longer necessary. The Baton Rouge serious ozone nonattainment area is required to have an enhanced I/M program under section 182 of the Clean Air Act (the Act) as amended in 1990. This disapproval initiates the sanction process of section 179(a) of the Act.

[FR Doc. 97–30376 Filed 11–18–97; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300557; FRL–5746–1]

Methyl Salicylate; Establishment of an Exemption from Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the insecticide methyl salicylate in or on food, when used as an insect repellent in food packaging and animal feed packaging at an application rate that does not exceed 0.2 mg of methyl salicylate per square inch of packaging materials.

EFFECTIVE DATE: NOVEMBER 19, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300557/PP 7F4818], may 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 should be identified by the docket control number [OPP–300557] and submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300557]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Sheryl K. Reilly, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Office location and telephone number: Room CS15-W31, 2800 Jefferson Davis Hwy., Arlington, VA, (703/308-8265); e-mail: reilly.sheryl@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Tenneco Packaging, 1603 Orrington Ave., Evanston, IL, 60201, requested in pesticide petition PP 7F4818 the establishment of an exemption from the requirement of a tolerance for residues of the insecticide methyl salicylate on food, when used as a insect repellent in food packaging and animal feed packaging materials alone or in conjunction with inert components which conform to the requirements of regulations issued by the Food and Drug Administration under section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA). A notice of filing (FRL–5721–6) was published in the **Federal Register** (62 FR 32331) on June 13, 1997, and the notice announced that the comment period would end on July 13, 1997; no comments were received.

The data submitted in the petition and all other relevant material have been evaluated. Following is a summary of EPA's findings regarding this petition as required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act.

I. Risk Assessment and Statutory Findings

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance 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 an in residential settings, 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 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... .'' EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Additionally, 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.'' Methyl salicylate (CAS Registry Number 119–36–8) is the primary chemical component of a naturally occurring fragrant oil, oil of wintergreen. If present at all, residues of methyl salicylate that may be found in foods in contact with treated packaging materials is expected to be minimal and considerably below the levels expected in existing GRAS uses of the active ingredient as a direct food flavoring ingredient.

The toxicity of methyl salicylate has been extensively studied in animal bioassays of acute, subchronic, and chronic duration. Studies include assessments of the mutagenicity, developmental toxicity, and reproductive effects of methyl salicylate. The petitioner submitted data from the scientific literature to support all toxicology studies typically required for registration of biochemical pesticides.

1. *Acute toxicity* . The acute oral LD_{50} for methyl salicylate in the rat ranges

from 887-1,250 mg/kg. Acute dermal toxicity (LD_{50}) has been reported to be > 5 g/kg in the rabbit.

2. *Skin and eye irritation*. Methyl salicylate has been reported to be a severe eye irritant. Methyl salicylate has been reported to produce mild dermal irritation in rabbits at a concentration of 1%. Moderate to severe irritation is produced in rabbits and guinea pigs at concentrations above 1%. Applied full strength to intact or abraded rabbit skin for 24 hours under occlusion, methyl salicylate was moderately irritating. However, tested at 8% in petrolatum, it produced no irritation after a 48 hour closed-patch test on human subjects.

3. *Mutagenicity*. No evidence for genotoxicity was observed in two studies with prokaryotic test systems; no data on genotoxicity in mammalian test systems are available.

4. *Subchronic toxicity*. Studies of subchronic duration with administration by the oral route have been conducted in both rats and dogs. In rats, no adverse effects were seen at a dose of 50 mg/kg/day in the diet. In dogs, doses ≤250 mg/kg/day did not result in any adverse effects, however, the liver appeared to be the target organ of toxicity at doses above this level. No toxicity was observed when rats were exposed to methyl salicylate via inhalation of saturated air (approx. 700 mg/m3) after twenty 7-hour exposures.

