are no acceptable, reliable exposure data available to assess any potential risks. However, given the small amount of material that is used, it is concluded that the potential for non-occupational exposure to the general population is unlikely.

D. Cumulative Effects

The potential for cumulative effects of metolachlor and other substances that have a common mechanism of toxicity has also been considered. It is concluded that consideration of a common mechanism of toxicity with other registered pesticides in this chemical class (chloroacetamides) is not appropriate. Since EPA has concluded that the carcinogenic potential of metolachlor is not the same as other registered chloroacetamide herbicides, based on differences in rodent metabolism (EPA Peer Review of metolachlor, 1994), it is believed that only metolachlor should be considered in an aggregate exposure assessment.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions described above, based on the completeness and reliability of the toxicity data, it is concluded that aggregate exposure to metolachlor will utilize 1.3% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Therefore, it is concluded that there is a reasonable certainty that no harm will result from aggregate exposure to metolachlor or metolachlor residues.

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

Developmental toxicity (reduced mean fetal body weight, reduced number of implantations/dam with resulting decreased litter size, and a slight increase in resorptions/dam with a resulting increase in post-implantation loss) was observed in studies conducted with metolachlor in rats and rabbits. The NOEL's for developmental effects in both rats and rabbits were established at 360 mg/kg/day. The developmental effect observed in the metolachlor rat study is believed to be a secondary effect resulting from maternal stress (lacrimation, salivation, decreased body weight gain and food consumption and death) observed at the limit dose of 1,000 mg/kg/day.

A 2-generation reproduction study was conducted with metolachlor at feeding levels of 0, 30, 300 and 1,000 ppm. The reproductive NOEL of 300 ppm (equivalent to 23.5 to 26 mg/kg/day) was based upon reduced pup weights in the F1a and F2a litters at the 1,000 ppm dose level (equivalent to 75.8 to 85.7 mg/kg/day). The NOEL for parental toxicity was equal to or greater than the 1,000 ppm dose level.

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 for children is complete. Further, for the chemical metolachlor, the NOEL of 9.7 mg/kg/day from the metolachlor chronic dog study, which was used to calculate the RfD (discussed above), is already lower than the developmental NOEL's of 360 mg/kg/day from the metolachlor teratogenicity studies in rats and rabbits. In the metolachlor reproduction study, the lack of severity of the pup effects observed (decreased body weight) at the systemic lowest observed-effect-level (equivalent to 75.8 to 85.7 mg/kg/day) and the fact that the effects were observed at a dose that is nearly 10 times greater than the NOEL in the chronic dog study (9.7 mg/kg/day) suggest there is no additional sensitivity for infants and children. Therefore, it is concluded that an additional uncertainty factor is not warranted to protect the health of infants and children and that the RfD at 0.1 mg/kg/day based on the chronic dog study is appropriate for assessing aggregate risk to infants and children from use of metolachlor.

Using the conservative exposure assumptions described above, the percent of the RfD that will be utilized by aggregate exposure to residues of metolachlor including the proposed use on sunflowers is 1.1% for nursing infants less than 1 year old, 3.3% for non-nursing infants, 2.7% for children 1 to 6 years old and 2.0% for children 7 to 12 years old. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, it is concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to metolachlor residues.

F. International Tolerances

There are no Codex Alimentarius Commission (CODEX) maximum residue levels (MRL's) established for residues of metolachlor in or on raw agricultural commodities.

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ENVIRONMENTAL PROTECTION AGENCY

[PF–769; FRL 5748–6]

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 food commodities.

DATES: Comments, identified by the docket control number PF–769, must be received on or before November 7, 1997.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), 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 to: opp-docket@epamail.epa.gov. Follow the instructions under ''SUPPLEMENTARY INFORMATION'' of this document. No Confidential Business Information (CBI) 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 CBI. Information so marked 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: The product manager listed in the table below:

Product Manager	Office location/telephone number	Address
Adam Heyward (PM 13)	Rm. 227, CM #2, 703–305–5418, e-mail: heyward.adam@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA
Beth Edwards (PM 13) ..	Rm. 206, CM #2, 703–305–5400, e-mail: edwards.beth@epamail.epa.gov.	Do.

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 food 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 granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–769] (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 number PF–769 and appropriate petition number. Electronic comments on notice may be filed online at many Federal Depository Libraries.

