■ 2. Section 180.505 is revised to read as follows:

**§ 180.505 Emamectin; tolerances for residues.**

(a) *General.* Tolerances are established for the combined residues of emamectin, (a mixture of a minimum of 90% 4″-epi-methylamino-4″-deoxyavermectin $B_{1a}$ and maximum of 10% 4″-epi-methylamino-4″-deoxyavermectin $B_{1b}$) and its metabolites 8,9-isomer of the $B_{1a}$ and $B_{1b}$ component of the parent (8,9-ZMA), or 4″-deoxy-4″-epi-amino-avermectin $B_{1a}$ and 4″-deoxy-4″-epi-amino-avermectin $B_{1b}$; 4″-deoxy-4″-epi-amino avermectin $B_{1a}$ ($AB_{1a}$); 4″-deoxy-4″-epi-(*N*-formyl-*N*-methyl)amino-avermectin ($MFB_{1a}$); and 4″-deoxy-4″-epi-(*N*-formyl)amino-avermectin $B_{1a}$ ($FAB_{1a}$), in or on the following commodities:

| Commodity | Parts per million |
|---|---|
| Cotton, gin byproduct | 0.050 |
| Cotton, undelinted seed | 0.025 |
| Tomato, paste | 0.150 |
| Turnip, greens | 0.050 |
| Vegetable, *Brassica*, leafy, group 5 | 0.050 |
| Vegetable, fruiting, group 8 | 0.020 |
| Vegetable, leafy, except *Brassica*, group 4 | 0.100 |

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect and inadvertant residues.* Tolerances are established for indirect or inadvertent combined residues of emamectin ($MAB_{1a}$ + $MAB_{1b}$ isomers) and the associated 8,9-Z isomers (8,9-$ZB_{1a}$ + 8,9-$ZB_{1b}$) in or on the following commodities when present therein as a result of the application of emamectin to crops listed in the table to paragraph (a) of this section:

| Commodity | Parts per million |
|---|---|
| Cattle, fat | 0.003 |
| Cattle, liver | 0.020 |
| Cattle, meat | 0.002 |
| Cattle, meat byproducts (except liver) | 0.005 |
| Cattle, milk | 0.003 |
| Goats, fat | 0.003 |
| Goats, liver | 0.020 |
| Goats, meat | 0.002 |
| Goats, meat byproducts (except liver) | 0.005 |
| Goats, milk | 0.003 |
| Hogs, fat | 0.003 |
| Hogs, liver | 0.020 |
| Hogs, meat | 0.002 |
| Hogs, meat byproducts (except liver) | 0.005 |
| Hogs, milk | 0.003 |
| Horses, fat | 0.003 |
| Horses, liver | 0.020 |
| Horses, meat | 0.002 |
| Horses, meat byproducts (except liver) | 0.005 |
| Horses, milk | 0.003 |
| Sheep, fat | 0.003 |
| Sheep, liver | 0.020 |
| Sheep, meat | 0.002 |
| Sheep, meat byproducts (except liver) | 0.005 |
| Sheep, milk | 0.003 |

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–2003–0134; FRL–7303–6]**

## Diallyl Sulfides; Exemption from the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of diallyl sulfides (DADs) in/on garlic, leeks, onions, and shallots. Platte Chemical Company submitted a petition to EPA under section 408(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of DADs in/on garlic, leeks, onions, and shallots.

**DATES:** This regulation is effective July 9, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0134, must be received on or before September 8, 2003.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION.**

**FOR FURTHER INFORMATION CONTACT:** By mail: Driss Benmhend, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9525; e-mail address: *Benmhend.driss@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

*B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0134. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html,* a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://*

*www.epa.gov/opptsfrs/home/guidelin.htm.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

**II. Background and Statutory Findings**

In the **Federal Register** of November 21, 2001 (66 FR 58481) (FRL–6802–2), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 1F6316) by Platte Chemical Company, 419 18th Street, Greeley, CO 80632. As required by section 408(d)(2)(A)(i)(I), this notice included a summary of the petition prepared by the petitioner Platte Chemical Company. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of diallyl sulfides.

