List of Subjects

Environmental protection, Pesticides, Voluntary cancellations.

Dated: April 15, 1997.

Lois A. Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

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ENVIRONMENTAL PROTECTION AGENCY

[PF–728; FRL–5600–8]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various agricultural commodities.

DATES: Comments, identified by the docket control number PF–728, must be received on or before May 30, 1997.

ADDRESSES: By mail submit written comments to: Public Response and Program Resources Branch, Field Operations Divison (7505C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail, George LaRocca, Product Manager, (PM 13), Registration Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460. Office location, telephone number and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, 703–305–6100; e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various raw agricultural commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports grantinig of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice, as well as the public version, has been established for this notice of filing under docket control number PF–728 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number (PF–728) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

Authority: 21 U.S.C. 346a.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 10, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Below summaries of the pesticide petitions are printed. The summaries of the petitions were prepared by the petitioners. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. Gowan Company

PP 6F4738

EPA has received a pesticide petition (PP 6F4738) from Gowan Company, P. O. Box 5569, Yuma, AZ 85366-5569. The petition proposes, pursuant to section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish tolerances for the acaricide hexythiazox (The chemical name of hexythiazox is trans-5-(4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide.) and its metabolites (Metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety are included in the tolerance expression.) in or on the raw agricultural commodities stone fruits (except plums) at 1 part per million (ppm), almonds at 0.2 ppm and almond hulls at 10 ppm, and also in milk, cattle meat and cattle fat at 0.05 ppm and cattle meat byproducts at 0.1 ppm. The proposed analytical method is high performance liquid chromatography with an ultraviolet detector (HPLC with UV detection).

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of hexythiazox in apples, pears, grapes and citrus has been studied. The major portion of the residue is parent compound. The metabolites are hydroxycyclohexyl and ketocyclohexyl analogs of hexythiazox and the amide formed by loss of the cyclohexyl ring.

2. *Animal metabolism*. The metabolism of hexythiazox in goats, hens and rats has been studied. Metabolic pathways in animals are similar to those in plants.

3. *Analytical method*. An adequate analytical method (HPLC with UV detection) is available for enforcement purposes. Parent compound and all of its metabolites are converted to a common moiety before analysis.

4. *Magnitude of residues.* Twenty-four stone fruit residue trials were conducted over three years. The geographic distribution of the trials agrees with the recommendation given in the ''EPA Residue Chemistry Guidance'' (1994). In these trials, the maximum combined residues of hexythiazox and its metabolites were 0.52 ppm. Seven almond residue trials were conducted over three years. In these trials, the maximum combined residues of hexythiazox and its metabolites were 0.17 ppm in almond nutmeat and 7.5 ppm in the raw agricultural commodity almond hulls.

B. Toxicological Profile

1. *Acute toxicity.* The acute oral and dermal LD_{50} of technical hexythiazox is greater than 5,000 mg/kg, and the 4-hour acute inhalation LC_{50} is greater than 2 mg/L. It is not a dermal irritant or sensitizer and is a mild eye irritant.

2. *Genotoxicity.* The following genotoxicity tests were all negative: Ames gene mutation, Chinese hamster ovary (CHO) gene mutation, CHO chromosome aberration, mouse micronucleus and rat hepatocyte unscheduled DNA synthesis.

3. *Reproductive and developmental toxicity.* Hexythiazox has not been observed to induce developmental or reproductive effects. The lowest reproductive or developmental NOEL (No Observed Effect Level) observed was 200 mg/kg/day, the highest dose tested, in a 2-generation rat reproduction study.

4. *Chronic toxicity.* The Office of Pesticide Programs has established the Reference Dose (RfD) for hexythiazox at 0.025 mg/kg/day. The RfD for hexythiazox is based on a 1-year dog feeding study with a NOEL of 2.5 mg/kg/day and an uncertainty factor of 100. The endpoint effect of concern was hypertrophy of the adrenal cortex in both sexes, decreased red blood cell counts, hemoglobin content and hematocrit in males.

5. *Carcinogenicity.* The Agency has classified hexythiazox as a category C (possible human) carcinogen based on an increased incidence of hepatocellular carcinomas ($p = 0.028$) and combined adenomas/carcinomas ($p = 0.024$) in female mice at the highest dose tested (1,500 ppm) when compared to the controls as well as a significantly increased ($p < 0.001$) incidence of pre-neoplastic hepatic nodules in both males and females at the highest dose tested. The decision supporting a category C classification was based primarily on the fact that only one species was affected and mutagenicity studies were negative. In classifying hexythiazox as a category C carcinogen, the Agency concluded that a quantitative estimate of the carcinogenic potential for humans should be calculated because of the increased incidence of liver tumors in the female mouse. A Q1* of 0.039 (mg/kg/day)-1 in human equivalents was calculated.

C. Aggregate Exposure

Tolerances have been established (40 CFR 180.448) for combined residues of hexythiazox [trans-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide] and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety in or on apples at 0.02 ppm and pears at 0.3 ppm. The nature and metabolism of hexythiazox in plants and animals is adequately understood.

Hexythiazox is also registered for use on outdoor ornamental plants by commercial applicators only. It is believed that non-occupational exposure from this use is very low. Hexythiazox is not registered for greenhouse, lawn, garden, or residential use. The environmental fate of hexythiazox has been evaluated, and the compound is not expected to contaminate groundwater or surface water to any measurable extent.

1. *Chronic Exposure.* The Agency has estimated in the **Federal Register** of February 21, 1996, [61 FR 6552–6554] (FRL–5350–6), that current uses on apples and pears would result in an exposure of 0.000051 mg/kg/day for the U.S. population, assuming that all residues are at tolerance levels and 100 percent of the crops are treated. Non-nursing infants, the subgroup having the highest exposure, would have an exposure of 0.000600 mg/kg/day. Using the same conservative assumptions, it is calculated that the current and proposed uses together would result in an exposure of 0.001920 mg/kg for the U.S. population and 0.006598 mg/kg/day for non-nursing infants, which remains the most highly exposed subgroup.

Actual exposure will be much lower, however. Only a small fraction of these crops will be treated with hexythiazox, and average residues are far below the tolerance levels. For example, residues in apples treated at 10 times the currently approved application rate remained below the limit of quantitation, 0.01 ppm. Also, residues in apple juice are expected to be less than 50 percent of the residue level in the whole fruit. Average residues in stone fruits except cherries are expected to be 7 percent of the proposed tolerance level, average residues in cherries are expected to be 11 percent of the tolerance level and average residues in almond nutmeat are expected to be below 20 percent of the proposed tolerance level. Furthermore, only a very small percentage of crops (less than 1 percent up to 5 percent, depending on the crop) are expected to be treated with hexythiazox. When actual residues rather than tolerance levels and the percentage of treated crop are taken into account, then the actual exposure is estimated to be 0.0000013 mg/kg/day for the U.S. population.

Gowan has not conducted a detailed analysis of potential exposure to hexythiazox via drinking water or outdoor ornamental plants. However, it is believed that chronic exposure from these sources is very small.

2. *Acute exposure.* No developmental, reproductive or mutagenic effects have been observed with hexythiazox. Therefore, an analysis of acute exposure has not been conducted.

3. *Cumulative effects note.* At this time Gowan has not reviewed available information concerning the potentially cumulative effects of hexythiazox and other substances that may have a common mechanism of toxicity. For purposes of this petition only, Gowan is considering only the potential risks of hexythiazox in its aggregate exposure.

D. Determination of Safety for U.S. Population

1. *Chronic Risk.* The Agency has calculated in the **Federal Register** of February 21, 1996, [61 FR 6552–6554], (FRL–5350–6), assuming that residues are at tolerance levels and 100 percent of crops are treated, that the current use on apples and pears utilizes 0.2 percent of the RfD for the U.S. population and 2.4 percent of the RfD for non-nursing infants. Using these same assumptions, it is calculated that all current and proposed uses would result in TMRCs equivalent to 7.7 percent of the RfD for the U.S. population and 26.4 percent of the RfD for non-nursing infants. However, when actual residues rather than tolerance levels and the percent of crop treated are taken into account, actual chronic risk for the U.S. population is expected to be only 0.005 percent of the RfD.