List of Subjects

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

Dated: September 25, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. 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. DowElanco

PP 7F4871

EPA has received a pesticide petition (PP 7F4871) from DowElanco, 9330 Zionsville Road, Indianapolis, IN 46268-1054, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of spinosad in or on the raw agricultural commoditIies almonds, nutmeat at 0.02 ppm; almonds, hulls at 2 ppm; citrus, whole fruit at 0.3 ppm; citrus, oil at 3 ppm; citrus, dried pulp at 0.5 ppm; and leafy vegetables at 8 ppm. Because of the amount of spinosad residue found in almonds, hulls and citrus, dried pulp as well as wet apple pomace (pending tolerance under PP 6F4761) and the amount of almond hulls, citrus dried pulp, and apple pomace potentially included in livestock rations, a livestock, fat residue tolerance of 0.7 ppm is also being proposed. The following meat and milk tolerances for residues of spinosad are presently pending under PP 6F4761: meat at 0.04 ppm, kidney and liver at 0.2 ppm, fat at 0.4 ppm, milk at 0.04 ppm, and milk fat at 0.5 ppm. An adequate analytical method is available for enforcement purposes. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of spinosad in plants (apples, cabbage, cotton, tomato, and turnip) and animals (goats and poultry) is adequately understood for the purposes of these tolerances. A rotational crop study showed no carryover of measurable spinosad related residues in representative test crops.

2. *Magnitude of residues*. Magnitude of residue studies were conducted for almonds (6 sites), citrus (13 sites on oranges, 6 sites on grapefruit, and 5 sites on lemons), and leafy vegetables (6 sites each on head lettuce, leaf lettuce, spinach, and celery). Residues found in these studies ranged from ND to 0.008 ppm on almonds, nutmeat; 0.22 to 1.45 ppm on almonds, hulls; 0.01 to 0.21 ppm on citrus, whole fruit; and ND to 6 ppm on leafy vegetables. A processed products study in citrus at a 5x application rate showed that residues of spinosad did not concentrate in citrus juice; however, there was aconcentration of spinosad residues in citrus oil (14x concentration factor) and citrus dried pulp (2x concentration factor).

B. Toxicological Profile

1. *Acute toxicity*. Acute Toxicity Spinosad has low acute toxicity. The rat oral LD_{50} is 3,738 mg/kg for males and >5,000 mg/kg for females, whereas the mouse oral LD_{50} is >5,000 mg/kg. The rabbit dermal LD_{50} is >2,000 mg/kg and the rat inhalation LC_{50} is >5.18 mg/l air. In addition, spinosad is not a skin sensitizer in guinea pigs and does not produce significant dermal or ocular irritation in rabbits. End use formulations of spinosad that are water based suspension concentrates have similar low acute toxicity profiles.

2. *Genotoxicty*. Short term assays for genotoxicity consisting of a bacterial reverse mutation assay (Ames test), an

in vitro assay for cytogenetic damage using the Chinese hamster ovary cells, an *in vitro* mammalian gene mutation assay using mouse lymphoma cells, an *in vitro* assay for DNA damage and repair in rat hepatocytes, and an *in vivo* cytogenetic assay in the mouse bone marrow (micronucleus test) have been conducted with spinosad. These studies show a lack of genotoxicity.

3. *Reproductive and developmental toxicity*. Spinosad caused decreased body weights in maternal rats given 200 mg/kg/day by gavage (highest dose tested). This was not accompanied by either embryo toxicity, fetal toxicity, or teratogenicity. The no-observed-effect levels (NOELs) for maternal and fetal effects in rats were 50 and 200 mg/kg/day, respectively. A teratology study in rabbits showed that spinosad caused decreased body weight gain and a few abortions in maternal rabbits given 50 mg/kg/day (highest dose tested). Maternal toxicity was not accompanied by either embryo toxicity, fetal toxicity, or teratogenicity. The NOELs for maternal and fetal effects in rabbits were 10 and 50 mg/kg/day, respectively. The NOEL found for maternal and pup effects in a rat reproduction study was 10 mg/kg/day. Neonatal effects at 100 mg/kg/day (highest dose tested in the rat reproduction study) were attributed to maternal toxicity.

4. *Subchronic toxicity*. Spinosad was evaluated in 13-week dietary studies and showed NOELs of 4.9 mg/kg/day in dogs, 6 mg/kg/day in mice, and 8.6 mg/kg/day in rats. No dermal irritation or systemic toxicity occurred in a 21–day repeated dose dermal toxicity study in rabbits given 1,000 mg/kg/day.

