ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA--HQ--OPP--2006--0204; FRL--8094--5]

Quinalphos ethyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of quinalphos ethyl in or on the raw agricultural commodities barley, grain; barley, hay; barley, straw; flax, seed; milk, fat; sunflower, seed; wheat, forage; wheat, grain; wheat, hay; and wheat, straw. Nissan Chemical Industries, Ltd requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 27, 2006. Objections and requests for hearings must be received on or before November 27, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA--HQ--OPP--2006--0204. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at http://www.regulations.gov. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office’s pilot e-CFR site at http://www.gpoaccess.gov/ecfr.

FOR FURTHER INFORMATION CONTACT: James A. Tompkins, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460--0001; telephone number: 703--305--5697; e-mail address: Tompkins.jim@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

• Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.

• Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.

• Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.

• Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Access Electronic Copies of this Document?


C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in

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### List of Subjects 40 CFR Part 180

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


Lois Rossi,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

§ 180.361 Pendi'methalin, Tolerances for Residues.

(a) * * *

<table>
<thead>
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<th>Commodity</th>
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<tr>
<td>Alfalfa, forage</td>
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<td>Alfalfa, seed</td>
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<tr>
<td>Wheat, straw</td>
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</table>
accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006–0204 in the subject line on the first page of your submission. All requests must be in writing, and be mailed or delivered to the Hearing Clerk on or before November 27, 2006.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in ADDRESSES. Information not marked confidential pursuant to 40 CFR part 22 will be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2006–0204, by one of the following methods:

- Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket’s normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the Federal Register of August 2, 2006 (71 FR 43762) (FRL–8057–2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (FP 0F6076) by Nissan Chemical Industries, Ltd (Nissan), 7-1-3 Chome, Kanda-Nishiki-Cho Chiyoda-Ku, Tokyo, 111–0054, Japan. The petition requested that 40 CFR 180.441 be amended by establishing a tolerance for residues of the herbicide quizalofop-p-ethyl on barley, flax (seed) and wheat at 0.05 part per million (ppm) and sunflower (seed) at 2.0 part per million. That notice included a summary of the petition prepared by Nissan Chemical Industries, Ltd, the registrant. There were no comments received in response to the notice of filing.

During the course of the review, the Agency determined that based on the calculated maximum dietary burdens (MTDBs) for quizalofop-p-ethyl the current tolerance for milk, fat should be increased. Therefore, the petition was subsequently amended to propose that 40 CFR 180.441(a)(2) be amended by proposing a tolerance be established for the combined residues of the herbicide quizalofop, [2-(4-(6-chloroquinoxalin-2-yl)oxy)phenoxy]propanoic acid, quizalof-ethyl (ethyl 2-(4-(6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoate), and quizalofop-methyl (methyl 2-(4-(6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoate), all expressed as quizalofop ethyl on milk, fat at 0.25 ppm. This tolerance will replace the current milk, fat tolerance listing of 0.05 ppm. During the course of the review the Agency also determined that the available data supported a reduction in the proposed tolerance for sunflower, seed and that the commodities for barley and wheat needed to be defined based on current terminology. The petition was also amended propose that 40 CFR 180.441(a)(3) be amended by proposing that tolerances be established for the combined residues of the herbicide quizalofop-p-ethyl ester (ethyl R)-2-(4-(6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoate) and its acid metabolite quizalofop-p [R-(2-(4-(6-(quinoxalin-2-yl)oxy)phenoxy)propanoic acid)] and the S enantiomers of both the ester and the acid, all expressed as quizalofop-p-ethyl ester, in or on the raw agricultural commodities barley, grain at 0.05 ppm; barley, hay at 0.05 ppm; barley, straw at 0.05 ppm; barley, straw at 0.05 ppm; flax, seed at 0.05 ppm; flax, seed at 0.05 ppm; flax, seed at 0.05 ppm; forage at 0.05 ppm; wheat, forage at 0.05 ppm; wheat, at 0.05 ppm; and wheat, straw at 0.05 ppm.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue.”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see http://www.epa.gov/fedreg/PEST/1997/November/Day-26/p30948.htm.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues of quizalofop, quizalofop-ethyl, and quizalofop-methyl, all expressed as quizalofop ethyl on milk, fat at 0.25 ppm, and for the combined residues of quizalofop-p-ethyl ester, quizalof-p, and the S-enantiomers of both the ester and the acid, all expressed as quizalofop ethyl in or on barley, grain at 0.05 ppm; barley, hay at 0.05 ppm; barley, straw at 0.05 ppm; flax, seed at 0.05 ppm; sunflower, seed at 1.9 ppm; wheat, forage at 0.05 ppm; wheat, grain at 0.05 ppm; wheat, hay at 0.05 ppm; and wheat, straw at 0.05 ppm. EPA’s assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic effects caused by quizalofop ethyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found in the Federal Register of June 16, 1998 http://www.epa.gov/fedreg/PEST/1998/June/Day-16/p15746.htm.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicity study identified as...
appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at http://www.epa.gov/pesticides/health/human.htm.


C. Exposure Assessment

1. Dietary exposure from food and feed uses. Tolerances have been established (40 CFR 180.441) for the combined residues of quizalofop, quizalofop-p ethyl and associated metabolites, all expressed as quizalofop ethyl, in or on a variety of raw agricultural commodities. Tolerances have been established under 40 CFR 180.441(a)(2) for quizalofop, quizalofop-ethyl, and quizalofop-methyl, all expressed as quizalofop ethyl in meat, fat, and meat byproducts of cattle, goat, hog, horse poultry, and sheep; milk and milk fat and egg. Risk assessments were conducted by EPA to assess dietary exposures from quizalofop ethyl in food as follows:

i. Acute exposure. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one-day or single exposure.

No such effects were identified in the toxicological studies for quizalofop ethyl; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. Chronic exposure. In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCIDTM), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments:

- tolerance level residues for all 
- commodities and 100 percent crop
- treated. The assessment included existing food uses as well as the newly 
- proposed tolerances for uses on barley, wheat, sunflower, and flax. 
- PCT and/or anticipated residues were not used.

iii. Cancer. EPA concluded that 
- quizalofop ethyl should be classified as a 
- Category D carcinogen (not classifiable 
- as to human carcinogenicity), based on 
- results of rat and mouse cancer studies 
- along with other relevant short-term 
- toxicity, mutagenicity studies, and 
- structure-activity relationships. The 
- Group D classification is based on an 
- approximatively doubling in the incidence 
- of mice liver tumors between controls 
- and the high-dose. This finding was 
- not considered strong enough to warrant 
- the classification of a Category C (possible 
- human carcinogen); the increase was of 
- marginal statistical significance, 
- occurred at high dose which exceeded 
- the MTD, and occurred in a study in 
- which the concurrent control for liver 
- tumors was somewhat low as compared 
- to the historical controls, while the 
- high-dose control group was at the 
- upper end of the previous historical 
- control groups. Based on the results of 
- the above adequate studies, the Agency 
- believes that quizalofop-p ethyl does 
- not pose a significant cancer risk to humans 
- and a quantitative cancer exposure 
- assessment is unnecessary.

2. Dietary exposure from drinking water. The Agency lacks sufficient 
- monitoring exposure data to complete a 
- comprehensive dietary exposure 
- analysis and risk assessment for 
- quizalofop ethyl in drinking water. 
- Because the Agency has not have 
- comprehensive monitoring data, 
- drinking water concentration estimates 
- are made by reliance on simulation or 
- modeling taking into account data on 
- the physical characteristics of 
- quizalofop ethyl. Further information 
- regarding EPA drinking water models 
- used in pesticide exposure assessment 
- can be found at http://www.epa.gov/ 

Based on the PRZM/EXAMS and SCI-GROW models, the estimated 
- environmental concentrations (EECs) of quizalofop ethyl for chronic exposures 
- are 1.99 parts per billion (ppb) for 
- surface water and 0.15 ppb for ground 
- water.

Modeled estimates of drinking water concentrations were directly entered 
into the dietary exposure model (DEEM-FCID). For chronic dietary risk 
assessment, the annual average concentration in surface water of 1.99 
ppb was used to assess the contribution to drinking water.

3. From non-dietary exposure. The term “residential exposure” is used in 
this document to refer to non-
- occupational, non-dietary exposure 
- (e.g., for lawn and garden pest control, 
- indoor pest control, termiteicides, and 
- flea and tick control on pets).

Quizalofop ethyl is not registered for use on any sites that would result in 
residential exposure.

4. Cumulative effects from substances with a common mechanism of toxicity. 
Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether 
to establish, modify, or revoke a 
tolerance, the Agency consider 
“available information” concerning the 
cumulative effects of a particular 
pesticide’s residues and “other 
substances that have a common 
mechanism of toxicity.”

Unlike other pesticides for which EPA has followed a cumulative risk approach 
- based on a common mechanism of toxicity, EPA has not made a common 
- mechanism of toxicity finding as to 
- quizalofop ethyl and any other 
- substances and quizalofop ethyl does 
- not appear to produce a toxic metabolite 
- produced by other substances. For the 
- purposes of this tolerance action, 
- therefore, EPA has not assumed that 
- quizalofop ethyl has a common 
- mechanism of toxicity with other 
- substances. For information regarding 
EPA’s efforts to determine which 
chemicals have a common mechanism 
of toxicity and to evaluate the 
cumulative effects of such chemicals, 
see the policy statements released by 
EPA’s Office of Pesticide Programs 
concerning common mechanism 
determinations and procedures for 
cumulating effects from substances 
found to have a common mechanism on EPA’s website at http://www.epa.gov/ 
pesticides/cumulative.

