3-31-97

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 03/31/97

SUBJECT: Tolerance Petition for Residues of **Cyfluthrin** in/on **Citrus Commodities.**

DP Barcode:	D230337	Caswell No.:	266E
PC No.:	128831	PRAT Case #:	285467
Class:	Insecticide	PP#:	4F04313

TO: George LaRocca, Manager, PM Team 13
Adam Heyward, Reviewer, PM Team 13
Registration Division (7505C)

FROM: George Kramer, Kathryn Boyle, Felecia Fort, Rich Griffin, Linnea Hansen, Barbara Madden, Deborah McCall and Steve Robbins
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Risk Characterization and Analysis Branch
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THROUGH: Michael S. Metzger, Acting Chief
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INTRODUCTION

Bayer Co. is petitioning for tolerances for cyfluthrin in/on citrus (PP#4F4313) from use of Baythroid® 2 Insecticide (3125-351). The proposed tolerances for residues of cyfluthrin, expressed as parent only, are:

Citrus, fruits,	0.2 ppm
Citrus, oil,	0.3 ppm
Citrus, dried pulp,	0.3 ppm

The product is intended for control of citrus thrips in CA and AZ. This petition is being examined with regard to the criteria set forth in the Food Quality Protection Act (FQPA). The Registrant submitted no new toxicology or residue chemistry data with this petition, but did include (1) a dietary exposure and risk

assessment for cyfluthrin including both current and proposed uses; and (2) a discussion of the impact of the FQPA on the proposed citrus tolerances.

RECOMMENDATION

HED has evaluated the petition for the establishment of tolerances for cyfluthrin on citrus commodities. At this time, no additional concerns for exposure to infants and children are identified. Estimated aggregate chronic and short-term risk from combined dietary, non-dietary and drinking water exposure for cyfluthrin does not exceed HED's level of concern for the purposes of establishing the proposed tolerances.

The acute and chronic dietary risk assessments were conducted using residue values for parent cyfluthrin only. Residue values for DCVA metabolites were not considered in the dietary risk assessments because of the absence of residue data for these metabolites. In the absence of these data, **HED can not recommend in favor of the proposed tolerances for cyfluthrin on citrus commodities.**

However, due to the high MOE (666) for the acute dietary risk assessment and low percentage of the RfD occupied by this proposed use plus all of the registered cyfluthrin uses, HED believes that the risk would not exceed our level of concern even if the DCVA metabolites were included in the risk assessment. HED could thus recommend in favor of granting the proposed tolerances on a **time-limited** basis **provided** that the petitioner commits to providing EPA with new ruminant feeding studies where residues of cis- and trans-DCVA and parent cyfluthrin are reported.

RISK CHARACTERIZATION

Dietary Risk- Food: Chronic dietary exposure estimates for cyfluthrin utilized **anticipated residues and percent crop treated** data where available. The published and proposed cyfluthrin tolerances for citrus commodities result in a Anticipated Residue Contribution (ARC) that is up to 12% of the reference dose. For acute dietary risk for the population subgroup of concern, females (13+ years old), the calculated Margin Of Exposure (MOE) value is 666. HED considers the acute and chronic dietary risks to be acceptable for the purposes of establishing the time-limited tolerances.

Dietary Risk- Water: HED does not have available data to perform a quantitative drinking water risk assessment for cyfluthrin at this time. No monitoring data are available. However, since

environmental fate data indicate that cyfluthrin is moderately persistent and relatively immobile in soil and water, **water risks will be assumed to account for 10% of the total allowable chronic and acute risk** until further data are provided (PR 97-1, 1/31/97). Based on analysis of water monitoring data for a large number of pesticides with varying toxicities, soil mobility characteristics, environmental fate profiles, the assumption of 10% of the total acute and chronic risk allocated to drinking water is considered conservative and protective of the public health.

Non-occupational (Residential) Risks: Cyfluthrin is registered for use on non-food sites including golf courses, lawns, ornamental shrubs, indoor fogger, wood surfaces, and human bedding. Upon considering the registered uses, formulation types, persistence, and toxicological endpoints, and in accordance with OPP Interim Decision Logic (PR 97-1, 1/31/97), HED has determined that, in the absence of exposure data, the registered non-dietary, non-occupational uses of cyfluthrin should be assigned a default value of 20% of the acceptable aggregate chronic; and short- and intermediate-term risk.

Aggregate Exposure/Risk: Based on the available data and assumptions used for dietary/water/residential exposure and risk estimates, the population group estimated to be the most highly exposed to cyfluthrin is non-nursing infants (<1 year old), with a risk estimate from combined sources equalling 42% of the RfD for chronic risk. For short-term risk, the calculated MOE for children (1-6 years old) is 527. HED considers the chronic and short-term risks to be acceptable for the purposes of establishing the time-limited tolerances.

Occupational Exposures: Occupational exposure and risk estimates for mixer/loaders and applicators of cyfluthrin indicate that MOEs are acceptable for the use of open pouring systems and open cabs during application.

CONCLUSIONS

Hazard Assessment for Cyfluthrin

1. Occupational Exposure Endpoint Selection

   a) Short- and Intermediate-Term Dermal Risk. For short- and intermediate-term dermal MOE calculations, an Ad Hoc TES Committee [SAB Chief, TB II Chief, TB I Chief, TB II Section Head, TB II Section Head, TB I reviewer] recommended use of the dermal toxicity NOEL of 250 mg/kg/day (highest dose tested) from the 21-day dermal rabbit toxicity study (MRID No. 00131527). There was no LOEL in the study.

b) Short- and Intermediate-Term Inhalation Risk. For short- and intermediate-term inhalation MOE calculations, an Ad Hoc TES Committee (TB I Chief, TB I Section Head, TB I reviewer and RCAB Section Head) recommended use of the maternal and developmental NOEL of 0.46 mg/m^3 from a rat inhalation developmental toxicity study (MRID No. 433934-01). The maternal (systemic) LOEL of 2.55 mg/m^3 was based on decreased body weight gain and reduced food efficiency.

c) Chronic Risk. Chronic MOE calculations have not been performed for occupational exposure since a chronic exposure scenario does not exist for this use pattern.

d) Cancer Risk. Cyfluthrin has been classified as a Group E chemical (evidence of non-carcinogenicity for humans) by the HED RfD Peer Review Committee. The classification was based on a lack of convincing evidence of carcinogenicity in adequate studies with two animal species, rat and mouse.

e) Dermal Penetration. The default value of 100% is being used for dermal penetration in the absence of actual data.

2. Dietary Endpoint Selection

a) Acute Dietary Risk. 20 mg/kg/day. For acute dietary risk assessment, an Ad Hoc TES Committee (same as above) recommended use of the NOEL of 20 mg/kg/day, based on resorptions at the LOEL of 60 mg/kg/day, from the oral developmental study in rabbits (MRID No. 42675401). This risk assessment will evaluate acute dietary risk to pregnant females 13+ and older.

b) Chronic Dietary Risk. RfD = 0.025 mg/kg/day. On March 14, 1986, the Reference Dose Peer Review Committee recommended that the RfD for cyfluthrin be established at 0.025 mg/kg/day. The RfD was established based on the rat chronic feeding/carcinogenicity study (MRID No. 00137303) with a NOEL of 2.5 mg/kg/day and an uncertainty factor of 100. The LOEL of 7.5 mg/kg/day based on treatment-related findings of decreased body weights and inflammation of the kidneys.

c) Cancer Risk. Cyfluthrin has been classified as a Group E chemical (evidence of non-carcinogenicity for humans) by the HED RfD Peer Review Committee. The classification was based on a lack of convincing evidence of carcinogenicity in adequate studies with two animal species, rat and mouse.

d) Infants and Children

i) Developmental Studies

Rat - In an oral rat developmental toxicity study (Acc. No. 72009), the maternal (systemic) NOEL is 3 mg/kg/day. The maternal (systemic) LOEL of 10 mg/kg/day was based on behavioral changes in gait and coordination. The developmental (fetal) NOEL is ≥30 mg/kg/day (highest dose tested). No developmental effects were noted.

Rat - In an oral rat developmental toxicity study (MRID No. 157794 & 42698901), the maternal (systemic) NOEL is ≥10 mg/kg/day (highest dose tested). The developmental (fetal) NOEL is ≥10 mg/kg/day (highest dose tested). No developmental effects were noted.

Rat - In a rat inhalation developmental toxicity study (MRID No. 433934-01), the maternal (systemic) NOEL is 0.46 mg/m^3. The maternal (systemic) LOEL 2.55 mg/m^3 was based on decreased body weight gain and reduced food efficiency. The developmental (fetal) NOEL is 0.46 mg/m^3. The developmental (fetal) LOEL of 2.55 mg/m^3 is based on reduced fetal and placental weight, reduced ossification in the phalanges, metacarpals and vertebrae.

