

US EPA ARCHIVE DOCUMENT

PMSD/ISB

2442



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

MAY 20 1988

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#0F2389. Tolerance Request For Residues of  
Permethrin in or on Alfalfa: Revised TAS Dietary  
Exposure Analysis.

FROM: Susan L. Stanton  
Tolerance Assessment Program *Susan L. Stanton 05/20/88*  
HED/RCB (TS-769C)

THRU: Karl Arne, Ph.D. *KArne*  
Branch Senior Scientist  
HED/RCB (TS-769C)

TO: George LaRocca/Adam Heyward, PM #15  
Insecticide - Rodenticide Branch  
Registration Division (TS-767C)

Action Requested

Provide a revised TAS dietary exposure analysis of the  
proposed use of the insecticide permethrin in or on alfalfa.

A previous analysis was conducted using proposed tolerances  
from the RCB review of 03/04/88 (memo Dodd to LaRocca). The  
petitioner has since been asked to submit a revised Section F  
which includes proposed tolerances for hogs, poultry, and eggs as  
well as the previously proposed tolerances for alfalfa; meat,  
fat, and meat byproducts of cattle, goats, horses, and sheep; and  
milk fat (personal communication, Nancy Dodd, 05/20/88). The  
present analysis incorporates these changes.

Discussion

1. A routine chronic analysis was conducted using a  
Reference Dose (ADI) of 0.05 mg/kg body weight/day based on a  
NOEL of 5 mg/kg/day from a 2-year rat feeding study with a  
safety factor of 100. This value has been approved by the Tox  
Branch ADI Committee (09/12/86) and verified by the Agency  
reference dose committee (10/28/86).

2. The food uses evaluated were those for which tolerances are established under 40 CFR 180.378, the proposed use on alfalfa, and other pending tolerances (including proposed tolerances on avocados, papayas, dry bulb onions, and sunflower seeds and a proposed increase in the tolerance for asparagus from 1 to 2 ppm). Table 1 provides a complete listing of residue information.

3. The TAS routine chronic analysis calculates the Theoretical Maximum Residue Contribution (TMRC) for the U.S. population and each of 22 population subgroups (see Table 2) and compares this exposure estimate to the reference dose (ADI in this case).

The TMRC from all food uses (including the new use on alfalfa and other pending tolerances) for the U.S. Population is calculated to be 0.017974 mg/kg body weight/day, which occupies approximately 36% of the ADI. The two most highly exposed population subgroups are infants (TMRC = 0.033779 mg/kg/day or 68% of the ADI) and children, ages 1 to 6 (TMRC = 0.030448 mg/kg/day or 61% of the ADI). Table 3 provides a more detailed summary of the analysis for these 3 populations and includes estimates of exposure by tolerance type (published, new action, and other pending).

4. This analysis uses tolerance level residues with an assumption of 100% crop treated, a conservative approach that likely overestimates exposure significantly. However, since estimated exposure and risk using this approach are acceptable, no further data are required at this time.

cc: TAS File  
Reading File  
circ.  
PP#0F2389

TOX (Rathman)  
Permethrin SF  
PMSD

Table 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 652BB

DATE: 05/20/88

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| CHEMICAL           | STUDY TYPE         | EFFECTS                   | REFERENCE DOSES   | DATA GAPS/COMMENTS        | STATUS                  |
|--------------------|--------------------|---------------------------|-------------------|---------------------------|-------------------------|
| Permethrin         | 2yr feeding- rat   | Decreased liver weights.  | ADI SF --> 100    | No data gaps.             | TOX complete 9/12/86.   |
| Caswell #652BB     | NOEL= 5.0000 mg/kg | Slight increase in liver  | OPP RfD= 0.050000 | Slight increase in liver  | EPA verified 10/28/86.  |
| CAS No. 52645-53-1 | 100.00 ppm         | Weights noted at 5 mg/kg. | EPA RfD= 0.050000 | weights at 5 mg/kg only   | WHO last reviewed 1987; |
| A.I. CODE: 109701  | LEL= 25.0000 mg/kg | Evidence of oncogenicity  |                   | noted in 1/3 rat studies, | (ADI extended to 25:75  |
| CFR No. 180.378    | 500.00 ppm         | in mice (liver, lung),    |                   | not considered toxicolo-  | mixture).               |
|                    | ONCO: Pending WOTE | negative rat.             | Q*= 0.022000      | gically significant.      | On IRIS.                |