The actual dietary carcinogenic risk to the U.S. population is calculated to be $5 \times 10–8$, which is well below the Agency's criterion of $1 \times 10–6$.

2. *Acute Risk.* An estimate of acute risk with this compound has not been conducted since no acute reproductive or developmental effects have been observed.

E. Determination of Safety for Infants and Children

In assessing the potential for additional sensitivity of infants and children to residues of hexythiazox, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

No developmental or reproductive effects have been observed in any study with hexythiazox. The lowest acute NOEL was 2,400 ppm in the diet (200 mg/kg/day), the highest dose tested, in the 2-generation rat reproduction study. In the rat developmental study, the maternal and fetotoxic NOEL was 240 mg/kg/day and the developmental NOEL was 2,160 mg/kg/day, the highest dose tested. In the rabbit developmental study, the maternal and developmental NOEL was 1,080 mg/kg/day, the highest dose tested.

Taking into account current toxicological data requirements, the database for hexythiazox relative to prenatal and postnatal effects is complete. In the rat developmental study, the NOELs for maternal toxicity and fetotoxicity were the same, which suggests that there is no special prenatal sensitivity in the absence of maternal toxicity. Furthermore, the lowest developmental or reproductive NOEL is two orders of magnitude higher than the chronic NOEL on which the RfD is based. It is concluded that there is a reasonable certainty of no harm to infants and children from aggregate exposure to hexythiazox residues.

F. International Tolerances

Codex maximum residue levels (MRLs) of 1 mg/kg (1 ppm) have been established for residues of hexythiazox in cherries and peaches. The U.S. tolerance proposal for stone fruits is in harmony with these MRLs. There are no Codex MRLs for the other commodities in this petition.

2. AgroEvo Environmental Health

PP 7F4820

EPA has received a pesticide petition from AgroEvo Environmental Health, 95 Chestnut Ridge Road, Montvale, NJ 07645. The petition proposes, pursuant to section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish tolerances for deltamethrin in or on food and feed items as a result of use in food and feed handling establishments at 0.05 part per million (ppm). This petition was assigned Pesticide Petition Number 7F4820 (formerly 4H5710) and was initially announced in the **Federal Register** of February 8, 1995 [60 FR 7539–7541], (FRL–4926–4). A tolerance of 0.02 ppm was proposed for residues of deltamethrin in or on food and feed items, and published for comment in the **Federal Register** dated November 30, 1995 [60 FR 61504–61506], (FRL–4983–5). In an effort to harmonize with a similar tolerance established in Germany, the proposed tolerance was increased to 0.05 ppm per comments received from the German Ministry of Health. The proposed analytical method is high performance liquid chromatography with an ultraviolet detector.

A. Residue chemistry

1. *Analytical Method.* A practical analytical method using gas - liquid chromatography is available for detecting and measuring levels of deltamethrin in food and feed items. This method is used for the determination of cis-deltamethrin, trans-deltamethrin, and alpha-R-deltamethrin. The limit of quantitation (LOQ) is 0.02 mg/kg (ppm). The enforcement methodology has been submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual Volume II (PAM II).

2. *Nature and Magnitude of the Residue in Food and Feed Items.* The nature of the residues of deltamethrin in plants and animals relevant to the establishment of food and feed additive tolerances is adequately understood. The residue of concern is deltamethrin. In studies conducted to support this use, residue levels of deltamethrin in food and/or feed items after applications to food- and feed-handling establishments were below the LOQ, i.e., below 0.02 ppm. There is no reasonable expectation of secondary residues in eggs, meat, milk, or poultry from the proposed use as delineated in 40 CFR 180.6(a)(3).

B. Toxicological Profile

1. *Acute Toxicity.* The acute rat oral LD_{50} of deltamethrin technical was 66.7 mg/kg (males) and 86 mg/kg (females) when administered in sesame oil and greater than 5,000 mg/kg in both sexes when administered in 1 percent aqueous methylcellulose. The acute dermal LD_{50} was greater than 2,000 mg/kg when administered to rabbits in either polyethylene glycol or 1 percent aqueous methylcellulose, and greater than 2,940 mg/kg when administered to rats in 1 percent aqueous methylcellulose. The 4-hour rat inhalation LC_{50} was 2.2 mg/l. Deltamethrin was slightly irritating to rabbit eyes, non-irritating to rabbit skin, and did not induce skin sensitization in guinea pigs.

2. *Subchronic Toxicity.* In a 90–day study, deltamethrin was mixed with polyethylene glycol 200 (PEG 200) and administered by gavage to rats at dose levels of 0, 0.1, 1, 2.5 and 10 mg/kg/day. The only treatment-related effects observed were reduced body weight gain in rats at 2.5 and 10 mg/kg/day and slight hypersensitivity in rats at 10 mg/kg/day at week 6, but not at week 13. The NOEL in this study was 1.0 mg/kg/day. In a more recent 90–day study (not yet submitted to the Agency), deltamethrin was administered via the diet to rats at dietary concentrations of 30, 300, 1,000, 3,000 and 6,000 ppm. All animals in the 3,000 and 6,000 ppm groups and several animals from the 1,000 ppm group died or were killed in extremis during the first few weeks of the study. Decreased food and water consumption, decreased weight gain and a variety of neurological signs of toxicity (including uncoordinated movement, unsteady gait, tremors, increased sensitivity to sound, ''wet dog shakes'' and spasmodic convulsions) were noted in these three dose groups. A slight but statistically significant decrease in weight gain was noted in females at 30 and 300 ppm but was considered to be of equivocal significance because of the lack of a clear, consistent dose-response relationship. There were no changes in clinical pathology parameters, organ weights or gross or microscopic pathology at any dose level. Thus, the NOEL for this study was considered to be 300 ppm (23.9 mg/kg/day in males and 30.5 mg/kg/day in females).

A 12-week feeding study of deltamethrin was conducted in mice at dietary concentrations of 0, 30, 300, 3,000 and 6,000 ppm. Effects noted at 3,000 and 6,000 ppm consisted of clinical signs of toxicity (clonic contractions, convulsions and poor condition), decreased weight gain and mortality. A very slight decrease in weight gain was noted in males at 30 and 300 ppm but was considered to be of equivocal significance. There were no effects on hematology, blood chemistry, or organ weights.

The only histopathological lesions noted were thymic involution and lipid depletion in the adrenal glands of animals at 3,000 and 6,000 ppm, which

were considered likely to be secondary effects of the stress induced by the poor physical condition of the animals. Consequently, 300 ppm (61.5 mg/kg/day in males and 77.0 mg/kg/day in females) was considered to be the NOEL.

In a 13-week study, deltamethrin was administered to beagle dogs by capsule at dose levels of 0, 0.1, 2, 2.5 and 10 mg/kg/day, using PEG 200 as a vehicle. There was no mortality but animals at the top two dose levels exhibited various clinical signs of toxicity (e.g., tremors, unsteadiness, jerking movements, excessive salivation, vomiting, liquid feces, and/or dilatation of the pupils) and modified EEG patterns. No histopathological findings were observed. The NOEL for this study was considered to be 1.0 mg/kg/day.

In a more recent study, deltamethrin was administered dry (without vehicle) via capsule to beagle dogs for 13 weeks at dose levels of 0, 2, 10 and 50 mg/kg/day. No mortality occurred during the study but animals at 50 mg/kg/day exhibited decreased food consumption and weight gain and a variety of clinical signs including unsteady gait, tremors, shaking of the head, vomiting and salivation. There were no effects on clinical pathology, ophthalmoscopy, organ weights or pathology. The NOEL for this study was 10 mg/kg/day. The difference in toxicity between the two dog studies is attributed to the enhanced absorption resulting from the use of PEG 200 as a vehicle in the first study.

In a 21–day dermal toxicity study, deltamethrin was admixed with polyethylene glycol and applied dermally to rats for 6 hours per day for 21 successive days at dose levels of 0, 100, 300 and 1,000 mg/kg/day. Signs of local dermal irritation were noted at all dose levels. No conclusive evidence of systemic toxicity was noted at any dose level. However, because of slight, non-statistically significant decreases in weight gain and food consumption in males at 300 and 1,000 mg/kg/day, the EPA concluded that the NOEL for this study was 100 mg/kg/day.

In a subchronic inhalation study, rats were exposed to aerosolized deltamethrin at concentrations of 0, 3, 9.6 and 56.3 g/l for 6 hours per day, 5 days per week, for a total of 14 days over 3 weeks. Signs of local irritation (agitated grooming and scratching) and excessive salivation were noted in all treated groups. Peripheral vasodilation was noted at 9.6 and 56.3 g/l. Ataxia and walking with arched back were noted at 56.3 g/l. Based on slightly decreased body weights and neurological effects at higher dose levels, AgroEvo Environmental Health concluded that 3 g/l was the NOEL for systemic effects in this study.

3. *Chronic Toxicity/Oncogenicity.* In a 2-year feeding study, deltamethrin was administered to beagle dogs at dietary concentrations of 0, 1, 10 and 40 ppm. No treatment-related effects were noted in any animal. Thus, 40 ppm (1.1 mg/kg/day) was considered to be the NOEL. In a more recent study, deltamethrin was administered dry, via capsule, to beagle dogs for 1 year at dose levels of 0, 1, 10 and 50 mg/kg/day. Effects observed at 10 and 50 mg/kg/day included clinical signs of toxicity (e.g., unsteadiness, abnormal gait, tremors, chewing/scratching of extremities and liquid feces), decreased food consumption (high dose only) and changes in several hematology and blood chemistry parameters. There were no treatment related gross or histopathological findings. The NOEL in this study was also considered to be 1 mg/kg/day.

No evidence of oncogenicity was noted in either of two chronic rat feeding studies. In the first study, deltamethrin was administered to rats for 2 years at dietary concentrations of 0, 2, 20 and 50 ppm. The NOEL was considered to be 20 ppm (1 mg/kg/day) based on slightly decreased weight gain at 50 ppm. In a more recent study, deltamethrin was administered to rats for 2 years at dietary concentrations of 0, 25, 125, 500 and 800 ppm. Neurological effects (uncoordinated movement of limbs, abnormal gait and unsteady gait) were noted at 500 and 800 ppm during the first week of the study but subsided and were no longer apparent by Week 8. Minor effects on weight gain were also noted at these two dose levels. Microscopic evidence of slight hepatotoxicity (increased incidence and severity of eosinophilic hepatocytes and/or ballooned cells) was noted in males at 125 mg/kg/day and above. The NOEL for this study was considered to be 25 ppm (1.1 and 1.5 mg/kg/day for males and females, respectively).

No evidence of oncogenicity was noted in two mouse oncogenicity studies. In the first study, deltamethrin was administered to mice for 2 years at dietary concentrations of 0, 1, 5, 25 and 100 ppm. No adverse effects were noted at any dose level. Thus, the NOEL was considered to be 100 ppm (12 and 15 mg/kg/day in males and females, respectively). In a more recent study, deltamethrin was administered to mice for 97 weeks at dietary concentrations of 0, 10, 100, 1,000 and 2,000 ppm. Effects noted at 2,000 ppm consisted of a slightly higher incidence of mice in poor physical condition and a slight, transient reduction in weight gain. Increased incidences of macroscopic and microscopic skin lesions, which were attributed to excessive scratching, were noted in animals at 1,000 and 2,000 ppm. The NOEL was considered to be 100 ppm (15.7 and 19.6 mg/kg/day for males and females, respectively).

4. *Genotoxicity.* No evidence of genotoxicity was noted in a battery of *in vitro* and *in vivo* studies, including Salmonella and E. coli reverse bacterial mutation assays, an *in vitro* chromosomal aberration assay in Chinese hamster ovary (CHO) cells, an unscheduled DNA synthesis assay in rat hepatocytes, and a dominant lethal assay in mice.