**III. Risk Assessment**

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, section 408(b)(2)(D) requires that 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.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

**IV. Toxicological Profile**

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 and considered its validity, completeness, and reliability and the relationship of this information 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.

DADs are a composition of diallyl sulfides that includes diallyl monosulfide, diallyl disulfide, diallyl trisulfide, and diallyl pentasulfide. They are naturally occurring compounds found in *Allium* crops, including onion and garlic and are partially responsible for the distinctive odor of garlic. The end-use product, Alli-Up is proposed for use as a soil fumigant solution for the control of white rot (*Sclerotium cepivorum*) in garlic, leeks, onions, and shallots. It contains 90% of DADs in a liquid formulation (8.3 lbs of active ingredient per gallon). Application is recommended for any field that shows evidence or has a history of white rot infestations. When applied to infected soils in conjunction with a rotational crop, DADs will mimic the presence of an *Allium* crop, which will in turn stimulate the germination of white rot spores (*sclerotia*). The germinated spores will subsequently perish since no host crop is present. The product is applied through conventional soil fumigation equipment such as an enclosed shanking system.

Toxicity studies submitted in support of the tolerance exemption petition, and the Agency reviews are compiled in the public docket established for this action under the docket ID number OPP–2003–0134.

1. *Acute oral toxicity (OPPTS Harmonized Guideline 870.1100; 152–10; Master Record Identification Number (MRID) 45422907).* Five male and 5 female rats were dosed with 200, 600, and 1,000 milligram/kilogram (mg/kg) and 10 of each were dosed with 5,000 mg/kg. The acute oral $LD_{50}$ was determined at 346 mg/kg. Treated rats displayed a number of abnormalities including breathing abnormalities, wobbly gait, decreased defecation, decreased activity, and pilo-erection. The abnormalities are attributed to hemolytic anemia as it is experienced by rodents when feeding on materials rich on sulfur and derived from onion and garlic.

2. *Acute dermal toxicity (OPPTS Harmonized Guideline 870.1200; 152–11; MRID 45422908).* Five male and 5 female rats were dosed with 1,500, 1,750, and 2,000 mg/kg, observed daily and weighed weekly. The acute dermal $LD_{50}$ of DADs in male rats was determined to be 1,826 mg/kg, in female 2,009 mg/kg, and in sexes combined 1,967 mg/kg, or a Toxicity Category II.

3. *Primary eye irritation (OPPTS Harmonized Guideline 870.2400; 152–13; MRID 45422909).* Six rabbits were administered DADs in the right eye with the left eye serving as an untreated control. Exposure of the test article produced corneal opacity in 3/6 test eyes at the 1 or 24–hour scoring interval. Conjunctivitis was noted in 6/6 test eyes at the 1–hour testing interval. The conjunctival irritation resolved completely in all animals by study day 14. Under the conditions of the test, DADs are considered a moderate eye irritant, and Toxicity Category III for eye irritation.

4. *Primary dermal irritation (OPPTS Harmonized Guideline 870.2500; 152–14; MRID 45422910).* These compound are Toxicity Category II for dermal irritation. Severe skin reactions of the rabbits exposed, with evident erythema grade 2 and 1 at 1 hour post-exposure were observed.

5. *Dermal sensitization (OPPTS Harmonized Guideline 870.2600; 152–15; MRID 45422911).* A dermal sensitization potential test for DADs was evaluated using guinea pigs. DADs were found to be contact dermal sensitizers in guinea pigs, in accordance with the Buehler test.