5. *Chronic toxicity*. Based on chronic testing with spinosad in the dog and the rat, the EPA has set a reference dose (RfD) of 0.0268 mg/kg/day for spinosad. The RfD has incorporated a 100-fold safety factor to the NOELs found in the chronic dog study. The NOELs shown in the dog chronic study were 2.68 and 2.72 mg/kg/day, respectively for male and female dogs. The NOELs shown in the rat chronic study were 2.4 and 3.0 mg/kg/day, respectively for male and female rats. Using the Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), it is proposed that spinosad be classified as Group E for carcinogenicity (no evidence of carcinogenicity) based on the results of carcinogenicity studies in two species. There was no evidence of carcinogenicity in an 18-month mouse feeding study and a 24-month rat feeding study at all dosages tested. The NOELs shown in the mouse oncogenicity study were 11.4 and 13.8 mg/kg/day, respectively for male and female mice. The NOELs shown in the rat chronic/oncogenicity study were 2.4 and 3.0 mg/kg/day, respectively for male and female rats. A maximum tolerated dose was achieved at the top dosage level tested in both of these studies based on excessive mortality. Thus, the doses tested are adequate for identifying a cancer risk. Accordingly, a cancer risk assessment is not needed.

6. *Animal metabolism*. There were no major differences in the bioavailability, routes or rates of excretion, or metabolism of spinosyn A and spinosyn D following oral administration in rats. Urine and fecal excretions were almost completed in 48-hours post-dosing. In addition, the routes and rates of excretion were not affected by repeated administration.

7. *Metabolite toxicology*. The residue of concern for tolerance setting purposes is the parent material (spinosyn A and spinosyn D). Thus, there is no need to address metabolite toxicity.

8. *Neurotoxicity*. Spinosad did not cause neurotoxicity in rats in acute, subchronic, or chronic toxicity studies.

9. *Endocrine effects*. There is no evidence to suggest that spinosad has an effect on any endocrine system.

C. Aggregate Exposure

1. *Dietary exposure*. For purposes of assessing the potential dietary exposure from use of spinosad on almonds, citrus, and leafy vegetables as well as from other existing and pending uses, a conservative estimate of aggregate exposure is determined by basing the TMRC on the proposed tolerance levels for spinosad and assuming that 100% of the almonds, citrus, leafy vegetables, and other existing and pending crop uses grown in the U.S. were treated with spinosad. The TMRC is obtained by multiplying the tolerance residue levels by the consumption data which estimates the amount of crops and related foodstuffs consumed by various population subgroups. The use of a tolerance level and 100% of crop treated clearly results in an overestimate of human exposure and a safety determination for the use of spinosad on crops cited in this summary that is based on a conservative exposure assessment.

2. *Drinking water*. Another potential source of dietary exposure are residues in drinking water. Based on the available environmental studies conducted with spinosad wherein it's properties show little or no mobility in soil, there is no anticipated exposure to residues of spinosad in drinking water. In addition, there is no established Maximum Concentration Level for residues of spinosad in drinking water.

3. *Non-dietary exposure*. Spinosad is currently registered for use on cotton with several crop registrations pending all of which involve applications of spinosad in the agriculture environment. Spinosad is also currently registered for use on turf and ornamentals at low rates of application (0.04 to 0.54 lb a.i. per acre). Thus, the potential for non-dietary exposure to the general population is not expected to be significant.

D. Cumulative Effects

The potential for cumulative effects of spinosad and other substances that have a common mechanism of toxicity is also considered. In terms of insect control, spinosad causes excitation of the insect nervous system, leading to involuntary muscle contractions, prostration with tremors, and finally paralysis. These effects are consistent with the activation of nicotinic acetylcholine receptors by a mechanism that is clearly novel and unique among known insecticidal compounds. Spinosad also has effects on the GABA receptor function that may contribute further to its insecticidal activity. Based on results found in tests with various mammalian species, spinosad appears to have a mechanism of toxicity like that of many amphiphilic cationic compounds. There is no reliable information to indicate that toxic effects produced by spinosad would be cumulative with those of any other pesticide chemical. Thus it is appropriate to consider only the potential risks of spinosad in an aggregate exposure assessment.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions and the proposed RfD described above, the aggregate exposure to spinosad use on almonds, citrus, leafy vegetables, and other existing and pending crop uses will utilize 20.0% of the RfD for the U.S. population. A more realistic estimate of dietary exposure and risk relative to a chronic toxicity endpoint is obtained if average (anticipated) residue values from field trials are used. Inserting the average residue values in place of tolerance residue levels produces a more realistic, but still conservative risk assessment. Based on average or anticipated residues in a dietary risk analysis, the use of spinosad on almonds, citrus, leafy vegetables, and other existing and pending crop uses will utilize 3.2% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not