5. *Developmental toxicity*. Methyl salicylate has been tested for developmental effects in hamsters, rats and mice by the oral and dermal routes. In hamsters, oral or dermal doses of methyl salicylate at doses of 1,750 mg/kg/day induced maternal toxicity and increased the incidence of neural tube defects. In rats given methyl salicylate at up to 6,000 mg/kg/day in petroleum based grease by the dermal route, no developmental effects were observed. However, undiluted methyl salicylate applied to the skin of pregnant rats caused total litter resorptions at 1,000 mg/kg/day (a dose that was reduced from 2,000 mg/kg/day because of excessive maternal toxicity). The results of a continuous breeding study in mice were consistent with findings in the developmental studies because of the decreased numbers of litters per pair, reduced average number of pups per litter, decreased proportion of pups born alive in each litter, and reduced mean pup weights in mice given 500 mg/kg/day. The no-observed-adverse-effect level (NOAEL) for these effects was 250 mg/kg/day.

6. *Chronic toxicity*. Toxicity resulting from chronic exposure has been evaluated in studies of two-years' duration as well as studies initially intended to evaluate multi-generational reproductive and developmental effects. In mice, the NOAEL for reproductive parameters and the other toxic endpoints examined has been reported as 250 mg/kg/day. When rats were exposed to methyl salicylate in the diet for two years, no adverse effects were noted at levels of 0.1% (approx. 50 mg/kg/day); pituitary lesions were increased in animals exposed to 0.5% (approx. 250 mg/kg/day). In dogs orally exposed to methyl salicylate for two years, no adverse effects were observed at 50 mg/kg/day; the LOAEL (liver effects) was reported as 150 mg/kg/day.

7. *Carcinogenicity*. No studies have been performed with the primary purpose of determining the oncogenicity of methyl salicylate; however, chronic exposure studies with two-year exposure durations that included extensive pathology did not indicate any increases in incidences of benign or malignant tumors.

8. *Toxicology data waivers*. Waivers for acute inhalation toxicity, dermal sensitization, and immune response studies were accepted by the Agency, based on the long history of use of methyl salicylate by humans without any indication of deleterious effects. Besides its use as a flavoring agent in foods (see GRAS Assessment, below), methyl salicylate has been used in mouthwash, suntan lotions, and in U.S. Pharmocopeia (U.S.P.) preparations as a counterirritant and analgesic for painful muscles or joints, in liniments, ointments, and other preparations. In addition, the manufacturing use product is a liquid, which is not expected to result in the release of appreciable quantities of inhalable methyl salicylate during the manufacturing process, and worker exposure via the dermal route will be minimized through the use of rubber gloves and splash proof goggles and/or face shields. In the end-use formulation, methyl salicylate will be incorporated into a solid matrix in the packaging materials, and the release of vapors at a very low rate over extended periods of time will not result in significant worker or consumer dermal and inhalation exposure.

9. *GRAS assessment*. The Flavoring Extract Manufacturer's Association (FEMA) has determined GRAS levels of methyl salicylate and oil of wintergreen in foods and beverages as indicated in the table below.

TABLE 1- FEMA GRAS LEVELS IN FOOD (PPM)

Food	Methyl Salicylate	Oil of Wintergreen
Beverages	59	56
Ice cream	27	44
Candy	840	260
Baked goods	54	1,500
Chewing gum	8,400	3,900
Syrups	200	---

GRAS food levels in Table 1 are above both the maximum food residue concentration (approx. 16 ppm) and the maximum dietary exposure concentration (approx. 4.7 ppm) estimated by the Petitioner for the proposed use pattern for methyl salicylate. These estimates used highly conservative assumptions for migration of methyl salicylate from packaging and food consumption. Petitioner has shown that even under worst-case exposure conditions (i.e., assuming 30% of all food consumed is in contact with packaging containing methyl salicylate, and 100% of the methyl salicylate migrates to food) exposure to methyl salicylate from use in packaging materials would be less than that received by chewing one stick of chewing gum at the GRAS-approved level. Residue data requirements were thus waived by the Agency.

III. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from groundwater or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

There is no established Maximum Contaminant Level (MCL) for residues of methyl salicylate in drinking water under the Safe Drinking Water Act.

There are five currently registered pesticide products that contain methyl salicylate as an active ingredient. These products include impregnated materials and pellets to be used as vertebrate repellents, and disinfectants/germicides registered for use in household, institutional, hospital, and eating establishment premises. In addition, methyl salicylate has many non-pesticidal uses, such as liniments, lotions, and other products listed above.