Rabbit - In an oral rabbit developmental toxicity study (MRID No. 42675401), the maternal (systemic) NOEL is 20 mg/kg/day. The maternal (systemic) LOEL of 60 mg/kg/day was based on decreased body weight gain and food consumption during the dosing period. The developmental (fetal) NOEL is 20 mg/kg/day. The developmental (fetal) LOEL is 60 mg/kg/day based on statistically significant increase in the numbers of resorptions and statistically significant post-implantation loss.

ii) Reproduction Studies

Rat - An oral three-generation reproduction study was conducted with (Acc. No. 072009), the systemic NOEL is 1.5 mg/kg/day. The systemic LOEL of 4.5 mg/kg/day was based on body weight decrease in pups. The reproductive (fetal) NOEL is 4.5 mg/kg/day. The reproductive (fetal) LOEL is 7.5 mg/kg/day based on decreased pup viability.

Occupational Exposures

Occupational exposure assumptions and estimates of exposure for workers applying cyfluthrin to citrus are summarized in Tables 1 and 2, respectively. HED has conducted its estimates of exposure with workers wearing a single layer of clothing plus gloves.

Table 1. Occupational Exposure Assumptions	
PARAMETER	**ASSUMPTION**
Pesticide Handlers Exposure Database (PHED), Version 1.1: Mixer/loader unit of exposure, run LIQ.OPN.MLOD (7/96); Ground applicator unit of exposure, run AIRBLAST.OPN.APPL (no date).	Mixer/Loader (liquid, open pour, single layer clothing plus gloves): Dermal = 22.9952 µg/lb ai handled, Inhalation = 1.2083 µg/lb ai handled
	Applicator - Ground (airblast, open cab, single layer clothing plus gloves): Dermal = 254.4638 µg/lb ai applied, Inhalation = 4.4655 µg/lb ai applied
Percent Absorption	Dermal: 100 % (Tox value) Inhalation: 100 % (default value)
Application Type	Ground
Minimum Finish Spray	Ground: 50 gal/A
Maximum Application Rate	0.1 lb ai/A
Duration of Occupational Exposure	Short-term (one day to one week)
Maximum Applications Per Year	1
Acres Treated/Day (Y. NG,BEAD)	Ground: 42 acres
Average Farm Size (1992 Ag Census)	Based on Tulare county, CA 46 acres
Worker Weight	Dermal 70 kg (based on Tox endpoint); Inhalation 60 kg (based on Tox endpoint)
Number of Farms Treated by PCO (Professional Chemical Operator)	Ground: 2 (OREB default value)

Table 2. Occupational Exposure and Risk Assessment[a]

Worker	Average Daily Dermal Dose[b] (ug/kg/day)	Average Daily Inhalation Dose[c] (ug/kg/day)	Short- and Intermediate-Term Dermal MOE[d]	Short- and Intermediate-Term Inhalation MOE[e]
Ground Mixer/Loader	1.38	0.09	180,000	910
Ground Applicator	15.27	0.31	16,000	270

[a] MOEs are expressed to two significant figures.

[b] Average Daily Dermal Dose (ADD) = PHED unit exposure (dermal x % absorption) x application rate x acres treated/day ÷ kg body weight.

[c] Average Daily Inhalation Dose (ADD) = PHED unit exposure (inhalation x % absorption) x application rate x acres treated/day ÷ kg body weight.

[d] Short-Term Dermal Occupational Exposure MOE = NOEL/ADD (where NOEL = 250 mg/kg/day).

[e] Short-Term Inhalation Occupational Exposure MOE = NOEL/ADD (where NOEL = 0.082 mg/kg/day).

Aggregate Exposure (Dietary- Food, Dietary- Water & Residential)

Dietary Exposure- Food

Based on the available toxicology and dietary exposure data, dietary risk estimates for adults, infants and children for cyfluthrin do not exceed HED's level of concern.

The nature of the residue in plants and animals, enforcement methodology and residue chemistry data in support of this petition were all previously evaluated by CBTS (PP#4F4313; Memos of S. Willett, 12/5/94 & 3/11/96; and J. Morales, 8/19/96).

