Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), 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).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance 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.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 et seq.).

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 (NTTAA) (15 U.S.C. 1501 et seq.).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), 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 the rule in the Federal Register. This action 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: December 3, 2015.

Susan Lewis,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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


2. In § 180.155, add to the table in alphabetical order an entry for “pomegranate” to read as follows:

§ 180.155 1-Naphthaleneacetic acid; tolerance for residues.

(a) * * *

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pomegranate</td>
<td>0.05</td>
</tr>
</tbody>
</table>

* * * * *

[FR Doc. 2015–31309 Filed 12–11–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


Polyamide Ester Polymers; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of several polyamide ester polymers as listed in this final rule. Spring Trading Co. on behalf of Croda, Inc. submitted a petition to EPA under 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 the listed chemicals on food or feed commodities.

DATES: This regulation is effective December 14, 2015. Objections and requests for hearings must be received on or before February 12, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0451, is available at http://www.regulations.gov or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at http://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT:

Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

• Crop production (NAICS code 111).
• Animal production (NAICS code 112).
• Food manufacturing (NAICS code 311).
• Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

C. Can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2015–0451 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 12, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2015–0451, by one of the following methods:

- **Federal eRulemaking Portal:** [http://www.regulations.gov](http://www.regulations.gov). Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at [http://www.epa.gov/dockets/contacts.html](http://www.epa.gov/dockets/contacts.html). Additional instructions on commenting or visiting the docket, along with more information about docket generally, is available at [http://www.epa.gov/dockets](http://www.epa.gov/dockets).

II. Background and Statutory Findings

In the Federal Register of Wednesday, August 26, 2015 (80 FR 51763) (FRL–9931–74), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP IN–10834) filed by Spring Trading Co., 203 Dogwood Trl., Manchester, NH 03104 (on behalf of Croda, Inc., 315 Cherry Ln., New Castle, DE 19720). The petition requested that


That document included a summary of the petition prepared by the petitioner and solicited comments on the petitioner’s request. No comments were received by the Agency in response to the notice of filing. Section 408(c)(2)(A)(i) of 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) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and use in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption from the requirement of 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.” and specifies factors EPA is to consider in establishing an exemption.

III. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be shown 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.

Consistent with FFDCA section 408(b)(2)(D), 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. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low-risk polymers are described in 40 CFR 723.250(d).

The polyamide ester polymers listed in this final rule conform to the definition of a polymer given in 40 CFR 723.250(b) and meets the following criteria that are used to identify low-risk polymers:

- The polymer is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.
2. The polymer does contain as an integral part of its composition the atomic elements carbon, hydrogen, and oxygen.

3. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(iii).

4. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.

5. The polymer is manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.

7. The polymer does not contain certain perfluoroalkyl moieties consisting of a CF3- or longer chain length as specified in 40 CFR 723.250(d)(6).

Thus, polyamide ester polymers listed in this final rule (i.e., fatty acids, C18-unsatd., dimers, polymers with ethylenediamine and stearyl alcohol; fatty acids, C18-unsatd., dimers, hydrogenated, polymers with ethylenediamine, neopentyl glycol and stearyl alcohol; fatty acids, C18-unsatd., dimers, hydrogenated, polymers with ethylenediamine and stearyl alcohol; fatty acids, C18-unsatd., dimers, polymers with 1-docosanol and ethylenediamine; fatty acids, C18-unsatd., dimers, polymers with 1-docosanol and ethylenediamine; fatty acids, C18-unsatd., dimers, polymers with cetyl alcohol, neopentyl glycol and stearyl alcohol; fatty acids, C18-unsatd., dimers, hydrogenated, polymers with cetyl alcohol and ethylenediamine; fatty acids, C18-unsatd., dimers, polymers with 1-docosanol and ethylenediamine; fatty acids, C18-unsatd., dimers, hydrogenated, polymers with neopentyl glycol, stearyl alcohol and trimethylenediamine; fatty acids, C18-unsatd., dimers, polymers with 1-docosanol and trimethylenediamine; fatty acids, C18-unsatd., dimers, polymers with 1-docosanol, hexamethylenediamine and neopentyl glycol; and fatty acids, C18-unsatd., dimers, polymers with 1,3-propanediol and sorbitol.

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that these polymers could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-diary exposure was possible. The minimum number average MW (in amu) of each of these polymers is 1,400 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since these polymers conform to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of 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 has not found these polymers to share a common mechanism of toxicity with any other substances, and these polymers does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that these polymers does not 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 EPA’s Web site at http://www.epa.gov/pesticides/cumulative.

VI. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of these polymers, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

VII. Determination of Safety

Based on the conformance to the criteria used to identify a low-risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population, including infants and children, from aggregate exposure to residues of fatty acids, C18-unsatd., dimers, polymers with ethylenediamine and stearyl alcohol; fatty acids, C18-unsatd., dimers, hydrogenated, polymers with ethylenediamine, neopentyl glycol and stearyl alcohol; fatty acids, C18-unsatd., dimers, hydrogenated, polymers with ethylenediamine and stearyl alcohol; fatty acids, C18-unsatd., dimers, polymers with 1-docosanol and ethylenediamine; fatty acids, C18-unsatd., dimers, polymers with 1-docosanol and ethylenediamine; fatty acids, C18-unsatd., dimers, polymers with 1-docosanol and trimethylenediamine; fatty acids, C18-unsatd., dimers, polymers with 1-docosanol, hexamethylenediamine and neopentyl glycol; and fatty acids, C18-unsatd., dimers, polymers with 1,3-propanediol and sorbitol.

VIII. Other Considerations

A. Existing Exemptions From a Tolerance

Not applicable.

B. Analytical Enforcement Methodology

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. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program,
and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for fatty acids, C_{18}^{18}-unsatd., dimers, polymers with ethylenediamine and stearyl alcohol; fatty acids, C_{18}^{18}-unsatd., dimers, hydrogenated, polymers with ethylenediamine, neopentyl glycol and stearyl alcohol; fatty acids, C_{18}^{18}-unsatd., dimers, hydrogenated, polymers with neopentyl glycol and ethylenediamine; fatty acids, C_{18}^{18}-unsatd., dimers, polymers with 1-docosanol and trimethylenediamine; fatty acids, C_{18}^{18}-unsatd., dimers, hydrogenated, polymers with 1-docosanol, hexamethylenediamine and neopentyl glycol; and fatty acids, C_{18}^{18}-unsatd., dimers, polymers with docosanoic acid, 1,3-propanediol and sorbitol from the requirement of a tolerance will be safe.

X. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) 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 action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), 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).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance 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.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, or on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 et seq.).

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 (NTTAA) (15 U.S.C. 272 note).

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), 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 the rule in the Federal Register. This action 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: November 30, 2015.

G. Jeffrey Herndon,
Director Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.960, alphabetically add the following polymers to the table to read as follows:

§ 180.960 Polymers; exemptions from the requirement of a tolerance.

* * * * *
NMFS is transferring 24.3 metric tons (mt) of Atlantic bluefin tuna (BFT) quota from the General category December 2016 subquota period to the January 2016 subquota period (from January 1 through March 31, 2016, or until the available subquota for this period is reached, whichever comes first). NMFS also is adjusting the Atlantic tunas General category BFT daily retention limit for the January 2016 subquota period to three large medium or giant BFT from the default retention limit of one. This action is based on consideration of the regulatory determination criteria regarding inseason adjustments and applies to Atlantic tunas General category (commercial) permitted vessels and Highly Migratory Species (HMS) Charter/Headboat category permitted vessels when fishing commercially for BFT.

DATES: The quota transfer is effective January 1, 2016. The General category retention limit adjustment is effective January 1, 2016, through March 31, 2016.

FOR FURTHER INFORMATION CONTACT: Sarah McLaughlin or Brad McHale, 978–281–9260.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 et seq.) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 et seq.) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006), as amended by Amendment 7 to the 2006 Consolidated HMS FMP (Amendment 7) (79 FR 71510, December 2, 2014). NMFS is required under ATCA and the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest the ICCAT-recommended quota.

Inseason Transfer to the General Category

Earlier this year, NMFS implemented a final rule that increased the U.S. BFT quota and subquotas per ICCAT Recommendation 14–05 (80 FR 52198, August 28, 2015). The base quota for the General category is 466.7 mt. See §635.27(a). Each of the General category time periods (January, June through August, September, October through November, and December) is allocated a portion of the annual General category quota. Although it is called the “January” subquota, the regulations allow the General category fishery under this quota to continue until the subquota is reached or March 31, whichever comes first. Based on the General category base quota of 466.7 mt, the subquotas for each time period are as follows: 24.7 mt for January; 233.3 mt for February through May; 123.7 mt for June through August; 123.7 mt for September; 60.7 mt for October through November; and 24.3 mt for December.

Any unused General category quota rolls forward within the fishing year, which coincides with the calendar year, from one time period to the next, and is available for use in subsequent time periods.

Quota Transfer

Under §635.27(a)(9), NMFS has the authority to transfer quota among fishing categories or subcategories, after