5. *Reproductive and Developmental Toxicity.* In a rat developmental toxicity study, deltamethrin was mixed with corn oil and administered by gavage during gestation days 6 through 15 at dose levels of 0, 1, 3.3, 7 and 11 mg/kg/day. Maternal toxicity, as evidenced by clinical observations, decreased weight gain and mortality was noted at 7 and 11 mg/kg/day. No evidence of developmental toxicity was noted at any dose level. Thus, the No Observable Effect Level (NOEL) was considered to be 3.3 mg/kg/day for maternal toxicity and 11 mg/kg/day (highest dose tested) for developmental toxicity.

In a rabbit developmental toxicity study, deltamethrin was administered by gavage in a vehicle of 0.5 percent aqueous carboxymethyl cellulose at dose levels of 0, 10, 25 and 100 mg/kg/day during gestation days 7 through 19. The maternal NOEL was considered to be 10 mg/kg/day based on decreased defecation at 25 and 100 mg/kg/day and mortality at 100 mg/kg/day. The developmental NOEL was considered to be 25 mg/kg/day based on retarded ossification of the pubic and tail bones at 100 mg/kg/day.

In a 3-generation reproduction study, deltamethrin was suspended in corn oil and administered to rats at dietary concentrations of 0, 2, 20 and 50 ppm. No treatment related effects were noted in either parents or offspring at any dose level. In a more recent 2-generation study (not yet submitted to the Agency), deltamethrin was administered to rats at dietary concentrations of 0, 5, 20, 80 and 320 ppm. The NOEL for both the parents and offspring was 80 ppm (equivalent to approximately 4 to 12 mg/kg/day in adults and 18 to 44 mg/kg/day in the offspring), based on clinical signs of toxicity, reduced weight gain, and mortality in both parents and offspring at 320 ppm. However, there were no effects on mating, fertility or developmental behavior at any dose level.

6. *Endocrine Effects.* No special studies have been conducted to investigate the potential of deltamethrin to induce estrogenic or other endocrine effects. However, the standard battery of required toxicity studies has been completed. These studies include an evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following repeated or long-term exposure. These studies are generally considered to be sufficient to detect any endocrine effects, yet no such effects were detected. Thus, the potential for deltamethrin to produce any significant endocrine effects is considered to be minimal.

7. *Metabolism.* The absorption of deltamethrin appears to be highly dependent upon the route and vehicle of administration. Once absorbed, deltamethrin is rapidly and extensively metabolized and excreted, primarily within the first 48 hours.

C. Aggregate Exposure

Deltamethrin is a broad spectrum insecticide used to control pests of crops, ornamental plants and turf, and domestic indoor and outdoor (including dog collars), commercial, and industrial food use areas. Thus, aggregate non-occupational exposure would include exposures resulting from non-food uses in addition to consumption of potential residues in food and water. Exposure via drinking water is expected to be negligible since deltamethrin binds tightly to soil and rapidly degrades in water. Because of the variety and nature of the non-food uses of deltamethrin, and the unavailability of reliable exposure data, we cannot fully evaluate potential exposure from these non-food uses. However, deltamethrin binds tightly to organic matter, is not easily dislodged from indoor surfaces, has very low vapor pressure, and is poorly absorbed through the skin. Furthermore, the formulations to which the general public would be exposed are relatively dilute and non-toxic. Thus, non-food exposures are not expected to pose a significant risk to the general public, or to infants and children.

Potential dietary exposures from food commodities under the proposed tolerances for deltamethrin, plus the established tolerances for deltamethrin (40 CFR 180.435 and 185.1580) on cotton and tomato commodities, plus the pending temporary tolerances (under an Experimental Use Permit) on soybean commodities for deltamethrin were estimated using the Exposure 1 software system (TAS, Inc.) and the 1977–78 USDA consumption data. Two scenarios were evaluated. In the first, worst case scenario, it was assumed that 100 percent of the crops for which a tolerance for deltamethrin is established or pending are treated with deltamethrin, all food and feed handling establishments are treated with deltamethrin, and that all residues resulting from these treatments are at tolerance level. In a second, slightly more realistic-case scenario, anticipated residues and percent crop treated adjustments were used, but again the unrealistic assumption was made that 100 percent of all food and feed handling establishments were treated with deltamethrin.