With regard to dietary exposure, as noted above in Table 1, methyl salicylate is used as a flavoring in many food products.

Aggregate exposure to methyl salicylate from all these sources is difficult to determine, largely because of its use in a wide variety of food products. While it is difficult to develop a precise estimate of total human exposure to methyl salicylate, EPA believes that its history of safe use as a flavoring additive and its low toxicity at relatively high doses indicate that current exposures are likely to be significantly below levels that may result in adverse health effects. The likely dietary exposures from the pesticidal use in food packaging would be indirect (i.e., resulting from food contact with a treated surface) and therefore unlikely to add significantly to existing exposures. However, because studies evaluated by the Agency indicate that methyl salicylate is toxic to humans at certain high levels, EPA believes it is appropriate to place some limitation on the amount of methyl salicylate that may be applied to packaging material for the purposes of repelling insects to ensure that large quantities of the substance are not used in food packaging. The limitation of 0.2 mg per square inch of packaging materials established by this regulation is based on the lowest GRAS level (27 ppm for ice cream) and a worst-case scenario, which assumes 100% transfer of the active ingredient from the packaging material to food contained within, without consideration of the physical and chemical barriers between the chemical and the food. Using the lowest GRAS level is a conservative step that ties the potential exposure to what is already likely to be in the food supply. The limit, therefore, ensures that any increased human exposure resulting from the pesticidal use of methyl salicylate in packaging material would add very little to the existing exposures -- exposures which EPA believes to be safe. Therefore, EPA concludes that there is a reasonable certainty of no harm from aggregate dietary exposure under this exemption.

A. Dietary Exposure

Dietary exposure of methyl salicylate via food or water is difficult to estimate due to the use of methyl salicylate as a flavoring in many food products. However, based upon its long history of safe use as an additive in food and beverages and its low toxicity at relatively high doses, the Agency believes that current dietary exposure is likely to be significantly below levels that may cause adverse health effects. The likely dietary exposures from the registered products would be indirect (i.e., resulting from food contact with a treated surface) and therefore add very little to existing exposures. Therefore, EPA concludes that there is a reasonable certainty of no harm from aggregate dietary exposure under this exemption.

B. Non-dietary, Non-occupational Exposure

There are five currently registered pesticide products that contain methyl salicylate as an active ingredient. These products include impregnated materials and pellets to be used as vertebrate repellents, and disinfectants/germicides registered for use in household, institutional, hospital, and eating establishment premises. In addition, methyl salicylate is already widely used in liniments, lotions, and other products listed above. The Agency considers the toxicology data base available to support non-pesticidal uses and exposures adequate to support a conclusion of insignificant increase in non-dietary, non-occupational exposure and toxicity from the pesticidal use in food and feed packaging materials.

IV. Cumulative Exposure

The Agency has considered the potential for cumulative toxicity effects of pesticidal uses of methyl salicylate and other substances that may have a common mechanism of toxicity. The Agency concluded that consideration of a common mechanism of toxicity is not appropriate because there is no information in the publicly available literature that indicates there are other substances that share a common mechanism of toxicity with methyl salicylate. Thus, only the potential risks of methyl salicylate were considered in this exemption from the requirement of a tolerance.

V. Safety Factors

A. U.S. Population

Methyl salicylate is the major component of a naturally occurring fragrant oil. FEMA has listed methyl salicylate on its GRAS list for use as a flavoring ingredient in foods and beverages. An FDA Advisory Review Panel has concluded that methyl salicylate is safe for use up to a concentration of 0.4% in the form of a rinse or mouthwash. The compound is extensively used in foods, beverages, pharmaceuticals, lotions and perfumes and has wide distribution in commerce with no reports of adverse outcomes associated with intended uses. The toxicity of methyl salicylate has been adequately and reliably characterized; it is summarized in this submission.

Based on this information, EPA concludes that there is reasonable certainty of no harm from aggregate exposures to pesticidal uses of methyl salicylate over a lifetime, and that no significant human health risks will result from such exposures.

