RCB 5483
4-1-83

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

Maybe
Fale petition

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 the "crop grouping" approach for Brassica leafy vegetables should be determined by RCB.

Summary of Toxicity Data:

°Acute Rat Oral $LD_{50}$ = 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 Unpublished but Tox approved tolerances utilize an additional 27.39%.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%.

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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 recommened that future requests for additional tolerances be viewed cautiously.

Gary J. Burin 4/1/83

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 mg/kg | ppm | S.F. | ADI mg/kg/day | MPI 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 |

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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 |

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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 |
| 4 Brassica leafy vegs.* (214) | 2.000 | 0.03 | 0.00090 |

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

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

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