pose appreciable risks to human health. Thus, it is clear that there is reasonable certainty that no harm will result from aggregate exposure to spinosad residues on almonds, citrus, leafy vegetables, and other existing and pending crop uses.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of spinosad, data from developmental toxicity studies in rats and rabbits and a 2-generation reproduction study in the rat are considered. 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 effects from exposure to the pesticide on the reproductive capability and potential systemic toxicity of mating animals and on various parameters associated with the well-being of pups.

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 for spinosad relative to pre- and post-natal effects for children is complete. Further, for spinosad, the NOELs in the dog chronic feeding study which was used to calculate the RfD (0.0268 mg/kg/day) are already lower than the NOELs from the developmental studies in rats and rabbits by a factor of more than 10-fold.

Concerning the reproduction study in rats, the pup effects shown at the highest dose tested were attributed to maternal toxicity. Therefore, it is concluded that an additional uncertainty factor is not needed and that the RfD at 0.0268 mg/kg/day is appropriate for assessing risk to infants and children.

Using the conservative exposure assumptions previously described (tolerance level residues), the percent (RfD) utilized by the aggregate exposure to residues of spinosad on almonds, citrus, leafy vegetables, and other existing and pending crop uses is 36.1% for children 1 to 6 years old, the most sensitive population subgroup. If average or anticipated residues are used in the dietary risk analysis, the use of spinosad on these crops will utilize 7.0% of the RfD for children 1 to 6 years old. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, it is concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to spinosad residues on almonds, citrus, leafy vegetables, and other existing and pending crop uses.

F. International Tolerances

There are no Codex maximum residue levels established for residues of spinosad on almonds, citrus, and leafy vegetables or any other food or feed crop. (Adam Heyward)

2. Zeneca Ag Products

PP 7F4875

EPA has received a pesticide petition (PP 7F4875) from Zeneca Ag Products, 1800 Concord Pike, P.O. Box 15458, Wilmington, DE 19850–5458. The petition proposes pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish tolerances for residues of the insecticide lambda-cyhalothrin and its epimer in or on the raw agricultural commodities avocados (imported) at 0.2 parts per million (ppm); cereal grain crop group (except rice and wild rice): grain, 0.2 ppm, forage (except sorghum) 6.0 ppm, hay 2.0 ppm, straw 2.0 ppm, aspirated grain dust 2.0 ppm, bran 0.8 ppm and flour 0.6 ppm; fruiting vegetable crop group (except cucurbits) 0.2 ppm; peas and beans - edible podded crop subgroup 0.2 ppm; peas and beans - succulent shelled crop subgroup 0.01 ppm; peas and beans - dried shelled subgroup (except soybean) 0.1 ppm; peanut hay 3.0 ppm; sorghum forage 0.3 ppm; sorghum fodder 0.5 ppm; and sugarcane 0.05 ppm. The names for lambda-cyhalothrin and its epimer are as follows: lambda-cyhalothrin, a 1:1 mixture of (*S*)-alpha-cyano-3-phenoxybenzyl-(*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*R*)-alpha-cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate. Epimer of lambda-cyhalothrin, a 1:1 mixture of (*S*)-alpha-cyano-3-phenoxybenzyl- (*Z*)(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*R*)-alpha-cyano-3-phenoxybenzyl- (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of lambda-cyhalothrin has been studied in cotton, soybean, cabbage, and wheat plants. The studies show that the metabolism generally follows that of other pyrethroid insecticides. The ester linkage is cleaved to form cyclopropanecarboxylic acids and the corresponding phenoxybenzyl alcohol. Overall the studies show that unchanged lambda-cyhalothrin is the principal constituent of the residue on edible portions of these crops.

2. *Analytical method*. An adequate analytical method (gas liquid chromatography with an electron capture detector) is available for enforcement purposes.

