D. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995, signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate, or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the proposed interim approval action promulgated today does not include a Federal mandate that may result in estimated costs of $100 million or more to state, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under state or local law, and imposes no new Federal requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Dated: November 2, 1995.

Patrick M. Tobin,

Acting Regional Administrator.

Part 70, title 40 of the Code of Federal Regulations is amended as follows:

PART 70—[AMENDED]

1. The authority citation for part 70 continues to read as follows:

Authority: 42 U.S.C. 7401, et seq.

2. Appendix A to part 70 is amended by adding the entry for North Carolina in alphabetical order to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

North Carolina

(a) Department of Environment, Health and Natural Resources, Western North Carolina Regional Air Pollution Control Agency, Forsyth County Department of Environmental Affairs and the Mecklenburg County Department of Environmental Protection: submitted on November 12, 1993, and supplemented on December 17, 1993; February 28, 1994; May 31, 1994; and August 9, 1995; interim approval effective on December 15, 1995; interim approval expires December 15, 1997.

(b) (Reserved)

* * * * *

[FR Doc. 95–28186 Filed 11–14–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 180

[PP 2F4072/R2188; FRL–4986–7]

RIN 2070–AB78

Metalaxyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes tolerances for combined residues of the fungicide metalaxyl [*N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl) alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety and *N*-(2-hydroxymethyl-6-methylphenyl)-*N*-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl equivalents, in or on the raw agricultural commodities brassica (cole) leafy vegetables group [except broccoli, cabbage, cauliflower, brussels sprouts, and mustard greens] at 0.1 part per million (ppm); brussels sprouts at 2.0 ppm; cabbage at 1.0 ppm; cauliflower at 1.0 ppm; and mustard greens at 5.0 ppm. Ciba-Geigy Corp. submitted a petition under the Federal Food, Drug and Cosmetic Act (FFDCA) for the regulation to establish a maximum permissible level for residues of the fungicide.

EFFECTIVE DATE: This rule becomes effective on October 27, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 2F4072/R2188], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections shall be labeled Tolerance Petition Fees and forwarded to EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P. O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of any objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the document number [PP 2F4072/R2188]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Connie B. Welch, Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305-6226; e-mail: welch.connie@.epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice of filing, published in the Federal Register of June 15, 1995 (60 FR 31465), which announced that Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419, had submitted a pesticide petition, PP 2F4063, to EPA requesting that the Administrator, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), establish tolerances for combined residues of the fungicide metalaxyl [*N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl) alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety and *N*-(2-hydroxymethyl-6-methylphenyl)-*N*-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl equivalents, in or on the raw agricultural commodities brassica (cole) leafy vegetables group [except broccoli, cabbage, cauliflower, brussels sprouts, and mustard greens] at 0.1 part per million (ppm); brussels sprouts at 2.0 ppm; cabbage at 1.0 ppm; cauliflower at 1.0 ppm; and mustard greens at 5.0 ppm.

There were no comments received in response to the notice of filing. The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the tolerance include:

1. A 3-month dietary study in rats with a no-observed-effect level (NOEL) at 17.5 milligrams per kilogram (mg/kg) body weight (bwt)/day (250 parts per million (ppm)).

2. A developmental toxicity study in rats with a NOEL of 50 mg/kg bwt for developmental toxicity and maternal toxicity.

3. A developmental toxicity study in rabbits with a NOEL of 300 mg/kg bwt highest dose tested (HDT). Metalaxyl did not cause developmental toxicity, even in the presence of maternal toxicity.

4. Metalaxyl was negative in bacterial and mammalian gene mutation. The fungicide also did not increase the frequency of reverse mutations in yeast. Metalaxyl was negative in an *in vivo* cytogenetics assay (hamsters) and a dominant-lethal assay (mice).

Metalaxyl did not increase unscheduled DNA synthesis in rat primary hepatocytes or in human fibroblasts. These results suggest that metalaxyl is not genotoxic.

5. A three-generation rat reproduction study with a NOEL of 63 mg/kg bwt/day (1,250 ppm).

6. A 6-month dog feeding study with a NOEL of 6.3 mg/kg bwt/day (250 ppm). Effects found at 25 mg/kg were increased serum alkaline phosphatase activity and increased liver weight and liver-to-brain weight ratios without histological changes.

7. A 2-year rat chronic feeding/carcinogenicity study with no compound-related carcinogenic effects under the conditions of the study at dietary levels up to 1,250 ppm. The NOEL is 13 mg/kg bwt/day (250 ppm). The lowest-observed-effect level (LOEL) is 63 mg/kg/day based upon slight increases in liver weight to body weight ratios and periacinar vacuolation of hepatocytes.

8. A 2-year mouse oncogenic study with no compound-related carcinogenic effects under the conditions of the study at dietary levels up to 190 mg/kg/day.

Because of concerns raised over some equivocal increases in tumor incidences in the male mouse liver and the male rat adrenal medulla, and the female rat thyroid, the two chronic feeding studies were submitted to the Environmental Pathology Laboratories (EPL) for an independent reading of the microscopic slides. The new pathological evaluation by EPL and the original reports of the rat and mouse oncogenicity studies were then both submitted for review to EPA's Carcinogen Assessment Group (CAG). A final review of the carcinogenicity studies and related material was performed by the Peer Review Committee of the Toxicology Branch (TB) of the Office of Pesticide Programs (OPP).