D. Safety Determinations

1. *US Population in General.* AgrEvo Environmental Health considers the toxicity and residue data base for deltamethrin to be valid, reliable and essentially complete according to existing regulatory requirements. No evidence of oncogenicity has been observed. A Reference Dose (RfD) of 0.01 mg/kg bodyweight/day has been established for deltamethrin based on the NOEL from the two-year rat feeding study and a 100-fold safety factor to account for interspecies extrapolation and intraspecies variation.

Using the dietary exposure assumptions described above in section D, chronic dietary exposures utilize 17 percent of the deltamethrin Reference Dose in the worst-case scenario, and only 2.6 percent of the Reference Dose in the slightly more realistic-case scenario for the general population. Thus, even utilizing a number of unrealistic assumptions, the total of the RfD utilized for deltamethrin did not exceed 17 percent. There is generally no concern for exposures below 100 percent of the RfD since it represents the level at or below which no appreciable risks to human health is posed. Therefore, there is reasonable certainty that no harm will result to the U.S. population in general from aggregate exposure to deltamethrin.

2. *Infants and Children.* Data from developmental toxicity studies in rats and rabbits, and multigeneration reproduction studies in rats are generally used to assess the potential for increased sensitivity of infants and children. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to reproductive and other effects on adults and offspring from prenatal and postnatal exposure to the pesticide.

No developmental effects were noted in a rat developmental toxicity study with deltamethrin, even at dose levels that produced clinical signs of toxicity, reduced body weight, and death in the dams. The maternal and developmental NOEL's in this study were 3.3 mg/kg/day and 11 mg/kg/day (highest dose tested), respectively. The only developmental effect noted in the rabbit developmental toxicity study was possibly retarded ossification at 100 mg/kg/day, a dose level which also produced maternal mortality. The maternal and developmental NOEL's in this study were 10 mg/kg/day and 25 mg/kg/day, respectively. No effects were noted in either parents or offspring at the high dose level (50 ppm) in a 3-generation rat reproduction study. In a more recent 2-generation rat reproduction study (not yet submitted to the Agency), the NOEL for both the parents and offspring was 80 ppm (equivalent to approximately 4 to 12 mg/kg/day in adults and 18 to 44 mg/kg/day in the offspring), based on a variety of toxic effects (clinical signs of toxicity, reduced weight gain, and mortality) in both parents and offspring at 320 ppm. However, there were no effects on mating, fertility, or developmental behavior at any dose level. Thus, these data do not provide any evidence of increased susceptibility to infants or children.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database relative to pre- and post-natal effects in children is complete. Although no indication of increased susceptibility to younger animals was noted in any of the above studies, or in the majority of studies with other pyrethroids, several recent publications have reported that deltamethrin is more toxic to neonate and weanling animals than to adults. However, a joint industry group currently investigating this issue was unable to reproduce these findings. Furthermore, the RfD (0.01 mg/kg/day) that has been established for deltamethrin is already more than 1,000-fold lower than the lowest NOEL from the developmental and reproduction studies. Therefore, the RfD of 0.01 mg/kg/day is appropriate for assessing aggregate risk to infants and children and an additional uncertainty factor is not warranted.

Using the dietary exposure assumption described above in section D, chronic dietary exposures utilize 54 percent of the deltamethrin RfD in the

worst-case scenario, and only 10.2 percent of the RfD in the slightly more realistic-case scenario for the population subgroup described as non-nursing infants, less than 1 year old. Thus, even utilizing a number of unrealistic assumptions, the total of the RfD utilized for deltamethrin did not exceed 54 percent . There is generally no concern for exposures below 100 percent of the RfD since it represents the level at or below which no appreciable risks to human health is posed. Therefore, there is reasonable certainty that no harm will result to the most sensitive population subgroup described as non-nursing infants, less than one year old, from aggregate exposure to deltamethrin.

