



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

RCB 5483
4-1-83

Mayer
Fulepetter

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

APR 1 1983

TO: H. Jamerson (43)
Registration Division (TS-767)

THRU: Orville E. Paynter, Ph.D.
Chief, Toxicology Branch
Hazard Evaluation Division (TS-769)

SUBJECT: PP#3E2819: Petition for the Establishment of Additional
Chlorpyrifos Tolerances on Brassica Leafy Vegetables
CASWELL#219AA

Requested By: Office of IR-4
Cook College
Rutgers, The State University of New Jersey
New Brunswick, New Jersey 08903

Action Requested:

The IR-4 Office is proposing to extend chlorpyrifos tolerances to additional brassica leafy vegetables; specifically, 2 ppm for chlorpyrifos and it's TCP metabolite on chinese broccoli, broccoli raab, savoy cabbage, collards, kale, kohlrabi, mustard greens and rape greens. Tolerances already exist for several members of this family including broccoli, brussels sprouts, cabbage and cauliflower.

Recommendation:

The extension of tolerances to all members of the brassica family is toxicology supported. The acceptability of using "crop grouping" approach for Brassica leafy vegetables should be ^{the} determined by RCB.

Summary of Toxicity Data:

- °Acute Rat Oral LD₅₀ = 118-245 mg/kg
- °Mouse Teratology: Negative at 25 mg/kg/day (highest dose)
- °3-Generation Rat Reproduction Study: NOEL = 1.0 mg/kg/day (highest dose)
- °Acute Delayed Neurotoxicity (hen): Negative at 100 mg/kg
- °2-Year Mouse Oncogenicity Study: Negative at 15 ppm (highest dose)
- °2-Year Rat Oncogenicity Study: RBC ChE NOEL = 0.1 mg/kg/day
Systemic NOEL = 3.0 mg/kg/day (highest dose)
Oncogenic potential: negative
- °2-Year Dog Feeding Study: RBC ChE NOEL = 0.1 mg/kg/day
Systemic NOEL = 3.0 mg/kg/day (highest dose)

The ADI is based on the RBC ChE NOEL of 0.1 mg/kg/day in the 2-year rat feeding study. This is the most sensitive species for which chronic toxicity are available. A 10-fold safety factor was used to calculate the ADI.

$$ADI = NOEL \times \frac{1}{10}$$

$$ADI = 0.1 \text{ mg/kg/day} \times \frac{1}{10} = 0.01 \text{ mg/kg/day}$$

The MPI for a 60 kg person is 0.6 mg/day

Published tolerances currently utilize 74.54% of the ADI (see attached computer printout). Unpublished but Tox approved tolerances utilize an additional 27.39%. The current action, will add an additional 1.16% of the % of the ADI utilized, raising this % to 103.09%.

Discussion:

Data gaps for Chlorpyrifos are rat teratology and repeat rat reproduction studies. These studies have been requested, protocols discussed between the Agency and the registrant, and they are presumably underway at the present time.

The % of the ADI utilized will surpass 100% with the establishment of all requested tolerances and it is recommended that future requests for additional tolerances be viewed cautiously.

Gary J. Burin

Gary J. Burin, Toxicologist
Review Section V

Toxicology Branch/HED (TS-769) *4/1/83*

Attachment

TS-769:th:TOX/HED:GJBurin:3-28-83:card 4

File last updated 3/28/83

ACCEPTABLE DAILY INTAKE DATA

RAT, Older	NOEL	S.F.	ADI	MPI
mg/kg	ppm		mg/kg/day	mg/day (60kg)
0.100	2.00	10	0.0100	0.6000

Published Tolerances

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Bananas (7)	0.050	1.42	0.00107
Corn, all types (38)	0.100	2.51	0.00377
Cottonseed (oil) (41)	0.500	0.15	0.00112
Eggs (54)	0.100	2.77	0.00416
Hogs (69)	0.500	3.43	0.02575
Milk&Dairy Products (93)	0.020	28.62	0.00858
Peaches (114)	0.050	0.90	0.00067
Almonds (1)	0.050	0.03	0.00002
Sugar, cane&beet (154)	0.200	3.64	0.01091
Pears (116)	0.050	0.26	0.00019
Plums, not prunes (124)	0.050	0.09	0.00007
Sweet Potatoes (157)	0.100	0.40	0.00060
Sorghum (147)	0.750	0.03	0.00034
Molasses (96)	3.000	0.03	0.00138
Broccoli (19)	2.000	0.10	0.00307
Cabbage, sauerkraut (22)	2.000	0.74	0.02207
Cauliflower (27)	2.000	0.07	0.00215
Rutabagas (139)	3.000	0.03	0.00135
Tomatoes (163)	0.500	2.87	0.02156
Radishes (133)	3.000	0.03	0.00135
Nectarines (100)	0.050	0.03	0.00002
Brussel Sprouts (20)	2.000	0.03	0.00090
Peanuts (115)	0.500	0.36	0.00268
Cucumbers, inc pickl (46)	0.100	0.73	0.00109
Pumpkin, inc squash (131)	0.100	0.11	0.00017
Seed&Pod Veg (143)	0.100	3.66	0.00549
Mint (193)	1.000	0.03	0.00045
Turnips (165)	3.000	0.05	0.00230
Turnip Greens (166)	1.000	0.03	0.00045
Chinese Cabbage (177)	2.000	0.03	0.00090
Peppers (120)	1.000	0.12	0.00184
Prunes (130)	0.050	0.04	0.00003
Goats (62)	1.000	0.03	0.00045
Sheep (145)	1.000	0.19	0.00291
Poultry (128)	0.500	2.94	0.02207
Horses (208)	1.000	0.03	0.00045
Strawberries (152)	0.500	0.18	0.00138
Soybeans (oil) (148)	0.500	0.92	0.00689
Cattle (26)	2.000	7.18	0.21553
Onion (dry bulb) (106)	0.500	0.72	0.00537
Sunflower (156)	0.250	0.03	0.00011
Citrus Fruits (33)	1.000	3.81	0.05718
Grapes, not raisins (67)	0.500	0.45	0.00337
Cherries (30)	2.000	0.10	0.00307
Apples (2)	0.050	2.53	0.00190
Figs (57)	0.100	0.03	0.00005

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MPI	TMRC	% ADI
0.6000 mg/day (60kg)	0.4472 mg/day (1.5kg)	74.54

Unpublished, Tox Approved 2E2644, 2682, 1G2438, 1F2620, 2778, 2684

CROP	Tolerance	Food Factor	mg/day (1.5kg)
All foods (197)	0.025	100.00	0.03750
Wheat (170)	0.150	10.36	0.02332
Asparagus (5)	2.000	0.14	0.00429
Cranberries (44)	1.000	0.03	0.00045
Almonds (1)	0.150	0.03	0.00007
Walnuts (167)	0.050	0.03	0.00002
Apples (2)	1.450	2.53	0.05503
Sugar, cane & beet (154)	0.800	3.64	0.04366

MPI	TMRC	% ADI
0.6000 mg/day (60kg)	0.6116 mg/day (1.5kg)	101.93

Current Action 3E2819

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Collards (37)	2.000	0.08	0.00245
Kale (75)	2.000	0.03	0.00090
Kohlrabi (76)	2.000	0.03	0.00090
Mustard Greens (99)	2.000	0.06	0.00184
<u>4 Brassica leafy vego.</u> (214)	2.000	0.03	0.00090

MPI	TMRC	% ADI
0.6000 mg/day (60kg)	0.6186 mg/day (1.5kg)	103.09

* Chinese broccoli, broccoli raab, savoy cabbage + rape greens

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