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 tolerances 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (NTTAA) (15 U.S.C. 272 note).

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, Pesticide and pests, Reporting and recordkeeping requirements.


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

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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


§ 180.628 [Amended]

2. Section 180.628, the table in paragraph (a), is amended as follows:

(a) General. * * *

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle, meat byproducts</td>
<td>0.5</td>
</tr>
<tr>
<td>Fruit, citrus, group 10–10</td>
<td>1.4</td>
</tr>
<tr>
<td>Fruit, pome, group 11–10</td>
<td>1.2</td>
</tr>
<tr>
<td>Goat, meat byproducts</td>
<td>0.5</td>
</tr>
<tr>
<td>Grain, cereal, except rice and corn, group 15</td>
<td>6.0</td>
</tr>
</tbody>
</table>

[FR Doc. 2013–22593 Filed 9–17–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


2,5-Furandione, Polymer With Ethenylbenzene, Hydrolyzed, 3-(Dimethylamino)propyl Imide, Imide With Polyethylene-Polypropylene Glycol 2-Aminopropyl Me Ether, 2,2′-(1,2-Diazenediyl)bis[2-Methylbutanenitrile]-Initiated; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of 2,5-furandione, polymer with ethenylbenzene, hydrolyzed, 3-(dimethylamino)propyl imide, imide with polyethylene-polypropylene glycol 2-aminopropyl me ether, 2,2′-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated (CAS Reg. No. 1062609–13–5) when used as an inert ingredient in a pesticide formulation. Evonik Goldschmidt Corporation (Evronik) 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 2,5-furandione, polymer with ethenylbenzene, hydrolyzed, 3-
(dimethylamino)propyl imide, imide with polyethylene-polypropylene glycol 2-amino propyl me ether, 2,2′-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated on food or feed commodities.

DATES: This regulation is effective September 18, 2013. Objections and requests for hearings must be received on or before November 18, 2013, 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–2013–0383, 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), EPA West 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: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090 email address: RDFRNNotices@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, anyone 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–2013–0383 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 November 18, 2013. 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 178.25(b).

You must file your objection to any aspect of this regulation pursuant to 40 CFR part 180 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–2013–0383 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 November 18, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at http://www.epa.gov/dockets.

II. Background and Statutory Findings

In the Federal Register of July 19, 2013 (78 FR 43115) (FRL–93292–9), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (IN–10559) filed by Evonik Goldschmidt Corporation, P.O. Box 1299, 914 East Randolph Rd. Hopewell, VA 23860. The petition requested that 40 CFR 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of 2,5-furandione, polymer with ethenylbenzene, hydrolyzed, 3-(dimethylamino)propyl imide, imide with polyethylene-polypropylene glycol 2-amino propyl me ether, 2,2′-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated; CAS Reg. No. 1062609–13–5. That document included a summary of the petition prepared by the petitioner and solicited comments on the petitioner’s request. The Agency received one comment.

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) for 2,5-furandione, polymer with ethylenbenzene, hydrolyzed, 3-((dimethylamino)propyl) imide, imide with polyethylene-polypolypeylene glycol 2-aminopropyl me ether, 2,2′-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated meets the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the criteria in this unit, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to 2,5-furandione, polymer with ethylenbenzene, hydrolyzed, 3-((dimethylamino)propyl) imide, imide with polyethylene-polypolypeylene glycol 2-aminopropyl me ether, 2,2′-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated.

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that 2,5-furandione, polymer with ethylenbenzene, hydrolyzed, 3-((dimethylamino)propyl) imide, imide with polyethylene-polypolypeylene glycol 2-aminopropyl me ether, 2,2′-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-diary exposure was possible. The number average MW of 2,5-furandione, polymer with ethylenbenzene, hydrolyzed, 3-((dimethylamino)propyl) imide, imide with polyethylene-polypolypeylene glycol 2-aminopropyl me ether, 2,2′-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated is 5,816 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since 2,5-furandione, polymer with ethylenbenzene, hydrolyzed, 3-((dimethylamino)propyl) imide, imide with polyethylene-polypolypeylene glycol 2-aminopropyl me ether, 2,2′-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated conforms 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 2,5-furandione, polymer with ethylenbenzene, hydrolyzed, 3-((dimethylamino)propyl) imide, imide with polyethylene-polypolypeylene glycol 2-aminopropyl me ether, 2,2′-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 2,5-furandione, polymer with ethylenbenzene, hydrolyzed, 3-((dimethylamino)propyl) imide, imide with polyethylene-polypolypeylene glycol 2-aminopropyl me ether, 2,2′-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated 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 2,5-furandione, polymer with ethylenbenzene, hydrolyzed, 3-((dimethylamino)propyl) imide, imide with polyethylene-polypolypeylene glycol 2-aminopropyl me ether, 2,2′-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.
protonated to become cationic when (dimethylpropyl amine) that can be imide, that leaves a tertiary amine DMAPA (dimentylaminopropyl amine) exemption. The comment stated, “When 40 CFR 723.250 low risk polymer exemption from both TSCA and to get approval on 40 CFR 180.960.” While this polymer does contain a tertiary amine functional group, the functional group equivalent weight is greater than 5,000 daltons. Therefore, this polymer is a cationic polymer of low cationic density and not excluded from the polymer exemption criteria given at 40 CFR 723.250(d).

B. 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 FFDC 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for 2,5-furandione, polymer with ethenylbenzene, hydrolyzed, 3-(dimethylamino)propyl imide, imide with polyethylene-polypropylene glycol 2-aminopropyl me ether, 2,2′-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated.

C. Response to Comments

The one comment received was an anonymous public comment regarding the acceptability of the polymer under 40 CFR 180.960 and whether it met the 40 CFR 723.250 low risk polymer exemption. The comment stated, “When DMAPA (dimethylaminopropyl amine) is reacted into the polymer to form the imide, a tertiary amine (dimethylpropyl amine) that can be protonated to become cationic when dispersed in water. If there are more than one of these DMAPAs per polymer molecule the equivalent weight will be below the 5,000 amu required to meet 40 CFR 723.250 low risk polymer exemption from both TSCA and to get approval on 40 CFR 180.960.” While this polymer does contain a tertiary amine functional group, the functional group equivalent weight is greater than 5,000 daltons. Therefore, this polymer is a cationic polymer of low cationic density and not excluded from the polymer exemption criteria given at 40 CFR 723.250(d).

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDC section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these rules from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule 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 19985, April 23, 1997). 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.), nor does it 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 (NNTTAA) (15 U.S.C. 272 note).

Since tolerances and exemptions that are established on the basis of a petition under FFDC 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 Denial of Objections Order, EPA is denying the objections submitted by AMVAC to a Revocation Order issued by EPA in the Federal Register of May 29, 2013 (Ref. 1), in which EPA ordered the revocation of all tolerances for the pesticide difenzoquat under FFDCA section 408, 21 U.S.C. 346a. EPA revoked the tolerances, consistent with the terms of a previously issued Data Call-In Order (Ref. 2), because no notices of intent to submit the required data were received by EPA as directed by that Data Call-In Order. In its objections (Ref. 3), AMVAC requested that EPA delay the effective date for the revocation of the difenzoquat tolerances for 4½ years to allow for importation of food commodities that will be treated with the pesticide in Canada over the next 2 years. EPA denies AMVAC’s objections because AMVAC has not filed a proper objection to the Revocation Order. The AMVAC objections are discussed in Unit IV., and EPA’s denial is discussed in Unit V.

B. What is the agency’s authority for taking this action?

The procedure for filing objections to tolerance actions and EPA’s authority for acting on such objections is contained in FFDCA section 408(g), 21 U.S.C. 346a(g), and 40 CFR part 178. For orders issued under FFDCA section 408(f)(2), the only material issue for consideration is whether a submission required under a FFDCA section 408(f)(1)(C) order was made by the time specified in that FFDCA section 408(f)(1)(C) order. 21 U.S.C. 346af(f)(2).