ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

Styrene-Ethylene-Propylene Block Copolymer; 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 styrene-ethylene-propylene block copolymer (CAS Reg. No. 108388–87–0) when used as an inert ingredient in a pesticide formulation. AgroFresh 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 styrene-ethylene-propylene block copolymer on food or feed commodities.

DATES: This regulation is effective April 3, 2013. Objections and requests for hearings must be received on or before June 3, 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).

ADDRESS: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0043, 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: David Lieu, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–0079; email address: lieu david@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–2013–0043 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 June 3, 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 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–2013–0043, by one of the following methods:

• Federal eRulemaking Portal: 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.htm.

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

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 safety factor is unnecessary, it will establish 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). Styrene-ethylene-propylene block copolymer conforms 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.

1. 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 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)(ii).
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 perfluoralkyl moieties consisting of a CF3– or longer chain length as specified in 40 CFR 723.250(d)(6).

Additionally, the polymer also meets as required the following exemption criteria specified in 40 CFR 723.250(e).
8. The polymer’s number average MW of 125,000 is greater than or equal to 10,000 daltons. The polymer contains less than 2% oligomeric material below MW 500 and less than 5% oligomeric material below MW 1,000.

Thus, styrene-ethylene-propylene block copolymer 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 styrene-ethylene-propylene block copolymer.

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA has considered that styrene-ethylene-propylene block copolymer 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 styrene-ethylene-propylene block copolymer is 125,000 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since styrene-ethylene-propylene block copolymer 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 styrene-ethylene-propylene block copolymer to share a common mechanism of toxicity with any other substances, and styrene-ethylene-propylene block copolymer does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that styrene-ethylene-propylene block copolymer 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 database unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of styrene-ethylene-propylene block copolymer, 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 styrene-ethylene-propylene block copolymer.

VIII. Other Considerations

A. 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.

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 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 styrene-ethylene-propylene block copolymer.

IX. Conclusion

Accordingly, EPA finds that exempting residues of styrene-ethylene-propylene block copolymer from the requirement of a tolerance will be safe.

X. Statutory and Executive Order Reviews

This final rule 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 rules from review under Executive Order 12866, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, 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 (NTTAA) (15 U.S.C. 272 note).

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 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, or otherwise have any unique impacts on local governments. 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.).

Although this action does not 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), EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. As such, to the extent that information is publicly available or was submitted in comments to EPA, the Agency considered whether groups or segments of the population, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide discussed in this document, compared to the general population.

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: March 26, 2013.

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:


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

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

* * * * *

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<tr>
<th>Polymer</th>
<th>CAS No.</th>
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<td>Styrene-ethylene-propylene block copolymer, minimum number average molecular weight (in amu), 125,000 ..</td>
<td>108388–87–0</td>
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Waste Landfill Permit Program

Adequacy of Oregon Municipal Solid Waste Landfill Permit Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: This action approves a modification to the State of Oregon’s approved Municipal Solid Waste Landfill (MSWLF) permit program. The approved modification allows the State to issue Research, Development, and Demonstration (RD&D) Permits to owners and operators of MSWLF units in accordance with its State law. On March 22, 2004, the EPA issued final regulations allowing RD&D Permits to be issued to certain municipal solid waste landfills by approved states. On June 14, 2012, Oregon submitted an application to EPA Region 10 seeking Federal approval of its RD&D Permit requirements. After thorough review, EPA Region 10 is determining that Oregon’s RD&D Permit requirements are adequate through this direct final action.

DATES: This direct final rule will become effective June 3, 2013 without further notice unless the EPA receives written adverse comments on or before May 3, 2013. If written adverse comments are received, the EPA will review the comments and publish another Federal Register document responding to the comments and either affirming or revising the initial decision.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–RCRA–2013–0105, by one of the following methods:

• www.regulations.gov: Follow the on-line instructions for submitting comments.
• Email: calabro.domenic@epa.gov
• Fax: (206) 553–8509, to the attention of Domenic Calabro.
• Hand Delivery or Courier: Deliver your comments to Domenic Calabro, Office of Air, Waste and Toxics, U.S. EPA, Region 10, 1200 Sixth Avenue, Suite 900, Mailstop: AWT–122, Seattle, WA 98101. Such deliveries are only accepted during the Office’s normal hours of operation.

Instructions: Identify your comments as relating to Docket ID No. EPA–R10–RCRA–2013–0105. The EPA’s policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or claimed to be other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or email. The www.regulations.gov Web site is an “anonymous access” system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through www.regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA’s public docket visit the EPA Docket Center homepage at http://www.epa.gov/dockets/.

Docket: EPA has established a docket for this action under Docket ID No. EPA–R10–RCRA–2013–0105. All documents in the docket are listed on the www.regulations.gov Web site. Although it may be listed in the index, some information might not be publicly available, e.g., CBI or other information the disclosure of which 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 through www.regulations.gov or in hard copy at the U.S. Region 10 Library, 1200 Sixth Avenue, Seattle, Washington by appointment only: please telephone (206) 553–1289 to make an appointment.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

I. Background

On March 22, 2004, the EPA issued a final rule amending the Municipal Solid Waste Landfill (MSWLF) criteria in 40 CFR part 258 to allow Research, Development, and Demonstration (RD&D) permits (69 FR 13242). This rule allows for variances from specified criteria for a limited period of time, to be implemented through state-issued RD&D permits. RD&D permits are available only in states with approved MSWLF permit programs that have been modified to incorporate RD&D permit authority. The purpose of the rule is to stimulate the development of new technologies and alternative operational processes for the landfilling of municipal solid waste. RD&D permits may provide variances from existing requirements for run-on control systems, liquid restrictions, and final cover requirements. There is no authority for variance of criteria for groundwater monitoring, closure and post-closure requirements (except alternative cover provisions), or financial assurance requirements. To issue an RD&D permit allowing variances from any of these criteria, the director of an approved state must be satisfied that a landfill operating under an RD&D permit will pose no additional risk to human health and the environment beyond that which would result from a landfill operating under the full MSWLF criteria.

While states are not required to seek approval to allow permits under this new provision, those states interested in providing RD&D permits to owners and operators of MSWLFs must seek approval from the EPA before issuing such permits. Approval procedures for the new provisions of 40 CFR part 258 are outlined in 40 CFR § 239.12.

On October 7, 1993, EPA published a final rule (58 FR 193) approving the State of Oregon’s MSWLF permit program. On June 14, 2012, Oregon Department of Environmental Quality (ODEQ) applied for approval of its RD&D permit provisions, codified at ORS 459.245(4). In addition, Oregon has a state flexibility rule (OAR 340–094–0020) which allows the Director of the ODEQ or a designee to approve an alternative schedule, procedure, or design as long as the procedure or design is at least as protective of the environment as the provisions in 40 CFR part 258 and