3. *Magnitude of residues*. Avocados - six trials were conducted at 3 sites within Mexico. In these trials the maximum observed residue was 0.11 ppm. Peppers (nonbell) - three trials were conducted with a maximum observed residue of 0.13 ppm. Peppers (bell) - eight trials were conducted with a maximum observed residue of 0.16 ppm. Edible podded peas - three trials were conducted with a maximum observed residue of 0.14 ppm. Edible podded beans - six trials were conducted with a maximum observed residue of 0.035 ppm. Succulent shelled peas - six trials were conducted with a maximum observed residue of 0.01 ppm. Succulent shelled beans - six trials were conducted with a maximum observed residue of 0.01 ppm. Dried shelled peas - five trials were conducted with a maximum observed residue of 0.06 ppm. Dried shelled peas - eight trials were conducted with a maximum observed residue of 0.015 ppm. Peanut hay - eleven trials were conducted with a maximum observed residue of 2.61 ppm. Sorghum forage and fodder - thirteen trials were conducted with a maximum observed residue of 0.3 and 0.42 ppm, respectively, in forage and fodder. Sugarcane - nine trials were conducted with a maximum observed residue of 0.035 ppm. A sugarcane processing study was conducted to determine if residues concentrated in molasses or refined sugar. No concentration of residues was observed in either processed commodity.

B. Toxicological Profile

The following toxicity studies have been conducted to support the request for a regulation for residues of lambda-cyhalothrin in or on rice.

1. *Acute toxicity*. Acute toxicity studies with the technical grade of the active ingredient lambda-cyhalothrin: oral LD_{50} in the rat of 79 milligram/

kilogram (mg/kg) (males) and 56 mg/kg (females), dermal LD_{50} in the rat of 632 mg/kg (males) and 696 mg/kg females, primary eye irritation study showed mild irritation, and primary dermal irritation study showed no irritation.

2. *Genotoxicity*. The following genotoxicity tests were all negative: a gene mutation assay (Ames), a mouse micronucleus assay, an in vitro cytogenetics assay, and a gene mutation study in mouse lymphoma cells.

3. *Reproductive and developmental toxicity*—i. A three-generation reproduction study in rats fed diets containing 0, 10, 30, and 100 ppm with no developmental toxicity observed at 100 ppm, the highest dose tested. The maternal no-observed-effect-level (NOEL) and lowest-observed-effect-level (LOEL) for the study are established at 30 (1.5 mg/kg/day) and 100 ppm (5 mg/kg/day), respectively, based upon decreased parental body weight gain. The reproductive NOEL and LOEL are established at 30 (1.5 mg/kg/day) and 100 ppm (5 mg/kg/day), respectively, based on decreased pup weight gain during weaning.

ii. A developmental toxicity study in rats given gavage doses of 0, 5, 10, and 15 mg/kg/day with no developmental toxicity observed under the conditions of the study. The developmental NOEL is greater than 15 mg/kg/day, the highest dose tested. The maternal NOEL and LOEL are established at 10 and 15 mg/kg/day, respectively, based on reduced body weight gain.

iii. A developmental toxicity study in rabbits given gavage doses of 0, 3, 10, and 30 mg/kg/day with no developmental toxicity observed under the conditions of the study. The maternal NOEL and LOEL are established at 10 and 30 mg/kg/day, respectively, based on decreased body weight gain. The developmental NOEL is greater than 30 mg/kg/day, the highest dose tested.

4. *Subchronic toxicity*—i. A 90–day feeding study in rats fed doses of 0, 10, 50, and 250 ppm with a NOEL of 50 ppm and a LOEL of 250 ppm based on body weight gain reduction.

ii. A 21–day study in rabbits exposed dermally to doses of 0, 10, 100, and 1,000 mg/kg/day, 6 hours/day, 5 days/week with a systemic NOEL > 1,000 mg/kg/kg. There were no clinical signs of systemic toxicity at any dose level tested.

5. *Chronic toxicity*—i. A 12–month feeding study in dogs fed dose (by capsule) levels of 0, 0.1, 0.5, and 3.5 mg/kg/day with a NOEL of 0.1 mg/kg/day. The LOEL for this study is established at 0.5 mg/kg/day based upon clinical signs of neurotoxicity.

ii. A 24–month chronic feeding/carcinogenicity study with rats fed diets containing 0, 10, 50, and 250 ppm. The NOEL was established at 50 ppm and LOEL at 250 ppm based on reduced body weight gain. There were no carcinogenic effects observed under the conditions of the study.

iii. A carcinogenicity study in mice fed dose levels of 0, 20, 100, or 500 ppm (0, 3, 15, or 75 mg/kg/day) in the diet for 2 years. A systemic NOEL was established at 100 ppm and systemic LOEL at 500 ppm based on decreased body weight gain in males throughout the study at 500 ppm. The Agency has classified lambda-cyhalothrin as a Group D carcinogen (not classifiable due to an equivocal finding in this study). Zeneca concludes that no treatment-related carcinogenic effects were observed under the conditions of the study.