D. Safety Factor for Infants and Children

1. In general. Section 408 of FFDCA provides that EPA shall apply an 
additional tenfold margin of safety for 
infants and children in the case of 
threshold effects to account for prenatal 
and postnatal toxicity and the 
completeness of the data base on 
toxicity and exposure unless EPA 
determines based on reliable data that a
different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. Prenatal and postnatal sensitivity. There are no concerns and no residual uncertainties for increased qualitative or quantitative susceptibility following in utero or prenatal/postnatal exposure or for prenatal and postnatal toxicity. See the Federal Register of June 16, 1998 http://www.epa.gov/fedrgstr/EPA-PEST/1998/June/Duy-16/p15746.htm.

A developmental neurotoxicity study is not required for quizalofop ethyl based on the following:

i. Quizalofop ethyl does not appear to be a neurotoxic chemical.

ii. No-treatment -related effects on brain weight or histopathology of the nervous system were observed in studies that measured these endpoints.

iii. No evidence of developmental anomalies of the fetal nervous system were observed in either rats or rabbits, at maternally toxic doses up to 300 and 600 mg/kg/day, respectively.

iv. No evidence of an effect on functional development was observed in a postnatal segment of the developmental toxicity study in rats.

3. Conclusion. There is a complete toxicity data base for quizalofop ethyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be removed. The FQPA factor is removed because the toxicology data base is complete; a developmental neurotoxicity study is not required; developmental toxicity studies showed no increased sensitivity in fetuses as compared to maternal animals following in utero exposures in rats and rabbits; a 2-generation reproduction study showed no increased sensitivity in pups as compared to adults; and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.

E. Aggregate Risks and Determination of Safety

1. Acute risk. Quizalofop-ethyl is not expected to pose an acute risk because no toxicological endpoints attributable to a single exposure (dose) were identified in the toxicology data base.

2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to quizalofop-ethyl from food will utilize 11% of the cPAD for the U.S. population, 27% of the cPAD for infants <1 year old, and 29% of the cPAD for children 1 to 2 years old. There are no current or requested residential uses for quizalofop-ethyl that result in chronic residential exposure to quizalofop-ethyl. Therefore, EPA does not expect the aggregate exposures, which are equivalent to chronic dietary exposures, to exceed 100% of the cPAD.

3. Short-term risk. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Quizalofop ethyl is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency’s level of concern.

4. Intermediate-term risk. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Quizalofop ethyl is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency’s level of concern.

5. Aggregate cancer risk for U.S. population. For the reasons stated in this unit, quizalofop ethyl is not expected to pose a greater than negligible cancer risk.

6. Determination of safety. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to quizalofop ethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (High Performance Liquid Chromatography (HPLC) Methods, SARS–98–06 (for flax and sunflower) and Morse Method Meth-147 (for wheat and barley)) are available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305–2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There is a Canadian maximum residue limit (MRL) in/on flax at 0.05 mg/kg, which is in agreement with the proposed tolerance on flax, seed. There are no Mexican or Codex MRLs established for quizalofop ethyl, therefore compatibility is not a problem at this time.

V. Conclusion

Therefore, the tolerance is established under 40 CFR 180.441(a)(2) for the combined residues of the herbicide quizalofop (2-[(4-chloroquinoxalin-2-yl)oxy]phenoxy)propanoic acid), quizalofop-ethyl (ethyl-2-[(4-(6-chloroquinoxalin-2-yl)oxy]phenoxy)propanoate), and quizalofop-methyl (methyl-2-[(4-(6-chloroquinoxalin-2-yl)oxy]phenoxy)propanoate), and all expressed as quizalofop ethyl in or on flax, milk, fat at 0.25 ppm. This tolerance will replace the current milk, fat tolerance listing of 0.05 ppm. Tolerances are also established under 40 CFR 180.441(a)(3) for the combined residues of the herbicide quizalofop-p ethyl ester (ethyl-R)- (R)-2-[(4-((6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoate) and its acid metabolite quizalofop-p [(R)-2-[(4-((6-quinolin-2-yl)phenoxy)propanoic acid) and the S enantiomers of both the ester and the acid, all expressed as quizalofop-p ethyl ester, in or on the raw agricultural commodities barley, grain at 0.05 ppm; barley, hay at 0.05 ppm; barley, straw at 0.05 ppm; flax, seed at 0.05 ppm; sunflower, seed at 1.9 ppm; wheat, forage at 0.05 ppm; wheat grain at 0.05 ppm; wheat, hay at 0.05 ppm; and wheat, straw at 0.05 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May
have federalism implications. 

Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the Federal Register. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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


Lois Rossi,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows: