

in place of an operating permit program submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. The EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the "Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings" issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. Submission to Congress and the Comptroller General

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 the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by *February 5, 2007*. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action fully approving Delaware's Title V operating permit program may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

This action approves an amendment to the Delaware Title V operating permit

program to correct the definition of a "major source."

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Reporting and recordkeeping requirements.

Dated: November 21, 2006.

William T. Wisniewski,

Acting Regional Administrator, Region III.

■ 40 CFR part 70 is amended as follows:

PART 70—[AMENDED]

■ 1. The authority citation for part 70 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. Appendix A to part 70 is amended by adding paragraph (c) in the entry for Delaware to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

Delaware

(c) The Delaware Department of Natural Resources and Environmental Control submitted program amendment on May 18, 2004. This rule amendment contained in the May 18, 2004 submittal is necessary to make the current definition as stringent as the corresponding provision of 40 CFR part 70, which went into effect on November 27, 2001. The State is hereby granted approval effective on February 5, 2007.

[FR Doc. E6-20645 Filed 12-5-06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0175; FRL-8084-2]

Pesticides; Food Packaging Treated with a Pesticide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: This rule excepts from the definitions of "pesticide chemical" and "pesticide chemical residue" under FFDC section 201(q), food packaging (e.g. paper and paperboard, coatings, adhesives, and polymers) that is treated with a pesticide as defined in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 2(u). As a result, such ingredients in food packaging treated with a pesticide are exempt from regulation under FFDC section 408 as pesticide chemical residues. Further, a food that bears or

contains such ingredients are not subject to enforcement by the Food and Drug Administration (FDA) under section 402(a)(2) (B) of the FFDC since the ingredients are not pesticide chemical residues. Instead, such ingredients are subject to regulation by the FDA as food additives under FFDC section 409. FDA generally regulates such food additives in food packaging as food contact substances under FFDC, section 409(h). This rule expands the scope of the provision in 40 CFR 180.4 which currently applies only to food packaging impregnated with an insect repellent - one type of pesticide. This rule, as with the rule it amends, only applies to the food packaging materials themselves; it does not otherwise limit EPA's FFDC jurisdiction over pesticides or limit FDA's jurisdiction over substances subject to FDA regulation as food additives. EPA, in consultation with FDA, believes this rule will eliminate the duplicative FFDC jurisdiction and economize Federal government resources while continuing to protect human health and the environment. Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), EPA still regulates the food packaging as an inert ingredient of the pesticide product and still regulates the pesticide active ingredient in the treated food packaging under both FIFRA and the FFDC.

DATES: This direct final rule is effective February 5, 2007 without further notice unless EPA receives adverse comments in writing. Any comments must be received on or before January 5, 2007. If EPA receives adverse comments, EPA will publish a timely withdrawal in the **Federal Register** informing the public that this direct final rule will not take effect.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2006-0175, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special

arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2006-0175. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or 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 e-mail. The Federal www.regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, 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 EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, 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.

Docket: All documents in the docket are listed in the docket index. Although listed in the index, some information is not publicly available, e.g., 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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The hours of operation of this Docket Facility are 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: Mari L. Duggard, Biopesticides and Pollution

Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0028; fax number: (703) 308-7026; e-mail address: duggard.mari@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 a manufacturer/wholesaler of sanitary food packaging products or are a pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Pesticide manufacturing (NAICS 32532)
- Food packaging manufacturers (NAICS 32222)

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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 180.4. 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. What Should I Consider as I Prepare My Comments for EPA?

1. *Docket.* EPA has established a docket for this action under docket ID number EPA-HQ-OPP-2006-0175. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date, and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions

or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

EPA has received applications for the registration of pesticides under FIFRA that, as proposed, will be applied to food packaging materials. These pesticides are generally intended to function as alternatives to more costly and more toxic applications of insecticides in food storage and retail establishments. The regulatory framework for this use of pesticides raises a number of complex jurisdictional issues for EPA and FDA.¹ Because the treated packaging materials will be sold to food distributors for the purpose of controlling pest infestations, as well as for packaging food, the pesticide treated food packaging materials will be subject to the pesticide product registration requirements of section 3 of FIFRA. Under FIFRA, the components of pesticides are either active ingredients or inert ingredients. Active ingredients are those which, among other things, will "prevent, destroy, repel or mitigate any pest." (FIFRA section 2(a)) Inert ingredients are ingredients "which are not active." (FIFRA section 2(m)). Thus, the components of the food packaging (paperboards, coatings, etc.) become inert ingredients of a pesticide product

¹This rule does not include within its scope substances which may be regulated as pesticides under FIFRA that are used to prevent, destroy, repel or mitigate microorganisms when such substances are included for such use in or are applied for such use on food packaging (without regard to whether the substances are intended to have an ongoing effect on any portion of the packaging) (see FFDCIA section 201(q)(1)(B)(ii) which excludes such substances from the definition of "pesticide chemical"). Because such substances are already excluded from the definition of pesticide chemical residue, it is unnecessary to address these substances in this rule.

under FIFRA whenever the food packaging is treated with a pesticide active ingredient and is distributed or sold with the purpose of controlling pests.² Such inert ingredients are not used for a pesticidal purpose in the production, storage, processing, or transportation of food. However, as inert ingredients, these components of food packaging are also subject to regulation as “pesticide chemical residues” under FFDCA section 408.