B. 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 data base unless EPA concludes 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 the use of a margin of exposure 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 this compound, EPA has not used a safety factor analysis in assessing the risk of these compounds. For the same reasons the additional safety factor is unnecessary.

VI. Determination of Safety for U.S. Population, Infants and Children

Based on its long history of use by humans without any indication of deleterious effects, there is reasonable certainty that no harm will result from aggregate exposure to the United States population, including infants and children, to residues of methyl salicylate. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As a result, EPA establishes an exemption from the requirement of a tolerance pursuant to FFDCA section 408(j)(3) for methyl salicylate, on the condition that Methyl salicylate be used in accordance with the following provisions:

Tenneco Packaging must immediately notify the EPA of any findings that have a bearing on safety. The company must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

This exemption from the requirement of a tolerance may be revoked if any experience with or scientific data on this pesticide indicate that the tolerance is not safe.

VII. Other Considerations

A. Endocrine Disrupters

Methyl salicylate has been studied in several tests of reproductive and developmental effects, including multigenerational studies. In addition,

the pathology of endocrine-sensitive tissues and organs has been evaluated following repeated (i.e., subchronic) and long-term (i.e., chronic) exposures. No such effects were reported in any of these studies. The Agency has no information to suggest that methyl salicylate will have an effect on the immune and endocrine systems. The Agency is not requiring information on the endocrine effects of this biochemical pesticide at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

B. Analytical Method

The Agency proposes to establish an exemption from the requirement of a tolerance with a numerical limitation. Therefore, for enforcement purposes, quantitative analysis of the active ingredient methyl salicylate may be performed by a gas chromatographic method using flame ionization detection as described by the Association of Official Analytical Chemists (Method 969.13, AOAC Official Methods of Analysis, 1990, pages 754–755).

VIII. Codex Maximum Residue Level

No known maximum residue limits (MRLs) have been established for methyl salicylate by the Codex Alimentarius Commission.

IX. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance exemption regulation issued by EPA under new section 408(e) as was provided in the old section 408. 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 adversely affected by this regulation may, January 20, 1998, file written objections to the 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 issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (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 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 issue(s) 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 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.

X. Public Docket

A record has been established for this rulemaking under the docket number [OPP–300557]. A public version of this record, 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 Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

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 address in ''ADDRESSES'' at the beginning of this document.

XI. Regulatory Assessment Requirements

The Office of Management and Budget has exempted this notice from the requirement of section 3 of Executive Order 12866.

This action does not impose any enforceable duty or contain any ''unfunded mandates'' as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), entitled Enhancing the Intergovernmental Partnership, or special consideration as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because tolerances established on the basis of a petition under section 408(d) of FFDCA do not require issuance of a proposed rule, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 604(a), do not apply. Prior to the recent amendment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence that the RFA is inapplicable. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950) (May 4, 1981).

XII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), 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 in today's **Federal Register**. This rule is not a major rule as defined by 5 U.S.C. 804(a).

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 5, 1997.

Stephen L. Johnson,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 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.

2. Section 180.1189 is added to read as follows:

§ 180.1189 Methyl salicylate; exemption from the requirement of a tolerance.

The biochemical pesticide methyl salicylate is exempt from the requirement of a tolerance for residues in or on food or feed when used as an insect repellent in food packaging and animal feed packaging at an application rate that does not exceed 0.2 mg of methyl salicylate per square inch of packaging materials.

[FR Doc. 97–30251 Filed 11–18–97; 8:45am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300571; FRL–5752–8]

RIN 2070–AB78

Fomesafen; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of fomesafen in or on dry beans. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on dry beans. This regulation establishes a maximum permissible level for residues of fomesafen in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on October 31, 1998.

DATES: This regulation is effective November 19, 1997. Objections and requests for hearings must be received by EPA on or before January 20, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300571], 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–300571], 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. 1132, 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 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–300571]. 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: Andrea Beard, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9356, e-mail: beard.andrea@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the herbicide fomesafen, in or on dry beans at 0.05 part per million (ppm). This tolerance will expire and is revoked on October 31, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

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. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(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 and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing 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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.