| FOOD CODE | FOOD NAME                              | PETITION NUMBER | NEW | TOLERANCE (PPM) | PUBLISHED |
|-----------|--|-----------------|-----|-----------------|-----------|
| 03001AA   | ALMONDS                                | 2F2675          |     |                 | 0.0500    |
| 03005AA   | FILBERTS/HAZELNUTS                     | 4F3130          |     |                 | 0.0500    |
| 03009AA   | WALNUTS                                | 4F3130          |     |                 | 0.0500    |
| 03011AA   | PISTACHIO NUTS                         | 4F2995          |     |                 | 0.1000    |
| 04001AA   | APPLES-FRESH                           | 1F2562          |     |                 | 0.0500    |
| 04001DA   | APPLES-DRIED                           | 1F2562          |     |                 | 0.0500    |
| 04001JA   | APPLES-JUICE                           | 1F2562          |     |                 | 0.0500    |
| 04003AA   | PEARS-FRESH                            | 0F2425          |     |                 | 3.0000    |
| 04003DA   | PEARS-DRIED                            | 0F2425          |     |                 | 3.0000    |
| 05002AA   | CHERRIES-FRESH                         | 5F3271          |     |                 | 3.0000    |
| 05002DA   | CHERRIES-DRIED                         | 5F3271          |     |                 | 3.0000    |
| 05002JA   | CHERRIES-JUICE                         | 5F3271          |     |                 | 3.0000    |
| 05004AA   | PEACHES-FRESH                          | 3F2802          |     |                 | 3.0000    |
| 05004DA   | PEACHES-DRIED                          | 3F2802          |     |                 | 5.0000    |
| 06001AA   | AVOCADOS                               | 4E3146          |     | 1.0000          |           |
| 06010AA   | PAPAYAS-UNSPECIFIED                    | 4E3146          |     | 1.0000          |           |
| 06010AB   | PAPAYAS-PULP                           | 4E3186          |     | 1.0000          |           |
| 06010DA   | PAPAYAS-DRIED                          | 4E3186          |     | 1.0000          |           |
| 06010JA   | PAPAYAS-JUICE                          | 4E3186          |     | 1.0000          |           |
| 06018AA   | KIWI                                   | 1E2514          |     |                 | 2.0000    |
| 08022AA   | HORSERADISH                            | 0E2377          |     |                 | 1.0000    |
| 10002AA   | CANTALOUPE-UNSPECIFIED                 | 5E3225          |     |                 | 3.0000    |
| 10002AB   | CANTALOUPE-PULP                        | 5E3225          |     |                 | 3.0000    |
| 10011AA   | PUMPKIN                                | 3E2861          |     |                 | 2.0000    |
| 11001AA   | EGGPLANT                               | 3E2892          |     |                 | 1.0000    |
| 11003AA   | PEPPERS (SWEET/GARDEN)                 | 3E2892          |     |                 | 1.0000    |
| 11005AA   | TOMATOES-WHOLE                         | 4F2985          |     |                 | 2.0000    |
| 11005JA   | TOMATOES-JUICE                         | 4F2985          |     |                 | 2.0000    |
| 11005RA   | TOMATOES-PUREE                         | 4F2985          |     |                 | 2.0000    |
| 11005TA   | TOMATOES-PASTE                         | 4F2985          |     |                 | 2.0000    |
| 11005UA   | TOMATOES-CATSUP                        | 4F2985          |     |                 | 2.0000    |
| 13002AA   | CELERY                                 | 8F2099          |     |                 | 5.0000    |
| 13003AA   | CHICORY (FRENCH OR BELGIAN ENDIVE)     | 4F3018          |     |                 | 20.0000   |
| 13005AA   | BRUSSELI                               | 9F2207          |     |                 | 1.0000    |
| 13006AA   | BRUSSEL SPROUTS                        | 9F2207          |     |                 | 1.0000    |
| 13007AA   | CABBAGE-GREEN AND RED                  | 9F2192          |     |                 | 6.0000    |
| 13008AA   | CAULIFLOWER                            | 9F2207          |     |                 | 1.0000    |
| 13009AA   | COLLARDS                               | 6E3360          |     |                 | 20.0000   |
| 13010AA   | CABBAGE-CHINESE/CELERY (INC. BOK CHOY) | 9F2192          |     |                 | 6.0000    |
| 13013AA   | LETTUCE-LEAFY VARIETIES                | 4F3018          |     |                 | 20.0000   |

Table 1. (cont.)

| CHEMICAL           | STUDY TYPE         | EFFECTS                   | REFERENCE DOSES   |                           | DATA GAPS/COMMENTS | STATUS                  |
|--------------------|--------------------|---------------------------|-------------------|---------------------------|--------------------|-------------------------|
|                    |                    |                           | ADI               | SF                        |                    |                         |
| Permethrin         | 2yr feeding- rat   | Decreased liver weights.  | 100               | No data gaps.             |                    | TOX complete 9/12/86.   |
| Caswell #652BB     | NOEL= 5.0000 mg/kg | Slight increase in liver  | OPP RfD= 0.050000 | Slight increase in liver  |                    | EPA verified 10/28/86.  |
| CAS No. 52645-53-1 | 100.00 ppm         | weights noted at 5 mg/kg. | EPA RfD= 0.050000 | weights at 5 mg/kg only   |                    | WHO last reviewed 1987; |
| A.I. CODE: 109701  | LEL= 25.0000 mg/kg | Evidence of oncogenicity  |                   | noted in 1/3 rat studies, |                    | (ADI extended to 25:75  |
| CFR No. 180.378    | 500.00 ppm         | in mice (liver, lung),    |                   | not considered toxicolo-  |                    | mixture).               |
|                    | ONCO: Pending NOTE | negative rat.             | Q*= 0.022000      | gically significant.      |                    | On IRIS.                |