The four major issues evaluated by CAG and the peer review group included: (1) Perifollicular cell adenomas in the thyroid of female rats; (2) adrenal medullary tumors (pheochromocytomas) in male rats; (3) liver tumors in male mice; and (4) whether the HDT (1,250 ppm) in the rat and mouse oncogenicity studies represented a maximum-tolerated dose (MTD).

Regarding the thyroid tumors in female rats, the peer review group concluded that the increased incidences of thyroid tumors in females of treated groups were not compound related. This conclusion was based on the following: (1) There was no progression of benign tumors (adenomas) to malignancy (carcinomas); (2) there was no increase in hyperplastic changes; (3) there was no dose-response relationship; and (4) the two reevaluations of the microscopic slides by the pathologists at EPL and TB in OPP further did not confirm any apparent effects observed in the original report.

The issue of a possible treatment-related increase of adrenal medullary gland tumors, namely, pheochromocytomas, in the male rat was also reassessed by both CAG and the Peer Review Committee. Both concluded that the data, especially in view of the reevaluation of the microscopic slides performed by EPL, did not support a compound-related increase of adrenal medullary tumors; the incidence of pheochromocytomas more accurately represented spontaneous variations of a commonly occurring tumor in the aged rat.

The analysis of the significance of the equivocal increase in the incidence of liver tumors in male mice was very similar to that performed for the rat thyroid and adrenal gland tumors. The original pathological reading of the tissue slides reported an elevated increase of tumors in some treatment groups; however, these increases were not evident after a reevaluation of themicroscopic slides was performed by an independent pathologist at EPL and by the reading of a CAG pathologist. The Peer Review Committee concurred that the reevaluation of the slides is reliable and does not show any compound-related increase in the incidence of liver tumors in the mouse.

The Agency believes that the data from the rat and mouse long-term studies are sufficient to support the conclusion that metalaxyl does not show a carcinogenic potential in laboratory animals. This conclusion is supported by the following: (1) The doses tested in both the rat and mouse long-term studies approached an MTD based upon compound-related changes in liver weight and/or liver histology; (2) extensive available mutagenic evidence indicates no potential genotoxic activity which correlates with the negative carcinogenic potential demonstrated in long-term testing; (3) metalaxyl is not structurally related to known carcinogens; and (4) under the conditions of the rat and mouse tests, no indication of compound-related carcinogenic effects was noted at any of the treatment doses, sexes, or species.

The reference dose (RfD), anticipated residue contribution (ARC), and food additive regulations are covered by existing tolerances.

The nature of the residue is adequately understood. The enforcement methodology has been submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual, Volume II (PAM II). Because of the long lead time for publication of the method in PAM II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-305-5232.

There are presently no actions pending against the continued registration of this chemical.

Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR part 180 will protect the public health. Therefore, the tolerances are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

EPA has established a record for this rulemaking under docket number [PP 2F4072/R2188] (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 a.m. to 4:30 p.m., Monday through Friday, except legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

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.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

Under Executive Order 12866, EPA must judge whether a rule is ''major'' and therefore requires a Regulatory Impact Analysis.

This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12866.

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

OMB has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq*.

List of Subjects in 40 CFR Part 180

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

Dated: October 27, 1995.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. In § 180.408, in paragraph (a) by amending the table therein by revising the entries for Brassica (cole) leafy vegetables group, cabbage, and cauliflower and by adding new entries for brussels sprouts and mustard greens, to read as follows:

§ 180.408 Metalaxyl; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Brassica (cole) leafy vegetables group [except broccoli, cabbage, cauliflower, brussels sprouts, and mustard greens]	0.1
Brussels sprouts	2.0
* * * * *	
Cabbage	1.0
* * * * *	
Cauliflower	1.0
* * * * *	
Mustard greens	2.0
* * * * *	

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[FR Doc. 95–28068 Filed 11–14–95; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 180

[PP 3F4258/R2181; FRL–4983–1]

RIN 2070–AB78

Avermectin B_1 and Its Delta-8,9-Isomer; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes a tolerance for combined residues of the insecticide avermectin B_1 and its delta-8,9-isomer in or on the raw agricultural commodity bell peppers. Merck Research Laboratories requested the regulation to establish a maximum permissible level for residues of the pesticide pursuant to a petition submitted to EPA under the Federal Food, Drug and Cosmetic Act (FFDCA).

EFFECTIVE DATE: This regulation becomes effective November 15, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 3F4258/R2181], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [PP 3F4258/R2181]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: George LaRocca, Product Manager (PM) 13, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 204, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6100; e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 20, 1995 (60 FR 48681), EPA issued a proposed rule that gave notice that Merck Research Laboratories, Inc., had submitted a pesticide petition, PP 3F4258, under section 408 of the FFDCA, 21 U.S.C. 346a, to establish a tolerance for combined residues of the insecticide avermectin B_1 and its delta-8,9-isomer in or on the raw agricultural commodity bell peppers at 0.01 part per million (ppm).

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The data submitted with the proposal and other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the tolerance will protect the public health. Therefore, the tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections and/or request a hearing with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted