

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

[OPP-300605A; FRL-5776-2]

RIN 2070-AD20

**Pesticides; FFDCA Jurisdiction over Food Packaging Impregnated with an Insect Repellent Transferred to FDA**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

**SUMMARY:** Elsewhere in today's **Federal Register**, EPA is issuing a direct final rule which gives 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. To effectuate that transfer, the rule excepts certain inert ingredients from the definitions of "pesticide chemical" and "pesticide chemical residue." Specifically, the 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. EPA is issuing the action as a direct final rule without prior proposal because the Agency believes that the action is not controversial and will not result in any adverse comments. A detailed rationale for the promulgation of the rule is set forth in the direct final rule, along with the details of the rule. With this corresponding action, EPA is providing an opportunity for the public to submit adverse comment on this issue. If no relevant adverse comment is submitted in response to this proposed rule, the direct final rule will become effective without any further action by the Agency. If, however, a relevant adverse comment is received during the comment period, the direct final rule will be withdrawn and the public comments received will be addressed in a subsequent final rule, or EPA may request additional public comments. Any parties interested in commenting on this action should do so at this time.

**DATES:** Comments must be received on or before 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 II. 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.

**FOR FURTHER INFORMATION CONTACT:** By mail: Robert Torla, Biopesticides and Pollution Prevention Division, 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:****I. Background**

For detailed information about the action, see the direct final rule which is published elsewhere in today's **Federal Register**.

**II. 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 proposed rule may be filed online at many Federal Depository Libraries.

**III. 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 proposed rule is not "significant" and is not subject to OMB review. This proposed 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.

**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.*

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