| FOOD CODE | FOOD NAME                   | PETITION NUMBER | NEW | TOLERANCE (PPM) |           |
|-----------|-----------------------------|-----------------|-----|-----------------|-----------|
|           |                             |                 |     | PENDING         | PUBLISHED |
| 13014AA   | DANDELION                   | 4F3018          |     |                 | 20.0000   |
| 13015AA   | ENDIVE (CURLY AND ESCAROLE) | 4F3018          |     |                 | 20.0000   |
| 13016AA   | FENNEL                      | 8F2099          |     |                 | 5.0000    |
| 13017AA   | CRESS (GARDEN/FIELD)        | 4F3018          |     |                 | 20.0000   |
| 13018AA   | ARTICHOKES-GLOBE            | 4F3114          |     |                 | 10.0000   |
| 13020AA   | LETTUCE-UNSPECIFIED         | 4F3018          |     |                 | 20.0000   |
| 13022AA   | PARSLEY                     | 4F3018          |     |                 | 20.0000   |
| 13023AA   | RHUBARB                     | 4F3018          |     |                 | 20.0000   |
| 13024AA   | SPINACH                     | 2E2701          |     |                 | 20.0000   |
| 13025AA   | SWISS CHARD                 | 4F3018          |     |                 | 20.0000   |
| 13026AA   | TURNIPS-TOPS                | 6E3360          |     |                 | 20.0000   |
| 13027AA   | WATERCRESS                  | 4E3113          |     |                 | 5.0000    |
| 13039AA   | CRESS/UPLAND                | 4F3018          |     |                 | 20.0000   |
| 13045AA   | LETTUCE-HEAD VARIETIES      | 9F2192          |     |                 | 20.0000   |
| 14007AA   | GARLIC                      | 8E3583          |     | 0.1000          |           |
| 14011AA   | ONIONS-DRY-BULB (CIPOLLINI) | 8E3583          |     | 0.1000          |           |
| 14011DA   | ONIONS-DEHYDRATED OR DRIED  | 8E3583          |     | 0.1000          |           |
| 14013AA   | POTATOES(WHITE)-WHOLE       | 0F2307          |     |                 | 0.0500    |
| 14013AB   | POTATOES(WHITE)-UNSPECIFIED | 0F2307          |     |                 | 0.0500    |
| 14013AC   | POTATOES(WHITE)-PEELED      | 0F2307          |     |                 | 0.0500    |
| 14013DA   | POTATOES(WHITE)-DRY         | 0F2307          |     |                 | 0.0500    |
| 14013HA   | POTATOES(WHITE)-PEEL ONLY   | 0F2307          |     |                 | 0.0500    |
| 14017AA   | SHALLOTS                    | 8E3583          |     | 0.1000          |           |
| 14019AA   | TURNIPS-ROOTS               | 6E3360          |     |                 | 1.0000    |
| 15004AA   | CORN/POP                    | 1F2476          |     |                 | 0.0500    |
| 15005AA   | CORN/SWEET                  | 3F2781          |     |                 | 0.1000    |
| 15018AA   | SUNFLOWER-SEEDS             | 4F2981          |     |                 |           |
| 15029AA   | SOYBEANS-SPROUTED SEEDS     | 9F2196          |     | 0.0500          |           |
| 16002AA   | ASPARAGUS                   | 3E2914          |     |                 | 1.0000    |
| 16002AA   | ASPARAGUS                   | 8F3595          |     |                 |           |
| 16003AA   | MUSHROOMS                   | 2F2752          |     | 1.0000          |           |
| 24002EA   | CORN/GRAIN-ENDOSPERM        | 1F2476          |     |                 | 6.0000    |
| 24002HA   | CORN/GRAIN-BRAN             | 1F2476          |     |                 | 0.0500    |
| 24002SA   | CORN SUGAR                  | 1F2476          |     |                 | 0.0500    |
| 270020A   | CORN/GRAIN-OIL              | 1F2476          |     |                 | 0.0500    |
| 270030A   | COTTONSEED-OIL              |                 |     |                 | 0.5000    |
| 27003WA   | COTTONSEED-MEAL             |                 |     |                 | 0.5000    |
| 270100A   | SOYBEANS-OIL                |                 |     |                 | 0.5000    |
| 270110A   | SUNFLOWER-OIL               |                 |     | 0.0500          |           |
| 28023AA   | SOYBEANS-UNSPECIFIED        |                 |     |                 | 0.0500    |

Table 1 (cont.)