1. The nature of the residue in plants is presently considered to be adequately understood. Studies have previously been conducted to delineate the metabolism of radiolabeled cyfluthrin in cotton and soybeans (PP No. 3G2976), potatoes (PP No. 4F3046), apples (PP No. 4F3046), wheat and tomatoes (PP No. 9F3731). All studies were considered to be acceptable, and produced similar results. The major terminal residue was cyfluthrin, which was shown to metabolize slowly. The residue to be regulated is parent cyfluthrin.

2. The nature of the residue in ruminants is also considered to be adequately understood. When a dairy cow was dosed with radiolabeled cyfluthrin at 33 ppm for five consecutive days, parent cyfluthrin constituted the major terminal residue in various tissues and milk. However, the cyfluthrin was not radiolabeled in a position which would allow detection of the metabolite DCVA. In the absence of toxicology data, the cis and trans isomers of metabolite DCVA (3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylic acid) are considered to be of comparable toxicity to the parent. Therefore, risk assessment should include cis and trans-DCVA. There are no radiolabeled metabolism data or feeding studies showing levels of DCVA in animal commodities. In the absence of these data, the petitioner is required to submit new ruminant feeding studies where residues of cis- and trans- DCVA and parent cyfluthrin are reported. Citrus commodities are not poultry feed items. Therefore, the metabolism of cyfluthrin in poultry is irrelevant to this petition.

3. Analytical methodology suitable for the enforcement of cyfluthrin tolerances in plant and animal commodities is available. The methodology was successfully validated by EPA's Beltsville lab in support of tolerances on cottonseed (see PP No. 4F3046). For crops the sample is ground and extracted with organic solvents, and cleaned up using florisil column chromatography. Residues are quantified by gas chromatography equipped with an electron capture detector. For meat, milk and eggs, the methodology also involves extraction with organic solvents and additional partitioning

with various solvents to remove polar and nonpolar interferences, followed by final cleanup using florisil column chromatography. Residues are quantified by gas chromatography equipped with an electron capture detector. Limits of quantification are as low as 0.01 ppm, but vary according to the commodity (see also 5/5/94 memo of J. Morales, PP No. 3F4204). The methods were forwarded to FDA for inclusion in PAM II in March 1988, but have not yet been published.

4. As a result of this use, residues of cyfluthrin are not expected to exceed:

Citrus, fruits,	0.2 ppm
Citrus, oil,	0.3 ppm
Citrus, dried pulp,	0.3 ppm

6. Secondary residues in animal commodities are expected from this use. However, the established livestock tolerances are adequate to cover secondary residues which may result from feeding citrus commodities with residues of cyfluthrin to animals.

7. Acute Dietary Risk. The acute dietary exposure endpoint of concern for cyfluthrin is developmental (resorptions). For the population subgroup of concern, females (13+ years old), the calculated Margin Of Exposure (MOE) value is 666. No anticipated residues were used in this assessment (see Attachment II for additional information). The MOE value of 666 is above the acceptable level and demonstrates no acute dietary concern.

8. Chronic Dietary Risk. Chronic dietary exposure estimates (DRES) for cyfluthrin are summarized in Attachment II (run dated 3/21/97). The DRES analysis utilized anticipated residues for meat and milk commodities and percent crop treated data for pears, peppers, pimientos, tomatoes, carrots, and corn. The published and proposed cyfluthrin tolerances for citrus commodities result in a Anticipated Residue Contribution (ARC) that is equivalent to the following percents of the RfD:

U.S Population (48 States)	5.4%
Hispanics	6.9%
Non-Hispanic Others	6.1%
Non-Nursing Infants (<1 year old)	12.5%
Females (13+ years, pregnant)	3.7%
Females (13+ years, nursing)	4.4%
Children (1-6 years old)	11.9%
Children (7-12 years old)	7.6%

The subgroups listed above are: (1) the U.S. population (48 states); (2) infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is

equal to, or greater than, that occupied by the subgroup U.S. population (48 states).

Incremental Dietary Risk. The incremental dietary risk from these new tolerances is 1% of the RfD for the US general population (48 states) and 2% of the RfD for the highest exposed population subgroup, non-nursing infants (<1 year old).

Percent crop treated information was provided by BEAD and is the best data available at this time.

9. Dietary Cancer Risk. Cyfluthrin has been classified as a Group E chemical (evidence of non-carcinogenicity for humans) by the HED RfD Peer Review Committee. Therefore, a quantitative dietary cancer risk assessment was not performed.

