ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0031; FRL–7698–3]

Octanamide, N,N-dimethyl and Decanamide, N,N-dimethyl; Exemptions from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of N,N-dimethyloctanamide or octanamide, N,N-dimethyl (CAS Reg. No. 1118–92–9), and N,N-dimethyldecanamide or decanamide, N,N-dimethyl (CAS Reg. No. 14433–76–2) when used as inert ingredients (emulsifier, solvent, and cosolvent) in pesticide formulations applied only to growing crops. The C.P. Hall Company, now doing business as CPH Services, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of N,N-dimethyloctanamide and N,N-dimethyldecanamide.

DATES: This regulation is effective February 16, 2005. Objections and requests for hearings must be received on or before April 18, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit XI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0031. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket*. Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., 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.

FOR FURTHER INFORMATION CONTACT: Princess Campbell, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8033; e-mail address: *campbell.princess@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 code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 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 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 Get Electronic Documents and Other Related Information?

In addition to using EDOCKET at *(http://www.epa.gov/edocket/)*, 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 E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of November 15, 2001 (66 FR 57450) (FRL–6808–6), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 1E6257) by The C.P. Hall Company, 311 S. Wacker, Suite 4700, Chicago, IL 60606, now doing business as CPH Services. The petition requested that 40 CFR part 180 be amended by establishing exemptions from the requirement of a tolerance for residues of N,N-dimethyloctanamide (CAS Reg. No. 1118–92–9) and N,N-dimethyldecanamide (CAS Reg. No. 14433–76–2) when used as inert ingredients as an emulsifier, solvent, and cosolvent in pesticide formulations applied only to growing crops at less than 15% of the total formulation by weight. That notice included a summary of the petition prepared by the petitioner.

In 2003, EPA received an amendment to the pending PP 1E6257. Subsequent to the publication of that notice of filing, the petitioner requested to amend the pending pesticide petition to remove the 15% limitation on the percentage of N,N-dimethyloctanamide and N,N-dimethyldecanamide used in formulated products. There were no other changes to the information presented by the petitioner in the 2001 notice. The amended notice was published in the **Federal Register** of November 19, 2003 (68 FR 65279) (FRL–7332–6). There were no comments received in response to either of the notices of filing.

Section 408(b)(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 tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA 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) of the FFDCA 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....''

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.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of

ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of the 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. The nature of the toxic effects caused by N,N-dimethyloctanamide and N,N-dimethyldecanamide are discussed in this unit.

A. Submitted Studies

The petitioner has also submitted information to the Agency as part of the High Production Volume Challenge Program. According to that information, N,N-dimethyldecanamide (CAS No. 14433–76–2) is produced commercially in a purified form (98%) as Hallcomid M–10. N,N-dimethyloctanamide (CAS No. 1118–92–9) and N,N-dimethyldecanamide are produced as a commercial mixture, Hallcomid M–8–10, containing 50–65% N,N-dimethyloctanamide, 37–50% of N,N-dimethyldecanamide, 0–5% N,N-dimethylhexanamide, and 0–2% N,N-dimethyldodecanamide.

The test substance for all of the studies reviewed by the Agency was identified as Hallcomid M–8–10. Thus, both the N,N-dimethyloctanamide and N,N-dimethyldecanamide were present in the test substance. Given that the octanamide and decanamide differ only in the carbon length (C8 versus C10) of the alkyl chain, the two chemicals can be considered as surrogates for each other.

The acute toxicity profile is presented in Table 1. below:

TABLE 1.—ACUTE TOXICITY PROFILE OF N,N-DIMETHYLOCTANAMIDE AND N,N-DIMETHYLDECANAMIDE

Study	Result	Category
Acute oral	LD_{50} = 1.77 g/kg (confidence limits is 95% for a range of 1.02 to 3.08 g/kg)	III
Acute dermal	Female LD_{50} > 400 and < 2,000 mg/kg Male LD_{50} > 2,000 mg/kg	II
Acute inhalation	LC_{50} > 3.55 mg/L	IV
Eye irritation	Corrosive	I
Dermal irritation	Moderate to severe erythema at 48 hours	II
Dermal sensitization	Not a sensitizer	N/A

The petitioner submitted oral subchronic studies in the rat and dog, a rat inhalation study, and developmental toxicity studies in the rat and rabbit. The results of the Agency's review of these studies are in Table 2. below:

TABLE 2.—TOXICITY STUDIES USING N,N-DIMETHYLOCTANAMIDE AND N,N-DIMETHYLDECANAMIDE

Type of Study/Route/Species	Doses	Results
6–week oral gavage dog	0, 20, 100, or 500 mg/kg/day Note that 500 mg/kg/day was increased to 1,000 mg/kg/day at 2 weeks	No observed adverse effect level (NOAEL) = 100 mg/kg/day Lowest observed adverse effect level (LOAEL) = 500/1,000 mg/kg/day based on clinical signs
90–day in the diet rat	0, 400, 2,000, or 10,000 parts per million (ppm) equivalent to 0, 27.4/35.2, 136.8/178.5, 787.5/894.6 (M/F) mg/kg/day	NOAEL = 136.8 (M) and 894.6 (F) mg/kg/day LOAEL = 787.6 (M) based on kidney effects. A LOAEL was not determined for females but would be greater than 894.6 mg/kg/day, the highest dose tested
5–day inhalation rat	0, 24.6, 111.2, or 521.2 mg/m^3	NOAEL = 111.2 mg/m^3 LOAEL = 521.2 mg/m^3 based on clinical signs, decreased body temperature, decreased body weight and weight gain, and histopathological findings in the respiratory tract

TABLE 2.—TOXICITY STUDIES USING N,N-DIMETHYLOCTANAMIDE AND N,N-DIMETHYLDECANAMIDE—Continued

Type of Study/Route/Species	Doses	Results
Developmental gavage rat gestation days 6–15	0, 50, 150, or 450 mg/kg/day	Maternal NOAEL = 150 mg/kg/day Maternal LOAEL = 450 mg/kg/day based on clinical signs, decreased weight gain, and food consumption Developmental NOAEL = 150 mg/kg/day Developmental LOAEL = 450 mg/kg/day based on increased post-implantation loss, decreased fetal body weight, increased incidence of skeletal malformations/variations
Developmental gavage rabbit gestation days 6–18	0, 100, 300, or 1,000 mg/kg/day	Maternal NOAEL = 300 mg/kg/day Maternal LOAEL = 1,000 mg/kg/day based on decreases in body weight gain and food consumption Developmental NOAEL was not determined but would be equal to or greater than 1,000 mg/kg/day Developmental LOAEL was not determined, but would be greater than 1,000 mg/kg/day

The petitioner also submitted the following mutagenicity assays, as described in Table 3. below:

TABLE 3.—MUTAGENICITY ASSAYS CONDUCTED USING N,N-DIMETHYLOCTANAMIDE AND N,N-DIMETHYLDECANAMIDE

Type of Assay	Test Culture	Results
In vitro (bacterial reverse gene mutation)	TA 98, 100, 1535, 1537 *S. typhimurium*	No evidence of induced mutant colonies over background
In vitro mutagenicity (mammalian forward gene mutation)	Chinese hamster V79 cells	No evidence of induced mutant colonies over background
In vitro cytogenetics (chromosomal aberrations)	Chinese hamster ovary (CHO) cells	No evidence of chromosome aberrations over background
UDS (unscheduled DNA synthesis)	Primary rat hepatocyte cultures	No evidence UDS was induced

B. Structure Activity Relationship (SAR) Assessment

Toxicity for N,N-dimethyloctanamide and several structurally-related analogs was assessed, in part, by a process called SAR. In this process, the chemical's structural similarity to other chemicals (for which data are available) is used to determine toxicity. For human health, this process, can be used to assess absorption and metabolism, mutagenicity, carcinogenicity, developmental and reproductive effects, neurotoxicity, systemic effects, immunotoxicity, and sensitization and irritation. This is a qualitative assessment using terms such as good, not likely, poor, moderate, or high. Since N,N-dimethyldecanamide is of a chain length intermediate between N,N-dimethyloctanamide and the analogs assessed, the SAR conclusions also apply to N,N-dimethyloctanamide.

The SAR conclusions were as follows: Absorption would be poor via all routes of exposure. Thus, no significant effects are expected. The SAR did indicate concerns that one of the analogs might be an irritant. These concerns can be appropriately addressed through labeling and the use of protective equipment.

C. Conclusions

The acute toxicity data indicated that N,N-dimethyloctanamide and N,N-dimethyldecanamide are eye and dermal irritants.

Subchronic toxicity studies revealed no significant treatment related effects for N,N-dimethyloctanamide and N,N-dimethyldecanamide. In the 6-week oral gavage study in dogs, there were no significant differences between treated and control groups. During a 90-day oral toxicity study in rats, N,N-dimethyloctanamide and N,N-dimethyldecanamide did not produce any significant effects on mortality, clinical signs, food consumption, hematology, or gross pathology. In the 5-day inhalation study, test animals exhibited signs of respiratory tract irritation. However, this respiratory irritant effect occurred only at high inhalation doses.

N,N-dimethyloctanamide and N,N-dimethyldecanamide showed no evidence of mutagenicity, or chromosome aberration, and did not show any signs of developmental toxicity in the study in rabbits at dose levels up to 1,000 mg/kg/day. In a rat developmental toxicity study there was a decrease in weight gain in the high dose group, which could possibly be explained by a decrease in food consumption. It is noted that the SAR did not identify any developmental or reproductive concerns.

There is a consistent pattern of NOAELs of 100 mg/kg/day or greater in both subchronic toxicity studies and the maternal NOAELs in the developmental toxicity studies. But, the effects noted were not clinically or toxicologically relevant especially when compared to the control groups. These effects were mainly decreased weight gain in all species tested, but this occurred in such a small number of animals that it was not even statistically significant. Also, there was a corresponding decrease in food consumption. Additionally, it is noted that the spacing between the NOAELs and LOAELs is large.

V. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA 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).

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Both N,N-dimethyloctanamide and N,N-dimethyldecanamide are sponsored under the High Production Volume Challenge Program. This is indicative of over 1 million pounds of N,N-dimethyloctanamide and N,N-dimethyldecanamide either produced or imported per year. Information indicates that N,N-dimethyloctanamide and N,N-dimethyldecanamide are used in personal care products and in paints.

The Agency has used various screening-level models to estimate some of the existing levels of exposure and those that could occur as a result of establishing this tolerance exemption. To assure protectiveness, the estimates in Table 4. below are deliberately intended to over-estimate exposure.

TABLE 4.—EXPOSURE ESTIMATES FOR N,N-DIMETHYLOCTANAMIDE AND N,N-DIMETHYLDECANAMIDE

Type of Exposure	Exposure Level
Dietary - Food (as a result of application to crops)	Acute exposure: All population subgroups less than 1 mg/kg/day at 95th percentile Chronic exposure: All population subgroups less than 1 mg/kg/day
Dietary - Drinking Water	Acute exposure: 0.0038 (child) and 0.0011 (adult) mg/kg/day Chronic exposure: 0.00062 (child) and 0.00018 (adult) mg/kg/day
Residential (as a result of using a spray paint product)	Acute inhalation exposure: 0.054 to 0.424 mg/kg/day
Residential (as a result of using a personal care product)	Chronic dermal exposure: 0.00032 mg/kg/day

VI. Cumulative Effects

Section 408 (b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider ''available information'' concerning the cumulative effects of a particular chemical's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticide chemicals 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 N,N-dimethyloctanamide and N,N-dimethyldecanamide and any other substances. N,N-dimethyloctanamide and N,N-dimethyldecanamide 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 N,N-dimethyloctanamide and N,N-dimethyldecanamide 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 policy statements released by EPA's Office of Pesticide Programs (OPP) 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/*.

VII. Safety Factor for Infants and Children

FFDCA section 408 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 unless EPA concludes that a different margin of safety will be safe for infants and children. The Agency has reviewed the results of two developmental toxicity studies conducted using N,N-dimethyloctanamide and N,N-dimethyldecanamide. Based on the observed insignificant clinical toxic effects such as decreased weight gain due to decreased food intake, and the fact that developmental signs were observed only at very high doses, EPA has not used a safety factor analysis to assess the risk. For the same reasons a tenfold safety factor is unnecessary.

VIII. Determination of Safety for U.S. Population, Infants, and Children

The Agency has reviewed and evaluated a toxicity database of 15 studies conducted using N,N-dimethyloctanamide and N,N-dimethyldecanamide. Studies indicate that N,N-dimethyloctanamide and N,N-dimethyldecanamide have a low systemic toxicity via oral exposure and are not mutagenic. Developmental effects were observed only at very high doses. The SAR assessments did not indicate any concerns for carcinogenicity, developmental, or reproductive effects. Based on the available information on toxicity and exposure, EPA finds that exempting N,N-dimethyloctanamide and N,N-dimethyldecanamide from the requirement of a tolerance will be safe for the general population including infants and children.

IX. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. . .'' EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency

proceeds with implementation of this program, further testing of products containing N,N-dimethyloctanamide and N,N-dimethyldecanamide for endocrine effects may be required.

B. Analytical Method(s)

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Existing Exemptions

There are no existing tolerances or tolerance exemptions for N,N-dimethyloctanamide and N,N-dimethyldecanamide.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for N,N-dimethyloctanamide and N,N-dimethyldecanamide nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

X. Conclusions

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of N,N-dimethyloctanamide or octanamide, N,N-dimethyl (CAS Reg. No. 1118–92–9), and N,N-dimethyldecanamide or decanamide, N,N-dimethyl (CAS Reg. No. 14433–76–2). Accordingly, EPA finds that exempting octanamide, N,N-dimethyl (CAS Reg. No. 1118–92–9) and decanamide, N,N-dimethyl (CAS Reg. No. 14433–76–2) from the requirement of a tolerance will be safe.

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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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) of the FFDCA, as was provided in the old FFDCA sections 408 and 409 of the FFDCA. 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–2005–0031 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 April 18, 2005.

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 (1900L), 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 Suite 350, 1099 14th St., NW., Washington, DC 20005. 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 (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit XI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0031, 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 **ADDRESSES**. 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: February 7, 2005.

Lois Rossi,

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. 321(q), 346a and 371.

■ 2. In § 180.920, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* *	*	* *
Decanamide, N,N-dimethyl (CAS Reg. No. 14433–76–2).	.....	Emulsifier, solvent, cosolvent
* *	*	* *
Octanamide, N,N-dimethyl (CAS Reg. No. 1118–92–9).	.....	Emulsifier, solvent, cosolvent
* *	*	* *

[FR Doc. 05–2975 Filed 2–15–05; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 041202338–4338–01; I.D. 021105A]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels 60 Feet (18.3 Meters) Length Overall and Using Pot Gear in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by catcher vessels 60 feet (18.3 meters (m)) length overall (LOA) and longer using pot gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2005 Pacific cod interim total allowable catch (TAC) of Pacific cod specified for catcher vessels using pot gear in the BSAI.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), February 13, 2005, until superseded by the notice of 2005 and 2006 final harvest specifications of groundfish for the BSAI, which will be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands