

ENVIRONMENTAL PROTECTION AGENCY

40 CFR PART 180

[OPP-300605; FRL-5766-9]

RIN 2070-AD20

Pesticides; FFDC A Jurisdiction Over Food Packaging Impregnated With an Insect Repellent Transferred to FDA

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The effect of this rule is to give the Food and Drug Administration (FDA) sole jurisdiction under the Federal Food, Drug, and Cosmetic Act (FFDCA) for food packaging (e.g., paper and paperboard, coatings, adhesives, and polymers) which is impregnated with an insect repellent. Currently, food packaging impregnated with an insect repellent is regulated under FFDCA by both Agencies. Under FFDCA section 409, FDA regulates the use of packaging material (e.g., paper and paperboard, coatings, adhesives, and polymers) when used in food packaging. Under FFDCA section 408, EPA would need to establish an exemption from the requirement for a tolerance for the food packaging material which is impregnated with an insect repellent, even though FDA may have already established the safety and permitted the use of these substances in food packaging pursuant to section 409. In essence, EPA's regulation of such material under FFDCA section 408, does not add any value or health benefits to the actions taken by FDA under section 409. Given FDA's expertise and experience in regulating the components of food packaging, both Agencies believe this rule will eliminate the duplicative FFDCA jurisdiction and economize Federal government resources while continuing to protect human health and the environment. To effectuate the transfer of EPA's FFDCA jurisdiction to FDA, EPA is issuing this rule to except certain inert ingredients from the definitions of "pesticide chemical" and "pesticide chemical residue." Specifically, this exception applies to those inert ingredients that are the components of the food packaging (e.g., paper and paperboard, coatings, adhesives, and polymers) which is impregnated with an insect repellent. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA still regulates the food packaging material impregnated with an insect repellent as an inert ingredient of the pesticide product.

DATES: This action is effective May 4, 1998 unless relevant adverse comments are received by April 3, 1998.

ADDRESSES: By mail, submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, deliver comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Follow the instructions under Unit V. of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. The public docket is available for public inspection in Rm. 119 at the Virginia address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Robert Torla, Biopesticides and Pollution Prevention Division (7511W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 5th Floor Crystal Station, 2800 Crystal Drive, Arlington, VA, (703) 308-8098; torla.robert@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Entities potentially affected by this action are those which manufacture pesticides, sanitary paper food containers, miscellaneous plastic products; those who process food and kindred products; and wholesalers of sanitary food containers.

Category	Examples of Affected Entities
Manufacturers	Manufacturers of sanitary paper food containers and miscellaneous plastic products used as food containers
Wholesalers	Wholesalers of sanitary food containers, food, and kindred products
Processors of food and kindred products	Persons who process food and feed products for wholesale or distribution to consumers

This table is not intended to be exhaustive, but rather provides examples of the types of entities that are likely to be affected by this action. To determine whether you or your business is affected by this action, you should carefully examine this document and the provisions in § 180.4 of the regulatory text. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the "FOR FURTHER INFORMATION CONTACT" unit above.

I. Background

EPA has recently received an application for the registration of an insect repellent under FIFRA that, as proposed, will be impregnated in food packaging materials. The active ingredient in this product, methyl salicylate, is a synthetic version of naturally occurring wintergreen oil, and may function as an alternative to more costly and more toxic applications of pesticides in food storage facilities and retail establishments. EPA refers to natural and synthetic versions of naturally occurring active ingredients that have a non-toxic mode of action as "biochemicals."

The regulatory framework for this proposed use of biochemicals raises a number of complex jurisdictional issues for EPA and FDA. Because the impregnated packaging materials will be sold to food distributors for the purpose of repelling insects, as well as for packaging food, the food packaging materials themselves 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]

Category	Examples of Affected Entities
Chemical industry	Persons who manufacture, process, sell, or distribute pesticide products

not active" (FIFRA section 2(m)). Thus, the methyl salicylate in the packaging constitutes the active ingredient, and the components of the food packaging (paperboard, coatings, etc.) are the inert ingredients.

To the extent that the use of these packaging materials results in residues of the active and inert ingredients on food (which includes both human and animal food), these active and inert ingredients are also subject to regulation under section 408 of FFDCA. This is true even though FDA may have previously issued regulations under section 409 of FFDCA permitting the use of these substances in the food packaging material. As a result, food packaging impregnated with an insect repellent is regulated under FFDCA by both Agencies. Under FFDCA section 409, FDA regulates the use of packaging material (e.g., paper and paperboard, coatings, adhesives, and polymers) when used in food packaging. Under FFDCA section 408, EPA would need to establish an exemption from the requirement for a tolerance for the food packaging material which is impregnated with an insect repellent, even though FDA may have already established the safety and permitted the use of these substances in food packaging pursuant to section 409. In essence, EPA's regulation of such material under FFDCA section 408, does not add any value or health benefits to the actions taken by FDA under section 409. Given FDA's expertise and experience in regulating the components of food packaging, both Agencies believe 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. EPA is therefore taking today's action in order to give sole FFDCA jurisdiction over food packaging material impregnated with an insect repellent to FDA.

II. Issuance of This Action as a Direct Final Rule

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. The Agency also believes that it is important to make this action effective as soon as possible, in order to address the current overlap in jurisdiction between EPA and FDA under FFDCA. Nevertheless, EPA is issuing a corresponding proposed rule elsewhere in today's **Federal Register** to provide an opportunity for the public to submit relevant adverse comment on

this issue. 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 direct 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 a 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. Legal Authority

Section 201(q)(3) of FFDCA, as amended by FQPA, allows the Administrator, under specified conditions, to except certain substances from the definition of "pesticide chemical" or "pesticide chemical residue." That provision reads as follows:

(3) Notwithstanding paragraphs (1) and (2) [the definitions of "pesticide chemical" and "pesticidal chemical residue"], the Administrator may by regulation except a substance 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.

IV. Findings and Agency Decision

After consultation with FDA, EPA is today excepting from the FFDCA definitions of "pesticide chemical" and "pesticide chemical residue" substances that are inert ingredients in food packaging impregnated with insect repellents, when such ingredients are the components of the food packaging (e.g., paper and paperboard, coatings, adhesives, and polymers). Upon the effective date of this rule, FDA alone will regulate such substances under FFDCA. Given FDA's expertise and experience in regulating the

components of food packaging, both Agencies believe that this rule will eliminate duplication and economize Federal government resources without any risk to public health.

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 an insecticidal effect. With the development of this technology, an ingredient in food packaging may be used for two purposes: (1) to repel pests, and (2) to be one of the materials which make up the container for the food. As a result of this rule, under FFDCA, EPA will continue to regulate the materials which repel pests and FDA will regulate the materials which 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 believes that section 201(q)(3) is applicable to inert ingredients in insect repellent-impregnated food packaging materials that are the components of the food packaging (e.g., paper and paperboard, coatings, adhesives, and polymers). When the inert substances are the components of the food packaging material itself, EPA believes the substance's occurrence as a residue in or on food is not attributable primarily to the use of a substance for a pesticidal purpose in the production, storage, processing, or transportation of food. For this reason, and because of FDA's considerable experience generally in regulating ingredients found in food packaging, both EPA and FDA believe it is appropriate for FDA to regulate these inert ingredients under section 409 of FFDCA.

While EPA has to date only received one application for the registration of an insect repellent in packaging material containing the active ingredient methyl salicylate, today's rule is not limited to inert ingredients in insect repellents containing only methyl salicylate. Rather, this regulation excepts from the definition of pesticide chemical and pesticide chemical residue any inert ingredient that is a component of the food packaging material of insect repellent-impregnated food packaging. Upon consultation, both EPA and FDA believe that the identity of the insect repellent in the packaging material is not relevant to a determination under

section 201(q)(3) regarding whether it is appropriate to except 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 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. Both EPA and FDA believe that inert ingredients that are the components of the food packaging material in insect repellent-impregnated food packaging are more appropriately regulated by FDA under FFDCA.

The exception authority under FFDCA section 201(q)(3) is new; no exceptions are currently established in 40 CFR part 180. The current structure of part 180 does not provide the space for EPA to create a new section devoted to these exceptions except at the end of subpart B, far removed from where it should be organizationally. This rule overcomes this difficulty by removing existing text under § 180.4, which currently contains provisions for certification of pesticide chemical usefulness and residue estimate opinions. These provisions were eliminated from FFDCA by FQPA and the corresponding regulations are no longer needed.

In its place, EPA is revising § 180.4 to contain exceptions granted under FFDCA section 201(q)(3). This would locate these exceptions close to the beginning of part 180 where they should logically reside.

V. Public Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number "300605" (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located at the Virginia address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at: opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number "OPP-300605." Electronic comments on this rule may be filed online at many Federal Depository Libraries.

VI. Regulatory Assessment Requirements

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). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by 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). 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.

VII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the

Agency will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in today's **Federal Register**. This is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 23, 1998.

Carol M. Browner,
Administrator.

Therefore, 40 CFR part 180 is amended as follows:

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

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

2. The part heading for part 180 is revised to read as follows:

PART 180—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN FOOD

3. Section 180.1 is amended by revising paragraph (k) and adding new paragraph (o) to read as follows:

§ 180.1 Definitions and interpretations.

* * * * *

(k) The term *pesticide chemical* means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide.

* * * * *

(o) The term *pesticide chemical residue* means a residue on or in a raw agricultural commodity or processed food of:

- (1) A pesticide chemical; or
- (2) Any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

4. By revising § 180.4 to read as follows:

§ 180.4 Exceptions.

The substances listed in this section are excepted from the definitions of "pesticide chemical" and "pesticide chemical residue" under FFDCA section 201(q)(3) and are therefore exempt from regulation under FFDCA section 402(a)(2)(B) and 408. These substances are subject to regulation by the Food and Drug Administration as food additives under FFDCA section 409.

(a) Inert ingredients in food packaging impregnated with an insect repellent

when such inert ingredients are the components of the food packaging material (e.g., paper and paperboard, coatings, adhesives, and polymers).

(b) [Reserved]

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