E. Cumulative Effects

At the present time, there are insufficient data available to allow AgrEvo to properly evaluate the potential for cumulative effects from the various pyrethroids now being used, or from any other chemicals that may have similar mechanisms of toxicity. Furthermore, because of the need to utilize data from multiple registrants, such an analysis cannot be conducted by a single registrant. AgrEvo is currently participating in a joint industry effort to evaluate the potential aggregate risks from exposure to all pyrethroids but the results from this evaluation are not yet available. As an interim measure, AgrEvo has performed an initial evaluation of the potential combined effectsfrom exposure to two pyrethroids, deltamethrin and tralomethrin, that are currently registered by AgrEvo Environmental Health and AgrEvo USA Companies. A combined assessment of these two active ingredients is considered appropriate because tralomethrin is rapidly debrominated into deltamethrin and because the two molecules have essentially identical toxicology profiles.

For the same reasons previously discussed for deltamethrin, non-dietary exposures to tralomethrin are not expected to pose a significant risk to human health and, therefore, have not been evaluated. Potential dietary exposures to tralomethrin are, however, considered here. The RfD established for tralomethrin is 0.0075 mg/kg bodyweight/day based on a two-year rat feeding study and a 100 fold safety factor to account for interspecies extrapolation and intraspecies variation. Using the dietary exposure assumptions described above in section D, chronic dietary exposures utilize 16.9 percent of the tralomethrin RfD in the worst-case scenario, and only 3.9 percent of the tralomethrin RfD in the slightly more realistic-case scenario for the general population. For the population subgroup described as non-nursing infants, less than one year old, 32 percent of the RfD for tralomethrin is utilized in the worst-case scenario, and only 11 percent of the RfD for tralomethrin in the slightly more realistic-case scenario. (The crops/uses considered for tralomethrin are those for which tolerances have been established for experimental use permits and those listed in 40 CFR 180.422, 185.5450, and 186.5450.)

A simple cumulative risk assessment can be made by adding the percent RfD utilized for deltamethrin and tralomethrin. However, this is a gross overestimate because, based on efficacy, economics, and/or label restrictions, crops and food/feed handling establishments would not be concurrently treated with both products. This is especially important in considering food/feed handling uses because all foods are considered to contain residues of both deltamethrin and tralomethrin. Nonetheless, looking at this simple summation, it is shown that in the worst-case scenario described in section D, chronic dietary exposures utilize 33.9 percent of the RfDs for tralomethrin/deltamethrin, while in the slightly more realistic-case scenario only 6.5 percent of the RfDs for tralomethrin/deltamethrin are utilized. For the population subgroup described as non-nursing infants, less than one-year old, 86 percent of the RfDs for tralomethrin/deltamethrin are utilized in the worst-case scenario, while only 21.2 percent of the RfDs for tralomethrin/deltamethrin are utilized in the slightly more realistic-case scenario. Thus, even utilizing a number of unrealistic assumptions, and using a simple summation of percent RfD utilized for each active ingredient, the total of percent RfD utilized for deltamethrin/tralomethrin did not exceed 86 percent, and is actually less than 21.2 percent, for the population subgroup non-nursing infants, less than one year old. Therefore, there is reasonable certainty that no harm will result from cumulative aggregate exposures to deltamethrin and tralomethrin for the general population and/or infants and children.

G. International Tolerances

Deltamethrin is a broad spectrum insecticide used throughout the world to control pests of livestock, crops, ornamental plants and turf, and household, commercial, and industrial food use areas. A reevaluation of the maximum residue limits (MRL s) was conducted in 1994, in accordance with the EC Directive (91/414/EEC) Registration Requirements for Plant Protection Products. A comparison of the proposed CODEX MRLs and proposed tolerances for deltamethrin is presented below:

Commodity	Proposed/Current MRL (CODEX)	Proposed/Established Tolerance (USEPA)
Food/Feed Handling Uses	0.05 ppm	0.05 ppm

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–181044; FRL 5713–4]

Carbofuran; Receipt of Application for Emergency Exemption, Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received specific exemption requests from the Mississippi Department of Agriculture and Commerce, and from the Louisiana Department of Agriculture and Forestry (hereafter referred to as the ''Applicants'') to use the pesticide flowable Carbofuran (Furadan 4F Insecticide/Nematicide) (EPA Reg. No.