Under section 408 of the FFDCA, any pesticide chemical residue in or on food is deemed unsafe, unless EPA has established a tolerance or tolerance exemption that covers the pesticide chemical residue. This is true even though FDA may have previously issued regulations under section 409 of FFDCA permitting the use of these materials in food packaging that has not been treated with a pesticide. As a result, the same food packaging materials would be subject to regulation under FFDCA by both Agencies. EPA is taking today’s action in order to give FDA jurisdiction under the FFDCA over the inert ingredients in food packaging treated with a pesticide as food additives. Consequently, EPA would no longer have jurisdiction over such substances as pesticide chemicals under the FFDCA since a pesticide chemical and a pesticide chemical residue are excluded from the definition of food additive in FFDCA section 201(s). Given FDA’s expertise and experience in regulating the components of food packaging, EPA, in consultation with FDA, believes this rule will eliminate the duplicative FFDCA jurisdiction and economize Federal government resources while continuing to protect human health and the environment without additional regulatory oversight by EPA.

In 1998, EPA consciously limited the exception at 40 CFR 180.4 to food packaging materials impregnated with an insect repellent, since at the time of promulgation EPA had only received an application for a pesticide product containing an insect repellent. EPA has

now received applications for other treated food packaging products that contain active ingredients that are not insect repellents and will not be applied through impregnation of the materials. EPA, in consultation with FDA, believes it is appropriate to extend the 1998 rule to give FDA sole jurisdiction under the FFDCA over the inert ingredients in such food packaging products without regard to the application technique and mode of action of the active ingredients in such products. Again, this action does not affect EPA’s jurisdiction under section 408 over ingredients other than the packaging materials in such products (including the pesticide active ingredient), nor does it affect EPA’s jurisdiction under FIFRA to regulate such products.

B. What Is the Agency’s Authority for Taking This Action?

Section 201(q)(3) of FFDCA, as amended by the Food Quality Protection Act (FQPA), allows the Administrator, under specified conditions, to exempt certain substances from the definition of “pesticide chemical” or “pesticide chemical residue” if:

A. Its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or human activities not involving the use of any substance for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food, and:

B. The Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under one or more provisions of this Act other than sections 402(a)(2)(B) and 408.

With today’s rule, EPA is excepting from the definition of “pesticide chemical” substances that are inert ingredients in food packaging treated with a pesticide, when such ingredients are the components of the food packaging (e.g. paper and paperboard, coatings, adhesives and polymers).

It is important to note that this rule does not affect EPA’s regulation of such substances as inert ingredients under FIFRA. EPA will continue to exercise jurisdiction over these substances when they are used as inert ingredients in food packaging material that is intended to produce a pesticidal effect. The materials that make up food packaging treated with a pesticide may serve one of two purposes: 1. To control pests, or 2. to be one of the materials that make up the container for food. As a result of this rule, under FFDCA, EPA will continue to regulate the materials which control pests and FDA will regulate the

materials that make up the food packaging material. Consistent with EPA’s pesticide registration regulations, EPA will not issue a registration under FIFRA for pesticide products containing food packaging inert ingredients if the presence of these ingredients in or on food is not authorized or permitted by FFDCA and the implementing regulations.

EPA, in consultation with FDA, believes that section 201(q)(3) is applicable to inert ingredients in pesticide treated food packaging materials that are the components of the food packaging (paperboard, coatings, etc). When such inert ingredients are the components of the food packaging itself, EPA believes the occurrence of these substances as residues in or on food would be appropriately excepted from the definition of “pesticide chemical” or “pesticide chemical residue” because such substances are not attributable primarily to the use of the substances for a pesticidal purpose in the production, storage, processing or transportation of food. Rather, the presence of such substances as residues in food is primarily attributable to their use for purposes of packaging food. For this reason, and because of FDA’s considerable experience in regulating such substances found in food packaging, EPA, after consulting with FDA, believes it is appropriate for FDA to regulate these inert ingredients under section 409 of FFDCA.

As noted, this regulation excepts from the definition of “pesticide chemical” and “pesticide chemical residue” any inert ingredient that is a component of food packaging material treated with a pesticide. EPA, in consultation with FDA, believes the identity of the pesticide in or on the packaging material is not relevant to a determination under section 201(q)(3) regarding whether it is appropriate to exempt an inert ingredient from the definition of pesticide chemical or pesticide chemical residue. As noted above, that determination turns only on whether: 1. the occurrence of the residues of the substance in or on food is attributable primarily to the use of substances for a pesticidal purpose in the production, storage, processing or transportation of food; and 2. whether it is more appropriate to regulate such substances under another provision of FFDCA other than sections 402(a)(2)(B) and 408. Thus, EPA has determined that inert ingredients that are the components of the food packaging material in pesticide treated food packaging are more appropriately regulated by FDA under FFDCA. This rule therefore amends 40 CFR 180.4 to

²It is important to understand that this rule only applies to a very small subset of food packaging materials: pesticide-treated food packaging that is distributed or sold with the purpose of controlling pests. Food packaging that is not distributed or sold to control pests is not a pesticide and is not subject to this rule. For example, packaged products that are simply treated with pesticides by food distributors, retailers or homeowners solely to control pests on site do not themselves become pesticides simply as a result of such applications. Rather, the product itself must be distributed with the purpose of providing pest control to become a pesticide. The treated packaging materials addressed in this rule are those that are sold for the express purpose of providing ongoing protection from pests that may contaminate the products made with the treated packaging.

extend to any food packaging materials treated with a pesticide.

EPA is issuing this action as a direct final rule without prior proposal because the Agency believes that this action is not controversial and will not result in any adverse comments. EPA previously received no adverse comments when it issued the current rule at 40 CFR 180.4 to except food packaging materials impregnated with insect repellents from EPA jurisdiction under section 408. Because this amendment to § 180.4 likewise only applies to the food packaging materials, and not to the pesticide active ingredient used in such products, EPA believes this action is similarly non-controversial. The Agency also believes that it is important to make this action effective as soon as possible, 1. in order to address the current, unnecessary overlap in jurisdiction between EPA and FDA under FFDCIA; and 2. to allow the Agency to act expeditiously on pending applications for registration by eliminating the need for developing numerous individual tolerance exemptions for the components of the packaging material. If no relevant adverse comment is submitted within 30 days of publication, this action will become effective 60 days after publication without any further action by the Agency. If, however, a relevant adverse comment is received during the comment period, this final rule will be withdrawn and the public comments received will be addressed in a subsequent final rule, or EPA may request additional public comments.

For the reasons set forth above, EPA believes that it is appropriate to issue this rule as direct final rule. In addition, this rule also conforms with the "good cause" exemption under section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(B)), which allows agencies to issue an action without additional notice and comment if further notice and comment would be unnecessary.

III. Statutory and Executive Order Reviews

As an exception, this action does not impose any regulatory obligations. Under Executive Order 12866 entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993), it has been determined that this rule is not "significant" and is not subject to OMB review. This 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) (Pub. L. 104-4). This rule has no federalism or tribal implications, because it will not have substantial direct effects on States or Indian tribes, on the relationship between the Federal Government and the States or Indian tribes, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes, as specified in Executive Orders 13132 (entitled Federalism, 64 FR 43255, August 10, 1999) and 13175 (entitled Consultation and Coordination with Indian Tribal Governments, 65 FR 67249, November 6, 2000). Nor does this rule raise issues that require 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 require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This rule is also not subject to Executive Order 13211, entitled Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use. In addition, this action does not involve any standards that would require Agency consideration pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (Pub. L. 104-113).

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this regulatory action will not have a significant economic impact on a substantial number of small entities, because this regulatory action is an exemption and imposes no regulatory obligations. EPA will provide this information to the Small Business Administration's office of Advocacy upon request.

IV. 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 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 the rule in the **Federal Register**. This 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 record-keeping requirements.

Dated: November 14, 2006.

Janet L. Andersen,

Division Director, Biopesticides and Pollution Prevention 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(q), 346(a), and 371

■ 2. Section 180.4 is amended by revising paragraph (a) to read as follows:

§ 180.4 Exceptions.

* * * * *

(a) *General.* Inert ingredients in food packaging treated with a pesticide, when such inert ingredients are the components of the food packaging material (e.g. paper and paperboard, coatings, adhesives, and polymers).

* * * * *

[FR Doc. E6-20270 Filed 12-05-06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0664; FRL-8100-3]

Paraquat Dichloride; Pesticide Tolerance Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; Correction.

SUMMARY: EPA issued a final rule in the **Federal Register** of September 6, 2006, concerning establishing tolerances for residues of paraquat dichloride in or on various food and feed commodities. This document is being issued to correct typographical errors.

DATES: This final rule is effective December 6, 2006.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0664. All documents in the docket are listed on the regulations.gov