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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Addenda to Dietary Exposure Analyses for the Use of Oxyfluorfen (Goal) on Several Commodities

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and

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Background

Several DRES (formerly TAS) analyses were conducted for the use of oxyfluorfen during the past several months (see J. R. Tomerlin to H. Jamerson memoranda dated 5/16/89, 5/24/89, 6/10/89, and 6/15/89). Since the distribution of these analyses, oxyfluorfen has been classified as a Group C_q (possible human) carcinogen with an upper bound carcinogen potency estimate (Q_1^*) of 1.28 $(mg/kg/day)^{-1}$ (K. L. Dearfield memo, 9/29/89). The purpose of this memo is to provide estimates of carcinogenic risk using the recently established Q_1^*, per Mr. Jamerson's request.

Discussion

1. Toxicology Endpoint: The routine chronic DRES analyses used a reference dose (ADI) of 0.003 mg/kg body weight/day, based upon a NOEL of 0.3 mg/kg body weight/day and an uncertainty factor of 100 from a 20 month mouse feeding study. This value has been approved by HED (4/14/86) and Agency (6/10/86) reference dose committees.

2. Residue Information: Food uses evaluated published tolerances from 40 CFR 180.381, food additive tolerances from 40 CFR 185.4600, and proposed uses on papaya (M. J. Nelson memo, 5/10/89), taro (M. J. Nelson memo, 5/4/89), persimmons (M. J. Nelson memo, 6/8/89),

(1)

and horseradish (M. J. Nelson, 6/13/89). The residue values used in the particular analyses may be found in the Tomerlin memoranda cited previously.

3. Exposure Analysis: The DRES chronic exposure analysis uses tolerance level residues and 100 per cent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. The TMRC summaries for all DRES population groups may be found in the Tomerlin memoranda cited previously. In those memoranda, the percentage of the reference dose occupied by the exposure estimates were 30.1% for the overall U.S. population, 152.8% for non-nursing infants, and 79.0% for children aged 1 to 6.

Carcinogenic risk is estimated by the relationship:

Risk = Exposure x Q_1*

= 0.000903 mg/kg/day x 1.28 $(mg/kg/day)^{-1}$

Exposure summaries for the overall U.S. population, non-nursing infants, and children aged 1 to 6, as well as an estimate of carcinogenic risk for the overall U.S. population are shown in the following table.

Oxyfluorfen Exposure and Risk Estimates

	Overall U.S. Exposure	Population Risk Est.	Non-Nurs. Infants	Children Aged 1 - 6
Published Tolerances	0.000903[a]	1.2×10^{-3}	0.004584	0.002369
Papaya	< 0.000001	4.9×10^{-7}	0	< 0.000001
Taro	0	0	0	0
Persimmons	< 0.000001	2.6×10^{-8}	0	0.000001
Horseradish	< 0.000001	5.1×10^{-9}	0	0
TOTAL	0.000903	1.2×10^{-3}	0.004584	0.002371

aExposure estimate in mg/kg body weight/day.

The bulk of the estimated exposure and the associated carcinogenic risk is concentrated in particular commodities. The exposure and carcinogenic risk estimates for the overall U.S. population are shown in the following table.

Commodity Contribution to Estimated Dietary Risk
in the Overall U.S. Population

Commodity	Exposure	Carcinogenic Risk Estimate
Soybean Oil	0.000528[a]	6.8×10^{-4}
Apples	0.000111	1.4×10^{-4}
Cottonseed	0.000080	1.0×10^{-4}
Pears	0.000039	5.1×10^{-5}
Meat	0.000029	3.7×10^{-5}
Corn	0.000025	3.2×10^{-5}
Stone Fruit	0.000018	2.3×10^{-5}
Banana	0.000016	2.1×10^{-5}
Onions	0.000011	1.5×10^{-5}
Grapes	0.000011	1.4×10^{-5}
Milk	0.000010	1.4×10^{-5}
Poultry	0.000008	1.0×10^{-5}
Eggs	0.000005	6.9×10^{-6}
Cole Crops	0.000005	6.5×10^{-6}
Other[b]	0.000001	1.3×10^{-6}
TOTAL	0.000902	1.2×10^{-3}

aEstimated exposure in mg/kg body weight/day.
bOther includes: pistachio, avocado, dates, figs, guava, loquats, olives, pomegranates, plantains, kiwi, coffee, artichokes, garlic, shallots, soybeans (other than oil), tree nuts, crabapples, and quinces.

4. Dietary Risk Assessment: The recent classification of oxyfluorfen as a Group C_q carcinogen changes the interpretation of the dietary risk assessment for the pesticide. Oxyfluorfen is a "List B" reregistration chemical for which HED now recommends that anticipated residue and pesticide usage data be obtained for the registered commodities listed in the body of the preceding table as part of the oxyfluorfen reregistration process. HED likewise recommends that in the future, proposed tolerances resulting in an estimated carcinogenic risk of 10^{-6} or greater not be granted pending the receipt and evaluation of these data.

The use of oxyfluorfen on papaya, taro, persimmons, and horseradish is not expected to result in estimated carcinogenic risk of 10^{-6}.

Attachments

cc: DRES (Tomerlin, SACB), DEB (Loranger), Caswell #188AA, TOX (Dykstra), Jamerson (RD), Kocialski (SACB)