10. There are no CODEX, Canadian, or Mexican MRLs established for cyfluthrin in/on citrus. Therefore, no compatibility problems exist.

Dietary Exposure and Risk Estimates- Water

HED does not have available data to perform a quantitative drinking water risk assessment for cyfluthrin at this time. No monitoring data are available. However, since environmental fate data indicate that cyfluthrin is moderately persistent and relatively immobile in soil and water, **water risks will be assumed to account for 10% of the total allowable chronic and acute risk** until further data are provided (PR 97-1, 1/31/97). Based on analysis of water monitoring data for a large number of pesticides with varying toxicities, soil mobility characteristics, environmental fate profiles, the assumption of 10% of the total acute and chronic risk allocated to drinking water is considered conservative and protective of the public health.

Non-Occupational Exposure

Cyfluthrin is registered for use on non-food sites including golf courses, lawns, ornamental shrubs, indoor fogger, wood surfaces, and human bedding. Upon considering the registered uses, formulation types, persistence, and toxicological endpoints, and in accordance with OPP Interim Decision Logic (PR 97-1, 1/31/97), HED has determined that, in the absence of exposure data, the registered non-dietary, non-occupational uses of cyfluthrin should be assigned a default value of 20% of the acceptable aggregate chronic; and short- and intermediate-term risk.

Total Aggregate Exposure (Dietary + Water + Residential)

a) Chronic Risk: Based on the available data and assumptions used for dietary/water/residential exposure and risk estimates, the population group estimated to be the most highly exposed to cyfluthrin is non-nursing infants (<1 year old), with a risk estimate from combined sources equalling 42% of the RfD (dietary = 12% + drinking water = 10% + non-occupational = 20%).

b) Short-Term Risk: In the absence of exposure data, HED is reserving 10% of the risk for drinking water and 20% for residential exposures. However, as non-quantifiable exposures can not be included in MOE calculations, the short-term MOE will include only dietary exposure. Since the short term NOEL is based on a dermal exposure toxicity, the dietary exposure will be adjusted for a dietary endpoint (from the developmental study). The NOEL from the developmental study (60 mg/kg/day) is 4.2-fold lower than that of the 21-day dermal study (250 mg/kg/day). The adjusted chronic dietary exposure is thus 0.114 mg/kg/day (TMRC of 0.0271 mg/kg/day multiplied by 4.2). As the calculated MOE for children (1-6 years old) is 527 (short term NOEL of 60 mg/kg/day divided by adjusted dietary exposure of 0.114 mg/kg/day), the addition of exposures from dietary water and residential sources would be unlikely to result in a MOE of <100. HED thus considers the short-term risk to be acceptable for the purposes of establishing the proposed tolerances.

c) Acute Aggregate Risk: The acute aggregate risk assessment takes into account exposure from dietary food and water only. As noted earlier in this memo, the MOE for females 13+ years was calculated to be 666 for exposure to food only. Based on the TES Committee meeting of 2/26/97 and reserving 10% of the acute MOE for water (OPP Interim Decision Logic (PR 97-1, 1/31/97)), the addition of exposure from dietary water sources would be unlikely to result in a MOE of <100. Therefore, HED has no aggregate acute concern.

Cumulative Effects

Cyfluthrin is structurally similar to other members of the synthetic pyrethroid class of insecticides (i.e., permethrin, esfenvalerate, cypermethrin, bifenthrin, etc.). Further, other pesticides may have common toxicity endpoints with cyfluthrin.

However, the Agency has not made a determination whether cyfluthrin and any other pesticide have a common mode of toxicity

and require cumulative risk assessment. For the purposes of these tolerances and registration application, the Agency has considered only risks from cyfluthrin. If required, cumulative risks will be assessed as part of Reregistration and tolerance reassessment, and when methodologies for determining common mode of toxicity and for performing cumulative risk assessment are finalized.

Determination of Safety for Infants and Children

The pre- and post-natal toxicology data base for cyfluthrin is complete with respect to current toxicological data requirements. The results of these studies indicate that infants and children are not more sensitive to exposure, based on the results of the oral rat and rabbit developmental toxicity studies, rat inhalation study and the 2-generation reproductive toxicity study in rats.