6. *Mutagenicity (OPPTS Harmonized Guideline 870.5195; MRID 45422912).* A *Salmonella*/mammalian-microsome reverse mutation assay (Ames Test) was done using DADs. The assay evaluated the test article for its ability to induce reverse mutations at the histidine locus in the genome of specific *Salmonella typhimurium* tester strains in both the presence and absence of an exogenous metabolic activation system of mammalian microsomal enzymes derived from Arocolr™ induced rat liver. The results of the assay indicate that under the conditions of the study, DADs did not cause a positive increase in the number of histidine revertants per

plate of any of the tester strains either in the presence or absence of the microsomal enzymes prepared from the Arocolr™ induced rat liver (S9). As a result, Diallyl disulfide, the main component of DADs, are not considered mutagenics.

Data Waivers were requested for the following studies:

Acute inhalation toxicity (OPPTS Harmonized Guideline 870.1300; 152–12).

Mammalian mutagenicity tests (OPPTS Harmonized Guideline 870.5195) except for an Ames test.

90–Day feeding (1 species) (OPPTS Harmonized Guideline 870.3100).

90–Day dermal (1 species) (OPPTS Harmonized Guideline 870.3250).

90–Day inhalation (1 species) (OPPTS Harmonized Guideline 870.3465).

Teratogenicity (1 species) (OPPTS Harmonized Guideline 870.3700).

Chronic exposure (OPPTS Harmonized Guideline 870.4100) (Tier III)

Oncogenicity (OPPTS Harmonized Guideline 870.4200) (Tier III)

DADs are naturally present in garlic and other *Allium* crops and in fields planted with these crops. In spite of the long history of garlic consumption and exposure to DADs by humans, no immunotoxic effects, such as induced dysfunction or inappropriate suppressive or stimulatory responses in components of the immune system of humans or test animals have been reported and are not expected from the exposure to DADs. As a result, the waiver requests listed above were approved.

## V. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

### *A. Dietary Exposure*

The product Alli-Up containing DADs is intended for agricultural use as a soil fumigant for the purpose of suppression of onion white rot (*Sclerotia cepivorum*). The presence of DADs in the soil will stimulate the pathogen to become active and seek out its host, an *Allium* sp., which is not present. The pathogen will then perish. DADs in the soil are then subject to microbial breakdown and adsorption to soil particles. By the time the soil is prepared and ready for a new crop, most DADs have already dissipated. As a result, when new crops are planted, the likelihood of DADs residue present in the mature crop is considered low.

1. *Food*. From food and feed uses. As explained above, the presence of DADs residue in food is unlikely. Moreover, the primary source for human exposure to DADs would occur through the consumption of garlic, other *Allium* crops or garlic derived products. There have been no reports of adverse reactions to humans resulting from the consumption of *Allium* crops and derived products. The over-all toxicology profile of DADs suggests that the risk associated with acute exposures by the oral route would be low.

2. *Drinking water exposure*. Since Alli-Up will only be used as a soil fumigant, there is little if any, potential for drinking water exposure from pesticide drift in the surface water. Moreover, DADs in the soil are then subject to microbial breakdown and adsorption to soil particles and dissipation in the air. Therefore, the level of residues that might get into the ground water or surface water would most likely be negligible.

### *B. Other Non-Occupational Exposure*

The potential for non-dietary exposure to DADs for the general population is unlikely because potential use sites are commercial agricultural. Since the material is shanked into the treated soil during commercial applications, any odor present would be similar to that of a commercial garlic field or to that arising from freshly cut or pressed garlic as found in a typical household kitchen. EPA is unaware of any reports of adverse reactions to humans resulting from *Allium* crops and derived products odor or consumption.

## VI. Cumulative Effects

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.''

EPA does not have, at this time, available data to determine whether DADs have a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, DADs do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that DADs have 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

## VII. Safety Factor for Infants and Children

1. *In general*. Section 408 of the 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 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.

2. *Prenatal and postnatal sensitivity*. Based on the lack of observed developmental toxicity, EPA has concluded there is reasonable certainty that no harm to infants, children, or adults will result from aggregate exposure to DADs residues. Exemption of DADs from the requirements of a tolerance should pose no significant risk to humans or the environment.

3. *Conclusion*. There is reasonable certainty that no harm will result from aggregate exposure to residues of diallyl sulfides to the U.S. population. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the low levels of toxicity, the long history of safe consumption of garlic and onions which naturally contain diallyl sulfides, and the lack of exposure. Levels of exposure resulting from use of diallyl sulfides would be significantly lower than those found in the U.S. population's consumption of onion and garlic foods (raw, cooked and processed). Moreover, the Agency concludes that diallyl sulfides is non-toxic to humans, including infants and children. Thus, there is no threshold effects of concern and, as a result the provision requiring an additional margin of safety does not apply. Further, the provisions of consumption patterns,

special susceptibility, and cumulative effects do not apply. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of diallyl sulfides.

**VIII. Determination of Safety**

Based on the preceding 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 DAD residues.

**IX. Other Considerations**

*A. Endocrine Disruptors*

EPA is required under section 408 of the FFDCA to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including, as part of the program, the androgen and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, DADs may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Based on available data, no endocrine system-related effects have been identified with consumption of DADs. In addition, DADs do not share any structural similarity to any known endocrine disruptive chemical.

*B. Analytical Method*

EPA is establishing an exemption from the requirement of a tolerance for the reasons stated above. Because a tolerance exemption does not establish numerical limit for the amount of the pesticide chemical residues that may be present, and for the reasons stated above that led the Agency to conclude that a tolerance exemption was warranted, the Agency has concluded that an analytical method is not necessary for enforcement purposes for DADs.

*C. Codex Maximum Residue Level*

No Codex maximum residue levels are established for residues of DADs in or on any food or feed crop. There are no established tolerances or exemptions from tolerance for DADs in the United States. The Agency has classified DADs as a biochemical pesticide.

**X. Conclusions**

Based on the toxicology data submitted, there is reasonable certainty no harm will result from aggregate exposure of residues of DADs to the U.S. population, including infants and children, This includes all anticipated dietary exposures and all other exposures for which reliable data were submitted, accepted and reviewed. The Agency has no reports of adverse reactions of humans resulting from *Allium* crops and derived products' odor or consumption. As a result, EPA establishes an exemption from tolerance requirements pursuant to FFDCA section 408(c) and (d) for residues of DADs in or on garlic, leeks, onions, and shallots.

**XI. Objections and Hearing Requests**

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. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

*A. What Do I Need To Do To File an Objection or Request a Hearing?*

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0134 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 8, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(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). Information submitted in connection with an objection or hearing request 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 information 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.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP–2003–0134, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

*B. When Will the Agency Grant a Request for a Hearing?*

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a 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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

## XII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the 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 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, 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, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

## XIII. 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 rule report, which includes a copy of the rule, to each House of the Congress and to 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.

Dated: June 13, 2003.

**James Jones,**

*Director, 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:

**Authority:** 21 U.S.C. 321(q), 346(a) and 371.

■ 2. Section 180.1228 is added to subpart D to read as follows:

**§ 180.1228 Diallyl sulfides; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of diallyl sulfides when used in/on garlic, leeks, onions, and shallots.

[FR Doc. 03–17106 Filed 7–8–03; 8:45 am]

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 648

**[Docket No. 030514123–3162–02; I.D. 041003B]**

**RIN 0648–AQ76**

## Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Framework Adjustment 38 to the Northeast Multispecies Fishery Management Plan

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.

**SUMMARY:** NMFS issues this final rule to implement measures contained in Framework Adjustment 38 (Framework 38) to the Northeast (NE) Multispecies Fishery Management Plan (FMP) to exempt a fishery from the Gulf of Maine (GOM) Regulated Mesh Area mesh size regulations. Framework 38 establishes an exempted small mesh silver hake (*Merluccius bilinearis*) (whiting) fishery in the inshore GOM. The exempted fishery is authorized from July 1 through November 30 each year; requires the use of specific exempted grate raised footrope trawl gear; establishes a maximum whiting possession limit of 7,500 lb (3,402 kg); and includes incidental catch restrictions.

**DATES:** This regulation is effective July 9, 2003.

**ADDRESSES:** Copies of the Framework 38 document, its Regulatory Impact Review (RIR), the Initial Regulatory Flexibility Analysis (IRFA), the Environmental Assessment and other supporting documents for the framework adjustment are available from Paul J. Howard, Executive Director, New England Fishery Management Council (Council), 50 Water Street, Mill 2, Newburyport, MA 01950. These documents are also available online at *http://www.nefmc.org*. The Final Regulatory Flexibility Analysis (FRFA) consists of the IRFA, public comments and responses contained in this final rule, and the summary of impacts and alternatives contained in this final rule.

**FOR FURTHER INFORMATION CONTACT:** E. Martin Jaffe, Fishery Policy Analyst, 978–281–9272.

**SUPPLEMENTARY INFORMATION:** This final rule implements measures contained in Framework 38 to the FMP. Details concerning the justification for and development of Framework 38 and the implementing regulations were provided in the preamble to the proposed rule (68 FR 27774, May 21, 2003) and are not repeated here.

### Exempted Grate Raised Footrope Trawl Fishery Area

The Exempted Grate Raised Footrope Trawl Fishery Area is an inshore area in the GOM extending to the Loran 44500 line and northward along the coast of Maine. This area most closely represents the historical whiting fishery and the area utilized by the fishermen who participated in the experimental whiting grate fisheries between 1996 and 2002. During the development of this framework adjustment, the Council considered three options for the fishery area, including the area option implemented by this final rule. The first option was the largest area under consideration and included an offshore component to the area implemented. Another option was the smallest area under consideration and represented a subset of the area implemented, where past experimental fishing was concentrated. The area implemented was selected by the Council, following an endorsement by the Plan Development Team (PDT), even though sampling was not conducted throughout the entire area. The area was selected because there were sufficient similarities (species composition, hydrography, habitat, current flow, bottom topography) between it and the subset where the experiment occurred to suggest that bycatch in the area implemented may be similar to that observed in the experiments. Thus, the rate of capture of regulated species is not expected to differ over the area implemented.

### Fishing Season

The season for the GOM Grate Raised Footrope Trawl Fishery is July 1-November 30. This period encompasses the traditional seasonal presence of whiting along the coast of Maine in the GOM and the period of documented catch and bycatch during research trials and experimental small mesh fisheries permitted by NMFS between 1996 and 2002. The PDT expressed support for a season from July 1 to November 30, based on documented catch rates and experimental data from 2001 and 2002, which were reviewed by the PDT in detail.

During the development of this framework adjustment, the Council considered establishing a season for this fishery from June 1 to November 30, but ultimately decided to eliminate the month of June from consideration after evaluating the data. These data show that the coastal whiting fishery started in July and ended in November.

The majority of experimental tows with the proposed sweepless trawl were conducted during October and November 2001 and 2002. Past experience demonstrates that the catches of whiting are generally lower and the bycatch of regulated species is relatively higher during these months than during the summer. Given that the 2001 and 2002 data for the proposed sweepless trawl show low absolute bycatch of regulated species during October and November, the gear is expected to fish with even lower bycatch during the summer.

### Gear Specifications

There are several gear specifications for this fishery, including net specifications for the raised footrope trawl, that are consistent with those in the Cape Cod Bay whiting fishery, a requirement to use a sweepless trawl, and a requirement to use a Nordmore-style grate with a maximum bar spacing of 50 mm (1.97 inches). There is also a minimum codend mesh requirement of 2.5 inches (6.35 cm) (square or diamond mesh). Vessels may use net strengtheners in this fishery, provided that they are consistent with the existing net strengthener provisions for 2.5 inch (6.35 cm) mesh.

### Whiting/Offshore Hake Possession Limit

There is a maximum whiting/offshore hake possession limit of 7,500 lb (3,402 kg) for this fishery. Vessels using mesh larger than the minimum 2.5 inches