.04
9. Females 13-49	0.5	0.000252	0.05



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