

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).

Since this extension of an existing time-limited tolerance does 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. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

IV. 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, EPA submitted 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 General Accounting Office 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: May 26, 1998.

James Jones,

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:

Authority: 21 U.S.C. 346a and 371.

§ 180.431 [Amended]

2. In § 180.431, by amending the tolerance listed for "Canola" in the table

under paragraph (b) by changing the date "7/31/98" to read "1/31/00".

[FR Doc. 98-15172 Filed 6-9-98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300656; FRL-5789-7]

RIN 2070-AB78

Polyvinyl Chloride; 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 polyvinyl chloride when used as an inert ingredient carrier in pesticide formulations applied to growing crops or raw agricultural commodities after harvest. American Cyanamid Company requested this exemption from the requirement of a tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170).

DATES: This regulation is effective June 10, 1998. Objections and requests for hearings must be received by EPA on or before August 10, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP-300656, must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, OPP-300656, must also be submitted 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, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-

docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number OPP-300656. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Bipin Gandhi, Registration Division 7505W, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Fourth Floor, CS#1, 2800 Crystal Drive, Arlington, VA, (703) 308-8380, e-mail: gandhi.bipin@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 29, 1997 (62 FR 45804) (FRL-5738-2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of pesticide petition (PP) 3E4246 for a tolerance exemption by American Cyanamid Company, Agricultural Products Research Division, P.O. Box 400, Princeton, NJ 08543-0400. This notice included a summary of the petition prepared by American Cyanamid Company, the petitioner. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001 be amended by establishing an exemption from the requirement of a tolerance for residues of polyvinyl chloride when used as an inert ingredient carrier in pesticide formulations applied to growing crops or raw agricultural commodities after harvest.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities

under a new section 408 with a new safety standard and new procedures.

New section 408(c)(2)(A)(i) allows EPA to establish an exemption from the requirement of a tolerance for a pesticide chemical residue on food only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) 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, but does not include occupational exposure. Section 408(c)(2)(B) 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 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.

II. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactant such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

III. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated 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 ingredient in

conjunction with possible exposure to residues of the inert ingredient in food, drinking water, and other nonoccupational exposures. 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.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of polyvinyl chloride and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance exemption for residues on polyvinyl chloride on growing crops and raw agricultural commodities after harvest. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

The data submitted in the petitions and other relevant material have been evaluated. As part of the EPA policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305) (FRL-3190-1), the Agency set forth a list of studies which would generally be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. However, where it can be determined without that data that the inert ingredient will present minimal or no risk, the Agency generally does not require some or all of the listed studies to rule on the proposed tolerance or exemption from the requirement of a tolerance for an inert ingredient.

A. Toxicological Profile

In the case of certain chemical substances that are defined as "polymers," the Agency has established a set of criteria which identify categories of polymers that present low risk. These criteria (described in 40 CFR 723.250) identify polymers that are relatively unreactive and stable compared to other chemical substances as well as polymers that typically are not readily absorbed. These properties generally limit a polymer's ability to cause adverse effects. In addition, these criteria exclude polymers about which little is known. The Agency believes that polymers meeting these criteria will present minimal or no risk. Polyvinyl chloride (PVC) conforms to the definition of polymer given in 40 CFR 723.250(b) and meets the following

criteria that are used to identify low risk polymers:

1. PVC is not a cationic polymer, nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

2. PVC contains as an integral part of its composition the atomic elements carbon, chlorine, and hydrogen.

3. PVC does not contain as an integral part of its composition, except as impurities, any elements other than those listed in 40 CFR section 723.250 (d)(2)(ii).

4. PVC is not designed, nor is it reasonably anticipated to substantially degrade, decompose, or depolymerize.

5. PVC is not manufactured or imported from monomers and/or other reactants that are not already included on the Toxic Substance Control Act (TSCA) Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. PVC is not a water absorbing polymer.

7. PVC does not contain any group as reactive functional groups.

8. The minimum number-average molecular weight of PVC is listed as 29,000 daltons. Substances with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 generally are not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response.

9. PVC has a minimum number-average molecular weight of 29,000 and contains less than 2 percent oligomeric material below molecular weight 500 and less than 5 percent oligomeric material below 1,000 molecular weight.

In addition, PVC is approved by the Food and Drug Administration (FDA) under 21 CFR for contact with food as a component in adhesives (21 CFR 175.105), coatings (21 CFR 175.320), and paper and paperboard (21 CFR 176.180). PVC is also approved by FDA as an indirect food additive used as a basic component of acrylic (21 CFR 177.1010) and cellophane (21 CFR 177.1200) polymers. PVC is also cleared for use as water pipe for potable water as per FFDC 201(s).

Based on the conformance of polyvinyl chloride to the above criteria, no mammalian toxicity is anticipated from dietary, inhalation or dermal exposure to polyvinyl chloride.

B. Exposures and Risks

1. From food and feed uses, drinking water, and non-dietary exposures. For the purposes of assessing the potential

dietary exposure, EPA considered that under this tolerance exemption polyvinyl chloride could be present in all raw and processed agricultural commodities and drinking water and that non-occupational, non-dietary exposure was possible. EPA concluded that, based on this chemical's categorization as a polymer conforming to the definition of a polymer under 40 CFR 723.250(b) that also meet the criteria used to identify low risk polymers, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable.

2. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) 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."

In the case of polyvinyl chloride, the lack of expected toxicity of this substance based on its conformance to the definition of polymers as given in 40 CFR 723.250(b) as well as the criteria that identify low risk polymers results in no expected cumulative effects; a cumulative risk assessment is therefore not necessary.

C. Aggregate Risks and Determination of Safety for U.S. Population

Based on this chemical's conformance to the definition of a polymer given in 40 CFR 723.250(b) as well as the criteria that are used to identify low risk polymers, EPA concludes that there is a reasonable certainty that no harm to the U.S. population will result from aggregate exposure to polyvinyl chloride. EPA believes this compound presents no dietary risk under reasonably foreseeable circumstances.

D. Aggregate Risks and Determination of Safety for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

Due to the low expected toxicity of polyvinyl chloride, EPA has not used a

safety factor analysis in assessing the risk of this compound. For the same reasons the additional safety factor is unnecessary.

V. Other Considerations

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation; therefore, the Agency has concluded that analytical methods are not required for enforcement purposes for polyvinyl chloride.

There are no Codex Alimentarius Commission (Codex), Canadian or Mexican residue limits for polyvinyl chloride.

VI. Conclusion

Therefore, an exemption from the requirement of a tolerance is established for residues of polyvinyl chloride.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by August 10, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue

of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP-300656] (including any comments and data submitted electronically). 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 public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may 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.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in "ADDRESSES" at the beginning of this document.

IX. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). 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.*, 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).

The Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the General Accounting Office

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).

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: May 21, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

PART 180 — [AMENDED]

Therefore, 40 CFR chapter I is amended as follows:

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

Authority: 21 U.S.C. 346a and 371.

2. In section 180.1001 the table in paragraph (c) is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.1001 Exemption from the requirement of a tolerance.

(c) *

Inert ingredients	Limits	Uses
* *	* * *	* *
Polyvinyl chloride (CAS Reg. No. 9002-86-2), minimum number average molecular weight (in amu) 29,000.	Carrier
* *	* * *	* *

* * *

[FR Doc. 98-15174 Filed 6-9-98; 8:45 am]

BILLING CODE 6560-50-F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 2

[ET Docket No. 94-45; FCC 98-96]

Marketing and Equipment Authorizations

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: By this *Memorandum Opinion and Order*, the Commission amends its regulations to increase the number of radio frequency products that can be imported, prior to receiving a grant of equipment authorization, for the purpose of testing and evaluation or demonstration at industry trade shows. This increase applies only to products designed to be operated within one of the allocated radio services and under the provisions of license issued by the Commission. In addition, manufacturers operating equipment for demonstration or evaluation purposes will be permitted to operate under the authority of a local FCC licensed service provider on the condition that the licensee gives the manufacturer permission to operate in this manner and accepts responsibility for the operation of the equipment. These amendments to the regulations respond to a Petition for Reconsideration and Clarification, filed by Ericsson, Inc.

EFFECTIVE DATE: August 10, 1998.

FOR FURTHER INFORMATION CONTACT: John A. Reed, Office of Engineering and Technology, (202) 418-2455.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Memorandum Opinion and Order* in ET Docket No. 94-45, adopted May 14, 1998, and released May 28, 1998. The complete text of this *Memorandum Opinion and Order* is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, N.W., Washington, D.C., and also may be purchased from the Commission's duplication contractor, International Transcription Services, Inc., (202) 857-3800, 1231 20th Street, N.W., Washington, D.C. 20036.

Summary of the Memorandum Opinion and Order

1. In the *Memorandum Opinion and Order*, the Commission amended part 2 of its rules regarding the importation and operation of radio frequency (RF) devices. Previously, the rules limited the importation of RF products, prior to receiving a grant of equipment authorization, to no more than 200 units for testing and evaluation purposes and to no more than 10 units for demonstrations at trade shows. A greater number could be imported only if written authorization was first obtained from the Chief, Office of Engineering and Technology, FCC.

2. Ericsson, Inc. filed a Petition for Reconsideration and Clarification to the *Report and Order* ("R&O") in this proceeding, 62 FR 10466, March 7, 1997. It requested that the above