| CHEMICAL           | STUDY TYPE         | EFFECTS                   | REFERENCE DOSES   |     | DATA GAPS/COMMENTS        | STATUS                  |
|--------------------|--------------------|---------------------------|-------------------|-----|---------------------------|-------------------------|
|                    |                    |                           | ADI               | SF  |                           |                         |
| Permethrin         | 2yr feeding- rat   | Decreased liver weights.  | 100               | --> | No data gaps.             | TOX complete 9/12/86.   |
| Caswell #652BB     | NOEL= 5.0000 mg/kg | Slight increase in liver  | 0.050000          |     | Slight increase in liver  | EPA verified 10/28/86.  |
| CAS No. 52645-53-1 | 100.00 ppm         | Weights noted at 5 mg/kg. | EPA RED= 0.050000 |     | weights at 5 mg/kg only   | WHO last reviewed 1987; |
| A. I. CODE: 109701 | LEL= 25.0000 mg/kg | Evidence of oncogenicity  |                   |     | noted in 1/3 rat studies, | (ADI extended to 25:75  |
| CFR No. 180.378    | 500.00 ppm         | in mice (liver, lung),    | Q*= 0.022000      |     | not considered toxicolo-  | mixture).               |
|                    | ONCO: Pending NOTE | negative rat.             |                   |     | gically significant.      | On IRIS.                |

| FOOD CODE | FOOD NAME                                 | PETITION NUMBER | TOLERANCE (PPM) |                   |
|-----------|---|-----------------|-----------------|-------------------|
|           |   |                 | NEW             | PENDING PUBLISHED |
| 28023AB   | SOYBEANS-NATURE/SEEDS DRY                 | 9F2196          |                 | 0.0500            |
| 28023WA   | SOYBEANS-FLOUR/FULL FAT                   | 9F2196          |                 | 0.0500            |
| 28023WB   | SOYBEANS-FLOUR/LOW FAT                    | 9F2196          |                 | 0.0500            |
| 28023WC   | SOYBEANS-FLOUR/DEFATTED                   | 9F2196          |                 | 0.0500            |
| 50000FA   | MILK-FAT SOLIDS                           | 3F2781          |                 | 3.7500 H          |
| 50000FA   | MILK-FAT SOLIDS                           | 0F2389          | 2.5000          | H                 |
| 53001BA   | BEEF-MEAT BYPRODUCTS                      | 1F2564          | 1.0000          |                   |
| 53001BA   | BEEF-MEAT BYPRODUCTS                      | 0F2389          | 1.0000          |                   |
| 53001BB   | BEEF (ORGAN MEATS)-OTHER                  | 1F2564          | 1.0000          |                   |
| 53001BB   | BEEF (ORGAN MEATS)-OTHER                  | 0F2389          | 1.0000          |                   |
| 53001DA   | BEEF-DRIED                                | 1F2564          | 1.0000          |                   |
| 53001DA   | BEEF-DRIED                                | 0F2389          | 0.1000          |                   |
| 53001FA   | BEEF (BONELESS)-FAT (BEEF TALLOW)         | 1F2564          | 1.0000          |                   |
| 53001FA   | BEEF (BONELESS)-FAT (BEEF TALLOW)         | 0F2389          | 1.0000          |                   |
| 53001KA   | BEEF (ORGAN MEATS)-KIDNEY                 | 1F2564          | 1.0000          |                   |
| 53001KA   | BEEF (ORGAN MEATS)-KIDNEY                 | 0F2389          | 1.0000          |                   |
| 53001LA   | BEEF (ORGAN MEATS)-LIVER                  | 1F2564          | 1.0000          |                   |
| 53001LA   | BEEF (ORGAN MEATS)-LIVER                  | 0F2389          | 1.0000          |                   |
| 53001MA   | BEEF (BONELESS)-LEAN (W/O REMOVEABLE FAT) | 1F2564          | 1.0000          |                   |
| 53001MA   | BEEF (BONELESS)-LEAN (W/O REMOVEABLE FAT) | 0F2389          | 0.1500          |                   |
| 53002BA   | GOAT-MEAT BYPRODUCTS                      | 1F2564          | 1.0000          |                   |
| 53002BA   | GOAT-MEAT BYPRODUCTS                      | 0F2389          | 1.0000          |                   |
| 53002BB   | GOAT (ORGAN MEATS)-OTHER                  | 1F2564          | 1.0000          |                   |
| 53002BB   | GOAT (ORGAN MEATS)-OTHER                  | 0F2389          | 1.0000          |                   |
| 53002FA   | GOAT (BONELESS)-FAT                       | 1F2564          | 1.0000          |                   |
| 53002FA   | GOAT (BONELESS)-FAT                       | 0F2389          | 2.0000          |                   |
| 53002KA   | GOAT (ORGAN MEATS)-KIDNEY                 | 1F2564          | 1.0000          |                   |
| 53002KA   | GOAT (ORGAN MEATS)-KIDNEY                 | 0F2389          | 1.0000          |                   |
| 53002LA   | GOAT (ORGAN MEATS)-LIVER                  | 1F2564          | 1.0000          |                   |
| 53002LA   | GOAT (ORGAN MEATS)-LIVER                  | 0F2389          | 1.0000          |                   |
| 53002MA   | GOAT (BONELESS)-LEAN (W/O REMOVEABLE FAT) | 1F2564          | 1.0000          |                   |
| 53002MA   | GOAT (BONELESS)-LEAN (W/O REMOVEABLE FAT) | 0F2389          | 0.1500          |                   |
| 53003AA   | HORSE                                     | 1F2564          | 2.0000          |                   |
| 53003AA   | HORSE                                     | 0F2389          | 2.0000          |                   |
| 53005BA   | SHEEP-MEAT BYPRODUCTS                     | 1F2564          | 1.0000          |                   |
| 53005BA   | SHEEP-MEAT BYPRODUCTS                     | 0F2389          | 1.0000          |                   |
| 53005BB   | SHEEP (ORGAN MEATS)-OTHER                 | 1F2564          | 1.0000          |                   |
| 53005BB   | SHEEP (ORGAN MEATS)-OTHER                 | 0F2389          | 1.0000          |                   |
| 53005FA   | SHEEP (BONELESS)-FAT                      | 1F2564          | 1.0000          |                   |
| 53005FA   | SHEEP (BONELESS)-FAT                      | 0F2389          | 2.0000          |                   |