6. *Animal metabolism*. Metabolism studies in rats demonstrated that distribution patterns and excretion rates in multiple oral dose studies are similar to single-dose studies. There is an accumulation of unchanged compound in fat upon chronic administration with slow elimination. Otherwise, lambda-cyhalothrin was rapidly metabolized and excreted. The metabolism of lambda-cyhalothrin in livestock has been studied in the goat, chicken, and cow. Unchanged lambda-cyhalothrin is the major residue component of toxicological concern in meat and milk.

7. *Metabolite toxicology*. The Agency has previously determined that the metabolites of lambda-cyhalothrin are not of toxicological concern and need not be included in the tolerance expression. Given this determination, Zeneca concludes that there is no need to discuss metabolite toxicity.

8. *Endocrine effects*. No evidence of such effects were reported in the toxicology studies described above. There is no evidence at this time that lambda-cyhalothrin causes endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. For the purposes of assessing the potential dietary exposure for all existing and pending tolerances for lambda-cyhalothrin, Zeneca has utilized available information on anticipated residues and percent crop treated. For all existing and pending tolerances the anticipated residue contribution (ARC) is estimated at 0.000212 mg/kg/body weight (bwt)/day.

ii. *Drinking water*. Laboratory and field data have demonstrated that lambda-cyhalothrin and its degradates are immobile in soil and will not leach into groundwater. Other data show that lambda-cyhalothrin is virtually insoluble in water and extremely lipophilic. As a result, Zeneca concludes that residues reaching surface waters from field runoff will quickly adsorb to sediment particles and be partitioned from the water column. Zeneca concludes that together these data indicate that residues are not expected in drinking water.

2. *Non-dietary exposure*. Other potential sources of exposure are from non-occupational sources such as structural pest control and ornamental plant and lawn use of lambda-cyhalothrin. Zeneca has no data upon which to estimate exposure from these uses. However, given the extremely low vapor pressure of lambda-cyhalothrin (1.5×10^{-9} millimeters (mm) of mercury (Hg)) and the low use rates, Zeneca concludes that inhalation and dermal exposure from these uses will be insignificant.

D. Cumulative Effects

At this time, Zeneca cannot make a determination based on available and reliable information that lambda-cyhalothrin and other substances that may have a common mechanism of toxicity would have cumulative effects. Thus, Zeneca concludes that for purposes of this tolerance it is appropriate only to consider the potential risks of lambda-cyhalothrin in an aggregate exposure assessment.

E. Safety Determination

The acceptable Reference Dose (RfD) based on a NOEL of 0.1 mg/kg/bwt/day from the chronic dog study and a safety factor of 100 is 0.001 mg/kg/bwt/day. A chronic dietary exposure/risk assessment has been performed for lambda-cyhalothrin using the above RfD. Available information on anticipated residues and percent crop treated was incorporated into the analysis to estimate the ARC. The ARC is generally considered a more realistic estimate than an estimate based on tolerance level residues.

1. *U.S. population*. The ARC from established tolerances and the current and pending actions are estimated to be 0.000212 mg/kg/bwt/day and utilize 24.9% of the RfD for the U.S. population.

2. *Infants and children*. The ARC for children, aged 1 to 6 years old, and non-nursing infants (subgroups most highly exposed) utilizes 77% and 48% of the RfD, respectively. Generally speaking, the Agency has no cause for concern if ARC for all published and proposed tolerances is less than the RfD.

F. International Tolerances

There are no Codex maximum residue levels (MRL) established for residues of lambda-cyhalothrin in or on avocados; cereal grain crop group: grain, forage, hay, straw, aspirated grain dust, bran, flour; fruiting vegetable crop group; peas and beans - edible podded crop subgroup; peas and beans - succulent shelled crop subgroup; peas and or beans - dried shelled subgroup. (Beth Edwards)

[FR Doc. 97–26536 Filed 10–7–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PP 5E4597; FRL–5746–7]

Milliken & Company; Correction of Pesticide Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of correction.