In the oral rat developmental toxicity studies, maternal (systemic) effects consisting behavioral changes in gait and coordination were the basis of the maternal LOEL of 10 mg/kg/day. No developmental (fetal) effects were noted in doses up to 30 mg/kg/day (highest dose tested). In the oral rabbit developmental study, the maternal (systemic) NOEL is 20 mg/kg/day and the maternal (systemic) LOEL of 60 mg/kg/day was based on decreased body weight gain and food consumption. The developmental (fetal) NOEL is 20 mg/kg/day and the developmental (fetal) LOEL of 60 mg/kg/day was based on increase in the numbers of resorptions and post-implantation loss.

In an inhalation developmental toxicity study, the maternal (systemic) and developmental (fetal) NOEL's are 0.46 mg/m^3 and the maternal (systemic) and developmental (fetal) LOEL's are 2.55 mg/m^3. The maternal (systemic) LOEL was based on decreased body weight gain and reduced food efficiency. The developmental (fetal) LOEL was based on reduced fetal and placental weight and reduced ossification. It should be noted that developmental toxicity was not observed at a dose where minor maternal effects were noted.

In the rat 2-generation reproduction study, parental toxicity was observed at 4.5 mg/kg/day based on body weight decrease in pups. The reproductive (fetal) NOEL is 4.5 mg/kg/day. The reproductive (fetal) LOEL is 7.5 mg/kg/day based on decreased pup viability.

These data taken together suggest minimal concern for developmental or reproductive toxicity and do not indicate any increased pre- or postnatal sensitivity. No additional uncertainty factor for increased sensitivity in infants and children is appropriate.

ATTACHMENTS

I. Magnitude of the Residue

II. DRES analysis for cyfluthrin.

cc: PP#4F04313, PP#5F04475, PP#2F04137, G. Kramer, RCAB Files
RDI: Team (//97), M.S. Metzger (//97)
G.F. Kramer:804V:CM#2:(703)305-5079:7509C:CBTS

Attachment I: Magnitude of the Residue

Magnitude of the Residue - Crop Field Trials

The following summary of residue field trial data are reproduced from previous CBTS reviews as noted below. No new residue data were presented with this revised petition.

CITRUS (Memo, S. Willett 3/11/96; D213306)

MRID 430765-01: In this study, seven field trials were conducted on oranges, grapefruit and lemons grown in California (2 on oranges; 1 on grapefruit; 1 on lemons) and Arizona (1 each on oranges, lemons and grapefruit). The proposed use of cyfluthrin will be limited by the label to California and Arizona only. One foliar application of BAYTHROID 2EC was applied to citrus trees at an application rate of 1.6 oz ai/acre (1X as specified on the proposed label). Applications were made using air-blast equipment by spraying each side of the tree row. Whole, mature fruit samples were collected from the four quarters of each tree, high and low areas, and portions exposed and sheltered by foliage at 0, 3, 7 and 14 days following treatment. Residue levels in citrus were determined using methodology previously described (see 12/5/94 memo of S. Willett), which is similar to the enforcement method. Residue levels were quantified using GC/ECD. The highest residue, 0.11 ppm, was found in a grapefruit sample taken 3 days after treatment. The proposed tolerance of 0.2 ppm on citrus is appropriate.

Concentration factors were determined to be 5.3X in both citrus oil and dried citrus pulp. The typical residues expected in these processed food/feed commodities is determined by multiplying the highest average field trial residue value by the appropriate concentration factor. The expected residue level in dried pulp and oil would be 0.32 ppm (0.06 x 5.3). The proposed tolerances of 0.3 ppm on citrus oil and dried citrus pulp are thus appropriate.

RUMINANT (Memo, S. Willett 3/11/96; D213306)

A 2.5 ppm tolerance for milkfat (reflecting 0.08 ppm in whole milk) and a 0.4 ppm tolerance for meat, fat and meat byproducts have already been established for cyfluthrin as a result of previously registered agricultural uses (see 40 CFR 180.436). The only animal feed item now associated with this proposed use is dried citrus pulp. It is estimated that dried citrus pulp would comprise no more than 20% of the diet of beef or dairy cattle. The animal dietary burden is estimated at 0.07 ppm (0.2/0.9 x 0.3). The currently established meat and milk tolerances are therefore adequate to cover this use on citrus since they are based on uses where exposure rates were much higher (see PP No. 2F4137, 3/5/96 memo of G. Otakie).