Table 1 (cont.)

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DATE: 05/20/88

CHEMICAL INFORMATION FOR CASWELL NUMBER 652BB

| CHEMICAL           | STUDY TYPE         | EFFECTS                   | REFERENCE DOSES   |                           | DATA GAPS/COMMENTS      | STATUS |
|--------------------|--------------------|---------------------------|-------------------|---------------------------|-------------------------|--------|
|                    |                    |                           | ADI               | SF -->                    |                         |        |
| Permethrin         | 2yr feeding- rat   | Decreased liver weights.  | 100               | No data gaps.             | TOX complete 9/12/86.   |        |
| Caswell #652BB     | NOEL= 5.0000 mg/kg | Slight increase in liver  | OPP RfD= 0.050000 | Slight increase in liver  | EPA verified 10/28/86.  |        |
| CAS No. 52645-53-1 | 100.00 ppm         | weights noted at 5 mg/kg. | EPA RfD= 0.050000 | weights at 5 mg/kg only   | WHO last reviewed 1987; |        |
| A.I. CODE: 109701  | LEL= 25.0000 mg/kg | Evidence of oncogenicity  |                   | noted in 1/3 rat studies, | (ADI extended to 25:75  |        |
| CFR No. 180.378    | 500.00 ppm         | in mice (liver, lung),    |                   | not considered toxicolo-  | mixture).               |        |
|                    | ONCO: Pending NOTE | negative rat.             | Q* = 0.022000     | gically significant.      | On IRIS.                |        |

| FOOD CODE | FOOD NAME                                 | PETITION NUMBER | NEW    | TOLERANCE (PPM) |           |
|-----------|---|-----------------|--------|-----------------|-----------|
|           |   |                 |        | PENDING         | PUBLISHED |
| 53005KA   | SHEEP (ORGAN MEATS)-KIDNEY                | 1F2564          |        |                 | 1.0000    |
| 53005KA   | SHEEP (ORGAN MEATS)-KIDNEY                | 0F2389          | 1.0000 |                 |           |
| 53005LA   | SHEEP (ORGAN MEATS)-LIVER                 | 1F2564          |        |                 | 1.0000    |
| 53005LA   | SHEEP (ORGAN MEATS)-LIVER                 | 0F2389          | 1.0000 |                 |           |
| 53005MA   | SHEEP (BONELESS)-LEAN (W/O REMOVEABLE FAT | 1F2564          |        |                 | 0.1500    |
| 53005MA   | SHEEP (BONELESS)-LEAN (W/O REMOVEABLE FAT | 0F2389          | 0.1000 |                 |           |
| 53006BA   | PORK-MEAT BYPRODUCTS                      | 1F2546          |        |                 | 3.0000    |
| 53006BB   | PORK (ORGAN MEATS)-OTHER                  | 1F2546          |        |                 | 3.0000    |
| 53006FA   | PORK (BONELESS)-FAT (INCLUDING LARD)      | 1F2546          |        |                 | 2.0000    |
| 53006FA   | PORK (BONELESS)-FAT (INCLUDING LARD)      | 0F2389          | 1.0000 |                 |           |
| 53006KA   | PORK (ORGAN MEATS)-KIDNEY                 | 1F2546          |        |                 | 3.0000    |
| 53006LA   | PORK (ORGAN MEATS)-LIVER                  | 1F2546          |        |                 | 3.0000    |
| 53006MA   | PORK (BONELESS)-LEAN (W/O REMOVEABLE FAT) | 1F2546          |        |                 | 0.1500    |
| 53006MA   | PORK (BONELESS)-LEAN (W/O REMOVEABLE FAT) | 0F2389          | 0.1000 |                 |           |
| 55008BA   | TURKEY-BYPRODUCTS                         | 1F2564          |        |                 | 0.0500    |
| 55008BA   | TURKEY-BYPRODUCTS                         | 0F2389          | 0.2000 |                 |           |
| 55008LA   | TURKEY-GIBLETS (LIVER)                    | 1F2564          |        |                 | 0.0500    |
| 55008LA   | TURKEY-GIBLETS (LIVER)                    | 0F2389          | 0.2000 |                 |           |
| 55008NA   | TURKEY-FLESH(W/O SKIN & W/O BONES)        | 1F2564          |        |                 | 0.0500    |
| 55008NB   | TURKEY-FLESH(+SKIN & W/O BONES)           | 1F2564          |        |                 | 0.0500    |
| 55008NB   | TURKEY-FLESH(+SKIN, W/O BONES)            | 0F2389          | 0.1000 |                 |           |
| 55008NC   | TURKEY-UNSPECIFIED                        | 1F2564          |        |                 | 0.0500    |
| 55008NC   | TURKEY-UNSPECIFIED                        | 0F2389          | 0.2000 |                 |           |
| 55013BA   | POULTRY/OTHER-BYPRODUCTS                  | 1F2564          |        |                 | 0.0500    |
| 55013BA   | POULTRY/OTHER-BYPRODUCTS                  | 0F2389          | 0.2000 |                 |           |
| 55013LA   | POULTRY/OTHER-GIBLETS (LIVER)             | 1F2564          |        |                 | 0.0500    |
| 55013LA   | POULTRY/OTHER-GIBLETS (LIVER)             | 0F2389          | 0.2000 |                 |           |
| 55013MA   | POULTRY/OTHER-FLESH (+SKIN & W/O BONES)   | 1F2564          |        |                 | 0.0500    |
| 55013MA   | POULTRY/OTHER-FLESH (+SKIN, W/O BONES)    | 0F2389          | 0.1000 |                 |           |
| 55014AA   | EGGS-WHOLE                                | 1F2564          |        |                 | 0.0500    |
| 55014AA   | EGGS-WHOLE                                | 0F2389          | 0.9500 |                 |           |
| 55014AB   | EGGS-WHITE ONLY                           | 1F2564          |        |                 | 0.0500    |
| 55014AB   | EGGS-WHITE ONLY                           | 0F2389          | 0.9500 |                 |           |
| 55014AC   | EGGS-YOLK ONLY                            | 1F2564          |        |                 | 0.0500    |
| 55014AC   | EGGS-YOLK ONLY                            | 0F2389          | 0.9500 |                 |           |
| 55015BA   | CHICKEN-BYPRODUCTS                        | 1F2564          |        |                 | 0.0500    |
| 55015BA   | CHICKEN-BYPRODUCTS                        | 0F2389          | 0.2000 |                 |           |
| 55015LA   | CHICKEN-GIBLETS(LIVER)                    | 1F2564          |        |                 | 0.0500    |
| 55015LA   | CHICKEN-GIBLETS(LIVER)                    | 0F2389          | 0.2000 |                 |           |
| 55015MA   | CHICKEN-FLESH(W/O SKIN & W/O BONES)       | 1F2564          |        |                 | 0.0500    |