SUMMARY: This notice corrects and extends the comment period of pesticide petition (PP) 5E4597, submitted by Milliken & Company proposing to establish an exemption from the requirement of a tolerance for Poly(ethylene glycol) modified FD&C Blue No. 1, Methyl Poly(ethylene glycol) modified FD&C Blue No. 1, and Poly(ethylene glycol) modified Methyl Violet 2B. Pesticide petition 5E4597, was published in the **Federal Register** on August 29, 1997 (62 FR 45804). EPA is extending the comment period to allow additional time for comment.

DATES: The comment period is extended to October 29, 1997.

FOR FURTHER INFORMATION CONTACT: By mail: Amelia Acierto, Registration Division, (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 4th Floor, CS #1, 2800 Crystal Drive, Arlington, VA (703)–308–8377; e-mail: ascierto.amelia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a Notice of Filing in the **Federal Register** of August 29, 1997 (62 FR 45804) (PF–758; FRL–5738–2) for pesticide petitions (PP) 3E4246, 7F4845, and 5E4597. This notice corrects PP 5E4597.

In FR Doc. 97-23097, in the issue for August 29, 1997, on page 45808, in the third column, in the first paragraph under PP 5E4597, the phrase ''not to exceed 0.6 parts per billion (ppb),'' should be corrected to read ''not to exceed 1 to 5% of the final formulation.''

List of subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Authority: 7 U.S.C. 136a.

Dated: September 25, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–26534; Filed 10–7–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Publication of Recommendations Relating to HIPA A Health Data Standards

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Section 1172 (f), Subtitle F of Pub. L. 104–191, the Health Insurance Portability and Accountability Act of 1996, requires the Secretary of Health and Human Services to publish in the Federal Register any recommendation of the National Committee on Vital and Health Statistics (NCVHS) regarding the adoption of a data standard under that law. On September 9, the NCVHS submitted recommendations to the Secretary relating to the unique identifier for payers, the unique identifier for individuals, and security standards. Accordingly, the full text of the NCVHS recommendations relating to HIPAA data standards is reproduced below. The text of the recommendations is also available on the NCVHS website: http//aspe.os.dhhs.gov/ncvhs/.

SUPPLEMENTARY INFORMATION: Under the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 HIPAA), the Secretary of Health and Human Services is required to adopt standards for specified administrative health care transactions to enable information to be exchanged electronically. The law requires that, within 24 months of adoption, all health plans, health care clearinghouses and health care providers who choose to conduct these transactions electronically must comply with these standads. Further, the law requires the Secretary to submit to Congress detailed recommendations on standards with respect to the privacy of individually identifiable health information. In preparing these reports and recommendations, the Secretary is required to consult with the NCHVHS, the statutory public advisory body to HHS on health data, privacy and health information policy. On September 9, the Committee submitted recommendations to the Secretary relating to the unique identifier for payers, the unique identifier for individuals, and security standards.

Accordingly, the full text of the NCVHS recommendations relating to HIPAA data standards is reproduced below.

Recommendations Relating to the National PAYERID

September 9, 1997.

The Honorable Donna E. Shalala,
Secretary, Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, D.C. 20201

Dear Secretary Shalala: On behalf of the National Committee on Vital and Health Statistics (NCVHS), I am pleased to forward to you our recommendations relating to another of the health data standards being proposed for adoption in accordance with the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The NCVHS is very pleased to provide support, advice and consultation to you in this effort.

The NCVHS has been briefed on the proposal for the national standard for identifiers for health plans or PAYERID, and we offer our strong support. The proposal includes a nine digit numeric identifier that would be assigned to all health plans. The identifier includes a check digit and contains no embedded intelligence. We recommend that HHS proceed to publish the proposal for public comment without delay. In the interests of operational efficiency and simplification, we suggest that the Department also leave open the option of moving to an alphanumeric identifier in the future. While public comments are likely to on the technical details of the number and the optimal approach to enumeration, we have found broad support for the proposal in general and urge you to proceed.

The Committee did identify one concern that we bring to your attention. The PAYERID, as proposed, replaces the plan ID and sub ID used in current transactions. The sub ID is currently used for electronic routing, and concern has been expressed that this function will be lost. We recommend that this functionality be addressed before the final rule is issued.

We appreciate you national leadership in health data standards, electronic data interchange and privacy, and we are privileged to work with you on these issues.