Magnitude of the Residue in Meat and Milk- Anticipated Residues

As a large percentage of the TMRC was associated with meat and milk, anticipated residues were determined for these commodities:

Table 1- Anticipated residues in animal feed items.

Crop	RAC	Tolerance (ppm)	Anticipated Residue (ppm)
Corn, Field	Forage	0.01	0.005
	Stover	0.01	0.005
Corn, Sweet	Forage	30.0	9.4
	Stover	15.0	8.5
Sorghum	Forage	2.0	0.7
	Stover	5.0	1.1
Alfalfa	Forage	5.0	2.0
	Hay	10.0	5.1

Table 2- Anticipated residues in aspirated grain fractions.

Grain	Tolerance (ppm)	Anticipated Residue (ppm)	Average Concentration Factor	Anticipated Residue X Concentration Factor
Corn	0.01	0.005	215	1.1
Wheat	0.05	0.025	130	3.2
Sorghum	4.0	0.76	33	25.2
Soybean	0.05	0.025	(126)*	3.2
Average		0.20		**8.2**

*There are no data available for soybean aspirated grain fractions, so the average of the factors derived from the corn, wheat and sorghum studies was used.

Table 3. Anticipated Dietary Burden for Beef and Dairy Cattle.

Feed Item[1]	Average AR/%DM[2]	% in Diet (Based on Table II)[3]		Anticipated Dietary Burden[4]	
		Beef	Dairy	Beef	Dairy
Grains	0.23	30	20	0.07	0.05
Forages	7.6	30	30	2.3	2.3
Hay/Stover	4.3	30	40	1.3	1.7
Aspirated Grain Fractions	9.6	10	10	1.0	1.0
Total				**4.7**	**5.1**

[1] Grains include corn, sorghum, wheat and soybeans. Forages include alfalfa, corn and sorghum. Hay/stover includes alfalfa, corn and sorghum.

Average AR/%DM = average of anticipated residues in feed items divided by the % dry matter (%DM) for the feed item. For grains, forages and hay/stover; the average (anticipated) residue in the different types were divided by the %DM, and this number was averaged.

[3] The % of each feed type assumed to be included in the diet was based on information contained in the Table I of OPPTS Test Guidelines, Series 860.1000. These diets were intended to be realistic, rather than worst-case (F.D. Griffith, personal communication).

[4] The anticipated dietary burden is calculated by multiplying the average AR/%DM by the % of the feed item in the diet.

The dosing levels used in the ruminant feeding study correspond to 3X, 10X and 29X the anticipated dietary burden for dairy cattle, and 3X, 11X and 32X the anticipated dietary burden for beef cattle. Based on this information, and based on the residues found in meat, meat by-products, fat and milk in the ruminant feeding study (Table 4), the anticipated residues in animal commodities are as follows:

meat	0.0038 ppm
meat by-products	0.0022 ppm
fat	0.27 ppm
milk	0.024 ppm
milkfat	0.72 ppm

The meat, fat and meat by-products anticipated residues were also used in place of maximum-level residues for hogs, horses, goats and sheep in the DRES run.

Table 4- Residues of cyfluthrin found in milk and tissues of dairy cattle following oral administration of technical cyfluthrin (92% ai, formulated in capsule) at various feeding levels for 28 consecutive days (Memo, J. Garbus 3/20?/97).

Day	Residues of Cyfluthrin (ppm) From Various Feeding Levels			
	0 ppm	15 ppm	50 ppm	150 ppm
			Milk	
7	<0.01	0.07(2),0.08	0.20,0.21,0.26	0.49, 0.50, 0.68
14	0.02	0.06,0.07,0.10	0.20,0.24,0.27	0.41, 0.56, 0.89
21	<0.01	0.04,0.05,0.07	0.16,0.20,0.22	0.50, 0.65, 0.96
28	<0.01	0.06(3)	0.08,0.13,0.16	0.43, 0.44, 0.49
			Liver	
28	<0.01	<0.01(3)	<0.01(3)	<0.01, 0.01, 0.03
			Kidney	
28	<0.01	<0.01(2), 0.01	<0.01,0.02,0.07	0.02, 0.05, 0.07
			Muscle	
28	<0.01	<0.01(2), 0.01	0.02,0.03,0.07	0.04, 0.05, 0.11
			Fat	
28	0.09	0.98,1.15,1.36	2.18,2.58,3.30	3.99, 6.49, 9.94