Table 1 (cont.)

| CHEMICAL           | STUDY TYPE         | EFFECTS   | REFERENCE DOSES   |        | DATA GAPS/COMMENTS   | STATUS   |
|--------------------|--------------------|---|-------------------|--------|--|--|
|                    |                    |   | ADI               | SF --> |  |  |
| Permethrin         | 2yr feeding- rat   | Decreased liver weights.                                      | AD1               | 1001   | No data gaps.  | TOX complete 9/12/86.                                    |
| Caswell #652BB     | NOEL= 5.0000 mg/kg | Slight increase in liver weights noted at 5 mg/kg.            | OPP RfD= 0.050000 |        | Slight increase in liver weights at 5 mg/kg only noted in 1/3 rat studies, not considered toxicologically significant. | EPA verified 10/28/86.                                   |
| CAS No. 52645-53-1 | 100.00 ppm         | Evidence of oncogenicity in mice (liver, lung), negative rat. | EPA RfD= 0.050000 |        |  | WHO last reviewed 1987; (ADI extended to 25:75 mixture). |
| A. I. CODE: 109701 | LEL= 25.0000 mg/kg |   |                   |        |  |  |
| CFR No. 180.378    | 500.00 ppm         |   | Q*= 0.022000      |        |  | On IRIS.   |
|                    | ONCO: Pending NOTE |   |                   |        |  |  |

| FOOD CODE | FOOD NAME                           | PETITION NUMBER | TOLERANCE (PPM) |           |
|-----------|-------------------------------------|-----------------|-----------------|-----------|
|           |                                     |                 | NEW             | PUBLISHED |
| 55015MB   | CHICKEN-FLESH(+SKIN & W/O BONES)    | 1F2564          |                 | 0.0500    |
| 55015NB   | CHICKEN-FLESH(+SKIN,W/O BONES)      | 0F2389          | 0.1000          |           |
| 90997AA   | INEST. RACS--TOLERANCE TOO SPECIFIC | 1F2546          |                 |           |
| 90999AA   | FEED RACS--INEST. FROM USDA SURVEY  | 2F2675          |                 |           |



## TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 05/20/88

PAGE: 1

| CHEMICAL INFORMATION                            | STUDY TYPE         | EFFECTS                            | REFERENCE DOSES            |                              | DATA GAPS/COMMENTS             |     | STATUS                  |
|---|--------------------|------------------------------------|----------------------------|------------------------------|--------------------------------|-----|-------------------------|
|   |                    |                                    | ADI                        | SF -->                       |                                |     |                         |
| Pemethrin                                       | 2yr feeding- rat   | Decreased liver weights.           |                            | 100                          | No data gaps.                  |     | TOX complete 9/12/86.   |
| Caswell #652BB                                  | NOEL=              | Slight increase in liver           | OPP RFD= 0.050000          |                              | Slight increase in liver       |     | EPA verified 10/28/86.  |
| CAS No. 52645-53-1                              | 100.00 ppm         | weights noted at 5 mg/kg.          | EPA RFD= 0.050000          |                              | weights at 5 mg/kg only        |     | WHO last reviewed 1987; |
| A.I. CODE: 109701                               | LEL=               | Evidence of oncogenicity           |                            |                              | noted in 1/3 rat studies,      |     | (ADI extended to 25:75  |
| CFR No. 180.378                                 | 500.00 ppm         | in mice (liver, lung),             | Q*= 0.022000               |                              | not considered toxicolo-       |     | mixture).               |
|   | ONCO: Pending NOTE | negative rat.                      |                            |                              | gically significant.           |     | On IRIS.                |
| <b>POPULATION SUBGROUP</b>                      |                    |                                    |                            |                              |                                |     |                         |
| U.S. POPULATION - 48 STATES                     |                    | TOTAL TMRC (MG/KG BODY WEIGHT/DAY) | NEW TMRC AS PERCENT OF RFD | DIFFERENCE AS PERCENT OF RFD | EFFECT OF ANTICIPATED RESIDUES | ARC | %RFD                    |
| U.S. POPULATION - SPRING SEASON                 |                    | CURRENT TMRC*                      | NEW TMRC**                 |                              |                                |     |                         |
| U.S. POPULATION - SUMMER SEASON                 |                    | 0.015461                           | 0.017974                   | 35.948832                    | 5.027798                       |     |                         |
| U.S. POPULATION - FALL SEASON                   |                    | 0.015735                           | 0.018212                   | 36.423944                    | 4.954038                       |     |                         |
| U.S. POPULATION - WINTER SEASON                 |                    | 0.016169                           | 0.018662                   | 37.324700                    | 4.987208                       |     |                         |
|   |                    | 0.014907                           | 0.017471                   | 34.941252                    | 5.128212                       |     |                         |
|   |                    | 0.015028                           | 0.017549                   | 35.098264                    | 5.041490                       |     |                         |
| NORTHEAST REGION                                |                    | 0.015873                           | 0.018435                   | 36.869668                    | 5.123958                       |     |                         |
| NORTH CENTRAL REGION                            |                    | 0.015109                           | 0.017575                   | 35.150138                    | 4.931980                       |     |                         |
| SOUTHERN REGION                                 |                    | 0.014257                           | 0.016649                   | 33.297192                    | 4.782686                       |     |                         |
| WESTERN REGION                                  |                    | 0.017503                           | 0.020235                   | 40.470886                    | 5.463946                       |     |                         |
| HISPANICS                                       |                    | 0.015958                           | 0.019141                   | 38.281344                    | 6.365884                       |     |                         |
| NON-HISPANIC WHITES                             |                    | 0.015344                           | 0.017807                   | 35.613224                    | 4.926208                       |     |                         |
| NON-HISPANIC BLACKS                             |                    | 0.015686                           | 0.018174                   | 36.347486                    | 4.975310                       |     |                         |
| NON-HISPANIC OTHERS                             |                    | 0.017983                           | 0.020832                   | 41.663826                    | 5.697294                       |     |                         |
| NURSING INFANTS (< 1 YEAR OLD)                  |                    | 0.013301                           | 0.014399                   | 28.798442                    | 2.197358                       |     |                         |
| NON-NURSING INFANTS (< 1 YEAR OLD)              |                    | 0.029004                           | 0.033779                   | 67.557100                    | 9.549880                       |     |                         |
| FEMALES (13+ YEARS, PREGNANT)                   |                    | 0.012279                           | 0.014030                   | 28.060902                    | 3.503328                       |     |                         |
| FEMALES 13+ YEARS, NURSING                      |                    | 0.016248                           | 0.018528                   | 37.055570                    | 4.559784                       |     |                         |
| CHILDREN (1-6 YEARS OLD)                        |                    | 0.024570                           | 0.030448                   | 60.896800                    | 11.756676                      |     |                         |
| CHILDREN (7-12 YEARS OLD)                       |                    | 0.020830                           | 0.024604                   | 49.208344                    | 7.548582                       |     |                         |
| MALES (13-19 YEARS OLD)                         |                    | 0.014273                           | 0.016970                   | 33.940272                    | 5.394036                       |     |                         |
| FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING) |                    | 0.013113                           | 0.015231                   | 30.461088                    | 4.235910                       |     |                         |
| MALES (20 YEARS AND OLDER)                      |                    | 0.012813                           | 0.014811                   | 29.622612                    | 3.995984                       |     |                         |
| FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS) |                    | 0.013810                           | 0.015477                   | 30.953904                    | 3.334078                       |     |                         |

\*Current TMRC does not include new or pending tolerances.

\*\*New TMRC includes new, pending, and published tolerances.

Table 3

TOLERANCE ASSESSMENT SUMMARY FOR Permethrin  
CASWELL #652BB

DATE: 05/20/88

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

|   |           |               |
|---|-----------|---------------|
| EXISTING TOLERANCES (PUBLISHED ONLY)            |           |               |
| RESULT IN A TMRC OF:                            | 0.015461  | MG/KG/DAY     |
| THE EXISTING TMRC IS EQUIVALENT TO:             | 30.921034 | % OF THE ADI. |
| PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY) |           |               |
| RESULT IN A TMRC OF:                            | 0.002456  | MG/KG/DAY     |
| THESE NEW TOLERANCES WILL OCCUPY:               | 4.912926  | % OF THE ADI. |
| IF THE NEW TOLERANCES (CURRENT PETITION ONLY)   |           |               |
| ARE APPROVED THE RESULTANT TMRC WILL BE:        | 0.017917  | MG/KG/DAY     |
| THE NEW TMRC WILL OCCUPY                        | 35.833960 | % OF THE ADI. |
| OTHER PENDING TOLERANCES EXCLUDING THE          |           |               |
| CURRENT NEW PETITION HAVE A TMRC OF:            | 0.000057  | MG/KG/DAY     |
| THIS TMRC WILL OCCUPY                           | 0.114872  | % OF THE ADI. |
| IF ALL PENDING TOLERANCES (INCLUDING THE        |           |               |
| CURRENT NEW PETITION) ARE GRANTED               |           |               |
| THE RESULTANT TMRC WILL BE:                     | 0.017974  | MG/KG/DAY     |
| THE TOTAL TMRC WILL OCCUPY                      | 35.948832 | % OF THE ADI. |

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

|   |           |               |
|---|-----------|---------------|
| EXISTING TOLERANCES (PUBLISHED ONLY)            |           |               |
| RESULT IN A TMRC OF:                            | 0.029004  | MG/KG/DAY     |
| THE EXISTING TMRC IS EQUIVALENT TO:             | 58.007220 | % OF THE ADI. |
| PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY) |           |               |
| RESULT IN A TMRC OF:                            | 0.004762  | MG/KG/DAY     |
| THESE NEW TOLERANCES WILL OCCUPY:               | 9.523884  | % OF THE ADI. |
| IF THE NEW TOLERANCES (CURRENT PETITION ONLY)   |           |               |
| ARE APPROVED THE RESULTANT TMRC WILL BE:        | 0.033766  | MG/KG/DAY     |
| THE NEW TMRC WILL OCCUPY                        | 67.531104 | % OF THE ADI. |
| OTHER PENDING TOLERANCES EXCLUDING THE          |           |               |
| CURRENT NEW PETITION HAVE A TMRC OF:            | 0.000013  | MG/KG/DAY     |
| THIS TMRC WILL OCCUPY                           | 0.025996  | % OF THE ADI. |
| IF ALL PENDING TOLERANCES (INCLUDING THE        |           |               |
| CURRENT NEW PETITION) ARE GRANTED               |           |               |
| THE RESULTANT TMRC WILL BE:                     | 0.033779  | MG/KG/DAY     |
| THE TOTAL TMRC WILL OCCUPY                      | 67.557100 | % OF THE ADI. |

ANALYSIS FOR POPULATION SUB-GROUP: CHILDREN (1-6 YEARS OLD)

|   |           |               |
|---|-----------|---------------|
| EXISTING TOLERANCES (PUBLISHED ONLY)            |           |               |
| RESULT IN A TMRC OF:                            | 0.024570  | MG/KG/DAY     |
| THE EXISTING TMRC IS EQUIVALENT TO:             | 49.140124 | % OF THE ADI. |
| PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY) |           |               |
| RESULT IN A TMRC OF:                            | 0.005814  | MG/KG/DAY     |
| THESE NEW TOLERANCES WILL OCCUPY:               | 11.627006 | % OF THE ADI. |
| IF THE NEW TOLERANCES (CURRENT PETITION ONLY)   |           |               |
| ARE APPROVED THE RESULTANT TMRC WILL BE:        | 0.030384  | MG/KG/DAY     |
| THE NEW TMRC WILL OCCUPY                        | 60.767130 | % OF THE ADI. |
| OTHER PENDING TOLERANCES EXCLUDING THE          |           |               |
| CURRENT NEW PETITION HAVE A TMRC OF:            | 0.000065  | MG/KG/DAY     |
| THIS TMRC WILL OCCUPY                           | 0.129670  | % OF THE ADI. |
| IF ALL PENDING TOLERANCES (INCLUDING THE        |           |               |
| CURRENT NEW PETITION) ARE GRANTED               |           |               |
| THE RESULTANT TMRC WILL BE:                     | 0.030448  | MG/KG/DAY     |
| THE TOTAL TMRC WILL OCCUPY                      | 60.896800 | % OF THE ADI. |